

# Early failures among 7,174 primary total knee replacements

## A follow-up study from the Norwegian Arthroplasty Register 1994–2000

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**ABSTRACT** – We studied primary total knee replacements (TKRs), reported to the Norwegian Arthroplasty Register, operated on between 1994 and 2000. A Cox multiple regression model was used to evaluate differences in survival among the prosthesis brands, their types of fixation, and whether or not the patella was resurfaced.

In Norway in 1999, the incidence of knee prosthesis operations was 35 per 100,000 inhabitants. Cement was used as fixation in 87% of the knees, 10% were hybrid and 2% uncemented implants. Bicompartamental (not resurfaced patella) prostheses were used in 65% of the knees. With all revisions as endpoint, no statistically significant differences in the 5-year survival were found among the cemented tricompartmental prostheses brands: AGC 97% (n 279), Duracon 99% (n 101), Genesis I 95% (n 654), Kinemax 98% (n 213) and Tricon 96% (n 454). The bicompartamental LCS prostheses had a 5-year survival of 97% (n 476). The type of meniscal bearing in LCS knees had no effect on survival.

Survival with revision for all causes as endpoint showed no differences among types of fixation, or bi- or tricompartmental prostheses. Pain alone was the commonest reason for revision of cemented bicompartamental prostheses. The risk of revision because of pain was 5.7 times higher ( $p < 0.001$ ) in cemented bicompartamental prostheses than cemented tricompartmental ones, but the revisions mainly involved insertion of a patellar component. In tricompartmental prostheses the risk of revision because of infection was 2.5 times higher than in bicompartamental ones ( $p = 0.03$ ). Young age ( $< 60$ ) and the sequelae after a fracture increased the risk of revision.

The 5-year survival of the 6 most used cemented tricompartmental knee prostheses brands varied between 95% and 99%, but the differences were not statistically significant. There were more revisions because of pain in bicompartamental than in tricompartmental knees. In tricompartmental knees, however, there were more revisions because of an infection. The relatively few patients with uncemented and hybrid implants showed no improvements in results compared to cemented knee prostheses.

The Norwegian Orthopaedic Association started the National Register for total hip replacements in 1987 (Havelin et al. 1993). In January 1994, the Register was expanded to include all artificial joint replacements (Havelin et al. 2000) and its aim was to detect inferior implants, cements and techniques as early as possible.

Knee joint replacement with total condylar knee prostheses fixed with methyl methacrylate bone cement has been established as a successful procedure (Insall et al. 1985, Ranawat et al. 1993, Ritter et al. 1995). Some new designs, which were introduced on the market without clinical documentation, have performed poorly (Bauer 1992). Only a few large comparative studies of knee prostheses have been done (Knutson et al. 1986, 1994, Rand and Ilstrup 1991, Robertsson 2000), and more are needed to help surgeons choose an implant (Liow and Murray 1997).

The fixation of primary total knee replacements (TKRs), whether the patella should be resurfaced and the use of rotating tibial inserts have been extensively discussed, but no general agreement has been reached (Bourne et al. 1995, Vince 1996, Whiteside 1996, Callaghan et al. 2000a). In the present paper, these questions are addressed on the basis of data from all TKRs performed in Norway during the first 6 years of the knee register. We present the results for 7,174 TKRs from 59 Norwegian hospitals.

### Patients and methods

After each operation, a standard form (Figure 1) is filled in by the surgeon and sent to the Register. The reporting is similar to that for hip replacements (Havelin 1999). Stickers with catalogue numbers are provided by the manufacturers along with the implants, and attached to the form by the operating surgeon. Femoral, tibial metal base, tibial polyethylene insert and patellar components are registered separately, according to the catalogue number.

The Norwegian Arthroplasty Register compares their reports with the Norwegian Patient Register (NPR)—i.e., the official discharge register located at SINTEF-Unimed in Trondheim, Norway. In the years 1995–1997, the Arthroplasty Register received 1% more reports on knee prostheses than the NPR. The latest survey showed that about 95% of the knee replacements at all 59 hospitals operating on knee prostheses in Norway were reported to the Norwegian Arthroplasty Register (Havelin et al. 2000).

The types of primary total knee prostheses reported were: AGC (Anatomical Graduated Components, Biomet Merck); Duracon (Howmedica); Genesis I (Smith and Nephew); Interax (Howmedica); Kinemax (Howmedica); LCS (Low Contact Stress, DePuy); NexGen (Zimmer); Profix (Smith and Nephew) and Tricon C, II and M (Smith and Nephew). Only the prostheses brands with more than 250 reported knees and a median follow-up of more than 1 year are presented in the survival analyses comparing prosthesis brands.

Information on revisions, defined as a surgical removal or exchange of a part or of the whole implant, or as an insertion of a patellar component,

was linked to the data on the primary operation using the unique identification number assigned to each inhabitant of Norway. For primary TKRs performed from January 1994 to the first of May 2000, we compared the time until revision for each type of prosthesis brand used. Separate analyses were done when the insertion of a patellar component was not counted as a revision. We also separately analyzed the type of fixation (cemented or not) and whether the prostheses were tricompartmental (patella resurfaced) or bicompartmental (patella not resurfaced). The surgeon could report one or more causes of failure leading to revision (Figure 1). Among the causes were aseptic loosening of the femur, tibia or patella component, dislocation of the patella, instability, malalignment, deep infection, peri-prosthetic fracture, pain, defect polyethylene insert, etc. The various causes of failure leading to revision were compared in cemented bi- and tricompartmental prostheses. When seen in combination with any other cause, infection was considered to be the main cause of revision. As only three operations with all-polyethylene tibial components were registered during the study, this type of component could not be compared to the modular tibial component.

### Statistics

Prosthesis survival was calculated with the Kaplan-Meier method. The follow-up period was 0–6.5 years. Since only a few prostheses were at risk after 5 years of follow-up, survival results were estimated at 5 years. If the number of prostheses at risk was less than 40 at 5 years, the survival percentage was not given. The median follow-up was calculated with the reverse Kaplan-Meier method (Schemper and Smith 1996). Patients who died or emigrated during the follow-up were selected from files provided by Statistics Norway, and the follow-up time for the prostheses in these patients were censored at the date of death or emigration. A Cox multiple regression model was used to study relative risks (incidence rate ratios) among the prostheses brands and to adjust for potential confounding for age (< 60, 60–70, > 70 years), gender, diagnosis (primary gonarthrosis, rheumatoid arthritis, sequelae after fracture, sequelae after ligament instability, sequelae after meniscal injury, and others) and use of systemic antibiotic prophylaxis.

Figure 1. English translation of the form used for reporting arthroplasties in knees and other joints.

THE NORWEGIAN ARTHROPLASTY REGISTER KNEES AND OTHER JOINTS (than hips)	
Patient ID and date of birth:.....	Hospital:.....
<b>Patient's weight:.....</b> <b>Localization:</b> 1 Knee                      5 Elbow 2 Ankle                     6 Wrist 3 Toe Joints:..... 7 Finger joints:..... 4 Shoulder                 8 Others:.....	<b>KNEE</b> <b>Prosthesis type:</b> 1 Tricompartmental.....2 Bicompartamental..... 3 Unicondylar.....4 Patellofemoral..... <b>Femoral component:</b> Name/size:..... Catalogue number:..... Stem/Stabilized/Wedge:..... 1 Cement with antibiotic. Name: ..... 2 Cement without antibiotic. Name: ..... 3 Uncemented <b>Tibial component (metal):</b> Name/size: ..... Catalogue number: ..... Stem/Stabilized/Wedge:..... 1 Cement with antibiotic. Name: ..... 2 Cement without antibiotic. Name: ..... 3 Uncemented <b>Tibial component (polyethylene):</b> Name/size:..... Catalogue number:..... Thickness:.....mm Stabilized:..... <b>Patella component:</b> Name/type: ..... Catalogue number:..... Metal-back 0 No 1 Yes 1 Cement with antibiotic. Name: ..... 2 Cement without antibiotic. Name: ..... 3 Uncemented <b>Cruciate ligaments</b> 1 Anterior, intact before operation 0 no 1 yes 2 Anterior, intact after operation 0 no 1 yes 3 Posterior, intact before operation 0 no 1 yes 4 Posterior, intact after operation 0 no 1 yes
<b>1 Right                      2 Left</b>  <b>Previous operation in index joint:</b> 0 No                         4 Arthodesis 1 Osteosynthesis        5 Synovectomy 2 Osteotomy              6 Other:..... 3 Prosthesis.Type..... Year.....  <b>Date of operation: .....</b>  <b>Index operation is:</b> 1 Primary op. 2 Revision  <b>Diagnosis (primary operation):</b> 1 Idiopathic arthrosis 2 Rheumatoid arthritis 3 Sequelae after fracture 4 Ankylosing spondylitis 5 Sequelae, ligament tear 6 Sequelae, meniscal tear 7 Acute fracture 8 Sequela, infection 9 Other .....  <b>Reasons for revision (one or more):</b> 1 Loose prox. comp.    7 Mal-alignment 2 Loose distal comp.   8 Deep infection 3 Loose patella comp.   9 Fracture 4 Dislocated patella   10 Pain 5 Dislocation            11 Defect polyethylene..... 6 Instability             12 Other.....  <b>Type of revision (one or more):</b> 1 Change of distal component 2 Change of proximal component 3 Change of all components 4 Change of patella component 5 Change of polyethylene:..... 6 Removal. Components:..... 7 Insert of patella component 8 Other: .....  <b>Structural bone transplant:</b> 0 No 1 Autograft 2 Allograft 3 Bone impaction prox. 4 Bone impaction distal 5 Other:.....  <b>Systemic Antibiotic prophylaxis:</b> 0 No 1 Yes: Type.....Combinations..... Dosage.....Duration, days.....  <b>Duration of operation: .....</b>  <b>Peroperative complication:</b> 0 No 1 Yes. Type:.....	<b>OTHER JOINTS:</b> <b>Prosthesis type:</b> 1 Total 2 Hemi 3 One-component prosthesis <b>Proximal component:</b> Name/size: ..... Catalogue number: ..... 1 Cement with antibiotic. Name: ..... 2 Cement without antibiotic. Name: ..... 3 Uncemented  <b>Distal component:</b> Name/size: ..... Catalogue number: ..... 1 Cement with antibiotic. Name: ..... 2 Cement without antibiotic. Name: ..... 3 Uncemented  <b>Intermediate component (e.g. caput humeri):</b> Name/size: ..... Catalogue number: .....  <b>Surgeon (who has filled in the form):</b> ..... (Surgeon's name is not registered)

laxis (yes or no). Separate analyses in the age group less than 60 years were also done. To make the material more homogeneous when we compared the prostheses brands, prostheses with posterior cruciate ligament sacrificing design and constrained condylar prostheses were excluded due to the small number of these designs (116 prostheses). Separate analyses with additional adjustment for a previous operation without a prosthesis in the same knee (yes or no) and intact posterior cruciate ligament after operation (yes or no) were done without changing the results. Only knees cemented with Palacos with or without gentamicin (Schering Plough) were included in the relative risk calculations among the prostheses brands (94% of the knees).

Estimates from Cox analyses, with the type of prosthesis as the stratification factor, were used to construct adjusted survival curves at mean values of the risk factors. The statistical analyses were done using the software SPSS (SPSS Inc. 1999) and S-PLUS (Statistical Sciences Inc. 1995).

## Results

### *Number of knee prosthesis operations performed in Norway*

During the study period, 7,174 primary total knee replacements were reported to the Norwegian Arthroplasty Register (Table 1). The number of knee prostheses operations has increased between 1994 and 1999 (Figure 2) in Norway from 23 per 100,000 inhabitants to 35 per 100,000 in 1999.

The mean age of all the patients was 70 years, and 74% were women. Uncemented prostheses were used more often in younger patients than cemented and hybrid prostheses (Table 1). Primary gonarthrosis was the diagnosis in 76% of the primary TKRs and rheumatoid arthritis in 15% (Table 2).

**Table 1. Number, age and gender distribution of the various types of primary total knee replacements (TKR) reported to the Norwegian Arthroplasty Register from January 1994 to May 2000**

	Number (% of total)	Mean age (range)	< 60 years %	Men %
<b>Cemented</b>				
Tricompartmental <sup>a</sup>	2209 (31)	70 (17–92)	13	26
Bicompartmental <sup>b</sup>	4030 (56)	71 (21–93)	10	25
<b>Hybrid <sup>c</sup></b>				
Tricompartmental	211 (3.0)	72 (32–92)	8	21
Bicompartmental	528 (7.4)	70 (30–91)	13	25
<b>Uncemented</b>				
Tricompartmental	64 (0.9)	61 (34–86)	39	39
Bicompartmental	95 (1.3)	65 (28–88)	32	27
Incomplete information or other combinations	37 (0.5)	–	–	–
<b>Total</b>	<b>7174</b>	<b>70 (17–93)</b>	<b>12</b>	<b>26</b>

<sup>a</sup> Tricompartmental prostheses are TKRs with a patellar component inserted (patellar resurfaced).

<sup>b</sup> Bicompartmental prostheses are TKRs without a patellar component (not resurfaced).

<sup>c</sup> Hybrid prostheses are TKRs with an uncemented femoral component and a cemented tibial component.

TKRs constituted nearly 92% of the primary knee prostheses in Norway. 8% were unicompartmental prostheses, 0.2% patellofemoral and 0.3% hinged prostheses. Bicompartmental prostheses were used in 65% of the TKRs (Tables 1 and 3), and bicompartmental cemented and bicompartmental hybrid prostheses increased throughout the study period, while uncemented implants decreased (Figure 2). The number of hospitals mainly using bicompartmental knee prostheses and occasionally using tricompartmental prostheses only in selected cases increased during the study. 17 hospitals did not change their practice of using tri- or bicompartmental prostheses, 25 hospitals changed their practice and 17 hospitals did not operate throughout the whole study period. Cement was used as fixation in 87% of the knees, 10% were hybrid and 2% uncemented. Of the patellar components, 91% were cemented (Table 3). Cement containing antibiotic was used in 93% of the cemented TKRs, and 94% of the cemented TKRs had been inserted with plain Palacos cement or Palacos with gentamicin cement. Systemic antibiotic prophylaxis had been used in 99% of the operations.

The two most commonly used prostheses in Norway were the Genesis I prosthesis with 36% of the market (2,583) and the Tricon prosthesis with

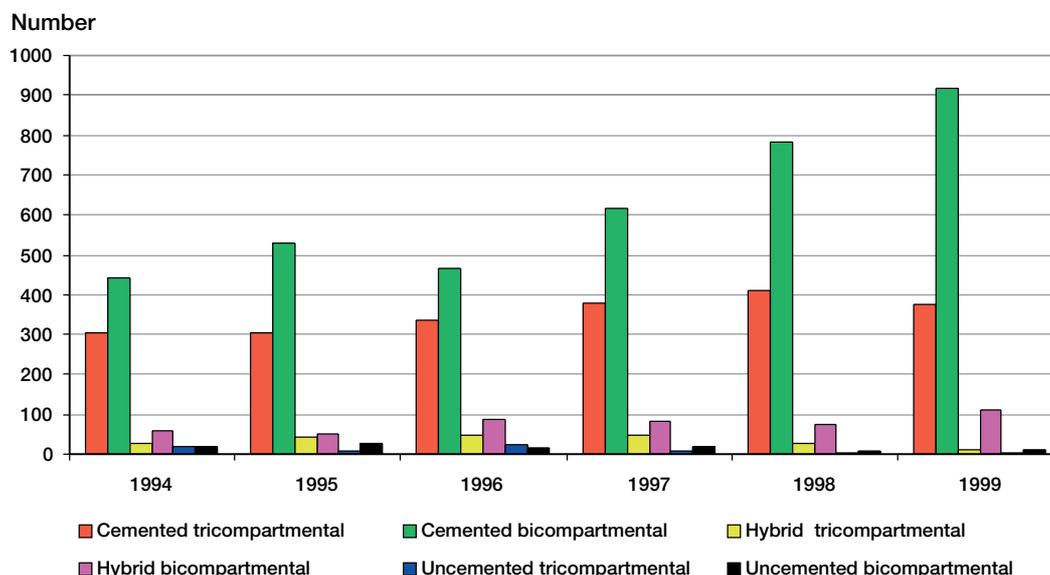


Figure 2. Number of various types of primary total knee replacements (TKRs) reported to the Norwegian Arthroplasty Register from January 1994 to December 1999.

Table 2. Diagnosis in 7174 primary total knee replacements (TKR) reported to the Norwegian Arthroplasty Register from January 1994 to May 2000

Diagnosis	Percent <sup>a</sup>
Primary gonarthrosis (OA)	76
Rheumatoid arthritis (RA)	15
Fracture sequelae	4.1
Meniscal sequelae	3.4
Osteochondritis	0.4
Osteonecrosis	0.2
Ankylosing spondylitis	0.5
Ligament injury sequelae	1.4
Infection sequelae	0.4
Psoriatic arthritis	0.7
Hemophilic sequelae	0.4
Malignant disease	0.1
Acute fracture	0.2
Others	1.7

<sup>a</sup> More than one diagnosis could be reported

20% of the market (1,416) (Table 3). The AGC, Duracon, Genesis I, Kinemax and LCS prostheses were used during the entire study. The use of Genesis I and LCS prostheses increased during the study, while that of the Tricon prostheses decreased. During the last 2 years, the Profix, Nex Gen and the Interax prostheses have been used more. Only the LCS and Interax prostheses have been used with rotating tibial inserts (Table 3). Of the LCS

knees, 67% had one rotating platform and 33% two meniscal bearings (Table 3). The LCS prosthesis has a metal-backed patellar component that can either be cemented or uncemented. The other prostheses had an all-polyethylene patellar component which was cemented, with the exception of the Duracon and Tricon prostheses where an optional metal-backed uncemented patellar component could be used. A previous operation without a prosthesis had been done in 26% of the knees and only small differences were found among the various brands of prostheses as regards previous operations (Table 3). The number of hospitals using the various types of prostheses varied from 34 hospitals that had used the Tricon prosthesis to 2 hospitals using the Interax prosthesis (Table 3). Intact posterior cruciate ligaments after the operation were reported in 87% of the cases. Cruciate-retaining prostheses were used in 98.4% of cases (Table 3). Of the tibial inserts, 91.5% were between 8 and 12 mm thick, the remainder were more than 12 mm thick.

#### Survival results

**Prosthesis brand.** We found no statistically significant difference in the 5-year survival among the brands of cemented knee prostheses (Table 4, Figures 3 and 4). This applied to the bicompartmental

Table 3. All primary total knee replacements (TKRs) reported to the Norwegian Arthroplasty Register from January 1994 to May 2000

A	B	C	D	E	F	G	H	I	J	K
AGC	1012	29	98	0.3	0	0	23	6	2.6	26
Duracon	448	29	86	28	2.9	0	21	6	1.6	9
Genesis I	2583	27	98	7.2	0.2	0	26	9	2.3	29
Interax	23	0		87	0	100	35	4	26	2
Kinemax	359	73	100	0	0	0	18	3	2.2	12
LCS	982	36 <sup>a</sup>	82	5.9	6.2	100 <sup>b</sup>	31	40	0.5	16
Nex Gen	99	94	100	0	0	0	23	19	2.0	5
Prefix	250	4	100	50	2	0	36	4	1.2	16
Tricon <sup>c</sup>	1416	45	81	16	4.7		28	14	0	34
Others	2									
Total	7174	35	91	10.3	2.2	14	26	13	1.6	59

A Name of prosthesis

B Number

C Tricompartmental (%)

D Cemented patella (%)

E Hybrid (%), i.e., uncemented porous-coated femoral components and cemented tibial components

F Uncemented tibia and femur (%)

G Rotating platform or meniscal bearing (%)

H Previous operation (%)

I Posterior cruciate ligament not intact after operation (%)

J Number of posterior stabilized and constrained condylar prostheses (%)

K Number of hospitals that have used this prosthesis

<sup>a</sup> All LCS patellar components are metal-backed.

<sup>b</sup> 33% of the tibial inserts in LCS prostheses had two rotating meniscal bearings and 67% had one rotating platform.

<sup>c</sup> Tricon C or Tricon M femoral component used on the femoral side and Tricon II used on the tibial side.

(Figure 3) and tricompartmental prostheses (Figure 4), even when insertion of a patellar component was not counted as a revision in the bicompartmental prostheses (Table 4). Table 5 shows that there was no statistically significant difference between the two versions of tibial inserts in the LCS prostheses. There were no revisions for patellar loosening of the metal-backed patellar component in the LCS prostheses.

#### Type of fixation and patellar resurfacing (tricompartmental vs. bicompartmental)

213 revisions were performed (Table 6), 145 were bicompartmental prostheses, of which 84 were only an insertion of a patellar component. There was no statistically significant difference between the cemented, hybrid and uncemented prostheses in bi- and tricompartmental prostheses (Table 6, Figure 5). This was also true of patients younger than 60 years. The 5-year survival with all causes of revision as endpoint for cemented tricompartmental prostheses was 95.9% (95% CI: 94.7–97.0) and for cemented bicompartmental it was 93.8% (92.6–95.1) ( $p = 0.2$ ) (Table 6).

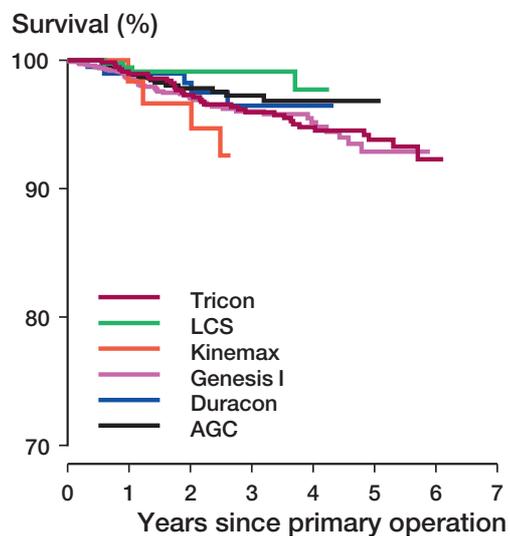


Figure 3. Cox-adjusted survival curves for cemented bicompartmental primary TKRs reported to the Norwegian Arthroplasty Register from January 1994 to May 2000. Adjustment was made for age, gender, diagnosis and antibiotic prophylaxis. Only prostheses fixed with Palacos cement (with or without gentamicin) were included. Posterior stabilized and constrained condylar prostheses were excluded from the analyses.

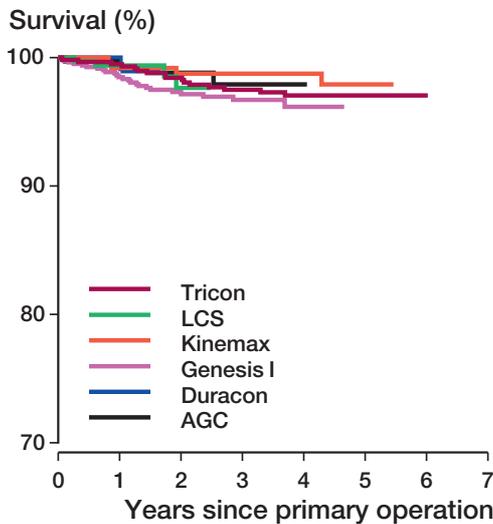


Figure 4. Cox-adjusted survival curves for cemented tri-compartmental primary TKRs reported to the Norwegian Arthroplasty Register from January 1994 to May 2000. Adjustment was made for age, gender, diagnosis and antibiotic prophylaxis. Only prostheses fixed with Palacos cement (with or without gentamicin) were included. Posterior stabilized and constrained condylar prostheses were excluded from the analyses.

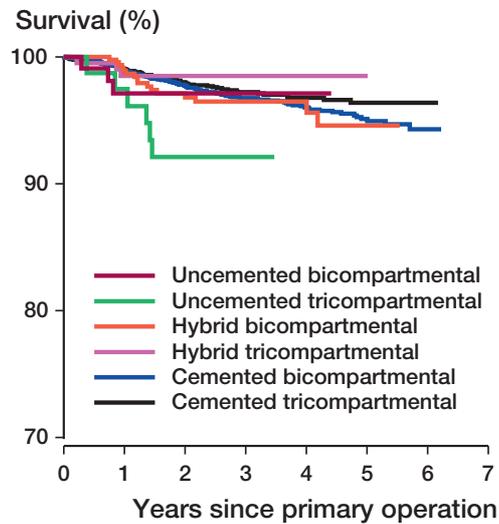


Figure 5. Cox adjusted survival curves for primary bi-compartmental and tri-compartmental TKRs reported to the Norwegian Arthroplasty Register from January 1994 to May 2000, by type of fixation. Adjustment was done for age, gender, diagnosis and antibiotic prophylaxis. Only prostheses fixed with Palacos cement (with and without gentamicin) were included. Posterior stabilized and constrained condylar prostheses were excluded from the analyses.

The main reason for revision of bi-compartmental cemented knee prostheses was pain. This accounted for a 5.7 times higher risk ( $p < 0.001$ , Table 7) of revision of bi- than of tri-compartmental prostheses for this reason. Of these revisions, 90% were insertion of a patellar component. With tri-compartmental prostheses, the risk of revision because of infection was 2.5 times higher than with bi-compartmental ones ( $p = 0.03$ ) (Table 7).

#### Age and diagnosis

There were statistically significant more revisions in the age group less than 60 years than in the older age groups. In the group with a diagnosis of sequelae after fracture, we found significantly more revisions for infection, instability and pain than for primary gonarthrosis (Table 7). We found no statistically significant difference between primary gonarthrosis and rheumatoid arthritis patients concerning the reason for revision and prosthesis survival.

## Discussion

### Number of knee prosthesis operations in Norway

The incidence of primary knee prosthesis surgery in Norway was 35 operations per 100,000 inhabitants in 1999, compared to Sweden's 63 operations per 100,000 inhabitants in 1996 (Robertsson et al. 2000b). 31% of the Norwegian population was 50 years or older in 1999 compared to 36% of the Swedish population in 2000 (Statistics Sweden and Statistics Norway). However, this difference in age distribution probably does not fully explain the nearly double incidence of knee prosthesis surgery in Sweden. The population of Norway is probably undertreated as regards knee prosthesis surgery. We should therefore expect an increase in the need for knee prosthesis operations not only because of an expected increase in the elderly population (Robertsson et al. 2000b).

### Age, gender and diagnosis

The average age of the patients was 70 years and the percentage of women 74%, which is higher than

Table 4. Cemented TKRs. Survival results reported for 6 knee prostheses brands. Kaplan–Meier (KM) estimated 5-year survival percentages and Cox<sup>a</sup> relative revision risk (RR), estimated with all causes of revision as endpoint

Prosthesis brand	Rev./ Total	MF <sup>b</sup> (year)	AR <sup>c</sup>	All revisions			Patella component insertion excluded		
				5-year KM survival (95% CI)	RR (95% CI) adjusted	P-value	5-year KM survival (95% CI) <sup>d</sup>	RR (95% CI) adjusted <sup>d</sup>	P-value
<b>Bicompartmental (not resurfaced)</b>									
AGC	16/687	2.4	224	96.5 (94.8–98.3)	1		98.5 (97.3–99.7)	1	
Duracon	6/188	2.4	– <sup>e</sup>	– <sup>e</sup>	1.2 (0.47–3.2)	0.7	–	1.5 (0.36–5.9)	0.6
Genesis I	54/1574	2.0	141	92.3 (89.5–95.0)	1.6 (0.90–2.9)	0.1	96.3 (94.4–98.3)	1.8 (0.74–4.5)	0.2
Kinemax	4/59	4.0	40	91.9 (84.2–99.6)	2.0 (0.67–6.2)	0.2	100	–	1.0
LCS	4/476	1.1	54	97.2 (93.5–100)	0.5 (0.17–1.6)	0.3	97.9 (94.3–100)	0.55 (0.11–2.8)	0.5
Tricon	32/571	4.6	244	93.7 (91.5–96.0)	1.6 (0.84–2.9)	0.2	98.3 (97.1–99.5)	1.1 (0.38–3.0)	0.9
<b>Tricompartmental (resurfaced)</b>									
AGC	4/279	1.9	87	97.4 (94.7–100)	1				
Duracon	1/101	1.5	68	98.6 (95.7–100)	0.72 (0.08–6.6)	0.8			
Genesis I	24/654	2.6	137	95.2 (93.0–97.3)	1.9 (0.64–5.6)	0.2			
Kinemax	4/213	4.3	99	97.5 (94.9–100)	0.83 (0.20–3.4)	0.8			
LCS	6/281	1.3	– <sup>f</sup>	– <sup>f</sup>	1.7 (0.47–6.3)	0.4			
Tricon	17/454	4.7	337	96.0 (94.2–97.9)	1.3 (0.43–4.1)	0.6			

<sup>a</sup> The Cox regression model included the brand of prosthesis, age (<60, 60–70, >70), gender, diagnosis and use of antibiotic prophylaxis. Only prostheses fixed with Palacos cement with or without gentamicin were included in the analyses. Posterior stabilized (PS) and constrained (CC) prostheses were excluded from the analyses. LCS prostheses with deep dish were also excluded.

<sup>b</sup> MF is median follow-up in years (yr).

<sup>c</sup> AR is number of prostheses at risk at last revision.

<sup>d</sup> Separate survival analyses where insertion of a patellar component was not counted as a revision.

<sup>e</sup> 96.2 (92.7–99.6) survival percentage at 2.6 years with 86 prostheses at risk.

<sup>f</sup> 96.8 (93.5–100) survival percentage at 1.9 years with 81 prostheses at risk.

Table 5. Cemented LCS knee prostheses. Cox<sup>a</sup> relative revision risk (RR), estimated with all causes of revision as endpoint

Type of cemented LCS primary knee prostheses	Revisions/ total operations	Median follow-up (yr)	RR (95% CI) adjusted	P-value
Tricompartmental with rotating platform	4/141	1.6	1	
with meniscal bearing	2/139	1.1	0.58 (0.10–3.3)	0.5
Bicompartmental with rotating platform	2/369	1.2	0.21 (0.03–1.2)	0.08
with meniscal bearing	2/105	0.9	0.54 (0.08–3.6)	0.5

<sup>a</sup> The adjustments of the Cox regression were done for age (< 60, 60–70, > 70), gender, diagnosis and use of antibiotic prophylaxis. Only Palacos cement with or without gentamicin was used in the analyses. Deep dish LCS prostheses were excluded.

#### Type of cement and antibiotic in cement

During the study period, 93% of the cemented knee prostheses inserted contained an antibiotic in the cement. The reasons for this were probably partly because of the good results reported for antibiotic-loaded cements in hip surgery (Havelin et al. 1995, Espehaug et al. 1997) and the problems with infections in knee arthroplasty in the past (Bengtson et al. 1986, Bengtson and Knutson 1991).

the 63% women reported in Sweden. The mean age in Sweden was about 72 years in 1993–1996. The percentage of primary gonarthrosis patients was the same as in Sweden (Robertsson 2000).

#### Type of prosthesis brand

We have shown that the results with the 6 most used cemented knee prosthesis brands in Norway were generally good and found no statistically significant differences between them during the

Table 6. Tricompartmental and bicompartmental knee prostheses by type of fixation. Kaplan–Meier (KM) estimated 5-year survival percentages and Cox<sup>a</sup> relative revision risk (RR), estimated with all causes of revision as endpoint

Type of fixation and type of primary knee prostheses	Revisions/total operations	Median follow-up (yr)	At risk at last revision	5-year KM survival (95% CI)	RR (95% CI) Adjusted	P-value
<b>Cemented</b>						
Tricompartmental	58/2165	2.6	399	95.9 (94.7–97.0)	1	
Bicompartmental	125/3968	2.2	509	93.8 (92.6–95.1)	1.3 (0.90–1.7)	0.2
<b>Hybrid</b>						
Tricompartmental	3/211	3.4	192	98.5 (96.8–100)	0.47 (0.15–1.5)	0.2
Bicompartmental	17/522	2.2	95	94.0 (90.7–97.3)	1.2 (0.70–2.2)	0.5
<b>Uncemented</b>						
Tricompartmental	7/63	3.7	50	88.3 (80.1–96.4) <sup>b</sup>	2.2 (0.91–5.3)	0.08
Bicompartmental	3/95	4.0	87	96.7 (93.1–100) <sup>c</sup>	0.93 (0.28–3.0)	0.9

<sup>a</sup> The adjustment in the Cox regression was done for age (< 60, 60–70, > 70), gender, type of prosthesis, type of cement, diagnosis and use of antibiotic prophylaxis. The posterior stabilized and constrained condylar prostheses were excluded. Adjustment for an intact posterior cruciate ligament after operation and previous operation had no effect on the RR.

<sup>b</sup> Last revision at 2.2 years.

<sup>c</sup> Last revision at 0.8 years.

Table 7. Reasons for revision of cemented TKRs. Cox multiple regression with adjustment for age, gender, diagnosis and type of prosthesis<sup>a</sup>

Type of prostheses	Number of revisions for each cause of revision									
	Loose femur <sup>b</sup>	Loose tibia	Loose patella	Infection <sup>c</sup>	Dislocation of patella	Instability <sup>d</sup>	Peri-prosth. fracture	Pain alone <sup>e</sup>	Defect tibial insert	Other causes
Tricompartmental (n 2165)	3	12	5	16	4	11	4	9	4	10
Bicompartmental (n 3968)	4	11	0	11	8	17	3	68	3	14
RR <sup>f</sup>	0.70	0.55	–	0.41	1.0	0.59	0.44	5.7	0.50	1.2
RR (lower limit) <sup>f</sup>	0.15	0.23	–	0.18	0.29	0.26	0.10	2.7	0.10	0.43
RR (upper limit) <sup>f</sup>	3.2	1.3	–	0.93	3.3	1.3	2.0	12	2.6	3.2
P-value	0.7	0.2	0.9	0.03	1	0.2	0.3	<0.001	0.4	0.8

<sup>a</sup> Prostheses inserted without giving systemic antibiotics, as well as posterior stabilized and constrained prostheses were excluded from the analysis. Only prostheses cemented with Palacos, with or without gentamicin were included in the analyses

<sup>b</sup> Increased risk of revision in patients with ligament instability.

<sup>c</sup> The risk of revision because of an infection was 2.5 times lower in women ( $p = 0.02$ ), but was 4.2 (1.2–15.3) times higher in patients with sequelae after a fracture ( $p = 0.03$ ).

<sup>d</sup> This group included revisions due to instability, malalignment and dislocation, not including the patella. This reason for revision gave a 3 times higher risk of revision in the age group < 60 years than in the age group above 70 ( $p = 0.04$ ). For the diagnosis sequelae after fracture, we found a 4.2 (1.3–13) times higher risk of revision, as compared to primary gonarthrosis ( $p = 0.01$ ).

<sup>e</sup> For pain alone, we found a 2.5 (1.2–5.3) ( $p = 0.02$ ) times higher risk of revision in patients with sequelae after fracture.

<sup>f</sup> The Cox relative revision risk (RR) is given for bicompartmental prostheses versus tricompartmental prostheses.

study period. This accords with the findings from Sweden that the new implants were better than the old ones (Robertsson 2000). Since confounding by unknown risk factors is possible in register studies, small differences among treatments with good

results must not be overestimated and changes in clinical practice should not be made on this basis. If procedures or implants are used at only one or a few hospitals, and probably by only one or a few surgeons, the results with these procedures or

implants may reflect the skill of the surgeon rather than characteristics of the implants.

Surgeons should be aware of the lack of long-term clinical documentation with some of the knee prostheses currently in use. As far as we know, there are no long-term results for the Genesis I prosthesis, but good short-term results (3–6 years) have been reported (Mokris et al. 1997), and these were confirmed by our study. To our knowledge, there are no published clinical results for the Nex-Gen, Profix and Interax prostheses. The AGC knee (Ritter et al. 1995, Robertsson 2000), LCS prostheses (Callaghan et al. 2000b) and Kinemax prostheses (Robertsson 2000, Back et al. 2001) have been well documented clinically, and our short-term results confirm these findings. The 5- and 10-year-results with the Duracon prosthesis are good, according to the Swedish Register (Robertsson 2000), and these findings were confirmed by our study. The results with Tricon prosthesis have also been good (Indrekvam 1996), and these findings were confirmed by our study, but Norwegian surgeons have stopped using this prosthesis during the past 2–4 years. This change in the use of prostheses was probably due partly to the policy of international orthopedic companies, which has entailed switching to new, so-called modern prostheses, without putting them through randomized controlled trials proving that they are better than the old implants.

#### *Rotating tibial insert*

The LCS prostheses have become popular in Norway during the last 5 years. This is a prosthesis with a long clinical history shown to have a good mid-term survival and clinical function (Callaghan et al. 2000b), but it is uncertain whether the rotating platform or meniscal bearing will provide any benefit later on (Callaghan et al. 2000a). The results of our study were good after 5 years for the bicompartamental LCS prostheses with 97.2% survival. The type of tibial insert in LCS prostheses, with a rotating platform or two rotating meniscal bearings, had no effect on the survival results after 5 years. The predicted benefit of less wear in rotating tibial inserts can not be evaluated until follow-up studies have been done for at least 10 years.

#### *Fixation*

Uncemented prostheses were used more than cemented and hybrid implants in younger patients, which is also true of hip replacements in Norway. Cemented prostheses are regarded as the gold standard for knee prosthesis surgery (Robertsson 2000). In our study, 87% of the prostheses were cemented. This is a higher percentage than in Sweden where 80% of the primary knee prostheses were cemented during the years 1988–1997 (Robertsson 2000). In total hip replacement, the situation is the opposite, with 85% cemented hips in Norway and 93% in Sweden. 10% of the prostheses were hybrid prostheses with uncemented porous-coated femoral components and cemented tibial components and the results were no better than those with all-cemented prostheses, even in patients less than 60 years of age. This finding does not favor the use of the more expensive uncemented implants and it has also been shown by others (Önsten et al. 1998). Only 8.3% of all knee prostheses operations in Norway were revision operations during the years 1994–2000 (Havelin et al. 2001). This is slightly less than in Sweden during the last 10 years (Robertsson 2000), probably because of the commoner use of unicompartmental and uncemented prostheses in Sweden during this period.

In our study, we found no statistically significant differences in the overall revision rates between cemented and uncemented prostheses, but the number of uncemented prostheses in our material was low. There was a tendency towards more revisions of uncemented tricompartmental TKRs than of cemented tricompartmental prostheses ( $p = 0.08$ ). Analyses from the Swedish register showed a 1.4 times higher risk of revision of uncemented tibial components ( $p = 0.01$ ) (Robertsson 2000). We found no increase in the risk of revision for aseptic loosening of the tibial component in uncemented prostheses, as compared to the cemented. The power of this comparison was weak since both components of the TKRs were uncemented in only 2%. The Swedish finding accords with the 7-year results of the St. Paul register in Minnesota (Gio et al. 1999) which showed higher, but not significant, revision rates of uncemented prostheses ( $p = 0.06$ ). These investigators, however, also studied a few uncemented prostheses. Ritter found higher revision

sion rates of uncemented than of cemented AGC knees (Ritter 1989).

#### *Tricompartmental or bicompartamental prostheses*

Of the primary TKRs during the study period, 65% were bicompartamental. This percentage increased from 59% in 1994 to 77% in 1999. Two thirds of the hospitals that had performed these operations during the whole study period had changed their practice. In our data, we found more reoperations in cemented bicompartamental TKRs than of cemented tricompartmental TKRs, but the difference was not statistically significant ( $p = 0.2$ ). However, there were distinct differences between the reasons for revision in these two groups of prostheses. There was a 2.5 times higher rate of revisions for infections in knees with tricompartmental prostheses than with bicompartamental prostheses. Revision because of an infection occurred in 14 hospitals in tricompartmental knees, and in 11 hospitals in bicompartamental knees; two hospitals accounted for 6 of them in tricompartmental knees, but the other hospitals had only one revision each. It therefore seems possible that the surgical technique in resurfacing the patella affected the results. A possible explanation may be that insertion of tricompartmental prostheses is a more extensive procedure that may compromise the circulation of the patella, traumatize the soft tissue of the patella and possibly overstuff the patellofemoral joint. The time taken for the cemented bicompartamental prostheses operations averaged 3 minutes less than that for the tricompartmental prostheses. The Swedish register found no increase in the risk of revision for infection in tricompartmental prostheses (Robertsson 2000).

There were statistically significant more revisions for pain in bicompartamental prostheses than in tricompartmental prostheses, and most of the revisions of bicompartamental prostheses involved insertion of a patellar component. We do not know, however, whether patients with bicompartamental knees really have more pain than those with tricompartmental knees. Robertsson et al. (2000a) has shown that nearly 20% of the patients with TKRs have some pain in their knee after knee surgery. If the patient who has a knee with a bicompartamental prosthesis complains of pain, the sur-

geon can perform an operation, a choice he would not have with a tricompartmental knee. This may explain the higher revision rate of bicompartamental knees even if the pain is the same with both prostheses. However, randomized studies have shown that there is a tendency to more anterior knee pain in bicompartamental knees (Partio and Wirta 1995). This has been ascribed to the design of the prostheses (Matsuda et al. 2000). The Swedish Register found that patients with bicompartamental prostheses were slightly less satisfied than those with tricompartmental prostheses. Although the satisfaction of patients with tricompartmental prostheses has decreased with time, this was not so in patients with bicompartamental prostheses (Robertsson et al. 2000a). The higher risk of infection in patellar resurfaced prostheses and of aseptic loosening of the patellar component must be weighed against the possible increase in the risk of revision with insertion of a patellar component because of pain in bicompartamental prostheses.

#### *Future studies*

We need longer follow-ups to draw conclusions on differences in performance of various knee prostheses brands, type of fixation, whether to resurface the patella and the use of rotating tibial inserts. In the meantime, the use of all cemented implants with a proven clinical record is recommended for all age groups.

We were unable to assess patient satisfaction and pain in patients who had no revisions, but it has been shown that the severity of pain varies between knee prostheses with the same survival rate (Murray and Frost 1998). Therefore, in addition to register studies, we need randomized ones that compare function and pain in currently used knee prostheses with or without patellar resurfacing.

In conclusion, the 5-year survival of the 6 most used cemented bi- and tricompartmental prostheses brands were good and showed no statistically significant differences. The results with relatively few uncemented and hybrid implants were no better than with the cemented knee prostheses. In tricompartmental knees, revisions were performed more often because of an infection, but in bicompartamental knees, they were performed more often because of pain.

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