Pain, function and risk of revision after primary knee arthroplasty

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Scientific environment

This study was carried out at the Norwegian Arthroplasty Register during the period 2006-2010. Supervision has been given by staff at the Department of Public Health and Primary Health Care, University of Bergen and at the Norwegian Arthroplasty Register, Department of Orthopaedic Surgery, Haukeland University Hospital, Bergen. During the study period grant support was given by the Norwegian Rheumatism Association with the aid of EXTRA funds from the Norwegian Foundation for Health and Rehabilitation.

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Contents

APPENDICES

PAPERS I-III

1. Acknowledgements

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2. List of abbreviations

ADL	Function in Daily Living
EQ-5D	the five-dimensional scale of EuroQol
KOOS	Knee Injury and Osteoarthritis Outcome Score
NAR	Norwegian Arthroplasty Register
NKLR	Norwegian Knee Ligament Register
PCR	Posterial cruciate retaining
PCS	Posterial cruciate stabilizing/sacrificing
QOL	Quality of Life
RCT(s)	Randomized Controlled Trial(s)
TKA(s)	Total knee arthroplasty(arthroplasties)
UKA(s)	Unicompartemental knee arthroplasty(arthroplasties)
VAS	Visual analogue scale
WOMAC	Western Ontario and MacMaster Universities Osteoarthritis Index

3. List of publications

The following papers formed the basis of this thesis:

I. Lygre, SHL, Espehaug B, Havelin L. Vollset SE. & Furnes O. Does patella resurfacing really matter? Pain and function in 972 patients with primary total knee arthroplasty. An observational study from the Norwegian Arthroplasty Register. *Acta Orthopaedica 2010; 81 (1): 99-107.*

II. Lygre, SHL, Espehaug B, Havelin L. Vollset SE. & Furnes O. Pain and function in patients with primary unicompartmental and total knee arthroplasty. A survey of 1344 patients reported to the Norwegian Arthroplasty Register. *Provisionally accepted, Journal of Bone and Joint Surgery (Am).*

III. Lygre, SHL, Espehaug B, Havelin L. Vollset SE. & Furnes O. Failures of total knee arthroplasties with or without patella resurfacing. A study with 0-15 years follow-up from the Norwegian Arthroplasty Register. *Submitted.*

4. Abstract

An increasing amount of patients have their knee disease (osteoarthritis, rheumatoid arthritis, etc.) treated with knee arthroplasty each year in Norway and world-wide. Even if accepted to be an excellent treatment method with relief of pain and better function there are issues that are widely discussed. Both the technique of resurfacing the patella and the choice of leaving it untreated have their supporters among orthopaedic surgeons, and the proportion of primary patella resurfaced total knee arthroplasties (TKAs) varies much from country to country. Further has use of unicompartmental knee arthroplasty (UKA) got renewed interest with possible changes in implant survival and in patients satisfaction after knee arthroplasty. Investigation of the quality of different treatment methods is needed to guide the orthopaedic surgeons in their process of decision making and is the purpose of this thesis.

In Paper I we investigated possible differences in patients' perception of pain and function in unrevised patella resurfaced and patella non resurfaced TKAs. The study was based on data from the Norwegian Arthroplasy Register (NAR) and from a self administrated patient survey. Based on 8 outcomes we did not observe any clinical or statistically significant differences in pain and function between the 2 groups of treatment at least 2 years following surgery.

In Paper II we investigated possible differences in perception of pain and function for patients that had undergone TKA or UKA at least 2 years following surgery. This study was also based on data from the NAR and from a self administrated patient survey. Based on the same 8 outcomes as in Paper I we observed some small but statistically significant differences in favor of UKA. However, except for range of motion these were not clinically significant.

In Paper III we compared time to failure (revision) of patella resurfaced and patella non resurfaced primary TKAs based on data from the NAR. We observed a non statistically significant lower risk for revision for patella resurfaced TKAs. After 15

years of follow-up the survival percentages for both treatment options were similar. We did however observe statistically significant differences in reason for revision. Patella non resurfaced implants were more often revised due to pain, while patella resurfaced were more prone to wear of polyethylene and to loosening of the tibial component.

In conclusion, there are no clear advantages of resurfacing the patella during primary TKA. Due to differences in reason of revision the potential consequences of patella resurfacing are more serious to the joint. Further, observed differences between UKA and TKA regarding pain and function were small and clinically insignificant, except for range of motion which was in favor of UKA.

Our findings indicate a need to reconsider the recommendation of primary resurfacing of the patella during primary TKA that exists in many countries. Further they question use of UKA instead of TKA based on less pain and better function at the cost of a higher risk of revision.

5. Introduction

5.1 Background

Severe pain and reduced function due to destruction of the knee joint caused by injury or disease may be treated by surgical use of knee implants. In 2008, 3984 primary knee arthroplasties were performed in Norway (1). This corresponds to an annual incidence of 83.5 operations per 100000 inhabitants. In Sweden the incidence in 2007 was about 120/100000 inhabitants (2). About 450,000 TKAs were performed in the USA in 2005. The demand is predicted to grow by 673 % to 3.48 million procedures by 2030 when assuming that the numbers performed procedures continues at the current rate (3).

The most common causes of primary knee arthroplasty are primary osteoarthritis of the knee which constituted 84 % of the knee arthroplasties performed in Norway from 1994 to 2008 (1). Knee prosthesis surgery is documented to have substantial positive impact on knee function and pain (4-6) and to be highly cost-effective (7, 8). However, many issues are currently debated that can be investigated based on data in The Norwegian Arthroplasty Register (NAR). The NAR was started in 1987. At first only total hip arthroplasties were registered, but from 1994 information on implants in all joints was included. The background of the register was that several prosthesis brands without documented long-term performance had been used in large numbers of patients. The most well-known example is the Norwegian Christiansen prosthesis which became very popular in the 70-ies and was in common use for about 10 years. Such poor prostheses inflict unnecessary pain and suffering on patients, and costs on the society. The register was therefore started to detect poor prostheses as early as possible. Participation of Norwegian surgeons is not compulsory but motivation for this type of quality control is high and 95 % of all implants are reported (9). The NAR has become an approved international reference for quality control of implants. The register represents a unique material for follow-up of implants and patients, and represents an important supplement to randomized clinical trials (RCT). So far the majority of studies based on data from the NAR, concern survival of total hip

arthroplasties (1). This is because hip implants have a longer follow-up time in the register. Now, about 15 years of follow-up is reached also for other joints, which makes it possible to study the quality also of knee arthroplasty.

For the patient it is important to find the best treatment to avoid pain and reoperations and to achieve as high level of function as possible. For the society better quality of knee arthroplasty will also mean important cost reductions. Reduced numbers of reoperations will free time and resources to treat an increasingly large patient group with need of knee surgery.

Many different knee prostheses are available on the market, but the best choice of prosthesis is still unclear and widely debated. Through this study we aimed to increase current knowledge on knee arthroplasty, where a number of issues were investigated. We wished to compare the risk for reoperation among different implants designs in common use in Norway, and also to focus on possible differences in reason for reoperation (e.g. prosthetic loosening, infection, and pain). Variation in long-term results among prosthesis brands has rarely been investigated and was also evaluated.

It has been shown that although the knee prosthesis is intact, it can be painful and have poor function (10). There is reason to believe that this is more likely for specific implant designs and even particular prosthesis brands. However, the register does not contain or receive information regarding pain and level of function. The quality of knee implants was therefore evaluated not only based on revision rates but also on additional information of pain and function collected from a survey among selected patients registered with primary knee arthroplasty in the NAR.

5.2 Knee Arthroplasty

5.2.1 Knee Arthroplasties; Basic concepts

Painful destruction of the knee joint caused by disease or injury may be treated with knee arthroplasty. The most common knee arthroplasties are total knee arthroplasty (TKA) where both compartments of the knee are resurfaced with artificial material and unicompartmental knee arthroplasty (UKA) where only one of the compartments is treated (Figure 1). The bearing surface of both TKA and UKA consist of a femoral component made of metal (often cobolt chrom) and a tibial platform normally consisting of a metal backed polyethylene insert on which the femoral component may articulate. The tibial component is most often modular but may also be a mono block. TKA does also offer resurfacing of the femoral side of the patella femoral joint and may also optionally include a patellar component made of polyethylene for resurfacing of the patellar side of the patella femoral joint. More sophisticated designs of both the tibia and the patellar components are however also in common use (See section 5.2.4).

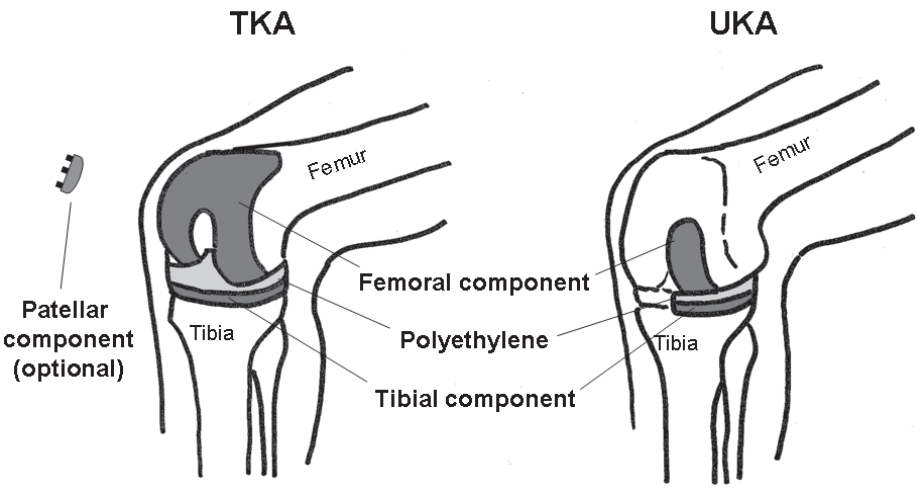

Figure 1. TKA=total knee arthroplasty. UKA=unicompartmental knee arthoplasty.

5.2.2 Knee disease

Different joint diseases can lead to pain and stiffness of the knee and eventually to the need of knee arthroplasty. The most common are osteoarthritis which in general can be separated into 2 categories by a set of criteria defined by the American Rheumatism Association (11). The first category is for those with no presently known events or disease related to the osteoarthritis (ideopathic or primary) while the second is for patients where their osteoarthritis is associated with known events or disease (secondary). Most cases of osteoarthritis of the knee are categorized as primary and do typically occur at ages above 60 with increasing prevalence with higher age (12, 13). Common causes of secondary osteoarthritis of the knee are sequela after fractures, ligament and meniscal injuries and osteoarthritis on the basis of inflammatory arthritis as rheumatoid arthritis (14). The etiology of osteoarthritis is complex where both biomechanics and biochemistry are involved and some possible risk factors are suggested to be diet, use of oestrogen, bone density, obesity, muscle weakness, joint laxity and genetics. These risk factors are also expected to be particularly important in the weight bearing joints (15).

In Norway 88 % of the patients that received primary knee arthroplasty were diagnosed with primary osteoarthritis in 2008. Rheumatoid arthritis constituted 3.8 % of the same patients, meniscal sequela 4.9 %, fracture sequela 3.1 %, ligament injury sequela 3.0 %, psoriatic arthritis < 1.0 %, ankylosing spondylitis < 0.1 and other diseases 2.2 % (1). A major decrease in inflammatory arthritis in recent years has been suggested explained by improved medical treatment (16, 17).

Treatments

Pain and stiffness of the joint caused by knee disease is usually first attempted treated with weight reduction, health education, analgesics like paracetamol and non-steroid anti-inflammatory drugs, use of a cane, physiotherapy and change of physical activity to a tolerable level (14). Osteotomy or knee arthroplasty is currently by far the most used approach when treating the more severe cases (18). TKA is the only available option for the majority of cases when knee arthroplasty is warranted but for disease

isolated to one compartment only, treatment by UKA may sometimes be used. Due to the development of minimal invasive operation techniques, UKA has also got renewed interest in the later years (19) and is currently an important and widely used treatment option in selected patient groups.

5.2.3 History

Treatment of a malfunctioning joint surface by any surgical reformation or formation of the joint, including osteotomy, has traditionally been named by the term arthroplasty, which has its origin in the Greek word for joint, arthron. During the evolution of the treatments of cartilage affected by injury or disease, the term has more commonly been used in the meaning joint replacement. Arthroplasty dates back to the early 19th century when osteotomy was used in an attempt to restore movement to a stiff and painful joint (20). Starting with Verneuil and Ollier in the 1860's interposition of various tissues such as facias was tried (21). Before the end of the century Pean had constructed shoulder prosthesis with a boiled rubber head and a platinum tube anchored to the humeral shaft. The first knee arthroplasty is believed to have been performed in 1891 by the German surgeon Theophilus Gluck who experimented with a number of different materials including a hinged implant made of ivory. All these attempts had limited success due to infections and poor performance of the chosen materials. Real improvement in joint arthroplasty was first achieved by the work of Smith-Petersen (22) who developed mould arthroplasty of the hip during the 1920's and 1930's. By using glass and later cobalt chromium to cover the head of the femur his treatment method developed to be the standard hip arthroplasty of the 1940's and 1950's. Case reports with, at restricted standards, well functioning Smith-Petersen arthroplasties have surfaced with more than 40 years of survival (23, 24) .

Inspired by the work of Smith-Petersen, Campbell reported in 1940 use of interposition arthroplasty made of cobalt chromium (Vitallium$_{RT}$) in the knee (Campbell 1988). Even if the material in the prosthesis was well tolerated the prosthesis did not offer sufficient pain relief and the next step in the search for better

knee arthroplasty was Shiers' and Waldius' construction of hinged prosthesis in the 1950's. The Waldius knee was reported to have offered functional improvement but with poor short-term survival, mainly due to infection and aseptic loosening (25) and was eventually succeeded by development of condylar prostheses. Treatment of osteoarthritis of the knee by UKA origins back to the early 1950's when McKeever realized that the entire knee joint did not need to be replaced when the disease was isolated to one compartment only (26, 27). Treatment with uncemented metallic hemiarthroplasty to resurface the tibial plateau was performed by McKeever and by others, but UKA did not become popular before the introduction of the first cemented metal-to-polyethylene prosthesis in 1972 (26). In his construction of a polycentric knee Gunston took use of many concepts of Charnley's low friction arthroplasty of the hip and the prosthesis was reported with improved kinematics over hinged implants but the rotational constraint and small contact area led to loosening of the tibial components (28). Later several designs with use of 2 separate unicondylar prostheses were tried, some connected with bridges to ensure parallel placements of the components. There were however still problems with the fixation and there were observations of deformation of the tibial component (28). For isolated disease these implants were however found to be suitable for treatment in one compartment only with acceptable performance. With some modifications some of them are still used as unicondylar prostheses (29-32).

5.2.4 Modern knee implants and designs

A forerunner to today's TKA, the first total condylar design with tibial stem and replacement of the trochelar groove was introduced in 1974 by Insall, Ranawat and Walker at the Hospital for Special Surgery in New York. The major concepts of this design have since become the standard for knee arthroplasty with high long-term survival rates (33), relief of pain (4-6) and with cost effectiveness (6-8). Search for improvement during almost 4 decades has however resulted in continuous modifications of the design which has sometimes produced inferior results when introduced on the market without clinical documentation. The cause of these

problems has often been identified to be the use of uncemented implants, metal backed patellar components and thin polyethylene (34-36).

The tibial component

Wear of the tibial polyethylene insert was early identified as a problem for long-term survival of the prostheses together with fixation of the implant to the bone. To better deal with these problems, the Low Contact Stress (LCS) design was introduced in 1977 with 2 types of mobile bearing systems. The implant can be used with either a moveable platform or 2 moveable meniscal bearings where both designs makes the polyethylene insert able to articulate with the metal backing fixated to the tibia. The design has become popular and several other manufacturers of knee implants now offer similar systems. It has however been hard to confirm any advantage of the mobile bearing systems and a recent meta analysis could not identify any advantages of the design as compared with fixed bearing platforms (37), neither could a large powered RCT focusing on patients short-term perception of their implant (5). Currently about 34 % of the performed TKAs in Norway have a mobile bearing system (Paper III).

Most knee prostheses in current use in Norway have a metal backed tibial component, either designed as fixed bearing or mobile bearing systems but could also be a mono block (as for the AGC prosthesis) where the polyethylene is fixated to the tibial metal plateau (AGC). Mono block tibial components have also been presented with an all polyethylene tibial component with good results (38) but the design has so far not been very popular in Norway.

Posterior cruciate sacrificing and posterior cruciate retaining designs

The anterior cruciate ligament is always sacrificed when performing TKA while the posterior cruciate ligament is normally preserved with the designs used in Norway (PCR). Posterior tibial subluxation and limited range of motion of the first introduced designs resulted in construction of a design where also the posterior cruciate ligament was sacrificed (39). In posterior cruciate sacrificing (PCS) prosthesis designs, the anterior cruciate ligament is substituted with a central tower on the tibial component

and a corresponding indentation on the femoral component in an attempt to reduce these disadvantages. TKA with PCS designs has been reported with good results regarding survival and function in several studies (40). Currently about 4 % of the TKAs performed in Norway have a PCS design.

Patella resurfacing

Simultaneously with the development of total condylar prostheses in the early 1970's focus was also put on the patella femoral joint since several patients reported anterior knee pain after having received a TKA (41). Initially an anterior flange was introduced on the femoral component to replace half of the patella femoral joint and better preserve the tracking of the native patella. Since this did not seem to improve the result, a patella resurfacing component was also designed (42). Later development of implants has resulted in the introduction of more "patella friendly" prostheses with an appropriate flange and groove in the femoral component and with a narrower fork to optimize the kinematics during bending and stretching. Such designs have been reported to also show a clear advantage to the unresurfaced patella regarding complications, as well as pain and function (43, 44). Treatment with patella resurfacing has however been disputed to this day and seems to have divided orthopaedic surgeons into 3 camps. These camps are surgeons who advocate resurfacing of the patella as a routine part of TKA, surgeons who avoid use of a patellar component and those who support selective patella resurfacing (41). The advantages of patella resurfacing has been claimed to be less anterior knee pain and avoidance of secondary resurfacing while disadvantages may be serious and even catastrophic complications related to the extra introduced component (41). Several observational studies, RCTs and meta analyses have investigated the topic and available evidence has been summarized in a recent systematic review (45) without producing any clear advice. A recent RCT including 1715 participants did not demonstrate any significant short-term differences between the 2 treatment groups regarding function and quality of life measurements (5). The study from Johnston et al has been included in a more recent meta analysis together with 15 other RCTs (43). He et al. reported a lower risk of revision after primary resurfacing of the patella but with limited benefits on other aspects.

In Norway most surgeons belong to one of the 2 first camps so that selective patella resurfacing has not been a widely used strategy. The use of patella resurfacing in Norway has also decreased from 40 % in 1994 to 3 % in 2008 (1, 46)(Figure 2). Five different prosthesis brands have been widely used since 1994 with both options of treatment, namely Tricon, Genesis I, AGC Universal, LCS and NexGen. Since around 2005, Profix and LCS-Complete have been the most commonly used prosthesis brands, almost exclusively without the extra patellar component.

Unicompartmental knee arthroplasty

UKA has received renewed interest in recent years and the number of performed UKAs has increased (Figure 2). Use of UKA provides less soft tissue dissection, less removal of bone mass and better preservation of knee anatomy. Expected short-term advantages like shorter hospitalization and faster recovery have further been shown when compared with TKA (32, 47). There are also observations of less morbidity in the form of less pain, less infection, less thromboembolic disease and better range of motion (2, 19, 30, 47). The survival of UKAs is also reported to compare well with TKAs in single centre studies (32, 48) and in the only currently available RCT (49). Indications for use of UKA are however debated as UKAs have been reported with about twice as many reoperations as compared with TKAs in register studies (19, 50, 51). The higher revision rates for UKA have been shown to be mainly due to aseptic loosening, pain and periprosthetic fractures (19). A weighting of the better short-term results of UKA against the possible higher risk of revision is therefore required and emphasizes the need for more knowledge of patient's perception of pain and function after knee arthroplasty. In Norway use of UKA has varied from 5 % to 16 % annually since 1994, and in 2008 11 % of all knee arthroplasties in Norway were performed with UKA.

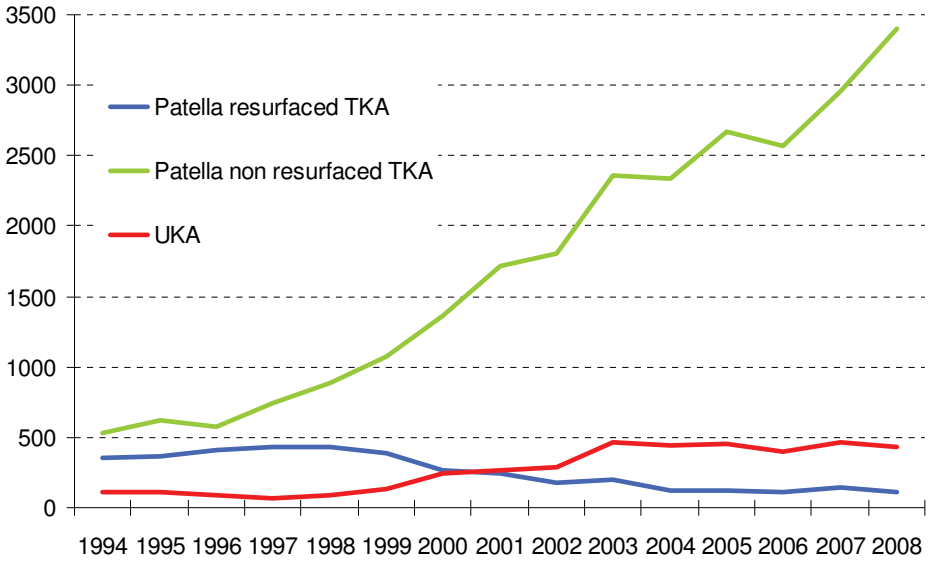

Figure 2. Number of primary unicompartmental knee arthroplasties (UKAs), patella resurfaced total knee arthroplasties (TKAs) and patella non resurfaced TKAs in Norway by year of operation (1994-2008). From: The Norwegian Arthroplasty Register.

6. Aims of the Study

The main objective of this thesis was to assess the quality of knee arthroplasty based on information reported to the NAR from 1994 to 2009, and by additional information on patients' perception of pain and function at least 2 years following surgery. The latter was retrieved through a questionnaire sent to a selected group of patients.

The specific aims of the 3 papers on which this thesis is based were:

Paper I — To compare pain and function among patients with unrevised TKA with or without patella resurfacing, based on data from a self-administrated patient survey and from the NAR.

Paper II — To compare pain and function among patients with unrevised UKA or TKA, based on data from a self-administrated patient survey and from the NAR.

Paper III — To compare the survival of patella resurfaced and patella non resurfaced TKAs and also of different prosthesis brands based on data from the NAR.

7. Methods

7.1 Data

7.1.1 The Norwegian Arthroplasty Register (NAR)

All papers in which this dissertation is based on were partly (Paper I and Paper II) or in whole (Paper III) based on data from the NAR. The NAR keeps records on TKAs performed in Norway since 1994 and each primary knee arthroplasty is followed prospectively until the implant is revised or the patient dies or emigrates. The main purpose of the NAR is to be a quality control system to identify inferior implants, bone cements and operation procedures as early as possible after being introduced. The NAR started as a hip arthroplasty register in 1987 (52) as a consequence of the discovery of the poor results of the Cristiansen prosthesis and it was extended to also include arthroplasty of other joints in 1994 (53). The NAR is owned by the Norwegian Orthopaedic Association, it is located at the Haukeland University Hospital and is funded by regional and local health authorities.

Information on knee arthroplasties performed at Norwegian hospitals is continuously reported to the NAR on paper forms (see Appendix III) inclusive data on diagnosis, operation side, earlier surgery to the joint, date of operation, use of antibiotic prophylaxis, cement and the prosthesis brand. The form is routinely filled in after the surgery by the orthopaedic surgeon while information on each implant component is obtained by stickers with catalogue numbers supplied by the manufacturers. The patients' national identification number is also registered and makes it possible to link future implant revisions to the correct patient and joint. Identity of the operating surgeons is not reported. From 2005 information on thrombosis prophylaxis, ASA classification, bone loss and computer navigation were included in the form. Still, motivated by the goal of keeping the completeness as high as possible, the form is one-sided and easy to fill in. The forms are sent to the NAR where electronic registration of the data is performed. Descriptive information from the register is published annually in a report that is sent to members of the Norwegian Orthopaedic

Association, to hospitals and to health authorities. These reports are also available in English versions and can be found at http://www.haukeland.no/nrl/eng. In addition are hospital-based reports sent back to each participating hospital to stimulate for improvement in treatment.

Records on dates of death and emigration are received from the National Population Register. These data are added to the NAR in accordance with the authorization from the Norwegian Data Inspectorate. A written consent to be entered into the register is further given by each patient (See section 7.3, Ethics and personal information protection).

Study Sample (Paper III)

By the end of the study presented in Paper III (December 10th, 2009), 32417 primary TKAs had been reported to the NAR. Only TKAs with all components cemented were eligible for inclusion. This was because use of cement was most common (n=27361, 85 %) and would make the results more comparable to results from other studies. We excluded hinged prostheses (n=22) and prostheses with posterior cruciate ligament sacrificing design (except for the LCS mobile bearing) or constrained condylar design (n=780) leaving 26559 (82 %) prostheses eligible for inclusion. A detailed description of the selection procedure is available in Figure 1 in Paper III.

When possible, prostheses brands were categorized in patella resurfaced and patella non resurfaced. For the patella resurfaced and patella non resurfaced prosthesis brands respectively, only those introduced prior to 2005 and reported with at least 200 operations were included (n=25590) for comparison of survivorship. These were the AGC Universal (Biomet Merck), Tricon (Tricon C or Tricon M femoral component in combination with Tricon II tibial component) (Smith and Nephew), Genesis I (Smith and Nephew), LCS (DePuy), NexGen (Zimmer), Kinemax (Howmedica/Stryker), Duracon (Howmedica/Stryker), AGC Anatomic (Biomet Merck), Profix (Smith and Nephew), LCS Complete (DePuy) and e.motion (Aesculap). Distribution of patella resurfaced and patella non resurfaced prostheses are given in Table I.

For comparison of the survival of patella resurfaced and patella non resurfaced TKAs the material was further restricted to those brands represented with both patella resurfaced and patella non resurfaced TKAs (n=11887) (Tricon, Genesis I, AGC, LCS and NexGen).

Table I **Number of prostheses by brand[1]**

Prosthesis brand	TKA	
	Patella resurfaced	Patella non resurfaced
AGC Universal[2]	425	2123
Tricon[2]	392	633
Genesis I[2]	704	2304
LCS[2]	532	3526
NexGen[2]	494	754
Kinemax	294	
AGC Anatomic		1298
Duracon		1283
Profix		6304
LCS Complete		4090
e.motion		434

[1]All prostheses listed are included in the study population (n=25590) for evaluation of the impact of prosthesis brands on survivorship.

[2]Prostheses included in the study population (n=11887) for evaluation of the impact of patella resurfacing on survivorship.

7.1.2 Patient survey

Questionnaire

Since the NAR does not keep track of any information of the patients' perception of pain and function we sent a questionnaire (see Appendix I) to a selection of patients registered in the NAR together with an information letter (see Appendix II). After 2 months a reminder was sent out to those who failed to respond to the initial questionnaire. Electronic registration of the questionnaires was performed at the

NAR. See section 7.2 for a detailed description of the questionnaire and section 7.3 for information of ethics and personal information protection.

Study sample (Paper I and Paper II)

Possible participants were patients with at least one unrevised (still intact) cemented primary TKA inserted due to osteoarthritis of the knee. Further inclusion criteria were that individuals should be aged 85 years or less, and the operation should be performed at least 2 years prior to the survey to ensure that the result of the intervention was stabilized (10, 54, 55). The included knees should have been treated with patella resurfaced or patella non resurfaced TKA, or with UKA. To ensure adequate representation of both patella resurfaced and patella non resurfaced TKAs for comparison on prosthesis brand level (Paper I), only patients with prosthesis brands registered with at least 100 operations in each group of treatment were eligible for further inclusion. All eligible patella resurfaced prostheses were included but since use of a patellar component had decreased over the years, patella resurfaced and patella non resurfaced implants were group matched by brand and year of operation. For comparison of UKA and TKA (Paper II) we also used a volume restriction of at least 100 performed operations on each brand of the UKAs. The number of patients included was based on a performed power analysis which is described in more detail in the Statistics section (section 7.4).

In total 1749 patients were asked to participate. 1284 of these had been treated with TKA (670 patella resurfaced and 614 patella non resurfaced). The remaining 465 individuals had received a UKA. A detailed description of the selection procedure is available in Figure 1 in Paper II. Numbers of patients invited to participate by prosthesis brand are presented in Table II.

We received completed questionnaires from 1344 (76.8 %) of the 1749 invited individuals. Of the responders, 504 had received a patella resurfaced TKA (Paper I and Paper II), 468 had received a patella non resurfaced TKA (Paper I and Paper II) and 372 had received a UKA (Paper II). Numbers of responders by prosthesis brand are presented in Table II.

Table II **Number of responders by brand**[1]

Prosthesis brand	Paper II[2]		
	Paper I[3]		
	TKA		UKA
	Patella resurfaced	Patella non resurfaced	
AGC	99 (134)	106 (134)	-
Genesis I	132 (186)	134 (180)	-
LCS	184 (238)	180 (238)	-
NexGen	89 (112)	48 (62)	-
Genesis Uni	-	-	104 (136)
Miller Galante	-	-	104 (129)
Oxford III	-	-	164 (200)
Total	504 (670)	468 (614)	372 (465)

[1] Number of invited patients in parentheses.
[2] Study population, Paper II.
[3] Study population, Paper I.

7.2 Exposures, outcomes and other measurements

Information on the studied exposures (use of primary patella resurfacing and choice of prosthesis brands) was collected from the NAR (all papers). Below we describe the outcomes and other measurements used in this thesis.

7.2.1 The Knee Injury and Osteoarthritis Outcome Score (KOOS)

To evaluate patients perception of their received knee arthroplasty, the knee specific instrument KOOS was included in the questionnaire. KOOS was developed to cover different types of knee injury and osteoarthrithis and consists of 42 individual questions (items), leading to 5 subscales (dimensions) (56) that were used as outcomes in Paper I and Paper II. These subscales are:

- **Pain** (9 items)
- Oher symptoms (**Symptoms**) (7 items)
- Function in daily living (**ADL**) (17 items)
- Function in sport and recreation (**Sport/Rec**) (5 items)
- Knee related quality of life (**QOL**) (4 items)

Only the last week should be considered when answering 40 of the 42 questions. Otherwise the frequency of pain and general knee related problems during the last month are reported. Each question received a score from 0 to 4 based on the patients' response by marking one of 5 options on a Likert scale. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) was calculated for each subscale. Calculation of the scores and treatment of missing data were done in accordance with the description at www.koos.nu.

The KOOS was chosen for several reasons. It had been demonstrated to be one of the most suitable instruments for assessment of knee-related health and outcomes from the patients' perspective in a structured review (57). The 16 instruments included in the review were evaluated by reported evidence of reliability, validity and responsiveness. The KOOS is an extension of the Western Ontario and McMaster Universities Index (WOMAC) (58) so that WOMAC scores could be calculated if needed. The KOOS had however been found to be more sensitive than WOMAC for younger and active patients, mainly due to the extra subscales function in sport and recreation (Sport/Rec) and knee-related quality of life (QOL) (59, 60). This was assessed to be applicable when trying to unveil differences among younger patients as for example those who have had an UKA.

The instrument had been validated for several languages but a validated Norwegian version did not exist at the start of this study. The National Knee Ligament Registry (NKLR) in Norway had however developed a Norwegian translation that was used in

routine follow-ups of patients reported with cruciate ligament surgery. That version was based on a former translation from the official Swedish version and a former translation from an official English version but did not completely fulfill the rules of a language translation validation process (61). A final version was therefore developed and validated by Lars Petter Granan MD, PhD at the Oslo Sports Trauma Center, Norwegian School of Sport Sciences and the authors of the studies included in this thesis. This final version was approved to be the official Norwegian translation of KOOS (www.koos.nu) and was named KOOS Norwegian version LK1.0. A detailed description of the validation process and a scoring manual are available at the KOOS website www.koos.nu. This version was later incorporated in the follow-up assessment of patients registered in NKLR. Further it was used when investigating knee arthroplasty patients' postoperative perception of pain and function in this thesis (Paper I and Paper II).

7.2.2 Visual Analogue Scale (VAS)

Characteristics like for example pain range across a continuum of values and may be difficult to measure directly. A Visual Analogue Scale (VAS) is a measurement instrument that tries to measure such attitudes on a continuous scale from complete absence of symptoms (score 0) to the extreme (score 100). Operationally a VAS is usually a horizontal line anchored by word descriptors at each end. The patients is asked to mark a point on the line that they feel best correspond to their perception of their current state. The VAS score is determined by measurement of the distance from the left end of the scale to the marked point.

VAS scores of pain from the operated knee [**Pain(VAS**)] and satisfaction with the operation [**Satisfaction(VAS)**] were included in the questionnaire and used as outcomes in Paper I and Paper II. In the analyses and presentations, the VAS-scores were reversed with 100 indicating the best possible state and 0 indicating the worst possible state to better portray the results together with the KOOS subscales.

7.2.3 Improvement in quality of Life (ΔEQ-5D)

Most of the outcomes incorporated in the questionnaire were on patients' postoperative perception of their operated knee. To account for possible difference in preoperative health status a measurement of the patients' preoperative health status was also needed. The NAR does not contain such information and a standardized non-disease-specific instrument for health related quality of life measurement, the EuroQol (EQ-5D) (62), was incorporated in the questionnaire. Information needed for calculation of preoperative EQ-5D index scores was rendered by the patients at the time when filling in the form.

To assess improvement in quality of life, questions needed to calculate postoperative EQ-5D was also included. **ΔEQ-5D** was finally calculated as the difference between the post- and preoperative EQ-5D index scores and was used as outcome in Paper I and Paper II.

The EQ-5D index score has 5 dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression). One of 3 possible responses (no problem, some problems and major problems) for each dimension should be indicated when filling in the form. A large European population has been used to generate preference scores (63). The range of the EQ-5D index score was from 0 that indicated a health status similar to death, to 1, meaning best possible health status.

The scores were finally multiplied by 100 to better portray the results with the results from the other outcomes, the 5 KOOS subscales and the 2 inverted VAS outcomes on pain and satisfaction.

7.2.4 Revision of the implant (reoperation)

A commonly used outcome measure for quality of arthroplasty is revision (reoperation) of an implant. This measure is widely used on data from arthroplasty registers. In Paper III time from primary operation to revision was focused on and used as outcome measure when comparing survival between primary patella resurfaced and patella non resurfaced TKAs and further among prosthesis brands.

Such comparisons were performed by use of survival analyses (see section 7.4). To perform such analyses, information on dates of deaths and emigrations is needed. This was collected from the National Population Register, using the individual identification number assigned to all inhabitants in Norway.

A revision is defined as removal or exchange of one or more prosthetic components. Need of revision is normally caused by factors like deep infection, aseptic loosening of components, instability, periprosthetic fractures, malalignment, instability, dislocation, defect polyethylene inserts (wear) or pain. For some knee implants a revision may also involve addition of an extra component to an already performed primary knee arthroplasty. An insertion of a patellar component to a primary patella non resurfaced implant is often performed in order to achieve less pain and better function. This type of revision is called secondary patella resurfacing. Reoperations not including a removal or exchange of components, such as soft tissue debridement are not reported to the register

7.2.5 Other measurements

NAR

Information on patient characteristics, operation characteristics and number of hospitals was collected from the NAR.

Survey

The importance of taking patients' level of co-morbidity into account when performing outcome studies has been demonstrated by the Swedish Knee Arthroplasty Register (64). To assess the potential effect of general functional ability (Paper I and Paper II), the questionnaire also included questions needed to calculate the Charnley category applied to knee arthroplasty patients (64, 65). The categories are as follows.

Category A: Involvement of the ipsilateral (actual) knee only.

Category B: Also involvement of the contra lateral (other) knee.

Category C: Also involvement of other joints or systematic problems limiting activity.

7.3 Ethics and personal information protection

Information on joint arthroplasties is reported to the Norwegian Arthroplasty Register only after the patient has given an informed written consent. All data and results are handled and presented anonymous according to the guidelines outlined in the license issued to the register by the Norwegian Data Inspectorate.

Information on function and pain is not reported to the Norwegian Arthoplasty Register and was retrieved from a group of patients with knee implants through a postal questionnaire. This information was added to existing data in the register. The study was approved by The Norwegian Data Inspectorate (date of issue: 04/25/2006, registration number: 2005/453-2), and The Regional Committee for Research Ethics in Western Norway (date of issue: 02/23/2006, registration number: 046:06). The patients received the questionnaire together with an information letter, and returned the questionnaire to the register with a signed consent to participate in the study.

7.4 Statistics

Numeric variables were described with mean and median values together with standard deviations as variability measure. Categorical variables were described as relative frequencies (all papers). Associations between exposure and outcomes were assessed as differences in mean scores using multiple linear regression models (66) for continuous outcomes (Paper I and Paper II) and as relative risks (hazard rate ratios) using multiple Cox regression analyses (67) for time to failure data (Paper III). Adjustment in the regression models for possible confounding factors was decided a priori based on information from previous studies and on assessment of their impact on the results. Covariates with more than 2 levels were represented with indicator variables when the assumption of linearity in the regression model was not fulfilled. P-values less than 0.05 were considered statistically significant in all papers. An exception was when the significance level was reduced according to the Bonferroni multiple comparison correction method (66) to account for chance findings (Paper II).

Clinical significance

For outcomes on patients perception of pain and function (Paper I and Paper II), clinically significance were assessed relatively to a stated minimal perceptible clinical difference (MPCD) of 8–10 units for the KOOS subscales (56) and 9–12 units on outcomes measured on a visual analog scale (68). When assessing the detailed KOOS questions (items) a 10 % difference between the 2 groups were assumed to be clinically significant, corresponding to 0.4 units.

Power analysis

A power analysis was performed to decide the necessary number of patients to be included in the patient survey. To have an 80 % chance of detecting as significant (at the 2-sided 5 % level) a difference of 10 units between the treatments under investigation in mean KOOS subscale values, with an assumed standard deviation of 20, 64 individuals in each treatment group were required. Thus, to ensure good representation for both treatment groups, we required at least 100 registered operations for each treatment option studied (Paper I, Paper II).

Statistical software

Statistical analyses were performed using the statistical software programs SPSS (SPSS Inc. Chicago, IL) version 15.0.0.1 (Paper I and Paper II), SPSS version 17.0 (Paper III) and R (The R Foundation for Statistical Computing) version 2.10.1 (Paper III).

7.4.1 Paper I

Differences in response rates among patients with patella resurfaced or patella non resurfaced TKAs (exposure) were tested with the Pearson chi-square test (69).

Associations between exposure and the 8 outcomes on patients perception of pain and function were assessed using multiple linear regression with adjustment for possible confounding by age when filling in the questionnaire (<65, 65-70, 70-80, >80), sex, preoperative EQ-5D index score (<30, 0.30-0.69, >0.69), Charnley category modified to knees (A,B,C) and prosthesis brand (Genesis I, AGC, LCS and NexGen). The

impact of patella resurfacing was also investigated within each prosthesis brand. Patella resurfaced implants were used as reference meaning that estimated differences were calculated as adjusted mean scores among non-resurfaced prostheses minus mean scores among resurfaced prostheses.

Since indication for revision may differ in treatment groups a sensitivity analysis was performed (see section 9.1.4 on differential misclassification). We compared pain and discomfort 2 years or more after the primary operation by adding reported information from varying numbers of revised patients. These comparisons were performed using the Mann-Whitney U test and presented in Table 5 in Paper I. Information for revised patients was obtained from another survey comprising all patients registered in the NAR with revised implants.

Multiple linear regression models were also used to investigate a possible association between prosthesis brands (exposure) and mean outcome scores. In these analyses, we also adjusted for time since operation. Adjusted differences in mean scores were presented relative to the AGC prosthesis brand.

Adjusted differences in mean scores were presented with p-values and 95 % confidence intervals.

7.4.2 Paper II

Differences in baseline characteristics between TKA and UKA regarding age, time since operation when filling in the form and preoperative EQ-5D index score were analyzed with the independent samples Student's t-test, while differences in sex and Charnley category were analyzed with the Pearson chi-square test. Impact on response rates from treatment option (UKA or TKA), sex, age and time since the operation were analyzed by a multiple logistic regression analysis (70).

Associations between use of TKA or UKA (exposure) and the 8 outcomes on patients perception of pain and function were assessed in multiple linear regression models with adjustment for age when filling in the questionnaire (<65, 65-70, 70-80, >80), sex, time since the operation, Charnley category modified to knees (A,B,C). TKA

implants were used as reference such that estimated differences were calculated as adjusted mean scores among UKAs minus mean scores among TKAs.

A multiple linear regression model based on UKA operations only was used to investigate a possible association between mean outcome scores and the 3 different UKA brands (Genesis Uni, Oxford III, Miller-Galante all polyethylene tibial Uni) with adjustment for distributional differences in gender, age, Charnley category and time since operation. The Oxford Uni III was used as reference.

As in Paper I adjusted differences in mean scores were presented with p-values and 95 % confidence intervals.

7.4.3 Paper III

The impact of use of primary patella resurfacing and of prosthesis brand (exposures) on prosthesis survival was investigated in Cox regression analyses with adjustment for age at the primary operation (<60, 60-70, >80), sex, previous operation of the knee (operated or not), diagnosis (primary osteoarthritis of the knee or not) and prosthesis brand (Tricon, Genesis I, AGC, LCS, NexGen). Revision was defined as a reoperation where one or more of the femoral, tibial or patellar components were removed or exchanged, or an addition of a patellar component to a primary untreated patella (secondary resurfacing). Information on deaths and emigrations was retrieved from the National Population Register, until December 10th, 2009. The survival times of implants in patients who had died or emigrated without revision of the prosthesis were censored at the date of death or emigration. Otherwise the survival times were censored at the end of the study on December 10th, 2009. The Wald test was used to calculate p-values.

Tests and inspections of plotted Schoenfeld residuals (71) were performed to investigate if the proportional hazards assumption of the Cox models were valid. The assumption of independent observations in the Cox proportional hazards model may not have been fulfilled since patients may have been operated in both knees (bilateral

observations). Several studies have however found that the impact on results is negligible both for hip and knee prostheses (72-75).

The survival curves for the adjusted percentage of unrevised implants were estimated with treatment option (exposures) as stratification factor and given for survival times where more than 50 implants remained at risk of revision. Survival percentages at 5, 10 and 15 years were presented in tables. The reverse Kaplan-Meier method was used to calculate the median follow-up (76, 77).

Since use of patella resurfacing and prosthesis brands changed throughout the study period, survival was also compared within 2 separate time periods, namely for operations performed from 1994 through 2000 (with follow-up until December 10th, 2009) and from 2001 to December 10th 2009.

Adjusted revision rate ratios were presented with p-values and 95 % confidence intervals relative to the relevant reference category (patella non-resurfaced implants or the non-resurfaced AGC Universal implant, respectively).

8. Summary of Papers I-III

Paper I

Lygre SHL, Espehaug B, Havelin LI, Vollset SE, and Furnes O. **Does patella resurfacing really matter? Pain and function in 972 patients after primary total knee arthroplasty. An observational study from the Norwegian Arthroplasty Register.**

Background and purpose: Resurfacing of the patella during primary total knee arthroplasty (TKA) is often recommended based on higher revision rates among non resurfaced knees. As many of these revisions are insertions of a patellar component due to pain, and since only patients with non resurfaced patella have the option of secondary resurfacing, we do not really know whether these patients have more pain and poorer function. The main purpose of the present study was therefore to assess pain and function for unrevised primary non resurfaced and resurfaced TKA, and secondary among prosthesis brands.

Methods: Information needed to calculate subscales from the Knee injury and Osteoarthritis Outcome Score (KOOS), were collected in a questionnaire from 972 osteoarthritis patients with intact primary TKA reported to the Norwegian Arthroplasty Register. Pain and satisfaction on visual analogue scales and improvement in EQ-5D index score (ΔEQ-5D) were also used as outcomes. Outcomes were measured on a scale from 0 (worst) to 100 (best) units. To estimate differences in mean scores, we used multiple linear regression with adjustment for possible confounders.

Results: We observed no differences between resurfacing and non-resurfacing in any outcome with estimated differences≤1.4 units and p-values>0.4. There was however a tendency for better results for the NextGen implant as compared to reference brand AGC for Symptoms (difference=4.9, p=0.05), Pain(VAS) (difference=8.3,p=0.004)

and Satisfaction(VAS) (difference=7.9, p=0.02). Non of these differences did however reach the stated level of minimal perceptible difference.

Interpretation: Resurfacing of patella has no clinical effect on pain and function after TKA. Differences between investigated brands were small and assumed to be clinically of less importance.

Paper II

Lygre SHL, Espehaug B, Havelin LI, Vollset SE, and Furnes O. **Pain and function in patients with primary unicompartmental and total knee arthroplasty. A survey of 1344 patients reported to the Norwegian Arthroplasty Register.**

Background: Unicompartemental knee arthroplasty (UKA) has received renewed interest. Use of UKA is however debated and short-term advantages over total knee arthroplasty (TKA) should be weighed against a higher risk of reoperation. More knowledge on results of pain and function after knee arthroplasty is therefore needed and was the purpose of this study.

Methods: Patient-reported pain and function were collected at least 2 years after the operation in postal questionnaires from 1344 arthritis patients reported to the Norwegian Arthroplasty Register with intact primary TKA (n=972) or UKA (n=372). Outcomes were the 5 KOOS subscales, Pain(VAS), Satisfaction(VAS), and change from pre- to postoperative EQ-5D index score. The outcomes were measured on a scale from 0 (worst) to 100 (best). Differences were analyzed with multiple linear regression, adjusted by age, sex, Charnley category and time since operation. To investigate possible underlying mechanisms we also studied all 42 KOOS questions (0=best to 4=worst) as outcomes. To be regarded as clinically significant the differences should be greater than 8 units for KOOS outcomes, 10 for VAS and 0.4 for the detailed KOOS questions.

Results: UKA performed better than TKA for the KOOS subscales “Symptoms” (adjusted mean difference, 2.7 [95 % confidence interval, 0.1 to 5.3]; p=0.04), “Function in Daily Living” (adjusted mean difference, 4.1 [95 % confidence interval, 0.9 to 7.4]; p=0.01) and “Function in Sport and Recreation” (adjusted mean difference, 5.4 [95 % confidence interval, 1.6 to 9.3]; p=0.006).

Of the 42 analyses of the detailed questions from KOOS, 4 differences reached level of statistical significance. All of these differences were in favor of UKA, but only the

question regarding “ability of bending of the knee”, reached level of clinical significance.

Conclusions: We found only small or no differences in pain and function between UKA and TKA investigated at least 2 years (mean 6.5 years) after surgery. Lower revision rates in combination with nearly equivalent pain and function scores indicate that TKA is still an excellent option for some patients with isolated disease.

Paper III

Lygre SHL, Espehaug B, Havelin LI, Vollset SE, and Furnes O. **Failures of total knee arthroplasties with or without patella resurfacing. A follow-up study from the Norwegian Arthroplasty Register.**

Introduction. Patella resurfacing during primary total knee arthroplasty (TKA) is disputed and new prosthesis designs have been introduced without documentation on their survival.

Patients and Methods. We assessed the impact on prosthesis survival of patella resurfacing (n=11887) and of prosthesis brand (n=25590) based on data from the Norwegian Arthroplasty Register. Cox regression analyses were performed with different reasons for revision as endpoints with adjustment for potential confounders.

Results. We observed a non statistically significant reduced overall risk for revision (RR=0.84, p=0.05) for patella resurfaced (PR) TKAs. At 15 years 92.1 % of PR and 91.4 % of patella non resurfaced (NR) prostheses were still unrevised. However, PR implants had a lower risk for revision due to pain alone (RR=0.12, p<0.001), but a higher risk for revision due to loosening of the tibial component (RR=1.42, p=0.03) and due to a defect polyethylene insert (RR=3.23, p<0.001).

At 10 years the survival for the reference brand NR AGC Universal was 93.2 %. The NR brands Genesis I, Duracon and Tricon (RR=1.43 to 1.67) performed statistically significant poorer than NR AGC Universal, while the NR prostheses e.motion, Profix and AGC Anatomic (RR=0.09 to 0.66), and the PR prostheses NexGen and AGC Universal (RR=0.40 to 0.48) performed statistically significant better. LCS, NexGen, LCS Complete (all NR), and Tricon, Genesis I, LCS and Kinemax (all PR) did not differ from the reference brand. A lower risk for revision (crude) was found for TKAs performed after 2000 as compared with those performed earlier (RR=0.81, p=0.001).

Interpretation. Although revision risk was similar for PR and NR TKAs, we found important differences in reasons for revision. Our results also imply that survivorship of TKAs has improved.

9. General Discussion

9.1 Methodological considerations

9.1.1 Study designs

Randomized clinical trials versus observational studies

The strongest level of evidence for assessment of treatment modalities is achieved when performing randomized controlled trials (RCT). Properly designed RCTs where the study units are randomly assigned to the treatment groups, offer highly reliable results which is hard to challenge by other methods.

There are however situations were RCTs are not suitable, mostly when it is impractical, unethical or even impossible to perform RCTs but also due to high cost and need of large groups of patients. Studies of different aspects of joint arthroplasty generally require long follow-up (10-15 years) and high number of patients since these studies normally involve assessment of rare incidents that develop over a long time and with small differences between the groups. In such cases observational studies can offer a good alternative and are even found to compare well with RCTs due to a broader range of patients, hospitals, operation techniques and of surgeon skill (78, 79). Rare side effects of treatment are also harder to detect by use of RCTs than with prospective observational studies since RCTs are designed to evaluate 1 or 2 outcome measures and have smaller sample size. For these reasons few RCTs are performed to investigate survival of TKAs and so far the number of patients and length of follow up have often been insufficient. For comparison of UKA and TKA only one small RCT (n=102) has been performed (47, 49). A two-sided log-rank test with an overall sample size of about 1000 study subjects achieves 80 % power at a 0.05 significance level to detect a difference in survival that corresponds to a hazard ratio equal to 2 (80). An exception is radiostereometric analysis (RSA) where clinical outcomes are wear and micro motion of the implant (81, 82) where a small number of study subjects and short follow-up is needed to unveil possible differences in indication of future failure among exposure groups (prosthesis designs, fixation

methods etc.). A RSA study evaluating different types of cementation of hip prosthesis have been performed by researchers at the NAR (83) and future studies are planned for evaluation of both hip and knee arthroplasty.

The ability of performing large scale continuous (post-marketing) control of the quality of joint arthroplasty is the main motivation for establishing national and large regional arthroplasty registers. Studies from the Norwegian Arthroplasty Registers are with a few exceptions prospective observational studies where the differences in treatment quality among procedures are measured in terms of time until revision. Since highly specialized surgeons and clinics generally do not dominate the data material the results presented is assumed to represent those for an average hospital and an orthopaedic surgeon.

Investigation of patients perception of pain and function as performed in Paper I and Paper II may also be investigated by use of RCTs, but use of observational studies based on data from arthroplasty register may also be valuable because of better external validity due to inclusion of a broader range of implants, hospitals, surgeon experience and operation techniques (84).

Even if data from arthroplasty registers is suitable for studying survival of knee arthroplasties, few studies with long-term results have so far been published. In Paper III we investigated and reported differences in survival of patella resurfaced and patella non resurfaced prostheses and among commonly used prosthesis brands based on data with more than 15 years of follow-up from the NAR.

9.1.2 Outcome Measures

To evaluate the quality of knee arthroplasty we have used different outcome measures in the studies included in this thesis. The majority of studies on data from the NAR use time until failure of the implant (revision) as outcome. This outcome is also used in Paper III were impact of patella resurfacing during primary TKAs is assessed. Other outcome measures like clinical evaluations performed by orthopaedic surgeons

and routine radiological findings can contribute in the evaluation of the quality of implants (85, 86)

However, even if not revised and with no other clinical findings demonstrated, primary implants may hurt and may not function properly. Revision as endpoint may therefore be characterized as a surrogate endpoint since the main objectives of knee arthroplasty are relief of pain, improvement of function and of quality of life. The patients own assessment has traditionally not played an important role in helping to evaluate the quality of operation techniques and knee arthroplasty (87). There are however studies focusing on pain and function and some of them have also been included in meta analyses (43, 88-90). In Paper I and in Paper II we focused on patients' perception of pain and function to better assess quality of knee arthroplasty.

9.1.3 Completness and quality of data

The NAR

Reporting to the NAR is voluntarily. The reports from the NAR have been compared with the compulsory national hospital administrative database, the Norwegian Patient Register (NPR). An estimated 99 % of the primary and 97 % of the revision knee prostheses were reported to the NAR as compared with the Norwegian Patient Register during the years 1999 through 2002 (9). At the time of performing this comparison, the data from NPR was not identifiable as pertaining to particular individuals and could not be individually matched to information from the NAR. However, from Mars 1th, 2007 the data from NPR is identified to individuals and one to one comparisons is now possible. Efforts are also made to reduce missing and erroneous data to a minimum in the NAR by contact with all the local hospital when ambiguous information is discovered. Reports on each hospitals result as compared to the global national results are also distributed to the hospitals annually to motivate for improvement but also as control of reported information.

Patient survey

The received forms were registered by employees at the NAR. All forms that were hard to interpret were discussed with Stein Håkon Låstad Lygre before they were

registered. Erroneous marking of Likert boxes was interpreted as stated by the guidelines for each instrument included in the questionnaire.

See section 9.1.4 for a discussion of the response rate of the postal patient survey.

9.1.4 Internal Validity

The internal validity of a study implies validity of inference for the source population of study subjects (91). In causal studies, internal validity is a precondition for generalizability to subjects outside the study population (external validity) (91). Internal validity in observational research may be threatened by various types of systematic errors which can be separated in to 3 different types: selection bias, information bias and confounding.

Selection bias (non-response bias)

Selection bias may occur if the procedures used to select participants to the study lead to an effect estimate among those included that differ from the estimate theoretically obtained from the source population (responders and non responders) (91).

Ideally the characteristics of the responders to a survey should be equal to those asked for participation. A comparison of the characteristics between responders and non responders is often performed when assessing presence of selection bias due to persons that refuse to participate. Discrepancy between responders and non responders will be of less importance when a high response rate is achieved as the characteristics of the responders will be similar to the subjects eligible for inclusion.

In each of Papers I and II we received completed questionnaires from over 75 % of the individuals selected for the study. The response rate was similar in the two papers since Paper II (n=1344) comprised all responders from Paper I (n=972) in addition to responding UKA patients (n=372) (Table II). In both papers assessment of response rates by Regional Health Authorities in Norway showed small geographical differences. Compared to non responders, responders were on average younger (at most 3.4 years), follow-up since the operation was shorter (at most 0.7 years) and they were more likely to be men (29 against 20 % in both studies). However, due to

the fairly high response rate the patient characteristics of the responders compared well with characteristics of the patients selected for the study. A multiple logistic regression analysis on response versus non response with adjustment for the above factors showed that the treatment options (exposure) under investigation were not associated with being a responder or non-responder.

Information bias (misclassification)

Errors in obtaining correct information on the subjects included in the study may also lead to bias in effect estimates. This type of systematic error is called information bias or misclassification and may affect both exposure and outcome measurements.

In all papers information on prosthesis designs (exposures) was collected from NAR and so was outcome in Paper III. After each operation, a standard form is filled in by the surgeon and sent to the register where electronic registration of the data is performed. Stickers with catalogue numbers are delivered by the manufacturers along with the implants (exposure) and are attached to the form by the operating surgeon. The presence of systematic errors in the registration of selected key variables have been investigated for hip arthroplasty in several studies and was found to be almost absent (92, 93). The similarity of the registration forms and the registration process between knee and hip arthroplasty indicate that there is no reason to believe that the rate of misclassification should be any higher for knee implants.

Two types of information bias are usually described. They are *differential misclassification* and *non differential misclassification* (91).

Differential misclassification

Misclassification of exposure or outcome variables that depend on the value of the other is called differential misclassification. This may lead to either overestimated or underestimated effect measures.

In Paper I and Paper II the main information sources on exposure (the NAR) and outcome (self-administrated questionnaire) were independent and any differential misclassification of exposure (prosthesis design) and outcome (patients' perception of

pain and function) was therefore unlikely. A common form of differential misclassification is recall bias. In Paper I and Paper II, every outcome measure except the ΔEQ-5D were based on the patients' perception of pain and function experienced the last week. There is however no reason to believe that information on preoperative EQ-5D index score were recalled differently in the exposure groups (people with different prosthesis design).

A differential misclassification of exposure may however have been introduced in Paper I and Paper II if patients having undergone one of the treatment methods studied are more likely to be revised for the same indications than patients in the other group of treatment, leaving a falsely low proportion of patients with poor results in that group. This may also be viewed as a type of selection bias. In Paper I such bias may have affected our findings in favor of patella non resurfaced TKAs since the option of secondary resurfacing may remove the poorest performing patients from the group of eligible patients. This effect was however evaluated as being of minor importance in a performed sensitivity analysis were varying numbers of revised prostheses were added to the original material. Since TKA is the main treatment of a malfunctioning UKA this type of bias may have been introduced in Paper II if patients with an UKA were more likely than those with a TKA to be revised for the same indications, for example pain. If so, a falsely low proportion of individuals with poor results after being treated with UKA would be eligible for inclusion and the estimated advantage of UKA would be too positive. This may have caused the results of UKA to be too positive and could thereby have increased differences in favor of UKA. Thus, any advantages of UKA may be even smaller than indicated by the observed differences and our conclusion of small differences would not have been altered.

In Paper III differential misclassification may occur if the outcome (revision) reported to the NAR depend on the value of the exposure (implant design). The reported low numbers of registration errors and use of stickers with exact prosthesis information, together with a high registration completeness of both primary and revision procedures (9), do however not indicate differential misclassification.

Non differential misclassification

Misclassification of exposure or outcome variables that do not depend on the value of the other is called non differential misclassification. For dichotomous exposure or outcome variables, non misclassification leads usually to attenuated risk estimates while more than 2 levels may produce exaggerated effect measurements (91). As discussed earlier misclassification of data in the NAR is assumed to be low. Hence, non differential misclassification in data from the NAR is assumed to be minor. Furthermore, as current perception of pain and function was reported by the patients, measurement bias would be limited.

Confounding

The observed association between the exposure and the outcome studied may partly or completely be explained by the influence from a third factor. In common epidemiological language such factors are called confounders. Rothman (91) has given the following formal definition of confounding:

- *A confounding factor must be a extraneous risk factor for the disease*
- *A confounding factor must be associated with the exposure of the study in the source population (the population at risk from which the cases are derived)*
- *A confounding factor must not be affected by the exposure or the disease. In particular, it cannot be an intermediate step in the causal path between the exposure and the disease*

The studies included in this thesis were based on observational data from the NAR and from a patient survey regarding pain and function after knee arthroplasty. Hence, extraneous risk factors may exist that are unevenly distributed among the treatment groups (exposure). UKA may for example be a more common method of treatment for young men with poor prognosis than for older women and thereby produce inferior failure rates since a large number of individuals with potentially poor prognosis have been treated with an UKA.

Prevention of confounding

The optimal treatment of potential confounding factors is to provide an even distribution of such factors among the exposure groups investigated. This can be achieved by performing RCTs which, when properly designed, will secure an even distribution both of factors that is unknown and of factors for which information is not collected. In observational studies restriction procedures can be performed to achieve an evenly distribution of confounders. This can however in practice only be performed on limited numbers of factors on which information can be collected. For continuous measurements these confounding variables often need to be categorized before restriction can be performed with potential risk of misclassification when choosing restriction limits. In Paper I and Paper II the materials were restricted by age, diagnosis and prosthesis brand. In Paper I treatment groups were also matched on year of operation to prevent possible confounding by prognostic factors that may change over time.

Control of confounding

In many studies the procedures described to prevent bias due to confounding can not secure complete absence of mixing of effects. Further control of confounding after data collection may be done by stratification or regression techniques. Multiple regression analyses were used in all papers included in this thesis to control for confounding. Obviously this technique can not adjust for residual confounding by factors which are not known or quantified.

An example would be if there were differences in preoperative status between the exposure groups. In Paper I and Paper III such a difference between the exposure groups (patella resurfaced TKA and patella non resurfaced TKA) is most likely absent, since in Norway, the choice of treatment studied was decided for all patients by the medical director in each orthopaedic department. Hence, the choice of prosthesis brand and use of a patella implant was normally not linked to the surgeons or the patients' characteristics. In Paper II however, UKAs could have had an advantage of a better preoperative condition, for example in terms of better range of motion. This is since an intact anterior cruciate ligament and a less severe

radiographic grade is recommended if treatment with UKA should be considered. If so, the results of UKA may have been too positive. The advantages of UKA may then however be even smaller than indicated by the observed differences and any bias caused by this confounder would therefore have been of less importance for the main conclusion.

On the other hand, a more serious impact may have occurred if patients with a more severe stage of the disease were treated with UKA. A fairly permissive approach to the use of UKA has been reported in Sweden during the 80s (94). In the study period however, use of criteria defined by the Oxford group were recommended to identify patients that were suitable for treatment by UKA. Hence, such a bias was not likely, since treatment with TKA was the only recommended option for patients with a more severe stage of the disease based on the Ahlbäck radiographic classification (95, 96) (classification 1 to 5 for TKA, 1 to 3 for consideration of UKA).

9.1.5 External Validity

Ability to generalize results and conclusions from the population under study to subjects outside that population is called external validity (91). In our situation this is the ability to generalize results and conclusions based on knee arthroplasties performed in Norway to the world-wide population of knee arthroplasties. As compared with RCTs, studies based on data from arthroplasty registers are often considered to have greater generalizability due to a broader range of patients, hospitals, operation procedures and surgeon skill etc. Since we put restrictions on diagnosis, age and fixation of implant in Paper I and Paper II, our findings may only be generalized to populations with the same restrictions. We did also restrict the inclusion of prosthesis brands in all papers but most of the brands included were also broadly used in other countries so the results are assumed to have good external validity.

9.1.6 Effect modification

Effect modification occurs when measurement of the effect of exposure on the outcome varies according to a third variable (91). In contrast to confounding, effect modification is not considered to be a confusion of effect but rather a property of the exposure effect. Effect modification may be assessed by use of stratification or inclusion of interaction terms in the multiple regression models. An evaluation of possible effect modification by time of the primary operation was performed in Paper III where the study period was stratified into 2 time periods (1994 to 2000 and 2001 to December 10th, 2009).

9.2 Results

9.2.1 Pain and Function, patella resurfaced and patella non resurfaced TKA

The major reason for primary patella resurfacing is to achieve less anterior knee pain and better function and thus avoid secondary resurfacing (43). The survey in Paper I did not unveil any relevant difference in pain and function in patients with primary patella resurfaced or patella non resurfaced TKAs at least 2 years following surgery. This finding indicates that the higher revision rates reported for patella non resurfaced TKAs (43, 45) are related to the exclusive option of secondary patella resurfacing and not necessarily because of more severe pain. The findings in Paper I partly contradict other reports summarized in a systematic review (45) but support findings from a recent high-powered multicenter RCT including 1715 patients (5) and a recent meta analysis (43) . To further appraise this topic, an investigation of survival and different reasons of revision in the 2 groups of treatment was performed in Paper III (see section 9.2.3).

Differences between the reference prosthesis brand AGC Universal and other brands included were small and did not reach the stated levels of minimal perceptible clinical difference (56, 68) even if being statistically significant for the NexGen implant for both Pain(VAS) and Satisfaction(VAS). The somewhat better results of the newer

NexGen implant may be due to a better anatomic design. This result should however be interpreted with caution due to the limited number of hospitals and surgeons using NexGen.

Men reported in general less pain and a higher level of function in all outcome measures except for improvement in quality of life after surgery (ΔEQ-5D). These findings are also in accordance with other studies where improvement in knee scores was found to be similar for men and women after TKA (97), but that women perform poorer before the operation and thereby also after the operation (55, 98, 99).

Better postoperative performance of the implant was also found to be associated with absence of co-morbidity, as measured by the Charnley category (for all utcomes), with higher age for the KOOS subscales Pain, Symptoms, and QOL, Pain(VAS) and ΔEQ-5D and by better preoperative quality of life as measured by the EQ-5D index score (for all outcomes). Some of these findings also reached stated levels of minimal perceptible clinical difference (56, 68). The observed positive effect of increasing age is supported by findings in other studies (100, 101). This has been suggested explained by more activity and thereby increased wear in combination with higher expectations among younger patients (100). Better prognosis regarding pain and function after treatment by TKA for patients without co-morbidity emphasizes the need for taking this in to account when performing such outcome studies. This has also been reported in a study from the Swedish Arthroplasty Register (64).

9.2.2 Pain and Function, TKA and UKA

In Paper II we found small but statistically significant differences between TKA and UKA 2 years or more after surgery for the KOOS subscales Symptoms, ADL and Sport/Rec. None of the differences did however reach the stated level of minimal perceptible clinical difference (56, 68). Other studies on data from arthroplasty registers have reported more than twice as high risk for revision for UKA as compared with TKA (19, 51). Furnes et al (2007) found that this was mainly due to pain, periprosthetic fractures and aseptic loosening of the tibial and the femoral components and was found for all age categories. A higher rate of failed prostheses is

expected when failure is defined not only as revisions but also painful joints (10). A higher proportion of loose prosthesis components after UKA may therefore explain why our findings indicate no advantage of UKA regarding pain. Progression of arthritis has also been suggested as an important reason of revision of UKAs (102, 103) and may also affect our findings in the same way when not treated.

Further investigation of the the 42 detailed KOOS questions did however unveil better performance in activities that involved bending of the knee for knees treated with UKA as compared with TKA. This was especially pronounced for specific questions regarding the ability of knee bending but was also indicated for ability to get in and out of a car, ability to get on/off toilet and pain when bending the knee. UKA preserves the anatomy of the knee better than treatment with TKA through preservation of cruciate ligaments. This may offer better postoperative range of motion and thereby explain our findings of better performance in activities that involve bending and stretching of the knee.

We could not find any statistically significant difference among prosthesis brands (Genesis Uni and Miller Galante as compared with Oxford Uni) in contrast to among TKAs (Paper I) where some statistically but not clinically significant differences were found among brands. Even if not being as pronounced as for TKAs (Paper I), we found better results for men than for women. There was however a tendency of better improvement for women after treatment, while this difference between men and women was absent for TKAs (Paper I). The suggested explanation of poorer preoperative status of the disease for women having a TKA (Paper I) may therefore also apply to UKAs but a possible better improvement after this treatment may have compensated for some of the postoperative difference. A positive effect was found for increasing age after undergoing UKA. This may as for TKAs in Paper I be explained by higher expectations by younger patients as well as higher level of activity and thereby increased wear (100). As for TKA, co-morbidity as measured by the Charnley category modified to knees was found to be associated with better results after treatment with UKA.

9.2.3 Implant survival, patella resurfaced and patella non resurfaced TKA

In Paper III we found a non significant 16 % reduced risk of revision of patella resurfaced TKAs as compared with patella resurfaced after 15 years of follow-up (RR=0.84, 95 % CI:0.71-1.00, p=0.05). The 15 years survival of patella resurfaced and patella non resurfaced implants were similar though with 92.1 % and 91.4 % respectively. There were however significant differences in reason of revision. Patella non resurfaced prostheses were found to be more often revised due to pain while patella resurfaced where more often revised due to a defect polyethylene insert or aseptic loosening of the tibial component. These findings were also present when restricting the material to early performed TKAs (1994 to 2001). Major arguments for recommendation of primary patella resurfacing are to reduce anterior knee pain and to avoid secondary patella resurfacing. In Paper I we did not observe any differences in level of pain and function between the patients in the 2 groups of treatment. Interpreted together with the findings in Paper I, the observed higher risk of revision due to pain for patella non resurfaced prostheses may be explained by the available option of secondary resurfacing and not necessarily because of more severe pain. Hence the surgeons may be more inclined to revise a patella non resurfaced knee by secondary patella resurfacing if the patient presents later with knee pain, given that option is still available (104).

Our findings do also indicate that difference in risk of revision due to pain was largest for the earliest performed TKAs (1994 to 2001). This might be due to the late introduction of the newer patella friendly prosthesis brand NexGen and stop in use of some older inferior brands that were represented in our material by Genesis I. This is supported by a finding from Paper I, where NexGen was found to perform better regarding pain than the reference brand AGC Universal and Genesis I.

Higher risk of revision of patella resurfaced TKAs due to aseptic loosening of the tibial component may be explained by higher volume of polyethylene particles in the joint due to wear of the extra polyethylene element (105). Such an association is also supported by similar mechanisms observed when assessing wear and loosening of

cups after total hip arthroplasty (106, 107). Patella resurfacing might also increase the patella femoral offset due to conservative bone resection. The resulting increased forces over the patella femoral joint and onto the tibia might thereby increase tibia loosening and wear of the tibial polyethylene insert. This is also supported by the observation of higher risk of revision due to a defect polyethylene insert among the patella resurfaced TKAs and was apparent after about 10 years of follow-up.

The 10 years survival percent for the reference brand, patella non resurfaced AGC Universal was 93.2 %. We observed some variability among prosthesis brands at 10 years of follow-up, ranging from 88.6 % survival for patella non resurfaced Tricon to 96.7 % for patella resurfaced NexGen. For prosthesis brands represented with both patella resurfaced and patella non resurfaced implants (Tricon, Genesis I, AGC Universal, LCS and NexGen) the patella resurfaced prosthesis had the highest survival percent except for the LCS design were non patella resurfacing demonstrated a higher survival percentage. This may be due to the major use of metal-backed patellar components which has been reported with poor results as compared with all-polyethylene patellar component for the LCS prosthesis (50). In Norway however, patella resurfaced LCS was used in few hospitals and the results should be interpreted with caution. This does also apply to the good results of the patella non resurfaced e.motion prosthesis.

We observed increased survival of TKAs performed in Norway when comparing operations performed from 2001 to 2009 with those performed from 1994 to 2000 (unadjusted RR=0.81, CI:0.72-0.91). This may partly be explained with better operation techniques and more experienced surgeons. Our results indicate however that the introduction of newer designs (patella resurfaced NexGen and patella non resurfaced Profix) and the stop in use of older designs with lower 10 years survival (the Tricon design, the Genesis I design, patella resurfaced Kinemax and patella resurfaced LCS) have contributed to the improved survivorship of TKAs in Norway. Good performance of newer brands may be explained by the development of more patella friendly designs. Deeper groove in the femoral component is suggested to give

better tracking of the patella-femoral joint, which especially applies to the non resurfaced patella (43, 44).

10. Conclusions

Paper I

- Using patient-reported degree of pain and function as outcome, our study did not show any differences between cemented patella resurfaced and patella non resurfaced primary TKAs 2 years or more after surgery.

- Differences between the prosthesis brands were small and did not reach the stated level of minimal perceptible clinical difference relative to the reference brand, AGC.

Paper II

- Our analyses showed only small differences in patient-reported pain and function between UKA or TKA. Some differences were statistically significant in favor of UKA, but did not reach the stated level of minimal perceptible clinical difference.

- Further analyses indicated that patients with UKA had fewer problems with activities that involved bending of the knee.

- The 3 UKA brands in this study were found to perform equally well.

Paper III

- We found a statistically non significant 16 % lower risk of revision (RR) for cemented patella resurfaced TKAs as compared with patella non resurfaced based on data with 0 to 15 years follow-up from the NAR.

- There were however statistically significant differences in reason of revision. Patella non resurfaced implants were more often revised due to pain but patella resurfaced TKAs had a higher risk for revision due to aseptic loosening of the tibial component and due to a defect polyethylene insert.

- Introduction of newer prosthesis brands with more patella friendly design together with termination in use of older brands with poor long time survival seems to have improved the survivorship of TKAs in Norway.

11. Implications and future research

Findings in Paper I and Paper III indicate that the widely accepted recommendation of routinely primary resurfacing of the patella needs to be reconsidered. A change in operation procedures towards less use of a patellar component during primary TKA could give advantages of less extensive operation procedures with better preservation of the soft tissue of the patella, lower risk of revision due to infections, shorter operation time, less periprosthetic patella fractures and lower cost (108, 109). Paper III also implies less total wear of polyethylene and less frequent loosening of tibial components. A change in use to more anatomic and patella friendly designs of total knee prostheses also seem warranted to achieve better function and durability.

Results from Paper II suggest use of UKA for patients with special need for wide range of motion. Lower total revision rates in combination with nearly equivalent pain and function scores indicate however that TKA is still an excellent option for some patients with isolated disease.

The main arguments for resurfacing the patella at the primary TKA have been to avoid anterior knee pain and possible secondary patella resurfacing. Recent studies, including Paper I indicate negligible differences between the 2 groups of treatment regarding pain and function for unrevised implants. The possible lower risk for revision for patella resurfaced TKAs observed in Paper III may be because orthopaedic surgeons are more inclined to revise a painful TKA when secondary patella resurfacing is possible. Findings in Paper III do indicate that primary patella resurfacing have increased risk for serious complications related to the patellar component. Since our findings contradict the findings in a recent review (45) our findings need to be confirmed by both RCTs and observational studies. A recent highly powered RCT (5) and a recent meta analysis (43) have confirmed our findings regarding pain and function but the topic is widely debated and more studies on primary patella resurfacing are still needed.

Further investigation on the effect of secondary resurfacing of the patella regarding pain, function, risk for re-revision and reason for re-revision is needed to justify the large number of such performed revisions.

The use of UKA has increased, partly due to the advantages of minimal invasive operation techniques. The treatment is however disputed and studies of the quality of the 2 treatment options are few and inconsistent. This is especially the case when long-term postoperative pain and function is assessed. Properly designed RCTs are currently almost absent and are missed in the process of making good decision guidelines. Further research, using several study designs, is needed to improve knowledge for better decision making regarding use of UKA. In Paper II we did observe an advantage of UKA regarding knee bending as compared to treatment by TKA which may suggest UKA in patients with special need of wide range of motion. Further research to help into ways of gaining better knee bending in TKA seems warranted. Previous findings from the NAR suggest about twice as high risk of revision for UKA as compared with patella resurfaced TKA with observations of differences in reasons of revision. Findings of differences in reason of revision between patella resurfaced and patella non resurfaced TKAs in Paper I indicate a need for a corresponding research on reasons of revision of UKA as compared to patella non resurfaced TKA.

New designs are continuously developed and need evaluation of quality regarding pain, function and survival. Further research into possible differences regarding specific reason of revision among brands and special designs is needed to further increase quality of knee arthroplasty. Data from the NAR makes it possible to unveil differences among commonly used brands but larger amounts of data is needed to faster perform quality control of recent introduced designs and for study of specific reason of revision. The Nordic Arthroplasty Register Association (NARA) has recently started their work with the establishment of a common Nordic database in order to pool data from the arthroplasty registers in Denmark, Norway and Sweden (2). This could help to faster achieve enough data to investigate such rare events.

Different diagnoses might have an effect on survival of knee implants but also on pain and function after having undergone knee arthroplasty. A recent study from NAR has observed a higher risk of revision of TKAs due to infection for patients with rheumatoid arthritis as compared to osteoarthritis of the knee (110). Further knowledge into quality of treatment options for specific diagnosis is missing and more research of this topic is needed.

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App I

Smerte og funksjon hos pasienter med kneprotese

Jeg har lest informasjonen om prosjektet og ønsker å delta i studien:

Dato for utfylling av skjema : |__|__| - |__|__| - |__|__|__|__|

Signatur _____

Spørreskjemaet er besvart av:

Meg selv ☐

eller ved hjelp av….(kryss av i ruten som gjelder)

Slektning (ektefelle, barn) ☐

God venn eller annen nærstående ☐

Annen privat person ☐

Hjemmesykepleier/hjemmehjelp ☐

Annen person, angi hvem:_____

NB! Dersom du er operert flere ganger i knærne, er det den operasjonen som er datert på klistrelappen øverst på denne siden som er aktuell for dette spørreskjemaet. Det er viktig å tenke på dette når du svarer på de spørsmålene som omhandler kneet.

Nasjonalt Register for Leddproteser
Helse Bergen HF, Ortopedisk klinikk
Haukeland Universitetssykehus
5021 Bergen

☎+47 -5597 6454/3742
+47 -5597 3749
www.haukeland.no/nrl/

I de neste 5 spørsmålene ønsker vi å vite hvordan **livssituasjonen** din var **før** du fikk den aktuelle kneprotesen (ble operert i kneet):

1. Hvordan opplevde du gangevnen din?

Jeg hadde ingen problemer med å gå omkring	Jeg hadde litt problemer med å gå omkring	Jeg var sengeliggende
☐	☐	☐

2. Hvordan klarte du personlig stell?

Jeg hadde ingen problemer med personlig stell	Jeg hadde litt problemer med å vaske meg eller kle meg	Jeg klarte ikke å vaske meg eller kle meg
☐	☐	☐

3. Hvordan klarte du dine vanlige gjøremål (f.eks. arbeid, studier, husarbeid, familie- og fritidsaktiviteter)?

Jeg hadde ingen problemer med å utføre mine vanlige gjøremål	Jeg hadde litt problemer med å utføre mine vanlige gjøremål	Jeg var ute av stand til å utføre mine vanlige gjøremål
☐	☐	☐

4. Smerter eller ubehag?

Jeg hadde verken smerte eller ubehag	Jeg hadde moderat smerte eller ubehag	Jeg hadde sterk smerte eller ubehag
☐	☐	☐

5. Angst eller depresjon?

Jeg var verken engstelig eller deprimert	Jeg var noe engstelig eller deprimert	Jeg var svært engstelig eller deprimert
☐	☐	☐

I de 5 neste spørsmålene ønsker vi å vite hvordan **livssituasjonen** din er **nå**:

6. Hvordan opplevder du gangevnen din?

Jeg har ingen problemer med å gå omkring	Jeg har litt problemer med å gå omkring	Jeg er sengeliggende
☐	☐	☐

7. Hvordan klarer du personlig stell?

Jeg har ingen problemer med personlig stell	Jeg har litt problemer med å vaske meg eller kle meg	Jeg klarer ikke å vaske meg eller kle meg
☐	☐	☐

8. Hvordan klarer du dine vanlige gjøremål (f.eks. arbeid, studier, husarbeid, familie- og fritidsaktiviteter)?

Jeg har ingen problemer med å utføre mine vanlige gjøremål	Jeg har litt problemer med å utføre mine vanlige gjøremål	Jeg er ute av stand til å utføre mine vanlige gjøremål
☐	☐	☐

9. Smerter eller ubehag?

Jeg har verken smerte eller ubehag	Jeg har moderat smerte eller ubehag	Jeg har sterk smerte eller ubehag
☐	☐	☐

10. Angst eller depresjon?

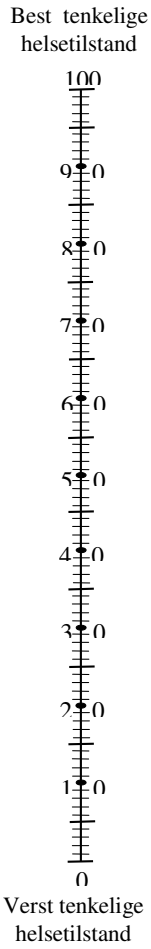
Jeg er verken engstelig eller deprimert	Jeg er noe engstelig eller deprimert	Jeg er svært engstelig eller deprimert
☐	☐	☐

Spørsmål 11 – 15 dreier seg om din helsetilstand **nå**.

Generell helsetilstand

11. For å hjelpe folk til å si hvor god eller dårlig en helsetilstand er, har vi laget en skala (omtrent som et termometer) hvor den beste tilstanden du kan tenke deg er merket 100 og den verste tilstanden du kan tenke deg er merket 0. Vi vil gjerne at du viser på denne skalaen hvor god eller dårlig helsetilstanden din er i dag, etter din oppfatning. Vær vennlig å gjøre dette ved å trekke en linje fra boksen nedenfor til det punktet på skalaen som viser hvor god eller dårlig din helsetilstand er i dag.

Din egen helsetilstand i dag



Smerte

12. Sett ett kryss på den streken som du synes tilsvarer din gjennomsnittlige smerte-opplevelse fra det opererte kneet den siste måneden:

Ingen smerte — Maksimal smerte

IııııııııIııııııııIııııııııIııııııııIııııııııIııııııııIııııııııIııııııııIııııııııIııııııııI

Lett — moderat — middels — sterk — uutholdelig

Tilfredshet

13. Sett ett kryss på den streken som du synes tilsvarer hvor fornøyd du er med operasjonsresultatet:

Fornøyd — Misfornøyd

IııııııııIııııııııIııııııııIııııııııIııııııııIııııııııIııııııııIııııııııIııııııııIııııııııI

svært fornøyd — fornøyd — middels fornøyd — misfornøyd — svært misfornøyd

Det andre kneet

14. Har du besvær fra det andre kneet?

Ja	Nei
☐	☐

Andre årsaker til gangproblemer

15. Er det andre årsaker til at du har problemer med å gå? (For eksempel smerter fra andre ledd, ryggsmerter, hjerte-karsykdom eller andre sykdommer som påvirker gangevnen din)

Ja	Nei
☐	☐

Resten av dette spørreskjemaet inneholder spørsmål om hvordan du opplever det aktuelle kneet ditt. Informasjonen vil hjelpe oss til å følge med i hvordan du har det og fungerer i ditt daglige liv. Besvar spørsmålene ved å krysse av for det alternativ du synes passer best for deg (kun ett kryss ved hvert spørsmål). Hvis du er usikker, kryss likevel av for det alternativet som føles mest riktig.

Symptom

Tenk på de **symptomene** du har hatt fra kneet ditt den **siste uken** når du besvarer disse spørsmålene.

16. Har kneet vært hovent?

Aldri	Sjelden	I blant	Ofte	Alltid
☐	☐	☐	☐	☐

17. Har du følt knirking, hørt klikking eller andre lyder fra kneet?

Aldri	Sjelden	I blant	Ofte	Alltid
☐	☐	☐	☐	☐

18. Har kneet haket seg opp eller låst seg?

Aldri	Sjelden	I blant	Ofte	Alltid
☐	☐	☐	☐	☐

19. Har du kunnet rette kneet helt ut?

Alltid	Ofte	I blant	Sjelden	Aldri
☐	☐	☐	☐	☐

20. Har du kunnet bøye kneet helt?

Alltid	Ofte	I blant	Sjelden	Aldri
☐	☐	☐	☐	☐

Stivhet

De neste spørsmålene handler om **leddstivhet**. Leddstivhet innebærer vanskeligheter med å komme i gang eller økt motstand når du bøyer eller strekker kneet. Marker graden av leddstivhet du har opplevd i kneet ditt den **siste uken**

21. Hvor stivt er kneet ditt når du nettopp har våknet om morgenen?

Ikke noe	Litt	Moderat	Betydelig	Ekstremt
☐	☐	☐	☐	☐

22. Hvor stivt er kneet ditt **senere på dagen** etter å ha sittet, ligget eller hvilt?

Ikke noe	Litt	Moderat	Betydelig	Ekstremt
☐	☐	☐	☐	☐

Smerte

23. Hvor ofte har du vondt i kneet?

Aldri	Månedlig	Ukentlig	Daglig	Hele tiden
☐	☐	☐	☐	☐

Hvilken grad av smerte har du hatt i kneet ditt den **siste uken** ved følgende aktiviteter?

24. Snu/vende på belastet kne

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

25. Rette kneet helt ut

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

26. Bøye kneet helt

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

27. Gå på flatt underlag

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

28. Gå opp eller ned trapper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

29. Om natten i sengen (smerter som forstyrrer søvnen)

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

30. Sittende eller liggende

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

31. Stående

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

Funksjon i hverdagen

De neste spørsmål handler om din fysiske funksjon. **Angi graden av vanskeligheter du har opplevd den siste uken ved følgende aktiviteter på grunn av dine kneproblemer.**

32. Gå ned trapper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

33. Gå opp trapper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

34. Reise deg fra sittende stilling

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

35. Stå stille

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

36. Bøye deg, f.eks. for å plukke opp en gjenstand fra gulvet

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

37. Gå på flatt underlag

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

38. Gå inn/ut av bil

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

39. Handle/gjøre innkjøp

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

40. Ta på sokker/strømper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

41. Stå opp fra sengen

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

42. Ta av sokker/strømper

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

43. Ligge i sengen (snu deg, holde kneet i samme stilling i lengre tid)

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

44. Gå inn og ut av badekar/dusj

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

45. Sitte

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

46. Sette deg og reise deg fra toalettet

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

47. Gjøre tungt husarbeid (måke snø, vaske gulv, støvsuge osv.)

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

48. Gjøre lett husarbeid (lage mat, tørke støv osv.)

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

Funksjon, sport og fritid

De neste spørsmålene handler om din fysiske funksjon. **Angi graden av vanskeligheter du har opplevd den siste uken ved følgende aktiviteter på grunn av dine kneproblemer.**

49. Sitte på huk

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

50. Løpe

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

51. Hoppe

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

52. Snu/vende på belastet kne

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

53. Stå på kne

Ingen	Lett	Moderat	Betydelig	Svært stor
☐	☐	☐	☐	☐

Livskvalitet

54. Hvor ofte gjør ditt kneproblem seg bemerket?

Aldri	Månedlig	Ukentlig	Daglig	Alltid
☐	☐	☐	☐	☐

55. Har du forandret levesett for å unngå å overbelaste kneet?

Ingenting	Noe	Moderat	Betydelig	Fullstendig
☐	☐	☐	☐	☐

56. I hvor stor grad kan du stole på kneet ditt?

Fullstendig	I stor grad	Moderat	Til en viss grad	Ikke i det hele tatt
☐	☐	☐	☐	☐

57. Generelt sett, hvor store problemer har du med kneet ditt?

Ingen	Lette	Moderate	Betydelige	Svært store
☐	☐	☐	☐	☐

Takk for at du tok deg tid og besvarte samtlige spørsmål!

App II

Bergen <<dato>>

«Navn»
«Adresse»
«PCODE» «POSTSTED»

Forespørsel om å delta i forskningsprosjektet "Smerte, funksjon og reoperasjoner hos pasienter med kneprotese"

Kjære «Navn»

Ved Nasjonalt Register for Leddproteser (se vedlagt informasjon om registeret) arbeider vi med et forskningsprosjekt for å kartlegge kvaliteten av ulike typer kneproteser. Hensikten med prosjektet er å finne ut hvordan det går med pasientene etter en kneproteseoperasjon, og å undersøke om enkelte protesetyper er forbundet med mer smerte og dårligere funksjon enn andre protesetyper.

I følge våre opplysninger ble du operert i **« side» kne « dato»**. Vi vil gjerne undersøke hvordan det har gått med deg i tiden etter denne operasjonen.

Nasjonalt Register for Leddproteser begynte å samle data om alle kneproteseoperasjoner i Norge i 1994. Registeret inneholder informasjon relatert til alle kneproteseoperasjoner, slik som hvilken type protese som ble satt inn, operasjonsteknikk og årsak til operasjon. Vi mangler imidlertid informasjon om smerte og funksjon før og etter operasjonen. Du er sammen med ca 2500 andre som har fått kneprotese trukket ut for å delta i denne undersøkelsen. Målet med prosjektet er å kunne gi best mulig behandling av pasienter i framtiden, og ditt svar er derfor viktig informasjon for oss.

Datatilsynet har gitt konsesjon til prosjektet og Etisk komité har godkjent prosjektet. Dersom du ønsker å hjelpe oss og delta i undersøkelsen ber vi deg være vennlig å besvare spørsmålene i vedlagt skjema så nøyaktig som mulig og returnere skjemaet i svar-konvolutten. Porto er betalt. Etter en tid vil vi sende en påminnelse til dem som ikke har returnert skjema. Dersom du ikke ønsker å besvare skjemaet ber vi deg derfor om å returnere dette ubesvart.

Nasjonalt Register for Leddproteser
Helse Bergen HF, Ortopedisk klinikk
Haukeland Universitetssykehus
5021 Bergen

The Norwegian Arthroplasty Register
Department of Orthopaedic Surgery
Haukeland University Hospital
N-5021 Bergen, Norway

+47 -5597 6454/3742
+47 -5597 3749
http://www.haukeland.no/nrl/

Alle opplysningene du gir vil bli behandlet strengt fortrolig, og opplysninger om enkelt-pasienter vil aldri offentliggjøres. Det er frivillig å delta og du har rett til å trekke deg fra undersøkelsen på et hvilket som helst tidspunkt uten at du behøver å begrunne dette.

Informasjon som allerede finnes i Nasjonalt Register for Leddproteser vil bli lagt til informasjonen du gir i denne undersøkelsen. Det kan også være aktuelt å oppdatere med ny informasjon fra registeret på et senere tidspunkt. Det er derfor ikke satt noen sluttdato for prosjektet. Dataene blir oppbevart så lenge de er aktuelle i forskningssammenheng og blir anonymisert ved deltakernes død. Databehandlingsansvarlig for dette forskningsprosjektet er klinikkoverlege Ove Furnes, leder for Nasjonalt Register for Leddproteser.

Har du spørsmål i forbindelse med utfyllingen kan du kontakte Stein Håkon Låstad Lygre, stipendiat ved Nasjonalt Register for Leddproteser, telefon 55 97 64 54 eller e-post stein.lygre@helse-bergen.no.

På forhånd takk for hjelpen!

Vennlig hilsen

Ove Furnes
Klinikkoverlege, dr. med.
Ortopedisk klinikk, Haukeland Universitetssjukehus
Leder Nasjonalt Register for Leddproteser

Stein Håkon Låstad Lygre
Stipendiat, cand. scient.

Informasjon om Nasjonalt Register for Leddproteser

I forbindelse med forskningsprosjektet "Smerte, funksjon og reoperasjoner hos pasienter med kneprotese", vil vi gi deg mer bakgrunnsinformasjon om Nasjonalt Register for Leddproteser.

Vi har fra 1987 hatt et register med opplysninger om hvert enkelt kunstig hofteledd som settes inn i Norge. Fra 1994 har registeret også omfattet informasjon om proteser satt inn i alle typer ledd, inkludert kneledd.

Hensikt med registeret: I begynnelsen av 1980-årene ble det påvist store forskjeller i resultatene for de protesetypene som var i bruk. Enkelte mindre gode proteser hadde dessverre blitt brukt i et stort antall pasienter før det lot seg gjøre å påvise de dårlige resultatene. For å forhindre liknende problemer i framtiden og for å avsløre slike protesetyper så tidlig som mulig, gikk alle norske ortopediske kirurger i 1987 sammen om å lage et landsomfattende proteseregister. Dette skulle gi raskere oversikt over resultatene av de forskjellige protesetypene. Selv om resultatene av protesekirurgi er gode i dag, er det fortsatt ønskelig med forbedring, og en del nye proteser og sementer er derfor stadig under utprøving. Registeret sammenligner nye og eldre proteser og arbeider for å fjerne dårlige proteser, sementer og operasjonsteknikker fra markedet så raskt som mulig. Registeret vil også benyttes til å undersøke forekomst, årsak og forebygging av sykdom og skade som leder til proteseoperasjon.

Opplysninger som registreres: Etter innsettelse av et kunstig ledd, fyller kirurgen ut et skjema som sendes til Nasjonalt Register for Leddproteser. Skjemaet inneholder opplysninger om pasientens fødselsnummer, diagnose, årsak til operasjon, protesetype o.a.

Datasikkerhet: Datatilsynet har gitt tillatelse til registrering av leddproteseoperasjoner. Dataene i registeret kan kobles med informasjon fra andre registre i videre forskning knyttet til leddlidelser. Bare registerets ansatte har innsyn i de personidentifiserbare dataene. Opplysninger om enkeltpasienter offentliggjøres aldri. Databehandlingsansvarlig er Helse-Bergen HF (Haukeland Sykehus i Bergen) ved øverste leder mens det daglige ansvaret er delegert til leder av registeret.

Etter Helseregisterloven har du rett til innsyn i hva som er registrert om deg. Dersom du ønsker å ta i bruk dine rettigheter etter Helseregisterloven kan du ta kontakt med Helse-Bergen HF ved øverste leder. Du har rett til å trekke deg fra registeret på et hvilket som helst tidspunkt uten at du må oppgi noen grunn. Registeret er et kontinuerlig prosjekt og det er ikke satt noen sluttdato for registeret. Ved opphør av registeret vil alle opplysninger bli slettet på en slik måte at informasjonen ikke kan gjenskapes. Etter gjeldende regler for taushetsplikt kreves det samtykke fra pasienten før sykehuset kan sende opplysninger til Nasjonalt Register for Leddproteser. Samtykkeerklæringen blir lagret på sykehuset i din journal.

App III

The Norwegian Arthroplasty Register
Department of orthopaedic surgery, Helse Bergen HF
Haukeland University Hospital
Møllendalsbakken 11, N-5021 BERGEN
Telephone +47 55973742/55973743

Personal ID (11 digits):.....

Name:.....

(Write clearly, or use patient sticker – **specify hospital**)

Hospital:.....

KNEE PROSTHESES and other joints

Insertion, exchange or removal of one or more prosthetic parts

LOCALISATION

☐1 Knee ☐6 Wrist
☐2 Ankle ☐7 Finger (report joint).....
☐3 Toe (report joint)..... ☐8 Other.....
☐4 Shoulder ☐9 Back (report level).....
☐5 Elbow

HIP (one mark only) (Bilateral operations = two forms)

☐1 Right ☐2 Left

PREVIOUS OPERATION IN INDEX JOINT (more than one mark possible)

☐0 No
☐1 Osteosynthesis for intraarticular fracture
☐2 Osteotomy
☐3 Arthrodesis
☐4 Prosthesis
☐5 Synovectomy
☐6 Other (e.g. meniscal and ligament operations).....

DATE OF OPERATION (dd.mm.yy) |__|__| |__|__| |__|__|

INDEX OPERATION (one mark only)

☐1 Primary ☐2 Reoperation (previous prosthesis)

INDEX OPERATION (CHOOSE OPTIONS UNDER A OR B)

A . Primary operation because (more than one mark possible)

☐1 Idiopatisc arthrosis
☐2 Rheumatoid arthritis
☐3 Sequelae, fracture.....
☐4 Ankylosing spondylitis
☐5 Sequelae, ligament tear
☐6 Sequelae, meniscal tear
☐7 Acute fracture
☐8 Sequelae,infection
☐9 Spondylosis
☐10 Sequelae, disc herniation surgery
☐11 Degenerative disc disease
☐12 Other .....

B . Reoperation because (more than one mark possible)

☐1 Loose proximal component
☐2 Loose distal component
☐3 Loose patella component
☐4 Dislocation of patella
☐5 Dislocation (not patella)
☐6 Instability
☐7 Malalignment
☐8 Deep infection
☐9 Fracture(near the prosthesis)
☐10 Pain
☐11 Defect polyethylene
Which part.....
☐12 Other (e.g. prev. removed prosth.).....

TYPE OF REOPERATION (more than one mark possible)

☐1 Exchange of distal component
☐2 Exchange of proximal component
☐3 Exchange of all components
☐4 Exchange of patella components
☐5 Exchange of polyethylene (e.g. tibia, ulna, humerus)
☐6 Removal of prosthestic parts
Components:... .....
☐7 Other .....
☐ Insert of patella comp.

BONE TRANSPLANT (more than one mark possible)

Proximal ☐0 No ☐1 Yes ☐2 Bone impaction
Distal ☐0 No ☐1 Yes ☐2 Bone impaction

SYSTEMIC ANTIBIOTIC PROPHYLAXIS

☐0 No ☐1 Yes, type (A).....

Dose (A).....Total number of doses.....Duration .....hrs

Possibly in combination with (B).....
Dose (B).....Total number of doses.....Duration .....hrs

OPERATION TIME (skin-to-skin) .....minutes

PEROPERATIVE COMPLICATION

☐0 No
☐1 Yes, which .....

THROMBOSIS PROPHYLAXIS

☐0 No ☐1 Yes, which type.....
Dosage day of operation.....First dose given preop. ☐0 No ☐1 Yes
Later dosage.....Assumed duration.....days
Possibly in combination with .....
Dosage..... Assumed duration.....days
Stocking ☐0 No ☐1 Leg ☐2 Leg + Thigh Assumed duration.....days
Mechanical pump ☐0 No ☐1 Foot ☐2 Leg Assumed duration.....days

MINIMAL INVASIVE SURGERY (MIS) ☐0 No ☐1 Yes

COMPUTER NAVIGATION (CAOS) ☐0 No ☐1 Yes

Type of navigation .....

ASA CLASSIFICATION (see back of the form for a definition)

☐1 Normal healthy
☐2 Mild systemic disease
☐3 Severe systemic disease
☐4 Severe systemic disease that is a constant threat to life
☐5 Moribund

PROSTHESIS (specify accurate, or place sticker on back of the form)

KNEE

PROSTHESIS TYPE

☐1 Tricondylar ☐3 Unicondylar ☐4 Patellofemoral
☐2 Bicondylar ☐5 Bi-compartmental ☐6 Hinged
☐ Medial ☐ Lateral

FEMORAL COMPONENT

Name/Type/Size.....
Catalogue number .....
Stem ☐0 No ☐1 Yes, length .....mm
Wedge ☐0 No ☐1 Yes
Stabilized ☐0 No ☐1 Yes, posterior ☐2 Yes, other
☐1 Cement with antibiotics – Name.....
☐2 Cement without antibiotics – Name .....
☐3 Uncemented

TIBIAL COMPONENT (baseplate)

Name/Type/Size.....
Catalogue number .....
Stabilized pegs ☐0 No ☐1 Yes, PE ☐2 Yes,metal ☐3 Yes,1 + 2
Extended stem ☐0 No ☐1 Yes, length..... .....mm
Wedge ☐0 No ☐1 Yes
☐1 Cement with antibiotics – Name.....
☐2 Cement without antibiotics – Name .....
☐3 Uncemented

TIBIAL COMPONENT (polyethylene insert)

Name/Type/Size.....
Catalogue number .....
Thickness..... mm
Stabilized ☐0 No ☐1 Yes, posterior ☐2 Yes, other

PATELLA COMPONENT

Name/Type/Size.....
Catalogue number .....
Metal back ☐0 No ☐1 Yes
☐1 Cement with antibiotics – Name.....
☐2 Cement without antibiotics – Name .....
☐3 Uncemented

CRUCIATE LIGAMENTS

Anterior, intact before operation ☐0 No ☐1 Yes
Anterior, intact after operation ☐0 No ☐1 Yes
Posterior, intact before operation ☐0 No ☐1 Yes
Posterior, intact after operation ☐0 No ☐1 Yes

OTHER JOINTS

PROSTHESIS TYPE

☐1 Total ☐2 Hemi ☐3 One component

PROXIMAL COMPONENT

Name/Type/Size.....
Catalogue number .....
☐1 Cement with antibiotics – Name.....
☐2 Cement without antibiotics – Name .....
☐3 Uncemented

DISTAL COMPONENT

Name/Type/Size.....
Catalogue number .....
☐1 Cement with antibiotics – Name.....
☐2 Cement without antibiotics – Name .....
☐3 Uncemented

INTERMEDIATE COMPONENT (e.g. caput humeri)

Name/Type/Size/Diameter.....
Catalogue number .....

Doctor .....
Doctor that filled in the form (name will not be registered).

I

Does patella resurfacing really matter? Pain and function in 972 patients after primary total knee arthroplasty

An observational study from the Norwegian Arthroplasty Register

Stein Håkon Låstad Lygre[1], Birgitte Espehaug[1], Leif Ivar Havelin[1,3], Stein Emil Vollset[2], and Ove Furnes[1,3]

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Background and purpose Resurfacing of the patella during primary total knee arthroplasty (TKA) is often recommended based on higher revision rates in non-resurfaced knees. As many of these revisions are insertions of a patella component due to pain, and since only patients with a non-resurfaced patella have the option of secondary resurfacing, we do not really know whether these patients have more pain and poorer function. The main purpose of the present paper was therefore to assess pain and function at least 2 years after surgery for unrevised primary non-resurfaced and resurfaced TKA, and secondary among prosthesis brands.

Methods Information needed to calculate subscales from the knee injury and osteoarthritis outcome score (KOOS) was collected in a questionnaire given to 972 osteoarthritis patients with intact primary TKAs that had been reported to the Norwegian Arthroplasty Register. Pain and satisfaction on visual analog scales and improvement in EQ-5D index score (ΔEQ-5D) were also used as outcomes. Outcomes were measured on a scale from 0 to 100 units (worst to best). To estimate differences in mean scores, we used multiple linear regression with adjustment for possible confounders.

Results We did not observe any differences between resurfacing and non-resurfacing in any outcome, with estimated differences of ≤ 1.4 units and p-values of > 0.4. There was, however, a tendency of better results for the NexGen implant as compared to the reference brand AGC for symptoms (difference = 4.9, p = 0.05), pain (VAS) (difference = 8.3, p = 0.004), and satisfaction (VAS) (difference = 7.9, p = 0.02). However, none of these differences reached the stated level of minimal perceptible clinical difference.

Interpretation Resurfacing of the patella has no clinical effect on pain and function after TKA. Differences between the brands investigated were small and they were assumed to be of minor importance.

There is an ongoing discussion regarding whether resurfacing of the patella during primary total knee arthroplasty (TKA) should be recommended or not. This has led to several observational and randomized studies, and eventually to meta-analyses (Forster 2004, Nizard et al. 2005, Pakos et al. 2005, Parvizi et al. 2005). The meta-analyses have included studies in which the main outcomes were risk of reoperation, level of anterior knee pain, and other knee scores. None of these reviews found firm evidence regarding superiority of resurfaced or non-resurfaced prostheses. However, these studies still reported indications of better results for resurfaced prostheses, mainly because of a lower risk of reoperation for resurfaced implants. A critical appraisal of available evidence found methodological limitations in all the studies examined and neither treatment option was clearly superior (Calvisi et al. 2009).

A previous observational study from the Norwegian Arthroplasty Register (NAR) found a 1.3 times higher but not statistically significantly elevated (p = 0.2) overall rate of revisions for non-resurfaced prostheses (Furnes et al. 2002). There was, however, a significantly (2.5-fold) higher rate of revision for infection in knees with resurfaced prostheses, while non-resurfaced prostheses had a 5.7-times higher risk of revision because of pain. Many of the revisions for pain involved addition of a patella component to the native patella. Since secondary resurfacing is an available option only in non-resurfaced knees, we do not really know whether there were any differences in perception of pain between the two treatment groups. Further investigation of patients' subjective pain and function would therefore be of value when assessing the quality of the two types of TKA.

The major goal of the present study was therefore to investigate whether the levels of function and pain are different for patella resurfaced and non-resurfaced, unrevised, total knee

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prostheses, and our secondary aim was to investigate whether function and pain vary with different prosthesis brands.

Patients and methods

The Norwegian Arthroplasty Register (NAR)

Practically all patients (99%) who receive a primary arthroplasty of the knee are reported to NAR (Espehaug et al. 2006). The register was established in 1987 as a hip prosthesis register, but from 1994 it was extended to cover all artificial joints including knee arthroplasty (Havelin et al. 2000, Furnes et al. 2002). NAR receives information directly from the orthopedic surgeons. Information on patient-related outcome such as pain and function is not reported to the register. To assess patients' perception of pain and function after undergoing TKA, we therefore invited selected individuals registered in the NAR to participate in a postal survey.

Participants

Possible participants were patients registered in the NAR with at least 1 unrevised cemented primary TKA inserted due to gonarthrosis. The individuals should be aged 85 years or less, and the operation should have been performed at least 2 years prior to the survey to ensure that the result of the intervention had stabilized (Murray and Frost 1998, Burnett et al. 2004, Lingard et al. 2004). Only patients with a prosthesis brand already registered with at least 100 resurfaced and 100 non-resurfaced implants were eligible for inclusion. All patients with a resurfaced implant meeting these criteria were invited to participate in the study (134 with AGC, 186 with Genesis I, 238 with LCS, and 112 with NexGen). Since the use of non-resurfaced prostheses has increased and the use of resurfaced prostheses has decreased over the years in Norway, the selection of patients with non-resurfaced prostheses was matched according to brand and year of operation to ensure compatibility (134 AGC, 180 Genesis I, 238 LCS, and 62 NexGen). It was not possible to match all resurfaced NexGen prostheses with corresponding non-resurfaced prostheses since resurfaced prostheses were almost exclusively used early in the period. This led to similar numbers of patients with resurfaced (n = 670) and non-resurfaced (n = 614) prostheses, making a total of 1,284 individuals. A detailed account of the selection procedure is given in Figure 1.

After 2 months, a reminder was sent out to those who failed to respond to the initial questionnaire. In all, 972 patients completed the questionnaire, 305 either declined or did not respond, and 7 patients had died or were unable to be located by the post office.

Questionnaire

The questionnaire consisted of the valid and reliable self-administrated instrument for calculation of the knee-specific knee injury and osteoarthritis outcome score (KOOS)

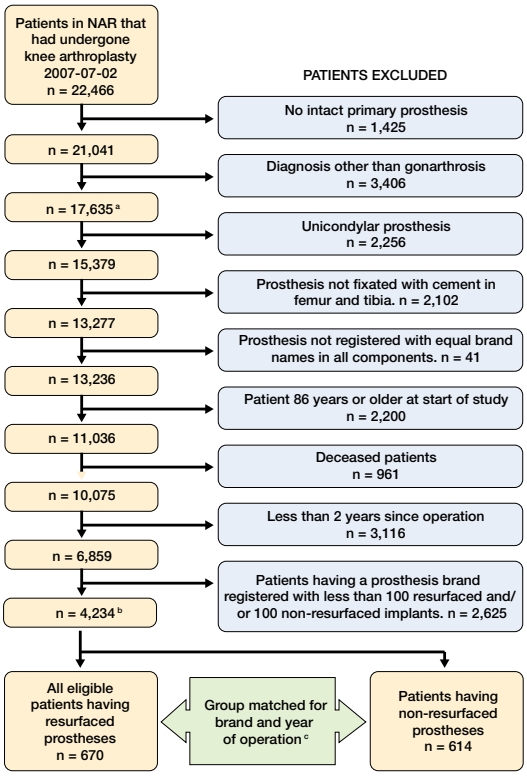

Figure 1. Description of the selection procedure.
[a] For patients with bilateral intact primary prostheses, only the most recent with gonarthrosis as diagnosis was eligible for inclusion.
[b] Genesis I, AGC, LCS and NexGen were eligible for inclusion.
[c] Resurfaced and non-resurfaced prostheses were matched for brand and year of operation. This led to exclusion of 2,950 patients with non-resurfaced implants.

(Roos and Lohmander 2003). A Norwegian translation from the Swedish version of KOOS was made for this study, and has been approved as the official Norwegian translation. A description of the validation process of this translation can be found at www.koos.nu.

To assess the potential effect of general health factors, the questionnaire also included questions needed to calculate the Charnley category applied to knee arthroplasty patients and the valid and reliable instrument for health quality measurement, the EQ-5D index score (Greiner et al. 2003). Information needed for calculation of preoperative and current EQ-5D index scores was given by the patients at the time when filling in the form. In addition, questions regarding patients' "satisfaction with the surgery", and degree of "pain from the operated knee" were included. With the exception of the latter two, where a visual analog scale (VAS) was used, all

questions had standardized answer options given as Likert boxes.

The study was approved by the Norwegian Data Inspectorate, Norwegian Social Science Data Services, and the Regional Committee for Research Ethics in Western Norway (date of issue: 02/23/2006, registration number: 046.06). The patients received the questionnaire together with an information letter, and returned the questionnaire to the register with a signed consent to participate in the study.

Outcome measures

KOOS, which was used as primary outcome on patients' perception of pain and function, consists of 42 individual questions, making up 5 subscales: Pain, other symptoms (Symptoms), activities in daily living (ADL), function in sport and recreation (Sport&Rec) and knee-related quality of life (QOL). Only the previous week was to be considered when answering most of the questions, and each question received a score from 0 to 4. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) was calculated for each subscale. Calculation of the scores and treatment of missing data were done in accordance with the description at www.koos.nu.

In addition, we used "pain from the operated knee" (Pain(VAS)) and "satisfaction with the operation" (Satisfaction (VAS)) as outcomes. In the analyses the VAS scores were reversed, with 100 indicating the best possible state and 0 indicating the worst possible state. Finally, improvement in quality of life (ΔEQ-5D), calculated as the difference between the present and preoperative EQ-5D index scores multiplied by 100, was used as outcome.

Sensitivity analysis of potential bias due to different revision criteria from resurfaced and non-resurfaced implants

A bias may have been introduced if a non-resurfaced prosthesis was more likely to be revised than resurfaced (Australian Orthopaedic Association National Joint Replacement Registry. Annual Report. 2008, Furnes et al. 2002). This would have given a falsely low proportion of patients with poor results in that group. The potential effect of this was assessed in a sensitivity analysis where we included information also from patients with revised prostheses. This was possible due to the availability of information from another survey comprising all patients registered in the NAR with revised implants.

The original study material consisted of all intact resurfaced knees in the register that met the inclusion criteria, and about the same number of intact non-resurfaced knees matched on year of operation. To these we added all revised resurfaced knees that met the inclusion criteria (n = 23) and varying numbers of revised non-resurfaced implants. The latter were randomly selected from the 148 revised non-resurfaced knees that met the inclusion criteria. The Mann-Whitney test was used to compare pain and discomfort between the groups using the specific EQ-5D question regarding pain and discomfort (1 = best, 3 = worst). This information related to when the questionnaire was filled in for patients with intact prostheses, while patients with a revised prosthesis gave information in retrospect regarding their situation before the revision.

Statistics

Minimal perceptible clinical difference is 8–10 units for KOOS subscales (Roos and Lohmander 2003) and 9–12 units on a visual analog scale (Ehrich et al. 2000). To have an 80% chance of detecting a significant (at the 2-sided 5% level) 10-point difference between the 2 groups in the mean KOOS subscales, with an assumed standard deviation of 20, 64 individuals in each treatment group were required. Thus, to ensure good representation for both treatment groups, a restriction on operation volume of each brand was set to at least 100 registered resurfaced and 100 registered non-resurfaced operations.

Differences in response rates were tested with the chi-squared-test. To estimate differences in mean outcome scores for non-resurfaced and resurfaced prostheses, we used multiple linear regression with adjustment for possible confounding by age (< 65, 65–70, 70–80, > 80), sex, preoperative EQ-5D index score (< 30, 0.30–0.69, > 0.69), Charnley category (A, B, C), and brand of prosthesis. We also investigated any differences within a particular prosthesis brand. Adjusted differences in mean values between resurfaced and non-resurfaced prostheses are presented with 95% confidence intervals (95% CIs) and p-values.

Multiple linear regression was also used to investigate any possible association between prosthesis brand and mean outcome scores. In these analyses, we also adjusted for time since operation. Adjusted differences in mean scores are presented with p-values relative to the AGC prosthesis brand. 9 patients who did not have the AGC Universal design were excluded from this analysis (5 resurfaced and 4 non-resurfaced).

In addition, all analyses were performed excluding prostheses with posterior cruciate ligament sacrificing design and also excluding constrained condylar prostheses (18 prostheses: 10 resurfaced and 8 non-resurfaced).

In the analyses, p-values less than 0.05 were considered statistically significant. The analyses were performed using SPSS statistical software version 15.0.0.1.

Results

We received completed questionnaires from 972 (76%) of the 1,284 individuals selected for the study. Thus, the study included 504 knees with resurfaced TKA and 468 knees with non-resurfaced TKA. The response rate was similar for non-resurfaced prostheses (76%) and resurfaced prostheses (75%) (p = 0.7), but it was lower for female patients (73%) than for male patients (82%) (p = 0.001). It was also less for older

Table 2. Patient characteristics by prosthesis type and prosthesis brand

	AGC	Genesis I	LCS	NexGen	Total
No. of prostheses					
Resurfaced	99	132	184	89	504
Non-resurfaced	106	134	180	48	468
All	205	266	364	137	972
No. of hospitals					
Resurfaced	16	18	9	3	40
Non-resurfaced	12	21	19	7	47
All					56
Men %					
Resurfaced	32	25	32	29	30
Non-resurfaced	32	29	24	40	29
All					29
Mean (SD) age (years) [a]					
Resurfaced	76 (7.2)	77 (7.1)	75 (8.1)	74 (8.1)	76 (7.7)
Non-resurfaced	76 (8.6)	78 (6.0)	76 (7.6)	74 (9.3)	76 (7.7)
All					76 (7.7)
Mean (SD) time since operation (years) [b]					
Resurfaced	7.2 (2.5)	9.2 (1.7)	6.5 (1.8)	5.2 (1.9)	7.1 (2.4)
Non-resurfaced	7.1 (2.4)	9.2 (1.6)	6.5 (1.8)	3.6 (0.9)	7.1 (2.5)
All				7.1 (2.4)	
Charnley Category C %					
Resurfaced	57	69	61	66	63
Non-resurfaced	66	65	69	61	66
All					65
Mean (SD) preoperativ EQ-5D index score					
Resurfaced	0.48 (0.23)	0.47 (0.22)	0.44 (0.23)	0.45 (0.23)	0.46 (0.23)
Non-resurfaced	0.47 (0.20)	0.46 (0.22)	0.48 (0.23)	0.43 (0.20)	0.47 (0.22)
All					0.46 (0.22)

[a] Mean age when completing the questionnaire.
[b] Mean time since operation when completing the questionnaire.

Table 3. Mean difference [a] in outcome between resurfaced and non-resurfaced prostheses

Prosthesis brands	Pain		Symptoms		ADL		Sport&Rec		QOL		Pain(VAS)		Satisfaction(VAS)		ΔEQ-5D	
	Δ	p	Δ	p	Δ	p	Δ	p	Δ	p	Δ	p	Δ	p	Δ	p
Total [b]	0.8	0.6	0.2	0.9	1.4	0.4	1.4	0.5	–0.2	0.9	-0.1	0.9	–0.7	0.7	0.4	0.9
AGC [c]	0.8	0.8	0.0	1.0	2.1	0.5	0.2	1.0	–1.9	0.6	–0.4	0.9	–1.2	0.7	1.4	0.8
Genesis I [c]	4.0	0.2	0.7	0.8	3.2	0.3	1.8	0.6	1.0	0.8	2.5	0.4	1.1	0.7	6.3	0.1
LCS [c]	–1.3	0.6	–0.1	1.0	0.9	0.8	2.9	0.4	1.0	0.8	–1.3	0.6	–2.5	0.4	–4.1	0.2
NexGen [c]	–0.6	0.9	–1.3	0.7	–4.0	0.4	–4.3	0.4	–4.3	0.4	–1.7	0.6	0.0	1.0	–1.3	0.8

[a] Differences (Δ) = mean scores among non-resurfaced prostheses minus mean scores among resurfaced prostheses.
[b] Differences in mean are adjusted for age, sex, preoperative EQ-5D index score (except for ΔEQ-5D), Charnley category and prosthesis brand.
[c] Differences in mean are adjusted for age, sex, preoperative EQ-5D index score (except for ΔEQ-5D) and Charnley category.

patients: 88% for those less than 65 years of age and 67% for those older than 80 ($p < 0.001$). Response rates for each brand of prosthesis varied between 71% and 79% (Table 1, see Supplementary data). Male patients constituted 29% of the material and the mean age at the time of completing the questionnaire was 76 (SD 8) years. Table 2 gives the distribution of patient characteristics by prosthesis type and prosthesis brand.

We observed no differences between resurfaced and non-resurfaced prostheses for any of the eight outcomes, with all p-values > 0.4 (Table 3 and Figure 2); nor did we find evidence of any differences between the 2 treatment options when analyses were performed within each brand of prosthesis (Genesis I, AGC, LCS, and NexGen) (Table 3 and Figure 3).

Since non-resurfaced and resurfaced prostheses generally showed similar results, we did not differentiate between the two treatment groups when investigating possible effects on pain and function of prosthesis brand, sex, age, Charnley Category, time since operation, and preoperative EQ-5D index score (Table 4) (Figure 4, see Supplementary data). Genesis I and LCS did not perform statistically significantly different from the reference brand AGC, but there was a tendency of

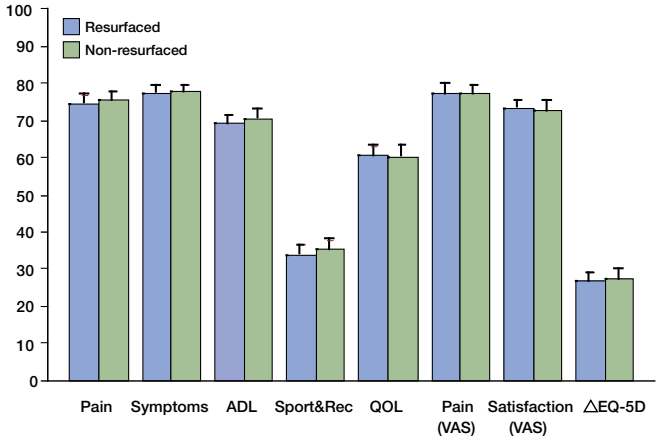

Figure 2. Mean outcome scores for resurfaced and non-resurfaced prostheses. The first 5 outcomes from the left represent the KOOS subscales. Adjustments were made for age, sex, preoperative EQ-5D index score (except for the outcome ΔEQ-5D), Charnley category, and prosthesis brand. Outcomes were measured on a scale from 0 to 100 units (worst to best).

poorer results for the Genesis I for all outcomes. NexGen had a tendency of better results than AGC, but this was only statistically significant for the outcomes Symptoms (difference = 4.9, p = 0.05), Pain(VAS) (difference = 8.3, p = 0.004) and Satisfaction(VAS) (difference = 7.9, p = 0.02).

We found that male patients performed statistically significantly better than females in all outcomes except for the ΔEQ-5D. Charnley group A performed better than both group B and C for all outcomes, while there was a positive effect of higher age except for the 2 KOOS subscales ADL and Sport&Rec and the outcome Satisfaction(VAS). Improvement as measured by ΔEQ-5D decreased, however, with increasing age (Table 4).

Exclusion of prostheses with posterior cruciate ligament sacrificing design and of constrained condylar prostheses gave only minor changes to the results above.

Sensitivity analysis

The mean pain and discomfort score (EQ-5D) was 1.6 both for intact resurfaced and non-resurfaced prostheses (original material). For resurfaced knees, the mean score increased to 1.7 when all revised knees (n = 23) were included. The mean score was also 1.7 for non-resurfaced knees when the same number of revised knees was added (Table 5). No statistically significant difference in mean scores was observed until the number of revised knees added was more than 3 times higher for non-resurfaced knees (n > 69) than for resurfaced knees (Table 5).

Discussion

We have studied performance of TKA based on data from the NAR. Using self-reported degree of pain and function as outcome, our analyses did not show any differences between resurfaced and non-resurfaced primary total knee prostheses 2 years or more after surgery. Differences between prosthe-

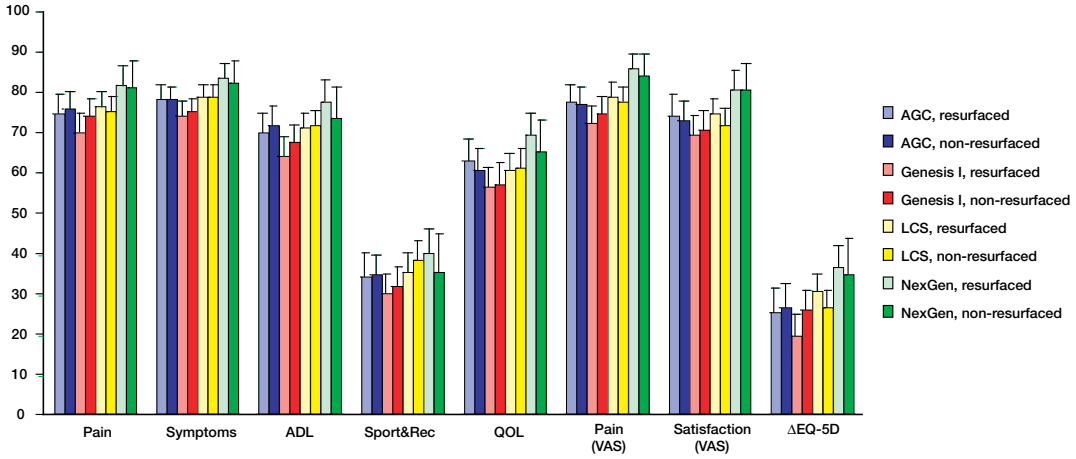

Figure 3. Mean outcome scores for resurfaced and non-resurfaced prostheses, for each brand of prosthesis. The first 5 outcomes from the left represent the KOOS subscales. Adjustments were made for age, sex, preoperative EQ-5D index score (except for the outcome ΔEQ-5D), and Charnley category. Outcomes were measured on a scale from 0 to 100 units (worst to best).

Table 4. Effects on mean outcome of gender, age, preoperative EQ-5D index score, time since operation, Charnley category and prosthesis brand

Risk predictors	n	Pain Δ [a]	p	Symptoms Δ [a]	p	ADL Δ [a]	p	Sport&Rec Δ [a]	p	QOL Δ [a]	p	Pain(VAS) Δ [a]	p	Satisfaction(VAS) Δ [a]	p	ΔEQ-5D Δ [a]	p
Sex																	
Male	284	ref		ref		ref		ref		ref		ref		ref		ref	
Female	679	−8.6	e	−6.5	e	−10.1	e	−15.5	e	−8.1	e	−6.1	e	−6.7	e	−2.9	0.2
Age (years) [b]																	
<65	94	ref		ref		ref		ref		ref		ref		ref		ref	
65–70	108	7.1	0.05	4.3	0.1	3.5	0.3	1.2	0.8	2.7	0.5	4.0	0.2	0.9	0.8	−0.2	1.0
70–80	396	7.9	0.01	6.3	0.01	1.9	0.5	−1.5	0.7	3.1	0.4	7.3	0.01	1.9	0.6	−4.6	0.2
>80	365	10.9	e	10.0	e	3.5	0.3	1.8	0.6	8.4	0.02	8.5	0.004	3.0	0.4	−11.5	0.002
Preoperative EQ-5D index score [c]																	
<0.30	286	ref		ref		ref		ref		ref		ref		ref			
0.30–0.69	469	8.6	e	4.7	0.002	7.2	e	3.8	0.09	6.0	0.006	5.9	e	3.2	0.1		
>0.69	148	11.3	e	9.2	e	12.1	e	9.1	0.004	13.3	e	9.3	e	7.5	0.006		
Years since operation		−0.5	0.2	−0.3	0.4	−0.6	0.2	0.2	0.7	−0.1	0.8	−0.1	0.9	0.2	0.8	−0.7	0.2
Charnley Category [c]																	
A	195	ref		ref		ref		ref		ref		ref		ref		ref	
B	128	−13.1	e	−9.1	e	−11.2	e	−17.8	e	−16.8	e	−13.2	e	−8.7	0.004	−11.2	0.001
C	585	−9.6	e	−6.6	e	−14.5	e	−15.3	e	−13.7	e	−10.6	e	−7.3	0.001	−5.9	0.02
Prosthesis brand																	
AGC [d]	196	ref		ref		ref		ref		ref		ref		ref		ref	
Genesis I	266	−1.5	0.5	−2.9	0.2	−2.6	0.3	−3.1	0.3	−4.2	0.2	−3.2	0.2	−3.1	0.2	−0.6	0.8
LCS	364	1.2	0.6	1.2	0.5	0.9	0.7	3.4	0.2	−0.1	1.0	1.9	0.4	0.5	0.8	1.8	0.5
NexGen	137	5.4	0.08	4.9	0.05	4.0	0.2	3.9	0.3	6.5	0.07	8.3	0.004	7.9	0.02	5.9	0.1

[a] Differences in mean scores are adjusted for all other variables in a linear regression model.
[b] Age when completing the questionnaire.
[c] Information on preoperative EQ–5D index score was not given by 60 patients and on Charnley category by 55 patients.
[d] 9 patients not having the AGC Universal design were excluded (5 resurfaced and 4 non-resurfaced).
[e] p-value < 0.001.

Table 5. Sensitivity analysis of potential bias due to different revision criteria from resurfaced and non-resurfaced implants

Ratio [a]	Non-resurfaced Primary (n)	Revised (n)	Mean pain [b]	Resurfaced Primary (n)	Revised (n)	Mean pain [b]	Mann-Whitney p-value
– [c]	468	–	1.6	504	–	1.6	0.9
– [d]	–	145 [e]	2.7	–	23	2.6	0.7
1.0	468	23	1.7	504	23	1.7	1.0
1.3	468	30	1.7	504	23	1.7	0.7
1.5	468	35	1.7	504	23	1.7	0.6
2.0	468	46	1.7	504	23	1.7	0.5
2.5	468	58	1.8	504	23	1.7	0.1
3.0	468	69	1.8	504	23	1.7	0.07
3.5	468	81	1.8	504	23	1.7	0.02

[a] Approximate ratio between number of revised non-resurfaced and revised resurfaced implants.
[b] Score from the EQ-5D question regarding pain and discomfort (1=best,3=worst)
[c] Original data; patients with unrevised implants.
[d] Additional data; patients with revised implants. Among the 23 revised resurfaced prostheses the most common reasons for revision were loose distal component (n=11) and pain (n=7). Among the 145 revised non-resurfaced prostheses the most common reasons for revision were loose distal component (n=38), instability (n=13), deep infection (n=14) and pain (n=72). More than one reason for revision may have been given.
[e] 3 of the 148 available patients with revised non-resurfaced implants failed to answer the specific EQ-5D question.

sis brands were small and did not reach the required level of minimal perceptible clinical difference relative to the reference brand, AGC.

Strengths and limitations

The strength of our study is that use of data from a nationwide register with almost complete coverage gives us the opportunity to include several implant designs and to involve large numbers of surgeons and hospitals performing various amounts of surgery. Since this gives us information from a broad spectrum of implants, surgical techniques, surgeon experience, and procedures, the validity of the results may be more global than that from randomized controlled trials (RCTs).

Despite having several advantages, observational studies may be affected by limitations that are absent in well-designed RCTs. We have treated the most common confounding factors by

using matching procedures and adjustments in the statistical model, but there may still have been variables that were not taken into account. Different criteria in the decision making by the surgeons might possibly lead to confounding. Imbalanced differences between the groups are, however, not very likely in Norway as most surgeons—for specific time periods—have used one of the two treatment options almost exclusively.

Selection bias is not very likely since the group of non-responding individuals was acceptably small and there were no statistically significantly different response rates between the most important subgroups. It is difficult to point out important factors that could have characterized the group of non-responding individuals and among those who were not eligible for inclusion, such as patients who had died.

Bias may, however, have been introduced if the study included a falsely low proportion of individuals with poor results among the non-resurfaced patients. This might be the case if non-resurfaced knees were revised more often than resurfaced knees, making such patients ineligible for inclusion in the study. This was investigated in a sensitivity analysis where information from varying numbers of revised prostheses were added to the original material. However, we observed no statistically significant difference between the treatment groups until more than 3 times as many revised non-resurfaced prostheses (n > 69) as revised resurfaced prostheses (n = 23) had been added to the material. Such a substantial difference is not supported by the results of large observational studies (Australian Orthopaedic Association National Joint Replacement Registry. Annual Report. 2008, Furnes et al. 2002), with a 30% higher rate of revision for non-resurfaced prostheses.

Since every outcome in our study, except the ΔEQ-5D, was based on the patients' perception of pain and function experienced during the previous week, we assume that the risk of recall bias was negligible.

Explanations/mechanisms

Our results suggest that resurfacing of the patella has no effect on patients' perception of pain and function in knees with unrevised implants. This is in contrast to the existing practice in many countries where the use of a patella component is recommended, often based on higher revision rates in non-resurfaced prostheses. The higher revision rates with non-resurfaced implants may, however, be due to possible overuse of the uniquely available option of secondary resurfacing of the patella if the knee is painful, and do not necessarily indicate poorer performance regarding pain and function.

Estimated differences between prosthesis brands (as compared to the reference brand, AGC) were small and less than the stipulated minimal perceptible clinical difference of 8–10 units for KOOS subscales (Roos and Lohmander 2003) and 9–12 units for outcomes on a visual analog scale (Ehrich et al. 2000). The somewhat better results with the newer NexGen implant are interesting, but there was a limited number of hospitals and surgeons involved using NexGen. Less prosthesis wear and improved surgical techniques over the years may, however, explain some of the differences observed since mean time since operation was lower for knees with a NexGen implant. We have, however, adjusted for the time since operation in the statistical models. A possible positive effect of the search for an optimal anatomical implant during the design of the NexGen implant cannot be discounted.

Male patients performed better than female patients on all postoperative outcome measures, but we did not observe any gender differences in improvement based on pre- and postoperative EQ-5D index scores (ΔEQ-5D). While the EQ-5D index score is not necessarily strongly related to having undergone TKA, this finding is in accordance with other studies that have shown that improvement in knee scores is similar for females and males after TKA (Bourne et al. 2007), but that women perform more poorly in preoperative scores and thereby also in postoperative scores (Hawker et al. 2000, Lingard et al. 2004, Ritter et al. 2008). Some manufacturers claim that newer implants specifically designed to match a woman's knee will improve the results in female patients. This suggestion has been questioned (Ritter et al. 2008), but we could not investigate this issue as gender-specific implants were not included in this study. The observed positive effect of increasing age on outcomes that are strongly related to pain has also been seen in other studies (Elson and Brenkel 2006, Singh et al. 2008). Possible explanations such as higher expectations of younger patients, and more activity and therefore increased prosthesis wear have been suggested (Elson and Brenkel 2006). We also found that patients with unilateral knee disease and without comorbidity (Charnley category A) performed better than patients with bilateral knee disease and other systematic disease (Charnley category B and C). This supports the findings of a study based on data from the Swedish Knee Arthroplasty Register (Dunbar et al. 2004) where a modified Charnley category was found to have a significant effect on outcome questionnaires after knee arthroplasty. This emphasizes the need to take comorbidity into account when performing such outcome studies.

Future research

Even though studies based on data from registers give a unique opportunity to discover and indicate underlying or hidden mechanisms, their limitations underscore the need for more studies. Further research performed by the use of both observational studies and clinical trials is therefore needed in order to confirm our findings, especially since our results contradict with findings in previous studies (Forster 2004, Nizard et al. 2005, Pakos et al. 2005, Parvizi et al. 2005).

Comparison with other studies

Recent studies not included in the meta-analyses that have focused on outcomes other than revision rates, have differed in their conclusions regarding recommendation to use a patella

component. 2 RCTs did not find any differences between the 2 treatment options when the Miller-Galante II system was used (Campbell et al. 2006, Burnett et al. 2007). This contrasts with the findings on Miller-Gallante II in a previous RCT study (Wood et al. 2002) included in 3 meta-analyses, where resurfacing was found to be the best choice of treatment. Another RCT investigating the Profix implant did not find evidence of any treatment option being superior to the other (Smith et al. 2008). Neither did a recent multicenter RCT, involving 1715 patients, observe any difference between paella resurfaced and non-resurfaced prostheses 2 years after surgery (Johnston et all. 2009). An open prospective multicenter study using the NexGen prosthesis concluded with a recommendation of resurfacing of the patella (Tabutin et al. 2005). In a recent study, an expected value decision analysis was used to determine the best pathway for treatment of the patella during TKA (Helmy et al. 2008). Based on data from seven RCTs, primary resurfacing of the patella was recommended.

Few studies make use of the advantages of data available from arthroplasty registers, but an 8-year-old study from the Swedish Knee Arthroplasty Register showed that resurfacing was the best choice of treatment as measured by rate of patient satisfaction with the result of the intervention, but this advantage decreased with the length of time that had passed since operation (Robertsson et al. 2000).

Possible implications

Our study indicates a need to reconsider the widely accepted recommendation of primary resurfacing of the patella. A change in operation procedures towards less use of a patella component during primary TKA might be advisable. This will probably give the advantages of less extensive operation procedures with better preservation of the soft tissue of the patella, lower risk of revision due to infections, lower risk of patella fractures, shorter operation time, and lower cost (Furnes et al. 2002, Chalidis et al. 2007).

Conclusion

The results of our study indicate that resurfacing of the patella has no clinical effect on pain and function after a TKA. The differences between the brands investigated were small and they were assumed to be of little importance clinically.

SHL: study design, data collection, and statistical analysis. BE: study design and statistical supervision. LIH: medical supervision. SEV: study design and statistical supervision. OF: study design and medical supervision. All authors were involved in the writing of the manuscript.

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No competing interests declared.

Supplementary data. Table 1 and Figure 4 can be found on the www.actaorthop.org website, identification number 3061/09.

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Table 1 Response rates for prosthesis type and brand

		Eligible for study	Included in study	Response rate %
Resurfaced				
	AGC	134	99	74
	Genesis I	186	132	71
	LCS	238	184	77
	NexGen	112	89	79
	All	670	504	75
Non resurfaced				
	AGC	134	106	79
	Genesis I	180	134	74
	LCS	238	180	76
	NexGen	62	48	77
	all	614	468	76
Total		1284	972	76

Figure 4

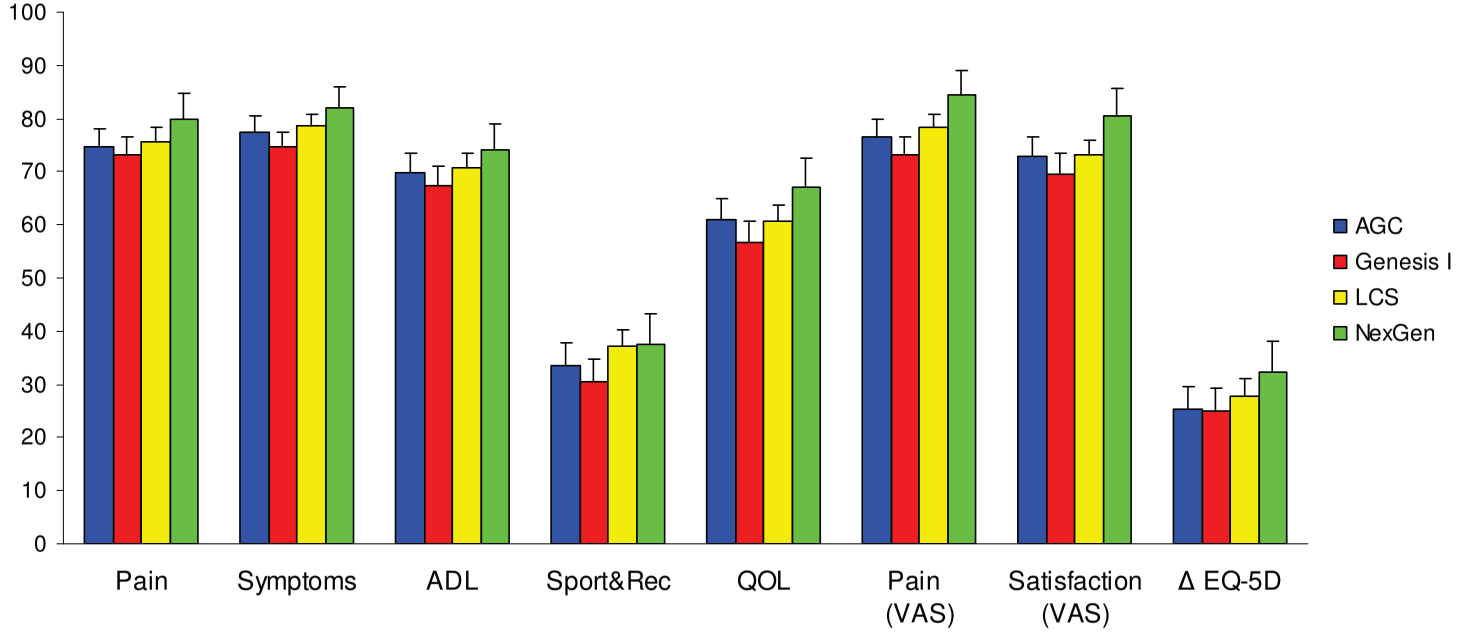

Figure 4. Mean outcome scores for all prosthesis brands (resurfaced and non resurfaced pooled together). The first 5 outcomes from the left represent the KOOS subscales. Adjustments were made for age, sex, preoperative EQ-5D index score (except for ΔEQ-5D), Charnley category and time since operation. Outcomes were measured on a scale from 0 (worst) to 100 (best) units. 9 patients not having the AGC Universal design were excluded from this analyses (5 resurfaced and 4 non resurfaced).

II

Pain and function in patients with primary unicompartmental and total knee arthroplasty.

A survey of 1344 patients reported to the Norwegian Arthroplasty Register.

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ABSTRACT

Background

Unicompartmental knee arthroplasty has received renewed interest; however, its short-term advantages over total knee arthroplasty should be weighed against a higher risk of reoperation. Information regarding pain and function after unicompartmental and total knee arthroplasty is therefore needed.

Methods

Patient-reported pain and function were collected at least two years after the operation in postal questionnaires from 1344 patients with arthritis reported to the Norwegian Arthroplasty Register with intact primary total knee arthroplasty (n=972) or unicompartmental knee arthroplasty (n=372). Outcomes (0=worst, 100=best) assessed were the five subscales from the Knee Injury and Osteoarthritis Outcome Score, Pain(visual analogue scale), Satisfaction(visual analogue scale), and change from pre- to postoperative health-related quality-of-life measure EuroQol-5D index score. Differences were analyzed with multiple linear regression, adjusted by age, gender, Charnley category and time since operation. We also studied all forty-two questions from the Knee Injury and Osteoarthritis Outcome Score as outcomes. To be regarded as clinically significant the differences needed to be greater than eight units for the Knee Injury and Osteoarthritis Outcome Score outcomes, 10 for visual analogue scales and 0.4 for the detailed Knee Injury and Osteoarthritis Outcome Score questions.

Results

Unicompartmental knee arthroplasty performed better than total knee arthroplasty for ”Symptoms” (adjusted mean difference, 2.7; p=0.04), “Function in Daily Living” (adjusted

mean difference, 4.1; p=0.01) and “Function in Sport and Recreation” (adjusted mean difference, 5.4; p=0.006).

Of the forty-two analyses of the detailed questions, four differences were statistical significant. These differences were in favor of unicompartmental knee arthroplasty, but only the question regarding “ability of bending of the knee”, reached the level of clinical significance.

Conclusions

We found only small or no differences in pain and function between unicompartmental knee arthroplasty and total knee arthroplasty investigated at least two years following surgery. Patients with unicompartmental knee arthroplasty had however fewer problems with activities that involved bending of the knee.

Level of Evidence

Therapeutic Level II

INTRODUCTION

Unicompartmental knee arthroplasty (UKA) has received renewed interest in recent years. Placement of a UKA involves less soft tissue dissection, less removal of bone mass and better preservation of knee anatomy. Expected short-term advantages such as shorter hospitalization and faster recovery have been reported when compared with total knee arthroplasty (TKA)[1,2]. Less morbidity in the form of less postoperative pain, less infection, less thromboembolic disease and better range of motion (ROM) have also been observed following UKA[1,3-5]. The longevity of UKA's is also found to compare well with TKA's in single center studies[2,6] and in randomized clinical trials (RCT)[7]. Indications for use of UKA are however debated as UKAs have been reported to be associated with approximately twice as many reoperations as compared with TKAs in register studies[5,8,9]. The higher revision rates for UKA have been shown to be mainly due to aseptic loosening, pain and periprosthetic fracture[5]. Since the better short-term results of UKA should be weighed against the possible higher risk of revision[5], more knowledge of patient's perception of pain and function after knee arthroplasty is needed.

The aim of this study was to compare level of pain and function among patients with unrevised TKA and UKA at least two years following surgery.

MATERIALS AND METHODS

The Norwegian Arthroplasty Register

Practically all patients (99%) receiving a primary arthroplasty of the knee are reported to the Norwegian Arthroplasty Register (NAR)[10]. The register was established in 1987 as a hip prosthesis register, but from 1994 it was extended to all artificial joints including knee arthroplasty[11,12]. The NAR receives information directly from orthopedic surgeons. Information on patient related outcome such as pain and function is not reported to the

register and was therefore obtained in this study through a mail survey among selected patients reported to the register.

Participants

Possible participants were patients registered in the NAR with at least one unrevised cemented primary UKA or TKA inserted due to primary osteoarthritis. The individuals were aged 85 years or less, and the operation was performed at least two years prior to the survey to ensure that the result of the intervention had stabilized[13-15].

A restriction was set on operation volume for each prosthesis brand with at least 100 registered operations. All eligible patients with a Genesis Uni (Smith and Nephew, Memphis, Tennessee)(n=136) or a Miller-Galante all polyethylene tibial Uni (Zimmer, Warsaw, Indiana)(n=129) prosthesis were included. To limit the number of patients asked for participation in the survey, 200 patients with Oxford III (Biomet, Bridgend, South Wales, United Kingdom) prostheses were selected randomly among 956 eligible patients. In total 465 individuals with a UKA were asked to participate. Total knee prosthesis brands were included if registered with at least 100 patella resurfaced and 100 non resurfaced implants. The total knee prosthesis brands were AGC (Biomet), Genesis I (Smith and Nephew), LCS (DePuy, Leeds, United Kingdom) and NexGen (Zimmer). All available resurfaced prostheses were included (134 AGC, 186 Genesis I, 238 LCS and 112 NexGen) while a subset of non-resurfaced prostheses (134 AGC, 180 Genesis I, 238 LCS and 62 NexGen) were randomly chosen from all eligible non resurfaced implants (715 AGC, 931 Genesis I, 1766 LCS and 152 NexGen), and were group matched on prosthesis brand and year of operation. It was not possible to match all resurfaced patella NexGen prostheses with corresponding non resurfaced patella NexGen prostheses since patella resurfacing was almost exclusively used

early in the study period. Hence only 62 patients having a non resurfaced patella NexGen prosthesis were included. A detailed account of the selection procedure is given in Figure 1. We did not differentiate between patella resurfaced and patella non resurfaced TKAs since a previous study from the NAR[16] did not demonstrate any difference in pain and function between the two groups.

A total of 1749 individuals were then invited to participate in the survey. A reminder was sent out after two months to those who failed to respond to the initial questionnaire. In all, 1344 patients completed the questionnaire, 393 either declined or did not respond and 12 patients were deceased or unable to be located by the post-office.

Questionnaire

The questionnaire consisted of the valid and reliable self-administrated instrument for calculation of the knee specific Knee injury and Osteoarthritis Outcome Score (KOOS)[17]. A Norwegian translation from the Swedish version of KOOS was developed for this study and was approved as the official Norwegian translation. A description of the validation process of this translation can be found on the www.koos.nu[17] website.

To assess the potential effect of general health factors, the questionnaire also included questions needed to calculate the Charnley category modified to knee arthroplasty patients[18,19] and the valid and reliable instrument for quality of life measurement, the EuroQol (EQ-5D) index score[20]. Information needed for calculation of preoperative and most recent EQ-5D index scores was also included in the questionnaire. In addition questions regarding patients "satisfaction with the surgery", and degree of "pain from the operated knee" were

included. With the exception of the latter two questions, where a visual analogue scale (VAS) was used, all questions had standardized answer options given as Likert boxes.

The study was approved by The Norwegian Data Inspectorate, Norwegian Social Science Data Services (date of issue: 04/25/2006, registration number: 2005/453-2), and The Regional Committee for Research Ethics in Western Norway (date of issue:02/23/2006, registration number:046:06). The patients received the questionnaire together with an information letter, and returned the questionnaire to the register with a signed consent to participate in the study.

Outcome measures

KOOS, which was used as primary outcome on patient's perception of pain and function, consists of 42 individual questions, comprising five subscales; Pain, other symptoms (Symptoms), function in daily living (ADL), function in sport and recreation (Sport/Rec) and knee related quality of life (QOL). Only the last week should be considered when answering most of the questions and each question received a score from 0 to 4. A normalized score (100 indicating no symptoms and 0 indicating extreme symptoms) was calculated for each subscale. Calculation of the scores and treatment of missing data were done in accordance with stated guidelines (www.koos.nu)[17].

In addition we used "pain from the operated knee" (Pain(VAS)) and "satisfaction with the operation" (Satisfaction(VAS)) as outcomes, both measured on a visual analogue scale. In the analyses these VAS-scores were reversed with 100 indicating the best possible state and 0 indicating the worst possible state. Improvement in quality of life (ΔEQ-5D), calculated as

the difference between the present and preoperative EQ-5D index scores multiplied by 100, was also used as outcome.

To further investigate possible underlying mechanisms in the performances of the two groups of treatment we also studied all 42 KOOS questions (0=best, 4=worst) as outcomes.

Statistics

Minimal perceptible clinical difference (MPCD) is 8-10 units for KOOS subscales[17] and 9-12 units for a visual analogue scale[21]. When assessing the detailed KOOS questions a 10 % difference between the two groups were assumed to be clinical significant, corresponding to 0.4 units. To have a 80% chance of detecting as significant (at the two sided 5% level) a ten point difference in mean KOOS subscales, with an assumed standard deviation of 20, 64 individuals in each group of treatment were required. Thus to ensure good representation for both groups of treatment, a restriction on operation volume of each brand was set to at least 100 registered operations.

Differences in age, time since operation when filling in the form and preoperative EQ5D index score were analyzed with the independent samples Student's t-test while differences in gender and Charnley category were analyzed with the Pearson chi-square test. Multiple logistic regression was used to analyze response rates for gender (men as reference), age, time since the operation and treatment option (TKA as reference). To estimate differences in mean outcome scores for UKA and TKA, we used multiple linear regression with adjustment for possible confounding by gender, age (< 65, 65 to 70, 70 to 80, > 80 years), time since operation and Charnley category. Crude and adjusted differences in mean scores are presented with 95% confidence intervals and p-values.

Multiple linear regression was also used to investigate a possible association between mean outcome scores and the different unicompartmental brands with adjustment for gender, age, Charnley category and time since operation.

In the analyses, a p-value less than 0.05 was considered statistically significant. To account for chance findings the critical p-value was reduced to 0.00119 in accordance with the Bonferroni correction method when exploring the forty-two detailed KOOS questions.

Source of Funding

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article. The study was funded by the Norwegian Rheumatism Association which has been financed with the aid of Extra funds from the Norwegian Foundation for Health and Rehabilitation. This was an external funding source that provided funding for salary for the study.

RESULTS

We received completed questionnaires from 1344 (76.8 %) of the 1749 individuals selected for the study. Assessment of response rates by Regional Health Authorities in Norway showed only small geographical differences with rates ranging from 69.1 % to 81.2 %. Compared to non responders (n=405) the responders were 3.4 years younger on average, they had 0.6 years shorter follow-up since the operation and were more likely to be males (Table I). However, due to the fairly high response rate the patient characteristics of the responders compared well with characteristics of the patients selected for the study (Table I). A multiple logistic regression analysis revealed that being female (OR=0.71, p=0.01), increasing age

(OR=0.95, p<0.001) and increasing time since operation (OR=0.95, p=0.02) was associated with lower response rates whereas treatment option was not (OR=0.79, p=0.11).

For the responders there were differences in baseline characteristics between the groups of treatment in age (p<0.001), gender (p<0.001), time since the operation (p<0.001), and Charnley category (p<0.001), but not for preoperative EQ5D index score (p=0.6). The observed differences in patient characteristics were assessed and adjusted for in the statistical models. Table II gives the distribution of patient characteristics by prosthesis type and prosthesis brand.

When comparing UKA and TKA (Table III and Figure 2) we found statistically significant differences in favor of unicompartmental implants for the KOOS subscales, Symptoms (adjusted mean difference, 2.7 [95% confidence interval, 0.1 to 5.3]; p=0.04), ADL (adjusted mean difference, 4.1 [95% confidence interval, 0.9 to 7.4]; p=0.01) and Sport/Rec (adjusted mean difference, 5.4 [95% confidence interval, 1.6 to 9.3]; p=0.006). We found no evidence of difference in improved quality of life between the two treatment options. Crude and adjusted analyses mostly gave similar results, but smaller differences were observed for ADL and Sport/Rec after adjustments (Table III). Over all, none of the estimated differences reached stated level of MPCD in any outcome.

In the forty-two analyses of the detailed questions from KOOS, we observed four statistically significant differences (0.119 % level, Bonferroni correction method) (Table IV). All of these were in favor of UKA, however, only the question regarding “ability of bending of the knee” reached the stated level of clinical significance of 0.4 units (adjusted mean difference 0.54, [95% confidence interval, 0.33 to 0.76]; p<0.001).

Using Oxford III as reference, we observed no statistically significant differences between the three UKA prosthesis brands for any of the eight outcomes with all differences ≤ 4.3 units and all p-values ≥ 0.2 (Table V). Among UKAs, men performed better than women for Pain (adjusted mean difference, -4.7 [95% confidence interval, -9.3 to -0.1]; p=0.045), ADL (adjusted mean difference, -5.2 [95% confidence interval, -9.6 to -0.9]; p=0.02) and Sport/Rec (adjusted mean difference, -6.4 [95% confidence interval, -11.9 to -1.0]; p=0.02). Charnley category A patients performed better than both category B or C for all outcomes (except for ΔEQ-5D when compared to Charnley category B) and patients younger than 65 years performed inferior to older patients except for the outcomes ADL and ΔEQ-5D (Table V).

DISCUSSION

We compared the quality of unicompartmental knee arthroplasty (UKA) and total knee arthroplasty (TKA) based on data from the Norwegian Arthroplasty Register (NAR) and with self-reported degree of pain and function as outcome. We observed only small or no differences in pain and function between UKA and TKA at least two years following surgery (mean 6.5 years). Some of the differences were statistically significant in favor of UKA, but did not reach the stated level of minimal perceptible clinical difference (MPCD). Analysis of the detailed questions from the Knee Injury and Osteoarthritis Outcome Score (KOOS), indicated however that patients in the two groups experienced pain and function differently with better range of motion (ROM) as the main advantage of UKA.

Better performance after UKA in activities that involve bending of the knee is probably related to better stability since this procedure preserves more of the anatomy of the knee such as the cruciate ligaments. More non functional prostheses are expected when the endpoint in survival analysis is expanded to not only include revisions but also painful joints[14]. A higher proportion of untreated loose prosthesis components after UKA may explain why our findings indicated no advantage of UKA regarding pain. Progression of arthritis has also been suggested as an important reason for revision of UKAs[22,23] and may affect our findings in the same way when not treated.

An alternative to evidence from randomized clinical trials (RCTs) is evidence from large observational studies. The patient selection in our study was based on information reported to the NAR. This made it possible to include large volumes of patients with several prosthetic designs operated by many surgeons and from hospitals performing various amounts of surgery. Thus, the external validity of the results might be higher than those from RCTs.

Observational studies may be affected by different forms of bias. We have treated the most common confounding factors by using adjustments in the statistical model, but there may still be variables that have not been taken into account. Preoperative differences between the groups of treatment may have biased our results. Better preoperative ROM for UKAs may have caused the results of UKA to be too positive and thereby have increased differences in favor of UKA. Thus, any advantages of UKA may be even smaller than indicated by the observed differences and would not have altered our conclusion. A bias of the opposite direction may have occurred if patients with bi- or tricompartmental arthritis were treated with UKA. In the study period however, use of criteria defined by the Oxford group[2] was recommended to identify patients that were suitable for treatment with UKA. Hence, such a bias was not likely, since treatment with TKA was the only recommended option for patients with a more severe stage of the disease based on the Ahlbäck radiographic classification[24,25] (classification 1 to 5 for TKA, 1 to 3 for consideration of UKA). TKA is the main available treatment of a failed UKA and bias may have been introduced if patients treated with UKA were more likely to be revised for identical indications, for example pain, than those with TKA. Then a falsely low proportion of individuals with poor results after UKA would have been eligible for inclusion. If so, results of UKA would be too positive. However, this would most likely not have altered our findings of no or small differences between TKA and UKA. When comparing UKA and TKA the selection of prosthesis brands might potentially play an important role. An adequate range of commonly used implants is represented in our material and is expected to offer a good representation of hospitals, surgical techniques and surgeon experience for both treatment options. Since the outcomes in our study, except the improvement in health related quality of life (ΔEQ-5D), was based on the patient's perception of pain and function experienced the last week, the risk of recall bias is assumed to be negligible. Despite of not reaching level of MPCD it may be that observed differences

in outcomes used in this study could have clinical relevance when assessed in combination with physical exam outcomes.

To our knowledge there has been only one RCT comparing UKA and TKA[1,7]. This study included 102 knees with 15 year follow up and showed a tendency for better ROM after UKA as compared to TKA. A similar number of knees in the two groups were however classified as either good or excellent. These findings compares well with the results in our study. Neither were any significant differences in survival between the groups found when using revision or pain assessment (Bristol knee score < 60) as endpoint. The study included one single brand in each group of treatment. Hence, the external validity of the results might be restricted. Observational studies from arthroplasty registers that have focused on pain and function after knee arthroplasty are few. A study from the Swedish Knee Arthroplasty Register did not find any difference in the proportions of satisfied patients in the two treatment groups[26]. Using risk of reoperation as outcome, several register based studies have reported statistically significant higher revision rates for UKA as compared with TKA[5,8,9]. A study from a specialized center[2] did not observe these differences. The latter results may be affected by strict exclusion criteria were some of the most challenging interventions with use of UKA were left out. The limited number of surgeons and implant designs involved may also explain why no differences were found.

Use of UKA is disputed and comparative studies of mid and long-term quality of the two treatment options are few and inconsistent. It has been suggested that UKA may be preferable total knee arthroplasty in most patients with anteromedial osteoarthritis and an intact ACL[2], thus indicating that UKA is suitable in as many as 20% to 30% of the patients considered for knee arthroplasty. Other suggest other restrictions in the selection procedure resulting in a

reduced percentage of suitable patients[27]. Data from RCTs are currently almost absent and missing in decision guidelines and further research is needed.

In conclusion, with similar level of pain and function but with higher risk for revision for UKA, TKA is still an excellent option for some patients with isolated disease. Better ability to bend the knee may however suggest a preference for UKA in patients with special need of a larger ROM.

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FIGURE LEGEND

Figure 1. Description of the selection procedure.

* For patients with bilateral intact primary prostheses, only the most recent with arthritis as diagnosis was eligible for inclusion.

† Total knee arthroplasty (TKA) prosthesis brands registered with less than 100 resurfaced and/or less than 100 non resurfaced implants. Unicompartmental knee arthroplasty (UKA) prosthesis brands registered with less than 100 implants.

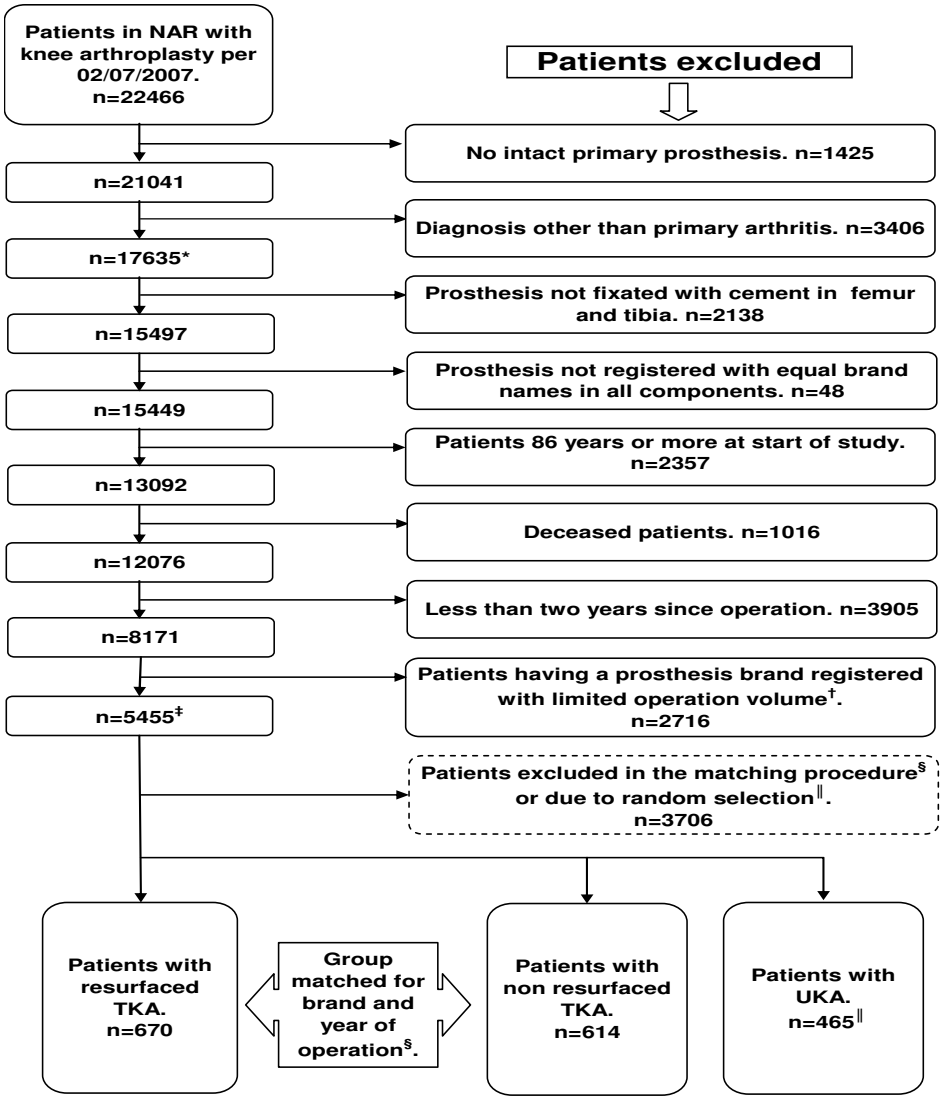
‡ Four total knee arthroplasty (TKA) brands (Genesis I, AGC, LCS and NexGen), and 3 unicompartmental knee arthroplasty (UKA) brands (Genesis Uni, Miller-Galante and Ocford III) were eligible for inclusion.

§ Non resurfaced total knee arthroplasties (TKAs) were group matched with all available resurfaced TKAs for brand and year of operation. This led to exclusion of 2950 patients with non resurfaced TKA.

‖ All available patients with Genesis Uni (n=136) and Miller-Galante (n=129) were included. Among 956 available patients with Oxford III, 200 patients were selected randomly for inclusion. This led to exclusion of 756 patients with unicompartmental knee arthroplasty (UKA).

Figure 2. Mean outcome scores among unicompartmental knee arthroplasty (UKA) prostheses and total knee arthroplasty (TKA) prostheses. The first five outcomes from the left represent the subscales from the Knee Injury and Osteoarthritis Outcome Score. Adjustments were made for age, gender, time since operation and Charnley category. Outcomes were measured on a scale from 0 (worst) to 100 (best) units.

Figure 1


Patients in NAR with knee arthroplasty per 02/07/2007. n=22466
Patients excluded
No intact primary prosthesis. n=1425
n=21041
Diagnosis other than primary arthritis. n=3406
n=17635*
Prosthesis not fixated with cement in femur and tibia. n=2138
n=15497
Prosthesis not registered with equal brand names in all components. n=48
n=15449
Patients 86 years or more at start of study. n=2357
n=13092
Deceased patients. n=1016
n=12076
Less than two years since operation. n=3905
n=8171
Patients having a prosthesis brand registered with limited operation volume†. n=2716
n=5455‡
Patients excluded in the matching procedure§ or due to random selection‖. n=3706
Patients with resurfaced TKA. n=670
Group matched for brand and year of operation§.
Patients with non resurfaced TKA. n=614
Patients with UKA. n=465‖

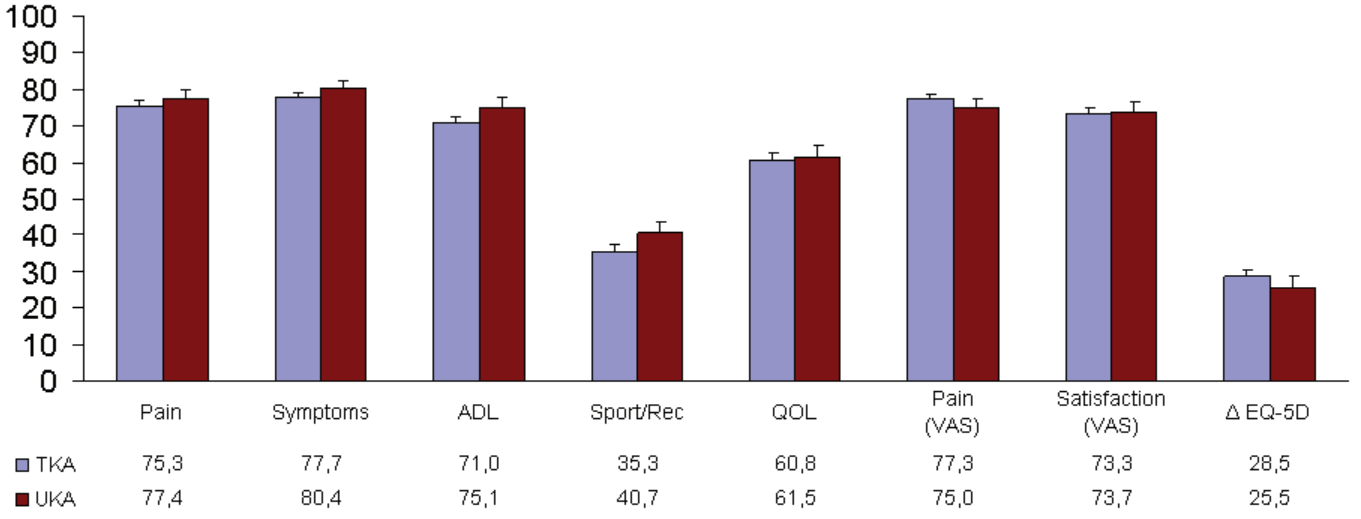

100
90
80
70
60
50
40
30
20
10
0
Pain
Symptoms
ADL
Sport/Rec
QOL
Pain (VAS)
Satisfaction (VAS)
Δ EQ-5D
TKA 75,3 77,7 71,0 35,3 60,8 77,3 73,3 28,5
UKA 77,4 80,4 75,1 40,7 61,5 75,0 73,7 25,5

Figure 2

Table I Patient characteristics for responders and non responders

	TKA	UKA	Total
No. of prostheses,	1284	465	1749
responders	972	372	1344
non responders	312	93	405
No. of hospitals,	57	42	61
responders	56	42	60
non responders	47	28	52
Men %	27	40	31
responders %	29	41	33
non responders %	20	37	24
Mean (SD) age*	76.7 (7.6)	69.4 (9.1)	74.8 (8.6)
responders	76.0 (7.7)	68.8 (8.8)	74.0 (8.6)
non responders	79.1 (6.5)	71.8 (10.0)	77.4 (8.1)
Mean (SD) time† since operation	7.1 (2.4)	5.1 (2.5)	6.6 (2.6)
responders	7.0 (2.4)	4.9 (2.3)	6.5 (2.6)
non responders	7.5 (2.5)	6.0 (2.8)	7.1 (2.6)

* Mean age (years) when sending the questionnaire.
† Mean time (years) since operation when sending the questionnaire.
TKA=total knee arthroplasty; UKA=unicompartmental knee arthroplasty; SD=standard deviation.

Table II **Patient characteristics by treatment option and prosthesis brand**

	TKA					UKA				All
	AGC	Genesis I	LCS	NexGen	Total	Genesis Uni	Miller-Galante	Oxford III	Total	
No. of prostheses	205	266	364	137	972	104	104	164	372	1344
No. of hospitals	16	25	20	9	56	11	16	29	42	60
men %	32	27	28	33	29	41	35	45	41	33
Charnley Category C %	62	67	65	64	65	56	45	52	51	61
Mean (SD) age (years)*	76 (7.9)	77 (6.6)	76 (7.9)	74 (8.5)	76 (7.7)	69 (9.4)	69 (7.5)	69 (9.1)	69 (8.8)	74 (8.6)
Mean (SD) time since operation (years)†	7.2 (2.4)	9.2 (1.7)	6.5 (1.8)	4.6 (1.8)	7.1 (2.4)	6.0 (3.2)	5.2 (1.9)	4.2 (1.4)	5.0 (2.3)	6.5 (2.6)
Mean (SD) preoperativ EQ-5D index score	0.47 (0.22)	0.46 (0.22)	0.46 (0.23)	0.44 (0.22)	0.46 (0.22)	0.47 (0.21)	0.46 (0.22)	0.48 (0.21)	0.47 (0.21)	0.46 (0.22)
Mean (SD) postoperativ EQ-5D index score	0.72 (0.25)	0.69 (0.26)	0.74 (0.24)	0.81 (0.19)	0.73 (0.25)	0.75 (0.25)	0.74 (0.24)	0.78 (0.22)	0.76 (0.23)	0.74 (0.24)

* Mean age when completing the questionnaire.

† Mean time since operation when completing the questionnaire.

TKA=total knee arthroplasty; UKA=unicompartmental knee arthroplasty; SD=standard deviation; EQ-5D=EuroQol.

Table III **Mean difference in outcomes between TKA and UKA**

	Crude difference*	(95 % CI)	P Value	Adjusted difference†	(95 % CI)	P Value
Pain	2.1	(-0.9 to 5.1)	0.2	2.1	(-1.1 to 5.3)	0.2
Symptoms	2.2	(-0.2 to 4.6)	0.07	2.7	(0.1 to 5.3)	0.04
ADL	7.1	(4.1 to 10.2)	<0.001	4.1	(0.9 to 7.4)	0.01
Sport/Rec	7.5	(3.8 to 11.1)	<0.001	5.4	(1.6 to 9.3)	0.006
QOL	0.7	(-2.8 to 4.3)	0.7	0.7	(-3.0 to 4.5)	0.7
Pain(VAS)	-2.6	(-5.5 to 0.3)	0.08	-2.3	(-5.4 to 0.8)	0.1
Satisfaction(VAS)	0.1	(-3.0 to 3.2)	0.9	0.4	(-3.1 to 3.8)	0.8
ΔEQ-5D	1.6	(-2.0 to 5.3)	0.4	-3.1	(-7.1 to 1.0)	0.1

* Difference is equal to mean score among UKAs minus mean score among TKAs (positive values are in favor of UKA).

† Difference is equal to mean score among TKAs minus mean score among UKAs (positive values are in favor of UKA), adjusted for age, gender, time since operation and Charnley category in a multiple linear regression model.

TKA=total knee arthroplasty; UKA=unicompartmental knee arthroplasty; CI=confidence interval; ADL=function in daily living; Sport/Rec=Function in sport and recreation; QOL=knee related quality of life; VAS=visual analogue scale; ΔEQ-5D=present minus preoperative EuroQol index score.

Table IV Mean difference in outcomes (detailed questions from KOOS) between TKA and UKA

		difference*	P Value	TKA best UKA best
Pain	How often do you experience knee pain?	-0,17	0,07	
	Twisting/pivoting on your knee	0,00	0,97	
	Straightening knee fully	0,17	0,02	
	Bending knee fully	0,35	<0.001	
	Walking on flat surface	0,01	0,9	
	Going up or down stairs	0,16	0,08	
	At night while in bed	0,09	0,2	
	Sitting or lying	0,09	0,2	
	Standing upright	0,06	0,4	
Symptoms	Do you have swelling in your knee?	0,01	0,9	
	Do you feel grinding, hear clicking or any other type of noise when your knee moves?	0,14	0,06	
	Does your knee catch or hang up when moving?	-0,10	0,04	
	Can you straighten your knee fully?	0,10	0,2	
	Can you bend your knee fully?	0,54	<0.001	
	How severe is your knee joint stiffness after first wakening in the morning?	-0,01	0,9	
	How severe is your knee stiffness after sitting, lying or resting later in the day?	0,04	0,6	
ADL	Descending stairs	0,15	0,09	
	Ascending stairs	0,16	0,06	
	Rising from sitting	0,15	0,07	
	Standing	0,12	0,1	
	Bending to floor/pick up an object	0,23	0,007	
	Walking on flat surface	0,09	0,2	
	Getting in/out of car	0,28	<0.001	
	Going shopping	0,20	0,02	
	Putting on socks/stockings	0,18	0,03	
	Rising from bed	0,07	0,3	
	Taking off socks/stockings	0,19	0,02	
	Lying in bed (turning over, maintaining knee position)	0,15	0,05	
	Getting in/out of bath	0,27	0,002	
	Sitting	0,13	0,04	
	Getting on/off toilet	0,26	<0.001	
	Heavy domestic duties (moving heavy boxes, scrubbing floors, etc)	0,18	0,04	
	Light domestic duties (cooking, dusting, etc)	0,21	0,003	
Sport/Rec	Squatting	0,28	0,003	
	Running	0,22	0,02	
	Jumping	0,27	0,003	
	Twisting/pivoting on your injured knee	0,23	0,01	
	Kneeling	0,14	0,09	
QOL	How often are you aware of your knee problem?	-0,09	0,4	
	Have you modified your life style to avoid potentially damaging activities	0,11	0,2	
	How much are you troubled with lack of confidence in your knee?	0,04	0,6	
	In general, how much difficulty do you have with your knee?	0,04	0,6	

* Difference is equal to mean score among TKAs minus mean score among UKAs (positive values are in favor of UKA), adjusted for age, gender, time since operation and Charnley category in a multiple linear regression model.

KOOS=The Knee Injury and Osteoarthritis Outcome Score; TKA=total knee arthroplasty; UKA=unicompartmental knee arthroplasty; ADL=function in daily living; Sport/Rec=function in sport and recreation; QOL=knee related quality of life.

Table V **Effects on mean outcomes of gender, age, time since operation, Charnley category and unicompartmental prosthesis brand.**

Risk predictors	Pain difference * (95% CI) P value	Symptoms difference * (95% CI) P value	ADL difference * (95% CI) P value	Sport/Rec difference * (95% CI) P value	QOL difference * (95% CI) P value	Pain(VAS) difference * (95% CI) P value	Satisfaction (VAS) difference * (95% CI) P value	Δ EQ-5D difference * (95% CI) P value
Gender								
Male (n=152)	ref	ref	ref	ref	ref	ref	ref	ref
Female (n=220)	-4.7 (-9.3 to -0.1) 0.045	-2.5 (-6.0 to 1.1) 0.2	-5.2 (-9.6 to -0.9) 0.02	-6.4 (-11.9 to -1.0) 0.02	-4.5 (-9.9 to 0.9) 0.1	-3.3 (-8.0 to 1.5) 0.2	-1.7 (-6.8 to 3.5) 0.5	4.7 (-1.4 to 10.7) 0.1
Age†								
< 65 years (n=128)	ref	ref	ref	ref	ref	ref	ref	ref
65-70 years (n=77)	8.5 (2.2 to 14.8) 0.008	4.5 (-0.4 to 9.5) 0.07	3.8 (-2.2 to 9.8) 0.2	8.6 (1.1 to 16.2) 0.03	8.9 (1.5 to 16.4) 0.02	10.2 (3.7 to 16.7) 0.002	9.9 (2.7 to 17.0) 0.007	7.1 (-1.4 to 15.6) 0.1
70-80 years (n=126)	10.1 (4.5 to 15.7) <0.001	6.9 (2.5 to 11.2) 0.002	7.1 (1.8 to 12.4) 0.01	11.3 (4.6 to 18.0) <0.001	12.9 (6.3 to 19.4) <0.001	11.5 (5.8 to 17.3) <0.001	8.2 (1.9 to 14.4) 0.011	2.8 (-4.6 to 10.2) 0.5
> 80 years (n=41)	14.3 (6.3 to 22.4) <0.001	10.8 (4.6 to 17.0) <0.001	4.8 (-2.9 to 12.4) 0.2	15.5 (5.7 to 25.4) 0.002	17.1 (7.7 to 26.5) <0.001	19.3 (10.8 to 27.8) <0.001	14.1 (5.0 to 23.3) 0.003	-0.6 (-11.2 to 9.9) 0.9
Years since operation	0.3 (-0.7 to 1.4) 0.6	0.5 (-0.4 to 1.3) 0.3	-0.1 (-1.1 to 1.0) 0.9	-0.1 (-1.4 to 1.2) 0.8	-0.2 (-1.5 to 1.0) 0.7	-0.2 (-1.3 to 0.9) 0.7	0.6 (-0.7 to 1.8) 0.4	0.2 (-1.3 to 1.6) 0.8
Charnley category‡								
A (n=109)	ref	ref	ref	ref	ref	ref	ref	ref
B (n=67)	-10.6 (-17.1 to -4.0) 0.002	-5.7 (-10.8 to -0.6) 0.03	-9.8 (-16.0 to -3.5) 0.002	-10.0 (-18.0 to -2.1) 0.01	-15.1 (-22.8 to -7.3) <0.001	-14.9 (-21.8 to -8.1) <0.001	-11.8 (-19.2 to -4.3) 0.002	-8.5 (-17.2 to 0.3) 0.1
C (n=184)	-11.4 (-16.6 to -6.1) <0.001	-7.7 (-11.8 to -3.6) <0.001	-15.2 (-20.2 to -10.2) <0.001	-14.7 (-20.9 to -8.4) <0.001	-15.5 (-21.6 to -9.3) <0.001	-11.4 (-16.9 to -5.9) <0.001	-8.8 (-14.8 to -2.9) 0.004	-8.8 (-15.8 to -1.8) 0.01
Prosthesis brand								
Oxford Uni (III) (n=164)	ref	ref	ref	ref	ref	ref	ref	ref
Genesis uni (n=104)	-4.1 (-9.9 to 1.6) 0.2	-3.2 (-7.6 to 1.3) 0.2	-2.7 (-8.1 to 2.7) 0.3	2.2 (-4.7 to 9.1) 0.5	-2.1 (-8.8 to 4.6) 0.5	-2.9 (-8.8 to 3.1) 0.3	-1.4 (-7.9 to 5.1) 0.7	-1.3 (-9.0 to 6.4) 0.7
Miller Galante (n=104)	-2.5 (-8.0 to 3.1) 0.4	-2.9 (-7.2 to 1.5) 0.2	-3.6 (-8.9 to 1.7) 0.2	-4.2 (-10.9 to 2.5) 0.2	-3.8 (-10.4 to 2.8) 0.3	-4.2 (-10.0 to 1.6) 0.2	-1.2 (-7.5 to 5.2) 0.7	-4.3 (-11.7 to 3.2) 0.3

* Differences in mean scores are adjusted for all variables in a multiple linear regression model.
† Age when completing the questionnaire.
‡ Information on Charnley category was not given by 12 patients.
ADL=function in daily living; Sport/Rec=function in sport and recreation; QOL=knee related quality of life; VAS=visual analogue scale; ΔEQ-5D=present minus preoperative EuroQol index score; CI=confidence interval.

III

Failures of total knee arthroplasties with or without patella resurfacing

A study with 0-15 years follow-up from the Norwegian Arthroplasty Register.

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Abstract

Introduction

Patella resurfacing during primary total knee arthroplasty (TKA) is disputed and new prosthesis designs have been introduced without documentation on their survival.

Patients and Methods

We assessed the impact on prosthesis survival of patella resurfacing (n=11887) and of prosthesis brand (n=25590) based on data from the Norwegian Arthroplasty Register. Cox regression analyses were performed with different reasons for revision as endpoints with adjustment for potential confounders.

Results

We observed a no statistically significant reduced overall risk for revision (RR=0.84, p=0.05) for patella resurfaced (PR) TKAs. At 15 years 92.1 % of PR and 91.4 % of patella non resurfaced (NR) prostheses were still unrevised. However, PR implants had a lower risk for revision due to pain alone (RR=0.12, p<0.001), but a higher risk for revision due to loosening of the tibial component (RR=1.42, p=0.03) and due to a defect polyethylene insert (RR=3.23, p<0.001).

At 10 years the survival for the reference brand NR AGC Universal was 93.2 %. The NR brands Genesis I, Duracon and Tricon (RR=1.43 to 1.67) performed statistically significant poorer than NR AGC Universal, while the NR prostheses e.motion, Profix and AGC Anatomic (RR=0.09 to 0.66), and the PR prostheses NexGen and AGC Universal (RR=0.40 to 0.48) performed statistically significant better. LCS, NexGen, LCS Complete (all NR), and Tricon, Genesis I, LCS and Kinemax (all PR) did not differ from the reference brand. A lower risk for revision (crude) was found for TKAs performed after 2000 as compared with those performed earlier (RR=0.81, p=0.001).

Interpretation

Although revision risk was similar for PR and NR TKAs, we found important differences in reasons for revision. Our results also imply that survivorship of TKAs has improved.

Introduction

Cemented total knee arthroplasty (TKA) has been a successful procedure providing improvement in function and relief of pain for the majority of patients. There are however issues that are controversial and widely discussed. Use of a patellar component (patella resurfacing) during primary TKA is still disputed. The search for improvement has further resulted in the introduction of several new designs which are widely used, although they are without documentation on their survival.

The discussion on whether primary patella resurfacing should be recommended or not, has lead to several observational studies, randomized clinical trials (RCT), several meta analyses (Forster 2004, Parvizi et al. 2005, Pakos et al. 2005, Nizard et al. 2005) and review articles (Meneghini 2008). A critical appraisal of the available evidence (Calvisi et al. 2009) was not able to find clear superiority of any of the two treatments due to methodological limitations in the available studies. Studies based on data from arthroplasty registers have found a higher risk for revision when the patella was left untreated (Furnes et al. 2002, The Swedish Knee Arthroplasty Register. Annual Report 2009, Clements et al. 2010). Furnes et al. (2002) found that the increased revision risk was mainly related to revisions due to pain. Some recent studies do however indicate that there is no difference in patients' perception of postoperative pain in the two groups of treatment (Johnston et al. 2009, Lygre et al. 2010) and that the observed differences in risk for revision due to pain may be caused by the exclusive option of a secondary patella resurfacing of the primarily patella non resurfaced knees. This is supported by a recent study from the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) that suggested that surgeons may be more inclined to revise a patella non resurfaced knee by a secondary patella addition if the patient presents later with knee pain, given that option is still available (Clements et al. 2010).

Studies that compare survival of different prosthesis brands and implant designs are few, but a previous study (Furnes et al. 2002) from the Norwegian Arthroplasty Register (NAR) did not

observe any statistically significant short term differences between the most commonly used brands in Norway. Other national arthroplasty registers with longer follow-up have reported statistically significant differences among some commonly used brands in their annual reports (Australian Orthopaedic Association National Joint Replacement Registry.Annual Report. 2009, The Swedish Knee Arthroplasty Register. Annual Report 2009).

The purpose of the present paper, based on data in the NAR, was to compare overall survival of cemented knee prosthesis with and without resurfacing of the patella, and to assess the survival of some widely used TKA brands.

Materials and Methods

The Norwegian Arthroplasty Register (NAR)

The NAR was started as a register for total hip arthroplasty in 1987 (Havelin 1999, Havelin et al. 2000) and was extended to include all artificial joint replacements by January 1994 (Havelin et al. 2000). Information on primary knee arthroplasties and revisions is reported on a standardized form by the orthopedic surgeon and individual reports on performed TKAs have since been received from 82 orthopedic departments performing this procedure. Practically all TKAs (99%) are reported to the NAR (Espehaug et al. 2006). The unique identification number assigned to each resident of Norway is used to link information on revisions to primary TKAs.

Study sample

By December 10th, 2009, 32417 primary TKAs had been reported to the NAR. Only TKAs with all components fixed with cement were eligible for inclusion in the present study. This was because use of cement was most common (n=27361, 85 %) and to make the results more comparable to results from other studies. We excluded hinged prostheses (n=22) and prostheses with posterior cruciate ligament sacrificing design (except for the LCS mobile bearing) or constrained condylar design (n=780) leaving 26559 (82 %) prostheses eligible for inclusion (Figure 1).

For patella resurfaced and patella non resurfaced prostheses respectively, those prosthesis brands introduced prior to 2005 and reported with at least 200 operations were included (n=25590) for comparison of survival of prosthesis brands. These prosthesis brands were the AGC Universal (Biomet Merck) (425 patella resurfaced/2123 patella non resurfaced), Tricon (Tricon C or Tricon M femoral component in combination with Tricon II tibial component) (Smith and Nephew) (392/633), Genesis I (Smith and Nephew) (704/2304), LCS (DePuy)(532/3526), NexGen (Zimmer) (494/754), Kinemax (Howmedica/Stryker) (294 patella resurfaced), Duracon (Howmedica/Stryker) (1283 patella non resurfaced), AGC Anatomic (Biomet Merck) (1298 patella non resurfaced), Profix (Smith and Nephew)(6304 patella non resurfaced), LCS Complete (DePuy) (4090 patella non resurfaced) and e.motion (Aesculap)(434 patella non resurfaced)

(Table I). When possible, prostheses brands were categorized in patella resurfaced and patella non resurfaced.

For comparison of patella resurfaced and patella non resurfaced TKAs the material was further restricted to those brands with both patella resurfaced and patella non resurfaced TKAs represented with larger numbers than 200 (n=11887) (Tricon, Genesis I, AGC, LCS and NexGen).

Statistics

We used survival analyses with revision of one or more of the femoral, tibial or patellar components, or secondary resurfacing of the patella as endpoint. Information on deaths and emigrations was retrieved from Statistics Norway, Oslo, until December 10th, 2009. The survival times of implants in patients who had died or emigrated without revision of the prosthesis were censored at the date of death or emigration. Otherwise the survival times were censored at the end of the study on December 10th, 2009.

The reverse Kaplan-Meier method was used to calculate the median follow-up (Altman et al. 1995, Schemper and Smith 1996). To evaluate the impact of patella resurfacing and of prosthesis brands, relative risk (RR) estimates from Cox regression models were obtained. Adjustments were performed for possible confounding by age (<60 years, 60-70 years, >70 years), sex, previous operation of the knee (operated or not), diagnosis (primary osteoarthritis of the knee, other) and prosthesis brand. The covariate age was represented with indicator variables since the assumption of a log-linear relationship between age and the revision rate was not justified. The impact of patella resurfacing was further assessed with different revision causes as endpoint. In some of these analyses, adjustment for prosthesis brand was done by stratification when one or more of the brands were without failures [periprosthetic fracture, dislocation of the patella, dislocation (not patella) and defect polyethylene insert]. Analogous survival curves for these specific endpoints are presented without adjustments for brands.

Patella non resurfaced TKAs were used as the reference when assessing the impact of patella resurfacing, while the patella non resurfaced AGC Universal was used as reference when comparing prosthesis brands. The latter was chosen because non resurfaced AGC Universal had been used throughout the study period in relatively large numbers. The AGC prosthesis has also been used as reference in reports from the Swedish Knee Arthroplasty Register (The Swedish Knee Arthroplasty Register. Annual Report 2009) and its results have been reported with favorable survival rates with long time follow-up (Ritter 2009). Tests and inspections of plotted Schoenfeld residuals (Grambsch et al. 1995) were performed to investigate if the proportional hazards assumption of the Cox models were valid. The assumption was found to be valid for comparison of patella resurfacing and patella non resurfacing prosthesis when using any revision as endpoint ($p=0.99$) and when using specific reasons as endpoint ($p=0.07$-0.9). Regarding comparison of prosthesis brands the assumption was valid for all brands except for PR Tricon, PR Kinemax and NR Tricon. Survival curves for the adjusted percentage of unrevised implants were estimated with treatment option as stratification factor. These were given for survival times where more than 50 implants remained at risk of revision. Survival percentages at 5, 10 and 15 years were presented in tables.

Since use of patella resurfacing (Figure 2) and prosthesis brands (Table II) changed throughout the study period, survival was also compared within two separate time periods namely for operations performed from 1994 through 2000 (with follow-up until December 10th, 2009) and from 2001 to December 10th, 2009. Within each time period, only brands used in more than 200 operations were compared.

All p-values less than 0.05 were considered statistically significant. The statistical software programs R version 2.10.1 (The R Foundation for Statistical Computing) and SPSS version 17.0 (SPSS Inc. Chicago, IL) were used.

Results

Of the 11887 prostheses included when evaluating resurfacing of the patella, 786 (6.6 %) were revised by the end of the study period while this applied to 1204 (4.7 %) of the 25590 prosthesis included when evaluating brands. The distributions of age, sex and patients previously operated in the knee were similar for patients having a patella resurfaced and those who had a patella non resurfaced TKA. Patella non resurfaced TKAs were performed in more hospitals and were more likely to have primary osteoarthritis of the knee as diagnosis (Table I). Among brands, differences were observed for most baseline characteristics of the patients (Table I). Median follow-up, and number at risk 0, 5, 10 and 15 years after the operation are reported in Table II.

Patella resurfacing

After 15 years the overall survival was 92.1 % (CI: 90.7-93.6) for patella resurfaced TKAs and 91.4 % (CI: 90.4-92.4) for patella non resurfaced TKAs (Table III). We found a non statistically significant lower risk for revision for patella resurfaced TKAs as compared with patella non resurfaced (RR=0.84, CI: 0.71 – 1.00, p=0.05) (Table III, Figure 3). We did not find any statistically significant differences in survival between patella resurfaced and patella non resurfaced TKAs within each time period (Table III).

Reasons for revision

For most of the revision reasons registered, we did not find statistically significant differences in survival between patella resurfaced and patella non resurfaced TKAs (Table IV)(Figure 4a, Figure 4c, Figure 4d, Figure 4e and Figure 4g). However, patella resurfaced TKAs had a statistically significant lower risk for revision due to pain alone (RR=0.12, CI: 0.06 – 0.23, p<0.001) (Table IV)(Figure 4h), but a statistically significant higher risk for revision due to loosening of the tibial component (RR=1.42, CI: 1.03 – 1.95, p=0.03) (Table IV)(Figure 4b) and due to a defect polyethylene insert or wear (RR=3.23, CI: 1.71 – 6.11, p<0.001) (Table IV)(Figure 4i). The increased risk of failure due to a defect polyethylene insert or wear is also reflected in Figure 3 at about 10 years follow-up.

The lower risk for revision due to pain alone for patella resurfaced prosthesis was also found when restricting the material to TKAs performed from 1994 to 2000 (RR=0.04, CI: 0.01 – 0.14, p<0.001) but not to those performed from 2001 to December 10th, 2009 (RR=0.70, CI: 0.27 – 1.78, p=0.45). Higher risk for revision due to loosening of the tibial component for patella resurfaced prosthesis was also found to be statistically significant for TKAs performed in the first time period (RR=1.52, CI: 1.03 – 2.23, p=0.04) but not in the last (RR=1.57, CI: 0.86 – 2.89, p=0.14). Higher risk for a defect polyethylene insert for patella resurfaced prosthesis was also found for TKAs performed in the first time period (RR=3.63, CI: 1.94 – 6.80, p<0.001) while a total of only two events of failure were observed in the last time period.

Prosthesis brands

At 10 years the survival for the reference brand, patella non resurfaced (NR) AGC Universal was 93.2 % (CI: 91.9-94.5) (Table III). We observed some variability among prosthesis brands at 10 years of follow-up, ranging from 88.6 % survival for NR Tricon to 96.7 % for patella resurfaced (PR) NexGen (RR=0.24, CI: 0.13 – 0.45, p=<0.001). For brands represented with both patella resurfaced and patella non resurfaced TKAs (Tricon, Genesis I, AGC Universal, LCS and NexGen) the patella resurfaced TKAs had the highest survival percent respectively except for the LCS were non patella resurfacing demonstrated higher survival percentage (Table III).

As compared with the reference brand, NR Tricon (RR=1.67, CI: 1.24 – 2.23, p=0.003), NR Genesis I (RR=1.43, CI: 1.14 – 1.79, p=0.002) and NR Duracon (RR=1.45, CI: 1.05 – 1.99, p=0.02) performed statistically significant poorer while NR Profix (RR=0.66, CI: 0.52 – 0.82, p<0.001), NR e.motion (RR=0.09, CI:0.02 – 0.37, p=0.001), NR AGC Anatomic (RR=0.66, CI: 0.45 – 0.99, p=0.04), PR AGC Universal (RR=0.48, CI: 0.27 – 0.83, p=0.009) and PR NexGen (RR=0.40, CI: 0.22 – 0.74, p=0.004) performed statistically significant better (Table III, Figure 5 and Figure 6).

A separate analysis performed on patella resurfaced LCS prostheses did not show any advantage of the mobile bearing rotating platform system (n=323) as compared with the mobile bearing

meniscal system (n=208) (RR=1.26, 95% CI: 0.64-2.43, p=0.5). A corresponding analysis performed on patella non resurfaced LCS prostheses, did neither show any advantage of the mobile bearing rotating platform system (n=3031, 375 with LCS-Universal tibial insert) as compared with the mobile bearing meniscal system (n=477) (RR=0.93, 95% CI: 0.62-1.40, p=0.7).

A statistically significant lower risk for revision was found when comparing crude survival of the TKAs performed in the last time period as compared with the first (RR=0.81, CI: 0.72 – 0.91, p=0.001).

Patient-related factors

We found no statistically significant difference in survival of TKAs for women as compared to men (RR=1.00, CI: 0.88 – 1.14, p=1.0) and for knees with osteoarthritis of the knee as compared with other diagnoses (RR=0.92, CI: 0.80 – 1.06, p=0.3). Knee prostheses in older patients (> 70 years) were found to perform better than in younger patients (<60 years) (RR=0.39, CI: 0.33 – 0.45, p<0.001) and previously operated knees performed poorer as compared with not previously operated (RR=1.26, CI: 1.11-1.43, p<0.001).

Discussion

Summary

We observed a statistically non significant 16 % reduced risk for revision for patella resurfaced TKAs as compared with patella non resurfaced TKAs based on data with 0 to 15 years follow-up in the NAR. There were however statistically significant differences in reason for revision. While patella non resurfaced TKAs were more often revised due to pain, patella resurfaced TKAs had a higher risk for revision due to aseptic loosening of the tibial component and due to a defect polyethylene or wear when assessed with long follow-up.

Regarding brands, NR Tricon, NR Genesis I and NR Duracon performed statistically significant poorer than the reference brand NR AGC Universal with about 1.5 times higher risk for revision. NR Profix, NR e.motion, NR AGC Anatomic, PR AGC Universal and PR NexGen had a statistically significant reduced risk for revision. NR LCS, NR NexGen and NR LCS complete compared similar to the reference brand, as did PR Tricon, PR Genesis I, PR LCS, and PR Kinemax. For brands that were evaluated both with and without patella resurfacing, patella resurfacing seemed to offer the best survival performance except for the LCS design were patella resurfacing had the poorest survival.

Explanations/mechanisms

The finding of the statistically non significant lower risk for revision for patella resurfaced TKAs was found to be mainly caused by fewer revisions due to pain only. A recent study from the NAR (Lygre et al. 2010) and a high powered multicenter RCT including 1715 patients (Johnston et al. 2009) could however not demonstrate any difference in level of pain between the two treatment groups. An explanation could be the exclusive option of secondary resurfacing of the patella for patella non resurfaced TKAs. Hence, lower risk for revision due to pain may not necessarily be caused by less severe pain but because surgeons may be more likely to revise a painful patella non resurfaced TKA than a painful patella resurfaced. This explanation is also supported in a recent study from the AOANJRR (Clements et al. 2010). Our findings also indicated that the

difference in risk for revision due to pain was largest for TKAs performed in the first time period (1994 to 2001). This might be due to the introduction of the newer and more patella friendly implant NexGen and due to the stop in use of some older inferior designs that were represented in our material by Genesis I and Tricon. The NexGen implant has also been found to perform statistically significant better regarding pain than the implants AGC Universal and Genesis I in a recent study from the NAR (Lygre et al. 2010).

More aseptic loosening of the tibial component for patella resurfaced TKAs was most pronounced with long follow-up and may be associated with wear also of the extra polyethylene element on the patellar side (Ogon et al. 2002) and might thus be explained by a higher volume of polyethylene particles in the joint (Goodman and Lidgren 1992). Such an association is also supported by similar mechanisms observed when assessing wear and loosening of cups after total hip arthroplasty (Wroblewski et al. 2004, Wilkinson et al. 2005). Patella resurfacing might also increase the patellofemoral offset due to conservative bone resection. The resulting increased forces over the patellofemoral joint and onto the tibia might thereby increase tibia loosening and wear of the tibial polyethylene insert. This is also supported by the observation of higher risk for revision due to a defect polyethylene insert among the patella resurfaced TKAs and was apparent after about 10 years follow-up.

Regarding brand specific results, the good performance of the NR e.motion prosthesis, as well as the inferior results of the PR LCS prosthesis as compared to the NR LCS, are interesting but could be caused by variables other than the implant itself since the use of NR e.motion and PR LCS were restricted to few hospitals. However, the revision rate for the PR LCS prosthesis has also been reported as higher then anticipated in operations reported to the AOANJRR (Australian Orthopaedic Association National Joint Replacement Registry. Annual Report. 2009). Higher failure rates was found to be associated with the use of metal backed LCS patellar component as compared with all-polyethylene LCS patellar component and may also explain our findings since metal backing was used in all patella resurfaced LCS TKAs performed in Norway in the study period.

Search for improvement in quality of TKAs has resulted in the introduction of varying designs of both the tibial and the femoral component. Most brands included in this study had a modular fixed-bearing tibial insert except for the AGC implants were the fixed-bearing tibial component was a metal-backed mono-block, and for the LCS, LCS-Complete and e.motion implants where a mobile bearing system was used. For the LCS implant both a mobile meniscal bearing and mobile rotating platform was used. We could however not identify any clear advantages related to any of these LCS designs in this study with more than 10 years of follow-up. Further follow-up is needed to investigate if the mobile bearing knees lead to lower wear and less loosening. In a recent meta analysis, no advantage using mobile bearing knees could be shown (Oh et al. 2009) which is supported by our findings.

The shape of the femoral component has been focused on in the search for optimal range of motion and minimal anterior knee pain after TKA. The idea is that the patella needs an appropriate flange and groove in the femoral component to perform satisfactory through kinematics of bending and stretching and has been reported to show a clear advantage to the unresurfaced patella regarding complications as well as pain and function (Whiteside and Nakamura 2003). More anatomic femoral components with a narrower fork and deeper grove have been introduced in newer designs and may explain the better performance of the NR AGC Anatomic, NR Profix and NR e.motion prostheses as compared with NR Tricon, NR Genesis I and NR Duracon. However, the RR estimates for PR Tricon, NR Tricon and PR Kinemax against NR AGC Universal might be overestimated due to the failing of the proportional hazards assumption of the Cox model (Schemper 1992). For NR e.motion the good results may also be caused by the highly congruent interface between the femoral component and the tibial insert (Morra and Greenwald 2005). This may potentially have decreased contact stress and thereby produced less wear. The relatively short follow-up of this prosthesis should however be noted.

Thus, even if observed improvement in survival of TKAs over time to a certain extent may be associated with better operation techniques and more experienced surgeons, some of the

difference may be explained by the introduction of newer prosthesis brands with better survival used in a high volume (PR NexGen and NR Profix) together with termination of the use of brands demonstrated to have poorer survival (NR/PR Tricon, NR/PR Genesis I, PR Kinemax and PR LCS). There were also more recently introduced brands with good short-term results that might have contributed to positive development of the overall survival of TKAs in the last time period (NR AGC Anatomic and NR e.motion).

Comparison with other relevant studies

Available evidence regarding patella resurfacing based on observational studies, RCTs and meta analyses, has been summarized in a recent systematic review (Calvisi et al. 2009). While they found it difficult to make any strict conclusions due to methodological limitations in available studies, they suggested the surgeons to be aware of lower risk for revision and lower level of postoperative anterior knee pain for resurfaced implants. These advantages were however found to be at the expense of potential complications related to the resurfaced patella.

Few studies have assessed the impact of patella resurfacing and of prosthesis brand on implant survival by use of data from arthroplasty registers. A previous study from the NAR (Furnes et al. 2002) found a statistically non significant higher risk for revision for non resurfaced implants. No statistically significant differences in revision rates were observed among brands, possibly due to short follow-up time. A lower risk for revision of patella resurfaced implants has also been reported from other arthroplasty registers (The Swedish Knee Arthroplasty Register. Annual Report 2009, Clements et al. 2010). In Sweden, PR Kinemax showed poorer survival as compared with PR AGC. NR NexGen performed better than NR AGC while NR Duracon, NR LCS and NR Profix performed similarly (The Swedish Knee Arthroplasty Register. Annual Report 2009). The NexGen implant has also been found to be the least revised cemented prosthesis brand at eight years as reported to AOANJRR (Australian Orthopaedic Association National Joint Replacement Registry. Annual Report. 2009).

Some of the prosthesis brands included in this study have been examined regarding survival in single centre studies. The PR AGC prosthesis have shown good long-term results (Ritter 2009). These results are in accordance with our findings and were partly explained by the non modular tibial component that is supposed to offer less backside wear of the polyethylene insert. Positive long-term results have also been demonstrated to uncemented Profix prostheses (Hardeman et al. 2006) but to our knowledge our study is the only that reports ten years survival results for cemented NR Profix prostheses.

Strengths & limitations

Due to economic and practical reasons comparison of rare incidences such as revisions of joint replacements by use of high-powered RCTs are rarely performed. The main alternative to RCTs is evidence from large observational studies such as arthroplasty registers. Even if accepted to be less conclusive, results from well designed observational studies may compare qualitatively well with those from RCT's (Benson and Hartz 2000). Register studies may also have advantages such as better external validity due to representation from a wider range of operation procedures, hospitals, implants, patients and surgeons.

Comparison of survival of different prosthesis designs in observational studies may however give results confounded by patient and procedure characteristics. We have treated known confounders; sex, age, previous operation of the knee, diagnosis and prosthesis brand (except when comparing brands) by use of adjustment in the statistical model. To avoid possible confounding by time of operation, separate analyses were performed within time periods. However, differences in survival may also be confounded by surgeon-related factors and by other variables not reported to the register. The results should therefore be interpreted with caution for brands used in a restricted number of hospitals since skill of the surgeons involved, follow-up routines and revision threshold may have biased the results. The practice in practically all hospitals in Norway is that implant brand and use or non use of patella resurfacing, is decided for all patients by the medical director in each orthopaedic department. Therefore, the choice of

brand and use of primary patella resurfacing is normally not linked to the surgeons or the patient characteristics.

Future research

The main argument for resurfacing the patella at the primary TKA is to avoid anterior knee pain and the need of secondary patella resurfacing, at possible cost of increased risk for serious complications related to the patellar component. A recent study from the AOANJRR found more revisions after secondary resurfacing of the patella than after primary insertion of a patellar component (Clements et al. 2010). Since recent studies (Johnston et al. 2009, Lygre et al. 2010) have found indications of non or negligible differences in pain between patients having a primary patella resurfaced or a patella non resurfaced TKA, more investigation of patients perceptions of the effect of secondary patella resurfacing should be performed.

Studies of rare events like revisions due to specific reasons need large numbers of observations. We have studied this for patella resurfaced and patella non resurfaced knee prostheses and our findings need to be verified in other studies. Studies on differences in revision reasons related to prosthesis brands are needed to further improve the quality of TKA. The Nordic Arthroplasty Register Association has recently started their work with the establishment of a common Nordic database in order to pool data from the arthroplasty registers in Denmark, Norway and Sweden (Robertsson et al. 2010). This could help to faster achieve enough data to investigate rare events.

A recent study from NAR has observed a higher risk for revision of TKAs due to infection for patients with rheumatoid arthritis as compared to osteoarthritis of the knee, especially after 5 years of follow-up (Schrama et al. 2010). More knowledge of differences in risk for revision for different diagnoses (and for different prosthesis designs) is still needed and should be focused on in future studies.

Possible implications

Our study indicates a need to reconsider the widely accepted recommendation of primary resurfacing of the patella. Less use of a patellar component during primary TKA might be advisable. This will probably give advantages in terms of less extensive operation procedure, shorter duration of the operation (Furnes et al. 2002), better preservation of the soft tissue of the patella, less periprosthetic patella fractures (Chalidis et al. 2007), less total wear of polyethylene, less loosening of the tibial component and lower cost.

Conclusion

We found a statistically non significant lower risk for revision of patella resurfaced TKAs as compared with patella resurfaced. There were however differences in reasons for revision. Resurfaced implants had statistically higher risks for revision due to aseptic loosening of the tibial component and due to wear of a polyethylene insert but had a statistically significant lower risk for revision due to pain alone. Further, our results might also imply that the introduction of newer implants and the stop in use of some older inferior designs have improved the survivorship of TKAs in Norway.

Figure Legends

Figure 1. Description of the selection procedure.

Figure 2. Time trends in the use of cemented patella resurfaced and patella non resurfaced TKAs in Norway 1994–2008. 2009 was not included since follow-up was only until December 10th, 2009.

Figure 3. Survival (%), cemented patella resurfaced and patella non resurfaced TKAs in Norway 1994–2009, all revisions. Cox regression results with adjustment for age, sex, diagnosis, previous operation of the knee and prosthesis brand.

Figure 4. Survival (%), cemented patella resurfaced and patella non resurfaced TKAs in Norway 1994–2009, specific reasons for revisions. Cox regression results with adjustment for age, sex, diagnosis, previous operation of the knee and prosthesis brand [(c), (g), (i) without adjustment for brand].

Figure 5. Survival (%), cemented patella resurfaced prosthesis brands in Norway 1994–2009, all revisions. Cox regression results with adjustment for age, sex, diagnosis and previous operation of the knee.

Figure 6. Survival (%), cemented patella non resurfaced prosthesis brands in Norway 1994–2009, all revisions. Cox regression results with adjustment for age, sex, diagnosis and previous operation of the knee.

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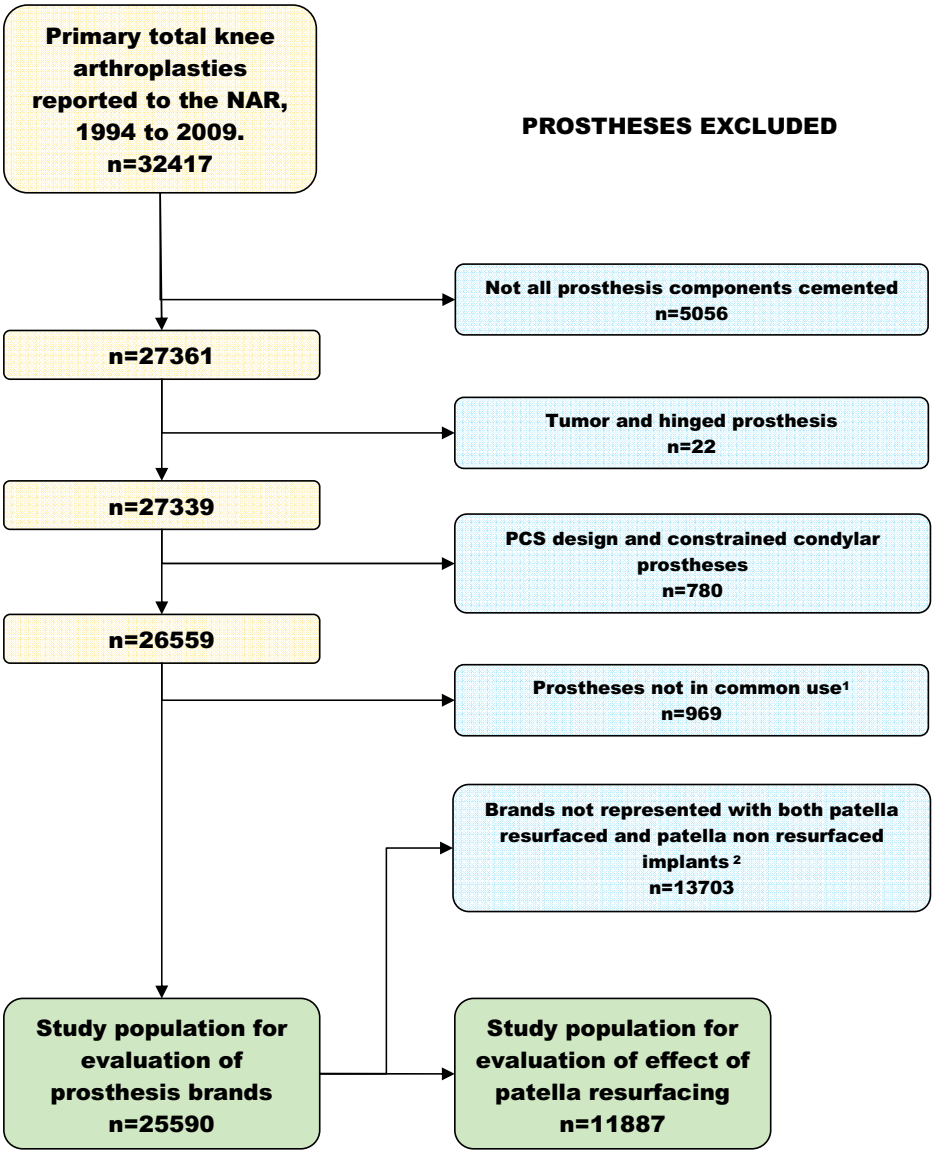

[1] For patella resurfaced and patella non resurfaced prostheses respectively, those brands reported with at least 200 operations where included (n=25590) for comparison of survival of prosthesis brands.

[2] For comparison of patella resurfaced and patella non resurfaced TKAs the material was further restricted to those brands with both patella resurfaced and patella non resurfaced TKAs represented with larger numbers than 200 (Tricon, Genesis I, AGC, LCS and NexGen).

Figure 1.

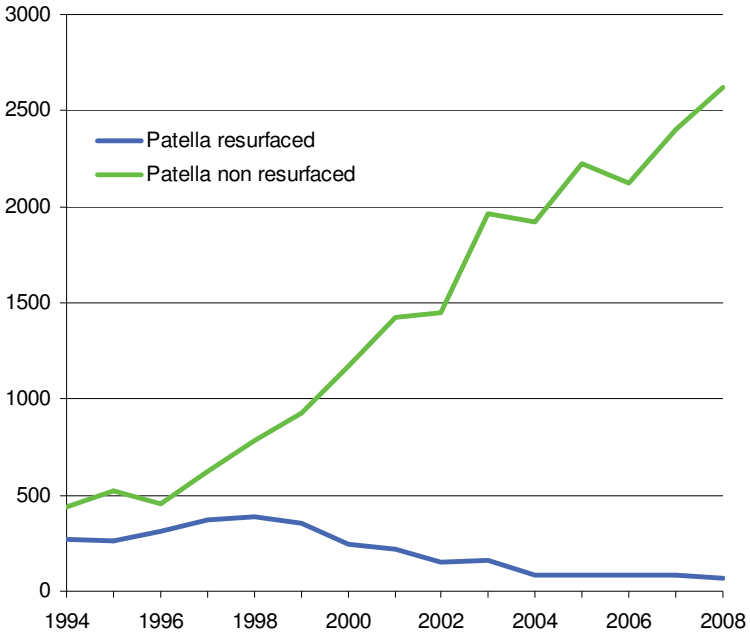
3000
2500
2000
1500
1000
500
0
Patella resurfaced
Patella non resurfaced
1994
1996
1998
2000
2002
2004
2006
2008

Figure 2.

Survival (%), all revisions

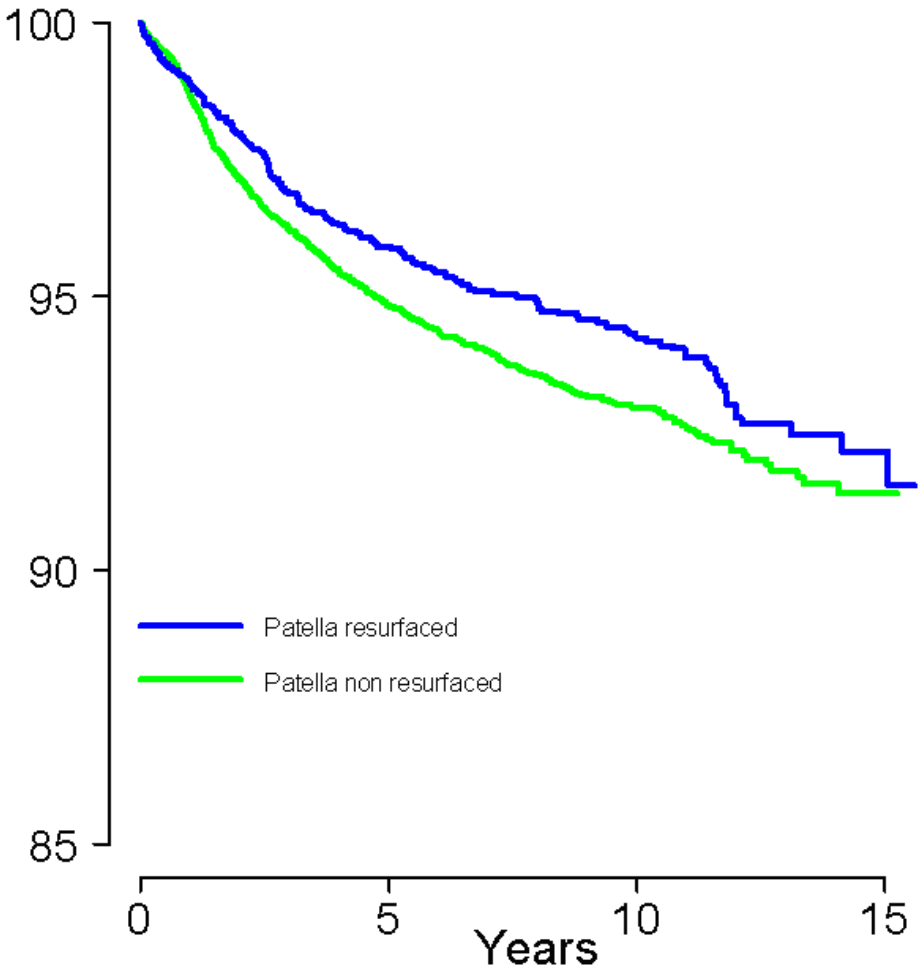

Figure 3.

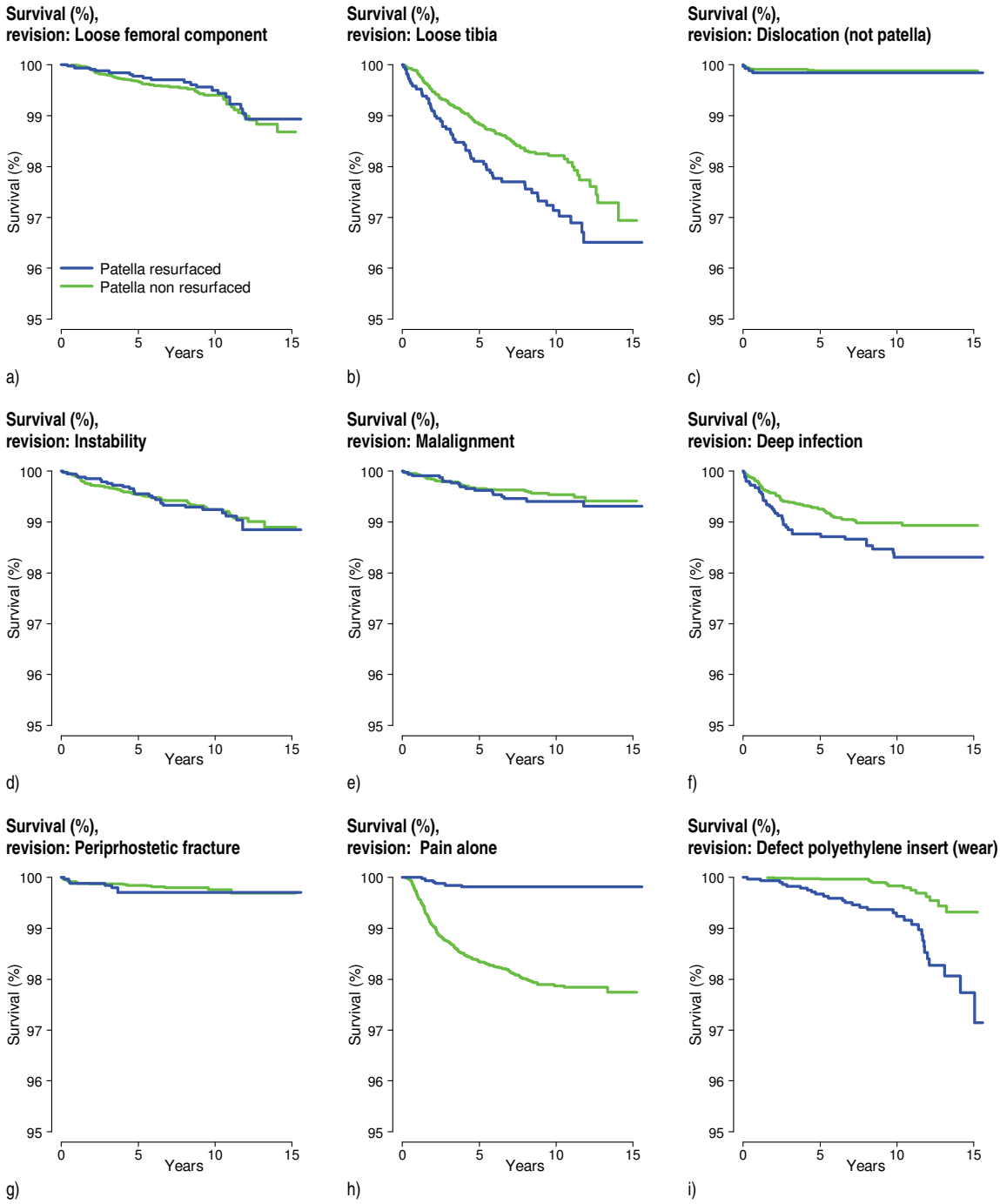
Survival (%),
revision: Loose femoral component
Survival (%),
revision: Loose tibia
Survival (%),
revision: Dislocation (not patella)
Survival (%)
Years
Patella resurfaced
Patella non resurfaced
a)
b)
c)
Survival (%),
revision: Instability
Survival (%),
revision: Malalignment
Survival (%),
revision: Deep infection
d)
e)
f)
Survival (%),
revision: Periprhostetic fracture
Survival (%),
revision: Pain alone
Survival (%),
revision: Defect polyethylene insert (wear)
g)
h)
i)

Figure 4.

Survival (%), all revisions, patella resurfaced prosthesis brands

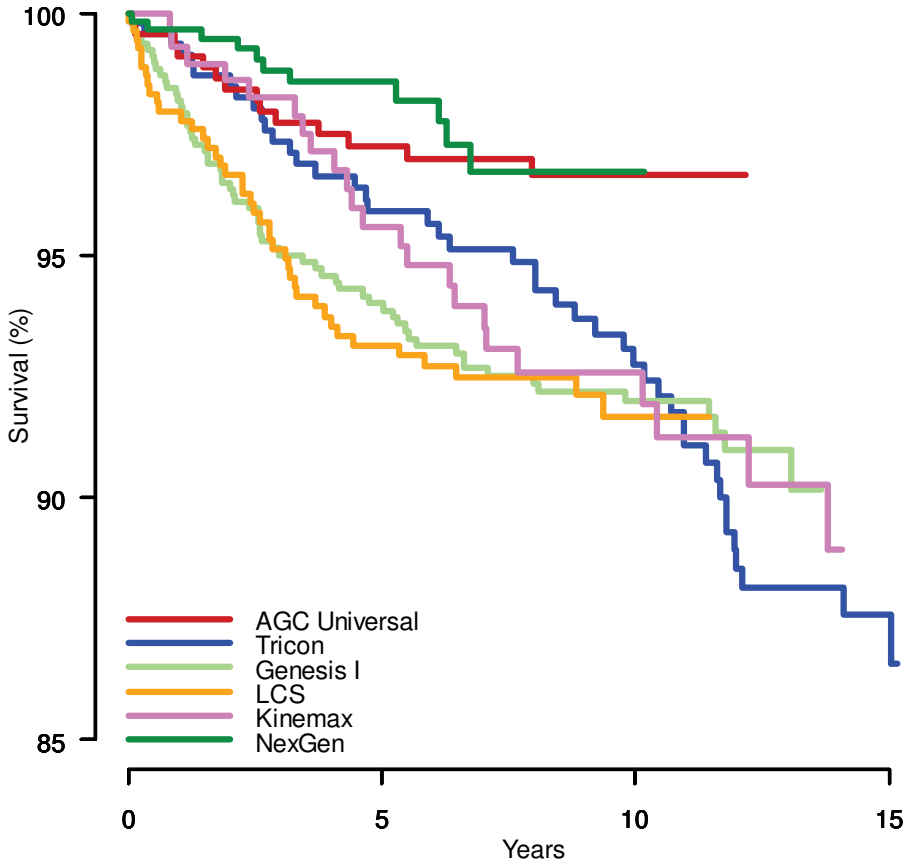

Figure 5.

Survival (%), all revisions, patella non resurfaced prosthesis brands

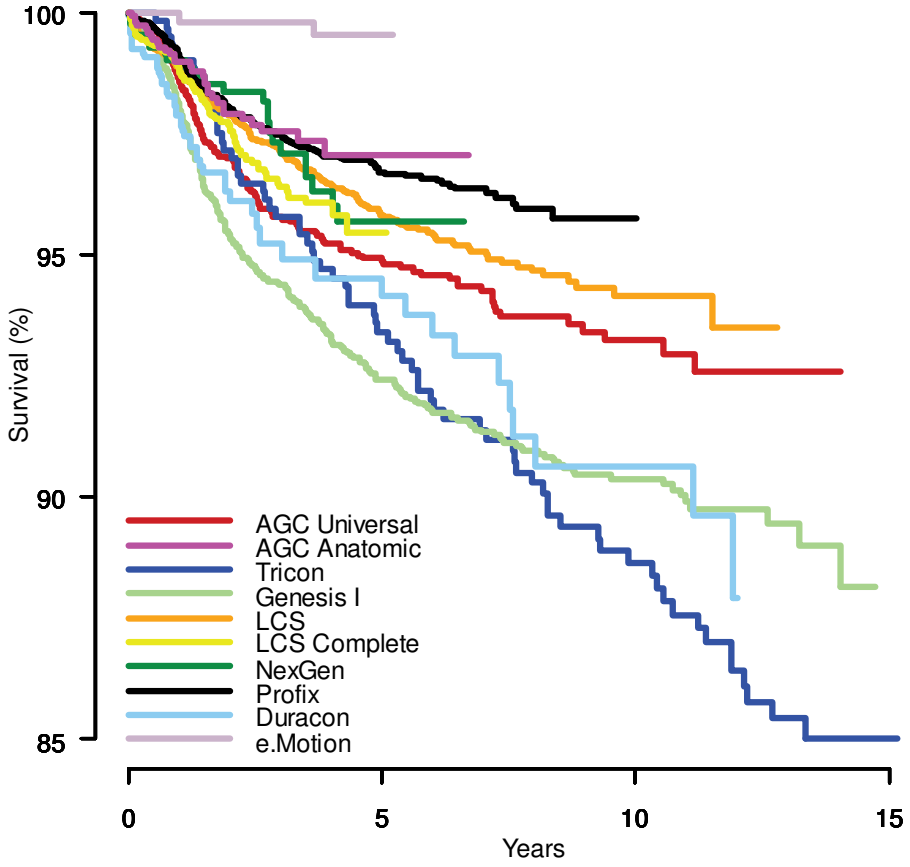

Figure 6.

Table I **Characteristics of primary total knee arthroplasties reported to the Norwegian Arthroplasty Register from 1994 to 2009**

Prostheses	n	Numbers of hospitals			Men	< 60 years	Median	OA[1]	PO[2]	MB[3]
		n	n>50	n>100	%	%	age	%	%	%
Patella resurfacing	11887	70	46	37	28	13	72	81	26	34
Patella resurfaced	2547	51	12	6	28	16	72	71	27	21
Patella non resurfaced	9340	69	41	32	28	13	73	83	25	38
Prosthesis brand	25590	79	61	53	31	15	72	84	27	34
NR AGC Universal	2123	31	11	7	31	12	73	86	22	0
NR Tricon[4]	633	23	5	1	22	7	73	75	24	0
NR Genesis I	2304	28	13	7	26	12	73	75	26	0
NR LCS[5,6]	3526	36	15	10	28	13	72	88	26	100
NR Duracon[7]	1283	18	10	5	33	14	71	87	30	0
NR NexGen	754	18	4	2	35	17	71	87	26	0
NR Profix	6304	40	25	20	31	16	71	85	25	0.2
NR LCS Complete	4090	36	15	13	33	16	70	90	30	100
NR e.motion	434	4	2	1	33	18	70	94	40	100
NR AGC Anatomic	1298	18	4	4	37	15	70	88	26	0
PR AGC Universal	425	21	3	1	24	13	73	66	25	0
PR Tricon[4]	392	21	3	0	26	21	71	54	29	0
PR Genesis I	704	23	5	1	25	14	71	72	28	0
PR LCS[8]	532	12	2	1	27	13	73	92	23	100
PR Kinemax	294	12	2	0	19	9	74	87	22	0
PR NexGen	494	11	1	1	36	21	69	64	28	0

[1] Primary osteoarthritis of the knee as diagnosis (%).

[2] Previously operated in the knee (%).

[3] Mobile bearing prostheses (%).

[4] Tricon C or Tricon M femoral component used on the femoral side and Tricon II used on the tibial side.

[5] 375 of the primary patella non resurfaced LCS prostheses where used in combination with a LCS-Universal tibial component.

[6] 3032 with mobile bearing rotating platform system and 494 with mobile bearing meniscal system.

[7] One Duracon prosthesis had an all polyethylene tibial component.

[8] 323 with mobile bearing rotating platform system and 209 with mobile bearing meniscal system.

Table II **Follow-up and numbers at risk by years after operation**

	1994 - 2009					1994 - 2000					2001 - 2009		
	Median follow-up (years)	Number at risk by years after operation				Median follow-up (years)	Number at risk by years after operation				Median follow-up (years)	Number at risk by years after operation	
Prosthesis		0	5	10	15		0	5	10	15		0	5
Patella resurfacing													
Patella resurfaced	9.1	2547	1930	986	76	10.6	1831	1519	986	76	6.0	716	411
Patella non resurfaced	7.2	9340	6522	1957	116	10.0	4255	3506	1957	116	5.8	5085	3016
Prosthesis brand													
NR AGC Universal	6.9	2123	1445	376	14	9.8	841	708	376	14	5.7	1282	737
NR Tricon	12.0	633	494	341	66	12.0	633	494	341	66	-	-	-
NR Genesis I	9.6	2304	1854	913	35	10.1	1946	1581	913	35	7.9	358	273
NR LCS	6.6	3526	2573	323	1	9.7	827	716	323	1	6.0	2699	1857
NR Duracon	1.7	1283	248	118	4	11.1	204	173	118	4	1.5	1079	75
NR NexGen	3.2	754	156	4	-	10.3	8	7	4	-	3.2	746	149
NR Profix	4.4	6304	2576	51	-	9.2	320	271	51	-	4.2	5984	2305
NR LCS Complete	1.9	4090	59	-	-	-	-	-	-	-	1.9	4090	59
NR e.motion	4.1	434	76	-	-	-	-	-	-	-	4.1	434	76
NR AGC Anatomic	2.7	1298	152	15	-	10.0	31	25	15	-	2.7	1267	127
PR AGC Universal	9.0	425	353	160	4	10.2	309	257	160	4	7.2	116	96
PR Tricon	12.5	392	313	226	67	12.5	392	313	226	67	-	-	-
PR Genesis I	10.9	704	581	316	5	11.1	672	557	396	5	7.2	32	24
PR LCS	8.9	532	446	150	-	9.9	346	293	150	-	7.5	186	153
PR Kinemax	10.1	294	240	138	30	10.7	265	214	138	30	7.2	29	26
PR NexGen	4.9	494	237	54	-	10.0	112	99	54	-	4.0	382	138

Table III **Cox relative revision risk (RR) and survival percentages, estimated with all causes of revisions as endpoint**

Prosthesis	1994-2009									1994-2000				2001-2009			
	n	Revised	RR	95% CI	p	5 yr	10 yr	15 yr	95% CI[1]	n	Revised	RR	p	n	Revised	RR	p
Patella resurfacing[2]																	
Patella non resurfaced	9340	614	1			94.8	93.0	91.4	90.4-92.4	4255	349	1		5085	265	1	
Patella resurfaced	2547	172	0.84	0.71-1.00	0.052	95.9	94.3	92.1	90.7-93.6	1831	138	0.84	0.09	716	34	0.99	1.0
Prosthesis brands[3]																	
NR AGC Universal	2123	120	1			94.9	93.2	-	91.9-94.5	841	51	1	-	1282	69	1	-
NR Tricon	633	72	1.67	1.24-2.23	0.001	93.4	88.6	85.0	81.7-88.3	633	72	1.84	0.001	0	-	-	-
NR Genesis I	2304	222	1.43	1.14-1.79	0.002	92.4	90.4	-	89.1-91.6	1946	175	1.46	0.02	358	47	2.01	<0.001
NR LCS	3526	177	0.84	0.67-1.06	0.14	95.8	94.1	-	93.2-95.1	827	50	0.90	0.6	2699	127	0.81	0.1
NR Duracon	1283	56	1.45	1.05-1.99	0.02	94.5	90.6	-	87.4-93.8	204	18	1.41	0.2	1079	38	1.39	0.1
NR NexGen	754	23	0.79	0.51-1.24	0.3	95.7	-	-	93.9-97.5	8	1	-	-	746	22	0.72	0.2
NR Profix	6304	195	0.66	0.52-0.82	<0.001	96.7	95.7	-	94.9-96.5	320	12	0.59	0.1	5984	183	0.62	0.001
NR LCS Complete	4090	111	0.94	0.72-1.22	0.6	95.4	-	-	94.2-96.6	0	-	-	-	4090	111	0.85	0.3
NR e.motion	434	2	0.09	0.02-0.37	0.001	99.5	-	-	98.9-100	0	-	-	-	434	2	0.09	0.001
NR AGC Anatomic	1298	31	0.66	0.45-0.99	0.04	97.1	-	-	95.9-98.2	31	1	-	-	1267	30	0.63	0.03
PR AGC Universal	425	14	0.48	0.27-0.83	0.009	97.2	96.6	-	94.9-98.4	309	13	0.69	0.2	116	1	-	-
PR Tricon	392	44	1.28	0.90-1.82	0.2	95.9	92.7	87.5	83.9-91.2	392	44	1.46	0.07	0	-	-	-
PR Genesis I	704	62	1.17	0.86-1.59	0.3	94.0	92.0	-	90.0-94.0	672	57	1.25	0.2	32	5	-	-
PR LCS	532	41	1.23	0.86-1.75	0.3	93.1	91.7	-	89.1-94.2	346	20	0.97	0.9	186	21	-	-
PR Kinemax	294	23	1.14	0.73-1.78	0.6	95.6	92.6	-	89.3-95.8	265	22	1.32	0.3	29	1	-	-
PR NexGen	494	11	0.40	0.22-0.74	0.004	98.6	96.7	-	94.6-98.8	112	4	-	-	382	7	0.33	0.005

[1] Confidence interval for last reported survival percentage.

[2] Cox relative risk estimates and survival percentages with adjustment for age, sex, diagnosis, previous operation of the knee and prosthesis brand

[3] Cox relative risk estimates and survival percentages with adjustment for age, sex, diagnosis and previous operation of the knee.

Table IV **Cox relative risk (RR), patella non resurfaced vs patella resurfaced primary TKAs by reason for revision, 1994-2009**

Reason for revision[1]	Revised		RR[2]	95% CI	P
	Patella resurfaced (n=2547)	Patella non resurfaced (n=9340)			
Loose femur	21	65	0.82	0.49-1.39	0.5
Loose tibia	57	149	1.42	1.03-1.95	0.03
Loose patella	13				
Dislocation, patella	7	22	0.98	0.42-2.32	1.0
Dislocation, other	4	12	2.22	0.71-6.95	0.2
Instability	30	73	0.96	0.61-1.50	0.9
Malalignment	17	43	1.18	0.65-2.12	0.6
Deep Infection	41	93	1.32	0.90-1.95	0.2
Periprostetic fracture	7	20	1.53	0.64-3.70	0.3
Defect polyethylene ins.	30	16	3.23	1.71-6.11	<0.001
Pain Alone	8	202	0.12	0.06-0.23	<0.001

[1] More than one reason for revision may have been reported.

[2] Cox relative risk for revision estimates (RR) adjusted for age, sex, diagnosis, previous operation of the knee and brand (AGC Universal, Tricon, Genesis I, LCS and NexGen) are reported for patella resurfaced vs patella non resurfaced prostheses.

Errata

Page 6. Third section, line 7:*"at to the Norwegian Arthroplasty Register*" is changed to *"at the Norwegian Arthroplasty Register"*

Page 9. Title of Journal, Paper II: "*American Journal of Bone and Joint Surgery (Am)."* is changed to "*Journal of Bone and Joint Surgery (Am)."*

Page 10. Last section, line 3: "*patella non resurfaced TKAs*" is changed to "*patella resurfaced TKAs*".

Page 11. First section, line 2: *"differencesin"* is changed to *"differences in"*

Page 17. First section, line 8: The term "*plateu were*" is changed to "*plateau was*".

Page 18. Third section, line 1: "*in Norway has a*" is changed to "*in Norway have a".*

Page 20. First section, line 3: "*67 %*" is changed to "*40 %*".

Page 24. Second section, line 4: "*See section 7.2*" is changed to "*See section 7.3*".

Page 25. Last section, line 2: *"(see Appendix II)"* is changed to *"(see Appendix I)".*

Page 25. Last section, line 3: *"a information"* is changed to *"an information".*

Page 25. Last section, line 3: *"(see Appendix III)"* is changed to *"(see Appendix II)".*

Page 39. Title of manuscript: "*among 1344 patients*" is changed to "*of 1344 patients*".

Page 41. Results section, line 1: "*no*" is changed to "*none*".

Page 45. Third section, line 2: The period after "*subjects*" is deleted.

Page 47. First section, line 1: "*was*" is inserted before "*therefore unlikely*".

Page 47. Second section, line 3: "*is*" is changed to "*are*".

Page 59. Third section, line 4 to 5: "*revisions*" is changed to "*revision*".

Page 59. Third section, line 9: "*in recent reviews*" is changed to "*in a recent review*".

Page 63. Source of data: "*Ref Type: Thesis*." is added to the end of reference 14.

*** Paper II ***

Page 12. First section, line 7: "*and injury*" is changed to "*injury and*".

Page 16. References:"*Thesis*." is added to the end of reference 3.

*** Paper III ***

Page 3. Second section, line 12: "*revisions*" is changed to "*revision*".

Page 5. Last section, line 4: "*2133*" is changed to "*2123*".

Page 7. First section, line 7: "*has*" is changed to "*have*".

Page 9. Second section, line 4: *"RR=24"* is changed to *RR=0.24"*.

Page 11. Second section, line 1: The acronym "*NR*" is inserted before "*Genesis I*" and before "*Duracon*".

Page 12. First section, line 1: "*the*" is inserted before "*first time period*".

Page 14. Third section, line 3: "*revisions*" is changed to "*revision*".

Page 16. Fourth section, line 1: "*revisions*" is changed to "*revision*".

Page 24. Figure 4c, 4g and 4i: The indications of a footnote are deleted.

Page 24. Figure 4: The text fonts are adjusted to make the text more readable. The legends have been deleted in Figure 4b to Figure 4i.

Page 29 Table III, heading: "*estimated survival*" is changed to "*survival*".