This 2004 annual report from the Swedish Knee Arthroplasty Register (SKAR) concerns data reported during 2003 and is based on the content of the register as of October 1st 2004.

The first and second parts of the report are general by nature and will be available for downloading from our website: www.ort.lu.se/knee/. They include a historical overview of the routines and definitions of the SKAR, information on implants reported in 2003 as well as a brief overview of our research and analyses for the latest 10-year period (1993-2002).

Each participating unit receives, together with this report, lists containing data on the arthroplasties the unit reported during 2003. Our hope is that the lists will be compared with locally available information in an attempt to find and correct any errors in the registration, if found. Unfortunately, our plans for a web-based report to the units has been delayed. However, the work continues.

In addition, each unit also receives a diskette containing information regarding all recorded arthroplasties reported by the unit. In case of patients having been revised later at different locations, information regarding those revisions has been added.

We find it appropriate to remind you that the Swedish Knee Arthroplasty Register is a prospective project and that revisions reported to the register are only entered if the primary operation has been reported previously according to prevalent routines. Thus, if a primary operation becomes known at a later time as it became a subject of a revision, neither the primary nor the revision will be entered into the database. Late reporting of primary procedures is only allowed in cases when all primaries performed during a time period are reported collectively.

The use of minimally invasive surgery (MIS) in unicompartmental arthroplasty (UKA) continues to increase in Sweden. In 1999 15% of the UKA were inserted using MIS, which had increased to 46% in 2002 and to 58% in 2003. Unicompartmental implants, even without MIS are sensitive to surgical routine and the rate of revision continues to be higher for UKA than for TKA. Infection is still a large problem that needs to be carefully followed up. New pharmacological treatments of rheumatoid arthritis have been introduced and routines in general thrombo-embolic prophylaxis has been changed which probably has affected the risk for postoperative bleeding and complications due to wound healing problems. The 10-year cumulative revision rate (CRR) for infection is 1.0 percent for arthrosis and 1.8 percent for rheumatoid arthritis. The result of an infection is still all too often amputation or arthrodesis. A group assigned by the Swedish Ortopaedic Association, with participants from the registry has developed algorithms for diagnosis and treatment of infected knee arthroplasties which can be found at the Swedish Orthopedic Association (SOF) Web-site; www.sofportal.org.

We at the knee register center in Lund want to thank you for your cooperation during the last year and ask you to analyze and circulate the presented information.

Lund, November 1st, 2004 On behalf of the Swedish Knee Arthroplasty Register

Kaj Knutson Lars Lidgren

Otto R

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Part III Only for participating units – Data for patients reported in 2003

1

Definitions

Revision is defined as a new operation in a previously resurfaced knee during which one or more of the components are exchanged, removed or added (incl. arthrodesis or amputation). This implies that soft tissue operations such as arthroscopy and lateral release are not considered revisions. The reason for this stringent definition is that some minor operations are not necessarily related to the primary surgery and thus cannot be considered a complication or failure.

All the Scandinavian registers do not use this stringent definition. For example the Finnish National Implant Register defines any reoperation as being a revision. However, in their reports, the additional operations account for only about 3 percent of the revision surgery.

TKA (Total or Tricompartmental Knee Arthroplasty) is defined as a knee arthroplasty where the femoral component has a flange and thus all three compartments of the knee are affected. Even in cases where a patellar button is absent, the flange resurfaces half of the femoropatellar compartment and the arthroplasty is still considered to be a TKA.

Bicompartmental arthroplasty (historical) uses two components, one on the femoral and one on the tibial side to resurface both the femorotibial compartments (medial and lateral) but not the femoropatellar compartment. Thus, this implant has no femoral flange and is not meant to allow for resurfacing of the patella.

UKA (Unicompartmental Knee Arthroplasty) implies an arthroplasty that separately resurfaces the medial or lateral femorotibial compartment. (med. UKA or lat. UKA). If 2 UKA implants are used to resurface both femorotibial compartments the arthroplasty it is named bilateral UKA.

Patellar arthroplasty is used to resurface only the femoropatellar compartment. Even if this

arthroplasty is unicompartmental by definition, it is accounted for separately.

Hinged implants. As the name implies these implants only allow for flexion and extension through a fixed axis.

Linked implants (Linked/Rotating hinge) have a mechanical coupling between the femoral and tibial components allowing for flexion and extension as well as for varying amount of rotation.

Stabilized implants. Even if the hinges and the linked implants are extremely stabilizing, the term stabilized implants is used for a group of prostheses that are a kind of TKA but use the form of the femoral and tibial components to restrict movement in valgus, varus and rotation. The posterior cruciate sacrificing type most often has an eminence in the middle part of the tibial polyethylene that can be contained by a box in the femoral component that lies between the medial and lateral sliding surfaces. By a camshaft-like property, the femoral component is forced to slide back during flexion, which simulates the effect of the posterior cruciate ligament. The fit between polyethylene and metal is such that it allows for some rotation. In so-called superstabilized implants the congruency has been increased by making the eminence larger with a total fit against the box of the femoral component thus, restricting the rotation and varus/valgus movement. Intermediary forms also occur. Stabilized implants are most often used for revision but also for the more difficult primary arthroplasties. The ordinary TKA can be made somewhat more stabilized by increasing the congruency between the sliding surfaces. In these instances there is a slight eminence of the polyethylene that fits against the femoral component. However, the term stabilized is only used for those implants that are more stabilized than usual by use the above mentioned camshaft construction.

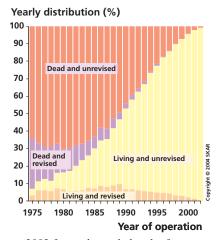
Filling in the Knee Register form

The Knee Register uses a form that it recommends to be filled in during the operation, (by a nurse or other attending staff). The implant stickers (containing the Part No's and Lot No's) for all used implants are to be affixed to the form. Besides the ID of the patient, the date of operation, diagnosis, side operated, brand of cement and cementing of components has to be filled in. For UKA, information whether a mini-arthrotomy was used must be specified. Information regarding the operating surgeon is voluntary. Forms are sent to Lund (once a month is recommended) where the data is computerized. In our opinion, this procedure has considerable advantages such as a minimal workload for the participating units and the most correct information with the least risk of wrong coding. Furthermore, it allows the staff of the registry to check unknown Part No's during input.

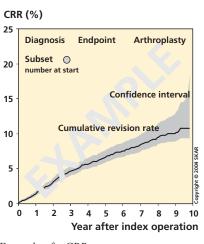
How the Knee Register compares implants

Survival analyses are used for graphical presentation of data. The curves show the Cumulative Revision Rate (CRR) which describes what percentage of the operated patients was expected to become revised with time. The calculation is based on the sum of all the revisions and expresses the rate for surviving patients. Most often the time axis shows a 10-year period. However, it has to be kept in mind that patients are continuously being added during this time. Thus, all the patients have not been followed for the whole period. This implies that if 1,000 patients were operated on each year (and nobody dies), a 10-year study would include 10,000 patients of which only 1,000 had been followed for more than 9 years. The last part of the curve (at the right) therefore expresses the long-term rate of revision for patients operated more than 9 years earlier. As the number of these patients is relatively small, the 95% confidence interval becomes large. When the number of patients at risk is small (at the right of the curve), each revision has a large effect (e.g. 50% are revised when 2 patients are left and one of them has a revision). For this reason the Register cuts the curves when less than 40 patients are left at risk.

With increasing observation time the fraction of deceased patients increases (see figure below). These patients are not disregarded because they were at risk of becoming revised during their lifetime and are thus allowed to deliver data for the period they lived. The probability for each revision is related to the number of remaining unrevised patients. The sum of all the probabilities is the cumulative risk of revision which specifies the risk for a surviving patient of becoming revised at a given time.



The status in 2002 for each yearly batch of patients operated since 1975.

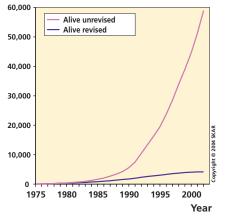


Example of a CRR curve.

Cox regression allows for taking into account different factors that may vary within groups. The results cannot be shown as curves with confidence intervals, but are expressed as risk ratios (RR) between factors. If a factor is a category (e.g. implant model), one category is defined as a reference with a risk of 1 to which the other categories are compared. An implant with the risk of 1.2 thus has a 20% increased risk of becoming revised etc.. For numerical variables (e.g. age) the risk ratio relates to the change in risk if the variable increases by one unit (e.g. 1 year). When comparing groups where uneven distribution of factors can be expected (e.g. age in cemented vs. uncemented implants) the Cox regression is especially important.

It is important to note that as the individual patient also is at risk of dying, the real percentage of revision is lower than CRR. As the figure below shows, half of the patients alive that were operated in 1975 have been revised but only one third of the patients that were operated at the time.



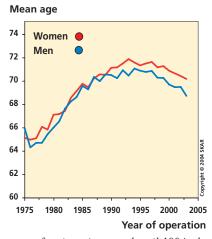


The cumulative number of revised and unrevised patients alive.

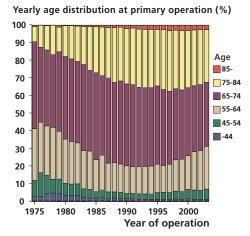
Age distribution and prevalence

Between 1975 and 1995 the mean age at primary operation increased from 66 years to almost 72 years. The main reason was the relative large increase in number of operations for the older age groups. Probable explanations are improvements in anesthetic techniques, which have increased the safety for older patients as well as a changed age distribution of the population. Since 1994 the proportion of younger patients having arthroplasty has increased again, why the mean age again has started to decrease. This can be explained by an increased confidence in the operation technique.

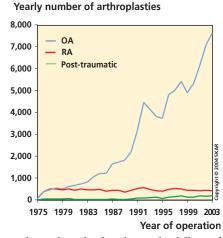
As the picture to the right shows, the real rise in number of operations started in the beginning of the eighties. This was mainly caused by a large increase in the number of operations for osteoarthrosis. Operations for rheumatoid arthritis have become marginally fewer while operations for posttraumatic conditions have only increased slightly.



The mean age of patients increased until 1994 when it started to decrease again. Therefore, when comparing the rate of revision in series of patients operated during different time periods, Cox regression or separate analyses for different age groups have to be performed.



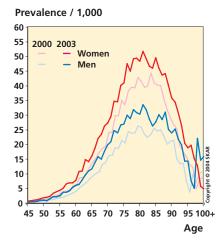
The relative percentage of older age groups increased untill the mid-ninties after which the relative proportion of younger increased again.



The yearly number of arthroplasties for different diagnoses

The large increase in number of operations causes a rise in the number of patients walking around with knee implants in the society. The picture below shows the prevalence in 2003 i.e. the number of patients per 1,000 inhabitants in different age groups that had a knee implant. The prevalence for both men and women peaks around 80 years of age. The decrease after 85 years of age is probably sign of that this group is provided below its actual needs (assuming they don't die from their arthroplasties).

Compared to the prevalence in 2002 the influx seems to be insignificant after 87 years of age. The increase in prevalence for the oldest age groups between 2000 and 2003 is caused by ageing of previously operated patients by three years. Thus, it seems that within few years there will be a steady state among the elderly in which at least one in twenty women has a knee implant. Further increase is still possible through widening of indications.



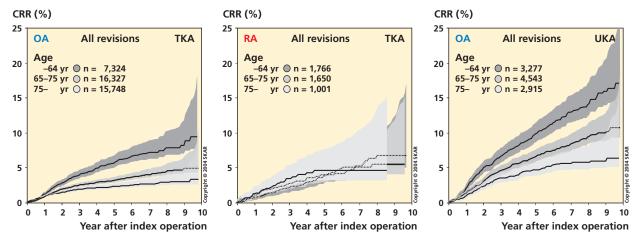
The prevalence of knee arthroplasty in 2000 and 2003. Accordingly, every twentieth woman has a knee arthroplasty

Factors that influence the revision rate

Primary disease – Early it became evident that patients with different primary disease, e.g. rheumatoid arthritis (RA) and osteoarthritis (OA) followed a different postoperative course with differences in the revision rate. Therefore the registry has always produced separate curves for these diagnoses. The differences in CRR between OA and RA treated with unicompartmental arthroplasty (UKA) demonstrate the importance of this.

Age – The effect that the age of the patients has on the CRR can be illustrated by analyzing different age groups separately. For OA the age has a considerable effect on the rate of revision both in TKA and UKA. One can wonder why this is the case. A possible explanation is that the younger have a higher level of activity, higher demand regarding pain-relief and a state of health that more often allows for revision surgery. In RA (TKA) there is no similar effect of age to be found which can be due to the fact that the younger have multiple joint disease, a lower physical level, a higher pain threshold and poorer general health which may reduce the likelihood of being offered revision surgery.

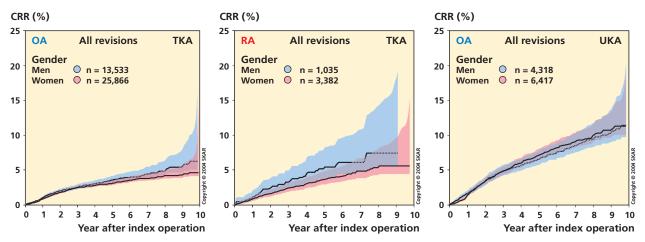
When calculating CRR it would be reasonable to only compare similar age-groups. However, this method would reduce the size of the material and thus the statistical usefulness.



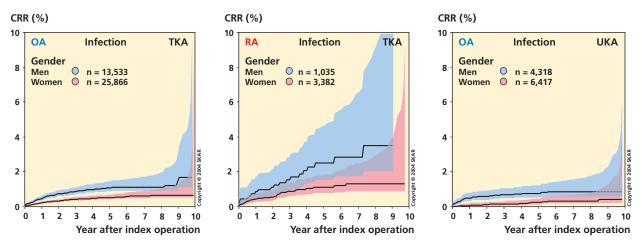
The differences in CRR (1993–2002) between the 3 age groups <65, 65-75, >75 were significant for OA operated on with TKA and UKA but not for RA with TKA.

Gender – Analyzing OA in the period 1993-2002 (Cox regression), no significant difference in CRR was found between the sexes, whether it was for TKA or UKA. However, in RA (TKA)

there was a significant difference where men had a higher risk. This difference is partly due to the fact that men had a higher risk of being revised for infection (see next page).



For OA in 1993–2002 (TKA & UKA), there was no significant difference in CRR between the sexes. In RA (TKA) men had 1.4 (1.0-2.0) times greater risk than women (p=0.05)

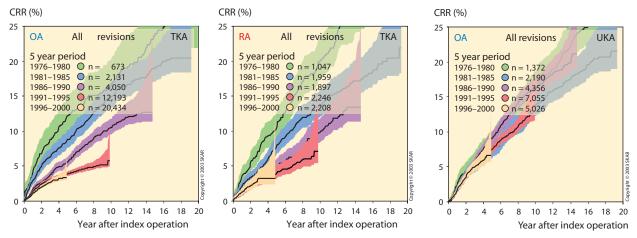


Using the end-point revision for infection, the CRR (1993–2002) shows in TKA for OA and RA that men are more affected than women (RR 2.0 and 2.3). UKA with its smaller implant size does better than the larger TKA but even in UKA men have 2.8 times the risk of women of becoming revised for infection. In TKA, patients with RA are more affected than than those with OA (RR 2.1).

It is well known that RA patients have a greater risk of infection which is ascribed to the effect of corticosteroid and immunosuppressive medications. However, it is not as obvious why men more often are having their knee arthroplasties revised for infection than women. Either men are more prone to infections or they more often than women are being offered revision surgery for their infected knee implants. The latter is contradicted by the fact that in other context men also have been found more susceptible to infections than women.

Year of operation – Over the years the risk of revision has lessened for TKA. The reduction can't only be explained by an increase in operations of the elderly. Even if improved implants may provide some explanation, reduction has also been seen for unchanged implants (Lewold et al. 1993). This indicates improvement in technique (cementing/ seating) or in patient selection which has caused

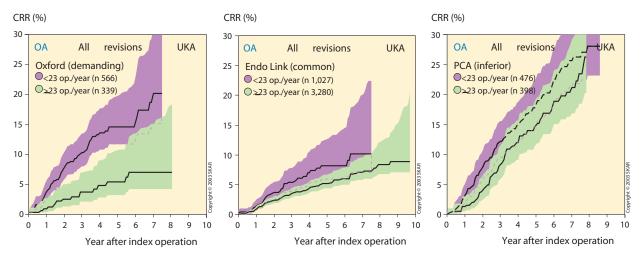
us to take into account the time-period during which the operations were made, when comparing implants by Cox regression. Improvement with time has not been seen for the UKA, which probably is caused by some newer models that have shown inferior results. Furthermore, the number of UKA operations has decreased which may have reduced the surgical routine.



Reduction in the revision rate with time was seen for TKA but not UKA when the time periods 1976–1980 (green), 1981–1985 (blue), 1986–1990 (violet), 1991–1995 (red) och 1996–2000 (orange) were compared.

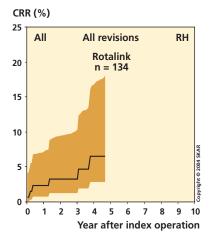
Surgical routine – For UKA (1986-1995) we found that there was a relationship between the number of operations performed in hospitals and their rate of revisions (Robertsson et al. 2000). Thus, a group of units that performed less than 23 operations/year had significantly more revisions than those that performed more. The Oxford implant with a meniscal bearing was found especially sensitive to the surgical routine. The Swedish results for this

implant were quite different and worse than what had been published from large centers in England. This led the producer to require that surgeons learned the operative technique before starting using the implant. Preliminary results indicate that this has had an effect, as the results of more recently inserted Oxford implants have improved. It seems likely that the surgical routine also can affect the results of other implant types such as the TKA.



The majority of orthopedic units performed relatively few UKA/year and there was a relation between the yearly number and the risk of later revision. For the 3 examined models (above) the effect of volume on CRR varied. The technically demanding Oxford implant was more affected than the most common Link implant while the inferior PCA implant was not affected by volume at all.

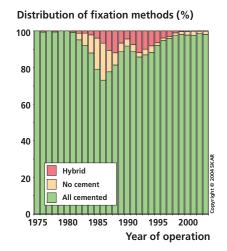
Type of implant – Hinges, linked and stabilized implants are mainly used for revisions or especially difficult primary cases. In uncomplicated primary cases a TKA is used and if the disease is



The linked implant Rotalink is used once in a while for primary arthroplasty in cases with serious instability and bone-loss. The limited number of implants of this type does not allow for further comparisons.

unicompartmental an UKA may do. For a proper comparison of TKA and UKA the results of patients with osteoarthritis are of interest. Although the UKA has been shown to have substantially higher CRR than TKA (see figures on page 5), the number of serious complications such as infection/ arthrodesis/amputation is much less. If a primary UKA is revised to a TKA at a later time, the risk of re-revision is not significantly increased compared to the risk of revision if the patient had primarily been treated with a TKA. As the UKA implants are less expensive than the TKA, the increased number of revisions due to their use has not resulted in additional cost. When asked, patients with TKA and UKA seem equally satisfied with their knees. In summary we conclude that it cannot be considered wrong to use UKA implants in OA patients with unicompartmental disease.

Use of bone-cement – As can be seen from the figure on the right, bone-cement has been used in the majority of arthroplasties that have been performed in recent years. We have previously found that cement free insertion of the tibial component is associated with an increased risk of revision. This is in agreement with the results of the Finnish implant register that also found substantially increased risk of revision for uncemented implants. For the period 1993–2002 we don't observe any significant differences any longer. However, it has to be kept in mind that during this period tibial components were inserted without cement in only 2.1% of the cases which makes statistical comparison difficult.



The figure shows the yearly distribution for cemented, uncemented and hybride fixation of components.

Patellar button in TKA – Estimating how the use of a patellar button affects the revision rate is complex. The use of a patellar button varies with the brand of prosthesis used and its use also has lessened in the recent years. Hitherto, when analyzing all TKA implants together, we have not found the use of patellar button to influence the revision rate. However, when comparing different time-periods we found that during the eighties when patellar buttons were used in half of the cases its use had a negative effect. In the nineties during which patellar buttons were used in one quarter of TKA the effect has started to change to the advantage of the button. For TKA in OA during the last 10-year period we find that the revision rate is significantly higher if a patellar button is not used (see page 11). This increased frequency of revisions is due to the need for a secondary resurfacing of the patella. This finding in combination with the previous finding that patients that receive a patellar button are more satisfied with their knee (at least early on) implies that a patellar button could be inserted more often - at least for the elderly.

Implant model (brand) – The model is the factor that generates most interest and most often is related to the result after knee arthroplasty. As can be suspected from what has been said, the results are not only affected by the model or design of the prosthesis. In Sweden the most commonly used implants have also been those with the lowest CRR. This can be due to a good design but also

Distribution (%) of TKA with and without patellar component 100 None Metal backed 80 All poly 60 40 20 0 1975 1980 1985 1990 1995 2000 Year of operation

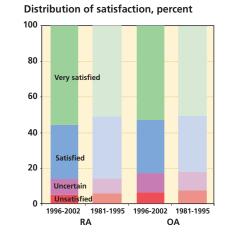
The figure shows the yearly distribution regarding the use of patellar button in TKA.

due to the surgical routine as the same implant is often used. However, some models have had considerably worse results than others. Of the newer brands the Miller-Galante can be mentioned but the use of that implant has now ceased. Regarding the UKA it seems that most the newer implants have not improved survivorship compared to the older ones.

The mailout to patients in 2003

During the spring of 2003, 35,000 patients operated on with knee arthroplasty between 1996 and 2002 were sent questionnaires by the register. These included Oxford12, SF12 and Euroqol health questionnaires, questions about satisfaction, re-operations and infections. The scanning of the answers has now been completed.

The rate of answering was 80% which is considerably less than was achieved in the previous mail-out in 1997 (93%) which did not include any health questionnaires. However, previous limited mail-outs that included health questionnaires have had a similar answering rate. Analyses have not been performed to any greater extent due to lack of resources. As the figure to the right shows, the distribution regarding patient satisfaction was very similar to what was found in 1997 (Acta Orthop Scand 2000; 71:262-267)



Answers from unrevised patients with RA and OA regarding how satisfied they were with the operated knee shows insignificant differences between the mail-outs in 1997 and 2003.

The impact of the Knee Register and "crude revision rate"

Articles published by the register are often cited, especially those that include large series describing survival of implants. Even though only a limited number of variables are being analyzed the findings reflect the results of the average surgeon which is in contrast to many smaller studies published from large highly specialized centers.

The national studies are a kind of quality control which has an effect on the performance of those participating. The registers can improve results by warning against inferior implants and surgical techniques. The average results work as a national standard which participating units are stimulated to compare against and then to reflect on their choices regarding implants and techniques. Probably, the registers have contributed to improvement in quality which can be illustrated by the "crude revision rate" i.e. the proportion of revisions of the total number of arthroplasties performed.

In comparison to other large or national reports Sweden has a low "crude revision rate" of ca. 7%. When comparing to countries that mainly perform TKA, UKA may be excluded and then the rate becomes 5%. We know that the median time from primary to revision is close to 4 years and thus that the revisions of today primarily were inserted some years ago. As the number of primaries continually has increased there is an effect of dilution. If we instead compare the number of revisions to the average number of primaries inserted during the past 8 years the rate becomes 9%. This shows the limitations of using "crude revision rate" for estimating risk of revision. However, if one assumes that all countries have experienced a similar rise in the number of primary arthroplasties the rate can be used as a measure of difference between the countries. A more correct measure is still the cumulative revision rate CRR.

Crude revision rate %	(yearly number of revisions	s / yearly number of primari	ies + revisions) (A Stefansdottir)
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Country	"Crude revision rate"	Period	Source
Australia	9	mid 2001 – mid 2002	The National Joint Replacement Registry 2003
Canada	8	April 2000 – March 2001	The Canadian Joint Replacement Register 2002
Finland	7	1998	The Finnish Arthroplasty Register 2000–2001
New Zealand	9	2002	The New Zealand National Joint Register
Norway	9	2002	The Norwegian Arthroplasty Register 2004
Scotland	8	April 2002 – March 2003	The Scottish Arthroplasty Project 2004
Sweden	7	2002	The Swedish Knee Arthroplasty Register 2004
USA	9	2000	American Academy of Orthopaedic Surgeons

Type of operation and implants in 2003

ТҮРЕ	Stockholm Gotland	Uppsala Örebro	Southeast	South	West	North
Hinges	-	-	_	1	-	_
Linked	2	10	2	3	4	1
ТКА	1,548	1,508	801	1,432	1,257	767
UKA medial	170	259	85	181	224	47
UKA lateral	7	3	2		3	-
Patella	2		1	1	4	2
Total:	1,729	1,780	891	1,618	1,492	817

8,327 primary arthroplasties reported in 2003, by type and region

Implants for primary TKA in 2003

	Number	Percent
PFC Sigma	2,394	32.7
AGC	1,512	20.7
NexGen	1,290	17.6
Duracon	833	11.4
F/S MIII	731	10.0
Kinemax	172	2.4
Scan	86	1.2
Profix	71	1.0
Natural II	57	0.8
LCS	47	0.6
Other	120	1.6
Total :	7,313	100

All active units reported to the registry during 2003 and although some additional reports may occur later, these are only expected to cause minor changes in the number of operations. As compared to 2002 the number of reported primary arthroplasties increased from 7,785 to 8,327 or by 7%. The increase was the same for both TKA and UKA.

Implants for primary UKA in 2003

	Number	Percent
Link Uni	466	47.6
MillerGalante Uni	282	28.7
Oxford Uni	154	15.7
Genesis	38	3.9
EIUS	19	1.9
Other	22	2.1
Total :	981	100

During 2003, 585 revisions were performed of which 121 were secondary revisions. In 352 of the revisions the primary procedure had been a TKA and in 219 cases an UKA. Thus the crude revision rate for TKA becomes 5% and for UKA 22%. One has to take into consideration that the use of primary UKA has been reduced by half in the last 10 years while the use of TKA has more than doubled.

The 3 most common im	nlants for	nrimary TKA in	each region in 2003
The 5 most common m	plants for p	ριπαιγ ικα π	each region in 2005

	Model 1	n	Model 2	n	Model 3	n	Others
Stockholm / Gotland	PFC S	926	NexGen	226	F/S MIII	143	253
Uppsala / Örebro	AGC	444	NexGen	361	F/S MIII	330	373
Southeast	PFC S	273	NexGen	272	AGC	224	32
South	PFC S	591	Duracon	404	AGC	312	125
West	AGC	324	PFC S	270	F/S MIII	258	405
North	AGC	207	NexGen	198	PFC S	138	224

The 3 most common implants for primary UKA in each region in 2003

	Model 1	n	Model 2	n	Model 3	n	Others
Stockholm / Gotland	MillerGal.	125	Link	27	Oxford	12	17
Uppsala / Örebro	Link	227	Genesis	17	MillerGal.	14	3
Southeast	Link	37	MillerGal.	22	Genesis.	20	8
South	Link	115	Oxford	31	EIUS	19	16
West	Oxford	107	MillerGal.	102	Link	18	
North	Link	42	MillerGal.	4	Oxford	1	

Bone cement and minimally invasive surgery in 2003

Use of cement in primary surgery during 2003

	Primary TKA		Primary UK	(A
No components inserted without cement	6,865		980	
Only the patellar button without cement	301			
The femur- and tibial components without cement	135			
Only the femoral component without cement	1			
Only the tibial component without cement	7			
The femur- and patellar components without cement				
The femur-, tibial and patellar components without cement				
Information missing	4		1	
Total	7,313		981	
	number	percent	number	percent
Palacos/Gentamycin	4,641	64.7	755	77.0
Refobacin-Palacos R	2,435	33.9	218	22.2
Palacos	71	1.0	6	0.6
CMW	10	0.1		
Simplex	5	0.1		
Copal	5	0.1		
Combinations	2	0.0		
Information missing	9	0.1	2	0.2
Total	7,178	100	981	100
All implanted parts without cement	135			
Grand Total	7,313		981	

NB Handwriting the type of the cement on the report may be a source of error.

The units are encouraged to use the sticker that comes with the cement package.

Type of bone cement

In Sweden, the use of bone cement is the most common method for fixing components to the bone. During 2003, approximately 1.8% of all TKA were completely without cement (1.4% in 2002) and cement was used in all UKA. Use of the cement-type Refobacin-Palacos R has gained popularity and was used in 33% of the cemented cases during 2003. In only 1% of the cemented cases the cement did not include addition of antibiotics.

We want to remind the surgical units to report the type of bone cement used using the stickers that normally are to be found in the cement packages.

Minimally invasive surgery in UKA

For UKA we have since 1999 registered whether the implant was inserted by a standard arthrotomy or by the new type of mini-arthrotomy.

Our definition of mini-incision implies that the surgeon gains access to the knee joint by the use of a very small arthrotomy and without dislocating / everting the patella. The benefit of the procedure has been claimed to be less traumatic surgery, quicker rehabilitation and shorter hospital stay. Minimally invasive surgery (MIS) seems to be gaining popularity. It was used in 58% of the UKA cases in 2003 compared to 46% in 2002 and 15% in 1999. MIS has not been reported for TKA.

Even though the material is still small and with a relatively short follow-up, there are indications that the mini-incision may increase the revision rate. If that is due to the learning curve and whether the results will improve in the future can only be speculated on. However, as the UKA has been shown to be sensitive to surgical routine without a mini-incision, it is not inconceivable that the new operating procedure may further deteriorate the long-term results.

The type of incision for 981 primary UKA in 2003

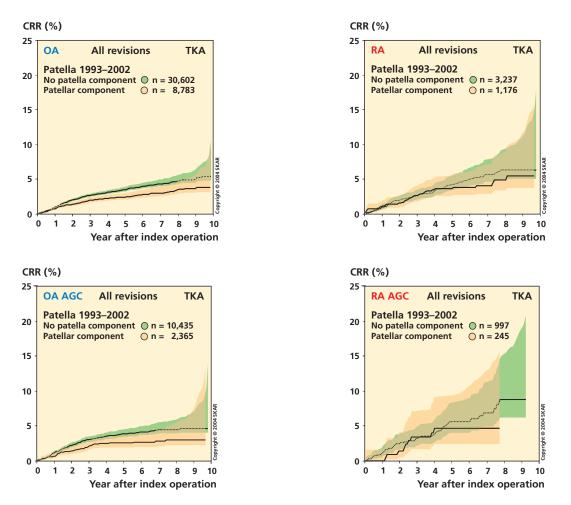
	Standard incision	Mini incision	missing
Link Uni	316	150	1
MillerGalante Uni	39	240	3
Oxford Uni	6	148	0
Genesis	32	6	0
EIUS	0	19	0
Preservation Uni	4	8	2
Allegretto	2	1	1
Other	2	0	1
Unknown implant	0	1	0

The use of patellar button is heavily dependent on the implant model used. Thus, in primary arthroplasty, surgeons using the Freeman-Samuelson implants commonly resurface the patella with a button while those using the LCS (New Jersey) and Scan Knee infrequently do so.

In previous analyses (1988–1997) we found no difference in CRR dependent on the use of patellar button. However, as mentioned in the last report, this has changed to the advantage of patellar resurfacing. For the analyzed period (1993-2002) we find that the CRR is 1.4 (1.2-1.6) times higher for TKA without a patellar button and if only AGC implants are analyzed, the risk for revision without a patellar button is 1.5 (1.1-2.0) times higher.

Use of patellar button with different implants in 2003

	No patellar button	%	Patellar button	%
PFC Sigma	2,273	94.9	121	5.1
AGC	1,408	93.1	104	6.9
NexGen	1,263	97.9	27	2.1
Duracon	765	91.8	68	8.2
Freeman/Samuelsson	326	44.6	405	55.4
KinemaxPlus	130	75.6	42	24.4
Scan Knee	84	97.7	2	2.3
Profix	58	81.7	13	18.3
Natural Knee II	45	78.9	12	21.1
New Jersey (LCS)	47	100.0	0	0.0
Other	112	93.3	8	6.7
Total	6,511	89.0	802	11.0



The figures show the 10-year CRR for TKA with and without patellar button during the presently analyzed period (1993-2002). Above the figures show the results for all TKA and below the results only for AGC. The higher CRR for TKA without patellar button is caused by the need for secondary resurfacing with a patellar button.

Operations performed early on during the analyzed period have a relatively large influence on the cumulative revision rate. Subsequently, the older models are mainly affected. To be able to account for the reasonably longterm results of relatively modern types of implant types, the register usually uses the latest 10-year period that is available for analysis.

Implants for primary UKA in 1993–2002

	number	percent
Link-Endo	4 526	40.5
Link St. Georg	293	2.6
MillerGalante	1 795	16.1
Marmor/Richards	1 110	9.9
Brigham	716	6.4
Duracon	630	5.6
PFC	614	5.5
Oxford	599	5.4
Genesis	378	3.4
Allegretto	263	2.4
Repicci (AARS)	206	1.8
EIUS	18	0.2
Other	18	0.2
Total	11,166	100

Linked implants (primary) in 1993–2002

number	percent
134	76.1
34	19.3
4	2.3
4	2.3
176	100
	134 34 4 4

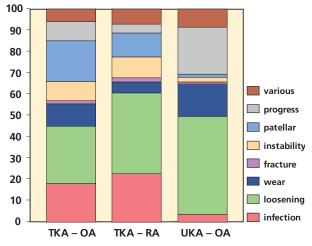
Implants for primary TKA in 1993–2002

	number	percent
AGC	14 528	31.7
PFC Sigma	6 255	13.7
PFC	2 548	5.6
F/S MIII	5 996	13.1
F/S unspec	119	0.3
Duracon	4 813	10.5
KinemaxPlus	3 137	6.8
Scan Knee	2 554	5.6
NexGen	2 319	5.1
MillerGalante2	1 082	2.4
MillerGalante unspec	209	0.5
АМК	634	1.4
LCS	479	1.0
Profix	324	0.7
Axiom	139	0.3
Synatomic	73	0.2
Osteonics	64	0.1
Rotaglide	63	0.1
Nuffield	37	0.1
Genesis	28	0.1
PCA-Mod	18	0.0
Natural Knee II	13	0.0
Other	380	0.8
Total :	45,812	100

Revisions during 1993–2002

1,471 revisions of TKA's for OA, 389 of TKA for RA and 1,610 revisions of UKA for OA were performed during the 10-year period. The indications for the revisions are shown in the diagram. Note that the primary operations may have been performed before the accounted 10-year period. Loosening remains the dominant reason for revision. "Progression" in TKA mainly reflects revisions performed for femoropatellar arthrosis/arthritis. "Patella" includes all kind of problems with the patella in patients that had their primaries inserted with or without a patellar button (although not loosening or wear). Please note that the distribution of the reasons for revision does not have to reflect the risk of these complications which preferably are evaluated by CRR.

Distribution of indications for revision (%) 1993–2002



Primary TKA implants for OA in the regions during 1993–2002

Stockholm + Gotland Implants for primary TKA in OA 1993–2002

	number	Procent
PFC Sigma	2,658	36.3
AGC	2,004	27.4
Duracon	895	12.2
KinemaxPlus	713	9.7
PFC	396	5.4
F/S MIII	294	4.0
NexGen	238	3.2
АМК	62	0.8
Genesis	14	0.2
Rotaglide	10	0.1
LCS	10	0.1
Free-Sam	8	0.1
Other	22	0.3
Total	7,324	100

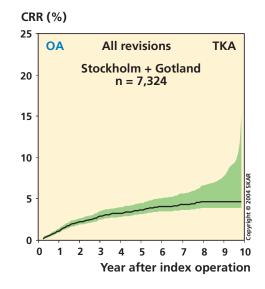
Uppsala-Örebro Implants for primary TKA in OA 1993–2002

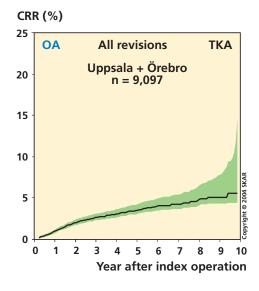
	number	percent
F/S MIII	2,656	29.2
AGC	2,426	26.7
KinemaxPlus	1,968	21.6
NexGen	692	7.6
MillerGalante2	365	4.0
АМК	305	3.4
Scan	288	3.2
PFC Sigma	198	2.2
PFC	77	0.8
MillerGalante unspec	35	0.4
Natural Knee II	10	0.1
Other	77	0.8
Total	9,097	100

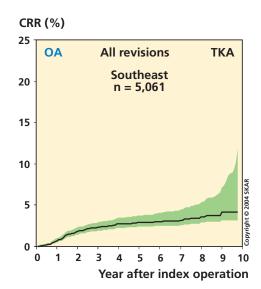
Southeast

Implants fo	r primary	TKA in	ΟΑ	1993-2002
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	number	percent
AGC	2,070	40.9
NexGen	962	19.0
PFC Sigma	718	14.2
PFC	433	8.6
MillerGalante2	391	7.7
Duracon	339	6.7
MillerGalante unspec	61	1.2
Scan	13	0.3
F/S MIII	10	0.2
PCA-Mod	10	0.2
Other	54	1.1
Total	5,061	100







South		
Implants for primary	TKA in OA	1993–2002

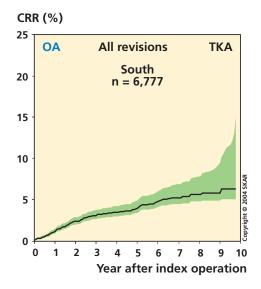
	number	percent
Duracon	1,878	27.7
AGC	1,482	21.9
PFC Sigma	1,156	17.1
Scan	1,087	16.0
PFC	740	10.9
Osteonics	63	0.9
Axiom	62	0.9
F/S MIII	60	0.9
Synatomic	52	0.8
Rotaglide	47	0.7
LCS	47	0.7
Nuffield	37	0.5
АМК	13	0.2
Other	53	0.8
Total	6,777	100

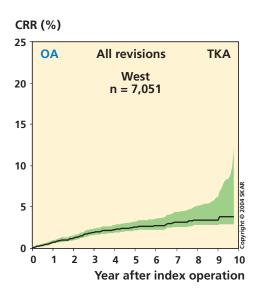
West Implants for primary TKA in OA 1993–2002

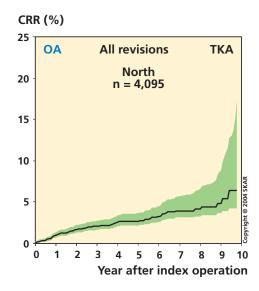
	number	percent
AGC	3,212	45.6
F/S MIII	1,906	27.0
Duracon	635	9.0
Scan	420	6.0
PFC Sigma	317	4.5
NexGen	179	2.5
AMK	113	1.6
Free-Sam	74	1.0
Axiom	72	1.0
MillerGalante2	42	0.6
PFC	33	0.5
MillerGalante unspec	18	0.3
Other	30	0.4
Total	7,051	100

North		
Implants for primary	TKA in OA	1993–2002

	number	percent
AGC	1,609	39.3
Duracon	523	12.8
PFC Sigma	469	11.5
PFC	412	10.1
LCS	345	8.4
Profix	231	5.6
Scan	133	3.2
F/S MIII	112	2.7
MillerGalante2	89	2.2
MillerGalante unspec	47	1.1
АМК	42	1.0
KinemaxPlus	31	0.8
Other	52	1.3
Total	4,095	100







Primary UKA implants for OA in the regions during 1993–2002

Stockholm + Gotland Implants for primary UKA in OA 1993–2002

	number	percent
MillerGalante-Uni	702	48.8
Brigham	436	30.3
Link-Uni	84	5.8
Oxford-Uni	81	5.6
Genesis	57	4.0
Allegretto	31	2.2
Repicci (AARS)	20	1.4
PFC-Uni+S	13	0.9
Duracon-Uni	12	0.8
Other	4	0.3
Total	1,440	100

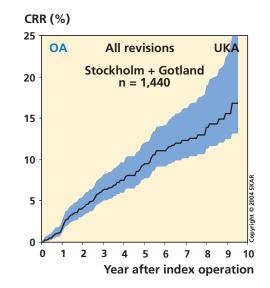
Uppsala-Örebro Implants for primary UKA in OA 1993–2002

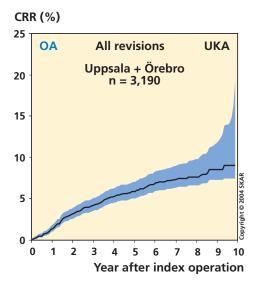
	number	percent
Link-Uni	1,853	58.1
Marmor	505	15.8
PFC-Uni+S	285	8.9
St.Georg	199	6.2
Genesis	120	3.8
Duracon-Uni	95	3.0
MillerGalante-Uni	46	1.4
Brigham	31	1.0
Allegretto	24	0.8
Oxford-Uni	21	0.7
Other	11	0.3
Total	3,190	100

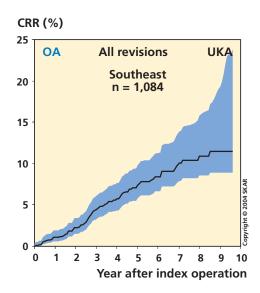
Southeast

Implants	; for	primary	UKA	in OA	1993–2002
mpiante		princip	0.0.1		

	number	percent
Link-Uni	259	23.9
Marmor	204	18.8
Duracon-Uni	145	13.4
Genesis	134	12.4
Brigham	133	12.3
PFC-Uni+S	67	6.2
Allegretto	64	5.9
MillerGalante-Uni	59	5.4
Oxford-Uni	17	1.6
Other	2	0.2
Total	1,084	100

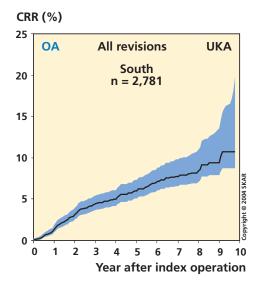






South		
Implants for primary	UKA in OA	1993–2002

	number	percent
Link-Uni	1,371	49.3
Marmor	315	11.3
Duracon-Uni	223	8.0
PFC-Uni+S	188	6.8
MillerGalante-Uni	156	5.6
Allegretto	118	4.2
Oxford-Uni	104	3.7
Repicci (AARS)	103	3.7
Brigham	87	3.1
Genesis	55	2.0
St.Georg	43	1.5
EIUS Uni	13	0.5
Other	5	0.2
Total	2,781	100

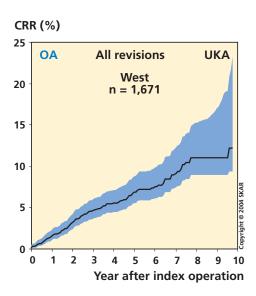


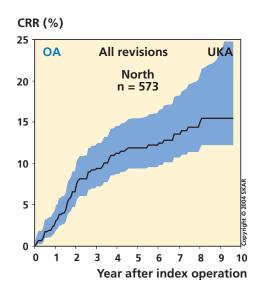
West				
Implants for primary	UKA	in OA	1993–2002	

	number	percent
MillerGalante-Uni	699	41.8
Link-Uni	404	24.2
Oxford-Uni	317	19.0
Duracon-Uni	109	6.5
Repicci (AARS)	75	4.5
Marmor	37	2.2
Allegretto	18	1.1
St.Georg	12	0.7
Other	0	0.0
Total	1,671	100

North	
Implants for primary UKA in OA 1993–2002	

	number	percent
Link-Uni	387	67.5
MillerGalante-Uni	63	11.0
St.Georg	36	6.3
Oxford-Uni	32	5.6
PFC-Uni+S	27	4.7
Duracon-Uni	15	2.6
Marmor	13	2.3
Other	0	0.0
Total	573	100

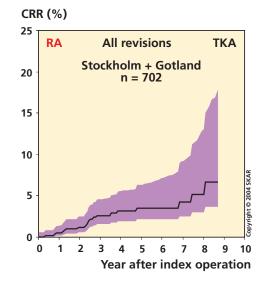




Primary TKA implants for RA in the regions during 1993–2002

Stockholm +	Gotland		
Implants for	primary TKA	in RA	1993–2002

	number	percent		
AGC	241	34.3		
PFC Sigma	211	30.1 15.8 8.7		
Duracon	111			
KinemaxPlus	61			
PFC	42	6.0		
F/S MIII	20	2.8		
Other	16	2.3		
Total	702	100		

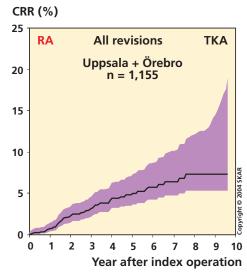


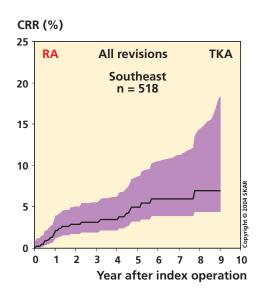
Uppsala-Örebro Implants for primary TKA in RA 1993–2002

	number	percent		
F/S MIII	367	31.8		
AGC	254	22.0		
KinemaxPlus	242	21.0		
Scan	116	10.0		
MillerGalante2	63	5.5		
NexGen	45	3.9		
MillerGalante unspec	16	1.4		
AMK	16	1.4		
PFC	22	1.9		
Other	14	1.2		
Total	1,155	100		

Southeast Implants for primary TKA in RA 1993–2002

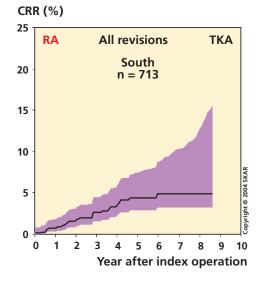
	number	percent
AGC	199	38.4
NexGen	99	19.1
PFC	75	14.5
PFC Sigma	55	10.6
MillerGalante2	37	7.1
Duracon	31	6.0
MillerGalante unspec	9	1.7
Other	13	2.5
Total	518	100





	Antal	Procent
Scan	272	38.1
PFC	117	16.4
AGC	116	16.3
Duracon	85	11.9
PFC Sigma	81	11.4
Synatomic	19	2.7
Other	23	3.2
Total	713	100

South Implants for primary TKA in RA 1993–2002



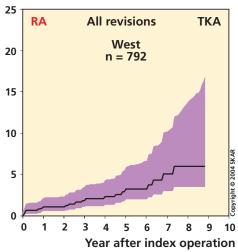
West Implants for primary TKA in RA 1993–2002

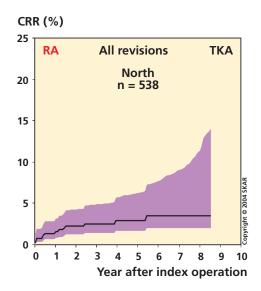
	Antal	Procent		
AGC	300	37.9		
F/S MIII	292	36.9		
Scan	90	11.4		
Duracon	39	4.9		
АМК	21	2.7		
Free-Sam	19	2.4		
PFC Sigma	11	1.4		
Other	20	2.5		
Total	792	100		

North Implants for primary TKA in RA 1993–2002

	Antal	Procent
AGC	132	24.5
Duracon	109	20.3
PFC	83	15.4
PFC Sigma	71	13.2
Profix	38	7.1
LCS	32	5.9
MillerGalante2	29	5.4
Scan	10	1.9
Other	34	6.3
Total	538	100







Implants used for primary arthroplasty in 1993–2002

The registry typically uses the latest 10-year period available for analysis when presenting the results of relatively modern implant types with a reasonable long-term follow-up.

It has to be observed that the implant definition MillerGalante unspec is a mix of older and newer improved variants of the implant where the reports to the register did not include an exact specification regarding the model brand.

The risk of becoming revised is one of the many ways of how the result of different implants may be measured. Although not accounted for here, the type of the revision should also be considered, e.g. if use of patellar button is deliberately avoided at primary operation, with readiness for a secondary resurfacing of the patella when needed, this will increase the risk of revision. Therefore, we have decided to also account for OA/TKA separately when used with and without a patellar button (see next page). On the following pages are CRR curves for TKA and UKA implants used for OA. As the table below shows, there were no significant differences for the various models when used in RA why we produced no curves.

In OA/TKA, the increased number of operations has led to previous small differences having become significant. Thus, some popular implants have now a lower risk of revision than AGC, the standard reference.

Presently we cannot definitely evaluate the effect of minimally invasive surgery (MIS) on the results of UKA. What we so far have found is that the UKA implants are differently influenced when used in MIS. The analyses are complicated by the fact that since the registration of MIS began in 1999 users of some implants e.g. the Oxford and Miller-Galante very quickly adapted MIS. Link UKA are still used with mixed type of incisions and here we initially see inferior results when using MIS.

95% confidence intervals for the risk ratio (RR) with respect to revision. AGC is the reference in TKA and Link-Uni in UKA. The Cox regression adjusts for differences in gender, age and year of operation.

	O n	A / TKA 95% Cl		R n	A / TKA 95% Cl		C n	A / UKA 95% Cl
AGC	12,803	ref.	AGC	1,242	ref.	Link-Uni	4,356	ref.
PFC-Sigma	5,514	0.71-1.23	PFC-Sigma	438	0.15-1.26	MillerGalante	1,723	0.96-1.63
PFC	2,090	1.04-1.63	PFC	330	0.40-1.33	Marmor/Richards	1,076	1.13–1.79
F/S MIII	5,037	0.53-0.85	F/S MIII	684	0.44-1.20	Brigham	687	0.89–1.60
Duracon	4,271	0.68-1.08	Duracon	374	0.34-1.33	Duracon	599	1.03-1.89
Kinemax	2,722	0.87–1.39	Kinemax	306	0.72-2.06	PFC	580	1.46-2.55
NexGen	2,075	0.21-0.68	NexGen	156	0.15-2.55	Oxford	572	0.90-1.80
Scan	1,942	1.00-1.64	Scan	489	0.39-1.19	Genesis	366	0.65–1.86
MillerGalante II	888	0.91–1.73	MillerGalante II	130	0.37-2.00	St. Georg	290	0.46-1.24
MillerG unspec	162	0.86-2.76	MillerG unspec	32		Allegretto	255	0.85-2.05
АМК .	542	0.95-2.17	АМК	47		Repicci (AARS)	198	1.31-2.92
LCS	404	0.80-2.17	LCS	35		Other	31	
Profix	231	0.09-1.43	Profix	38				
Axiom	138	0.87-3.54	Axiom	1				
Other	580	0.67–1.62	Other	115	0.20-2.09			
Gender (ref. mei	Gender (ref. men) 0.81–1.05		Gender (ref. men)		0.50-1.02	Gender (ref. men)		0.89–1.21
Age (per year)		0.95-0.96	Age (per year)		0.99-1.02	Age (per year)		0.95-0.96
Year of op. (per	year)	0.94–1.00	Year of op. (per year)		0.90–1.05	Year of op. (per yea	ar)	0.94–1.02

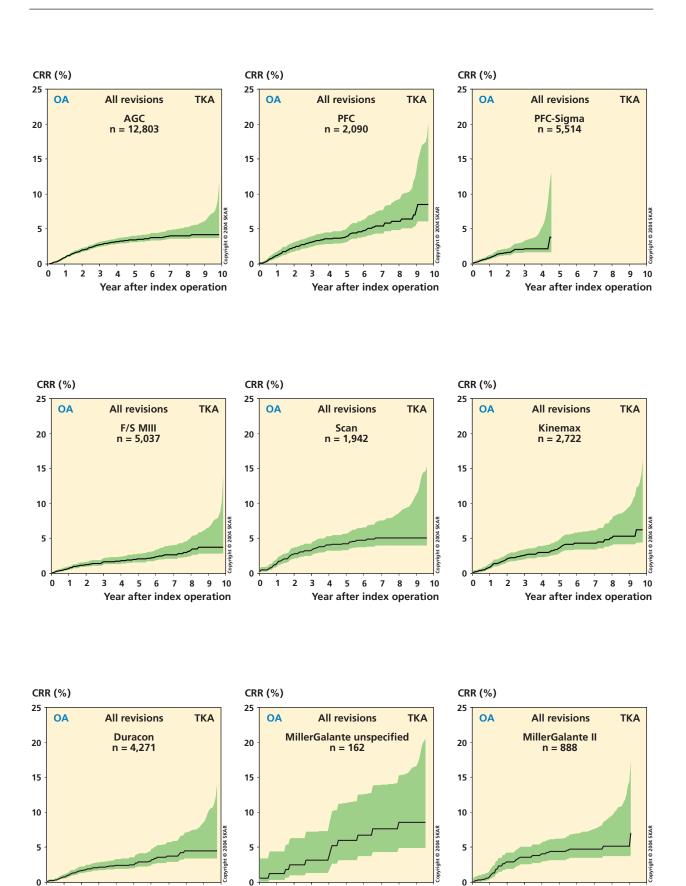
Significant difference with higher risk ratio Significant difference with lower risk ratio

> Compared to the 2002 report, Synatomic, F/S unspec and PCA have disappeared. No new implants have reached sufficient numbers to become analyzed.

95% confidence intervals for the RR (risk ratio) of becoming revised. TKA, with and without patellar button are analyzed separately. The Cox regression adjusts for differences in gender, age and year of operation. The rightmost table uses F/S MIII (most commonly used with a patellar button) as a reference.

Without patellar button	O n	0A / TKA 95% Cl		With patellar button	O/ n	A / TKA 95% Cl		With patellar button	O n	A / TKA 95% Cl
AGC	10 435	ref.		AGC	2 365	ref.		F/S MIII	4241	ref.
PFC-Sigma	4 938	0,69–1,24	F	PFC-Sigma	576	0,48–2,22		AGC	2365	0,80–1,63
PFC	1 898	0,93–1,51	F	PFC	192	0,97–4,00		PFC-Sigma	576	0,55–2,48
F/S MIII	796	0,48–1,40	F	F/S MIII	4 241	0,62–1,25		PFC	192	1,12–4,50
Duracon	3 937	0,60–0,99		Duracon	327	0,87–3,20		Duracon	327	1,01–3,60
Kinemax	2 155	0,85–1,41	ŀ	Kinemax	566	0,62–2,02		Kinemax	566	0,72–2,27
NexGen	2 028	0,21–0,68	ſ	NexGen	47			NexGen	47	
Scan	1 850	0,88–1,48	5	Scan	92	1,36–6,58		Scan	92	1,56–7,45
MillerGalante II	820	0,82–1,63	ſ	MillerGalante II	68	0,66–5,13		MillerGalante II	68	0,76–5,83
MillerG unspec	143	0,60–2,29	ſ	MillerG unspec	19			MillerG unspec	19	
AMK	478	0,76–1,94	1	АМК	63	1,27–7,99		АМК	63	1,47–9,03
LCS	404	0,73–2,01	L	LCS	0			LCS	0	
Profix	196	0,03–1,44	F	Profix	35			Profix	35	
Axiom	129	0,87–3,53	1	Axiom	9			Axiom	9	
Other	39		0	Other	183	0,68–3,32		Other	183	0,78–3,76
Gender (ref. men) 0,83–1,11		c	Gender (ref. men)		0,60–1,08	Gender (ref. men)			0,60–1,08	
Age (per year)		0,95–0,96	1	Age (per year)		0,96-0,99		Age (per year)		0,96-0,99
Year of op. (per y			0,94–1,07		Year of op. (per ye	ear)	0,94–1,07			
-										

Significant difference with higher risk ratio Significant difference with lower risk ratio



1 2

3 4 5 6 7 8 9 10

Year after index operation

0 1 2 3 4 5 6 7 8 9 10

0

CRR for commonly used TKA implants in OA during 1993–2002

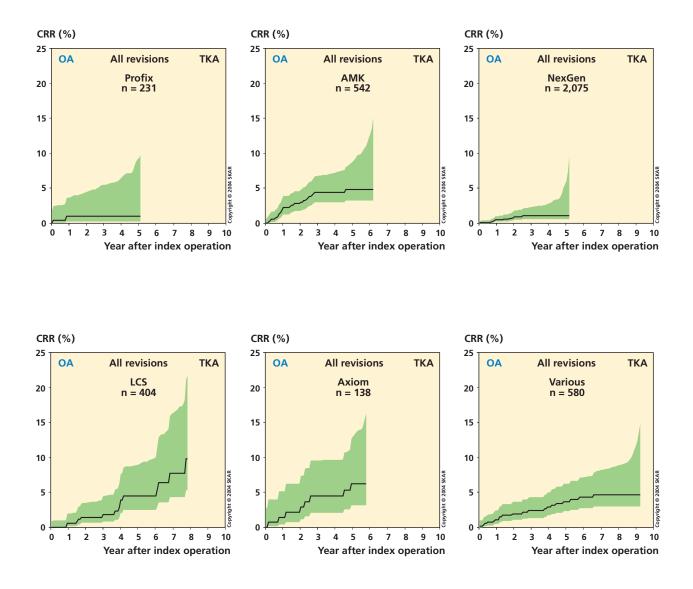


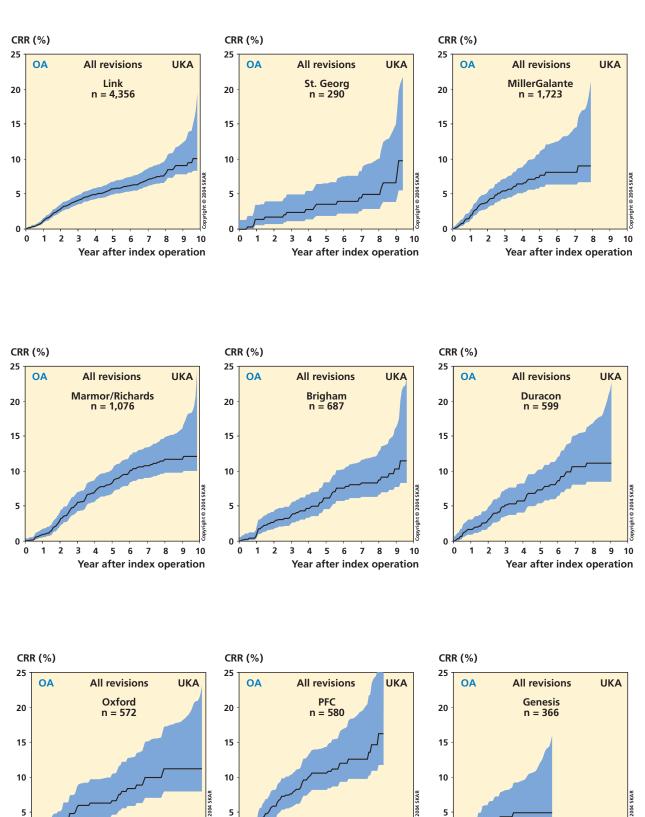
3 4 5 6 7 8 9 10 Year after index operation

2

0 1

Year after index operation





0

Year after index operation

0 1 2 3 4 5 6 7 8 9 10

0

0 1 2 3 4 5 6 7 8 9 10

CRR for commonly used UKA implants in OA during 1993–2002



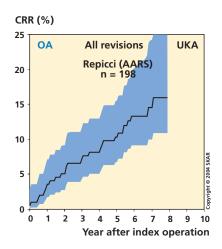
2 3 4 5 6 7 8 9 10

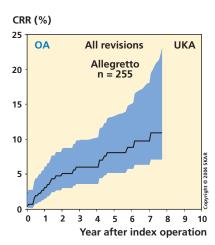
0

Year after index operation

0 1

Year after index operation





For more information regarding publications, doctoral theses and prior annual reports, please see our webpage: www.ort.lu.se/knee/