

The Swedish knee arthroplasty register

A nation-wide study of 30,003 knees 1976–1992

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1976 through 1992, 30,003 primary knee arthroplasties and their revisions have been recorded in a nation-wide Swedish study. We report on the structure of the register, demographic data and survivorship. We found that operations for osteoarthritis (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 unicompartmental 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.

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In 1975, the Swedish Orthopedic Society initiated a prospective nation-wide study of knee arthroplasties (Bauer et al. 1980). Since then knee arthroplasties have been recorded in the project center at the Department of Orthopedics in Lund. The project has had no authority over participants. Each hospital has used their own indications for arthroplasty, choice of prostheses, and indications for revision. The entry form contained information on the condition of the knee, type of replacement, and any complications during the first hospital stay. Subsequent complications and revisions were reported annually from each unit or at the individual 3, 6, and 10 year follow-ups by written inquiries. The first two years, radiographic data, i.e. the degree of joint degeneration, was reported but this was stopped as the quality of the radiographs did not allow uniform measurements. An attempt was also made to include a clinical evaluation at the 3-year follow-up using the British Orthopaedic Association Knee Assessment Chart. This failed because clinicians found the extra work-load unacceptable. Today the project aims only at prosthetic survival analysis.

By September 1, 1993, 34,000 operations had been reported (Lidgren et al. 1994). The outcome of 30,003 primary knee arthroplasties performed between 1976 and 1992 is reported here.

At the start in 1975, data were recorded on a Digital Equipment LA 36 printing terminal connected to a Univac 1100/80 computer at Lund University Computing Center. From 1990 the information was transferred to a PC. Initially information was given yearly by the participants in written reports. From 1991 a computer program for local use was developed, and 1993 three fourths of the participating departments sent in their data on a diskette.

The project has been extensively documented since the start with reports at national and international meetings. Five larger presentations starting in 1982, have been given at the AAOS meetings, the latest in February 1994 (Lidgren et al. 1994). Two dissertations, "The Failed Knee Arthroplasty" (Knutson 1985), and "The Infected Knee Arthroplasty" (Bengtson 1991) have emanated from the project. More detailed analyses of subsets of patients have also been reported (Knutson et al. 1986, Bengtson and Knutson 1991, Al-Rowaih et al. 1993). Selected references from the register 1980–1994 are given in the Addendum.

A yearly report is given back to the participating units where they can compare their own data with unidentified aggregated data from Sweden. Each unit can get detailed information on their own material but has no access to that of other units. No information is

given concerning individual units to the National Board of Social Welfare, the County Council or to any other administrative body. However, aggregated information concerning important aspects of the register, such as demographic data, complications, patient related factors, technical improvement over time, failure rate of various implants, and the results of revision surgery, etc, are reported. These, mainly outcome, results are not only reported in scientific journals but are also reported yearly to the funding bodies.

In a recent independent evaluation it was obvious from the participant view that the register had given valuable information leading to improvement especially in relation to benchmarking, i.e., comparison between units. A suggestion was given to create an external board to guide future register work (Garpenby and Carlsson 1993).

In each unit an orthopedic surgeon and a secretary have been appointed as responsible for sending in and receiving data. These surgeons are also the communicating links to the register and gather at the yearly national orthopedic meeting for exchange of information. Since 1994 also the knee replacement marketing companies are yearly given the same information.

At present one secretary, two senior and two junior researchers are participating in the program, all at the Department of Orthopedics in Lund. The statistical analysis has been carried out with the help of the Biostatistical Unit, Lund University by Jonas Ranstam, Ph.D.

The yearly cost in 1993 for running the Lund register office amounts to 80,000 USD, equivalent to a one time payment of 15 USD for each implant entering the study. This does not include the costs for detailed analyses and reports which until now had to be covered by research grants. The main economical support was initially given by the Swedish Medical Research Council but the running costs are now funded by the Board of Social Welfare.

The survival of implants has been calculated with the Kaplan-Meier technique (SPSS software). The endpoint has been revision, defined as removal, exchange or addition of any prosthetic component. Revisions are only recorded if the primary procedure has been previously reported. In all revisions an operative report has been requested and filed for more detailed analyses. The register has been regularly updated on patient mortality against national census registers. The unique social security number makes it possible to identify and track all patients. For convenience results are presented as cumulative revision rate thus indicating the type of endpoint. The decreasing number of cases over time is not indicated

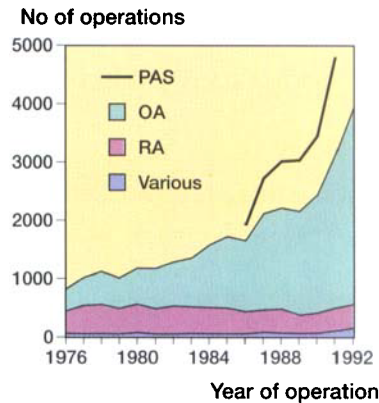


Figure 1. Knee arthroplasty surgery in OA is still expanding. PAS is the official patient administration system indicating the probably true number of yearly operations.

on the graphs but instead the 95% confidence limits. The cut-off point is 30 cases. Note, when comparing revision-curves, that the left part of the curves are more valid and conclusions drawn from the often more striking right part must be taken with caution.

A validation of statistical conclusions drawn from the register showed good concordance in a comparison with completed material from some units (Lindstrand et al. 1992) and with medical reports.

The aim of this report is to give an update of the important uses of the register.

Demography

The number of reporting units has increased over the years and today it is 67 out of 72 units performing knee arthroplasty. Through the official Swedish patient administration system (PAS) the true number of annual operations has been estimated (Figure 1). The number of reported primary arthroplasties in the register is lower than the actual annual number reported in PAS. The size of the material is sufficient but the risk of patients being lost to follow-up has to be considered using survival curves for statistical evaluation (Carr et al. 1993, Dorey et al. 1993, Murreay et al. 1993).

The number of patients treated for arthrosis (OA) has increased over the years versus a slight decline for rheumatoid arthritis (RA)(Figure 1).

In Sweden, the yearly number of total knee replacements (TKR) per 100,000 inhabitants is increasing and it is just below that of the Olmsted county in USA (Quam et al. 1991) which is believed to represent the plateau level of incidence. It is higher than in a recent report from the national health authorities in UK (Williams et al. 1994; Table 1). If

Table 1. The age- and sex-related incidence of knee arthroplasty (TKRs per 100,000 inhabitants) in Sweden, England (Williams et al. 1994), and Olmstead County (Quam et al. 1991).

Age	Sweden 1991	England 1989-1990		Olmsted C 1983-1986	
		M	F	M	F
<45		0.4	0.1		
40-49	10				
45-54		6	11	1	4
50-59	35				
55-64		28	42	162	170
60-69	160				
65-74		70	112	208	268
70-79	325				
75-84		85	130	392	643
80-89	165				
>85		31	41		235
>90	15				

the backlog of patients waiting for a knee replacement could be treated, around 6.000 new replacement per year could be expected in Sweden

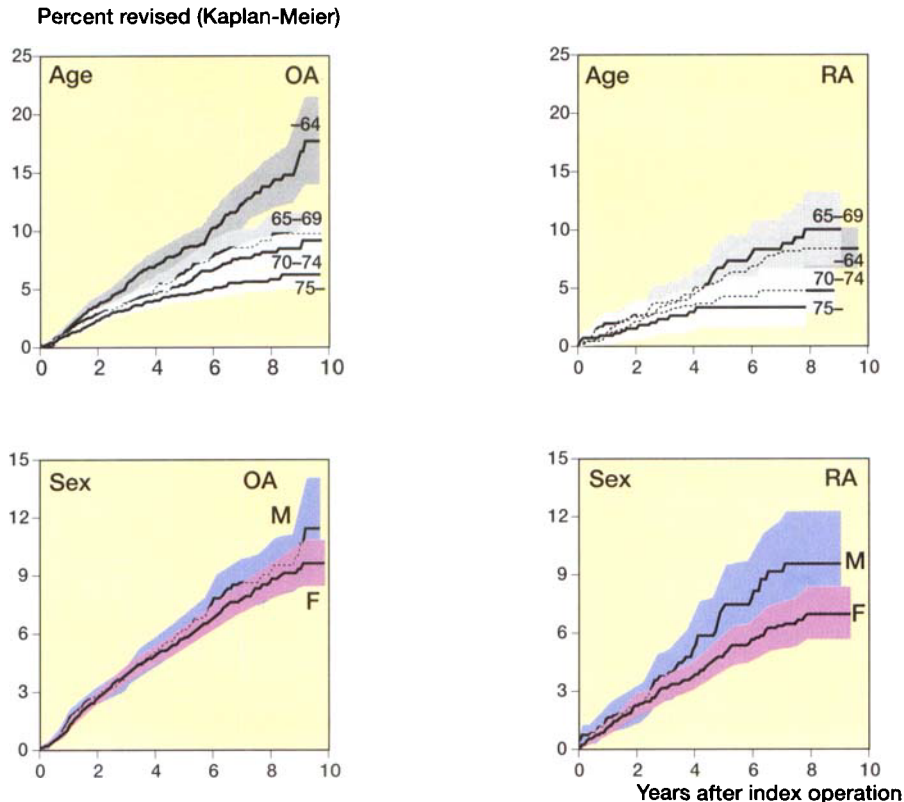
Table 2. Age and gender in knee arthroplasties

Diagnostic group	Percent women		Median age	
	1976	1992	1976	1992
OA	78	74		
OA, women			69	71
OA, men			67	69
RA	70	65	62	65

with the present age profile and a population of 8.8 million people.

There was a slight increase in age at operation, both in female and male OA and RA patients (Table 2) and this is in accordance with the change of the age profile in the society (SCB 1993). This increase in mean age over time should be taken into consideration when prosthetic concepts from different time periods are compared. The decreasing failure rate with increasing age may be caused by less demand on the implant (Figure 2).

Figure 2. Prosthetic revision rate (actuarial) related to patient age and gender in OA and RA with index operation between 1983-1992.



Distribution of arthroplasty types in percent per year

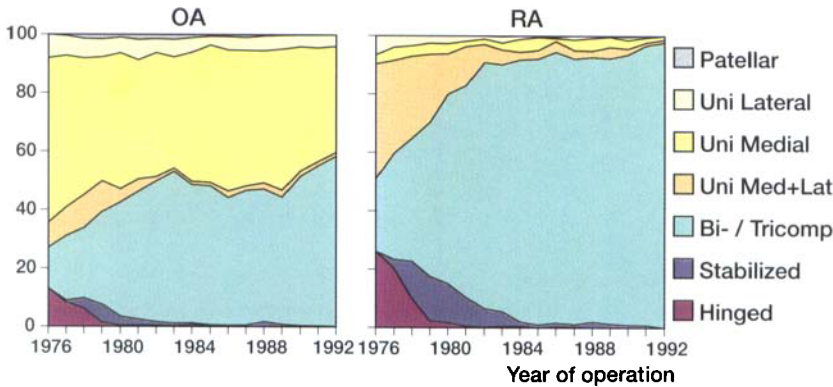


Figure 3. Tricompartmental knee prostheses are increasingly popular, now the only viable alternative in RA, replacing the hinged, stabilized and unicompartmental types.

Table 3. Age and indication for 22,364 knee arthroplasties in Sweden 1983-1992

	OA		RA	Various	Total
	Uni	Total			
<40	7	9	124	33	173
40-	43	48	267	41	399
50-	541	427	657	118	1743
60-	2887	2552	1451	262	7152
70-	4295	4897	1320	318	10830
>80	708	1114	141	104	2067

Table 4. The commonest implants for primary and exchange arthroplasty during 1983-1987 and 1988-1992

Prosthesis	1983-1987	Prosthesis	1988-1992
Marmor	1547	AGC2000	2977
PCA Tri	1195	Link Uni	1684
St George Schlitten	1039	Marmor	1449
Freeman-Samuelson	961	Freeman-Samuelson	1029
TCCK	794	PCA Uni	880
Townley	655	Scan Knee	847
AGC2000	459	St George Schlitten	737
PCA Uni	388	PCA Tri	702
Gunston-Hult	276	Oxford	673
Freeman	245	PCA Modular MkII	639
Total Condylar	232	Kinemax	502
Richard's Max. Cont.	218	Brigham	329
Oxford	160	PFC	321
Brigham	140	Richard's Tricon	281
Richard's Tricon	130	Synatomic	257
Deane	94	PCA Duracon Tri	219
Synatomic	94	Miller-Galante	163
Freeman Revision	79	Kinematic standard	151
Attenborough	72	Townley	139
PCA Revision	49	Freeman	112
Kinematic standard	46	St George Rotation	110
St George Rotation	40	New Jersey LCS	101
Guepar	32	Richard's Max.Cont.	77
Thackary-Johnson	25	PCA Revision	76
Scan Knee	20	PCA Duracon Uni	76
Total	9224		14797

Percent med / lat uni replacement

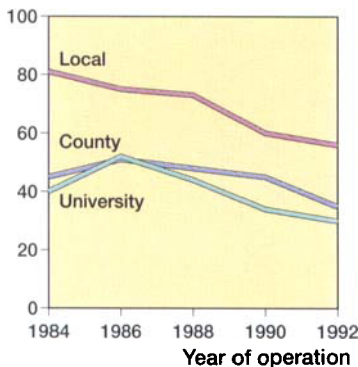


Figure 4. Through 1992 the unicompartmental arthroplasty has been the preferred technique at smaller hospitals doing one fifth of the OA operations.

Choice of prosthesis (Table 4)

Tricompartmental prostheses are increasingly used and have been the preferred alternative in RA since 10 years, when it replaced the hinged, stabilized and unicompartmental types (Figure 3). In recent years

the use of tricompartmental prostheses has increased also in OA. The rationale for this change is supported by other long-term studies from specialized centers showing excellent results, few serious complications, and more than 95 percent survival at 10 years (Rand

Table 5. Distribution of pain on walking and at rest among 362 patients scheduled for knee arthroplasty during 1992, percentages

	No pain		Visual Analogue Scale							Max. pain	
	0	1	2	3	4	5	6	7	8	9	10
Walking	0	0	2	20	19	14	13	12	13	4	2
At rest	5	9	18	20	14	12	8	5	7	1	0

Table 6. Distribution of radiographic changes according to Ahlbäck (1968) among 362 patients scheduled for knee arthroplasty during 1992, percentages

Radiographic classification		Distribution
I	Cartilage reduction	4
II	Cartilage loss	35
III	Bone attrition <5 mm	40
IV	Bone attrition 5–10mm	14
V	Bone attrition >10mm	7

Percent revised

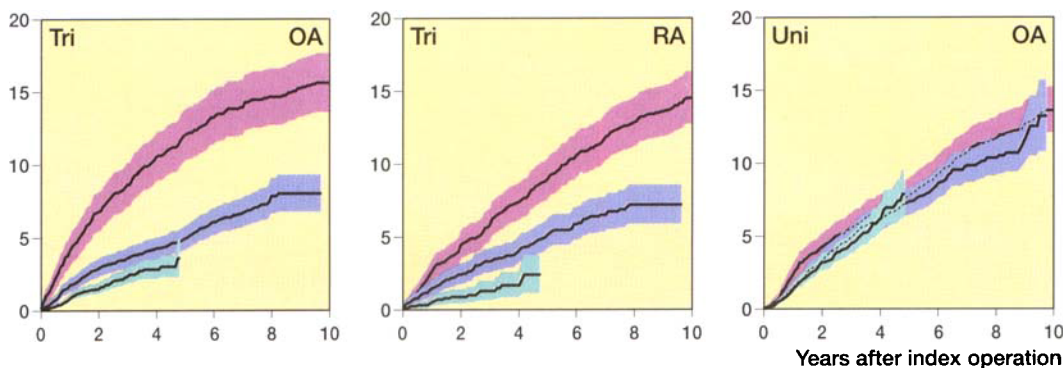


Figure 5. Cumulative revision rates (percent; all indications) and 95 percent confidence intervals according to Kaplan-Meier for TKR used for OA and RA and uni knees (demiarthroplasties) for OA related to the year of the index operation. Violet area 1976–1982, blue 1983–1987 and green 1988–1992. Initial numbers of arthroplasties were in OA Tri 1360, 2827, and 6041, in RA Tri 1741, 1884, and 1751, and in OA Uni 2067, 2986, and 5252, respectively. *P*-values were over-all (and 1982–1987 vs 1988–1992) in OA Tri < 0.0001 (0.0001), in RA Tri < 0.0001 (0.0006), and in OA Uni 0.17 (0.85).

and Ilstrup 1991, Ranawat et al. 1992).

Unicompartmental arthroplasty was more often performed in younger patients with OA (Table 3). It was earlier the preferred technique in smaller hospitals doing one fifth of all operations for OA (Figure 4). There is still a difference between large and small hospitals in their use of unicompartmental arthroplasty.

It could be questioned whether a small hospital using only the unicompartmental concept made an appropriate choice.

Indication

Pain is the main indication for knee replacement followed by loss of motion and instability. During 1992, a sample of 362 patients from 22 departments were analyzed concerning indications, radiographic classification, and pain on walking and at rest. All patients had pain on walking, and most patients some pain at rest, all had severe cartilage destruction and most had some bone attrition. Very few early or mild cases were operated on (Tables 5 and 6).

Technical improvement

There was an improvement in prosthetic survival over time for TKRs with a steady decline of complications when analyzed in 5-year intervals, all aspects taken into consideration, such as surgical technique, implant design, patient selection, etc (Figure 5). Severe complications leading to fusion or prosthetic removal have also decreased over time (Figure 6), as have revisions for infection (Figure 7). Improvement over time was evident also in the National Hip Register Study (Malchau et al. 1993). The infectious problems in knee replacements, both peroperative and hematogenous, have been summarized in recent reports from the register (Bengtson et al. 1987, Bengtson and Knutson 1991).

Even in prosthetic designs that have been unchanged for several years it has been possible to show less revision over time. This indicates the importance of patient selection and technical improvements such as the use of alignment and cutting guides, better cementing technique, improved bone cement and last but not least surgical experience (Lewold et al. 1993).

Percent removal of prostheses

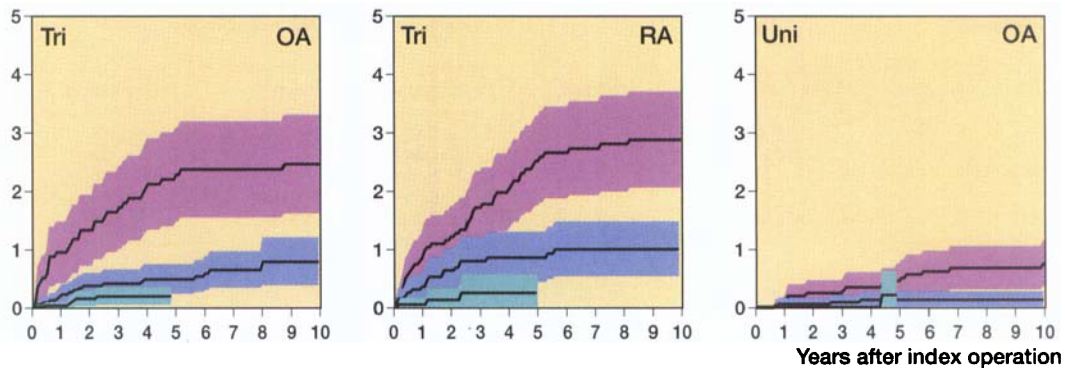


Figure 6. Cumulative fusion or prosthetic removal rates (percent) and 95 percent confidence intervals according to Kaplan-Meier for TKR used for OA and RA and uni knees (demiarthroplasties) for OA related to the year of the index operation. Violet area 1976-1982, blue 1983-1987 and green 1988-1992. Initial numbers of arthroplasties are given in Figure 5. *P*-values were over-all (and 1982-1987 vs 1988-1992) in OA Tri < 0.0001 (0.06), in RA Tri < 0.0001 (0.03), and in OA Uni < 0.0001 (0.13).

Percent revised for infection

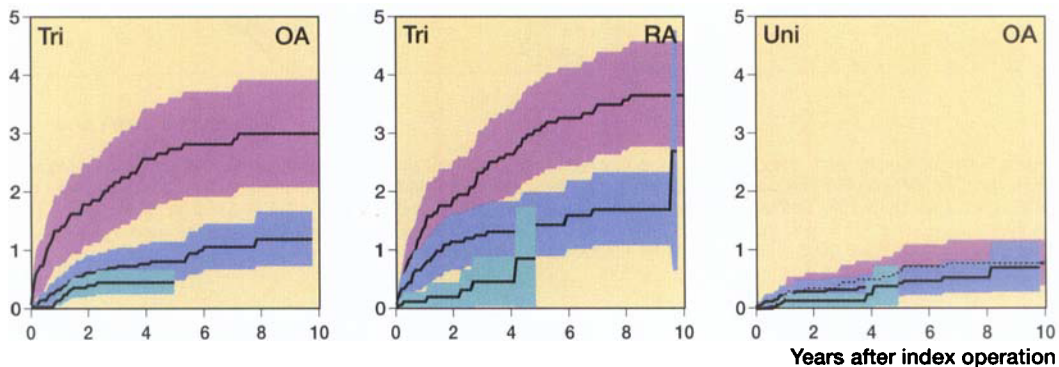


Figure 7. Cumulative revision rates (percent) for infection and 95 percent confidence intervals according to Kaplan-Meier for TKR used for OA and RA and uni knees (demiarthroplasties) for OA related to the year of the index operation. Violet area 1976-1982, blue 1983-1987 and green 1988-1992. Initial numbers of arthroplasties are given in Figure 5. *P*-values were over-all (and 1982-1987 vs 1988-1992) in OA Tri < 0.0001 (0.11), in RA Tri < 0.0001 (0.014), and in OA Uni < 0.26 (not analyzed).

In TKR for OA and RA, the cumulative revision rate for loosening has also decreased even in the last years (Figure 8). This trend is not seen in unicompartmental knees indicating that this concept is more technically demanding or results worsened by recent concepts not giving uniform results, but instead more early failures caused by instability, loosening, wear and contralateral joint degeneration (Figure 8).

Age and gender

The female to male ratio has changed over the years both in TKR for OA and in RA, and is now 3:1 (Table 2) compared to radiographic OA where the ratio is reported to be 2:1 (Ahlbäck 1968, Felson 1988). Whether men with OA have a lower risk of joint dete-

rioration leading to TKR is not known and there are only a few studies on the natural history of OA especially in men. There is a difference between men and women undergoing TKR with a worse functional status before the operation in women but with a better functional improvement after surgery. This indicates that OA progression is not inevitable (Dieppe 1991, Katz et al. 1994).

In OA patients, the cumulative revision rate is higher in men and in low age (Figure 3), which is in accordance with earlier studies on hip arthroplasty (Johnsson et al. 1988). In young male OA patients, other alternatives such as osteotomies seem recommendable (Odenbring et al. 1990). The yearly number of osteotomies, about 600, was reported to the

Percent revised for loosening

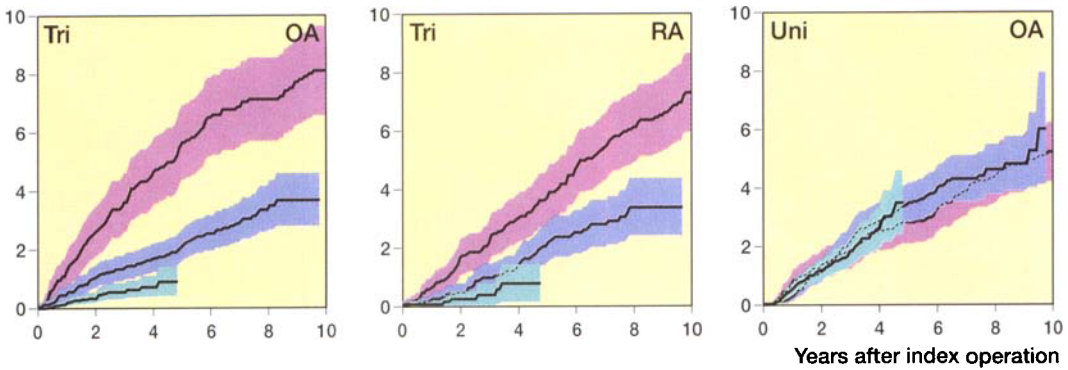


Figure 8. Cumulative revision rates (percent) for loosening and 95 percent confidence intervals according to Kaplan-Meier for TKR used for OA and RA and uni knees (demiarthroplasties) for OA related to the year of the index operation. Violet area 1976-1982, blue 1983-1987 and green 1988-1992. Initial numbers of arthroplasties are given in Figure 5. P-values were over-all (and 1982-1987 vs 1988-1992) in OA Tri < 0.0001 (0.0002), in RA Tri < 0.0001 (0.16), and in OA Uni < 0.84 (not analyzed).

Distribution in percent

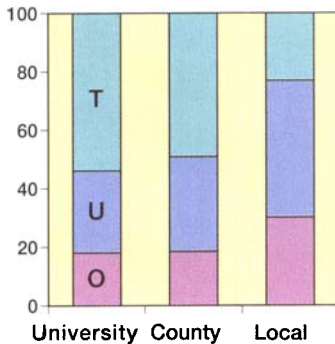


Figure 9. Use of osteotomies (O), unicompartmental (U) and tricompartmental (T) prostheses in university, county and local hospitals during 1989-1991 in 65 units.

register for the 3-year-period 1989-1991 (Figure 9). The number of osteotomies is one tenth of the number of knee replacements for the same period.

Design

Probably one of the most important uses of the register is to look at the cumulative revision rate (CRR) of various implants, used in a large number of unselected units, i.e., biofunction. This reflects better the outcome of average knee arthroplasty surgery than limited trials with specialized surgery and sometimes narrow indications. The CRR of the best uni knees is twice that of the best TKR at 10 years (Figure 5). However, there is still a slightly lower rate of severe complications with fusion or prosthetic extraction in uni knees than in TKR (Figure 6).

Percent revised

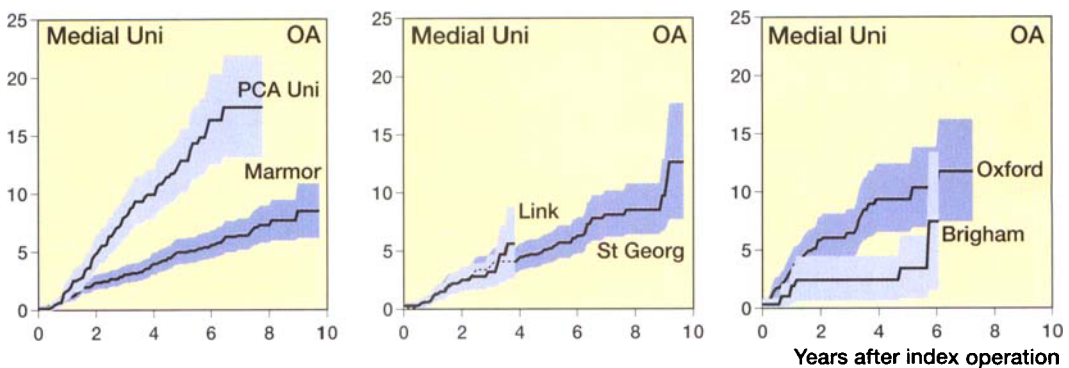
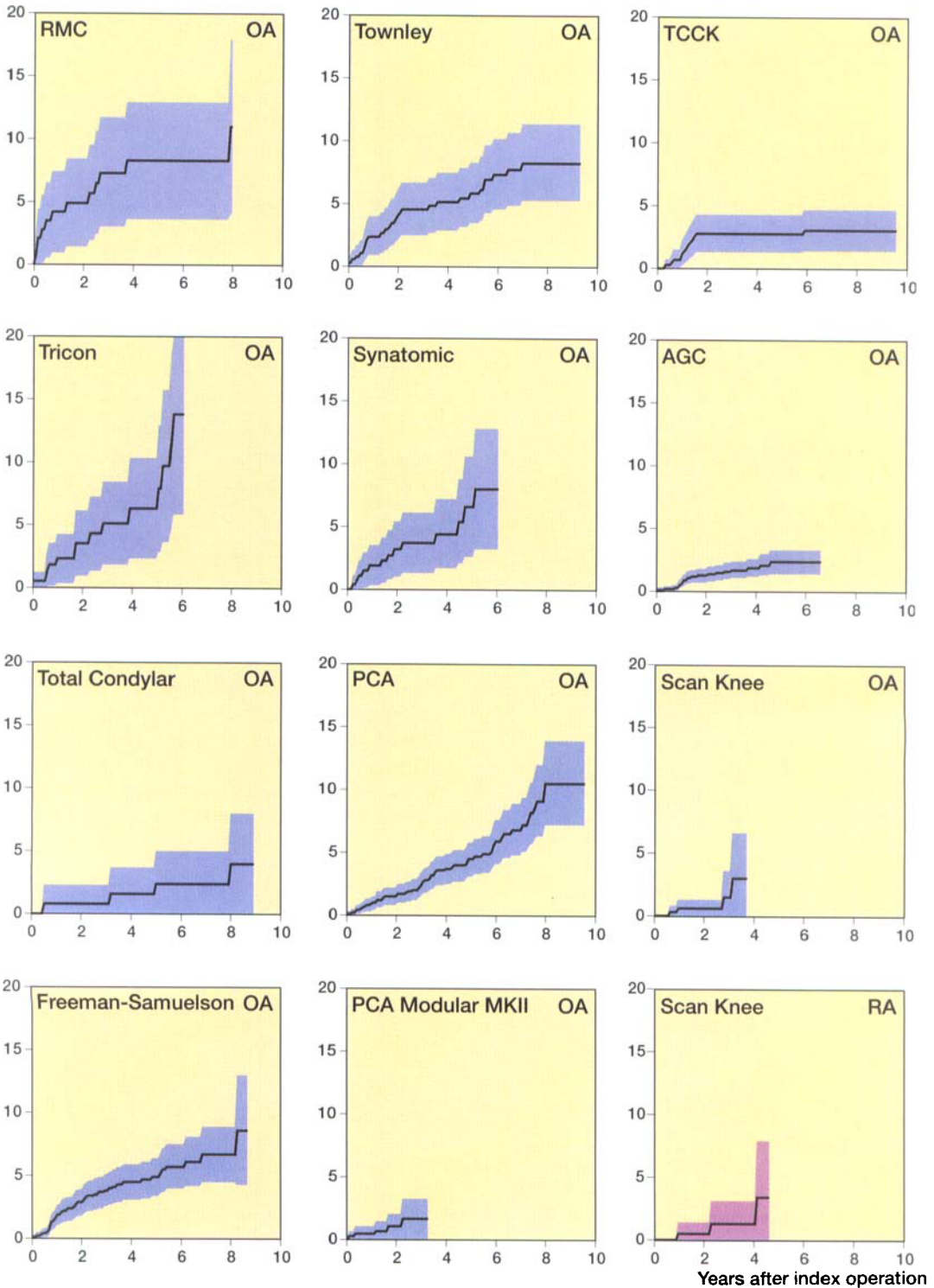


Figure 10. The outcome defined as cumulative revision rate (percent) for some recently introduced unicompartmental concepts is inferior to older designs. Initial numbers were PCA Uni 921, Marmor 2354, St Georg 1345, Link Uni 1407, Oxford 833, and Brigham 389.

Figure 11. Cumulative revision rates (percent; all indications) and 95 percent confidence intervals according to Kaplan-Meier for some tricompartmental knee prostheses used for OA and Scan Knee for RA.

Percent revised



Primary and exchange arthroplasties

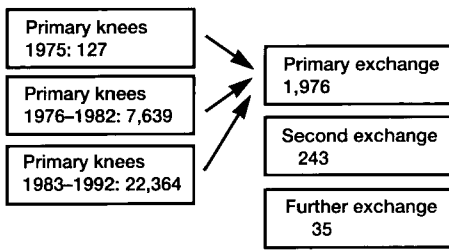


Figure 12. 2,254 exchange arthroplasties recorded during 15 years. For cumulative re-revision rate of 1,976 primary exchange arthroplasties see Figure 19.

The outcome defined as prosthetic survival for some recently introduced concepts is inferior. The "anatomically designed" uni- and tricompartmental prostheses have an increased contact stress with severe wear of the HDPE tibial component (Lindstrand et al. 1992; Figure 10). A sliding meniscal knee has given dislocation of the meniscal bearing together with impingement caused by or causing instability (Lewold et al. 1994; Figure 10). In this register, some but not all TKR with a cemented stem tibial component has given the lowest CRR and for comparison the most commonly used concepts in Sweden are shown (Figure 11).

Revisions

There were 1,976 primary exchange arthroplasties reported to the register (Figure 12). The indications for these are given in Table 7.

The number of revisions is increasing but less than the primary operations with a ratio of 5 percent of the

Table 7. Indication for and type of first revision 1976-1992

	Year of revision (number and %)			
	1976-1982	1983-1987	1988-1992	Total
<i>Indications for exchange arthroplasty</i>				
Infection	47 9	45 7	19 2	111 6
Loosening	218 43	309 46	390 49	917 46
Other mech.	64 13	65 10	115 15	244 12
Fracture	5	4	6	15 1
Patellar	23 5	68 10	36 5	127 6
Instability	76 15	35 5	36 5	147 7
Progress	64 13	142 21	135 17	341 17
Various	11	8	55	74 4
<i>revised to</i>				
Hinge	66	21	6	93
Stabilized	101	51	58	210
Bi-/Tricomp.	199	454	534	1187
Unicomp.	142	150	194	486
Total	508	676	792	1976
<i>Indications for removal, fusion, or amputation</i>				
Infection	82	47	35	164 63
Loosening	27	16	6	49 19
Other	20	18	9	47 18
Total	129	81	50	260

annual primary number (Figure 13) which is less than the annual ratio of hip revision (Malchau et al. 1993). The outcome of the revision procedures could also be followed in the register. Revision from a unicompartmental to a similar concept gave a higher re-revision rate than if a TKR is used for the revision. However, also the CRR for a TKR revised to a new TKR replacement is slightly higher than if unicompartmental prostheses are exchanged for a TKR (Figure 14). It is also interesting to analyze whether exchange

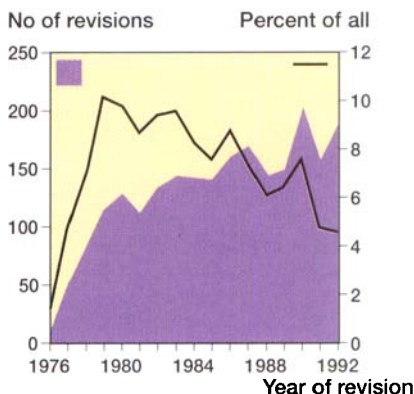


Figure 13. The yearly number of knee arthroplasty revisions are slowly increasing (grey area) but less than the number of primary arthroplasties. Revisions now accounts for 5 percent of the net volume (black line).

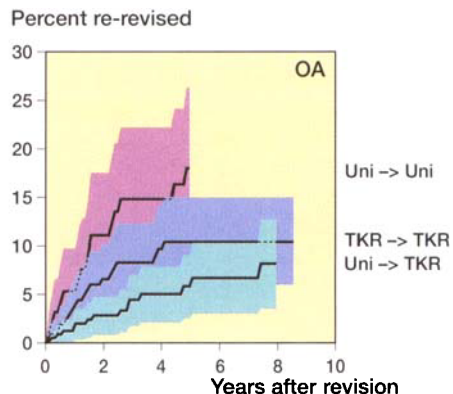


Figure 14. Cumulative re-revision rates (percent) after exchange from uni to a new uni knee (n 98) or to a TKR (n 303) (P 0.001). For comparison the cumulative re-revision rate after exchange of a TKR (n 219) is illustrated.

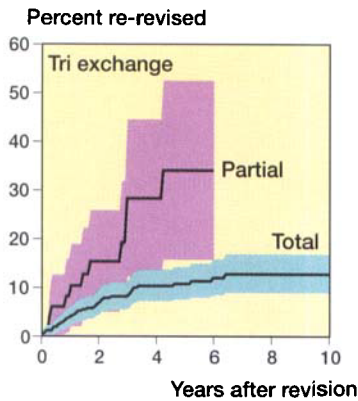


Figure 15. Cumulative re-revision rates (percent) after partial (n 58) and total (n 403) exchange from TKR to a new TKR for tibial component loosening during 1983–1992 (P 0.011).

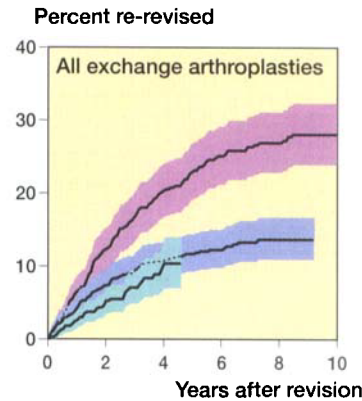


Figure 16. Cumulative re-revision rates (percent) after exchange arthroplasty related to the year of revision (P < 0.0001). Violet area 1976–1982 (n 508), blue 1983–1987 (n 676) and green 1988–1992 (n 792).

of only the tibial component without femoral exchange has given a comparable result to exchange of both components. In the light of our knowledge of third body wear with abrasion in prosthetic joints (Goodman and Lidgren 1992) the risk for revision should be higher if only one component is revised. This was verified in our study where exchange of the tibial component gave a higher revision rate than revision of both components (Figure 15).

The survival of TKR revisions has improved over time with better patient selection, operative technique, etc (Figure 16). The same applies to the largest subset, the tricompartmental revisions in OA.

Complications, analysis and treatment

Better treatment of specific complications, such as infection, has been possible by collecting information from a large number of cases from the register. Infection problems have decreased even in the last years and are now caused by postoperative wound healing complications and by late bacterial hematogenous seeding. Specific attention should be focused on prophylactic measures directed towards the soft tissue problems in patients with RA (Bengtson 1990).

Fusion attempts carried out in several Swedish units gave inferior results compared to centralized treatment where a stable fixation was used by biplanar external fixation and spongy bone transplantation. The fusion rate increased from about half to 90 percent by a centralized treatment (Knutson et al. 1985). A failed fusion led to more frequent use of wheel-chairs, walking aids, orthoses, and institutionalized care (Knutson et al. 1984).

Summary

The Swedish knee arthroplasty study has given valuable information on the following aspects:

Epidemiology, describing the patient population over time in relation to age, diagnosis, surgical procedures and treatment principles.

Demography, showing differences in the incidence, patient selection, choice of implant and technique on the hospital level and the effect on the outcome.

Benchmarking, comparison between orthopedic units and aggregated data from all units which may lead to improvements in patient selection and the surgical procedures.

Biofunction, long-term follow-up of implant performance in a large number of unselected units giving the result of the average surgery. The use of survival analyses on a large population may give early warnings.

Complications, analysis, prevention and treatment.

Acknowledgements

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Addendum

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