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The Swedish Knee Arthroplasty study with special reference to unicompartmental prostheses

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Lund 1997

CONTENTS

LIST OF PAPERS

This thesis is based on the following papers, which will be referred to by their roman numbers in the text.

I.   Lindstrand A, Stenström A, Lewold S. Multicenter study of unicompartmental knee revision. PCA, Marmor, and St Georg compared in 3,777 cases of arthrosis. *Acta Orthop Scand* 1992; 63(3): 256-9.

II.   Lewold S, Knutson K, Lidgren L. Reduced failure rate in knee prosthetic surgery with improved implantation technique. *Clin Orthop* 1993; (287): 94-7

III. Knutson K, Lewold S, Robertsson O, Lidgren L. The Swedish knee arthroplasty register. A nation-wide study of 30,003 knees 1976–1992. *Acta Orthop Scand* 1994; 65(4): 375-86.

IV.   Lewold S, Goodman S, Knutson K, Robertsson O, Lidgren L. Oxford meniscal bearing knee versus the Marmor knee in unicompartmental arthroplasty for arthrosis. A Swedish multicenter survival study. *J Arthroplasty* 1995; 10(6): 722-31.

V.   Lewold S, Olsson H, Gustafson P, Rydholm A, Lidgren L. Overall cancer incidence not increased after prosthetic knee replacement: 14,551 patients followed for 66,622 person-years. *Int J Cancer* 1996 68 (1): 30-3.

VI.   Lewold S, Robertsson O, Knutson K, Lidgren L. Prognosis of revision after failed unicompartmental knee arthroplasty for arthrosis. Submitted.

ABBREVIATIONS AND DEFINITIONS

BKA	Bicompartmental knee arthroplasty
CRR	Cumulative revision rate
CRRR	Cumulative rerevision rate
Crude revision rate	Fraction of arthroplasties revised
HDPE	High density polyethylene
OA	Osteoarthrosis
PMMA	Polymethyl methacrylate (bone cement)
RA	Rheumatoid arthritis
Revision	Any operation at which a prosthetic component has either been exchanged, removed or added
RSA	Radiostereometric analysis
TKA	Tricompartmental knee arthroplasty
UKA	Unicompartmental knee arthroplasty

INTRODUCTION

Osteoarthrosis (OA) is associated with degeneration of the articular cartilage. It can be secondary to, among others, infection, inflammatory diseases or trauma, although the cause is generally unknown. The patient presents with a history of pain, often of long duration. Although initially intermittent and related to strenuous activity, pain later on usually becomes more continuous and finally disturbs the patient even at rest. If untreated the joint may become increasingly deformed, malaligned and unstable, and the range of motion gradually reduced.

For the knee, the clinical diagnosis of OA is established by radiographic examination, and may be graded according to Ahlbäck (1968) where relative loss of joint space is estimated in weight bearing and, if present, also the grade of bone attrition. Primary knee OA of the femorotibial articulation usually starts in the medial compartment with gradual loss of leg alignment. It is progressive but usually remains confined to the initially affected compartment (Hernborg & Nilsson 1977, Odenbring et al 1991). End stage OA may cause subluxation of the condyles with secondary arthrosis in the contralateral compartment (Ahlbäck 1968).

In OA with complete loss of cartilage (Grade II or more), surgery should be considered. The options are tibial osteotomy and endoprosthetic replacement.

Knee prosthetic surgery has, in terms of success in relieving pain and restoring function, over the years been one of the most rewarding fields in orthopedics. More than 90 percent of those operated on during the last decade have a stable, mobile and painfree knee still after 10 years. This has of course not always been the case but is the result of four decades of aggregated experience both experimentally and clinically. The earliest mode of operation for incapacitating arthrosis (apart from amputation) was resection of the destroyed joint, with the objective either of obtaining a solid union (arthrodeses) or by interposing various tissues (fat, tendon, fascia lata or xenografts etc) or inorganic materials to eliminate the pain while still preserving a reasonably functioning joint. Gluck in 1890 is accredited to have performed the first endoprosthetic arthroplasty. He, however, soon cautioned others against this type of surgery because of the bad results, mainly because of infection. In the 1950s Walldius, after having changed from an acrylic to a cobalt-chromium hinge prosthesis, was the first to report encouraging results (Walldius reprinted 1996). This was followed in England by Shiers

who designed a similar metal hinge prosthesis for use with bone cement (Shiers 1954). In the seventies a hinged design with a patellar flange was adopted by the French GUEPAR group.

MacIntosh in 1954 introduced a tibial spacer which initially was made of acrylic (MacIntosh & Hunter 1972). In this design the material was shown to be inadequate and after 1964 it was changed to metal with the addition of a fin for fixation. Its function was to correct malalignment and prevent direct bone to bone contact in the deranged compartment.


Medial gonarthrosis Ahlbäck I

Applying the principle of a low friction arthroplasty with a metal to HDPE articulation fixated with polymethyl methacrylate (PMMA) led, in the seventies, to a major breakthrough often denoted as the beginning of the modern era of knee prosthetic surgery. Gunston, in 1968, designed the Polycentric prosthesis with separate rather constrained, unicompartmental components while he was working in the UK (Gunston 1971). By connecting the femoral and later also the tibial components, a bicompartmental prosthesis was created (Freeman & Levack 1986), which was later transformed into a tricompartmental design by adding an anterior femoral flange for the femoropatellar articulation. In 1974, the Total Condylar prosthesis with metal femoral and HDPE tibial components was designed and successfully introduced by Insall and Walker (Insall et al 1976).

At that time early promising results with some exceptions led to an accelerating proliferation of tricompartmental prostheses with a cobalt-chromium femoral component articulating with an HDPE tibial component.

Over the last two decades the hinged prostheses, because of the great numbers of septic and aseptic loosening often with substantial bone loss (Knutson et al 1986), were used less frequently for primary procedures but were reserved for severe cases and for revision surgery. Attempts were made to combine the stability of the hinge with a metal to HDPE articulation (e.g. St Georg hinged knee), but they often failed because of fracture of the HDPE part. Further attempts were made to create stable hingelike prostheses with more than single axis mobility to reduce the stress transmitted to the fixation interface (e.g. Attenborough;
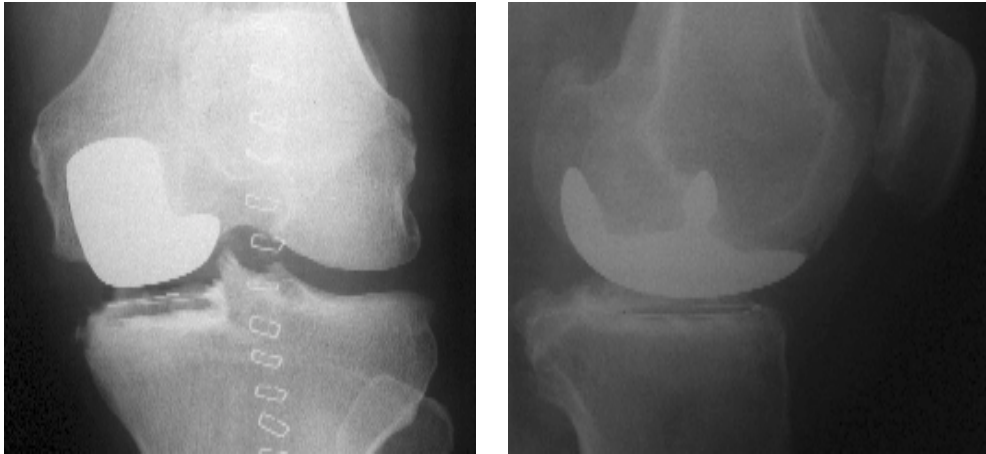
Medial unicompartmental knee arthroplasty using L-resection and a Marmor prosthesis.

Boegård et al 1984). The latter type has evolved into various rotation hinges that are still used for complicated revisions (Nieder 1991).

For the unicompartmental knee, the rather constrained Polycentric prosthesis (Gunston & MacKenzie 1976) with its narrow tibial component, which was prone to subside, was followed by some unconstrained designs that were to become the standard for many years. One of these was the Marmor Modular prosthesis which was initially designed to be used with a tibial component that was cemented on cancellous bone within a cortical rim as an inlay prostheses (Marmor 1973). The designer after reporting a 10–13-year follow-up (Marmor 1988) recommended the widest tibial component be used to allow the prosthesis to also rest on the peripheral cortical rim. The concept of modularity, by variable thicknesses of the tibial components, offered the possibility of correcting alignment of the knee more accurately at the time of surgery.

Inspired by the work of Gunston and McKenzie, Engelbrecht in 1969 designed the St Georg sledge prosthesis (Engelbrecht 1971). As for the Marmor prosthesis, fracture of the surrounding cortex was seen and the initial inlay design was abandoned for a wider component implanted with an L-shaped resection.

Both the Marmor and the St Georg sledge prostheses were later, in the mideighties, also offered with metal backed tibial components and were at the same time slightly modified as regards the femoral component, resulting in the Richard Mk III and Endo-Link, respectively. These unconstrained designs both

The Richards MkIII prosthesis.


The Robert-Brigham prosthesis.

The St Georg sledge prosthesis.

The Endo-Link prosthesis.

had femoral components fitted on the femoral condyle with one or two pegs for additional fixation and were used with bone cement. A similar designs is the Robert-Brigham unicompartmental knee (Scott & Santore 1981). One concern was the small contact area between the components which could create high point stress of the HDPE surface with delamination and wear (Blunn et al 1997). A new concept in dealing with this problem was introduced by Goodfellow and O'Connor (1978). The Oxford Meniscal Bearing knee offered a large contact area by a congruent femoromeniscal articulation while the sliding
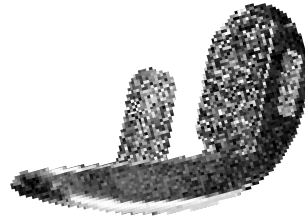
The Oxford Meniscal Bearing prosthesis   *The PCA Uni prosthesis*

of the meniscal component on a flat metal tray on the tibia reduced the shearing forces. The latest unicompartmental designs today have a full range of guide instruments and are at some centers implanted using a miniarthrotomy. The femoral component is fitted to the knee with resection of the femoral condyle in the same manner as for tricompartmental prostheses. In this way a thicker plastic tibial component may be used with the same amount of tibial resection since the femoral component is more deeply seated.

The most common mode of failure in knee arthroplasty is aseptic loosening of the tibial component. Early designs were constrained leading to shear forces being transmitted to the bone-cement interface. Later, by making the prostheses less conforming, those forces were allowed to dissipate through the ligaments. Unfortunately this instead introduced new modes of failure, namely excessive delamination wear of the HDPE tibial component because of higher point contact stress, as well as abrasion during the sliding and roll-back of the femoral component on the tibial plastic surface (Blunn et al 1997). This was even further accelerated with some more anatomic designs e.g. the PCA Uni knee (Lindstrand & Stenström 1992).

All-polyethylene tibial components have been shown to deform by creep or cold flow (Ryd et al 1990) and hereby possibly break up the cement-bone interface allowing for micromotion and later clinical loosening. Metal backing, which was introduced to eliminate the effect of cold flow, could also, if provided with a porous surface, offer the possibility of cementless fixation by direct bone ingrowth into the pores.

However, although cold flow is reduced with metal backed tibial components (Ryd et al 1992), aseptic loosening still remains the major cause of failure. A possible explanation is the different elastic modulus of metal vs. the underlying bone leading to micromovements. Also, metal backing increases the high stress induced on the HDPE surface by point contact with the femoral component. This is less pronounced in prostheses with thicker plastic components (Engh et al 1992) where forces possibly are absorbed by the elasticity of the material. Adding a metal backing, everything else equal, however, also requires a thinner plastic to be used which may have an adverse effect on the durability of the component.

Cementless fixation was introduced to reduce the risk of particle generation and third body wear from cement debris with resulting prosthetic loosening. However, HDPE wear has remained a problem. Early attempts with a layer of beads as a porous surface resulted in bead loosening and increased wear of metal and HDPE (Rosenquist et al. 1986). With modern surface coatings this problem seems to have diminished. When combined with hydroxyapatite-coating a stable initial fixation may be achieved (Søballe & Overgaard 1996). From specialized centers good early results have been reported (Jordan et al 1997, Whiteside 1994) although this has not been demonstrated in more widespread use (Rand & Ilstrup 1991). The cementless fixation technique is more demanding with difficulties in achieving the necessary primary mechanical stability.

The flora of prostheses offered by the industry today is vast, and the continuous development of new designs is by no means diminishing. There has been a tendency to accredit the current improved results solely to the development of new prostheses. The design and characteristics of the prostheses are without question of great importance. But it is obvious today that many other factors such as selection of patients, individual and collective learning, introduction of new techniques and instruments and rehabilitation also have a significant influence on the final outcome.

Most prostheses are introduced after a short period of experience by the designer and in a limited number of patients. This is remarkable since to justify the introduction of new designs the results must at least be as good as the prevailing when used in a number of units. To prove such a benefit a new prosthesis would have to be tested longer than it usually stays on the market. The conclusion must be that the general use of an implant is the final clinical test of its usefulness. To monitor this and be able to detect underperforming designs and potential hazards as early as possible the prospective nation-wide Swedish Knee Arthroplasty study was started in 1975 as the first national register in Sweden.

The Swedish Knee Arthroplasty study

In 1975, the Swedish Orthopedic Society initiated the prospective nationwide study called the Swedish Knee Arthroplasty study.

In Sweden, as well as in the other Scandinavian countries such studies can be undertaken primarily because of the unique social security number that all citizens are provided with. This enables us to follow patients over a long period of time. If a patient is revised at another institution, the record of that revision will be sent to the coordinating center and appended to the primary procedure in the computer by use of the social security number. When analyzing the survival of prostheses one also has to detect and censor those that have died with the prostheses in situ or for some other reason are lost to follow-up. Again the social security number makes this possible, by annually running the database against a census register carrying this information as well as for those that have emigrated and hereby no longer are possible to follow for a possible revision.

The Swedish Knee Arthroplasty register is intended for monitoring purposes only and has never had any authority over the participating members or units.

Initially, all patients entered in the study were followed with a simple questionnaire addressed to the surgeon at 1, 3, 6 and 10 years (Appendix) after the operation to verify that the patient was not revised and to estimate patient satisfaction. The 3-year questionnaire was extended to include a modified translation of the British Orthopaedic Association Knee Assessment Chart (Aichroth et al 1978). It had to be abandoned because the participating surgeons had difficulties handling the increased number of patient visits. During the first two years, preoperative radiographs were centrally screened for staging according to the Ahlbäck classification (Appendix; Ahlbäck 1968). As the annual number of arthroplasties grew an attempt was made to decentralize this work but it failed because of difficulties in obtaining standardized examinations.

For consistency we have chosen revision as indicator of failure, since that is indisputably the ultimate failure of the prostheses and there is no reason to believe that the hesitation to revise a failed arthroplasty today would be greater than in the past.

By 1991, because of the great diversity and gradual mutation of prostheses with resulting confusion in nomenclature, a system was developed to allow the individual unit to specify the characteristics of the prostheses used (Appendix) enabling a categorization for comparison not only of actual prostheses but also similar concepts. At the same time a computer program was designed to allow

the individual unit to record their operations on a PC locally and yearly forward the file to the project center in Lund.

Feedback to the participating units are given annually by a detailed report plotting and comparing their results with aggregated data from Sweden (Appendix) as well as, for verification, a printout of the information in the register from that unit.

AIMS OF THE STUDY

The aims of the study were

to describe the Swedish Knee Arthroplasty Register including demography, epidemiology and general knee prosthetic biofunction.

to evaluate the possible effect of design and material on knee prosthetic revision rate.

to evaluate if other factors than prosthetic design are of importance for knee prosthetic revision rate.

to evaluate the possible long term adverse effects of knee prosthetic implants by cancer incidence analysis.

to study the prognosis of primary and revised unicompartmental arthroplasties in a longer perspective.

PATIENTS AND METHODS

Material

The Swedish Knee Arthroplasty Register entry form contained data on the age, sex and social security number of the patient, the underlying diagnosis, the type and model of prosthesis being implanted and whether any component had been inserted without cement. In case of a revision, a copy of the operation record was requested for further detailed analysis.

Recognizing the lack of universal agreement on criteria for failure, we have used revision as the endpoint for survival analyses of implants, revision being defined as a procedure where prosthetic components have been removed, added or exchanged.

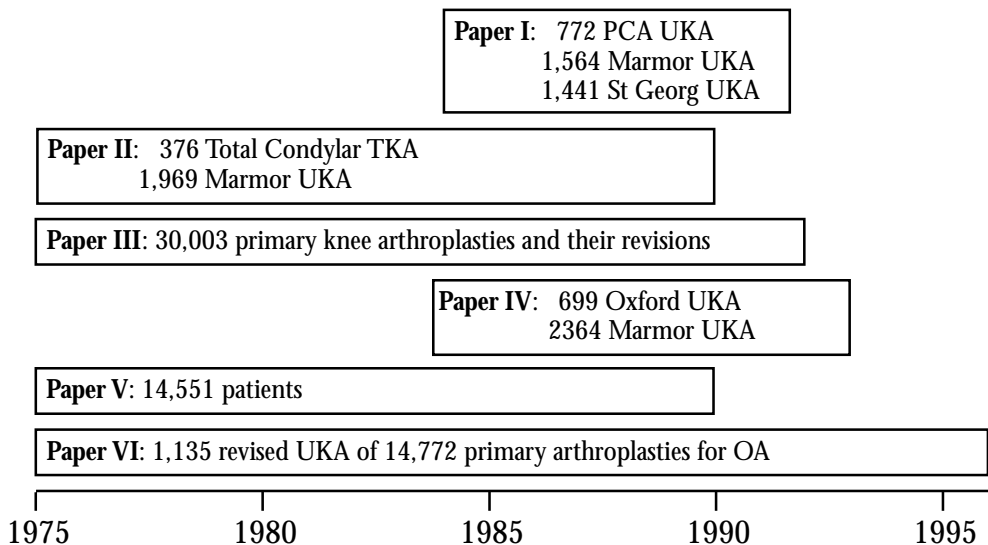### Overview of patient allocation in Paper I–VI

Paper I: 772 PCA UKA
1,564 Marmor UKA
1,441 St Georg UKA

Paper II: 376 Total Condylar TKA
1,969 Marmor UKA

Paper III: 30,003 primary knee arthroplasties and their revisions

Paper IV: 699 Oxford UKA
2364 Marmor UKA

Paper V: 14,551 patients

Paper VI: 1,135 revised UKA of 14,772 primary arthroplasties for OA

| 1975 | 1980 | 1985 | 1990 | 1995 |

Table 1. Knee prostheses in the Swedish Knee Arthroplasty Register up to 1996

UKA for OA	1975–1985		1986–1996
Marmor	1736	Marmor/Richards	2866
St. Georg	1198	Link Uni	2368
Gunston-Hult	450	St. Georg	1402
PCA Uni	91	PCA Uni	998
Oxford	53	Oxford	930
Brigham	10	Brigham	860
Other	93	Gunston-Hult	57
		Other	1660
Total	3631	Total	11141

TKA for OA	1986–1996	TKA for RA	1986–1996
AGC	5585	AGC	938
Freeman-Samuelson	1714	Freeman-Samuelson	574
Scan	1083	Scan	505
Kinemax	1050	PCA	339
PFC	961	F/S Modular	179
PCA	891	Kinemax	168
F/S Modular	795	PFC	162
PCA-Modular	645	PCA Modular	136
Synatomic	345	Tricon	118
Tricon	258	Other	924
Other	2409		
Total	15736	Total	3796

Statistics

The database is annually updated against national census registers for deceased patients. Only emigrating patients are lost to follow-up. The cumulative revision rates have been calculated using Kaplan-Meyer survival statistics (SPSS software). The log-rank test was used to compare curves with a significance level of 0.05. Graphs were plotted with a one-month time-base and confidence intervals were calculated using Wilson Quadratic equation with Greenwood and Peto effective sample size estimates (Dorey et al 1993). Only UKA and TKA were analyzed and the cutoff point was 40 remaining knees. For differences between groups the chi-squared test was used and a probability level of < 0.05 was considered significant.

SUMMARY OF PAPERS

Paper I. Multicenter study of unicompartmental knee revision

A study of the PCA unicompartmental knee prosthesis was initiated because some reports showed varying results in small series with short time follow-ups (Bernasek et al 1988, Wanivenhaus et al 1990), not on par with previous reports on established unicompartmental knee prostheses (Knutson et al 1986). We hence, in June 1990, identified all patients reported to the Swedish Knee Arthroplasty Register having had this type of prostheses for arthrosis from December 1983 through June 1990 and compared these with age-, sex- and time- matched groups of Marmor Modular and St Georg sled prostheses. The medical records of revised PCA prostheses were analyzed for failure pattern. By September 1991, revision was reported in 65 of 772 PCA, 50 of 1562 Marmor and 56 of 1441 St. Georg prostheses. As early as 2 years after the primary operation, the PCA uni prostheses had a higher CRR (Kaplan-Meier; $p < 0.001$) than both the Marmor and St. Georg prostheses. This difference gradually increased and at 6 years it was 16%, i.e., 3 times that for the two other prostheses. There was no difference between the Marmor and St Georg prostheses. The reason for revisions of the PCA prostheses was femoral component loosening in half the cases. This was a new experience and was interpreted as a consequence of shortcomings in the design of femoral component with its intended anatomic but surgically demanding configuration. The three departments with the highest number of PCA operations had a crude revision rate one fourth of that of the other departments, indicating that there was a learning curve. However, there was also a polyethylene wear problem in that one fourth of the revised tibial components showed substantial wear not previously seen.

Paper II. Reduced failure rate in knee prosthetic surgery with improved implantation technique

Current problems with knee arthroplasty are mechanical loosening, subsidence, HDPE wear, patellar pain and/or subluxation and infection. To overcome these problems, not only prosthetic design changes but also changes in surgical technique have been introduced. The latter, mainly introduced in the 1980s, include soft-tissue balancing, improved precision of bone cutting with guide instruments, improved cement and cementing technique, as well as improved asepsis and antibiotic prophylaxis.

To investigate if factors other than prosthetic design were of importance for the revision rate, the Marmor unicompartmental (n=2345) and the Total Condylar (n=367) prostheses were studied since they had remained relatively unchanged and been used in sufficient numbers over a length of time. Only patients treated for arthrosis were included. All prostheses were cemented. The studied period was divided in 4 three-year implantation periods (1975–1977, 1978–1980, 1981–1983, and 1984–1986) and the survey ended 1989.

The 5-year CRR (life table technique) for the Marmor unicompartmental prostheses was reduced from 11% to 5% and for the Total Condylar prostheses from 10% to 2%. Cox regression analysis showed that the results for the Marmor prostheses improved with time (p=0.001) whereas for the Total Condylar prosthesis this improvement with time was not statistically significant.

The continuous improvement over time is probably an effect of several concurrent factors. These might be better selection of patients, improved surgical skill (soft tissue handling, bone preservation, and transplantation), as well as better technique by the gradual introduction of guide instruments, and improved cement mixing and delivery systems.

Paper III. The Swedish knee arthroplasty register. A nation-wide study of 30,003 knees 1976–1992

1976 through 1992, 30,003 knee arthroplasties were recorded in the Swedish knee arthroplasty register. Primary arthroplasties were analyzed in three sets by year of implantation: 1976–1982, 1983–1987 and 1988–1992. There were 2067, 2986 and 5252 unicompartmental arthroplasties and 1360, 2827 and 6041 total knee arthroplasties for arthrosis, respectively. Thus, the number of arthroplasties for arthrosis increased annually, while the opposite was seen for rheumatoid arthritis, where the yearly number, on average 400, decreased by 20 percent during the study period. There was a change in types of prostheses being used. Hinged and constrained prostheses for primary arthroplasty were already abandoned during the first study period. Total knee prostheses are increasingly used and in rheumatoid arthritis it has replaced other types of prostheses.

Three fourth of the arthrosis patients were women with a median age of 69 years at the beginning of the study period increasing to 71 at the end. Men had a median age of 67 and 69 years, respectively.

Aggregated data for OA showed a higher CCR in younger patients. When comparing CCR for the three study periods, a reduction to one third was seen in TKA for OA, but none in UKA. Half the revisions were done for loosening and when CRR for loosening was analyzed separately the same pattern remained. The lack of improvement in UKA is partly explained by the recent introduction of underperforming designs, notably the PCA Uni knee and the Oxford Meniscal knee. Rerevision rates were also analyzed. Overall the CRRR for exchange arthroplasties showed an improvement over time. UKAs revised with unicompartmental components had a CRRR two times higher than UKAs converted to TKA.

Paper IV. Oxford Meniscal Bearing knee versus the Marmor knee in unicompartmental arthroplasty for arthrosis

The Oxford unicompartmental knee, a novel design with a sliding HDPE meniscus which creates strict congruency between the femoral and tibial components and at the same time reduced shearing forces at the cement-bone interface, was studied. 699 Oxford knees, reported to the Swedish knee arthroplasty register in 1983–1992, were identified and compared with 2364 Marmor prostheses reported during the same period. Also, a time-, age-, and sex matched subset of the Marmor prostheses was compared by means of survival statistics and by mode of failure. One would expect less wear and also a reduced frequency of loosening, especially of the tibial component, with this prosthesis. We found that the revision rate for the Oxford prostheses was already after 1 year higher than that for the Marmor prostheses. This difference increased gradually and after 6 years the CRR was more than twice that of the Marmor group. No significant wear problems were noted in the revised Oxford prostheses. However, a relatively frequent new mode of failure was noted, namely dislocation of the meniscus, and there were more cases of femoral than tibial component loosening. Exchange of the meniscus rarely (2 of 9) prevented the need for further revision with exchange arthroplasty. Two units having done more than 100 Oxford operations had the same crude revision rate as those doing fewer and there was no improvement in revision rate of Oxford knees over time.

Paper V. Overall cancer incidence not increased after prosthetic knee replacement: 14,551 patients follow for 66,622 person-years

Patients with arthrosis are not known to have a higher cancer incidence than the general population, whereas patients with rheumatoid arthritis have a higher risk of lymphomas and brain tumors, but a lower risk of colorectal cancer. Wear and corrosion products from knee prosthetic implants have a potential carcinogenic effect. By matching the Swedish knee arthroplasty register with the Swedish cancer register we compared the observed cancer incidence in 14,551 patients (10,120 with arthrosis and 4,431 with rheumatoid arthritis) with the expected incidence for a Swedish reference population. The cohort was followed for 66,622 person-years. 33 percent of the arthrotic and 59% of rheumatoid patients were followed more than 5 years.

We found no increased overall incidence of cancer in either group, on the contrary, a lower than expected total cancer incidence was noted in both groups and also a markedly lower incidence for colorectal carcinoma in rheumatoid patients. The risk of lymphoma and brain tumor in rheumatoid patients was elevated regardless of latency time indicating a link to the disease and not to the operation.

Paper VI. Prognosis of revision after failed unicompartmental knee arthroplasty for arthrosis

1975 through 1995, the Swedish knee arthroplasty register recorded 14,772 unicompartmental arthroplasties for arthrosis. The Marmor/Richards and St Georg sledge/Endo-Link prostheses were used in 65%. 1,135 of the primary arthroplasties were revised. 67% of the revised patients were women (64% in primary arthroplasties) with mean age 72 (71) years; men had a mean age of 71 (70). In medial unicompartmental arthroplasties, indication for revision was component loosening in 45% and joint degeneration in 25%; in lateral unicompartmental arthroplasties, it was 31% and 34%, respectively.

232 revisions were performed as exchange (partial in 97) of unicompartmental components while 94 had unicompartmental components added to the initially untreated components, in 14 combined with exchange of components. 750 revisions were conversion to a TKA. These three methods of revision were analyzed for CRRR using survival statistics. By the end of 1995, rerevision was recorded in 58, 17 and 42 cases, respectively, loosening being the predominant cause. After 5 years the CRRR was three times higher for cases revised with exchange of unicompartmental components than for those being converted to TKA, 26% and 7%, respectively. This difference remained even if those revised before 1985, when modern operating technique was introduced, were excluded; 5-year CRRR 31% and 5%, respectively. This also applied when comparing only cases revised for loosening after 1985; 5-year CRRR 33% and 4%, respectively. Addition of components to the untreated compartment for joint degeneration with or without exchange of components also carried a higher rerevision risk than that achieved with conversion to total knee arthroplasty; 5-year CRRR 17% and 8%, respectively.

A third revision was recorded in 25, a fourth in 6, a fifth in 2 and sixth in 1 patient. 23 patients eventually had an arthrodesis giving a crude arthrodesis rate of 0.16%.

DISCUSSION

Knee arthroplasty is a safe and effective operation, not only by relieving pain and discomfort but also by allowing patients to retain an almost normal life in terms of self-dependency and ambulation. In more than 90% the prosthesis is retained for more than 10 years (Knutson et al 1994). In Sweden more than 4,000 primary and 2–300 revision arthroplasties are now being done annually. A decade ago revisions accounted for more than 10% of the procedures done. Revision surgery, apart from the obvious suffering and hazards inflicted on the patient is still a challenge to the orthopedic profession. It has been shown in cost-effectiveness studies that revision arthroplasty is at least one third more costly than primary procedures in non-infected, but up to seven times more costly in infected cases (Bengtson et al 1989, Lavernia et al 1995). Hence there are good reasons to continue not only to improve the actual performance of the prostheses but also to minimize the risk for revision. New knee prosthetic designs are being introduced continuously, often with a short follow-up and with historical comparison neglecting the fact that improvements could be associated with factors not related to the prosthesis per se. Such factors could be the effect of individual or collective learning as well as stepwise introduction of new surgical techniques.

In the 1960s it was regarded as impossible to design prostheses that would last as long as 30 years in an active patient. Today this statement may not be true. Not only is the life expectancy of patients increasing but also there is a natural wish to be able to help also younger patients with incapacitating joint disease. The average age of Swedish knee arthroplasty patients is about 70 years at the time of the primary operation. According to the Swedish census register the average life expectancy of a 70-year-old woman/man is 15/12 years, while in a 55-year-old woman/man it is 28/23 years. Thus, many patients will be outlived by their prostheses even if they belong to the healthier part of the population.

Design

The major cause for revision has since the 1970s been aseptic loosening. To improve the survival of the implants a number of new designs were introduced in the 1980s. As for the tibia it has been shown that the HDPE components are

subject to cold flow under loading and the resulting deformation is considered responsible for breaking up the implant-cement interface, which may lead to intra-articular liberation of cement particles. Apart from mechanical wear, the particles may also be incriminated in triggering an inflammatory reaction leading to osteolysis which may accelerate loosening of the prostheses (cement disease). Metal backing of the tibial component has experimentally been shown to reduce the compressive loads and when covered with a porous coating it allows cementless implantation which may eliminate osteolysis. The PCA Uni prosthesis had metal backing and porous coating, and the femoral and tibial components were contoured so as to mimic the normal anatomy with an articulation tilted in the horizontal plane by an elevation of the tibial component centrally towards the tbial spine. Previous UKAs had been of resurfacing, onlay type, meaning they were inserted with minimal bone resection. The femoral PCA Uni component was designed to be inserted after having made condylar cuts (distal, posterior and chamfer) similar to most TKAs. For this concept to work, accurate positioning and cuts were called for and guide instruments were used. Initially this prosthesis performed well (Lindstrand et al 1988, Magnussen & Bartlett 1990). However, it was soon shown to fail in ways previously not seen in less conforming unicompartmental prostheses (Wanivenhaus et al 1990). In our study half of the PCA Uni prostheses that were revised had loosening of the femoral component regardless if inserted with or without cement (I). There are several possible explanations. The anatomical constraining shape of the femoral component made it mandatory to position the components accurately and the peg, of the femoral component being oriented parallel with the posterior cut, effectively hindered the prostheses from settling safely. This specific mode of failure has also been verfied in several reports (Lindstrand & Stenström 1992, Harilainen et al 1993, Bergenudd 1995).

Acknowledging the contradiction with excessive shearing forces being transmitted to the fixation of a congruent prosthesis, and the potential hazard of accelerated wear of the tibial component by the increased point contact stress with less constrained prostheses, Goodfellow and O'Conner (1978) in the seventies designed a prosthesis with a mobile meniscus, the Oxford knee. While maintaining congruency and a large contact area between the femoral component and the plastic insert the contact stress is reduced and the otherwise imminent shearing forces are minimized as the tibial component is allowed to slide on a flat metal tibial tray. The decreased wear for the Oxford knee has also been documented (Argenson & O'Connor 1992) as for other prostheses with congruent articula-

Table 2. Literature review of revision of failed unicompartmental knee arthro-

Author(s)	Year of publication	Prosthesis	N	Lost knees	Follow-up mean (range)
Insall and Walker	1976	Various [a]	24	0	2–4
Cartier and Cheaib	1987	Marmor	186	27	5 (2–10)
Larsson et al	1988	St Georg	102	0	8 (5–11)
Bernasek et al	1988	PCA uni	33	1	minimum 2
Lindstrand et al	1988	PCA uni	93	0	2–4
MacKinnon et al	1988	St Georg	115	9	5 (2–12)
Marmor	1988	Marmor	87	0	11 (10–13)
Kozinn et al	1989	Brigham	60	4	6
Magnussen and Bartlett	1990	PCA uni	51	4	minimum 2
Wanivenhaus et al	1990	PCA uni	19	0	2–4
Christensen	1991	St Georg	575	0	0–9
Rand and Ilstrup	1991	Various [b]	676	?	
Scott et al	1991	Brigham	100	4	8–12
Stockelman and Pohl	1991	Hybrid [c]	63	4	7 (5–12)
Goodfellow and O'Connor	1992	Oxford	309	8	2–9
Hodge and Chandler	1992	PCA uni	37		4 (2–12)
		Various [d]	50	4	4 (2–12)
Lindstrand and Stenström	1992	PCA uni	120	0	4–8
Lindstrand et al	1992	PCA uni	772		
		Marmor	1562		
		St Georg	1441		
Carr et al	1993	Oxford	121	0	4
Harilainen et al	1993	PCA uni	61	9	3 (2–5)
Heck et al	1993	Various [e]	294	0	
Lewold et al	1993	Marmor	831		
Swank et al	1993	Fibermesh	82		
		+ Microlock	22		minimum 4

plasty

| Revised | | CRR or | Comments |
n	%	cum failure rate	
3	13%		15 had patellectomy
8	4%		1 failed
5	5%		
6	18%		All cementless, 5 impend. failures
1	1%		
7	6%	24% at 6 year	Endpoint = pain+failure+revision
			21 failures (30% of living patients)
0	0%		All metal backed
1	2%		
3	15%		Initially 35 all cementless
8	1.4%		
		14% at 5 year	
		32% at 10 year	
13	13.5%	10% at 9 year	
		15% at 10 year	
		18% at 11 year	
4	6%		
25	8.1%	17% at 6 year	96 were rheumatoid patients
10	27%		
4	8%		
6	5%		3 failures
65	8%	16% at 6 year	
52	3%	4.7% at 6 year	
55	4%	7.3% at 6 year	
1	1%	1% at 9 year	All with functioning cruciate ligam.
6	10%		
		8.6% at 10 year	
		5.2% at 5 year	
8	8%	19% at 8.5 year	

Literature review, continued

Author(s)	Year of publication	Prosthesis	N	Lost knees	Follow-up mean (range)
Bartley et al	1994	PCA uni	55	5	3
		Fibermesh			
		+ Microlock	82	4	5
Knutson et al	1994	Marmor	2,354		
		St Georg	1,345		
		Endo Link	1,407		
		PCA uni	921		
		Oxford	833		
		Brigham	389		
		All	7,249		
Sarangi et al	1994	St Georg	335		6 (2–12)
Bergenudd	1995	PCA uni	108	1	3–9
Callahan et al	1995	Various	2,391		5
Lewold et al	1995	Oxford	699		
Cartier et al	1996	Marmor	207	58	
Knight et al	1997	PCA uni	43	0	5

[a] Gunston, Polycentric Marmor and Buchholtz.
[b] Various Polycentric, Geometric and PCA uni.
[c] Compartmental II and Robert-Brigham hybrid.
[d] Marmor, Richards and Robert-Brigham.
[e] Compartmental I + II and Marmor

tion (Plante Bordeneuve & Freeman 1993). Wear was not a problem in the 699 Oxford prostheses implanted in Sweden 1983–1992 (IV). However, with the introduction of a mobile meniscus new modes of failure were introduced. Compared with the Marmor prosthesis, the Oxford prosthesis had a higher revision rate already after one year, and the CRR increased to twice that of the Marmor prosthesis after 6 years. The main indication for revision of 50 failed Oxford prostheses was dislocated/dislocating menisci, which occurred in 16 knees. Loos-

Revised		CRR or	Comments
n	%	cum failure rate	
11	20%		37% revised of 30 available knees
			17% revised of 23 available knees
7	9%		8% revised of 37 available knees
		6% at 6 year	
		6% at 6 year	
		6% at 4 year	
		17% at 6 year	
		12% at 6 year	
		7% at 6 year	
		8% at 6 year	
33	10%		All medial
25	23%		2 impending failures
	9.2%		Meta analysis with 75% OA
50	7%	11.2% at 6 year	
		7% at 10 year	
12	28%		3 failures

ening of the femoral component was also frequent. This was noted in ten knees (6 as the single cause for revision and a further 4 with concomitant tibial loosening) indicating a design related or possibly a technical problem. For both these designs early warning was given to the reporting units. The PCA Uni was abandoned and the Oxford prosthesis was changed with improved instruments and stricter indications for this implant.

The published results with different unicompartmental prostheses vary considerably depending on the follow-up time and number of patients lost to follow-up but are in accordance with our findings for the PCA Uni and Brigham prostheses (Table 2).

Material

Not only the design but also the material is of importance for the survival of prostheses. A knee prosthesis consist of a polished metal femoral component articulating against ultra-high molecular weight HDPE tibial and patellar components. HDPE has been used in joint prostheses for 30 years. Minor alterations in the processing of HDPE may cause dramatic changes. The quality of HDPE can be altered by the production process by varying for instance the temperature, time and pressure during polymerization. The sterilization with gamma irradiation increases crosslinking but also splits polymer chains which speeds up the wear rate. One fourth of the revised PCA prostheses (I) showed substantial delamination wear of the HDPE. As discussed previously, the wear could partly be explained by the overload imposed on the tibial component by point contact of the femoral component if not positioned accurately during surgery. But in this particular prosthesis there also was a material problem as the HDPE component was treated with surface heat molding which hardened the surface as well as made it more susceptible to oxidation of the polymer chains hereby altering its elasticity relative to the subsurface layers where cracking and delamination occurred (Engh et al 1992, Bartley et al 1994, Blunn et al 1992, 1997).

Continuous minor alterations of the materials are undertaken to improve the wear resistance. The introduction of these alterations are sometimes done after limited preclinical testing with wear studies including only 2–4 million weight-bearing cycles amounting to only 1–2 years of normal walking. Analysis of clinical failures and retrieved implants related to material is thus important.

The release of particles and metal ions from the implants may have other than local effects in the joint. They are potentially carcinogenic. It is, however, unknown whether patients with knee prostheses are at a higher risk of developing cancer. By running a cohort of knee arthroplasty patients against the Swedish National Cancer Registry the cancer incidence could be estimated.

Two earlier studies found no increase in total cancer incidence after total hip arthroplasty but an increased incidence of tumors in the lymphatic and hematopoetic systems (Gillespie et al 1988, Visuri & Koskenvuo 1991). This could not be shown in a similar Swedish series (Mathisen et al 1995). A 3% increase of total cancer incidence was shown by Nyrén et al (1995). None of these studies analyzed OA and RA separately. OA patients are not known to have a higher underlying cancer incidence than the general population while RA patients have a higher incidence of lymphomas and possibly also brain tumors (Monson & Hall 1976, Lindberg & Nilsson 1985, Gridley et al 1993).

In our series, the total cancer incidence was lower for knee arthroplasty patients with OA and RA, even when varying latency times were accounted for. Patients undergoing total hip arthroplasty are known to be healthier than the general population and this can be assumed for knee arthroplasty patients as well. However, the decreased incidence of colorectal cancer, seen in OA and RA patients may also be an effect of the often longtime use of non-steroid anti-inflammatory drugs preceding arthroplasty (Gridley et al 1993, Muscat et al 1994).

The Cancer Registry allows for almost complete follow-up and complete information on vital status of our patients, which makes it unlikely that our findings are biased due to uncomplete follow-up. About one third of the patient-years came from patients with more than 5-year follow-up and some had up to 15-year follow-up. It remains to be shown whether cancer incidence remains low after even longer follow-up.

Technique

The gradual improvement in results of knee prosthetic surgery seen over the years is often attributed to the introduction of new designs or modifications of previous successful prostheses.

In the Swedish Knee Arthroplasty study two prostheses, the Marmor Modular and the Total Condylar knee, have been relatively unchanged over a length of time which allows for analysis of time dependent changes in cumulative revision rate together with multivariate analysis.

For both types of prostheses there was continuous improvement with time. This indicates that factors not related to the actual prostheses also significantly affect the results measured as prosthetic revision rate. Such factors may be an individual and collective learning curve affecting the performance of the surgery (soft tissue handling, bone stock preservation and transplantation) and also the proper selection of patients.

The stepwise introduction of accessories such as guide instruments for better positioning of the implants, standardized mixing of cement, cement gun for better penetration and interdigitation of the cement into the trabecular bone are factors that possibly may have influenced the results.

As the first periods of this study coincided with the introduction of knee arthroplasty in some units, there is a possibility that there initially was a backlog of

patients with advances disease and hence the results would expectedly be less favorable than for those operated later on. This could perhaps be the case for the Total Condylar group but is less likely for the UKAs since those would reasonably have been offered a TKA instead.

Another possible factor affecting the results is the gradual increase in mean age, from 69 to 71 for the Marmor prosthesis and correspondingly from 69 to 73 for the Total Condylar prosthesis , as increasing age correlates with lower CRR.

Sex is also considered a factor of importance as men are thought to be at greater risk for revision but in this study the proportion of men increased during the study period.

We found that overall the Marmor prosthesis had a slightly higher CRR than the Total Condylar prosthesis. Since a UKA has to be implanted with high precision to avoid secondary changes in the remaining compartment, it would be reasonable that units performing more Marmor arthroplasties had relatively fewer revisions. This could not be demonstrated, perhaps partly due to an overlap in selection of patients. Only one third of the units were using both implants whereas the remaining two thirds predominantly used either the Total Condylar or the Marmor knee. All units in the study performed fewer than 50 Marmor arthroplasties a year.

For the Oxford knee, our findings (IV) stand in contrast with the experience of the originator who reported only 3 dislocations and 5 loosening in 103 knees (Goodfellow et al 1988), all of which affected the tibial component. This is an example of when the surgical technique and application of strict inclusion criteria is so demanding that the results obtained by the originating group are hard to reproduce by other surgeons.

Most prostheses are introduced after varying follow-up often performed by the designer and his associates. However, to justify the introduction of new designs or techniques the results have to be reproducible by the general orthopedic surgeon in an ordinary setting.

Screening

Any introduction of new prostheses should ideally be evaluated and compared to the current standard before being offered to the orthopedic society in general. Preferably it should also bring some improvement to current treatment, but at least not endanger the hitherto generally good results obtained.

Success can be defined in many ways such as relief of pain, increased stability and increased range of motion, or as function in activities of daily living or perceived health. Correspondingly, the definition of failure may entail many detailed variables. Detailed analyses of such variables can at best and probably only be done in limited settings. They should include standardized preclinical testing. The addition of RSA and other refined radiographic methods such as DEXA, digitized radiographic evaluation, gait analysis and clinical performance related to patient satisfaction (Ryd et al 1995, Hilding et al 1996, Dawson et al 1996) may predict prosthetic survival. To actually demonstrate a superior prosthetic survival with the current low revision rate thousands of cases must be followed for decades. Thus, new designs will enter the market without such proof. It forces the orthopedic community to monitor the evolution of knee arthroplasty in nation-wide settings as has been done with the Swedish Knee Arthroplasty Study.

Survival statistics gives an estimate of the risk of revision but results cannot be extrapolated beyond the current observation time. Also a given risk level cannot be directly compared to that of a competing implant. Revision entails procedures ranging from addition of a patellar button to amputation. Since revision is not weighted after severity in survival statistics similar cumulative revision rates may not be very similar. Survival statistics were developed for, among other things, cancer research where the death of the patient was the only endpoint making comparison more valid. Further, the clinical outcome is not accounted for. A slightly higher revision rate for one implant may be combined with a superior clinical outcome making the additional revision acceptable. This may be the situation with some of the modern UKA when compared to TKA (Rougraff et al 1991, Laurencin et al 1991).

There may also exist a difference in ease of revision making UKA more often revised than TKA. This could be detected by using a wider definition of failure when doing survival analyses including both revisions and clinical failures. Using this endpoint one could test whether TKA and UKA have the same cumulative failure rate. Such an extended endpoint is unsuitable for a nation-wide study because in order to use it patients have to be seen regularly to establish when clinical failure appears. For survival statistics both a well defined endpoint and a well defined time of onset of failure are needed. Attempts have been made in smaller settings to include even unfavorable radiographic signs (Ewald 1989) in the endpoint. With the current knowledge of gradual onset of loosening, possibly starting directly after the operation the time of such an event cannot be estab-

lished. Paradoxically, if the endpoint used is changed from revision for loosening to the preceding radiographic loosening the time to failure will be shorter with larger number of patients being observed which could in fact reduce the cumulative risk.

For comparative survival studies in a multicenter setting one has to use criteria for failure that are universally agreed upon and easy to detect and hence we have used only revision. To minimize the risk of selection bias and to keep the study prospective we have only included revisions when the primary implant was already recorded. When our data were compared to official compiled data on knee prosthetic surgery a discrepancy was observed (III). An attempt has been made to get the missing observations of primary operations and revision in a limited series of implants (I, IV). When calculations of CRR was compared between the original set and the extended set of patients no changes occured in the CRR supporting an unbiased loss of observations.

Revision

The usual argument for UKA is that if a revision is needed it is often straightforward (Marmor, 1988), which may also be one reason for the higher revision rate in UKA. It is easier for the surgeon to take the decision to revise when this can be done with standard implants and technique. This has, however, been questioned by Padgett et al (1991) who reported that 16 of 21 revised unicompartmental knees had a major osseous defect at revision making the operation a challenge. On the other hand, Levine et al (1996) reported that although 13 of 31 failed UKA required bone transplantation most knees could be managed with simple wedges or a cancellous graft. There is no real explanation for this difference, except that maybe more severe cases were referred to one of the centers.

We found that patients with an UKA have a lower risk of finally loosing their knee function. We also found that a failed UKA should be revised to a TKA. Not even the addition of components to the contralateral compartment was safe. By applying this, the rerevision rate would have been considerably reduced. However, it is notworthy that the failure rate was low, when revising UKA to TKA, although data were collected from a number of centers in Sweden not specialized in revision surgery. The 5-year CRRR rate was 7% compared to a 5-year CRR in primary TKA for arthrosis of 4%. Thus, we could not confirm that revision of UKA was a challenge, at least not in terms of prosthetic survival. Our CRRR

was considerably lower than reported by others (Table 2). This difference could be explained by later intervention with more severe bone loss in other reports. Swedish surgeons have extensive experience with UKA and thus also with UKA revisions leading to improvement over time due to learning. In addition, total knee prostheses with modular stems suitable for revision have been introduced.

UKA is a safe primary procedure when performed with well-designed components and modern surgical technique. It gives documented good patient satisfaction, range of motion, pain relief and relatively few serious complications. However, once failed, the knee should be revised to a TKA.

Table 3. Literature review of outcome after first revision of failed unicompartmental knee arthroplasties

Author	Year	N	Lost	Follow-up mean	Rerevised n	%	Comments
Barrett & Scott	1987	32	1	5 (2–10)	4	13%	6 rheumatoid patients
Padgett et al	1991	21	1	2–10	2	10%	Major osseous defects in 15
Lai & Rand	1993	48		5 (2–11)			Bone defects managed with cement, 40 good or excellent
Jackson et al	1994	24	0	4 (2–8)	1	4%	Bone defects managed with thick implants
Levine et al	1996	31		4 (2–9)			Bone defects easily managed with cement results comparable with primary TKA
Otte et al	1997	29		3	5	17%	Cementless revisions

CONCLUSIONS

From 1976 to 1992 the annual number of knee arthroplasties increased fourth fold while the relative use of UKA decreased as TKA increased. Local hospitals performed one fifth of the OA knee arthroplasties. Their annual percentage of UKA was twice that of larger hospitals. The 5-year CRR decreased for each 5-year period studied for TKA in OA from 13% in 1976–1982 to 3% in 1988–1992, in RA from 10% to 2% but for UKA no change was seen and the CRR remained 8%. As a consequence the annual percentage of revisions has diminshed from 10% to 5%.

In OA, modern TKA have a lower CRR than UKA, with a 5-year CRR of 3% and 8%, respectively. The most commonly used unicompartmental prostheses (Marmor and St Georg) have a 5-year CRR of 5–6%. A problem was identified with the PCA Uni prosthesis with a 5-year CRR of 16%. Failed prostheses showed a high HDPE wear rate and femoral component loosening to an extent not seen with earlier designs. The Oxford Meniscal knee, designed to prevent excessive wear, had a 5-year CRR of 10%, twice that of a matched set of Marmor UKAs. The mode of failure was dislocation of the meniscus and femoral component loosening.

Two relatively unchanged prostheses, Marmor and Total Condylar, were used from 1975–1986 with continuous improvement in CRR over time. For the Total Condylar prostheses the 5-year CRR was reduced from 11% to 2% and for the Marmor UKA from 11% to 5%. The CRR was not correlated to the number of operations at each hospital. This indicates that factors other than prosthetic design affect the CRR and should be considered when evaluating results obtained over different periods.

In OA, overall, young patient age was related to higher CRR particularly in those younger than 65. The median age has increased by 2 years during the study period. Correction for age should be included in comparative studies.

The cancer incidence was not increased after knee arthroplasty in a cohort of 14,551 patients followed for 66,622 patient years.

In UKA for OA, the predominat mode of failure was component loosening. Revision with exchange using new unicompartmental components gave a 5-year CRRR of 26% while conversion to TKA gave 7%. When analyzing revisions performed after 1985 the 5-year CRRR was 31% and 5%, respectively. Addition of components in the contralateral compartment gave a 5-year CRRR of 17%. Failed UKA should be converted to TKA. In comparison modern primary TKA had a CRR of 3%.

SUMMARY

The Swedish Knee Arthroplasty Register is a prospective nationwide study of knee arthroplasty. It started 1975 and now comprises information on 55,000 arthroplasties. The register has been used for prosthetic survival analyses.

Two relatively unmodified knee prostheses were chosen for analyses of time dependent changes in revision rate. 1,969 Marmor unicompartmental and 376 Total Condylar arthroplasties, all cemented, were followed until the end of 1989. The cumulative revision rates (CRR) calculated with survival statistics showed a continuous improvement with time. The 5-year CRR was reduced from 11% to 5% for the Marmor prosthesis and from 10% to 2% for the Total Condylar prosthesis. This indicates that factors other than improved design are important. Such factors could include guide instruments, better surgical technique, influence of a learning curve, and better patient selection.

Oxford Meniscal Bearing cemented unicompartmental prostheses were identified and analyzed regarding failure pattern and compared with all Marmor prostheses. After one year there was already a higher CRR, and after 6 years the CRR of the Oxford group was more than twice that of the Marmor group. It is still unclear if designs with sliding menisci, will in the long run, reduce wear and loosening, and thereby compensate for the initially inferior results.

722 PCA, 1,564 Marmor and 1,441 St Georg unicompartmental prostheses implanted from December 1983 to July 1990 were analyzed. There was a significant difference in the CRR after only 2 years, increasing to 15% for the PCA, compared with 5–7% for the two other types at 5 years. The difference between PCA and Marmor/St Georg was loosening of the femoral component. Major polyethylene wear was noted in a quarter of the revised PCA tibial components.

1976 through 1992, 30,003 primary knee arthroplasties and their revisions had been recorded in the Swedish Knee Arthroplasty study. We reported on the structure of the register; demographic data and survivorship. We found that operations for osteoarthrosis (OA) counted for the increase in number of arthroplasties in contrast to rheumatoid arthritis (RA), where the number had slightly declined. For primary operations, the total knee prostheses have practically eliminated other types in RA and are steadily gaining popularity in OA at the expense of the unicompartmental prostheses. Total knee replacements showed gradually improving survival even in unchanged designs while the unicompart-

mental prostheses don't, partly because of newly introduced inferior designs. We also found that failed unicompartmental prostheses were best replaced with a tricompartmental prosthesis and that a total revision was to be preferred when a tricompartmental tibial component failed. The risk of the most devastating complications, e.g., infection, leading to extraction of the prosthesis or arthrodesis has decreased considerably also in the last years.

It is unknown whether patients as a consequence of prosthetic joint replacement are at a higher risk of developing cancer. We therefore analyzed cancer incidence following prosthetic knee replacement. The observed cancer incidence in 14,551 patients from the Swedish Knee Arthroplasty Register who have undergone knee replacement because of OA (n = 10,120) or RA (n = 4,431) were compared with the expected cancer incidence for a Swedish reference population. The cohort was followed for a total of 66,622 person-years. We followed 33% of the patients with OA and 59% of those with RA for more than 5 years. All patients who underwent knee replacement, whether for OA or for RA, had lower than expected total cancer incidence. We found a markedly low incidence of colorectal carcinoma, especially in patients with RA. Our results do not indicate an increased incidence of cancer following knee replacement.

1975 through 1995, 14,772 primary unicompartmental knee arthroplasties (UKA) were performed. End of 1995, 1,135 (7.7%) had been revised. Already after 5 years, the risk of having a second revision was more than three times higher for failed UKAs revised to a new UKA than for those revised to a total knee arthroplasty (TKA); 5-year cumulative rerevision rate (CRRR) was 26% and 7%, respectively. This difference remained even if those revised before 1985, when modern operating technique was being introduced, were excluded; 5-year CRRR 31% and 5%, respectively. UKA is a safe primary procedure when performed with well-designed components and modern surgical technique. It gives documented good patient satisfaction, range of motion, pain relief and relatively few serious complications. However, once failed, the knee should be revised to a TKA. This applies to most modes of failure. Not even joint degeneration of the nonoperated compartment can safely be treated by adding contralateral unicompartmental components, since 5-year CRRR was 17% as compared to 8% when revised to a TKA.

Acknowledgements

I wish to express my sincere appreciation to everyone who has helped, in various ways, to make this work possible. Especially I would like to thank:

The late Professor Göran Bauer, not only for his foresight as regards the need for long-term monitoring of the results of knee prosthetic surgery in the community at large and hereby the initiator of the Swedish Knee Arthroplasty study, but also for his inspiration and many good advice along the road.

Professor Lars Lidgren for his patience and great support in all aspects of this work and also his active part in the process of improving and maintaining the register as it has grown over the years.

Associate Professor Kaj Knutson my friend and tutor for his cleverness and valuable advice in penetrating the many times complex questions/obstacles during the work.

My co-authors Stuart Goodman, Pelle Gustafson, Anders Lindstrand, Håkan Olsson, Otto Robertsson, Anders Rydholm, and Anders Stenström.

The staff at the Department of Orthopedics in Lund for their friendship and supporting attitude, especially our secretaries in the project over the years, starting with Ulla Wetterlundh, Katharina Eriksson and now Mariann Hökmark without whose tedious work and endurance the project would not have been possible.

All collegues and staff at the participating departments, all over Sweden, for their cooperation without whom our common unique project would not have been conceivable.

But most of all, my wife Kerstin and my beloved sons Marcus and Clemens.

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APPENDIX

RADIOGRAPHY FORM

```
Date of review: _ _ _ _ _ _          _Standing radiographs
                                     _Possibly standing radiographs
Reviewer: _____            _Patellar view missing
                                     _Lateral radiographs missing
Operation method: Arthroplasty RIGHT  LEFT knee
Name:              _ _ _ _ _ _ - _ _ _ _   _____
Hospiral:
Preop. investigations (dates): _ _ _ _ _ , _ _ _ _ _ , _ _ _ _ _
DIAGNOSIS
RIGHT                              LEFT
_Medial arthrosis                 _Medial arthrosis
_Lateral arthrosis                _Lateral arthrosis
_Rheumatoid arthritis             _Rheumatoid arthritis
_ _____                _ _____
Medial:                           Medial:
    _sclerosis                        _sclerosis
    _bone attrition ___mm             _bone attrition ___mm
    _osteophytes                      _osteophytes
    _cysts                            _cysts
    _chondrocalcinosis                _chondrocalcinosis
Lateral:                          Lateral:
    _sclerosis                        _sclerosis
    _bone attrition ___mm             _bone attrition ___mm
    _osteophytes                      _osteophytes
    _cysts                            _cysts
    _chondrocalcinosis                _chondrocalcinosis
Patellar:                         Patellar:
    _osteophytes                      _osteophytes
Standing femorotibial angle___    Standing femorotibial angle___
_Standing med. trans. femur___mm  _Standing med. trans. femur___mm
_Attrition tibial spine           _Attrition tibial spine
    PARTLY  MAJOR  COMPLETE           PARTLY  MAJOR  COMPLETE

Postop investigations (dates): _ _ _ _ _ , _ _ _ _ _ , _ _ _ _ _
Arthroplasty:    RIGHT  LEFT knee with    SURFACE PROSTHESIS   HINGE
Type
_St. Georg sledge   MED LAT  _Freeman Swanson (s)        _Walldius
_Marmor             MED LAT  _Freeman Swanson (x)        _Guepar
_Gunston-Hult       MED LAT  _Freeman Swanson (high)     _St. Georg
_Savastano          MED LAT  _Geomedic                   _Shiers
_Lotus              MED LAT  _Townley
_Manchester         MED LAT  _Charnley
_ _____        MED LAT  _Spherocentric

_All parts cemented          _Tibia with metal marker wire
```
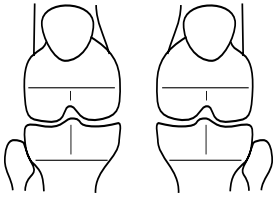
ENTRY FORM

From ....

Swedish Knee Arthroplasty Register
Department of Orthopaedics
University Hospital
221 85 LUND

Patient identification

To be coded in Lund: | ID: | | | | - | | Name: | |

Underline the diagnosis(-es):

☐ Primary arthroplasty

☐ Reoperation

Rheumatoid arthritis   (71239)
Other immunologic arthritis (71498)
Septic arthritis   (71005)
Primary arthrosis   (71301)
Arthrosis with pseudogaout (73108)
Posttraumatic arthrosi   (71400)
Osteonecrosis   (71306)
Neoplasm   (17071)
Osteochondritis dissecans   (72221)
Psoriatic arthropathy   (69600)
TBC sequelae   (01932)
Other - specify............

a) What was removed?..............

b) Why? (state compl.)...........

c) When was the removed prosthesis

   implanted?....................

d) Was the primary operation
   reported to the Register: Yes ☐

Sex: | | Side/No: | | Dept.: | | Diagnosis I: | |

Date of operation: | | | | |

Mark right or left
Draw the prosthesis below
including a patellar
component, if any

Name of prosthesis.....................

Type of prosthesis

Type of arthroplasty

Surface pr. ⌠ Fem.-Pat.-prosthesis ☐
           ⎮ Unicompartmental   ☐
           ⎮ Bicompartmental   ☐
           ⌡ Tricompartmental   ☐

Stem prosth. ⌠ Stabilized ☐
             ⌡ Hinged   ☐

Was patellar component used: Yes ☐ No ☐

Bone cement;...........................

Right   Left

Diagnosis II: | | Date of op. | Prosth.: | | | |

Prophylactic antibiotics: Yes ☐ No ☐
Antibiotics:
Dosage:
Treatment time:

Local antibiotics: Yes ☐ No ☐
Antibiotics:
In wound, irrigation fluid or cement
(Do not forget gentamicin in cement

Cement: | A/D/B: | | Local: | Date of discharge

Date of discharge: | | | | |

None

Underline early complications, if any:

Other complications:.................

Wound dehiscence
Evacuated hematoma
Infection, superficial
Infection. deep
Peroneal nerve palsy
Embolism
Mors

Complications:

Form completed by:............

Do not enter data here =

Specify preoperative anamnesis and status on opposite page

FOLLOW-UP FORM

DATE
* 1/ 3/ 6/ 10-FOLLOW-UP FORM *

FROM THE DEPARTMENT OF ORTHOPEDICS   TO ....
UNIVERSITY HOSPITAL   DEPARTMENT OF ORTHOPEDICS
221 85 LUND

1/ 3/ 6/ 10 YEARS HAVE PASSED SINCE THE FOLLOWING PATIENT WAS OPERATED ON

CASE NO: 13585

CIVIC NO	NAME	SEX	SIDE	DEPT.	DIAGN.	DATE OF OP.	ARTHROPLASTY
500515-4090	SLE	M	L	41001	71301	78-09-23	MED MARMOR

PLEASE ANSWER THE FOLLOWING QUESTIONS REGARDING THE
LEFT KNEE

THE PATIENT IS TODAY

– EXAMINED
– CONTACTED BY PHONE (SUFFICIENT IF SATISFIED AND PAINFREE)
– CHECKED MEDICAL RECORD (IF PATENT WAS SEEN DURING THE LAST 6 MONTHS)

THE PATIENT IS:	SATISFIED	NONCOMMITTAL	DISSATISFIED
PAIN AT REST:	NONE	MODERATE	SEVERE
PAIN WHILE WALKING:	NONE	MODERATE	SEVERE

COMPLICATION:

– NONE
– YES (MARK ONE OR MORE ALTERNATIVES BELOW)

INFECTION:	SUSPECTED – VERIFIED BY CULTURE – SINUS
PROSTHESES:	LOOSENING – SUBSIDENCE – DEFORMATION – FRACTURE
INSTABILITY:	SEVERE – TRANSLATORY – DISLOCATION
EXTENSOR:	INSUFFICIENCY – RUPTURE
PATELLAR:	PAIN – SUBLUXATION – DISLOCATION
VARIOUS:	LOOSE CEMENT – CONTRACTURE – CONFLICT PROSTH.–BONE

OTHER: …………………………......…(IF NEEDED USE BACKSIDE OF FORM)
RADIOGRAPHIC SIGNS WITHOUT
DISCOMFORT: ZONE > 2MM – SUBSIDENCE – DEFORMATION – FRACTURE

WHEN WAS THE COMPLICATION DISCOVERED? ………………………..

IS THE PATIENT REOPERATED? (YES / NO) ….. WHEN? ……..……(SEND FULL REPORT)

FOLLOW-UP PERFORMED BY ……………….. DATE ………………

3-YEAR B.O.A. FOLLOW-UP FORM

INTERVIEW   NOTE   The follow-up examination concerns one knee only, left or right according to the statement in the computer printout after the social security number (L/R)

1. **Patients** opinion on the knee

☐ 0   Enthusiastic
☐ 1   Satisfied
☐ 2   Non-committal
☐ 3   Disappointed

2. **Pain at rest** in the knee

☐ 0   None or insignificant
☐ 1   Moderate, not interfering with sleep
☐ 2   Severe, disturbing sleep
☐ 3   Very severe

3. **Pain on loading** in the knee

☐ 0   None or insignificant
☐ 1   Moderate, not interfering with activities
☐ 2   Severe, disturbing activities
☐ 3   Very severe

4. **Walking ability,** maximum useful
(state the walking distance in the first hand)

☐ 0   More than 1 km   or   > 60 min
☐ 1   501 m – 1 km   or   30–60 min
☐ 2   101 m – 500 m   or   10–30 min
☐ 3   50 m – 100 m   or   5–10 min
☐ 4   Less than 50 m outdoors or indoors only
☐ 5   Only a few steps of practical importance
       (e.g. from wheelchair to bed)
☐ 6   Unable to walk

5. **Other joint complaints** that limits walking ability
(such as complaints from the other knee or hips)

☐ 0   None
☐ 1   Yes, moderate, somewhat limiting
☐ 2   Yes, severe, that limits the walking ability

6. **Stair climbing ability**
(in stairs with normal steps, approximately 17 cm)

☐ 0   Normal
       Only one step at a time
☐ 1   <u>examined</u> knee first when climbing stairs
☐ 2   <u>other</u> knee first when climbing stairs
☐ 3   Only with support (e.g. stick, bannister)
☐ 4   Unable

7. **Rising from a chair**
(when using a chair with arms approximately 45 cm high)

☐ 0   With ease
☐ 1   With difficulty but <u>without</u> the use of arms
☐ 2   Only by using arms
☐ 3   Unable

CLINICAL ASSESSMENT   NOTE   Use a goniometer. Varus / valgus is measured along the midline of the thigh, knee and lower part of the leg giving a normal knee a slight physiologic valgus angle

	active	passive	flexion	
Reply to question:	8	9	10	
8. <u>Active</u> extension defect 0	☐	☐	☐	0°
(straight leg = 0°) 1	☐	☐	☐	1° – 10°
2	☐	☐	☐	11° – 20°
9. <u>Passive</u> extension defect 3	☐	☐	☐	21° – 30°
(straight leg = 0°) 4	☐	☐	☐	31° – 40°
5	☐	☐	☐	41° – 60°
10. <u>Maximum</u> flexion ability 6	☐	☐	☐	61° – 80°
(measure from straight leg = 0° 7	☐	☐	☐	81° – 100°
regardless of whether the patient 8	☐	☐	☐	101° – 120°
can straighten the leg fully 9	☐	☐	☐	> 120°

	valgus	varuse	standing		
Reply to question:	11	12	13		
11. Alignement when lying during manual 0	☐	☐	☐	varus	30° or more
valgus provokation of the extended knee 1	☐	☐	☐	varus	20° – 29°
2	☐	☐	☐	varus	10° – 19°
12. Alignement when lying during manual 3	☐	☐	☐	varus	5° – 9°
varus provokation of the extended knee 4	☐	☐	☐	varus	0° – 4°
5	☐	☐	☐	valgus	1° – 4°
13. Alignement when standing 6	☐	☐	☐	valgus	5° – 9°
with maximum extended knee 7	☐	☐	☐	valgus	10° – 19°
8	☐	☐	☐	valgus	20° – 29°
0	☐	☐	☐	valgus	30° or more

14. Was the knee radiographically examined during this follow-up

☐ 0   No
☐ 1   Yes, without remarks
☐ 2   Yes, with signs of
       complication
       (Specify on opposite page)

Own questions and coding
(Use only one letter or number in each box)

15.   16.   17.   18.   19.

THE SWEDISH KNEE ARTHROPLASTY PROJECT

HOSPITAL

Primary arthroplasty

Nationella Knäplastik Registret
Ort klin, Universitetssjukhuset
221 85 LUND   046-17 13 45

* An individual code, for each surgeon, is asked for. This may be used when extracting material for local use from the register

Please write (vertically) the names of the prostheses used at your unit at the base of the arrows. Mark, with crosses, the corresponding specification for each prosthesis used. If different models are used, give each one a unique name. For every new operation mark with a cross under the name of the prosthesis used. The configuration does not have to be repeated unless you adopt new types or models. If necessary, use two or more forms.

Configuration

Femur: Central stem | Plastic pegs | Metal pegs | Right/left asymmetric | Stabilized | Gliding surface of Ti-alloy | Porous Cr-Co-coating | Porous Ti-coating | Hydroxyapatite-coating

Tibia: All plastic | Metal backing | Modular | Meniscal bearing | Sliding disk | Plastic pegs | Metal pegs | Screws | Short stem | Long stem 8 cm | Anterior X-band saving | Posterior X-saving | Porous Cr-Co-coating | Porous Ti-coating | Hydroxyapatite-coating

Civic number	Side	Diagnosis	Op. date	Prothesis			Other prothesis or configuration	Patella		Cementless		
		RA, OA or			Uni				Metal-	Noncemented:		
10 numbers	Right/Left	WHO-code	Year–month–day	Med	Lat	M+L		No	Plastic backed	femur	tibia	patella

HOSPITAL

Revisions* and reoperations

| | | | | | Configuration as specified on first page | Send copies of the revision report | Nationella Knäplastik Registret Ort klin, Universitetssjukhuset 221 85 LUND   046-17 13 45 |

Civic number	Side	Diagnosis	Revision date	Prothesis					Other	Patella		Cementless
		RA, OA or			Uni							Metal- Noncemented:
10 numbers	Right/Left	WHO-code	Year-month-day	Med	Lat	M+L			Other prothesis or configuration	No	Plastic backed	femur tibia patella

				❑ ❑ ❑	❑ ❑ ❑ ❑ ❑ ❑		❑ ❑ ❑ ❑ ❑ ❑

Revisions/reoperation cause:

| | | | | ❑ ❑ ❑ | ❑ ❑ ❑ ❑ ❑ ❑ | | ❑ ❑ ❑ ❑ ❑ ❑ |

Revisions/reoperation cause:

| | | | | ❑ ❑ ❑ | ❑ ❑ ❑ ❑ ❑ ❑ | | ❑ ❑ ❑ ❑ ❑ ❑ |

Revisions/reoperation cause:

| | | | | ❑ ❑ ❑ | ❑ ❑ ❑ ❑ ❑ ❑ | | ❑ ❑ ❑ ❑ ❑ ❑ |

Revisions/reoperation cause:

| | | | | ❑ ❑ ❑ | ❑ ❑ ❑ ❑ ❑ ❑ | | ❑ ❑ ❑ ❑ ❑ ❑ |

Revisions/reoperation cause:

| | | | | ❑ ❑ ❑ | ❑ ❑ ❑ ❑ ❑ ❑ | | ❑ ❑ ❑ ❑ ❑ ❑ |

Revisions/reoperation cause:

| | | | | ❑ ❑ ❑ | ❑ ❑ ❑ ❑ ❑ ❑ | | ❑ ❑ ❑ ❑ ❑ ❑ |

Revisions/reoperation cause:

COMPUTED ANNUAL FEEDBACK REPORT

Hospital   **X**
Diagnosis   **OA**
Type   **UKA**

| Year	No of knees	Excluded	Revised	CRR
1	233	17	0	0.00
2	216	27	4	1.98
3	185	27	6	5.40
4	152	42	6	9.74
5	104	6	3	12.42
6	95	15	4	16.42
7	76	19	4	21.45
8	53	19	3	26.87
9	31	14	1	29.91
10	16	15	1	38.16
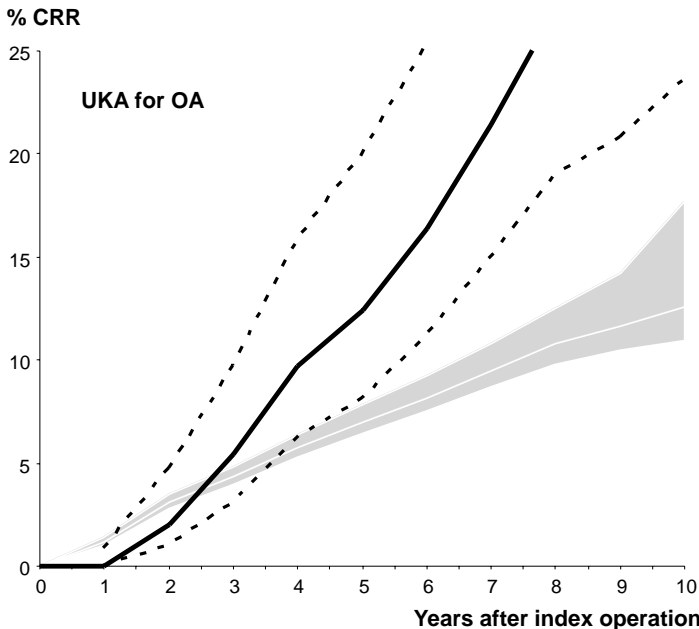
Your CRR during the period 1986–1995 is drawn as a solid line. The dotted lines gives the corrected 95% confidence interval. For comparison the compound results of other units are drawn in gray. The statistical uncertainty in CRR is indicated by the confidence interval. Fewer patients gives greater uncertainty. However, if the number of patients is small and revisions are few the calculated confidence interval could be misleading.

COMPUTED ANNUAL FEEDBACK REPORT

Hospital   **X**
Diagnosis   **OA**
Type   **TKA**

Year	No of knees	Excluded	Revised	CRR
1	470	59	5	1.14
2	406	92	4	2.23
3	310	60	2	2.93
4	248	70	4	4.75
5	174	43	0	4.75
6	131	46	1	5.64
7	84	30	1	7.00
8	53	23	0	7.00
9	30	18	1	11.43
10	11	11	0	11.43
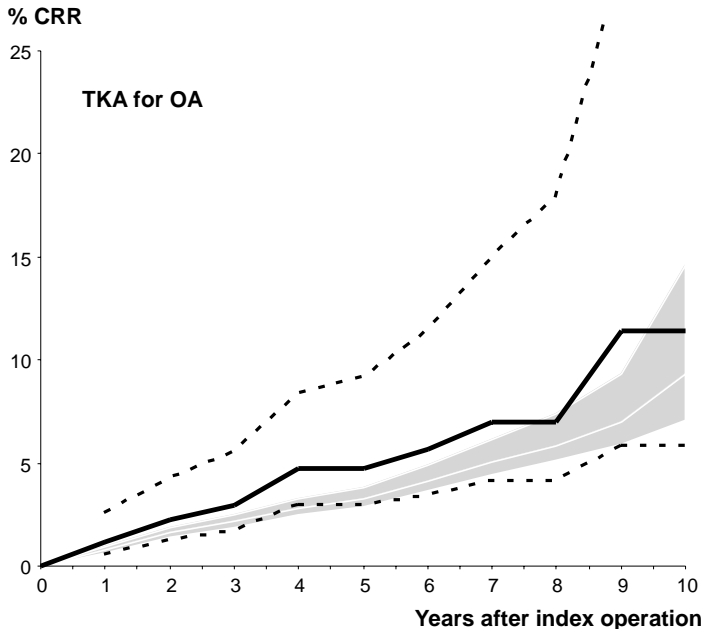
% CRR

TKA for OA
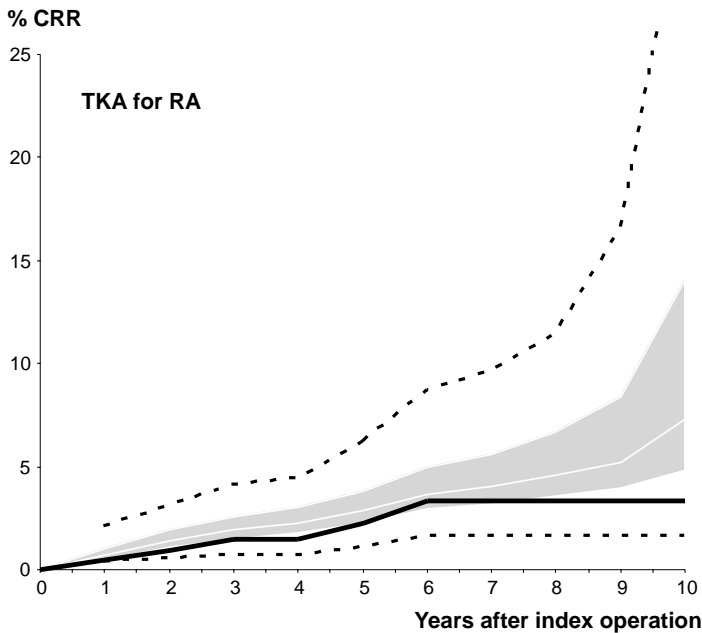
Years after index operation

Your CRR during the period 1986–1995 is drawn as a solid line. The dotted lines gives the corrected 95% confidence interval. For comparison the compound results of other units are drawn in gray. The statistical uncertainty in CRR is indicated by the confidence interval. Fewer patients gives greater uncertainty. However, if the number of patients is small and revisions are few the calculated confidence interval could be misleading.

COMPUTED ANNUAL FEEDBACK REPORT

Hospital   **X**
Diagnosis **RA**
Type   **TKA**

Year	No of knees	Excluded	Revised	CRR
1	240	22	1	0.44
2	217	20	1	0.92
3	196	19	1	1.45
4	176	32	0	1.45
5	144	39	1	2.24
6	104	23	1	3.30
7	80	16	0	3.30
8	64	30	0	3.30
9	34	22	0	3.30
10	12	12	0	3.30

% CRR

TKA for RA

Years after index operation

Your CRR during the period 1986–1995 is drawn as a solid line. The dotted lines gives the corrected 95% confidence interval. For comparison the compound results of other units are drawn in gray. The statistical uncertainty in CRR is indicated by the confidence interval. Fewer patients gives greater uncertainty. However, if the number of patients is small and revisions are few the calculated confidence interval could be misleading.

PRESENT PARTICIPANTS IN THE SWEDISH KNEE ARTHROPLASTY STUDY

Hospital	Orthopedic surgeon	Secretary
Akademiska sjukh.	Jan Milbrink	Zerny Paulsson
Alingsås	Rolf Appelqvist	Ing-Britt Gustavsson
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Borås	Krister Sundholm	Viveka Lindell
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Falun	Anders Henricson	Irené Gradén
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