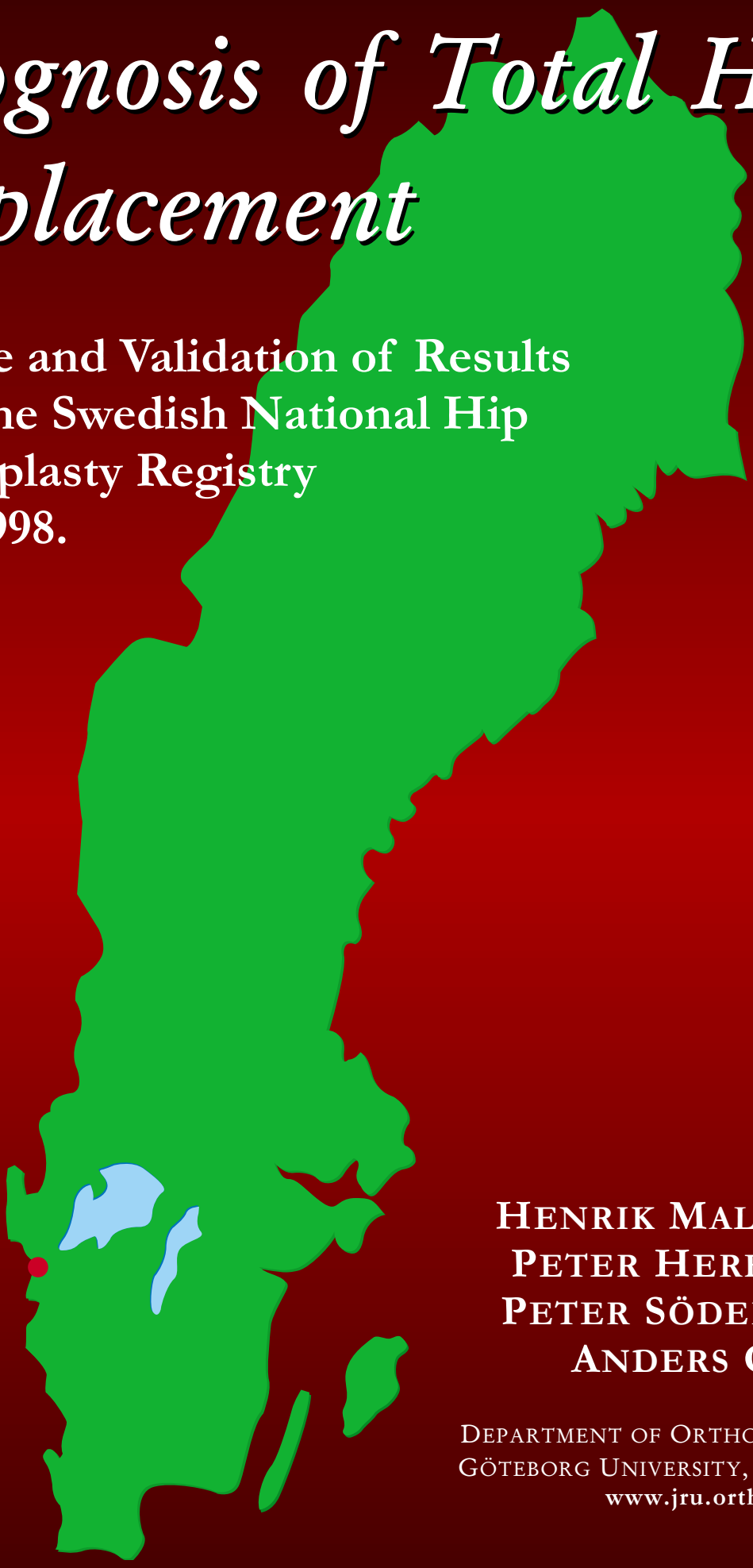
2000

Prognosis of Total Hip Replacement

Update and Validation of Results from the Swedish National Hip Arthroplasty Registry 1979-1998.



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Prognosis of Total Hip Replacement

INTRODUCTION

The Swedish Total Hip Replacement Registry began in 1979 to describe the outcome of primary hip replacements and to provide information regarding serious complications. The importance of the register and the continual quality improvement over the long-term has been well documented (Herberts et al, 1989; Herberts et Malchau, 1997; Malchau et al, 1993). The great benefit of using modern surgical technique and well functioning implants has been well described by documentation of serious complications and failures.

The first function of the register is to describe the epidemiology of hip replacement surgery in Sweden. The second goal is to identify, through the study of revisions, risk factors for poor outcome related to the patient, fixation mode, implant and surgical technique.

The hypothesis behind the project is that sharing information on a yearly basis with the profession will give the individual clinic the opportunity to compare their own results with the national average. The clinics will then be forced to improve, if necessary, according to the principle of the good example.

In the project definition for failure is revision (exchange or removal of the implant), but this strict criterion must be validated which is one of the important results and information provided in this exhibit.

The exhibit also reports updated results from all primary hip replacements and revision procedures performed in Sweden during 1979 to 1998. The epidemiological analysis is based on 169,419 primary procedures and 13,561 revisions. The specific aim in this analysis is to identify factors proved to be important for failure at an early stage due to the vast number of observations. The importance of the Registry has increased with the number of years of registration, with greater experience and long-term results, which motivates this updated report. Differences in patient demographics, fixation methods, implant design and surgical technique can now be compared and investigated for possible independent effects.

AIMS OF THE STUDY

The specific aims for this exhibit are:

1. Report an updated epidemiological analysis of hip replacement in Sweden.

2. Identify risk factors for failures leading to revision procedures.

3. Describe the importance of continual improvement of surgical technique by independent risk factor analysis.

4. Describe an extensive validation of the Registry results using several independent methods.

ACKNOWLEDGEMENT

All orthopaedic surgeons in Sweden. Their assistance is of vital importance for the Registry.

Computer engineer Roger Salomonsson, MSc. The software development and the outstanding and perfect condition of the databases are prerequisites for the analysis.

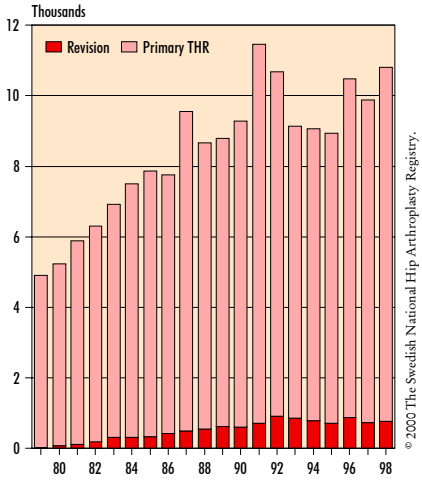
The secretaries A. K. Erikson, K. Lindborg, C. Sporre for continuous work.

The National Board of Health and Welfare and Volvo Research Foundation for financial support. ❖

Epidemiology of Primary and Revision THR

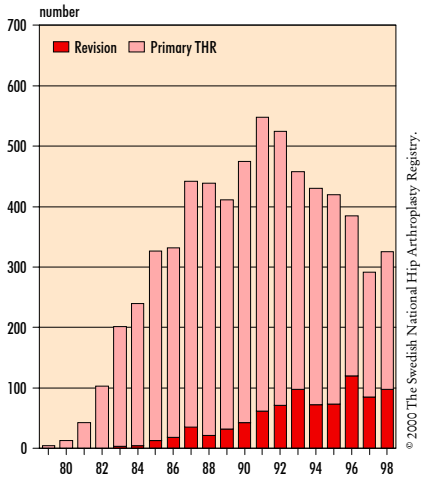
THR with Cemented Implants

158,614 Primary THR observations 1979-1998



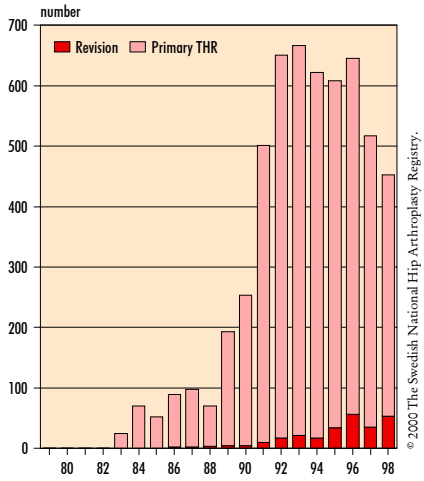
THR with Uncemented Implants

5,559 Primary THR observations 1979-1998



THR with Hybrid Implants

5,246 Primary THR obervations 1979-1998



The number of primary hip replacements increased continuously up to 1992. During the last years we perform approximately 10,000 primary operations per year (100/100,000 inhabitants) in Sweden, which is too few to meet the needs. There is a large variation between the regions in the country and the larger cities have the longest queues. The cemented implant is the predominant type of replacement, accounting for 93% of productivity. Uncemented and hybrid procedures were performed to a much smaller extent. The revision rate is low for cemented implants and has dropped to 7%, whereas it is higher for uncemented, around 13%.

Mean age at the primary hip replacement is still 70 years. The trend is an increase in the average age for women and a decline for men. Over all, female gender predominates (60%) and their proportion increases with age. Primary osteoarthrosis (75.8%), trauma (11.3%) and arthritis (6.0%) are the indications for the operation. The spectrum of diagnosis for this procedure varies considerably with age and in the younger patient group rheumatoid arthritis (RA) and secondary osteoarthrosis (OA) are more prevalent. Among the elderly with a displaced hip fracture becomes a steadily increasing indication for hip replacement in Sweden, due to inferior results with hip nailing.

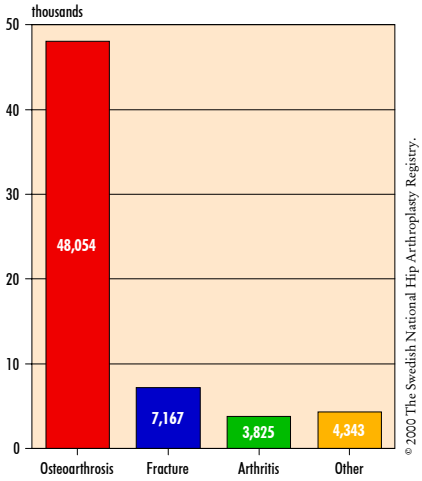
Age at Primary THR

64,110 observations 1992-1998

Gender	Mean	SD	N
Men	68.8	10.5	25,114
Women	71.0	10.8	38,996
All patients	70.1	10.8	64,110

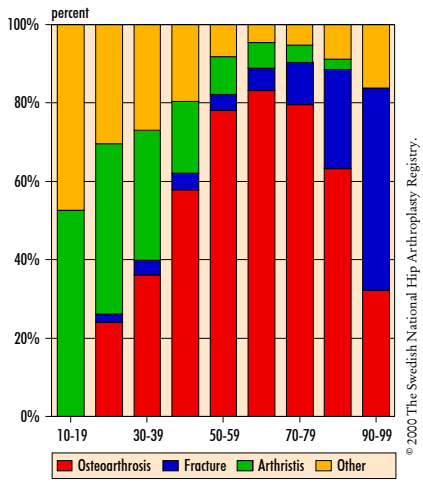
Frequency of Diagnosis

63,289 observations 1992-1998



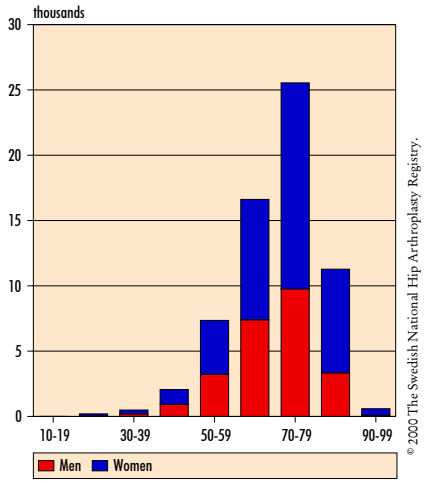
Diagnosis by Age

63,389 observations 1992-1998



Age and Gender

64,110 observations 1992-1998



EPIDEMIOLOGY OF PRIMARY AND REVISION THR, CONT.

Most Commonly used Implants 1979-1998

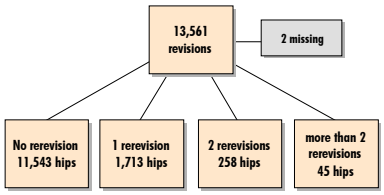
Cemented Implants (cup/stem)	1979 -1987	1988 -1998	Share of Total
Charnley	19 298	29 363	30.7%
Lubinus SP II	860	24 404	15.9%
Lubinus IP	14 374	3 286	11.1%
Scan Hip Collar	1 391	5 077	4.1%
Exeter Polished All-Poly		5 862	3.7%
Exeter Polished (mixed cup)	2 298	2 822	3.2%
Lubinus SP I	3 302	1 034	2.7%
Exeter Polished (metal-backed)		4 122	2.6%
Muller Straight	1 996	2 062	2.6%
Exeter Matte	3 694		2.3%
Brunswik	2 158	57	1.4%
Stanmore	1 500	592	1.3%
Christiansen	1 939		1.2%
CAD	1 738	174	1.2%
Spectron (metal-backed)	447	999	0.9%
Biomet Müller/Bi-Metric (cem.)		1 404	0.9%
Spectron EF All-Poly		1 376	0.9%
HD II	804	351	0.7%
Charnley-Muller	1 070		0.7%
ITH	145	844	0.6%
Others (366 implants)	2 621	15 147	11.2%
Total	59 636	98 978	100%

Uncemented Implants (cup/stem)	1979 -1987	1988 -1998	Share of Total
PCA	564	666	22.1%
Romanus/Bi-Metric (uncem.)		569	10.2%
Securefit/Omnifit		412	7.4%
CLS Spottorno	6	362	6.6%
Lord	311		5.6%
ABG HA/ABG (uncem.)		303	5.5%
Harris-Galante-I	80	146	4.1%
Romanus HA/Bi-Metric HA (uncem.)		154	2.8%
TTAP/LMPCH Ritter	116	37	2.8%
Romanus/Bi-Metric HA (uncem.)		147	2.6%
Garches/Lord	142		2.6%
Zweymuller	63	33	1.7%
LMT	39	45	1.5%
SLS/CLS Spottorno		72	1.3%
PCA E HA		61	1.1%
Harris-Galante-I/Anatomic		60	1.1%
Rippen	35	25	1.1%
Anaform	34	24	1.0%
Trilogy HA/Anatomic HA		55	1.0%
Landos		53	1.0%
Others (103 implants)	239	705	17.0%
Total	1,630	3,929	100%

Hybrid Implants (cup/stem)	1979 -1987	1988 -1998	Share of Total
Romanus/Bi-Metric (cem.)		560	10.7%
ABG HA/ABG (cem.)		332	6.3%
Harris-Galante-I/Lubinus SP II	8	264	5.2%
Harris-Galante II/Lubinus SP II		268	5.1%
ABG HA/ABG (cem.)		255	4.9%
Harris-Galante-I/Charnley	34	189	4.3%
Securefit/Lubinus SP II		213	4.1%
Trilogy HA/Spectron EF Primary		166	3.2%
Romanus/RX90		164	3.1%
Harris-Galante II/Spectron EF		162	3.1%
Harris-Galante II/Charnley		154	2.9%
Trilogy HA/Lubinus SP II		153	2.9%
Romanus/Lubinus SP II		139	2.6%
Mecron/Lubinus IP	137		2.6%
Harris-Galante-I/Spectron EF		123	2.3%
HGPII/Spectron EF		93	1.8%
Trilogy HA/Optima (cem.)		87	1.7%
Duralock/Spectron EF Primary		82	1.6%
Mecron/Lubinus IP	61	17	1.5%
PCA/Exeter Polished		66	1.3%
Others (149 implants)	88	1,431	29.0%
Total	328	4,918	100%

THR Revisions

1979-1998



The most commonly used primary and cemented hip implants are illustrated during the last ten-year period 1988 – 1998. The decrease in the diversity of implants used in Sweden is probably a result of this Registry effort and continuous information about individual implant failures. During 1998 five major cemented implants constituted 76% of the market in Sweden and this decrease in diversity of implants is an important finding. A small number of uncemented and hybrid implants were used during the last ten years and many of those are evaluated in prospective open or randomized trials at specific centers. Revision total hip replacements performed in the country during 1979–1998 were 13,561 cases. Of those, 11,543 hips were revised for the first time and 1,713 were second-time revisions. The major reason for revision is still aseptic loosening with or without osteolysis, constituting 75.7%, whereas primary deep infection contribute with 7.2% of the revisions. Technical error and dislocation constitutes 8.5% of the revisions. This cohort is generally related to malpositioned implant parts and additional effort in designing aiming instruments could potentially reduce the problem.

Polyethylene wear is only accounting for 0.5% of the revisions and as underlined in definitions, exchange of liner and head component is not considered a revision.

The proportion of serious complications leading to revision has been fairly constant over the last years but deep infection is slowly a diminishing problem in the hip.

DEFINITIONS

Reoperation: any new hip operation on a patient who previously has undergone total hip replacement.

Revision: exchange or removal of one or both components. Exchange of liner or head component is not considered a revision. ❖

Reason for Revision

11,543 observations 1979-1998

Reason	N	Share
Aseptic loosening	8,735	75.7%
Primary deep infection	828	7.2%
Fracture only	582	5.0%
Dislocation	576	5.0%
Technical error	399	3.5%
Implant fracture	179	1.6%
Secondary infection	100	0.9%
Polyethylene wear	60	0.5%
Pain	43	0.4%
Miscellaneous	41	0.4%
Missing	0	0.0%
Total	11,543	100.0%

METHODS

This national registry started as a research project but is since more than 10 years financed by the National Board of Health and Welfare and during this period also supported by the Swedish Orthopaedic Association. The project started in 1979 and all orthopaedic departments in Sweden participate on a voluntary basis. The Registry consists of three different data bases.

The primary hip replacement data base included initially information on the interventions per year and clinic (1979-1991) with collection of the number of operations and the type of implant. Since 1992, all primary surgical procedures are registered in detail using the unique identification number assigned to all permanent residents in Sweden. The id number gives information about age and gender. The diagnosis and side is registered. The implant during this later period is characterized in detail as well as cement brand. 82% of the clinics report this information via an Internet site (http://www.jru.orthop.gu.se) during the last year and the remaining on specific forms.

The second data base, the revision data base, is derived from analysis of the hospital records from all reoperated patients since 1979. 116 parameters are registered per operation.

The third data base is related to the surgical technique and includes information on preventive actions against aseptic loosening, i.e. a careful description of surgical technique used at each department per year. The cementing technique and the cement brand is reported in detail. Prophylactic antibiotics and other measures to prevent deep infection are also reported yearly.

STATISTICAL METHODS

For the whole material patient-related factors and implant-related factors were analyzed by estimation of the survival function for the implants depending on age, gender, diagnosis, type of implant and fixation technique (Kaplan et Meier, 1958).

For the material reported 1992—1998 all primary operation are reported with patient identification number. This cohort is analyzed by means of regression analysis and serves as a validation of the different assumptions used in the statistical analysis in earlier presentations. In the regression analysis (by using the general relationship between the hazard and survival functions), the probability of revision within a specified time period can be calculated for any combination of variables. For example, the estimated six years probability of revision for a man operated 1993 at the age of 61 for a fracture complication is 6%. The corresponding probability for a women operated 1993 due to primary osteoarthrosis at the age of 76 is only 2%. Cemented fixation was assumed in both cases.

The effect of various surgical and cementing techniques on revision rates is analyzed by Poisson models (Breslow et Day, 1987). The hazard functions of revision are thereby estimated by a stepwise procedure ending up with the significant variables in a multivariate model. The influence of these elements on the risk of revision for aseptic and septic loosening is calculated using multiple regression survival analysis.

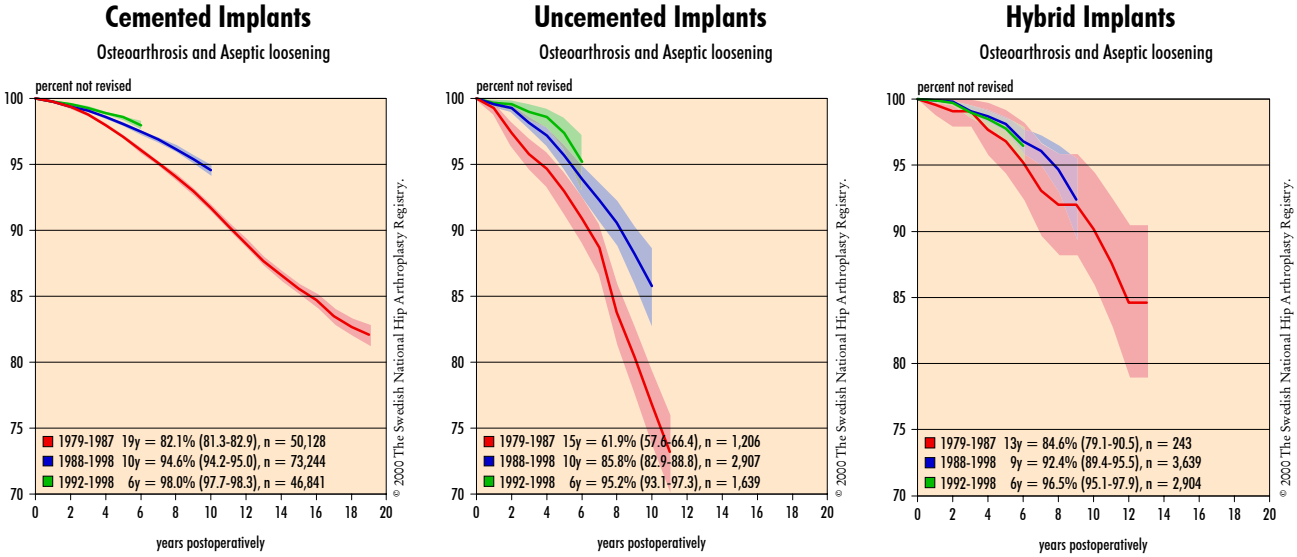
Several methods have been used to validate the registry results. The primary and revision databases are validated by the participating units annually prior to reports and presentations. Specific validation is performed by means of retrospective audits of hospital medical files and by an extensive comparison with the Swedish Discharge Registry. The results from this validation is presented in the current exhibition.

IMPLEMENTATION

Registry information is reported regularly to the Swedish Orthopaedic Association and the participating departments, annually or every second year. Public information provided to the profession, administrators, producers or the press is based on aggregated regional or national data. The individual surgeon is assured confidentiality. The orthopaedic community in Sweden agreed in 1998 that the results with modern cementing technique on the cohort operated for osteoarthrosis and revised due to aseptic loosening are open information presented at the internet site.

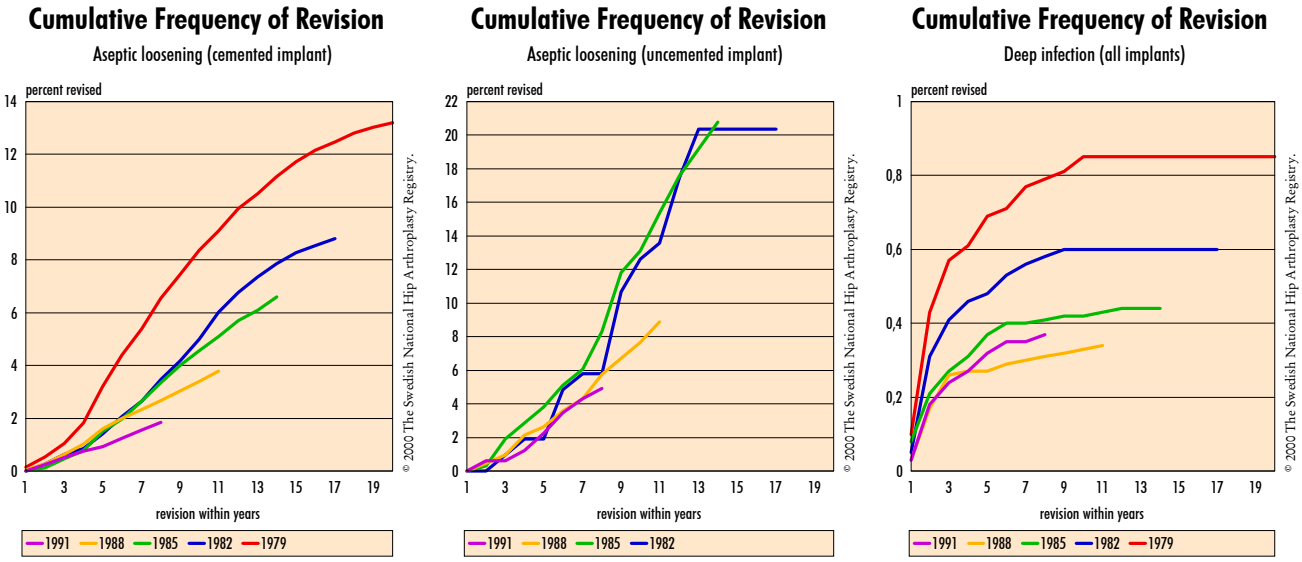
The Registry holders have visited several of the participating units during the past 5-7 years. These visits include specific presentations of local and regional results. Based on the individual unit patient profiles and choice of implants, various implementation problems are discussed. The most vital part for the project is to be as precise and comprehensive as possible at the local level. ❖

RESULTS



Survival of all primary total hip replacement procedures separated in cemented, uncemented and hybrid fixation techniques are illustrated. The first period covers 1979–1987 and the second 1988–1998. The cut off between these two time periods is consistent with the general change to a modern cementing technique in Sweden. It is therefore relevant to speak of an early versus a modern surgical cementing technique during these two time periods. The third time period, 1992–1998, was chosen as modern uncemented technology was introduced around 1992. The cemented implants have improved substantially over time. The uncemented implants also display some improvement during the three time intervals.

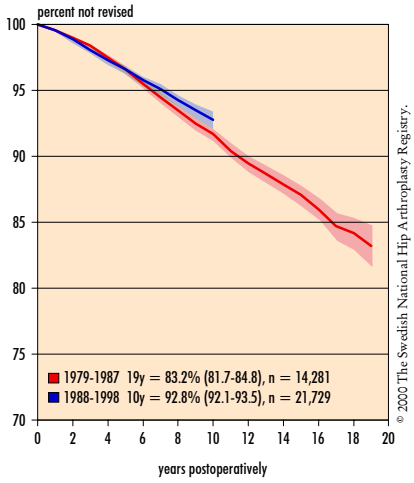
Using modern cementing technique, a 94,6% 10-year survival is obtained for hip replacement with index diagnosis osteoarthrosis and revised due to aseptic loosening. Including all other causes for revision would decrease the survival rate by 1-2%. The uncemented technology had a disappointing result in the cohort operated prior to 1988. In the last period modern cup designs and active surface coating on the femoral component were used. Results have improved and cementless fixation still have worse results but are used in younger patients. The continuous quality improvement is well illustrated in the figures below. There has been a reduction, for cemented implants, in revision for mechanical failure from 9% (the 1979 cohort) to 3% (the 1988 cohort) after ten years. A major improvement is seen for revision due to deep infection and the cumulative revision rate for deep infection after 10 years is approximately 0.3%. ❖



IMPLANT-RELATED FACTORS

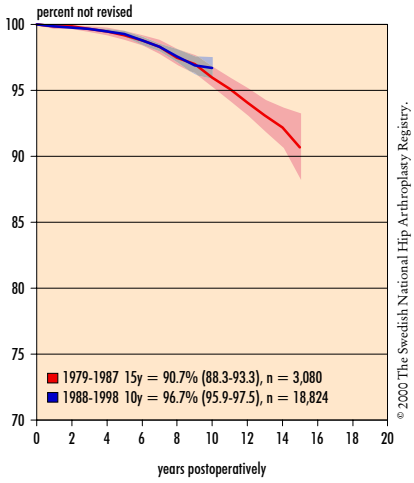
Charnley

Osteoarthrosis and Aseptic loosening



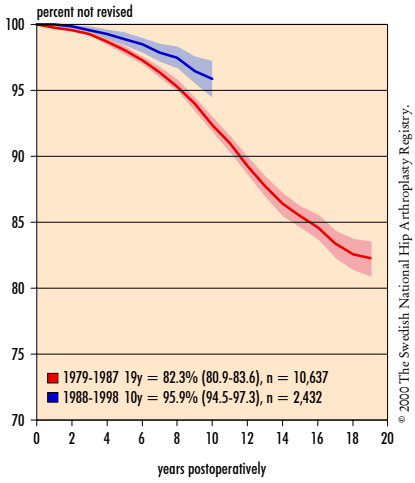
Lubinus SP

Osteoarthrosis and Aseptic loosening



Lubinus IP

Osteoarthrosis and Aseptic loosening

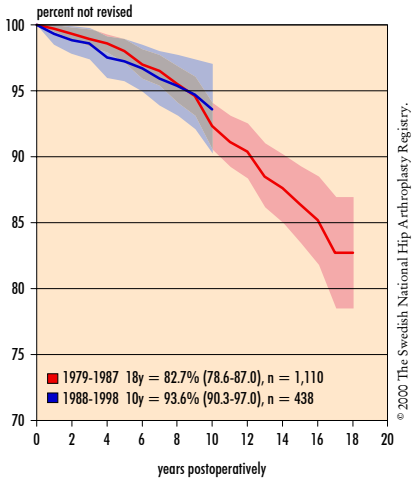


Most types of cemented hip implants show an improved survival between the early period 1979–1987 and the later period 1988–1998. Revision for aseptic loosening in patients with osteoarthrosis are analyzed and depicted in the figures. On all survival diagrams the 95% confidence interval is indicated. The standard error increases with a decreasing number of prostheses at risk. None of the curves are depicted when less than 50 hips remain at risk.

The survival at 17 years varies between 80-87% for well documented and commonly used implants. Some implants can only be followed up to 15 years from the early period. The curves illustrate that the Lubinus SP and CAD prostheses performed best at comparable follow-up times during the first period and significantly worse outcome was documented for Müller straight and the Exeter matte prostheses. The most commonly used prostheses during the first period was the Charnley and the Lubinus IP and they performed in the middle range of all implants and equally well. The improvement during the second period for cemented implants is obvious and the 10-year survival for most cemented implants

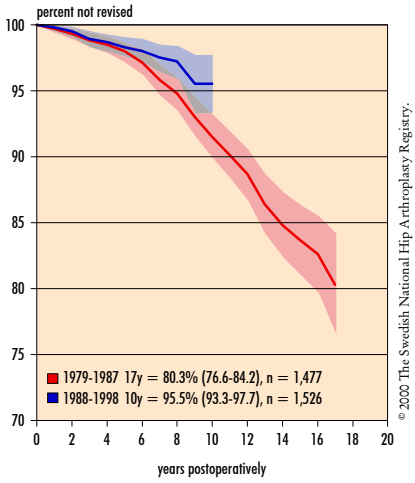
Stanmore

Osteoarthrosis and Aseptic loosening



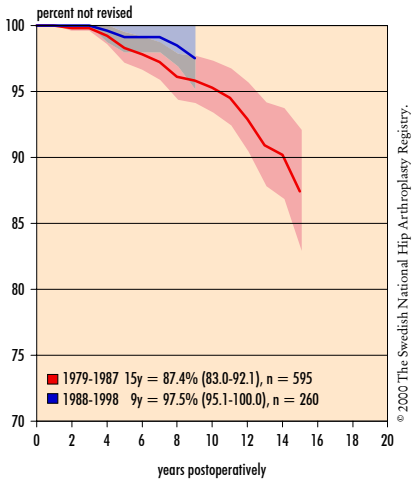
Müller Straight

Osteoarthrosis and Aseptic loosening



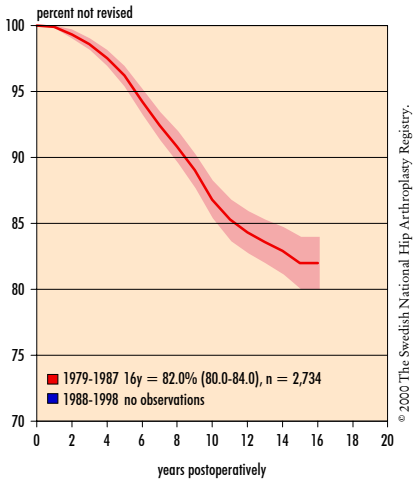
HD II

Osteoarthrosis and Aseptic loosening



Exeter Matte

Osteoarthrosis and Aseptic loosening



IMPLANT-RELATED FACTORS, CONT.

in Sweden is now between 93 and almost 97%. These figures are related to the analysis of the most common complication, i.e. aseptic loosening. If all other causes for revision is included the survival rate would decrease by 1-2%.

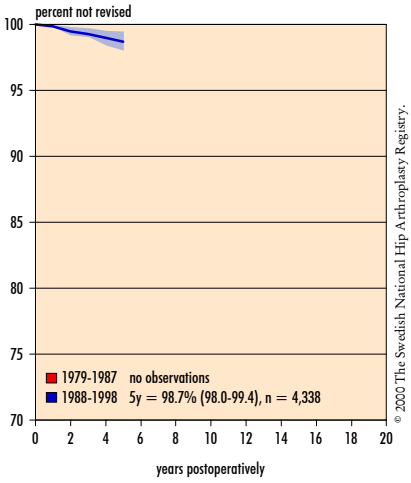
For the Charnley implant we observe only a slight improvement. The failures are predominately related to the femoral component. The majority of the Charnley procedures in Sweden are performed with the posterior approach during the last 15 years. An increased frequency of malpositioned Charnley stems with inferior cement mantles has been documented in Sweden and can explain these results (Garellick et al, 1998).

The Exeter polished implant has performed as well as the best implants with a satin surface, i.e. the Lubinus SP. The Exeter implant was used with a variable cup design including one with a partial metal-backed configuration. They have similar outcome but the follow-up is only medium long-term. Other metal-backed designs of the cup such as the Spectron implant performed poorly with many failures showing up at the 8-10 year period. The reason for this increased failure rate is multi-factorial and probably includes increased wear rate for metal-backed cups in combination with the 32 mm head diameter that was used.

The most essential point is that improved cementing technique resulted in a reduction in serious complications irrespective of the type of implant used. The question, whether the stem should be highly polished or have a satin surface finish, can still not be answered from our Registry data. It seems as if well designed products can demonstrate equally

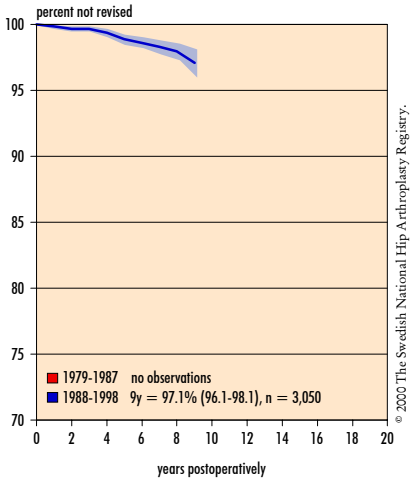
Exeter Polished (all-poly)

Osteoarthrosis and Aseptic loosening



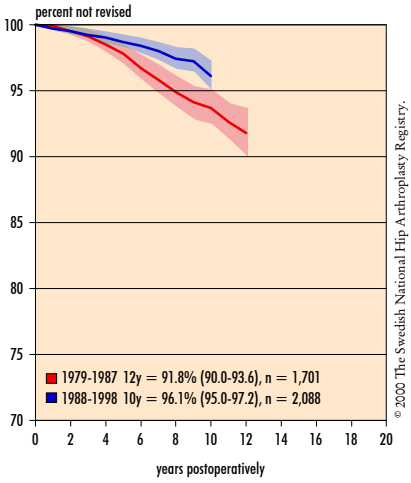
Exeter Polished (metal-backed)

Osteoarthrosis and Aseptic loosening



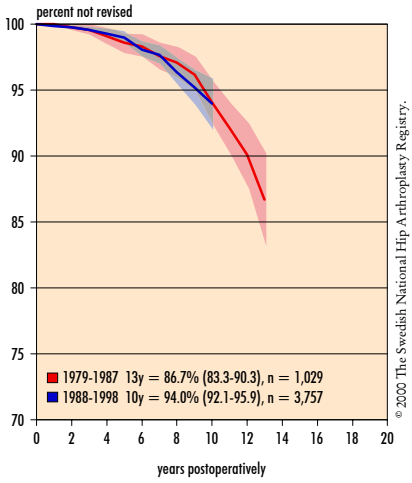
Exeter Polished (mixed)

Osteoarthrosis and Aseptic loosening



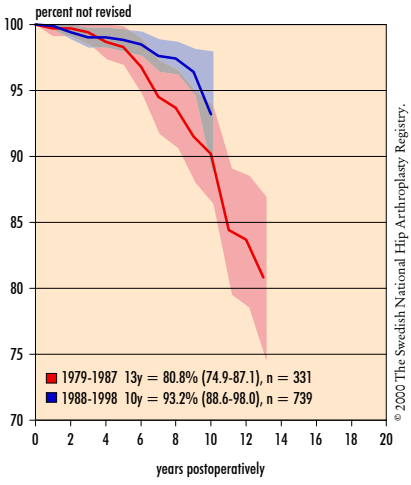
Scan Hip Collar

Osteoarthrosis and Aseptic loosening



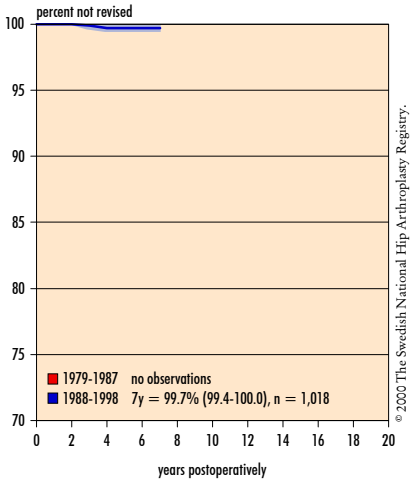
Spectron (metal-backed)

Osteoarthrosis and Aseptic loosening



Spectron EF (all-poly)

Osteoarthrosis and Aseptic loosening



IMPLANT-RELATED FACTORS, CONT.

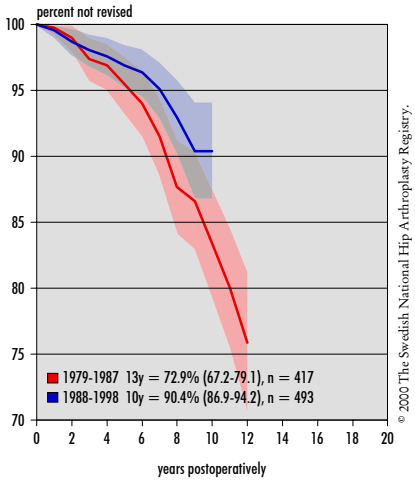
good long-term results irrespective of the fixation principle between stem and cement mantle.

Cementless implants were used in a small number during both time periods. This makes the information more uncertain and the confidence intervals are much broader. The third generation of uncemented implants used in the nineties has functioned relatively well with excellent fixation (Thanner, 1999). The majority had hydroxyapatite coating or textured titanium surfaces with limited rate of revision for aseptic loosening. The long-term results of the modern uncemented implants are, however, not yet known.

The hybrids, claimed to be the fixation principle of the present decade have rather contradictory outcome. The first generation porous coated HG1 cups has a superior result compared to the second generation HG2, here illustrated in combination with the Lubinus SP II cemented stem. The difference, in survival rate is probably related to the thickness of the polyethylene liner. The increased thickness of the HG2 cup gives a thinner poly liner with increased risk for wear and osteolysis. ❖

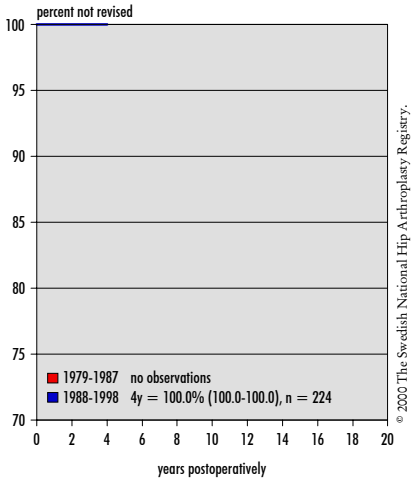
PCA

Osteoarthrosis and Aseptic loosening



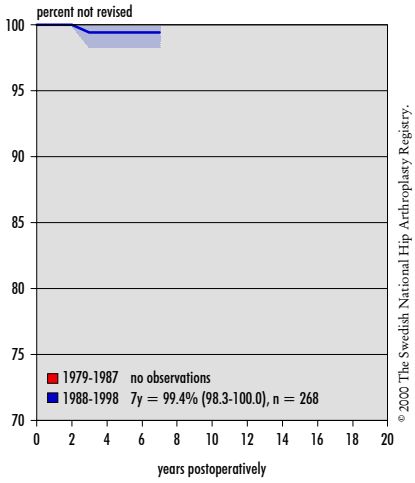
ABG HA

Osteoarthrosis and Aseptic loosening



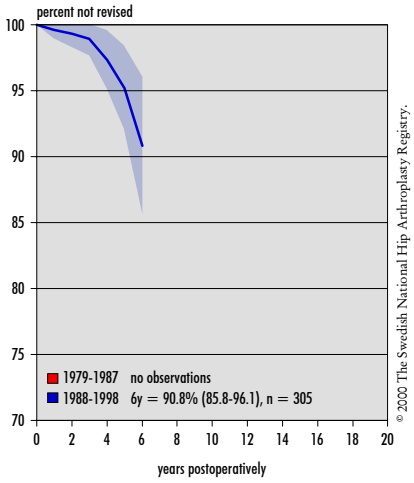
CLS Spottorno

Osteoarthrosis and Aseptic loosening



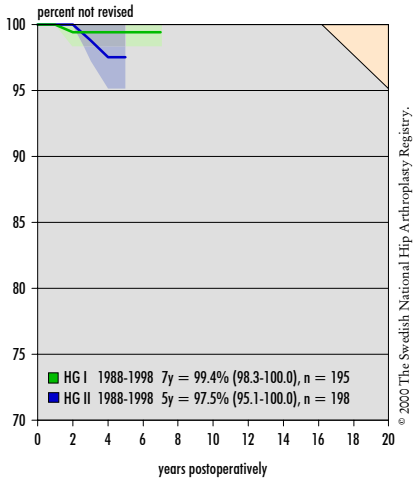
Omnifit

Osteoarthrosis and Aseptic loosening



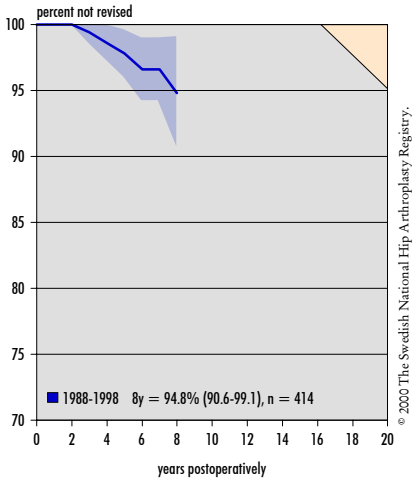
HG/Lubinus SP II

Osteoarthrosis and Aseptic loosening



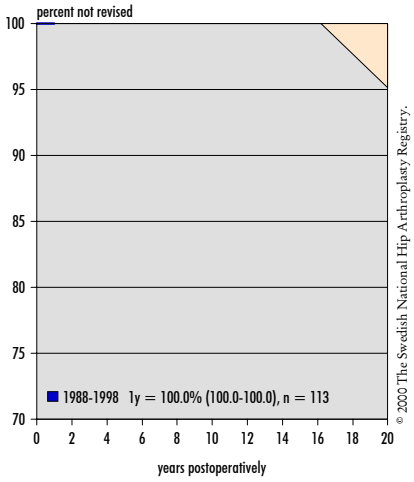
Romanus/Bi-Metric (cem.)

Osteoarthrosis and Aseptic loosening



Trilogy HA/Lubinus SP II

Osteoarthrosis and Aseptic loosening



PATIENT-RELATED FACTORS

Men are at a significantly higher risk for revision procedures than women, when analyzed for revisions attributable to aseptic loosening. During the later time period, this difference became less pronounced as a result of technique improvement.

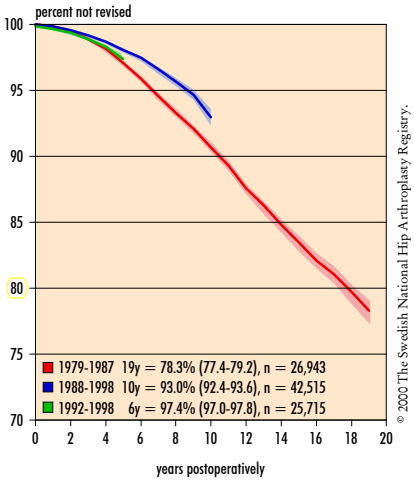
With respect to age we find that the younger and more active patients are at greater risk in all diagnostic groups. This is especially true for patients younger than 55 years of age. The previous observed exception for OA male below 55 years is no longer valid.

The importance of patient demographics for THR outcome in the young population has not been well elucidated in the literature. We find the worst results for total hip replacement in young women and men with osteoarthrosis. Even patients with previous fracture around the hip and young women with rheumatoid arthritis have inferior long-term outcome. The supreme challenge for this procedure is the young and active patients as identified by the register. Further development of implant designs and surgical techniques are necessary for this cohort. Approximately 12,000 young patients are included in the cohort (1979-1998) with a high failure rate. It is for these patients that further scientific effort is mandatory. A possible solution could be referral of these patients to centers of excellence to be included in randomized clinical trials.

For the elderly patient, the outcome of primary hip replacement surgery is very good. If modern cementing technique is combined with an implant with proven performance, more than 95% of these patients will outlive their implants. ❖

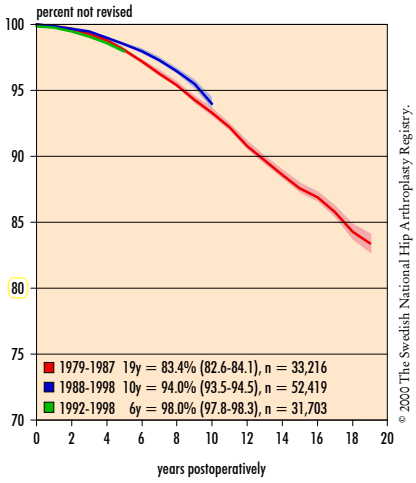
All diagnosis

Male Patients of Any Age



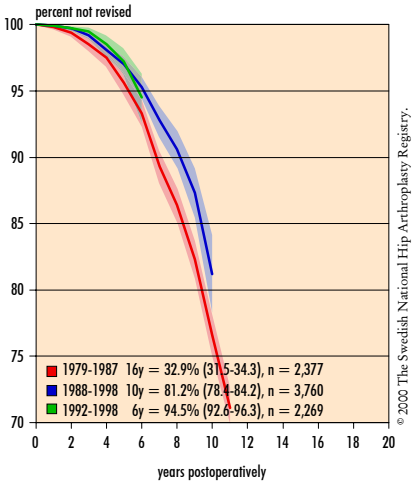
All diagnosis

Female Patients of Any Age



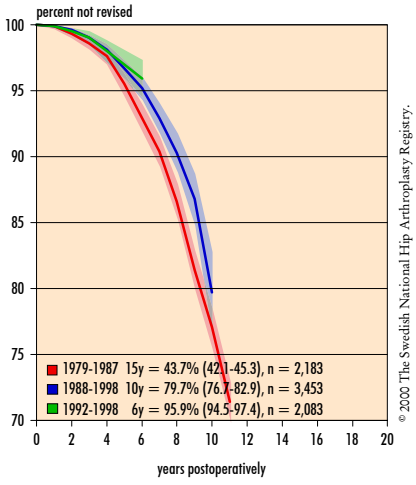
Osteoarthrosis

Male Patients Younger than 55



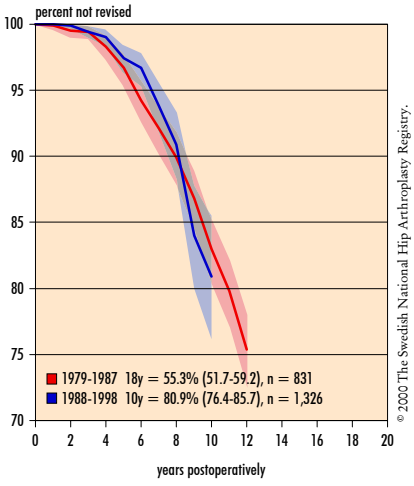
Osteoarthrosis

Female Patients Younger than 55



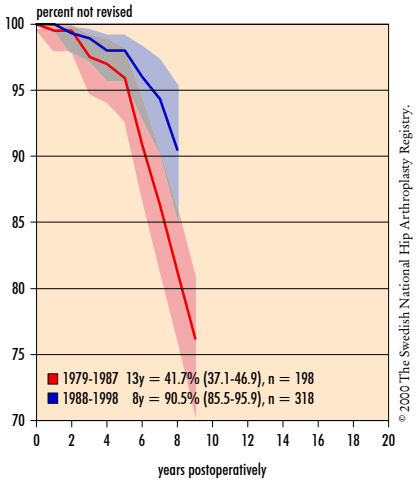
Rheumatoid Arthritis

Female Patients Younger than 55



Fracture

Female Patients Younger than 55



VALIDATION OF THE RESULTS FROM THE REGISTRY

BACKGROUND AND AIM

The end-point for failure in the Swedish National Total Hip Arthroplasty Registry (the Swedish THA Registry) is revision. The aim of this particular study was to validate the failure end-point in the register and thereby the results presented by the register. We wanted to know if the register captured all revisions in the country and if the sensitivity was adequate.

MATERIAL AND METHODS

Since 1986, all hospitals in Sweden annually report number and type of operation to the Discharge register (the Swedish National Board of Health and Welfare). Patients in this study were randomly selected from the Discharge register to make comparison with the Swedish THA Registry possible. The study consisted of four parts;

Part I: All patients operated on with a primary or revision hip replacement and any other reoperation between 1986 and 1995 were selected. These cohorts were compared to the data in the Swedish THA Registry during the same period. Gender, age, number of registered operations (primary and revision) and the annual procedure incidence (operations per 100,000 inhabitants) were calculated.

Part II: From the Discharge register a randomly selected cohort of 2,604 patients operated with THR in Sweden between 1986 and 1995 received a short questionnaire asking, among other items, if they had been reoperated. The medical records for these patients were collected and studied, thus providing information about the type of repeated surgery that had been performed.

Part III: From the cohort in part II, 1,056 patients operated with primary hip prosthesis in Sweden between 1986-1995, were randomly selected. The patients received two self-administered general health questionnaires, the Nottingham Health Profile (NHP) and the SF-36.

Part IV: The same patients as in part III were asked to fill in a disease-specific self-administered questionnaire (WOMAC) and an age and gender matched subcohort of 344 patients were randomly selected from nine cities which included regional, county and rural hospitals. An independent physician or an independent physiotherapist examined this cohort clinically using the Harris Hip Score system. The patients were also examined using conventional radiographic techniques.

Standard anteroposterior pelvis (centered over the symphysis) and true lateral radiographic were performed. The patients were separated into two groups: one with radiographic failure and one without radiographic failure. The Hodgkinson criteria for loosening of the cup were used (Hodgkinson et al, 1988). Postoperative radiographs were not saved in all hospitals and hence migration of the cup could not be measured as the patients were examined only once, 2-10 years postoperatively. Failure of the cup was classified as Hodgkinson type 3 with a 100 % circumferential radiolucent line. The criteria for stem failure was debounding, stem fracture, cement fracture or a 100% circumferential radiolucent line (Mullroy et Harris, 1997). The frequency of revision was noted for each hospital type.

STATISTICS

A professional statistician did the power analyses. SPSS for Windows were used for the calculations. Total score, domain scores, mean, median, standard deviation (95% CI), minimum value and maximum value (range) were calculated for all patients. The Mann-Whitney U test was used for statistical analysis (non-parametric tests). For the 10-year survival analysis, logistic regression analysis was used and the results were compared to the survival statistics in the Swedish THA Registry. To study correlation between the different clinical and radiographic parts in the study, the spearman correlation was calculated between same domains (convergent validity) and different domains (divergent validity). The hypothesis was that equal domains should show greater correlation with each other than with different domains. The Cronbach alpha index was used to study internal consistency reliability in Harris Hip Score and WOMAC. To make the results

comparable with other score system all domains and total scores were transformed to 0-100 point scales. 100 point indicated best health.

RESULTS

The mean age at the follow up for the whole group in part II was 76.9 years (range 37-99, std 9.7, n=2,441). 44% were men and 56% women. There were no major differences between gender even though men received higher scores than women.

31% of the total group had disability in one hip (Charnley category A), 18% in both hips (Charnley category B). The remaining 51% had a general disease or another disease that impaired gait (Charnley category C). The response rates for part II, III, and IV were 96, 93 and 84% respectively. 86% was operated for arthrosis, 3% for arthritis and 2% for sequels after hip fracture.

Primary operations: A total of 84,884 and 83,137 primary operations were registered 1986-1994 according to the Swedish THA Registry and the Discharge register, respectively. The primary procedure incidence for hip replacement in the three major cities in Sweden was found to vary between 81 and 129 per 100,000 inhabitants and year (figure 1).

Revision operations: In 1996, a total of 10,176 and 11,323 revision operations were registered according to the Swedish THA Registry and to the Discharge register, respectively. The number increased until 1992 (figure 2). The Swedish THA Registry showed a lower number of revisions, which can be related to different definitions for revisions. The results showed 10% missing revisions during 1987 and 1995. Of the 42 hospitals randomly selected for the self-administered questionnaire, two were responsible for 46% of the non-reported revisions. These missing revisions are now included in the Swedish THA Registry. This means that 95% of the units that reported currently to the Swedish THA Registry during these years covered on average 94% of the performed revisions.

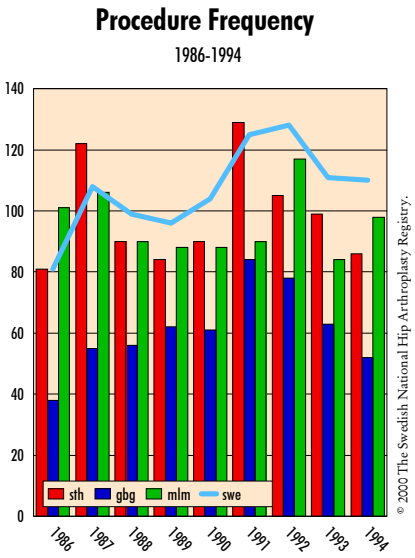


Figure 1. Procedure frequency (per 100,000 inhabitants) for primary hip replacements in the Swedish THA registry between 1986-1994. sth = Stockholm, gbg = Göteborg, mlm = Malmö, swe = Sweden.

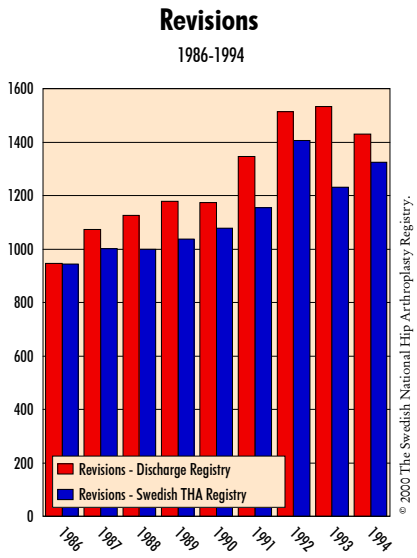


Figure 2. Number of hip revisions (extraction or exchange of prosthesis) in the Discharge register, the Swedish THA registry between 1986-1994.

Clinical follow-up. Total score for NHP increased from 14.6 to 24.4 from two up to 10 years postoperatively and for SF-36 the total score decreased from 69.7 to 59.7 during the same period. Figure 3 illustrates the SF-36 and NHP results for male and female patients in the different domains of the score systems. (observe the conversion to 100 scales, 0 = worst health).

The standard deviation for domain and total score (95% confidence interval), was 7.3-38.6 for NHP and 20.9-43.9 for SF-36. As expected, the mean total score for the Harris Hip Score and WOMAC declined with increased follow-up time. The domain and total score in the Harris Hip Score were higher than the WOMAC scores (figure 4).

The clinical investigations (Harris Hip Score) and the postal survey (NHP, SF-36 and WOMAC) showed significant differences between patients in Charnley category A, (median Harris Hip Score 96, range 37-100) compared to patients in Charnley category C, (Harris Hip Score 79, range 34-98) (figure 5).

There were no significant differences in survival rates based on the total cohorts from the Swedish THA Registry (10y=92.3%) and the Discharge register (10y=93.9%).

The ten year survival based on the randomly selected Discharge register cohort (10y=90.7%) was not significantly different from the Swed-

VALIDATION OF THE RESULTS FROM THE REGISTRY, CONT.

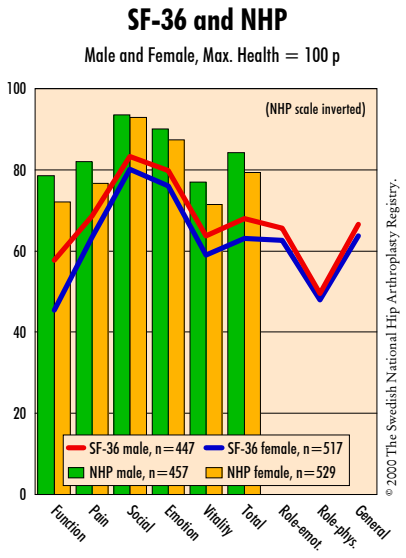


Figure 3. SF-36 and NHP results for male and female patients at follow-up 2-10 years.

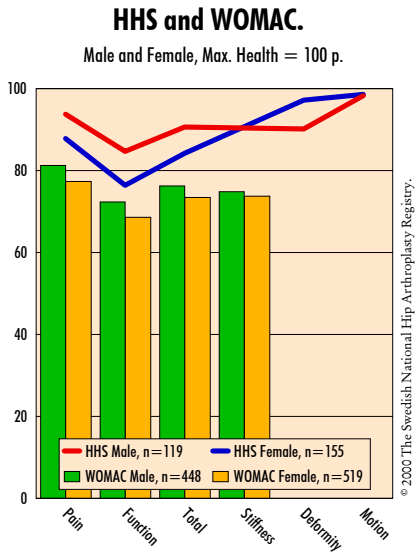


Figure 4. HHS and WOMAC results for male and female patients at follow-up 2-10 years.

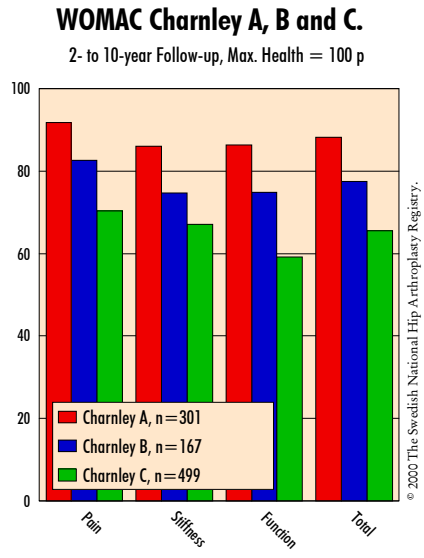


Figure 5. WOMAC for the different Charnley categories.

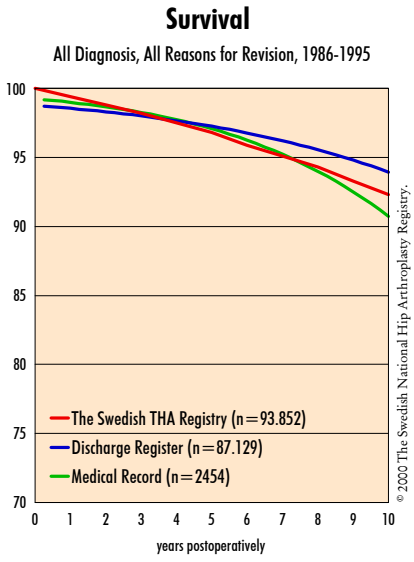


Figure 6. Survival rate for the cohort from the Swedish THA Registry, the Discharge Register and the randomly selected cohort (Medical Record).

ish National Total Hip Arthroplasty Registry. The survival according to this study of the two registers that was chosen for validation was thus 91-94% after 10 years (figure 6). The Swedish THA registry showed a 93% survival rate, on a national level, after 10 years during the same period as this study.

The survival based on an arbitrary estimated clinical failure definition were dependent on the level chosen for this parameter for each score system. Patients that were revised or scored lower than 60 points in total score in the Harris Hip Score had an 87% ten-year survival rate in this study. For WOMAC, the corresponding result was 80%.

There was no difference in general or disease specific health and 10-year survival between regional, county and rural hospital in survival based on the analysis of NHP and SF-36.

Radiographic follow-up. One hospital had no compliance for the radiographic examinations and patients who did not reply completely to the Harris Hip Score or WOMAC were not included in the statistics for the radiographic results. Only 76% of the patients were included in the radiographic analysis. The statistical evaluation included radiographic failure of the cup and the stem separately as well as failure of both. The results did not show any significant difference between the failure and the non failure groups according to pain, function and total score in the two disease specific instruments (WOMAC, HHS). This was observed for the cup and the stem individually as well as both prosthetic components, even if the group with radiographic failure showed lower scores. ❖

ENVIRONMENTAL FACTORS

The participating units report the prophylactic measures against aseptic loosening and infection annually. The reported variables are: surgical approach, type of cement, cement mixing and application mode, use of brush and pulsatile lavage, use of distal plug and proximal seal in the femur, number and diameter of anchorage holes in the acetabulum and type, length and administration mode of antibiotic prophylaxis. In the past 10 years the variance in use of the different prophylactic measures has decreased. This is reflected by the fact that several of the risk ratios is rather close to one. The possibility of the register to analyze surgical technique is in a way threatened by its own success.

In order to evaluate patient related factors (gender, age and diagnosis) and fixation mode independently, a new Poisson model has been applied on the cohort operated between 1992 and 1998. This cohort has been chosen as both primary and revision data were reported by use of the specific patient id number. Certain general parameters (time since operation, calendar time) are a prerequisite for this specific statistical analysis.

The following text summarizes the results of the new Poisson models: the estimated risk for revision is 20% lower for women compared to men ($p < 0{,}01$). This risk decreases with increasing age. If two patients of same gender is compared, 66 and 76 years old, the model indicates that the older patient has 22% lower risk for revision if the follow up time is identical. Between 1992 and 1998 the risk for revision decreases 11% per year. The risk for revision reaches a minimum 3.2 years after surgery.

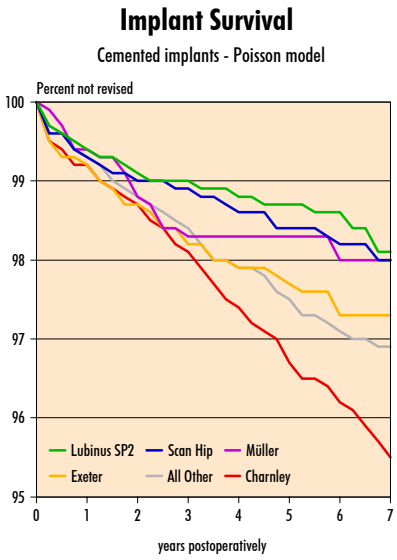


Figure 7. Implant survival for cemented implants estimated through Poisson models. Primary THR performed 1992-1998.

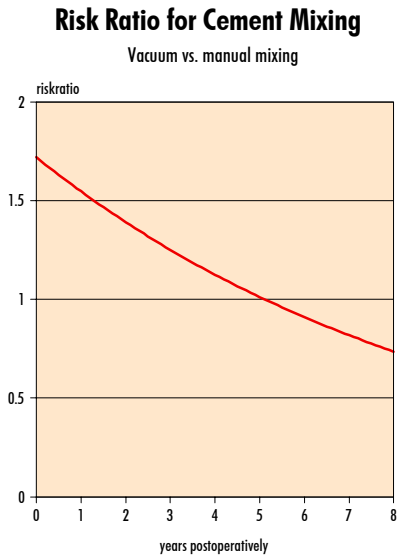


Figure 8. Poisson models for cement mixing estimating revision risk for vacuum versus manual mixing.

Index diagnosis osteoarthrosis (OA) is associated with lower risk for revision than the remaining diagnostic groups. Risk ratio between OA and rheumatoid arthritis is 0.84. The corresponding risk ratio between OA and fracture is 0.56.

Risk ratio uncemented/cemented is below one (lower risk for uncemented) up to 4.3 years after surgery and hereafter without significant difference up to 7 years postoperatively. This finding underlines the importance of taking age into consideration when discussing different fixation modes (Havelin et al, 1993).

The Poisson model has also been applied on the most used cemented implants. Figure 7 shows the survival rates for five different implants, all with more than 1000 implantations 1992-1998. The results are adjusted for age, gender and index diagnosis. The failure end-point definition is revision or extraction of either cup, stem or both. The most successful implants are Lubinus SP II, Scan Hip and Müller, Exeter polished and all other cemented implants form an intermediate group and the Charnley implants have the lowest survival rate. All implants were used with cemented polyethylene cups.

An update of the Poisson models for analysis of surgical technique presented in previous publications from the register (Malchau et Herberts, 1998) now shows risk ratios closer to one. Use of pulsatile lavage, proximal femoral seal and distal plug are all, however, still associated with significant reduction in risk for revision (table 1).

As previously reported by us and others (Havelin et al, 1995), Poisson models from multivariate variables show pronounced association between risk reduction and the specific cement brands. Lowest risk is observed in association to Palacos Gentamycin®, Palacos® and Simplex®. CMW® has significant less risk reduction and the highest risk is associated to use of Sulfix® (table 2).

ENVIRONMENTAL FACTORS, CONT.

This cement type is no longer available on the market.

It is still difficult to explain the background for the association between surgical approach and risk for revision. The posterior and the lateral with osteotomy have a significant lower risk than the transgluteal approach (table 3). In order to get more insight in this specific problem a new parameter has been added to the registration of primary THR for the next year.

The use of vacuum mixing of cement seems to be justified. The time dependent Poisson model indicates, as previously reported, a higher risk for revision in the first 4-5 years after operation. Further follow up shows a continuous reduction of the risk for revision. At eight years the risk is 0.74 when vacuum is compared to manual mixing (figure 8). ❖

Poisson models for univariate variables

	All revisions – all diagnoses		Aseptic loosening and arthrosis	
Variable	Risk ratio	95% confidence limits	risk ratio	95% confidence limits
Vacuum mixing	1.05	0.97-1.12	1.04	0.95-1.13
Pulsatile lavage	0.93	0.87-0.99	0.89	0.82-0.96
Proximal femoral seal	0.88	0.83-0.94	0.83	0.77-0.90
Distal femoral plug	0.88	0.83-0.93	0.87	0.81-0.93

Table 1. Poisson models for univariate variables. Estimated risk for revision is shown for vacuum mixing, pulsatile lavage, proximal femoral seal and distal femoral plug. The risk ratios with 95% confidence limits are shown for all revisions in all diagnosis and aseptic loosening in osteoarthrosis.

Poisson model for type of cement

In the risk ratio the risk for the Sulfix® is nominator	All revisions – all diagnoses		Aseptic loosening and arthrosis	
Variable	Risk ratio	95% confidence limits	risk ratio	95% confidence limits
Simplex®	0.60	0.55-0.66	0.65	0.59-0.72
CMV®	0.73	0.56-0.94	0.66	0.52-0.84
Palacos®	0.51	0.45-0.57	0.53	0.46-0.61
Palacos Gentamycin®	0.49	0.44-0.54	0.52	0.46-0.59

Table 2. Poisson models for multivariate variables. Estimated risk for revision is shown for the different cement brands reported to the register. The risk ratios with 95% confidence limits are shown for all revisions in all diagnosis and aseptic loosening in osteoarthrosis. The risk ratio for Sulfix® is nominator (equals one).

Poisson model for surgical approach

In the risk ratio the risk for the transgluteal incision (supine) is nominator	All revisions – all diagnoses		Aseptic loosening and arthrosis	
Variable	Risk ratio	95% confidence limits	risk ratio	95% confidence limits
Posterior	0.70	0.66-0.75	0.68	0.63-0.73
Lateral with trochanterosteotomi (supine)	0.65	0.59-0.72	0.64	0.56-0.72
Transgluteal (lateral)	1.32	1.18-1.47	1.07	0.91-1.25

Table 3. Poisson models for multivariate variables. Estimated risk for revision is shown for the different incisions reported to the register. The risk ratios with 95% confidence limits are shown for all revisions in all diagnosis and aseptic loosening in osteoarthrosis. The risk ratio for transgluteal approach (supine position) is nominator (equals one).

DISCUSSION

The Swedish National Total Hip Arthroplasty Registry is an important instrument for outcome study of THR. Determination of how valid the results from the register are have been a major challenge for several years.

In the present paper the register results are validated by two different methods.

The first includes a comparison to other national databases in Sweden as well as an examination of a random selected cohort of patients. The random selected patients have been addressed with different questionnaires and a subcohort have been physically and radiographically examined.

The second validation procedure is a comprehensive statistical analysis. In this analysis Poisson models are applied to the cohort reported by means of the unique Swedish id number. Both validation attempts have provided important information and we feel comfortable to continue the register effort without major methodological changes.

Over the years the register has been continually validated through feedback to the clinics from the register (Ahnfelt, 1986). Validation is also performed by means of retrospective controls through medical hospital files regarding number of procedures and even by comparison of national registries in other countries (Havelin et al. 1993). Validation by means of these methods is, however, crude and not register specific and the actual validity is difficult to interpret. In a survival analysis of total hip replacement, the result from 410 prospective studied patients were compared to the Swedish THA Registry (Garellick et al 1998). This study showed that a prospective procedure could result in a slightly increased revision rate compared to observational studies.

In the present first validation study, the patients were randomized from the whole country and for the clinical and radiographic evaluations the patients were stratified due to age and gender in three areas of Sweden. This selection provided patients who were not operated in the authors' hospital, minimizing potential bias.

Compared to the Swedish Discharge register and the results from the different other parts of the present validation study we find the Swedish THA registry reliable and revision is a useful end-point for failure.

The layout of the validation study and power analysis estimating the number of patients needed, was performed by a professional biostatistician (Anders Odén). Hence, the material was representative for the whole nation which made this comparison with the Swedish THA registry possible. By the use of logistic regression, survival analyses were performed in this study using clinical score levels as failure end point definition comparing the clinical results to the register. An obvious problem in these calculations was to decide the level for clinical failure since there is no or few guidelines in the literature. The results of hip replacements are not only dependent on implant and surgical technique but also demographic parameters as age, gender and co-morbidity (Charnley category). Another important factor is the choice of evaluation system or systems (Brinker et al, 1996, Callaghan et al, 1990). These authors observations were confirmed in the present study. The clinical and radiographic failures are in several trials constant with a 10-year THR survival at around 87%. The difference in survival rate using revision as failure and clinical and/or radiographic failure definitions are similar to this figure in several studies (Garellick et al, 1998).

The assumptions used in previous presentations from the Swedish THA Registry (Ahnfelt, 1986) seems to be adequate according to the "new" statistical information based on Poisson models. Young age, non-osteoarthrosis as index diagnosis and male gender are all associated to a higher risk for revision. The implant survival with maximum 8 years follow-up gives no contradictory results when compared to the modified Kaplan-Meier methods used earlier. Further follow-up is needed before long-term conclusions can be made, especially with respect to cemented fixation versus uncemented.

In summary, the 10-year survival of THR presented from the Swedish THA Registry are 93%. This result is not significantly different from the result in the present validation study or the result from the Discharge register. The new Poisson models also confirm the previous statistical results with respect to patient demographics, fixation mode and surgical technique.

The results from the Swedish THA registry are reliable and the register has contributed to improve hip replacement surgery in Sweden. ❖

CONCLUSIONS

The primary reason for documenting failures and the need for revision surgery is to improve and refine indication, surgical technique and implant choice. Too high a variation reflect autonomy in a region and in order to follow the principles of evidence based medicine, it is necessary to standardize around excellence. Registry results can potentially provide information needed in this process. The following conclusions are well founded:

- A slightly increased number of THR is performed in Sweden with well documented implants. The needs are not fulfilled.
- The most serious complications have declined threefold over the past two decades.
- Aseptic loosening still constitutes the major problem.
- Specific patient cohorts have increased failure risks, especially among younger patients in all diagnostic groups.
- Cementing technique improvement was implemented in Sweden as a result of this registry effort and outcome differences between units diminished.
- The improved efficiency and clinical practice is mainly related to the surgical technique, with an individual 10-17% reduction of revision rate for each step in the procedure.
- Porosity reduction of bone cement do not effect the overall survival but is associated with a reduced risk for revision in the longer follow-up perspective.
- The revision rate over the whole study period is only 7% for primary cemented implants, which sets the standard for this surgical procedure.
- Based on comparison to the Swedish Discharge register the results from the Swedish THA Registry seems to be valid.
- A random selected cohort of patients examined with specific questionnaires, outcome score systems, clinical and radiographic examination have assured that 95% of the revision procedures have been captured by the Swedish THA Registry.
- Revision is an exact and useable failure end-point definition. We will continue to use this failure definition, but more specific outcome studies are needed as well.
- Total hip replacement has advanced in Sweden as a result of this joint responsibility among surgeons to work in accordance with the principle of "evidence based medicine". ❖

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