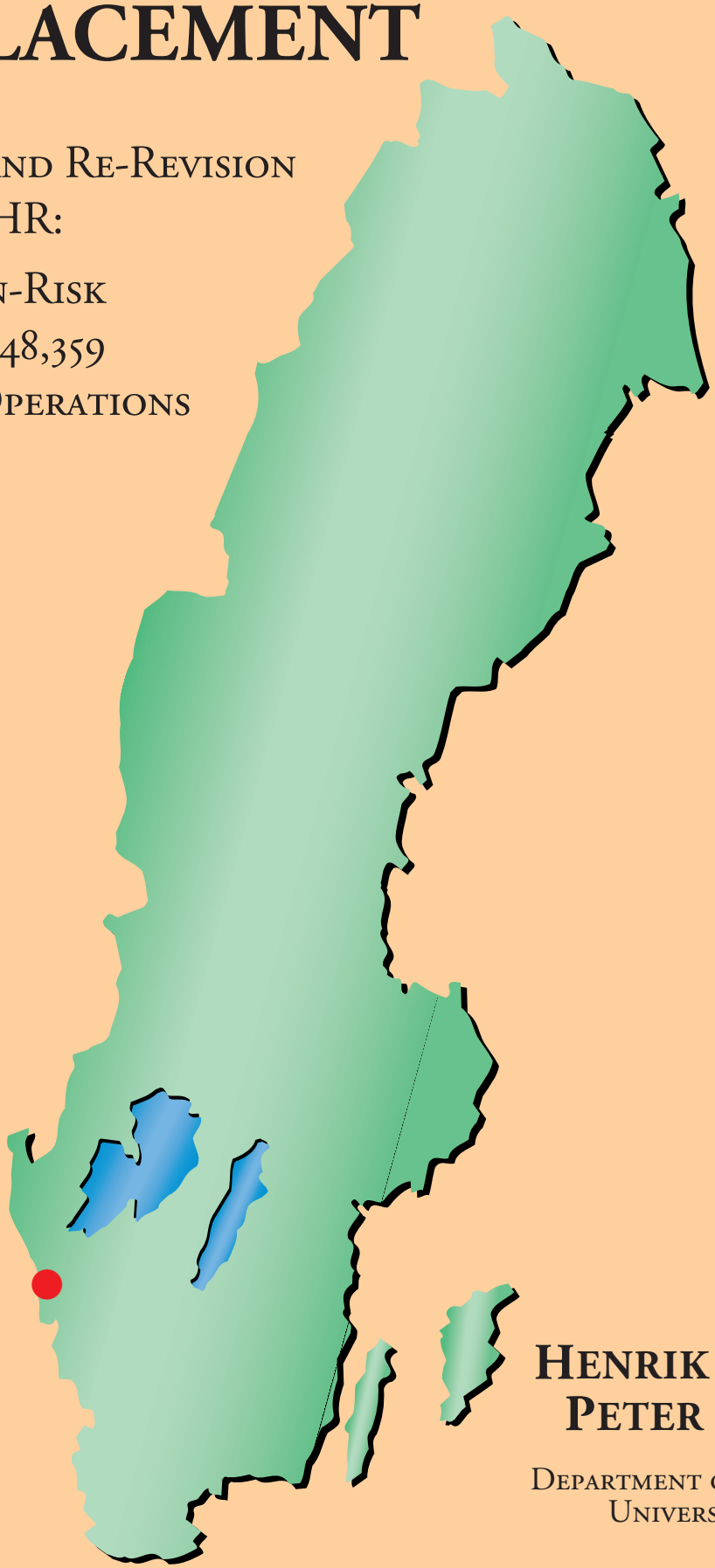
1998

Prognosis of Total Hip Replacement

Revision and Re-Revision Rate in THR:

A Revision-Risk Study of 148,359 Primary Operations



Henrik Malchau
Peter Herberts

Department of Orthopaedics
University of Göteborg
Sweden

Scientific Exhibition presented at the 65th Annual Meeting of the American Academy of Orthopaedic Surgeons, March 19–23, 1998, New Orleans, USA

PROGNOSIS OF TOTAL HIP REPLACEMENT

INTRODUCTION

Population registries of hip replacement procedures can be effective sources of information needed for a more scientific choice of implant technology. The Swedish National Hip Arthroplasty Registry was initiated in 1979 and is based on voluntary co-operation by all clinics and hospitals in the country (1,2). The purpose of the Registry is to provide treatment outcome information to the participating units. Central issues involve the choice of prosthesis and the optimal technique in individual cases. Differences in implant design, fixation methods and surgical techniques need to be compared and the hospital environment should be investigated for possible independent effects.

The dual objectives of the Registry include describing the epidemiology of total hip replacement in Sweden and identifying risk factors for poor outcomes related to the patient, implant and surgical technique. The definition for failure is revision of the implant with exchange of components or permanent extraction.

Assessment of results provides base-line information for refining indications and defining causes underlying differences in treatment results. The working hypothesis has been that sharing this information with the profession shall cause individuals to act according to the good example and lead to improvement. Furthermore, risk factors leading to accelerated prosthetic failure and serious clinical problems can be detected early due to the vast number of observations.

This exhibit reports results from all revisions after primary total hip procedures performed in Sweden during 1979 to 1996. The epidemiological analysis is based on 148,359 primary procedures and the outcome analysis on 11,198 revisions. Factors that strongly influence the risk for revision and re-revisions due to different complications are analyzed separately. The specific aim is to identify these factors that prove to be detrimental for success or failure to improve hip replacement surgery in Sweden. The advantages with a national observational study are that a wide range of surgical techniques and implants are evaluated on all types of patients.

AIMS OF THE STUDY

The specific aims for the registry are:

1 **Epidemiological analysis of hip replacement in Sweden.**

2 **Risk factor identification for primary and revision surgery.**

3 **Improvement of surgical technique by risk factor analysis.**

4 **Bench marking by comparison between regions.**

5 **Quality assurance of all hip replacements performed in Sweden.**

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.

Anders Odén, Ph.D. for biostatistical assistance.

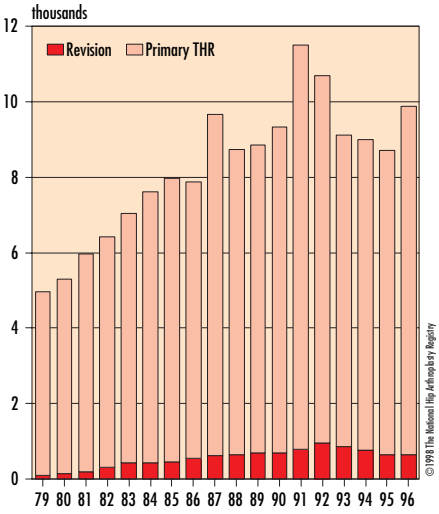
The secretaries A. K. Erikson and M. Hagman for continuous work.

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

Epidemiology of primary and revision THR

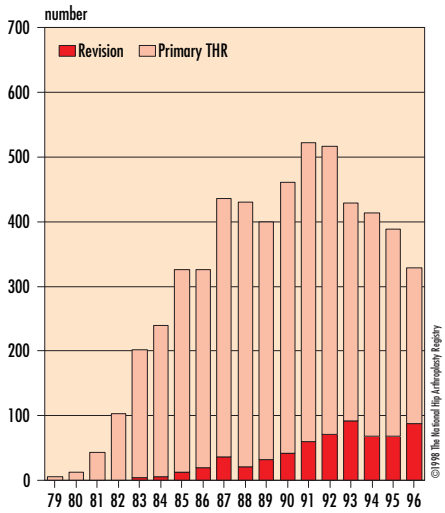
THR with Cemented Implants

138,830 Primary THR observations 1979-1996



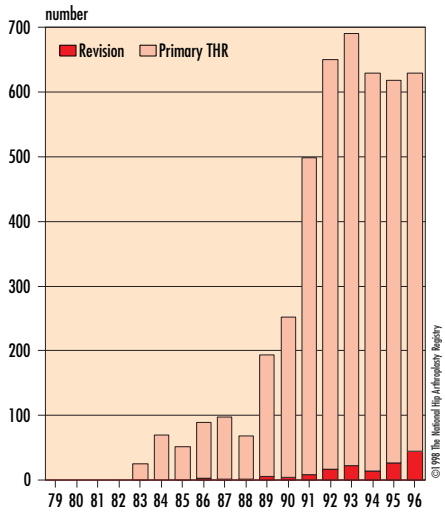
THR with Uncemented Implants

4,965 Primary THR observations 1979-1996



THR with Hybrid Implants

4,564 Primary THR obervations 1979-1996



A linear increase in the number of primary hip replacements was found for cemented implants inserted between 1979–1996. Uncemented and hybrid procedures were performed to a much smaller extent. The total procedure incidence for hip replacement has varied between 102–141 per 100,000 inhabitants during the past five years. 93.4% of the primary implants are cemented and the revisions constitute only 7.2 % in this group. The revision rate is 12.5% among the primary uncemented implants, and the corresponding figure for the hybrid procedures is 3.4%, but increasing. Age at primary replacement was 70 years and primary osteoarthrosis (76%), trauma (11%) and arthritis (6%) are the main diagnoses for total hip replacement in Sweden. The mean age has increased slightly for women and decreased for men, which can be a reflexion of widening of the indication. Among the younger patients, arthritis and secondary arthrosis are more prevalent and among the oldest patients, hip fracture is more prevalent. Overall female gender constitutes 60% and their proportion increases with age.

Age at Primary THR

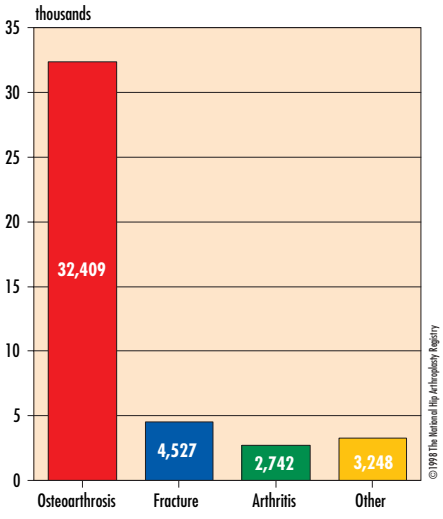
45,508 observations 1992-1996

Gender	Mean	SD	N
Men	68.8	10.5	17,891
Women	71.0	10.9	27,617
All patients	70.1	10.8	45,508

©1998 The National Hip Arthroplasty Registry

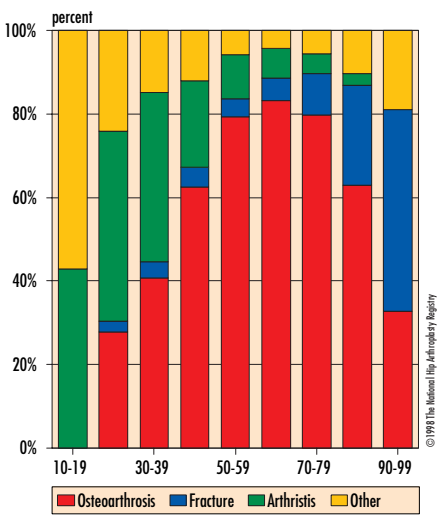
Frequency of Diagnosis

42,923 observations 1992-1996



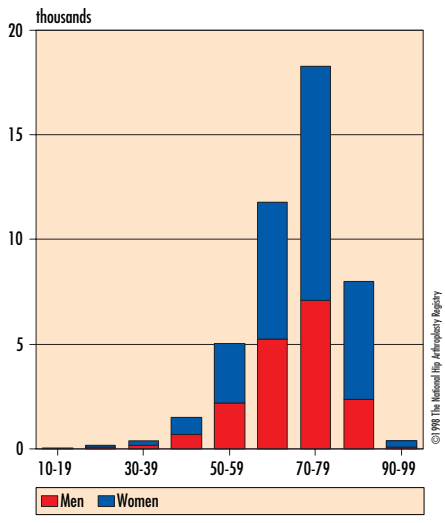
Diagnosis by Age

42,923 observations 1992-1996



Age and Gender

45,505 observations 1992-1996



Most Commonly Used Primary THR Implants 1979–1996

Cemented Implants	1979 -1986	1987 -1996
Charnley	16,054	28,525
Lubinus SP II	480	18,363
Lubinus IP	13,505	4,099
Scan Hip Collar	920	5,310
Exeter Polished (mixed cup)	552	4,567
Lubinus SP I	2,553	1,781
Exeter Polished Metal-backed		4,071
Müller Straight	1,721	2,137
Exeter Matte	3,694	
Exeter Polished All-Poly		3,508
Brunswik	1,946	269
Stanmore	1,251	865
Christiansen	1,939	
CAD	1,666	244
Spectron Metal-backed	296	1,150
Biomet Müller/Bi-Metric (cem.)		1,405
Spectron EF All-Poly		1,253
HD II	575	580
Charnley-Müller	1,059	12
ITH	10	978
Others (249 implants)	2,343	9,149
Total	50,564	88,266

Uncemented Implants	1979 -1986	1987 -1996
PCA	389	841
Romanus/Bi-Metric (uncem.)		568
Omnifit		385
Lord	309	2
CLS Spottorno		246
Harris-Galante-I	42	184
ABG HA/ABG (uncem.)		175
TTAP/LMPCH Ritter	81	72
Romanus/Bi-Metric HA (uncem.)		147
Garches/Lord	142	
Zweymüller	47	49
LMT		84
Harris-Galante-I/Anatomic		60
Rippen	19	41
PCA E-series HA		59
Anaform	11	47
Harris-Galante-I/Ti-Fit		51
Optifix/Ti-Fit		50
Ceraver	47	1
SLS/CLS Spottorno		47
Others (79 implants)	129	639
Total	1,216	3,748

Hybrid Implants	1979 -1986	1987 -1996
Romanus/Bi-Metric (cem.)		503
ABG HA/ABG (cem.)		324
Harris-Galante-I/Lubinus SP II	8	255
Harris-Galante II/Lubinus SP II		259
ABG HA/Lubinus SP II		235
Harris-Galante-I/Charnley	5	228
Omnifit/Lubinus SP II		202
Harris-Galante II/Spectron EF		159
Harris-Galante II/Charnley		142
Romanus/Lubinus SP II		140
Mecron/Charnley	123	14
Romanus/RX90		134
Harris-Galante-I/Spectron EF		123
Harris-Galante-II HA/Spectron EF		93
Mecron/Lubinus IP	47	31
PCA/Exeter Polished		65
Harris-Galante-I/Spectron		54
Duralock/Spectron EF		51
Optifix/Spectron EF		49
Optifix/Charnley		47
Others	50	1,074
Total	233	4,182

The most commonly used primary total hip replacement implants during the periods, 1979–1986 and 1987–1996, are illustrated. More than 240 types of prostheses have been used in Sweden since 1967. There has been a decrease in this diversity as a result of data shared with the orthopaedic community from the Registry. At present five major cemented implants constitute 78% of the market in Sweden and this is an important evolution (3). A small number of uncemented and hybrid implants were used during both periods.

The revision material constitutes all revisions performed in the country during 1979–1996. There were 11,198 revisions and the majority was first or second time revisions. The major reason for revision is aseptic loosening with or without osteolysis constituting 72.3% and primary deep infection only 7.2%. The proportion of serious complications leading to revision has been constant over the last years.

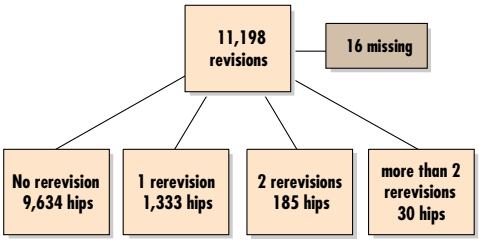
DEFINITIONS

Revison: Exchange or removal of one or both components.

Re-revison: Exchange or removal of one or both components after previous revision.

THR Revisions

1979-1996



Reason for Revision

9,634 observations 1979-1996

Reason	N	Percent
Aseptic loosening	6,965	72.3%
Primary deep infection	690	7.2%
Fracture only	454	4.7%
Dislocation	403	4.2%
2-stage procedure	386	4.0%
Technical error	372	3.9%
Implant fracture	161	1.7%
Secondary infection	94	1.0%
Pain	37	0.4%
Polyethylene wear	26	0.3%
Miscellaneous	33	0.3%
Missing	13	0.1%
Total	9,634	100.0%

METHODS

DATABASES

The National Registry is supported by the Swedish Orthopaedic Association and the National Board of Health and Welfare. It was started in 1979 and all orthopaedic departments in Sweden participate on a voluntary basis. The Registry consists of three different databases:

1 The number of primary operations from 1979 to 1991 were registered annually and per department, and included the type of implant. Since 1992, all primary operations have been reported in more detail, including the patient's social security number and diagnosis. The unique identification number used for all permanent residents in Sweden gives information about age and gender. The implant during this later period is characterized in detail.

2 The revision database includes complete copies of the medical records from all reoperated patients since 1979. 116 parameters are given per patient and computerized in the analysis of the revision data. Results obtained are described by calculating survival curves in relation to patient-related factors and also in relation to implant-related factors.

3 Information of preventive actions against aseptic and septic loosening are given per department and per year. Especially important is the detailed reporting of surgical technique, cementing technique and cement brand.

VALIDATION OF FAILURE END-POINT

In 1996 a project was initiated aiming at defining and analyzing the sensitivity of different failure end-points in THR analysis. A cohort of approximately 4,500 patients is addressed with disease specific and general health outcome questionnaires. A subsample will be examined clinically and radiographically. We expect that the knowledge from this project will be helpful in setting the guideline for the future of the Registry. The question is whether or not revision has sufficient sensitivity as a failure end-point definition or if general health outcome measures will be necessary to add in future evaluations.

STATISTICAL METHODS

In contrast to previous reports from the Registry the primary and revison material in this analysis includes patients operated between 1979 and 1996.

Patient-related factors and implant-related factors were analysed by estimation of the survival function for all implants depending on age, gender, diagnosis, type of implant and fixation technique (4).

The effect of various surgical and cementing techniques on revision rates is analyzed by Poisson models (5). 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.

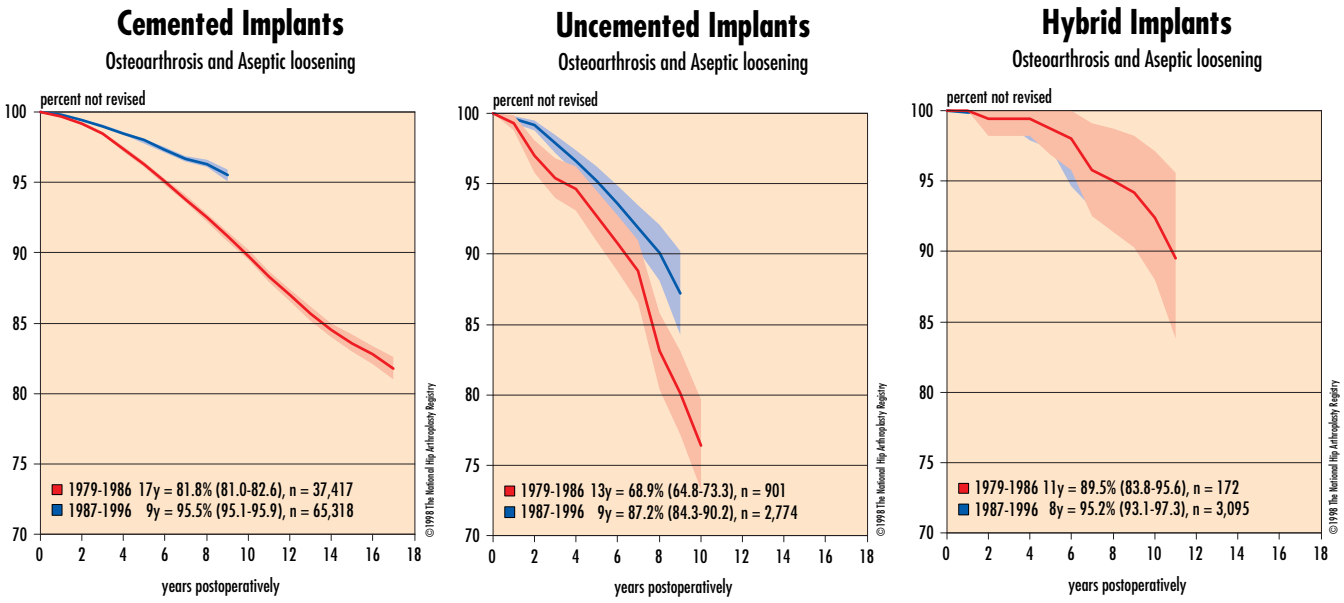
Several methods have been used to validate the registry material. The primary and revision data are validated by the participating units every year in written form before reports and presentations. Validation is also performed by means of retrospective audits of hospital medical files and by comparison with the Swedish Discharge Registry.

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.

IMPLEMENTATION

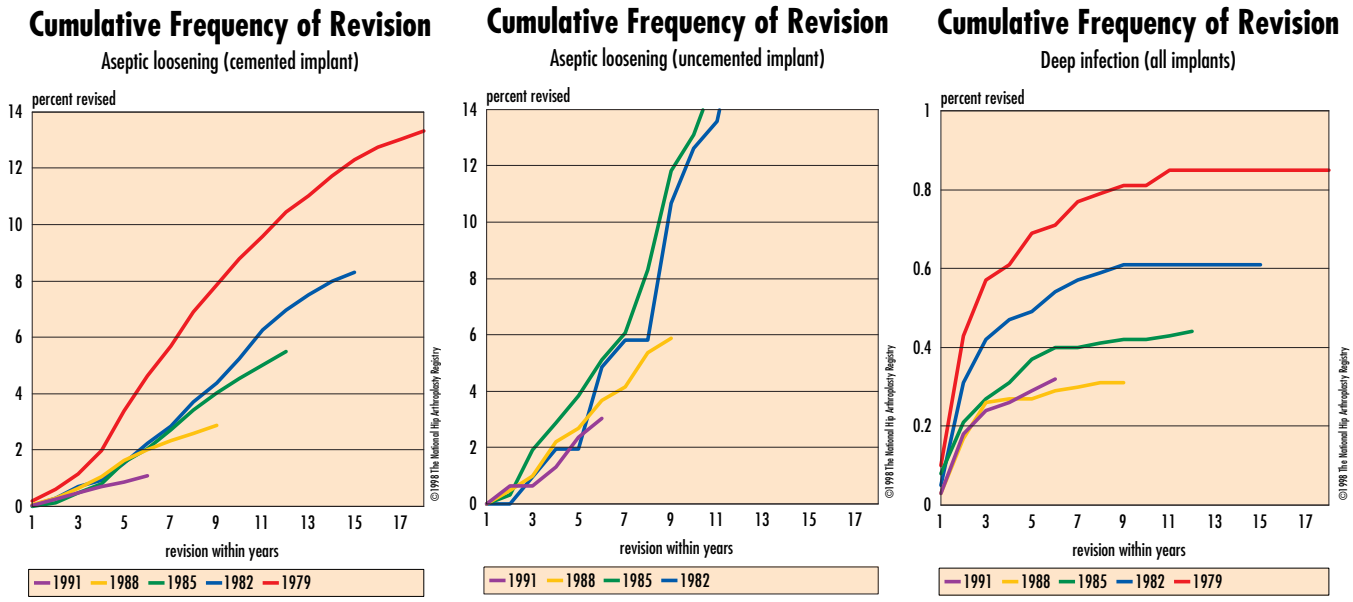
Implementation at the departmental level relics on the individual department. At present we have an ongoing discussion in Sweden whether some information from the individual units about revision rates should be available to the patients and media.

RESULTS



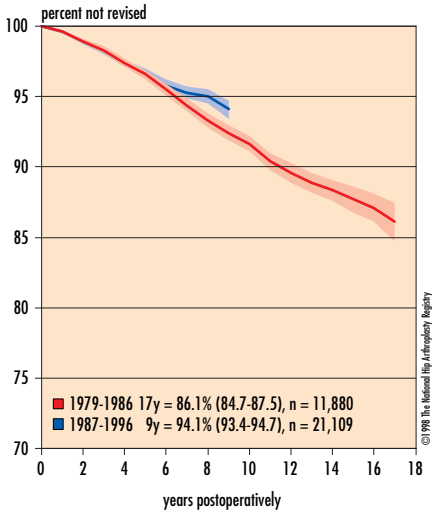
In these diagrams all primary total hip replacement implants are illustrated during two time periods. The cut off 1986–1987 was chosen because at that time most orthopaedic units in Sweden adopted a modern cementing technique. When the material was classified as cemented, uncemented and hybrid implants during the two time periods, we observed a clear improvement in cemented prostheses. The uncemented implants showed a minor improvement. The reason may be the large number of various types of uncemented implants used during these years. The improvement in uncemented technology introduced around 1990 with various surface coatings and improved cup designs will not be reflected in this analysis. Too many uncemented designs with inferior performance were still used in 1991, thus affecting the overall results. A similar finding was reported from the Norwegian Registry (6).

Severe complications following total hip replacement have decreased in Sweden successively over the past 20 years. The frequency of aseptic loosening declined concurrently with the introduction of improved fixation techniques and implant designs. For cemented implants, the cumulative revision rate attributed to aseptic loosening after nine years has declined from 9% for those operated in 1979 to 3% for those operated in 1988. A similar improvement is seen for the complication, deep infection, with a more than 50% reduction of the revision rate due to this complication. The diagrams illustrate the continuous quality improvement of total hip replacement observed in Sweden.

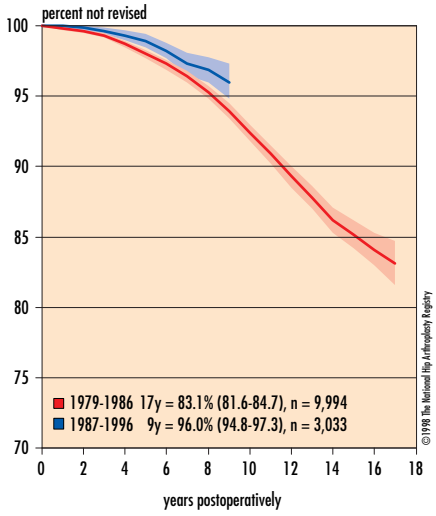


Implant-Related Factors

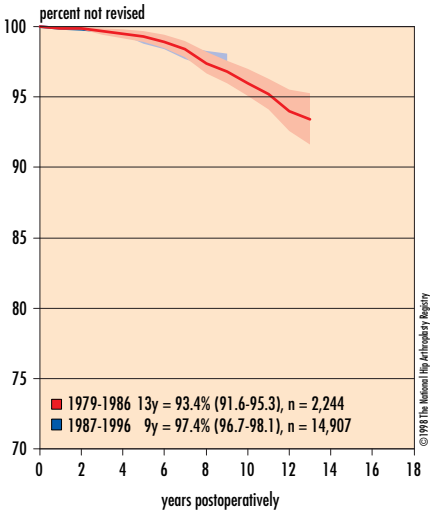
Charnley
Osteoarthrosis and Aseptic loosening



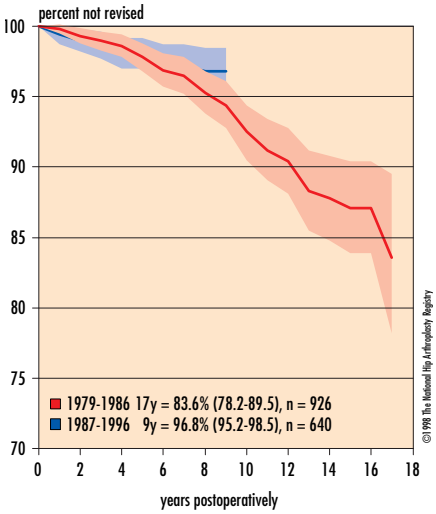
Lubinus IP
Osteoarthrosis and Aseptic loosening



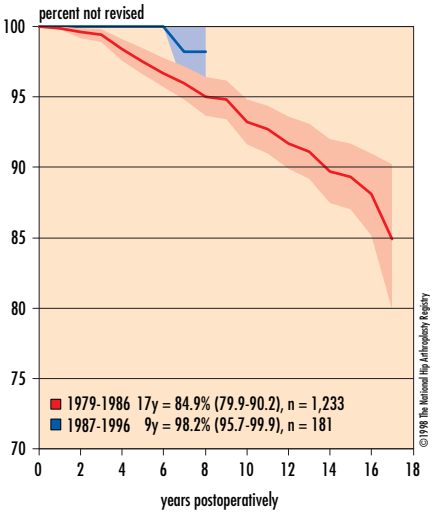
Lubinus SP
Osteoarthrosis and Aseptic loosening



Stanmore
Osteoarthrosis and Aseptic loosening



C. A. D.
Osteoarthrosis and Aseptic loosening

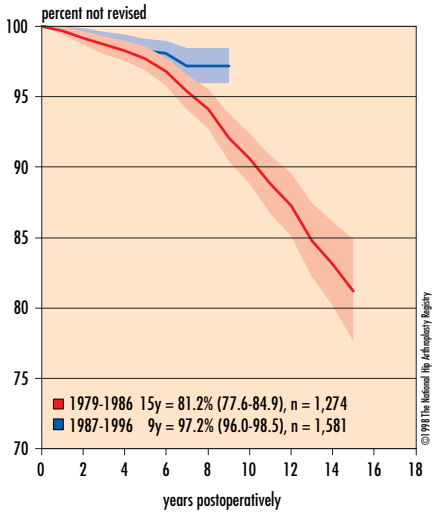


Almost all of the cemented implants show a significantly improved survival between the early period 1979–1986 and the later period 1987–1996. In the statistical analysis, revisions for aseptic loosening in patients with osteoarthrosis are analyzed and depicted in the figures. On all survival diagrams the 95% confidence interval is indicated.

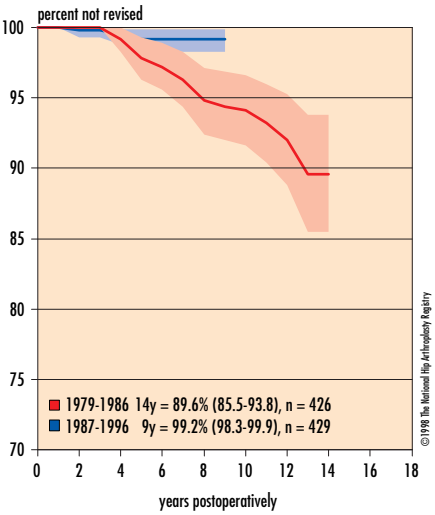
This implant survivalship analysis describes the probability of failure due to revision for aseptic loosening. The standard error increases with decreasing number of prostheses at risk. None of the curves are depicted when less then 50 hips remain at risk.

The survival at 17 years varies between 81–86% for well documented and common implants. The curves illustrate that the Charnley, Lubinus IP, Müller Straight, HD II and Spectron metal-backed implants performed significantly worse at comparable follow-up times during the first period.

Müller Straight
Osteoarthrosis and Aseptic loosening



HD II
Osteoarthrosis and Aseptic loosening

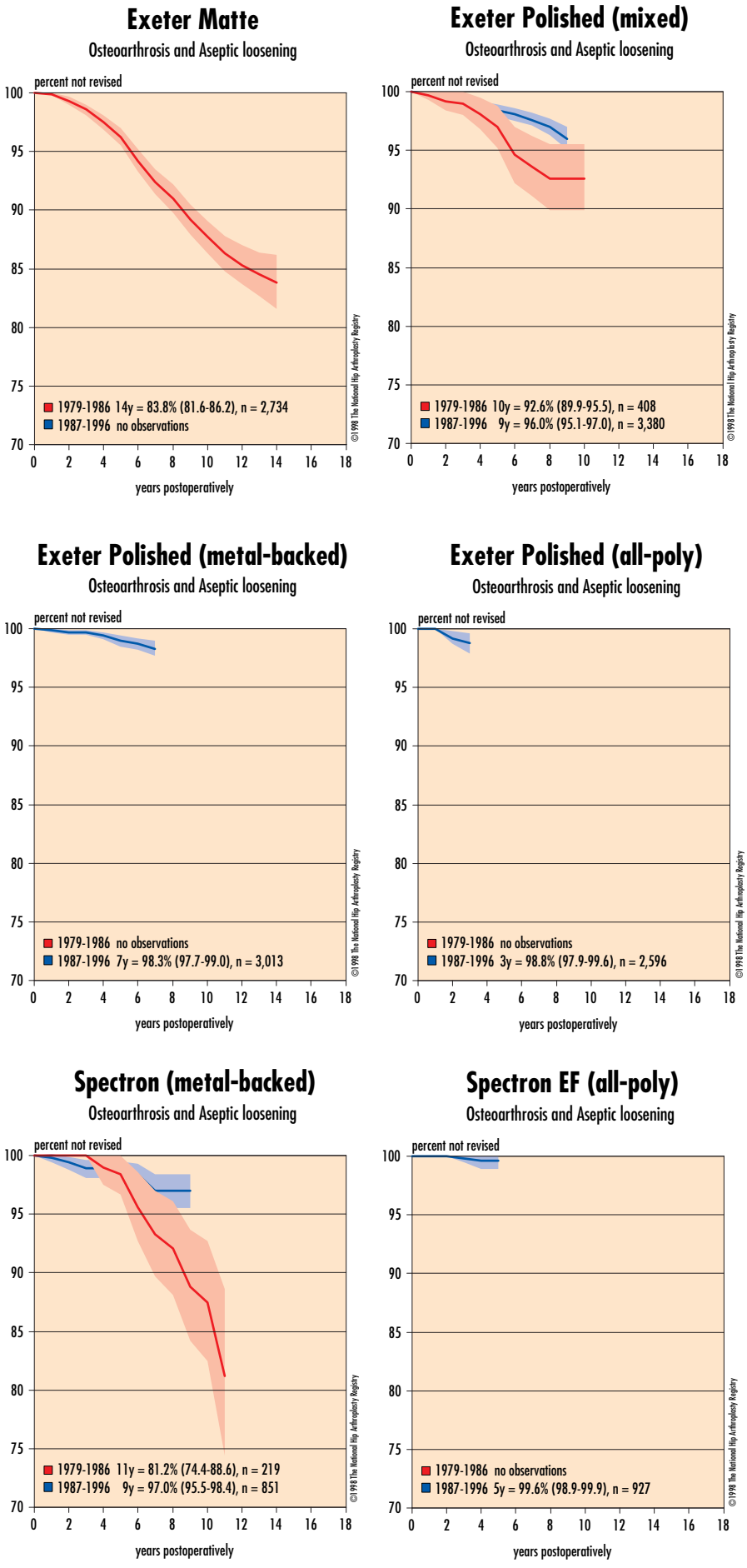


The improvement during the second period for cemented implants is well illustrated and the 9 year survival for most implants is 94–97%.

For the Charnley implant we observed a modest improvement which might be associated with the rather old fashioned instruments used up to 1994. Furthermore, almost all Charnley procedures in Sweden are performed with the posterior approach. An increased frequency of malpositioned Charnley stems and inferior cement mantles has recently been documented in Sweden (7).

A well designed implant as the Lubinus SP has performed extremely well during both periods. This illustrates that good instrumentation per se is important for obtaining a good surgical technique.

The Exeter prosthesis has been used with variable cup designs. In retrospect, we asked the clinics which cup they used, metal-backed or all-poly. The information we have obtained does not permit a clear separation and we therefore also report a fairly big cohort with uncertain information about which cup that was used with the polished stem. The Exeter polished implant has done very well, both with the mixed cups and with the metal-backed cups. It should be noted that this metal-backed cup design is specific and not complete around the whole hemisphere. Other metal-backed designs such as the Spectron implant have performed poorly although modern technique seems to improve the result. An increased wear rate has been reported for several metal-backed cups, and

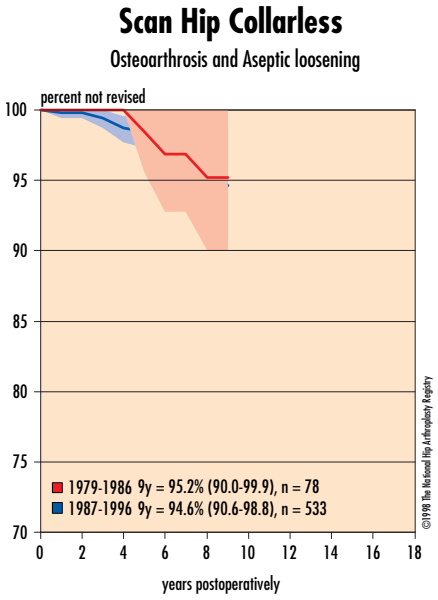


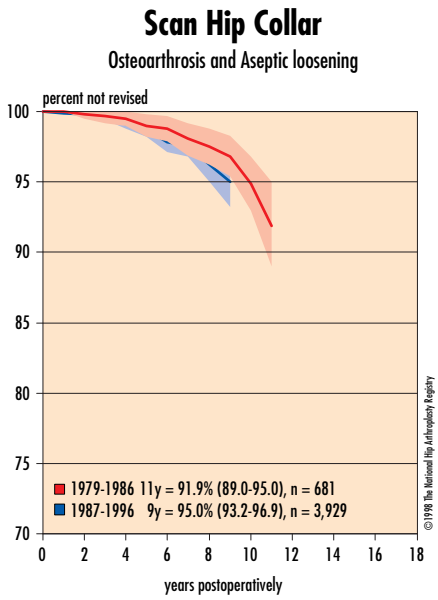
poor wear characteristics in combination with the 32 mm head diameter used with the Spectron cup, can explain the increased failure rate. Failure of metal-backed cups is usually a late phenomenon and further follow-up is necessary for these patients.

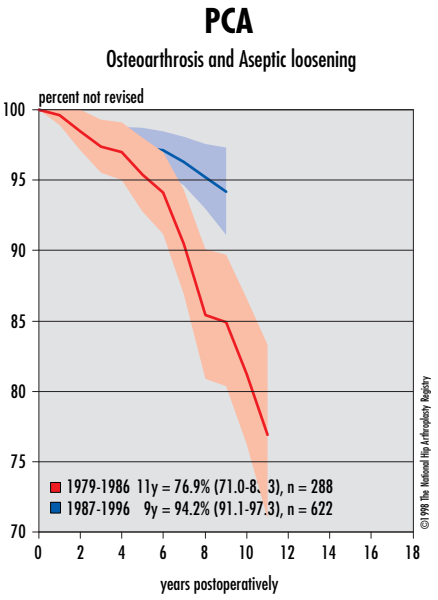
The question, whether the stem should be highly polished or have a matte surface finish, cannot be answered from current Registry data.

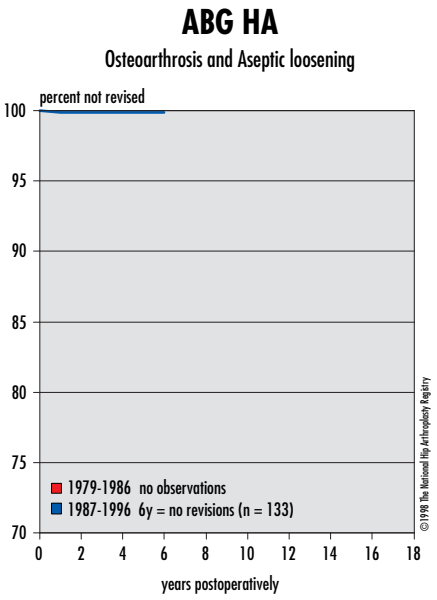
Cementless implants have been used in a limited number, both during the first and the second time period. Since the number of observations is limited, there is a broad confidence interval and more uncertain information. For certain uncemented implants, there is a statistically significant improvement with this separation in two time periods. The third generation of uncemented implants used during the last seven years (often with hydroxyapatite coating or textured titanium surfaces) has functioned well in the short perspective up to five years.

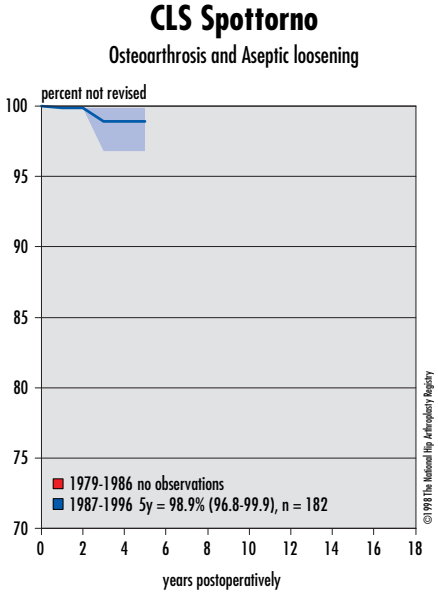
In summary, most modern cemented implants have a nine year survival for aseptic loosening around 95% and the best have shown a survival rate of approximately 98%. These figures illustrate the excellent results for hip replacement surgery in Sweden obtained by the average orthopaedic surgeon. With respect to surface finish condition, there is no difference in the nine year survival between polished and more rough stem designs. The excellent short-term result for some cementless implants is promising, but the observation is too short to accept uncemented fixation as a safe and efficacious procedure.

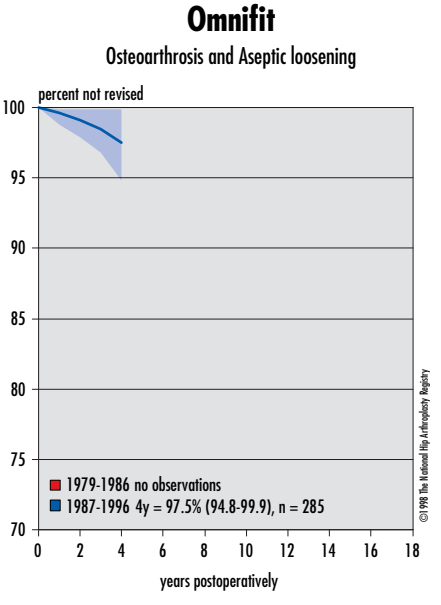












Patient-Related Factors

Men are at 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.

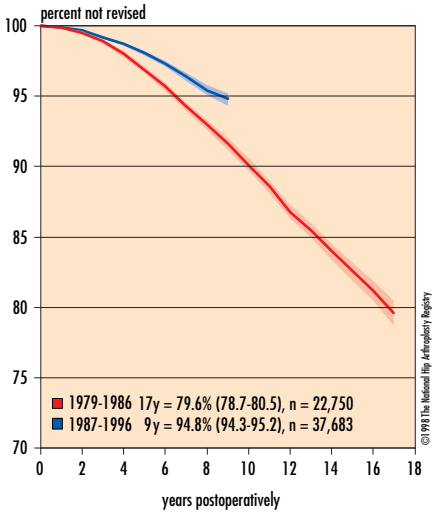
With respect to age we find that the younger and more active patients are at greater risk in all diagnostic groups. This is especially true for patients younger than 55 years of age with one exception; men with osteoarthrosis show the worst failures for patients aged 55–64 years at surgery. The reason for this unexpected finding is unknown to us, but has been constant over the years in the registry.

The worst results for total hip replacement are seen in young men with a previous fracture around the hip and also in young women with rheumatoid arthritis. The supreme challenge for this procedure is still young and active patients as identified by the Registry. Efforts and further development of implant designs and surgical techniques are necessary for this population.

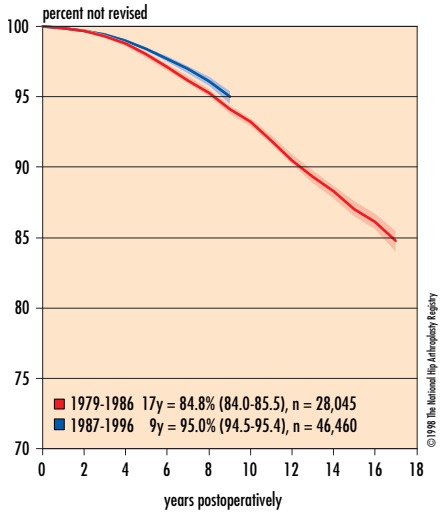
Approximately 20,000 patients are included in the cohort with a higher failure rate. It is for this cohort of patients that further scientific effort is mandatory. A possible solution could be referral of these patients to centers of excellence.

In summary, 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.

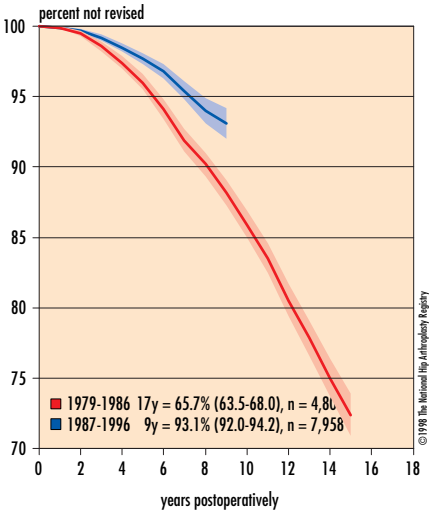
All diagnosis
Male Patients of Any Age



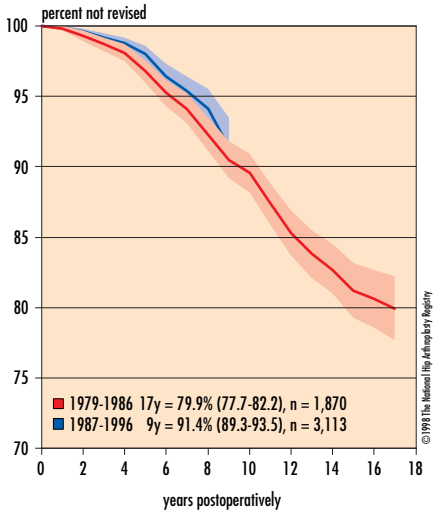
All diagnosis
Female Patients of Any Age



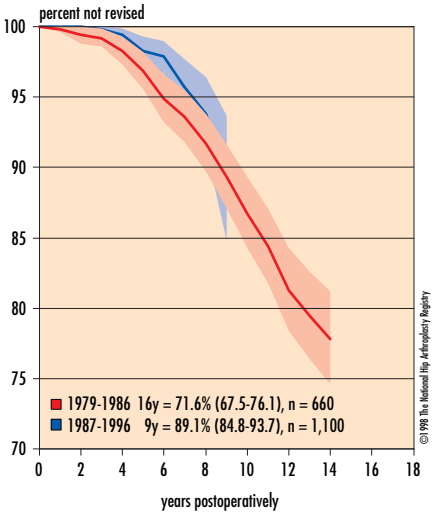
Osteoarthrosis
Male Patients Between 55 and 64 Years Old



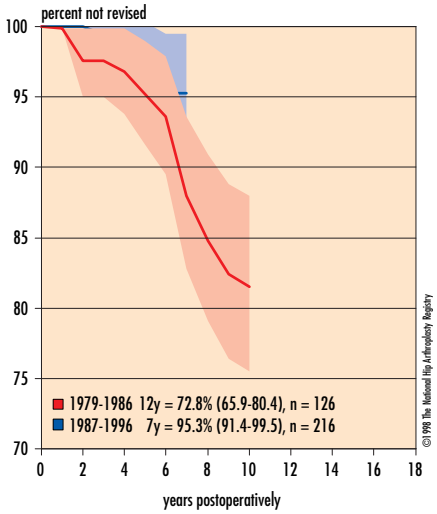
Osteoarthrosis
Female Patients Younger than 55 Years



Rheumatoid Arthritis
Female Patients Younger than 55 Years



Fracture
Male Patients Younger than 55 Years



Environmental Factors And Revision

The participating units in Sweden report the prophylactic measures against aseptic loosening and infection annually. The variables included in the reports are: surgical approach, type of cement and cement mixing technique, use of brush and pulsative lavage, number and diameter of anchorage holes in acetabulum, cement application technique including use of distal femoral plug and proximal seal, type of antibiotic prophylactics, length and administration mode. The variables are not reported for the individual patient but for the department as a whole.

By applying a Poisson model (5), the hazard function for revision (all reasons), revisions due to septic complications and revision due to aseptic loosening (index diagnosis osteoarthrosis) can be estimated by a stepwise procedure resulting in significant variables from the multivariate model.

The statistical technique used is more advanced than usual when applying Poisson or Cox models, because the number of patients at risk are calculated by use of specific death hazard functions for patients operated with THR. In the Poisson models the yearly revision rate is assumed to be ($ß_0x_0 + ß_1x_1 \ldots\ldots\ldots ß_nx_n$) where $ß_0 \ldots. ß_n$ are constants and $x_0 \ldots. x_n$ are variables. The time t (years) since the primary operation is introduced in the model through two variables x_1 = maximum (t,5) and x_2 = minimum (0,t-5). Therefore, the hazard function is a continuous function of time since the index THR. The variable x_3 equals the calendar years of the THR. All other variables in the model are environmental factors. The majority of the variables have a yes/no alternative and one is continuous (diameter of anchorage holes). For three variables (surgical approach, type of cement and cement application) an extended multivariate analysis have been performed. The variable representing the most extreme significance in the previous model was chosen as yes and the remaining as no.

In the analysis, 137,287 primary cemented THRs are included (uncemented and hybrids excluded), representing 865,730 observations years and 7,477 revisions.

Risk ratios

By use of the estimated ß-values it is possible to calculate the survival curves of hundreds of combinations for the different variables in the model. A description of the importance of each factor is obtained by the quantity exp(ß), which equals the risk ratio for a patient with all other variables equal. Thus for a variable with the level no and yes, the risk ratio is the quotient of the hazard function for a patient with yes divided by that of another one with no and identical in all other aspects.

All revisions in all diagnoses

Variable	ß	SD of ß	p	Risk ratio	95 % confidence limits of risk ratio	
Constant	-5.027	0.055	0.0000	0.01	0.01	0.01
Min(t,5)	0.126	0.008	0.0000	1.13	1.12	1.15
Max(0,t-5)	0.021	0.005	0.0000	1.02	1.01	1.03
Calendar year	-0.030	0.006	0.0000	0.97	0.96	0.98
Incision	0.302	0.033	0.0000	1.35	1.27	1.44
Type of cement	0.592	0.042	0.0000	1.81	1.67	1.96
Cement application	0.555	0.059	0.0000	1.74	1.55	1.95
Vacuum mixing	0.102	0.043	0.0172	1.11	1.02	1.21
Pulsative lavage	-0.229	0.038	0.0000	0.80	0.74	0.86
Femur proximal seal	-0.100	0.037	0.0074	0.90	0.84	0.97
Femur plug distal	-0.113	0.035	0.0012	0.89	0.83	0.96

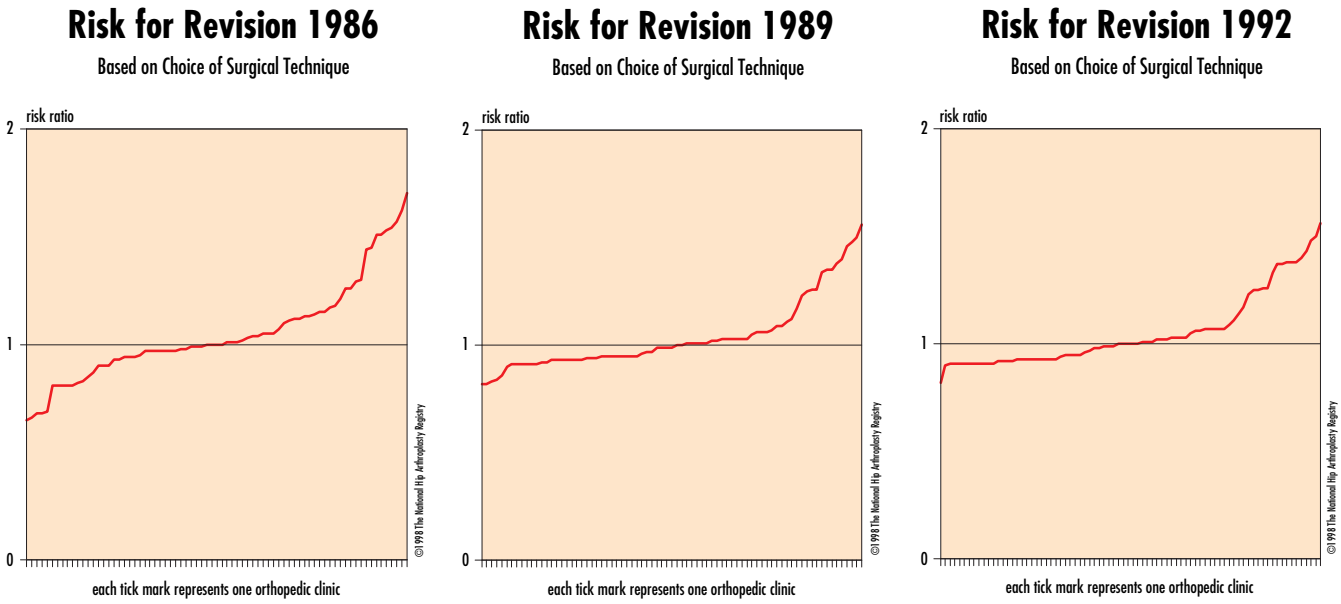
ASEPTIC LOOSENING IN OSTEOARTHROSIS

Variable	ß	SD of ß	p	Risk ratio	95 % confidence limits of risk ratio	
Constant	-6.234	0.073	0.0000	0.00	0.00	0.00
Min(t,5)	0.356	0.012	0.0000	1.43	1.40	1.46
Max(0,t-5)	0.006	0.006	0.2618	1.01	1.00	1.02
Calendar year	-0.027	0.007	0.0001	0.97	0.96	0.99
Incision	0.410	0.039	0.0000	1.51	1.40	1.63
Type of cement	0.697	0.048	0.0000	2.01	1.83	2.20
Cement application	0.627	0.070	0.0000	1.87	1.63	2.15
Vacuum mixing	0.109	0.054	0.0409	1.12	1.00	1.24
Pulsative lavage	-0.322	0.046	0.0000	0.72	0.66	0.79
Femur proximal seal	-0.233	0.048	0.0000	0.79	0.72	0.87
Femur plug distal	-0.142	0.040	0.0005	0.87	0.80	0.94

If the optimum choice of surgical and cementing steps in cemented THR is evaluated, the difference between units is striking. Three diagrams show the risk ratios for revision in 1986, 1989 and 1992. The risk ratio for 1986 varies between 0.6 and 1.72, and improves to a variation between 0.82 and 1.56 in 1989 and 1992. The observed improvement in choice of surgical technique is a striking example of the quality improvement that, at least partly, can by associated to feed-back from the Registry. The difference between hospitals does not reflect the individual surgeons ability to perform or choose implant when equal techniques are used.

The cementing technique is of utmost importance for prevention of revision due to aseptic loosening. Cleaning of the bone-bed by use of pulsative lavage, the distal plug and the proximal seal reduces the risk for revision approximately 20% each.

The multivariate Poisson models indicate an association between retrograde filling of cement and reduction in risk for revision, as well as the beneficial effect of pressurization of the cement in acetabulum. As previously reported by both the Norwegian and Swedish Registries (8,1), the type of cement has a drastic association to risk for revision. Lowest risks are associated with Palacos® Gentamicin, plain Palacos® and Simplex®. CMW® has a sligthly worse result and the highest risks are associated with use of Sulfix®.



MULTIVARIATE POISSON MODELS

	All revisions		Aseptic loosening and osteoarthrosis	
Type of cement	*Risk ratio*	*95% confidence limits*	*Risk ratio*	*95% confidence limits*
Simplex®	0.57	0.50 - 0.65	0.58	0.50 - 0.68
CMW®	0.62	0.56 - 0.68	0.68	0.61 - 0.75
Palacos®	0.54	0.49 - 0.61	0.53	0.46 - 0.60
Palacos® Gentamicin	0.46	0.41 - 0.51	0.48	0.42 - 0.55

The risk-quotes are expressed with the risk-ratio of Sulfix as nominator

	All revisions		Aseptic loosening and osteoarthrosis	
Cement application	*Risk ratio*	*95% confidence limits*	*Risk ratio*	*95% confidence limits*
Antegrade femur, Gun acetabulum	0.67	0.54 - 0.83	0.63	0.47 - 0.85
Retrograde femur, Gun acetabulum	0.58	0.47 - 0.70	0.57	0.46 - 0.71
Antegrade femur, Hand acetabulum	0.62	0.54 - 0.72	0.65	0.55 - 0.77
Retrograde femur, Hand acetabulum	0.54	0.46 - 0.64	0.57	0.47 - 0.70

The risk-quotes are expressed with the risk-ratio of finger-packing in acetabulum and femur as nominator

	All revisions		Aseptic loosening and osteoarthrosis	
Type of incision	*Risk ratio*	*95% confidence limits*	*Risk ratio*	*95% confidence limits*
Posterior in lateral position	0.69	0.64 - 0.74	0.65	0.60 - 0.70
Trochanteric osteotomi (supine)	0.80	0.72 - 0.89	0.71	0.62 - 0.81
Transgluteal (lateral position)	1.03	0.90 - 1.19	0.94	0.77 - 1.14

The risk-quotes are expressed with the risk-ratio of the transgluteal (supine) incision as nominator

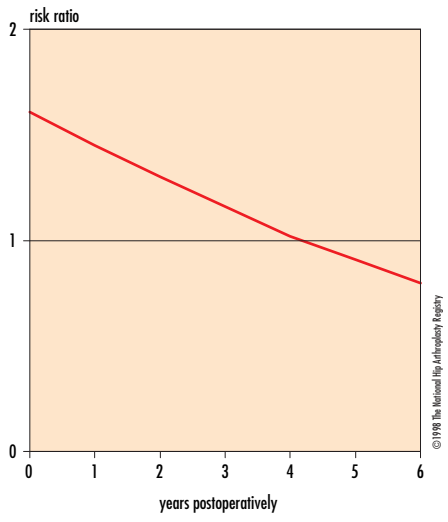
The most used surgical approach in Sweden is the posterior. The analysis shows a significantly lower risk for revision for the posterior incision (lateral position) and the lateral incision with trochanteric osteotomy than the transgluteal (lateral or supine position). The reason for this finding is not associated to certain implants, and in the analysis only includes cemented implants. We have no explanation for this observation.

The Poisson models applied on the variables for prevention of septic complications have shown an association between use of gentamicin containing Palacos® in combination with isoxazolyl-penicillin or cefalosporine-type antibiotics. Palacos® Gentamicin has the most pronounced association with a risk ratio of 0.61 (confidence limits 0.50–0.74). We find no significant effect associated to ventilated suits or laminar airflow enclosures (compared to modern ventilation with >20 airchanges/hour).

Whether porosity reduction implies a risk reduction is still unclear. In agreement with previous reports (1) we find a significantly increased risk for revision associated to use of vacuum mixing. Three different systems have been used in Sweden: Mitvac®, Optivac® and Cemvac®. Comparison shows no significant difference in risk ratio between the systems. A time dependent Poisson model indicates a higher risk for revision the first four years after the operation indicating technical mishandling and perhaps too early stem insertion (Palacos® needs to be chilled for vacuum mixing) as the major problem. Follow-up exceeding four years shows a risk ratio below 1 and we therefore still find it justified to use vacuum mixing.

Risk Ratios in Cement Mixing

Vacuum Mixing vs. Manual Mixing



RE-REVISIONS

The result of revision surgery can be analyzed very correctly by means of data compiled in the Registry. Most parameters of interest are documented from the medical records of revision procedures, whether it is the first, second or any multiple procedure. This data collection is prospectively run since 1979 and the results are based on 11,189 observations between 1979–1996. The major difficulty of the survival analysis of re-revisions is the lack of precise documentation of the exact indication for performing the new revision.

All statistical analyses of re-revisions are with first re-revision as the failure end-point. Repeated re-revision is not included in the survival statistics.

The patient's original diagnosis and the reason for revision was analyzed for the first, second and third time revisions. The results indicate that two diagnostic groups, hip fracture and childhood disease, have an increased risk for multiple revisions ($p < 0.01$).

The most prominent finding in this analysis is the difference in survival of revised implants when they are analysed against the different reasons for the first revision. This seems to overcome the effect of primary diagnosis. Although the survival of the first revision does not differ significantly with respect to the various reasons, we find a significant increase in the number of multiple revisions in particular cases.

If the reason for revision was bony fracture, deep infection or recurrent dislocation, there was an increased risk for re-revision ($p < 0.01$). When a failure occurs the Registry has identified these categories with an increased risk for repeated revisions. The group rerevised because of aseptic loosening has a fairly good outcome (80% at 10 years). The best result was obtained in patients where hips were revised because of implant fracture, which can be anticipated.

In general, the survival of revision procedures is 10% lower than primary total hip replacement. The 17-year survival for the first revision is 70.2% based on 8,728 cases. The cohort with osteoarthrosis as index diagnosis has a 17 year result of 71.4%. As in the primary situation we find a striking difference between younger and more active patients and the older population. The 15-year survival of the first revision for patients older than 75 years at the revision was 87.9%, in contrast to 70% for those aged 55–64 years.

Reason per Gender

11,198 observations 1979-1996

Reason for revision	Male	Female	Total
Aseptic loosening	71.5%	68.2%	7,820
Primary deep infection	8.2%	7.1%	856
Fracture only	5.2%	6.1%	634
2-stage procedure	3.1%	5.9%	509
Dislocation	4.8%	4.2%	502
Technical error	3.2%	4.8%	447
Implant fracture	1.6%	1.7%	183
Secondary infection	1.1%	0.8%	106
Pain	0.4%	0.4%	42
Polyethylene wear	0.2%	0.4%	31
Miscellaneous	0.4%	0.3%	42
Missing	0.2%	0.2%	26
Total	5,596	5,602	11,198

Reason per Number of Revisions

11,198 observations 1979-1996

Reason for revision	None	1 or more	Total
Aseptic loosening	72.3%	54.7%	7,820
Primary deep infection	7.2%	10.6%	856
Fracture only	4.7%	11.5%	634
Dislocation	4.2%	6.8%	509
2-stage procedure	4.0%	7.4%	502
Technical error	3.9%	4.8%	447
Implant fracture	1.7%	1.4%	183
Secondary infection	1.0%	0.8%	106
Pain	0.4%	0.3%	42
Polyethylene wear	0.3%	0.3%	31
Miscellaneous	0.3%	0.6%	42
Missing	0.1%	0.8%	26
Total	9,634	1,564	11,198

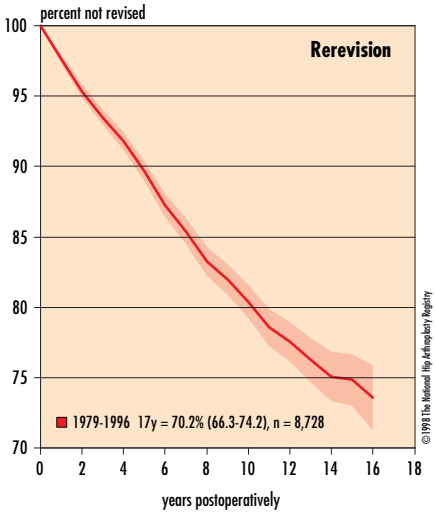
Primary Diagnosis per Gender

11,198 observations 1979-1996

Diagnosis	Male	Female	Total
Primary osteoarthrosis	82.8%	67.4%	8,409
Fracture	5.9%	13.3%	1,072
Rheumatoid Arthritis	6.2%	10.0%	910
Childhood diseases	2.3%	7.0%	518
Avascular necrosis	1.2%	1.2%	139
Secondary arthrosis	1.3%	0.6%	107
Tumour	0.1%	0.2%	16
Other arthrosis	0.1%	0.1%	14
Missing	0.2%	0.1%	13
Total	5,596	5,602	11,198

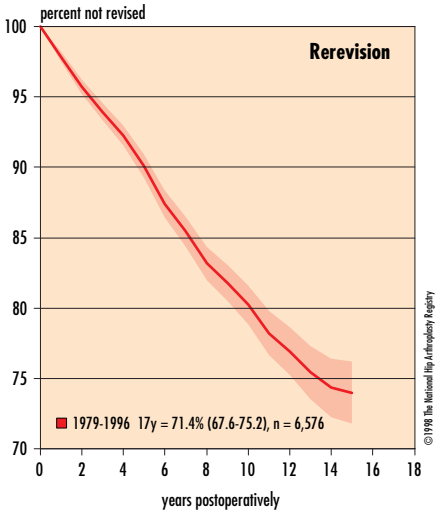
All Implants

8,728 patients 1979-1996



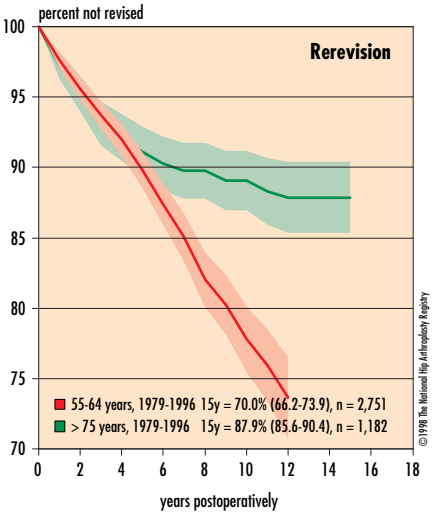
Primary Diagnosis

Osteoarthrosis



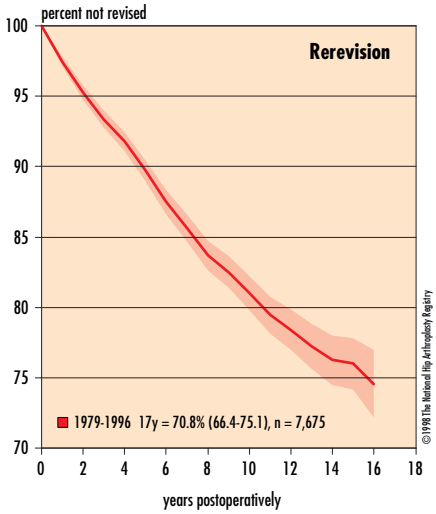
Age at Primary THR

55 to 64 Years Old / Older than 75 Years



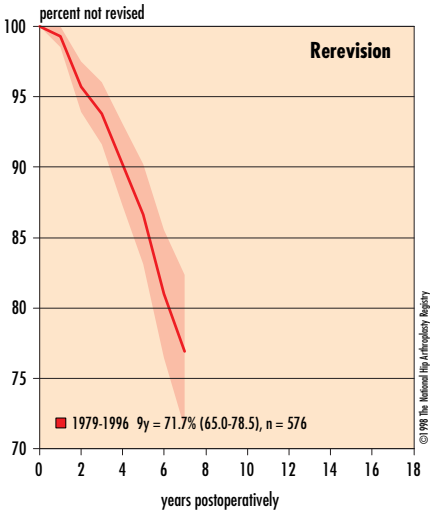
Type of Fixation at Primary THR

Cemented Implants



Type of Fixation at Primary THR

Uncemented Implants

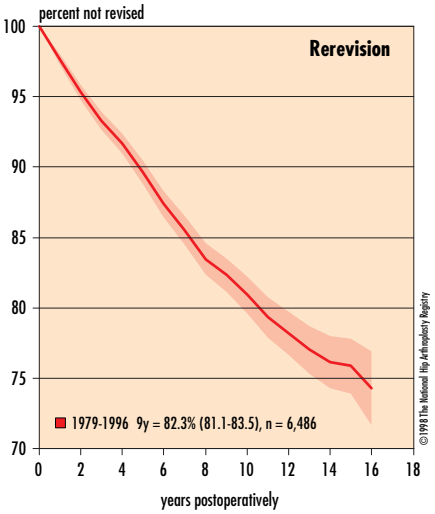


The type of fixation at the primary procedure (cemented versus uncemented implants) is of importance also when we analyze the result of the first revision. Uncemented technology gives a higher failure rate of the first revision at nine years. This difference is significant and can be related to the high incidence of osteolysis, especially on the pelvic side. The technique at the revision surgery shows a slight difference with inferior results for uncemented technology of previously cemented cases. This difference is, however, not significant and is of course a reflection of first and second generation uncemented techniques used during the last 15 years.

In summary, there are several confounding factors to take into account when discussing the prevalence and results of revision procedures. The demographics of the group of patients who had re-revision procedures, and increased co-morbidity, affect the willingness of surgeons to perform re-revisions. Also, waiting lists of variable lengths will probably affect this decision process to a great extent.

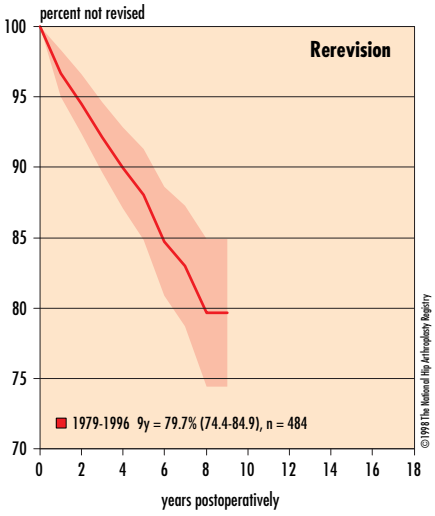
Change of Fixation

Transition from Cemented to Cemented



Change of Fixation

Transition from Cemented to Uncemented



DISCUSSION

Joint replacement procedures lend themselves particularly well to national observation studies. The current study describes a national registry effort aimed at providing outcome studies via systematic audits of results of hip replacement surgery in a defined parameter, the need for revision surgery.

From a methodological point of view, the Registry has improved and since 1992 we have detailed information of the primary procedure reported annually. We now obtain information not only about the patient´s age, gender and diagnosis, but also detailed information about each implant. In the future this will enable us to report more exactly the failure scenario for any type of device with its specific modification, which has not been the case up till now. There will always be a lack of precise documentation on the exact indication for performing the revision, especially the reason why the individual component was revised or not. This type of important information is often not precisely documented in the medical records. With this in mind we will, however, in the future try to separate cup and stem implants in the failure analysis.

The Registry has led to improved efficiency of clinical practice and will allow optimizing of resources by identifying specific patients at risk. The important issue that we must address in the orthopaedic community is which patient should be referred to specific centres of excellence. The information in the Registry study should be of importance in the discussion of allocation of resources for both primary and revision surgery.

The Swedish orthopaedic community has decided to stay with well documented and cemented implant technology for THR. As a result the revision rate is very low and has actually declined during recent years down to 6.8%. This promising evolution has taken place despite the fact that primary hip replacements have increased continuously and the number of patients at risk for failure thereby multiplied. Several other countries have reported higher failure rates and in Canada (patients >65 years) revision surgery constitutes 11%, in Finland more than 18%, (9) in Norway 22% and in the United States, figures around 20% have also been reported. This difference can be attributed to the fact that 80% of implants used in Sweden are cemented, safe and have been well documented for decades.

The most important information obtained by this registry effort is related to the third database. The fact that we have information about surgical technique from every department for almost two decades has had a profound effect on technique improvement in Sweden. It has been possible to annually distribute information to every unit about the immense importance of improving technique. The significant difference between the various generations of cementing techniques was detected already after 3–4 years due to the large number of patients evaluated. During the last decade, most centres have used a modern cementing technique and each step has contributed with approximately a 20% reduction of revision for aseptic loosening. This high technical standard in performing the surgery is in contrast to reports from other countries and in Great Britain it was recently reported than only 25% of surgeons used modern cementing techniques (10).

Porosity reduction of the cement by means of vacuum mixing has shown a variable effect in the Registry. In our last exhibit (11) we reported for the first time an increased failure rate due to aseptic loosening, when vacuum mixing was used. We attributed this to the introduction of new systems and a change of technique when using these systems. We now find that the beneficial effect of vacuum mixing still is not present, but there is a change in the positive direction indicating that some of the mistakes have been addressed.

Recently an increased interest has focused on the surface finish of the stem implant. The original polished stems from the seventies were replaced by rougher stems during the eighties to a great extent. By means of the Registry we can report that polished as well as matte stem finishes have worked well with several implant designs. Up to this date we are not able to separate implant survival when they are analysed with respect to stem roughness. The size of the study and the great number of cases included in this national registry implies that this information will soon be available.

In summary, the information obtained by the Registry has enabled the surgeons in Sweden to refine their indications for surgery, use implants with a verified durability and most important to improve their surgical technique. The extremely low revision rate obtained is important information not only to the profession, but also to patients, providers and payers.

CONCLUSIONS

Joint replacement procedures lend themselves particularly well to national registry studies. The primary reason for documenting failures and the need for revision surgery is to gain information from dearly bought experience. The following conclusions are well founded.

- An increasing number of primary procedures are performed in Sweden successively, with well documented implants.
- 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 younger patients.
- 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 related to each step in the surgical technique, with a 20% reduction of revision rate.
- No positive effect was associated to porosity reduction of bone cement in the short to mid-term follow-up perspective.
- The revision rate over the whole study period is only 72% for primary cemented implants, which sets the standard for this surgical procedure.
- The index diagnoses had low association with risk for repeated revisions. Childhood disease and hip fracture patients, hovewer, have higher risk for multiple revisions.
- The outcome of revisions was significantly related to the reason for intervention. Groups of patients with bony fracture, primary deep infection and recurrent dislocation were at significantly higher risk for multiple revisions.
- Overall the 10-year survival of the first revision was 10% inferior to primary hip replacement procedures.
- Based on the findings in the Registry it would be desirable to refer certain types of patients (including both primary and revision) to centres of excellence.
- 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”.

REFERENCES

1. Herberts P, Malchau H: How outcome studies have changed total hip arthroplasty practices in Sweden. Clin Orthop 344:44-60, 1997

2. Malchau H, Herberts P, Ahnfelt L: Prognosis of total hip replacement in Sweden. Follow-up of 92,675 operations performed 1978-1990. Acta Orthop Scand 64:497-506, 1993.

3. Murrey DW, Carr AJ, Bulstrode CJ: Which primary total hip replacement? JBJS 77B:520-527, 1995.

4. Kaplan EL, Meier P: Nonparametric estimation from incomplete observations. J Am Stat Assoc 457-481, 1958.

5. Breslow NE, Day NE:Statistical methods in cancer reasearch. Vol II, IARC Scientific Publications 32:131-135; Lyon 1987.

6. Havelin LI, Espehaug B, Vollset SE, Engsaeter LB, Langeland N: The Norwegian arthroplasty register. A survey of 17,444 hip replacement 1987-1990. Acta Orthop Scand 64:245-251, 1993.

7. Garellick G: On Outcome Assessment of Total Hip Replacement. Thesis, Göteborg University, 1998.

8. Havelin LI, Espehaug B, Vollset SE: The effect of the type of cement on early Revision of Charnley Total Hip Prostheses. JBJS 77A:1543-1550, 1995.

9. Nevalainen J, Hirvonen A, Pulkkinen P: The 1996 Implant Yearbook on Orthopaedic Prostheses, National Agency for medicines, 1997. ISBN 952-5099-05-9

10. Hashemi-Nejad A et al: Current attitudes to cementing techniques in British hip surgery. Ann R Coll Surg Engl 76:396-400, 1994.

11. Malchau H, Herberts P: Prognosis of Total Hip Replacement. Surgical and Cementing Technique in THR: A Revision-Risk Study of 134,056 Primary Operations. Scientific Exhibition, 63rd AAOS Meeting, Feb. 22-26, Atlanta, USA.

Joint Replacement Unit
Department of Orthopaedics
University of Göteborg
Sweden

Salomongruppen/second edition