

# **Influence of hospital procedure volume on the risk of revision in knee arthroplasty surgery**

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## Errata

Contents section corrected: page numbers were incorrect

## Scientific Environment

The present work has been conducted at the Norwegian Arthroplasty Register during the period 2012-2016 while working as an orthopaedic surgeon at Kysthospitalet in Hagavik, Haukeland University Hospital, Bergen, Norway. I was granted 'consultant on leave' for 24 weeks to do research and writing full time.

The thesis is a part of the PhD program at the Department of Clinical Medicine, Faculty of Medicine and Dentistry, University of Bergen.

The project has had no external funding in paper 1 and 2. For paper 3, funding was received from NordForsk (an organization under the Nordic Council of Ministers) to enable 6 weeks on leave from regular clinical work.



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Orthopaedic surgery in general and knee surgery in particular, has been a major passion in my working life. Being able to combine clinical work with scientific research has been even more rewarding. My ideas and suggestions for research were supported with surprising enthusiasm by my current supervisor and project leader, and for that I am deeply grateful. Professor and orthopaedic surgeon Ove Furnes (MD, PhD) has been a remarkable supervisor in all possible ways. He has provided a perfect mixture of energy, challenges, optimism, rapid feedback and a sincere interest throughout the years of our collaboration. I appreciate our continuous academic communication and discussions, and I hope they will continue in the future.

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Special thanks to my parents who always supported my choices to do whatever I wanted in life. Steinar, my husband, best friend and father of my two diamonds, Alexander and Oliver, always encouraged and supported my work with love.

## List of Abbreviations

ACL	Anterior Cruciate Ligament
AP	Anteroposterior
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
CR	Cruciate Retaining
CCK	Constrained Condylar Knee
DKAR	Danish Knee Arthroplasty Register
FAR	Finnish Arthroplasty Register
ICOR	International Consortium of Orthopaedic Registries
ISAR	International Society of Arthroplasty Registers
KM	Kaplan Meier
ML	Mediolateral
MRI	Magnetic Resonance Imaging
NAR	Norwegian Arthroplasty Register
NARA	Nordic Arthroplasty Register Association
NJR	National Joint Registry of England and Wales

NOA	Norwegian Orthopaedic Association
NPR	Norwegian Patient Register
OA	Osteoarthritis
OA	Orthopaedic Association
PS	Posterior Stabilized
RCT	Randomized Controlled Trial
RECORD	The Reporting of studies Conducted using Observational Routinely collected health Data
RR	Risk Ratio
SKAR	Swedish Knee Arthroplasty Register
TKA	Total Knee Arthroplasty
UKA	Unicompartmental Knee Arthroplasty

## List of Publications

The thesis is based on the following papers:

- I. Influence of Hospital Volume on Revision Rate After Total Knee Arthroplasty with Cement. *Badawy M, Espehaug B, Indrekvam K, Engesaeter LE, Havelin LI, Furnes O. The Journal Of Bone and Joint Surgery (Am) 2013.*
  
- II. Higher Revision Risk for Unicompartmental Knee Arthroplasty in low-volume hospitals. Data from 5 791 cases in the Norwegian Arthroplasty Register. *Badawy M, Espehaug B, Indrekvam K, Havelin LI, Furnes O. Acta Orthopaedica 2014.*
  
- III. Oxford Unicompartmental Knee Arthroplasty in the Nordic Countries: effect of hospital caseload on revision rates. 12 986 cases from the Nordic Arthroplasty Register Association, 2000-2012. *Badawy M, Fenstad AM, Bartz-Johannessen CA, Indrekvam K, Havelin LI, Robertsson O, W-Dahl A, Eskelinen A, Mäkelä K, Pedersen AB, Schröder H, Furnes O. Submitted.*

## **Abstract**

The knee is a complex joint consisting of three anatomically and kinematically different compartments; the medial, the lateral and the patellofemoral compartment. When developing painful and disabling osteoarthritis (OA), there are different treatment options. Conservative treatment consisting of pain medication, injection therapy, physiotherapy and exercises can delay or prevent surgical treatment in many patients. However, many OA patients will need knee replacement surgery if all other fails. Most of these patients need a total knee arthroplasty (TKA), but in many cases with isolated unicompartmental OA, unicompartmental knee replacement (UKA) is sufficient.

Knee replacement surgery is rapidly increasing in Norway and worldwide. Both total knee and unicompartmental knee arthroplasty surgery are technically difficult procedures with multiple possible pitfalls perioperatively. The procedures require thorough knowledge of the bony and soft tissue anatomy and kinematics, as well as proper surgical technique and experience with the implants and concomitant instruments.

The purpose of Paper I was to investigate whether there was a correlation between annual hospital procedure volume and the risk of revision in total knee arthroplasty using data from the Norwegian Arthroplasty Register. We found a significantly higher revision risk following total knee arthroplasty in low-volume hospitals in comparison to high-volume hospitals.

In Paper II we compared high and low-volume hospitals regarding risk of revision in patients operated with the Oxford III UKA based on data from the NAR. We also investigated possible variations in the reasons for revision. Our interpretation was that

higher hospital volumes were beneficial for improved survival of the Oxford III implant.

Paper III was an expansion and further development of Paper II, investigating the effect of hospital procedure caseload on the risk of revision upon the usage of Oxford III UKA in the four Nordic countries using data from the Nordic Arthroplasty Register Association database. In this study we used a combination of three different methods of calculating annual hospital procedure volume. Lower volume hospitals had inferior results in all 3 methods of analysis as well as in the combined model with a 3-year moving average estimate.

In conclusion, to optimize knee arthroplasty results and to avoid high rates of revision, acceptable procedure volumes should be achieved. TKA patients operated in hospitals performing more than 100 cases per year had a lower risk of revision. UKA patients operated in hospitals performing >40 cases per year had the lowest risk of revision in the NAR, whereas UKA patients in the NARA had a higher risk of revision if operated in hospitals performing less than 25 per year.

# 1. INTRODUCTION

## 1.1 The Osteoarthritic Knee

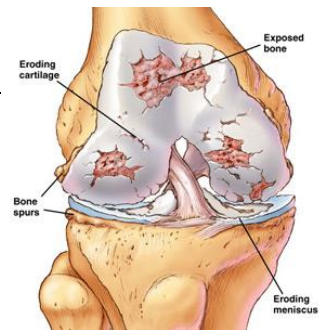
### 1.1.1 Epidemiology and Kinematics

Age is the strongest risk factor for osteoarthritis (OA) indicating a reduction in regenerative capacity and accumulation of risk factors and it is more common in women than in men (1). Injury can cause damage to the menisci, ligaments and cartilage, and increases the risk of development of OA more than 4 times (2). Obesity is a known risk factor increasing the load on the knee joint and the risk of OA by more than 3 times (3) and obesity is increasing the future need for knee replacement by 6.2 for men and 11.1 for women in a study from Apold et al (4) (Fig.1).

*Fig.1 Healthy knee(top), OA knee (left bottom) and knee replacement (right bottom). By permission of Mayo Foundation for medical Education and Research. All rights reserved.*

Cartilage is regulated by chondrocytes which upon activation can produce multiple inflammatory response proteins with both pathogenetic effects and with potential remodeling effects (1).

Tibial and femoral bone morphology as well as limb malalignment with a varus and valgus knee can predict development of knee osteoarthritis. Furthermore, with leg length inequality of 1 cm or greater the risk of knee osteoarthritis is almost two times higher in the shorter than in the longer limb.



**Fig.2** Damaged cartilage (OA) in all 3 compartments. By courtesy of Oxford University Hospitals NHS Foundation Trust.

Kinematics during gait is altered in severe OA of the knee,

due to changes in the biomechanical properties of the cartilage and menisci (5) (Fig.2). In a normal knee, on average 58% of load, is transmitted through the meniscus and 42% through the uncovered cartilage (6). Rotational geometry can be altered due to coronal alignment differences in the osteoarthritic knee. Limb alignment is an important factor in developing OA and increasing the progression of OA in the overloaded compartment of the knee joint (7, 8).

Valgus knees have the highest degree of internal rotation (9). Osteoarthritis in a valgus knee is commonly located in the lateral compartment due to increased load laterally. Previous lateral meniscectomy or a tibial plateau fracture could be predisposing factors for lateral OA. Lateral osteoarthritis also commonly has a posterior location (10), thus is most commonly visible in radiographs in flexion.

Tibial torsion can be significantly reduced in OA patients with varus malalignment (11), probably due to the tight popliteus tendon in the severe varus OA knee. Medial osteoarthritis is the most common feature (Fig.3), and an anteromedial location is most common assuming the ACL is functional. White et al described medial tibial plateau excised from a series of Oxford UKA, all with intact ACL and all with central and anterior cartilage erosions (12). Isolated medial OA is a common disease of the knee.

**Fig.3** Medial OA in a varus malaligned knee. By permission of Mayo Foundation for medical Education and Research. All rights reserved.



Sometimes the patellofemoral joint is affected by cartilage degeneration, probably due to normal wear and tear and is asymptomatic. In a few cases, patellofemoral joint OA can lead to a painful knee with bone-on-bone and lateralization of the patella commonly caused by trochlear dysplasia. The need for a patellar joint replacement is still debated both for TKA (13-17) and for UKA (18-21).

In the NAR, OA contributes to 90% of reported diagnoses leading to total knee replacement and OA is the cause in 95% for unicompartmental knee replacement.

### **1.1.2 Diagnosing Knee Osteoarthritis**

Pain and loss of mobility due to osteoarthritis of the knee is the most common reason for the initial patient-surgeon contact to discuss knee replacement surgery. If lifestyle modifications such as weight loss in obesity have been tried as well as strengthening exercises, surgical alternatives such as unloading of the affected compartment or repair of localized cartilage lesions should be considered before knee replacement surgery (30).

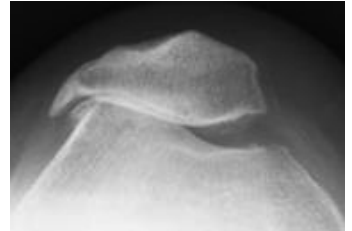
Arthritis of the knee can be either monoarticular or part of an oligo- or polyarticular disease. In addition to osteoarthritis, inflammatory diseases such as rheumatoid arthritis and spondylo-arthropathy often require arthroplasty surgery (22).

Sometimes the osteoarthritis is secondary to previous trauma or injury to the bone, cartilage, meniscus and/or ligaments of the knee. Many of these patients have had previous surgery to the knee. Pain is the most predominant symptom of OA in addition to swelling and loss of mobility. The pain is often relieved by rest. Night pain and morning stiffness is uncommon. Pain on active or passive movement, local tenderness, crepitus, joint swelling and quadriceps muscle atrophy are typical features on clinical examination.

Single compartment involvement of the joint is most common in the medial compartment, but can also be presented as retropatellar OA or isolated lateral OA (23). Radiographic imaging confirms the diagnosis of OA.



**Fig.4** AP (anteroposterior) and ML (mediolateral) view of tricompartmental OA of the left knee.



**Fig.5** Patella skyline radiograph with bone-on-bone lateral patellofemoral OA.



Since the knee has three compartments, anteroposterior, mediolateral and patella skyline views are recommended (Fig.4 and Fig.5). Joint space narrowing, subchondral sclerosis and osteophytes are common findings. MRI can detect early changes in OA but is not necessary to establish the indication for joint replacement surgery. Diagnostic arthroscopy to determine whether there exists an indication for surgery is rarely indicated. Planning before knee replacement surgery also involves determination of the limb axis to measure the Hip-Knee-Ankle angle (Fig.6).

**Fig.6** Long axis anteroposterior radiograph of patient with severe valgus malalignment and lateral OA. She also has severe dysplasia of her left hip.

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Varus/valgus stress x-rays or Rosenberg views (45 degrees of flexion in standing AP view) (24) can be useful when planning for unicompartmental knee arthroplasty (Fig.7).



**Fig.7** Rosenberg view with 45° flexion in AP view, visualizing posterolateral OA.

Assessment of the ligament status is done clinically and is important considering the choice of arthroplasty. A ML view gives valuable information of the status of the cruciate ligaments.

## 1.2 Total Knee Arthroplasty

### 1.2.1 Introduction and Indication for Surgery

Multiple factors may affect the outcome of total knee arthroplasty (Fig.8) and the patient satisfaction has been reported to vary between 80-90% (25-27). Patient satisfaction and outcome after knee arthroplasty varies between studies, and is multifactorial (28). 33-54% of patients reported residual symptoms and functional problems in a recent national multi-center study (29).

*Fig.8 Total knee arthroplasty viewed from the frontal plane (left) and the side view (right). By permission of Mayo Foundation for Medical Education and Research. All rights reserved.*

The knowledge and understanding of the knee replacement surgery has evolved during the last decades, leading to better and more durable implants. TKA has proved better results than non-surgical treatments (30). However, Skou et al. also showed that 74% of the patients receiving non-surgical treatment did not undergo TKA before the 12-month follow-up. Additionally, TKA was associated with a high number of serious adverse events. Knee replacement surgery could be recommended when various conservative treatment options no

longer provide adequate pain relief or functional improvement. Conservative treatment options in knee OA are pain medication and injection therapy (31, 32) in addition to physiotherapy with strengthening and mobility exercises (33). Other surgical treatment options could also be considered in earlier stage OA such as various cartilage surgery techniques (34), or limb correcting osteotomy (35).

Degree of pain and functional impairment combined with sufficient radiographic cartilage loss are factors in decision-making regarding indication for surgery.

Implant related issues that are debated, are resurfacing of the patella (13), cemented or uncemented fixation (36), and fixed versus mobile bearing (37).

### **1.2.2 Implant Designs**

There are fixed bearing and mobile bearing designs in knee arthroplasty. Mobile bearing knee arthroplasty has a mobile polyethylene insert where the purpose is better kinematics and improved range of motion. The intention is reducing wear of the polyethylene by reducing point loading, but these goals have not been achieved compared to the fixed bearing designs. There are pros and cons to both designs and the surgical principles are mainly the same for fixed and mobile bearing components. Currently there are no major differences in the risk of revision comparing the two designs (38). An international meta-analysis based on registry data found a greater risk of revision in mobile-bearing non-posterior-stabilized designs (37). In the NAR, 28.7% of knee replacements are mobile bearing designs.

There are different levels of constraint in knee arthroplasty. The most constraint is a hinged prosthesis. The indication for a hinged design is medial or lateral collateral ligament deficiency/insufficiency or significant axial malalignment with a varus or valgus axis of more than 20 degrees where the polyethylene height may exceed 20mm (39). It is however recommended to use as little implant constraint as possible. In the majority of cases, no constraint is necessary as in posterior cruciate retaining implants (CR). It is

dependent on functionally intact soft-tissues around the knee and an intact posterior cruciate ligament in particular. Only the anterior cruciate ligament is sacrificed. In posterior cruciate deficient knees a posterior cruciate substituting design (PS) is necessary. For primary knee arthroplasty, CR and PS are most commonly used, but the preference differs between countries, hospitals and surgeons and remains a matter of discussion. Most studies on the subject addresses clinical and functional differences, but no clinical relevance has been found (40, 41). An international registry based study showed higher revision rates with PS knees (42). Intercondylar stabilizing implants (CCK) has a taller and broader central cam post compared to the PS cam that can provide varus-valgus stability and rotational stability as well (43). This design in addition to the hinge design is rarely used in primary cases, and there are limitations to the existing literature regarding long-term results and indications for usage (44). In the NAR, only 3% of primary knee replacements are PS, CCK and hinged implants. 97% are CR designs including the mobile bearing implants.

### **1.2.3 Fixation Method**

Cemented knee arthroplasty has been the golden standard of fixation supported by long-term survival rates in registries worldwide. Cementing technique with optimal penetration into the cancellous bone is dependent on the bone preparation and the management of the cement (45). The bone cuts should be precise allowing 1 mm of cement mantle to a tight fit. Ideal cement penetration should be 3-5 mm (45). In hard sclerotic bone it is recommended to drill several small holes in the bone to facilitate cement into the bone. It is important to remove all excess cement to avoid third-body wear and damage to the polyethylene component. The polymerization process from liquid to solid state takes several minutes, varying with temperature and humidity and also from one cement brand to another.

Earlier failures of cementless fixation in TKA have been loosening of the tibial plateau or early polyethylene wear of the metal-backed patellar components. Improved fixation

and bony ingrowth depends on the structure and quality of the component surface. Better materials in addition to bone growth-enhancing factors could improve the cementless knee replacement in the future (36). Some surgeons use a hybrid technique of cemented tibia component and a cementless femoral implant (46, 47). In the NAR, 83.6% are cemented, 4.9% are uncemented and 11.5% are hybrid with cemented tibial and uncemented femoral components (62).

### 1.2.4 Patella Resurfacing

The patellofemoral joint is complex, and individual variations are common regarding alignment and patellar tracking (48). The kinematics of the patella is changed in TKA and is dependent of the design of the femur. Femoral components used in earlier implant designs had a shallow trochlear groove and were so-called patella-unfriendly (Fig.9). Patellar



*Fig.9 Private photo after revision of knee arthroplasty implanted in 1989 in Haugesund Rheumatism Hospital in a rheumatoid patient. The femoral component has a non-existing trochlear groove and therefore so-called patella-unfriendly design. The implant was known as Accord, the Johnson/Elloy concept by Thackray.*

components were more commonly used to avoid anterior knee pain. Current knee arthroplasty designs have a deeper trochlear groove with an elevated lateral flange that are more patella-friendly and facilitates a more normal tracking throughout the flexion movement (Fig.10). In addition, patellar maltracking is not so common in newer designs due to the possibility to externally rotate the femoral component leading to lateralization of the trochlear groove. Internal malrotation of the tibia component could also affect the patellar tracking negatively (49, 50).



**Fig.10** Private photo of extracted femoral component after revision surgery, demonstrating a deep trochlear groove with elevated lateral flange, so-called patellar-friendly design.

There are two different patellar designs in use, the inset or the resurfacing design (51, 52). The common method of insertion is medial placement and resection of the unresurfaced lateral facet, thus improving patellar tracking.

In Norway the majority (98%) of knee arthroplasty is without a patellar component (16), but there are different traditions in other countries where inserting a patellar component in total knee arthroplasty is preferred and recommended (53). Some surgeons prefer to resurface the patella in cases of severe patellofemoral osteoarthritis only and otherwise do not use it (13, 15, 54).

### **1.2.5 Failure Mechanisms**

Aseptic loosening, instability, malalignment, and periprosthetic infection are the primary failure mechanisms leading to revision surgery after TKA, whereas there have been a reduction in implant-associated revisions such as those due to polyethylene wear. Common early and intermediate failure mechanisms, such as deep prosthetic infection, instability, and malalignment (55) remains common. Furnes et al. found that unicompartmental knee replacement was associated with an increased risk of revision due to pain alone, aseptic loosening of the tibial and of the femoral component and periprosthetic fracture as compared



with total knee replacement. Unicompartmental knee replacement was associated with a lower risk of infection compared with total knee replacement (56). Also, Leta et al. found that deep infection was the most frequent cause of failure of revision of aseptic total knee arthroplasties (57). In Norway, 19 % of revisions of non-resurfaced total knee arthroplasties done for knee pain between 1994 and 2011 were secondary patella resurfacing. However, more than a third of the patients were dissatisfied with the result after the procedure (58).

## 1.3 Unicompartmental Knee Arthroplasty

### 1.3.1 Indications and Contraindications

Pain on standing or walking is the principal sign of anteromedial OA of the knee. In this context we only focus on the medial UKA, since the definition of a UKA also could mean an isolated lateral or a patellofemoral arthroplasty. The localization of the pain is commonly on the medial side of the joint, but not always. The severity of the pain decides the need for surgery.

Full-thickness cartilage loss with bone-on-bone on the medial side on the x-ray is a requirement for surgery. In addition, the cartilage on the lateral side should be intact. A plain standing AP view, a Rosenberg view or stressed films are the different options to demonstrate this (Fig.11). The varus deformity should be correctable in 20 degrees of flexion (59).

Intraoperatively the ACL should be intact and functional and the lateral side should be inspected for possible central articular cartilage ulcers (60, 61).

Inflammatory arthritis is a contraindication as well as previous high tibial osteotomy. Absent or damaged



**Fig.11** Varus stress radiograph demonstrating full cartilage loss in the medial compartment of the knee.

ACL, PCL and/or MCL are also contraindications (59). Lateral cartilage loss is a contraindication. High BMI, high activity level, age <60, chondrocalcinosis and patellofemoral OA were 5 contraindications proposed by Kozinn and Scott(21), but later opposed by users of the Oxford mobile-bearing implant (60, 61).

### **1.3.2 Surgical Technique**

Unicompartmental knee replacement comprises 10.5% of all knee arthroplasty in the NAR from 1994-2014. 72% of all UKA in Norway since 1994 was Oxford III mobile bearing implants. There are both mobile and fixed bearing implant designs in UKA. 8 different fixed bearing implant brands have been utilized in small numbers from 1994 till now (62).

The main object is to restore the affected medial compartment and also restoring the ligament tension both in flexion and extension (Fig.12). The ligaments are never released in UKA; they are restored to normal tension by the right size meniscal bearing. The ligament tension should be equal throughout the entire range of motion. The presumed advantage is preservation of undamaged structures such as the lateral compartment and the anterior cruciate ligament.

***Fig.12** Isolated medial osteoarthritis of the left knee with intact ligaments and implanted Oxford unicompartmental knee replacement. By permission of ZimmerBiomet. All rights reserved.*

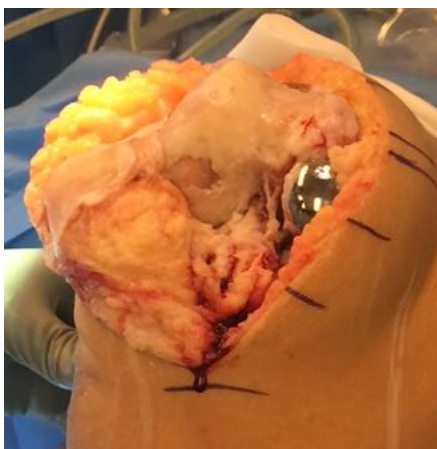
### 1.3.3 The Oxford Uni Knee

The Oxford UKA has an unconstrained mobile bearing. It articulates with the femoral condyle with the upper concave surface and the flat surface against tibial surface (59) (Fig.13). The Oxford phase 1 was first introduced in 1974 and Oxford phase 2 in 1987. They were both implanted through a large open approach as in TKA. In 1998, the Oxford phase 3 was introduced, and the short minimally invasive incisions were introduced. 5 different sizes for the femoral component replaced the single size in phase 1 and 2. The tibial plateau became side-specific. Instruments were miniaturized to allow minimally invasive technique. The concept of using spherical and flat articular surfaces on the two metal components and a fully conformed meniscal bearing was to minimize polyethylene wear and to restore natural mobility and stability by retaining all ligaments (50).

*Fig.13 The Oxford mobile bearing implant design with a mobile meniscal bearing where the meniscomfemoral interface is a "ball-in-socket" due to the spherical femoral component and the meniscotibial interface is a "flat-on-flat" allowing translation and rotation. By permission of ZimmerBiomet. All rights reserved.*

### 1.3.4 Failure Mechanisms

Long-term failure rates of uni knees have been high in several registries compared to total knee arthroplasty (56, 63). Loosening of the components or luxation/spin out of the insert is usually due to technical issues. Anatomic bearings were designed to prevent 90° of bearing rotation on the tibial tray. Radiolucency has been reported in cemented Oxford UKA components and could be interpreted as a sign of loosening, but should be radiographically interpreted with caution (64, 65). Fracture due to collapse of the tibial plateau is another known failure mechanism in knee replacement surgery, but new instrumentation has also been developed to avoid that complication. Development of lateral OA occurs in some patients and presents as pain and radiographic lateral OA (Fig.14). Revision due to pain alone is thought to be a problem of inappropriate surgical indication (59), both for the primary and the revision procedure. Persisting pain after primary surgery where the degree of OA was modest could suggest that the indication for surgery was doubtful. This issue has been explored comparing revisions for pain alone in UKA and TKA with conflicting results. The argument whether the threshold for revising a UKA is lower than for the same level of patient reported pain after a TKA is controversial (66, 67). Revising a TKA is considered more difficult than revising a UKA since one occasionally could get by just replacing the UKA with a TKA. However, that is not always the case, and stems and augments are frequently required for revision from a UKA to a TKA (62, 68) depending on the depth of the previous tibial cut.

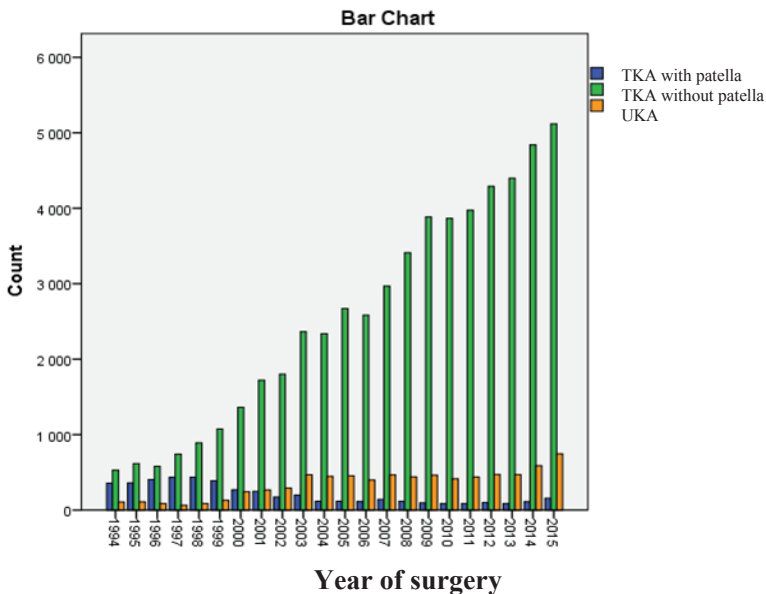


**Fig.14** Progression of lateral OA is also a well-known cause of revision in UKA surgery. Private photo from revision surgery of a medial Oxford III UKA due to painful progression of lateral OA 7 years after primary surgery. (Photo taken by one of our nurses).

## 1.4 Impact of Procedure Volume in Surgery

### 1.4.1 Procedure Volume

Superior results after knee replacement surgery depends on a variety of factors. The main aim of our studies was to show the association between procedure volume and risk of revision after both total and unicompartmental knee arthroplasty. The number of TKA procedures has increased gradually over the years whereas UKA did not have the same increase over time (62) (Fig.15). Using the year 2008 as an example, the mean annual hospital volume for TKA was 60 compared to 8 for UKA.



*Fig.15 Bar graph from the NAR report 2016 showing the distribution of TKA with and without patellar components and UKA.*

To become a specialist in orthopaedic surgery it is mandatory to perform 15 TKA, whereas UKA is not a mandatory procedure.

There still is an ongoing debate in a variety of surgical specialties as well as in orthopaedic surgery whether procedure volume influences patient outcome and reoperation rates. The expectation that experienced surgeons or units performing high volume surgery impacts the outcome has been debated by numerous authors. Chowdhury et al. (69) reviewed 163 publications within 13 surgical specialties and showed 74% significantly better outcome for high volume units and surgeons. Major oncological surgical procedures such as oesophagectomy and pancreatectomy has established major differences in mortality (70) and the same results have been shown for breast cancer and lung cancer (71, 72) regarding impact of high volume surgery.

Whether or not there should be established a threshold value for procedure volume in surgery below which surgery should be avoided is debated. Pediatric cardiac surgery has established a minimum threshold volume in different studies varying from 100-300 operations annually. There are also literature that shows no association between procedure volume and outcome regarding the previously mentioned conditions (73).

There are papers reporting higher mortality rates after joint replacement surgery in low volume units, even though this is a rare complication (74, 75). Shorter hospital stays in total joint arthroplasty has been demonstrated for high volume units in both Denmark and Finland (76, 77). Judge et al. found an increased risk of death and pulmonary embolus after total hip and knee arthroplasty in low volume hospitals (78). Others have found that patient related factors were more important predictors of outcome than volume (79). Threshold values have also been proposed by several studies regarding TKA, varying between 15 and 100 a year (80-82).

Some papers present only hospital volume, others surgeon volume and some both. The relationship between the two was studied by Shrag et al. (83). They demonstrated that high volume surgeons in high volume hospitals had the best results regarding colorectal resection. Low volume surgeons had better results if they worked in a high volume hospital than in a low volume hospital. Medium volume surgeons achieved excellent results in medium or high volume units. That study indicated that volume of a hospital has equal or greater effect on outcome than surgeon volume for colorectal resection.

Hospital volume is one of many predictors of and possible consequences of hospital quality. In a study by Curry et al. (84) hospitals in the high-performing and low-performing groups differed substantially in the domains of organizational values and goals, senior management involvement, broad staff presence and expertise in acute myocardial infarction (AMI) care, communication and coordination among groups, and problem solving and learning.

### **1.4.2 Hospital Volume**

Patient survival after open heart surgery and the findings of a relationship with institutional volume led to one of the first recommendations for minimum hospital volume (85, 86). Hospitals in which 200 or more of these operations were done annually had death rates, adjusted for case mix, 25 to 41 per cent lower than hospitals with lower volumes. Colorectal cancer surgery has also been investigated extensively focusing on provider volume and the effect of specialization (87). For rectal cancer, there was a significant association between high-volume hospitals and improved 5-year survival (HR=0.85, 95% CI 0.77 to 0.93), but not with operative mortality. Further recommendations of regionalization appeared in procedures like hip replacement (85, 88) as well as multi injury trauma care to reduce adverse outcomes (89). Since then, numerous publications have documented the correlation between caseload of procedures and the postoperative outcome for various surgery (81, 90, 91). A recent study using Medicare data, showed that despite recent improvements in surgical safety, high procedure volume hospitals still had significantly lower mortality rates than lower volume centers for all procedures examined (92).

Multiple studies have been published regarding TKA and the effect of procedure volume using with various outcome measures, such as complications and mortality (80, 81, 93), length of hospital stay (94, 95) and functional outcome (96). Starting this study, only a few studies existed on the relation between procedure volume and the risk of revision regarding TKA (93) and there were no existing national registry studies on the issue.

On UKA there was one existing study on the subject of hospital volume in correlation to revision risk for UKA; a Swedish register study by Robertsson et al (97) finding a decreased risk of revision in hospitals with a caseload of more than 23 procedures a year. They also concluded that technically demanding implants were most sensitive to the routine of surgical management, in this case the Oxford meniscal knee (Biomet Ltd, Bridgend, UK).

### **1.4.3 Surgeon Volume**

In a systematic review and metaanalysis, surgical outcomes for surgeons performing a procedure once a month or less had increased rates of adverse outcomes in gynecology, gynecological oncology and urogynecology (98). Kreder et al (1997) found that there were higher mortality rates, more infections, more revisions and other complications after total hip replacements if the patient had been managed by low-volume surgeons (88). Others have also found this correlation in other types of surgery (99), and in TKA there is some documentation of the surgeon volume effect (96, 100).

The first registry study finding a lower risk of revision by high volume surgeons performing Oxford III UKA was from The New Zealand National Joint Registry (101). Surgeons performing more than 10 Oxford III UKA annually had fewer revisions than the lower volume surgeons.

Baker et al (102) has later demonstrated a minimum of 13 procedures per year to gain comparable results with high-volume operators. Additionally, they found a greater revision risk for low-volume surgeons at low-volume centers compared too high-volume surgeons at high-volume centers. Bini et al. (103) found similar results in the US population with higher revision rates for patients operated by surgeons performing less than a mean of 12 UKA a year.

A recent study from the National Joint Registry (NJR) of England and Wales found a correlation between surgeon caseload and implant survival of both UKA and TKA (104). They found a plateauing of revision rates at 30 cases per year for UKA.



Studies related to outcome after UKA has focused on surgeon and hospital procedure volume over the years due to the presumption that surgical skill is a predicting factor for success. National registry studies have been recommended for assessment of the outcome of implants to avoid potential bias, and the existing studies confirm the importance of surgical caseload (61, 97, 101, 102, 105).

#### 1.4.4 Learning Curve

Supervision by more experienced surgeons to ensure appropriate skills performing specific procedures is essential when learning new techniques (Fig.16). Achieving sufficient experience to minimize complications and inferior results takes a certain amount of time and should not be rushed. Learning curve is an ongoing process, to be considered even for experienced surgeons with a large time-interval between operations(106). Increasing volume and year of practice has been associated with improved performance, but may deteriorate toward the end of the surgeons' career (107).



**Fig.16** Private photo in the operating room at Kysthospitalet in Hagavik performing revision knee replacement. (Photographer: H.A. Kjærnsli).

Complex skills must be achieved in surgical training and the level of capability to acquire the desired level of competency will be individual. Price et al. demonstrated a significant correlation between experience and performance during diagnostic knee arthroscopy in a simulator study comparing trainees of different levels to consultants. Consultant performance was only reached by fellows with experience level of >150 arthroscopies. They found significant improvement in performance with increasing experience (108).

The assessment of technical proficiency is of paramount importance in the training in many surgical procedures. Young et al. found that the average intern required approximately 19 intubation attempts to complete the learning curve experience whereas there was no learning curve for airway assessment (109). For UKA there is a learning curve to improve surgical technique (110, 111). A study has also demonstrated the importance of continuing medical education courses from manufacturers and experts in the field (112).

However, surgical expertise exceeds technical and operative competency, especially in arthroplasty surgery. Surgical indication for both primary surgery and decision-making prior to revision surgery is crucial determinants for the outcomes and critical for revision rates in knee replacement surgery. Criteria for levels of performance before practicing independently in addition to careful education in decision making will improve results in all surgical specialities.

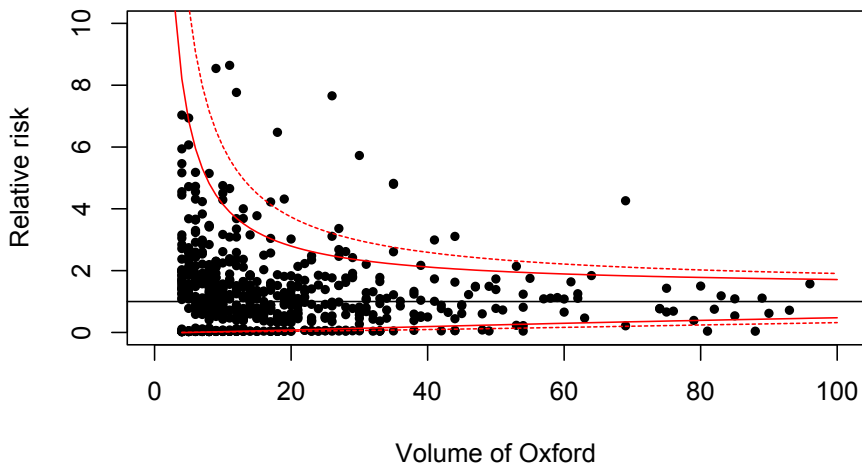
### **1.4.5 Calculation of Procedure Volume**

Many different definitions have been used for hospital volume, and between 2 and 5 volume categories have been used. How to calculate annual procedure volume or caseload has also varied between studies. Previous studies on procedure volume have used an average volume over the whole study period. More recent studies have counted each year separately or used percentage/usage of UKA of the total volume of knee replacements. This limits the conclusiveness and the possibility of comparison between studies.

One method of determining hospital volume used in several papers is an average annual volume defined as the mean procedure volume of the hospital in a given period of time. Average volume over the whole time period does not take the variability into account, and could be a valuable and easy method where the caseload is relatively constant from year to year.

Another method of measuring annual hospital volume is counting procedures or patients operated upon in each hospital each year separately. The results for the different volume groups are compared accordingly. In this method, hospitals could contribute to different volume groups depending on the actual number of procedures or patients operated that particular year.

Usage/proportion of rare procedures compared to the total proportion of similar procedures occurring in larger numbers per hospital is a third method of evaluating surgical caseload. The usage or percentage takes into account the total procedure volume of surgery, not only the specific procedure of interest. The method assesses the differences in indication threshold for UKA compared to all knee arthroplasty in percentage.



**Fig 22.** Funnel plot

‘Funnel plots’ can be used as a tool for institutional comparison, assessing comparison between outcome and volume of cases. 3 standard deviations are commonly used as a demarcation if any hospital lies outside the 99% limits. Using funnel plots as an initial assessment of the relationship with volume, hospitals with diverging performance will stand out as a point outside the funnels (Fig.22).

As hospital volume could be a proxy for surgeon experience, a moving average with each average based on for example the last 3 years would smooth out year-by-year fluctuations in annual procedure volume. This could prevent bias regarding surgeons leaving the hospital leading to a sudden decrease in volume and also a drop in experience.

Common for existing UKA procedure volume studies is the generally low procedure numbers per surgeon and hospital. In the New Zealand Joint Registry, the average hospital volume of unicompartmental knee replacements in 2014 was 21, and the average number of UKA per surgeon was 10. 39 of the 40 registered surgeons performed less than 5 UKA a year (113).(ref register). In the Swedish register study, a hospital threshold value of 23 UKA a year was proposed as a minimum caseload and the study revealed that 75% of the hospitals performed less than 23 UKA a year. 25% of the hospitals performed less than 7.8 UKA a year (97). In a more recent study from England and Wales, 82.8% of the hospitals performed less than 100 UKA procedures during the 8 year study period and 85.6% of the surgeons performed  $\leq 50$  procedures during the same study period (102). Similarly, another England and Wales registry study found 5.4 UKA a year per surgeon on average and 25% had a mean caseload of only 1 UKA per year. In comparison, the mean annual TKA number per surgeon was 33.6. In the latter study, surgeon annual volume was divided into groups of  $<10$ , 10-30 and  $>30$ . Another study from Liddle et al. investigated the optimal UKA usage defined as the percentage of knee arthroplasty practice comprised by UKA. They concluded with acceptable results with 20% usage and optimal results with usage between 40-60% (61).

The different calculation methods have never been assessed against each other and the described statistical analyses can lead to conflicting results. How to best analyze institutional performance is a highly relevant topic with several methodological issues. This study is a contribution to the comparison of hospital volume association on knee replacement results.

## 2. AIMS OF THE STUDY

The main objective of this thesis was to determine if there was a relation between hospital procedure volume and the risk of revision for all reasons and for specific causes in knee arthroplasty surgery based on data from the Norwegian Arthroplasty Register and the Nordic Arthroplasty Register Association. The second objective was to assess different statistical methods used in calculating procedure volume.

*The specific aims of the 3 papers were:*

### Paper I

- To establish the numbers of TKA procedures performed annually at all hospitals in Norway
- To investigate a possible association between low hospital procedure volume and high risk of revision regarding TKA for 5 different volume groups using hospital volume data from the NAR.

### Paper II

- To establish the numbers of UKA procedures performed annually at all hospitals in Norway.
- To investigate a possible association between low hospital procedure volume and high risk of revision regarding the Oxford III UKA, using 4 different volume groups using hospital volume data from the NAR.
- To investigate possible variations in the reasons for revision between the volume groups.

### Paper III

- To determine the current practice in the Nordic countries regarding the annual procedure volume of Oxford III UKA.

- To investigate a possible association between low hospital procedure volume and high risk of revision regarding the Oxford III UKA, using hospital volume data from the NARA.
- To assess different statistical methods used in calculating procedure volume.
- To investigate possible variations in the reasons for revision between the volume groups.

## 3. MATERIAL

### 3.1 The Norwegian Arthroplasty Register

The Norwegian Orthopaedic Association (NOA, (NOF in Norwegian)) initiated the establishment of the NAR in 1987 due to the lack of documentation regarding longevity of implants and the implementation of low quality hip replacement implants in the early 1980s. Only the Charnley hip implant had satisfactory long term follow-up results at 10 years. The remaining 49 implant brands utilized had no long term documentation available from clinical studies. From being a hip register, NAR developed into a joint register from 1994, including all other joint replacements.

The main reason for establishing a nation-wide register was the introduction of undocumented implants with high failure rates in the 1970s and 80s. Initially, it worked to reveal inferior implants and methods that increase the risk for revision as only patients with severe osteoarthritis were offered surgery. The intention later, when knee arthroplasty surgery became more popular, was also to improve the results and quality of treatment over time.

Orthopaedic surgeons report to the NAR immediately after surgery by filling out a 1-page form (appendix 1) providing information regarding the patient, the surgical procedure and the choice of implants. Stickers with catalogue numbers to identify the implants are used. Revision surgery demands a new report using an identical form as the primary with added information about the reason and type of revision. The revision procedure is linked to the primary procedure by the patient's unique personal identification number given to all inhabitants of Norway at birth or on immigration.

Annual reports are published with information concerning the choice of implants, methods and degree of reporting completeness in addition to separate hospital reports with results

including comparison to other hospitals results. Peer-reviewed publications are presented in scientific journals (62). Implant specific results are only given in peer-reviewed publications to discuss the strength and limitations of the study (114-116).

The NAR provides information on hospital procedure volume, but lacks information on surgeon volume and PROM data. Some cross-sectional studies have used PROM data obtained by postal questionnaire (16, 117, 118). The completeness of primary procedures was 96% and 89% for revision surgery between 2008-2014 (62).

Currently, the NAR provides information regarding 68 271 primary knee arthroplasties from 1994-2015. There are 229 published research articles associated with the NAR.

There is an ongoing collaboration with the Nordic Arthroplasty Register Association (NARA) (119-121) as well as the International Consortium of Orthopaedic Registries (ICOR) (37) and the International Society of Arthroplasty Registers (ISAR) (122).

## 3.2 The Nordic Arthroplasty Register Association

The collaboration of the Scandinavian countries' arthroplasty registers was established in 2007 by creating a common database including hip replacements from 2008 and knee replacements from 2009. Denmark, Sweden and Norway were included initially, and Finland joined in 2010. This was enabled since the respective countries have similar health organizations, personal identity numbers and national joint registers.

All 4 countries have different registration forms, different variables and some different definitions of variables. Therefore a common code set was defined that all the registers could provide. Every year a new dataset is made after discussion and consensus regarding inclusion or exclusion of variables. Selection and transformation of the respective data sets and de-identification of the patients, including deletion of the national civil registration numbers are performed within each register. Hospital names are also de-identified.



Anonymous data are then merged into the common database using a safe data transfer site (123).

The first studies focused on differences in patient demographics, surgical methods and implant brands (120, 121, 124). The main purpose was the ability to analyze a larger statistical material, which is an advantage especially for uncommon methods and implants. It reflects the current practice in 4 different countries (125). The NARA group has also published statistical guidelines for recommended analysis of arthroplasty registry data to improve the reliability and value of the research (126, 127).

The knee dataset currently includes 390 525 primary knee arthroplasty operations performed during 1995-2012 (119). The NARA collaboration has resulted in numerous research projects and currently 19 publications.

### 3.3 Hospital Survey – Surgeon Volume

Since information on surgeon procedure volume is absent in the NAR, we performed a survey to gather this information otherwise. A hospital survey was constructed and sent to all hospitals known to perform knee replacements. We asked the chief consultant at the orthopaedic departments to fill out the received form and return it to the NAR. There were 72% responders to the questionnaire after one reminder. We asked for the exact number of procedures per surgeon in the year of 2000 and 2009. These data were extrapolated  $\pm$  2 years to increase the number of cases. A low volume surgeon was defined as a surgeon performing  $\leq 10$  TKA or  $\leq 5$  UKA a year, respectively. Hospitals were then categorized as low (if more than 66 % of the surgeons were low volume surgeons), medium (35-66% of the surgeons were low volume surgeons) and high (<35 % of the surgeons were low volume surgeons) surgeon volume hospitals.

However, we did not include these results in the publications as the statistical validity was too low and we were not able to link the surgeons to the specific patients. Nevertheless, we got an overview of the distribution of surgeon volume both regarding TKA and UKA in Norway.

## 4. METHODS AND STATISTICS

### 4.1 Study Design

Paper I and II were based on a population based register study with data collection from the NAR. The data collection was from 1994-2010 in paper I and from 1994-2012 in paper II. Paper III was a population-based register study with data collection from the NARA from 2000-2012 with revision as endpoint. Revisions were linked to the primary surgery by the unique national identification number of the patient. Information on deaths or emigrations was retrieved from the Norwegian Resident Registration Office until December 2012 in paper I and II and similarly from the Nordic countries in paper III.

### 4.2 Inclusion Criteria

26 698 TKA registered in NAR were selected for inclusion in paper I, excluding UKA, TKA with patella components, uncemented components or cemented without antibiotics and more constrained than CR TKA. 92% of TKAs in Norway has been performed without a patellar component, and 96.7% are unconstrained implants. CR TKA without a patellar component cemented with antibiotics was the preferred implant choice for most hospitals in Norway.

The NAR has registered UKA surgery since 1994 and Oxford III since 1999. The 2015 report showed 11% UKA as primary knee arthroplasty surgery. 51 hospitals performed UKA surgery in 2012. 5 791 UKAs were registered in the study period from 1994-2012 in paper II and of these 4 460 cemented medial Oxford III UKAs were analysed from 1999. We selected this particular implant for analysis as it was the most commonly used UKA implant in

Norway during the study period. Primary TKA, uncemented and cemented without antibiotics UKA and lateral UKA were excluded for analysis.

The Oxford UKA was also the most commonly registered UKA implant in the NARA. Implant brand and type could be a source of confounding in comparison of revision rate according to hospital volume, and therefore all other brands and types than Oxford III UKA were excluded. Diagnoses other than OA were excluded as inflammatory disease is a contraindication. Additionally, uncemented knee arthroplasty, TKA, lateral UKA and hospitals with less than 10 Oxford III UKA implanted during the whole time period were excluded in paper III. We identified 4131 (31.6%) Oxford III implants in Denmark in 32 different hospitals: 2180 (16.8%) in Sweden distributed among 18 hospitals, 3826 (29.6%) in Finland in 41 hospitals and 2849 (21.9%) in Norway in 35 hospitals.

### 4.3 Hospital Volume Categorization

In paper I, annual TKA hospital volume was categorized into 5 groups; 1-24, 25-49, 50-99, 100-149 and 150+. In paper II we analysed 4 different annual UKA hospital volume groups with procedure volume from 1-10, 11-20, 21-40 and >40. Patients were entered into the hospital volume groups according to the number of procedures at their hospital in the year of surgery. Each year was examined individually for every hospital. Consequently, many hospitals had inconsistent procedure volume over time and contributed to more than one volume group. The different hospital procedure volume groups were compared for the risk of revision.

As paper III was an expansion of paper II comparing different methods of volume calculations, the volume categories varied according to the methods:

1. *Volume calculation based on annual procedure hospital volume counting each year separately:* We used quartiles to divide into 4 different annual hospital volume groups: <13, 13-25, 26-45 and >45.
2. *Average hospital procedure volume over a 13-year time span:* Group 1 had an average annual hospital volume of less than 12, group 2 from 12-26 and group 3 had an annual average volume of more than 26 UKA per year. The measures were chosen based on equal sizing of the 3 groups.
3. *The usage/proportion of Oxford III UKA compared to the total proportion of primary knee replacement per hospital:* we used a proportion of more or less than 20% UKA relative to all primary knee replacements as categorical variables with  $\leq 20\%$  used as reference.

In the combined model in paper III, volume was used as a continuous variable, as categories are an average of the group and not a true cut-point estimate. I.e. the <13 group is actually the average within that group and not the estimate at 13.

## 4.4 Patient and Procedure Variables

Patient characteristics were assessed by descriptive analysis for the different hospital volume categories. In paper I and II, adjustments were made for sex, age and diagnosis. In paper I, age was used as a continuous variable, whereas in paper II age was categorized into 4 groups (< 60, 61–70, 71–80, and > 80). Diagnoses were divided into 2 groups (osteoarthritis (OA) and others).

As many prosthesis brands had been used in small numbers in paper I and were associated with few revisions in each volume group, adjustment for brand was not feasible in the Cox analyses. Therefore, a subanalysis was performed including two commonly used implant brands combined; AGC (Biomet, Warsaw, Indiana) and LCS (DePuy, Warsaw, Indiana) as

these implants were some of the most commonly used and were well represented in all the volume groups.

In paper III, confounding variables such as sex, age category (<55, 55-64, 65-74,  $\geq 75$ ), time period (2000-3, 2004-6, 2007-9, 2010-12) and nation were available and used for analysis in the NARA material.

## 4.5 Statistics

Survival analyses were performed with any revision of the implant as endpoint. Implant survival was defined as time from primary surgery to first revision. Revision was defined as complete or partial removal/exchange/addition of implant component(s).

In paper I, II and III Kaplan-Meier survival percentages were reported and survival curves were constructed for the different hospital volume groups. The Cox regression model was used to evaluate the effect of volume on implant survival calculating hazard rate ratios (RR), both unadjusted and with adjustment for age, gender, diagnosis. They were presented with 95% confidence interval (CI) and p-values relative to the lowest volume group. All p-values less than 0.05 were considered to be statistically significant. Adjusted Cox regression survival curves were constructed for hospital volume categories with volume as stratification factor.

In paper III death as competing risk was investigated and frailty term for hospitals was added to the analyses of the 3 models. The combined Cox model included sex, age, calendar year of surgery, nation, Oxford III UKA annual hospital volume, proportion Oxford III UKA, and TKA annual hospital volume. A moving average was added to the combined model including a 3-year moving average estimate of annual hospital procedure volume of the Oxford III UKA. The revision risk was calculated for each hospital volume per year and then plotted against the corresponding hospital volume with use of funnel plots.

## 4.6 Revision Causes

In paper II and III, reasons for revision were analysed in all the volume groups. In a material restricted to revised implants, the Pearson chi-square test was used to test whether proportions of specific revision causes differed among volume groups. The log-rank test was used to compare implant survival among volume groups with revision due to pain only, infection, loosening, dislocation, instability, malalignment, fracture, or to progression of osteoarthritis (OA) as endpoint (Paper II). Cox regression analysis was used to test whether proportions of specific causes of revision differed between the volume groups in the material including only revised implants. Relative risk with 95% CI was used to compare implant survival among the different volume groups with the different revision causes as endpoint for all 3 methods. The various reasons for revision were organized hierarchically with infection first and pain alone last (Paper III).

## 5. SUMMARY OF PAPERS I-III

### *Paper I*

#### **Influence of Hospital Volume on Revision Rate after Total Knee Arthroplasty with Cement**

Mona Badawy, Birgitte Espehaug, Kari Indrekvam, Lars B. Engesæter, Leif I. Havelin and Ove Furnes.

*J Bone Joint Surg Am.* 2013 Sep 18; 95 (18): e131

**Background:** The number of total knee replacements has substantially increased worldwide over the past ten years. Several studies have indicated a correlation between high hospital procedure volume and decreased morbidity and mortality following total knee arthroplasty. The purpose of the present study was to evaluate whether there is a correlation between procedure volume and the risk of revision following total knee arthroplasty.

**Methods:** Thirty-seven thousand, three hundred and eighty-one total knee arthroplasties that were reported to the Norwegian Arthroplasty Register from 1994 to 2010 were used to examine the annual procedure volume per hospital. Hospital volume was divided into five categories according to the number of procedures performed annually: one to twenty-four (low volume), twenty-five to forty-nine (medium volume), fifty to ninety-nine (medium volume), 100 to 149 (high volume), and  $\geq 150$  (high volume). Cox regression (adjusted for age, sex, and diagnosis) was used to estimate the proportion of procedures without revision and the risk ratio (RR) of revision. Analyses were also performed for two commonly used prosthesis brands combined.

**Results:** The rate of prosthetic survival at ten years was 92.5% (95% confidence interval, 91.5 to 93.4) for hospitals with an annual volume of one to twenty-four procedures and



95.5% (95% confidence interval, 94.1 to 97.0) for hospitals with an annual volume of >150 procedures. We found a significantly lower risk of revision for hospitals with an annual volume of 100 to 149 procedures (relative risk = 0.73 [95% confidence interval, 0.56 to 0.96],  $p = 0.03$ ) and  $\leq 150$  procedures (relative risk = 0.73 [95% confidence interval, 0.54 to 1.00],  $p = 0.05$ ) compared with hospitals with an annual volume of one to twenty-four procedures. Similar results were found when we analyzed two commonly used prosthesis brands.

**Conclusions:** In the present study, there was a significantly higher rate of revision knee arthroplasties at low-volume hospitals as compared with high-volume hospitals.

*Paper II***Higher revision risk for unicompartmental knee arthroplasty in low-volume hospitals**

Mona Badawy, Birgitte Espehaug, Kari Indrekvam, Leif I Havelin & Ove Furnes

*Acta Orthopaedica* 2014; 85 : 342–347

**Background and purpose** — Some studies have found high complication rates and others have found low complication rates after unicompartmental knee arthroplasty (UKA). We evaluated whether hospital procedure volume influences the risk of revision using data from the Norwegian Arthroplasty Register (NAR).

**Materials and methods** — 5,791 UKAs have been registered in the Norwegian Arthroplasty Register. We analyzed the 4,460 cemented medial Oxford III implants that were used from 1999 to 2012; this is the most commonly used UKA implant in Norway. Cox regression (adjusted for age, sex, and diagnosis) was used to estimate risk ratios (RRs) for revision. 4 different volume groups were compared: 1–10, 11–20, 21–40, and > 40 UKA procedures annually per hospital. We also analyzed the reasons for revision.

**Results and interpretation** — We found a lower risk of revision in hospitals performing more than 40 procedures a year than in those with less than 10 UKAs a year, with an unadjusted RR of 0.53 (95% CI: 0.35–0.81) and adjusted RR of 0.59 (95% CI: 0.39–0.90). Low-volume hospitals appeared to have a higher risk of revision due to dislocation, instability, malalignment, and fracture than high-volume hospitals.

*Paper III***Oxford Unicompartmental Knee Arthroplasty in the Nordic countries: effect of hospital procedure volume on revision rates.****12 986 cases from the Nordic Arthroplasty Register Association, 2000-2012.**

Mona Badawy, Anne M Fenstad, Kari Indrekvam, Leif I Havelin, Otto Robertsson, Anette W-Dahl, Antii Eskelinen, Keijo Mäkelä, Alma B Pedersen, Henrik Schröder, Ove Furnes.

*Submitted*

**Background and Purpose** Survival of unicompartmental knee arthroplasty (UKA) is in part determined by procedure volume. The volume of UKA is much lower than total knee arthroplasty (TKA) in most hospitals worldwide, so the aim of this study was to quantify hospital volume effect on revision risk. The second objective was to assess different statistical methods used in calculating procedure volume and to implement the previously described methods of counting hospital procedure volume into one statistical model.

**Methods** 12 986 cases were analysed from the NARA database over a 13 year time span since January 1st 2000 to December 31st 2012. The volume-revision rate relationship was assessed and quantified utilizing multivariate regression techniques and characterized graphically.

**Results** Hospitals with low procedure volume and usage had an increased risk of revision compared to higher volume hospitals in the single statistical models, whereas the combined model showed only minor differences. Hospitals with consistent high volume over time, using a 3-year moving average, improved their results. The revision rate gradually improved from a moving average of 25 procedures per year; when performing a moving average of 75 cases per year we found RR=0.8 (0.6-1.1).

**Interpretation** Various statistical models have been utilized determining the effect of procedure volume on the risk of revision in UKA surgery. Depending on how the statistical analyses were conducted in this study, the association between hospital volume and the

survival of Oxford III UKA varied and therefore must be interpreted with caution. Hospitals with consistent high volume in the 3-year moving average analysis had improved results compared to the 3-year moving average less than 25 UKA per year. Continuous experience over years seems to improve the results.

## 6. GENERAL DISCUSSION

### 6.1 Methodological Considerations

#### 6.1.1 Study Design

Registry studies are observational, contrary to randomized clinical studies which are investigational. The effectiveness of a device is measured by how well it performs in a general population of patients with wide selection criteria with multiple confounding factors such as cause of knee disease, the stability and axis of the knee preoperatively, level of comorbidity, as well as activity level, age and gender.

Planning a registry study involves identifying the specific data set required for analysis, determining the outcome and endpoint and identifying inclusion and exclusion criteria. Registry studies can answer research questions like clinical practice in a historical perspective, measure effectiveness and safety of different devices, assess subgroup differences in treatment outcome due to high external validity (heterogeneous patient populations), short – and long term follow-up of devices and evaluation of current medical practice. They are complementary to clinical trials as they provide different information (128).

Arthroplasty registers were developed to detect early implant or method failure. Common statistical analysis techniques in registry studies are Kaplan-Meier analysis and Cox regression (125). The Kaplan-Meier method was originally developed to investigate events occurring in all patients, i.e. death. Estimating the survival of arthroplasty, some patients will die before revision, but the method assumes that competing events do not exist, thus assuming 100% follow-up (129). The Cox regression model is used to adjust for differences

in confounding variables such as gender, distribution of age and various diagnoses when comparing survival estimates.

There is continuing debate regarding the value of registry data. Its value lies in the ongoing monitoring and identifying different outcomes in a country or countries combined without excluding any hospitals, patients or implant brands (130).

Methodological guidelines for statistical analyses and presentation of results has improved the reliability for randomized clinical trials through the CONSORT guidelines (131). For observational studies, the STROBE statement (132) has provided a checklist of items that should be included in reports of observational studies. Recently, RECORD guidelines of routinely collected data was created as an extension to the STROBE statement to address reporting items specific to observational studies using routinely collected health data (133). Additionally, the Nordic Arthroplasty Register Association (NARA) group has developed statistical recommendations for analysis of registry data (126, 127). Due to the need for large groups of patients and hospitals in our studies, a RCT would not have been possible for this purpose.

NAR studies are mainly prospective observational studies where the primary joint replacement surgery is followed until the occurrence of revision surgery or death of the patient. Thus, the time interval from primary surgery till revision of the implant represents the “survival” of the implant, often defined in years.

The advantage of a registry study for our purpose was the representation of all surgeons in all hospitals in Norway (NAR) and in Sweden, Denmark, Finland and Norway (NARA) including different experiences, techniques and skills, gaining a high external validity. The national registries evaluate implants and techniques in a real-world environment resulting in more generalizable findings. The disadvantage is the risk of uneven distribution of confounding factors in the study groups. Despite the fact that adjusting for different confounders in the analysis is utilized, there still will be possible unknown confounders not available in the data set. This could potentially lead to misinterpretation of treatment effects.

RCTs are considered the golden standard with the highest level of evidence. However, RCTs may not represent the average surgeon or hospital. Clinical trials establish causality while national registers are collecting data and monitoring differences within the country. Both clinical trials and registry studies are important tools towards the achievement of improved outcome in knee replacement surgery. Both provide valuable information. The main goal for arthroplasty surgery is improving function and satisfaction compared to pre-surgery, to diminish the pain and to avoid complications. Patient reported outcome measures are not included in the registry data and hence not in these studies.

### **6.1.2 Outcome Measure**

An observational register study was the best option to answer the research question on current medial practice in TKA and UKA regarding hospital caseload on an annual basis and the changes over time. There could be ethical challenges associated with the conception of randomized controlled studies regarding the effect of caseload on outcome, randomizing patients into the lowest volume group with possible risk of receiving an inexperienced team. Due to the high degree of registration completeness, the results from registry studies are accurate. Improvement over time has been demonstrated for TKA, and is probably caused by better implants, surgical and cementing techniques with revision as endpoint. The time to first revision is an indication of a problem with the index operation requiring further surgical intervention (134).

A limitation to evaluating TKA and UKA results by revision alone without patient reported outcome measures is the relatively large proportion of dis-satisfied patients. Revision as endpoint is an outcome measure that disguises the number of patients with unrevised implants that are unhappy with their knee due to pain or functional imparity (67).

Patient reported outcome measures (PROM) would add valuable information concerning patient satisfaction. The NAR wishes to implement prospective PROM data in the register, but the work is still in progress.

Differences in mortality and major complications are additional outcome measures to be considered when choosing between UKA and TKA (135, 136). This has to weigh up the differences in rates of revision.

Radiological investigations are another outcome measure that could add valuable information regarding indications both for primary and revision surgery and the evaluation of quality of surgery. Confounding by indication is a possibility, both regarding the degree of OA before primary surgery and regarding the actual reason for revision stated in the registry form.

### **6.1.3 Completeness and Quality of Registry Data**

In Norway, all hospitals performing knee arthroplasties report to the NAR. However, the patients are not obliged to consent to registration to the NAR. To obtain complete registration in the future, presumed consent should substitute the current written consent. The completeness of registered knee surgery is calculated using the following formula:

$$\frac{\text{Registered in NAR only} + \text{Registered in both registers}}{\text{Registered in NPR only} + \text{Registered in NAR only} + \text{Registered in both registers}}$$

Compared with the National Patient Register (NPR), the completeness for primary knee arthroplasty was 95.3% and for knee revisions 88.9% in 2008-2012. These analyses are conducted every second year and are presented in the annual report. The linkage between the two registers is done using the unique personal identification number of the patients.

The completeness varies between hospitals from 78-100%. Low completeness of reporting could be due to lack of submitting the registry form or application of a wrong surgical code to the NPR. Reported revisions vary between hospitals from 48-100%.

The registration completeness for all the Nordic countries is reported in the NARA report. NARA as data-source has proved to have high accuracy of registered variables and



registration completeness, DKR 97%, NAR 95.3% and SKAR (Swedish Knee Arthroplasty Register) 97.2%, FAR (Finnish Arthroplasty Register) 91.6% (119).

#### **6.1.4 Validity**

Validity of registries consists of four aspects; coverage, registration completeness of procedures, registration completeness of variables and the accuracy of registered variables. Accuracy is the probability that variables are registered correctly. Validation studies are part of the registries' publications (62, 137-140)

*Internal validity* in observational studies may be threatened by confounding, selection bias or information bias. The association between exposure and outcome may be influenced by confounding factors that allows alternative explanations for an observed relationship between variables. To avoid mixing of effects in registry studies, either regression techniques or stratification can be used. Multiple regression analyses were used in all papers in this thesis to control for confounding. Additionally, the materials in paper II and III were also restricted by implant brand, and by diagnosis in paper III. It is important to control or to eliminate confounding variables to maintain the internal validity of the study.

Selection bias occurs when the sample of the study is unrepresentative due to either under-coverage (inadequately represented population) or nonresponse bias (unable/unwilling participants in the study leading to low response rate). In the NAR 95.3% of all primary knee replacements was reported and 97.6% to the NPR during the period from 2008-2012. 88.9% of all revision surgery was reported during the same time period to the NAR and 88.5% to the NPR. Reporting to the NAR is voluntary, whereas information to the NPR is mandatory. A study on registration completeness in the NAR was also published in 2006 (138). Our studies relied on the high registration completeness to obtain accurate and unbiased results. Information bias or misclassification could be systematic errors either in obtaining information or incorrect registration. Some hospitals have low registration completeness, and this could lead to false results, i.e. high volume hospitals not reporting their revisions,

leading to excellent results in the register. Misclassification regarding implant brand is not likely in the NAR due to use of reference codes on the stickers on the register report from the hospitals regarding implants and cementing. However, misclassification could occur creating hospital volume categories and also regarding whether implants are classified as revised or not due to registration and clerical errors. Nevertheless, the high degree of registration completeness diminishes the risk for the variables mentioned. The 3 studies are based on data from the NAR and the NARA where selection bias and nonresponse bias is unlikely due to near completeness of reporting and complete follow-up of revisions and death.

*External validity* is defined as the ability to generalize results and conclusions from the current study population to populations outside that particular community or country. Arthroplasty register studies are considered to have a broad range of patients and hospitals and therefore greater generalizability than i.e. RCT studies. Concomitantly, one could argue that the results are valid for the restricted population of Norway or the Nordic countries with similar population and health service.

*Precision* occurs in the absence of random errors and is normally high in studies with large samples such as registry studies. However, the number of revisions is small in our studies, and to make reliable conclusions based on small numbers increases the need for collaboration with other similar registries. Paper III therefore was a consequence of and expansion of the small numbers of revisions in paper II.

### **6.1.5 Statistical Methods**

The starting point in analysis of survival data in arthroplasty registers is the date of primary surgery and the endpoint is the date of revision of the primary implant. Censored observations include unrevised implants as well as implants in persons who died or emigrated. The most commonly used survival analyses in registries are the Kaplan-Meier approach and the Cox proportional hazards regression model (126).

### *Kaplan-Meier Method*

The survival function is calculated as the cumulative probability that an implant will not be revised through various time intervals and is commonly presented as a table or a graph (141). For knee arthroplasty, the Kaplan-Meier analysis estimates the probability of the implant surviving (not being revised) a given length of time after primary surgery; i.e. a 2-, 5-, or 10-year cumulative survival can be quoted.

*The log rank test*, used in paper II, is a hypothesis test, comparing the survival distributions of independent groups. It was used to compare implant survival among volume groups with revision due to pain only, infection, loosening, dislocation, instability, malalignment, fracture, or to progression of osteoarthritis (OA) as endpoint. However, as the log-rank test is purely a significance test, it cannot provide an estimate of the size of the difference between groups and a related confidence interval (142). Secondly, the Kaplan–Meier method and the log-rank test can only study the effect of one factor at the time, and therefore they cannot be used for multivariate analysis. For these purposes, the Cox proportional hazards model a regression technique was used (143).

### *Cox Regression Model*

This is a common method in analysing survival data and it enables estimation of the effect of covariates on the hazard rate(144). It is commonly used in arthroplasty register studies when several variables are investigated at the same time. To avoid selection or confounding bias that may affect the validity of the results, adjustments by the Cox proportional hazards regression model can be made. (126). A strong assumption is made that the effects of the different variables on survival are constant over time visualized by the separation between the curves remaining proportional across analysis time. Two ways of investigating proportionality is by use of the log minus log plot or Schoenfeld residuals (145).

While Kaplan-Meier survival curves illustrates unadjusted results regarding implant survival, Cox regression analyses gives possibilities for adjustment for relevant factors such as age and gender.

Investigating death as competing risk, *Fine and Grey competing risk models* can be used (129) and is an alternative to treating death as censored observation, thus avoiding underestimation of survival probabilities.

*Bilateral observations* should also be included in the analyses. While this theoretically may affect the results, arthroplasty register studies assume that the revision risks for uni- or bilateral implants are identical (146). Ignoring bilaterality seems not to affect risk estimates.

*Pearson chi-square test* was used to test whether proportions of specific revision causes differed among volume groups in paper II.

*Linear regression model* was fitted for the 3 different methods in paper III by plotting Cox estimated risk ratios for each volume observation. Regression analysis was used to describe *the linear dependence* of the risk ratio from hospital volume. The black dots (scatter of observed data) around the fitted line indicate hospitals with a certain procedure volume (Fig.20). The 95% confidence interval (CI) is shown in greyscale. The CI gets wider with increasing distance from the mean. The vertical axis represents the relative risk of revision, and  $RR < 1$  demonstrates a decreased risk of revision in comparison to the average patient ( $RR = 1$ ). The regression line fitted in our sample is computed with the degree of uncertainty of our estimate by calculating the 95% confidence interval of the regression line (147). Multiple linear regression analysis allowed estimation of the linear effect after controlling for the confounding effect of other variables.

## **6.1.6 Procedure Volume Calculations**

The numerical definitions assigned to hospital volume categories assessing effect on outcome, vary between studies. Katz defined TKA low volume hospitals as  $< 25$  procedures annually (81), whereas Hervey defined low-volume as  $< 85$  (80). Some used actual patient numbers while others used statistical measures like quartiles (148). Since there were such widespread differences in in hospital volume definitions for total knee arthroplasty surgery, discrepancies between number of categories and methods utilized for analysis, we chose to

define cut-point for volume categories based on clinical evaluation of the existing material and comparable previously used volume categorization in paper I and II (78, 81, 93, 148). To our knowledge there were few previous papers analyzing the volume effect on the relative risk of revision for TKA (93, 149).

In paper I annual hospital volume was counted for each year separately, thus some hospitals changed volume group during the study period. We chose 5 volume categories from 1-24, 25-49, 50-99, 100-149 and  $\geq 150$ . Since no uniform categorization existed in the literature, the cut points were chosen based on evaluation of the current material in the NAR and other comparable studies available. Demographics were comparable in all the 5 volume groups (age, gender, diagnosis). All procedures were entered into the corresponding hospital TKA volume group 1-5 according to the number of primary TKAs at the hospital in the year of the procedure. There were 49 hospitals performing the TKA procedure during the study period. Hospitals with changing procedure volumes therefore could contribute to more than one volume group. 20 hospitals remained in the lowest volume group throughout the study period. 6 hospitals changed group one time, 22 hospitals changed 2 times to increasing volume groups, and 3 hospitals contributed to 4 volume groups. None contributed to all five groups.

The method of counting each year separately for every hospital had not previously been used to our knowledge, but was later used in the TKA hospital volume study by Pamilo et al. in 2015 (150). Fluctuating hospital procedure volume was also utilized by Glassou et al. in 2016 in their study regarding hip arthroplasty (151). The advantage of this method of analysis is that if a hospital for 1 or more years belongs to the lowest-volume group, it actually reflects the rarity of the procedure that particular year. Even if a surgeon had a reasonable surgery volume during previous years, continuous training in a technically demanding procedure is essential to achieve reproducible results. One limitation of the study was the lack of information on surgeon procedure volume, and there was no information regarding the correct/incorrect indication for the subsequent primary procedure or revision. The gradual improvement of the survival following total knee arthroplasty is probably multifactorial, but the impact of volume probably is a crucial contributor. The benefits of

high volume probably include not only improved surgical technique but also a better understanding of the importance of patient selection and the indications for surgery. Better implants, implant-specific education, better surgical and cementing techniques are also important factors (103).

In paper II, our method of counting procedures corresponded to Paper I, counting each year separately. Annual hospital procedure volume was calculated for all hospitals as the number of cemented Oxford III UKAs performed during a calendar year from January 1st until the December 31st. The effect of center volume was analyzed further by grouping the hospitals into four categories of approximately equal size according to the volume of primary procedures performed during the study period; 1-10, 11-20, 21-40 and >40. Patients were entered into the hospital volume groups according to the number of procedures at their hospitals the year of surgery. For every hospital, each year was examined individually. 51 hospitals performed Oxford III UKA procedures during the study period, and 36 of those contributed to more than one volume group.

Both Robertsson et al. and Baker et al. used average procedure volume in their papers (97, 102) defining the mean procedure volume for the hospital during a given period of time. Robertson et al. analysed 10 474 UKA over a 10 year period, while Baker analysed 23 400 UKA during an 8-year span. Our study had a lower number of patients (4 460), but over a 14-year period. The more recent study by Liddle et al. included 37 131 UKA over 8 years (104). They calculated each surgeon's UKA volume for each calendar year and then used the mean volume. Years with zero performance were excluded to prevent artificial reduction in caseload for surgeons who stopped performing UKA for any reason (104). Liddle et al. also used another method of determining the effect of caseload of UKA; as a percentage or proportion UKA compared to the total number of knee arthroplasties (61).

Several new publications appeared during our publication of paper II, investigating the procedure volume effect on revision risk after Oxford UKA using alternative calculation methods. Therefore, our third publication assessed to compare different statistical methods of calculating hospital procedure volume.

Paper III was a NARA study including Oxford III UKA data from 4 countries' registers (Sweden, Denmark, Finland and Norway), hospital procedure volume was calculated in 3 methods previously described in the literature and finally added into one model. As implant brand and type could be a source of confounding in comparison of revision rate according to hospital, all other brands and types than Oxford III UKA were excluded. Diagnoses other than OA were excluded as inflammatory disease is a contraindication. Hospitals with less than 10 Oxford procedures during the complete study period were excluded from the material and considered an extremely low volume. The study period was 13 years; hence 10 procedures during the entire period would mean less than 1 as a mean number of UKAs.

The first calculation of hospital volume was similar to Paper I and II, counting each year for every hospital separately. Quartiles were used to make 4 hospital volume groups; <13, 13-25, 26-45 and >45. Patients were entered into the hospital volume groups according to the number of procedures at their hospitals the year of surgery. This led to a distribution of UKA procedures that were relatively equal in each volume group. Due to the large number of hospitals changing volumes from year to year, this was our method of choice. To capture the variances happening in hospitals for different reasons, such as a decrease in volume of cases due to bad experience with the implant or dedicated surgeons moving to another hospital or retiring from work, analysing each year separately addresses this issue more properly in our opinion than an average volume would.

The second method was the previously described average volume used by i.e. Baker et al.(102), in which we analyzed the procedure volume performed during the entire study period of 13 years and calculating the mean number of operations per year, using the total hospital volume as nominator and the actual numbers of years as denominator. When calculating average procedures volume, any year without reported procedures did not count. Consequently, if a hospital had zero procedures in 2 out of 10 years examined, the mean number of UKA operations was calculated over 8 years instead of 10 years. The measures of 3 hospital volume categories were chosen based on equal sizing of the 3 groups (<12, 12-26 and >26) according to the procedure volume performed during the entire study period and calculating the mean number of operations per year. Only 4 hospitals had an average annual

hospital volume above 50 a year, and that reflects the problem in choosing this method when the majority of hospitals are low volume.

One could argue that mean volume over the whole time period is a more reliable method: if hospital A suddenly reduces its annual procedure volume to less than 10 but in the preceding 5 years has had a high annual procedure volume of  $> 40$ , the team knows the procedure so well that one random year with a low volume would not have an impact on the results. However, since 36 of the 51 hospitals changed volume group during the study period, the advantage of the first method of analysis was that if a hospital for 1 or more years belonged to the lowest-volume group, it actually reflected the rarity of the procedure those particular years. If the hospitals had relatively constant annual hospital procedure volumes, an average number would be an appropriate method of choice.

The third method was described by Liddle et al. (61), adding the volume of all knee replacements performed by the hospitals or surgeons. The purpose of this method was to determine the optimal usage defined as the percentage of knee arthroplasty practice comprised by UKA. This method would catch the proportion of highly selective units, offering UKA only to a small proportion of patients requiring arthroplasty of the knee, and consequently performing few UKAs each year. We decided to use their recommended threshold value of acceptable results with usage  $\geq$  or  $\leq$  than 20% in our study. Consequently, 157 hospitals performed  $\leq 20\%$  UKA compared to 22 hospitals with  $> 20\%$ . Thus, only 20.4% of the patients were operated at hospitals with a recommended Oxford III usage of  $> 20\%$ .

In the study from Liddle et al., acceptable results were achieved with the use of 20% or more. Optimal results were achieved with usage between 40% and 60% and surgeons with the lowest usage (up to 5%) had the highest rates of revision. Liddle's study also had generally low UKA procedure numbers where most surgeons performed very few (81.4% performed fewer than ten UKAs per year). In total, 8.3% of arthroplasties were UKAs. The mean number of cases performed annually per surgeon was 2.8 for UKA and 31.1 for TKA. Excluding the 1338 (50.5%) surgeons who performed no UKAs, these figures were 7.6 and 45.2. Among surgeons who perform both TKA and UKA, the mean usage of UKA was



11.0%. Even if NJR has a much larger statistical material, our material and results are corresponding to theirs.

To avoid confusion using different groupings in the 3 different methods and the similarity between method 1 and 2, we constructed a combined model, implementing the previously described methods into one fitted Cox model; Oxford III UKA annual hospital volume, proportion/usage of Oxford III UKA, and TKA annual hospital volume in addition to including sex, age, calendar year of surgery and nation as adjustment variables.

Using a 3-year moving average estimate as a proxy for surgeon experience, to avoid the random effect of sudden decreases in volume due to i.e. a surgeon moving to another hospital generated a set of smoothed estimates.

When a high number of hospitals have low procedure volumes, the low procedure volume units will be reported as operating approximately at the national standard. Increasing and continuous volume could independently be associated with quality (i.e., practice makes perfect), and current low volume could be a consequence of previously observed poor quality (152).

### **6.1.7 Revision Causes**

Revision is defined as a partial or complete removal/exchange/addition of implant component(s). Revisions are linked to the primary surgery by the unique national identification number of the patient, laterality and specific joint. In the NAR, more than one reason for revision can be reported for one patient. When more than one reason is reported, there is a hierarchy with infection as the top reason for revision and pain only at the bottom. Addition of implant components is common in TKA when adding a patellar component, but in study II and III, UKA were studied, and there is no addition of components.

In paper II, in the material restricted to revised implants, the Pearson chi-square test was used to test whether proportions of specific revision causes differed among the groups. The

log-rank test was used to compare implant survival among volume groups with revision due to infection, aseptic loosening or polyethylene wear, dislocation, instability, malalignment or fracture, progression of OA or pain alone (in hierarchical order from top to bottom) as endpoint. The logrank test is most likely to detect a difference between groups when the risk of an event is consistently greater for one group than another and was therefore considered appropriate for this purpose. The numbers of revisions in each group were too small to allow us to make any conclusions regarding the differences between the groups. In the >40 group there were only 26 revisions registered. Because the logrank test is purely a test of significance it cannot provide an estimate of the size of the difference between the groups or a confidence interval, thus to make assumptions about the data we should have included a risk ratio using Cox proportional hazards model (142).

In paper III, there were 1344 revisions after cemented medial Oxford III UKA. Revision due to all reasons as well as specific causes for revision were analysed. The various reasons for revision were organized hierarchically with infection first and pain alone last. They were analysed using risk ratio with 95% confidence interval to test whether proportions of specific revision causes differed between the groups. Adjustments were made in the analysis for gender, age, time period and nation. The numbers of revisions were more evenly distributed in the different volume groups in this paper than in paper II in method 1 and 2. Using the Cox proportional hazard model enabled an estimate of the size of the differences between the groups with a risk ratio and a confidence interval.

## 6.2. Results

### 6.2.1 Paper I

#### 6.2.1.1 Patient and Procedure Characteristics

In 1995, 88% of Norwegian hospitals performed less than 50 TKAs a year. In contrast, 84% of the hospitals performed more than 50 procedures a year in 2010. There has been a gradual increase in number of procedures every year regarding the total knee arthroplasty procedure. This is confirmed by data in the NAR report; 3954 TKA implanted in 2010, increasing to 4930 in 2014. Hospitals with more than 100 TKA procedures a year was first registered in 1999 and hospitals with >150 TKA a year in 2005.

17.5% of the TKA were in the lowest volume group of <25, 28.1% in the 26-50 group, 39.5% in the 51-100 group, 8% in the 100-149 group and 6.9% in the  $\geq 150$  group. Thus, the lowest number of implants was in the highest volume groups. 47 hospitals performed less than 25 TKA a year, 29 hospitals contributed to the 25-49 group, 26 hospitals performed between 50-99 TKA annually, 4 hospitals contributed to the 100-149 a year group, whereas only 2 hospitals performed  $\geq 150$  TKA annually.

23 different TKA implant brands were registered in the NAR from 1994-2010. Prosthesis brands registered in less than 100 knees during the study period were excluded as well as hinged implants and PS/CCK designs. Due to small numbers of revision arthroplasties in each group and since all implant brands were not represented in all groups, we were not able to make adjustments for implant brands in the Cox model. Consequently, we decided to assess 2 commonly used implant designs combined in a subanalysis (AGC (Biomet, Warsaw, Indiana) and LCS (Depuy, Warsaw Indiana)). Implant variations could be a source of confounding in any comparison of revision rates according to hospital, and we considered it a weakness of the study not to be able to adjust for implant brand.

Regarding sex, the <25 group had the lowest percentage of male patients (29%), whereas the 100-149 group had the highest percentage (37%). Sex could be considered a demographic risk factor, but in a recent review article, 10 publications were considered and inconsistent findings were reported on whether males had a higher risk of revision surgery in general (153). Men do however have a twofold risk of revision due to infection in arthroplasty surgery compared to women found in several studies (154-156), but infection is (97) a minor cause of revision compared to the total number. In this study, we did not examine sex as an independent risk factor, but made adjustments for sex in the Cox model.

Age as an independent risk factor, has been reported in 13 of 15 examined papers in the review article (153) previously mentioned. Revision rates decreased with older age. National registries have also reported on the age-influence on revision rates in arthroplasty surgery. Younger age has been associated with higher activity levels and higher levels of expectations as possible reasons for increased risk of revision. The median age values in this study were 72 in the two lowest volume groups and 70 in the highest volume group.

The majority of TKA patients had OA as reported diagnosis in our study. The lowest volume group <25 had the lowest percentage of OA diagnosis (81%), whereas the 100-149 group had 90% OA patients. A higher proportion of inflammatory diseases in the lowest volume group could lead to higher revision risk in this group. Estimated risk ratios were however adjusted for diagnosis in this study. Kreder et al. reported no association between OA and the risk of revision (149), whereas others found mixed results (153, 157). Diagnosis could be a source of information bias due to incorrect registration from surgeons. Secondary causes of OA may be underrepresented, but this has not been validated.

Comorbidities could be a potential confounder increasing the risk of revision. Obesity, cardiac disease and diabetes has been associated with higher risk of revision(153). We did not assess ASA status in this study since it was first included for registration in 2005.

Knee implant factors, such as fixation status, patellar resurfacing and posterior cruciate ligament sacrificing could potentially affect the risk of revision. In this study these factors were therefore exclusion factors to obtain homogeneity.

### 6.2.1.2 *Survival Analyses*

The risk of revision was assessed in comparison with the results for the lowest volume procedure group <25. In conclusion, low volume hospitals had an increased risk of revision after primary TKA in that study. The two highest volume hospitals had statistically significantly lower risk of revision compared to the lowest volume group in the Cox regression analysis. Annual volume from 100-149 had RR=0.73 (0.56-0.96), p=0.03, and annual volume >150 had RR=0.73 (0.54-1.0), p=0.05. The two medium volume hospital groups had a slightly lower risk of revision than the <25 group, but not statistically significant.

In the subanalysis of the AGC and LCS implants combined, we found similar and corresponding results. Comparing the hospitals with annual hospital volume 100-149 to hospital with annual volume <25, we found RR=0.56, p=0.007. For the other groups there were no statistically significant differences.

Limitations to the study were other relevant factors contributing to continuous improvements in TKA; improvements in surgical technique and better implants and materials as well as evolving implant-specific education and increasing surgeon volumes. The increasing focus over the years on improving technique regarding placement of the components, improving ligament balancing and range of motion as well as cementing technique could also influence the results and cannot be controlled for and these measures have taken place parallel to the increase in hospital volume. A method to assess early revisions due to technical issues could be dealt with dividing into early and late revisions. Other factors to be considered confounders are BMI, comorbidity, smoking, educational level, preoperative pain and function levels which were lacking in this study.

In view of the literature, our findings are in agreement with the findings of other earlier studies from the US (93) and Canada (149). A study assessing surgeon volume from the NJR

of England and Wales have supported the correlation between provider volume and revision risk after TKA (104). A recent study from the Finnish arthroplasty register found that lower volume hospitals were associated with longer length of stay and more readmissions than higher volume centers (150). The relationship between volume and outcome in knee replacement procedures has been studied by several groups. Some studies examined hospital volume, some examined surgeon volume. Most of the older studies examined outcome as frequency of mortality, morbidity, length of stay or financial outcomes (158, 159). Some studies examined the relationship between volume and risk of revision (102, 103).

## **6.2.2 Paper II**

### *6.2.2.1 Patient and Procedure Characteristics*

During the period of analysis from 1999-2012, approximately 10% of all knee replacements were unicompartmental. While TKA procedures have increased constantly during the years, the number of UKA has been relatively unchanged. However there has been an increase the last years of registration with 584 (10.5%) UKA in 2014 and 746 UKA in 2015.

21.6% of UKAs were in the  $\leq 10$  annual volume group, 34.6% in the 11-20 group, 36.6% in the 21-40 group and 7.2% in the  $>40$  group. Thus, the lowest number of implants belonged to the highest volume group. 49 of the 51 operating hospitals contributed to the  $\leq 10$  group, 34 hospitals contributed to the 11-20 group, 22 hospitals contributed to the 21-40 group, whereas only 5 hospitals had a yearly volume of  $>40$  UKAs.

12 different UKA implant brands were registered in the NAR, and the Oxford III UKA implant constituted 72% of UKAs during 1994-2014. The Oxford Partial Knee was introduced in Norway in 2012, and is gradually replacing the Oxford III implant. The Oxford Partial Knee is a further development of the Oxford III implant, but will not be discussed in this context. In this study, all implant brands other than Oxford III were excluded to obtain homogeneity and to avoid implant variation as a source of confounding.

Median age for UKA was substantially younger than for TKA; 65 years versus 71 years respectively. The lowest volume group of  $\leq 10$  UKA a year had the youngest patients with median age 62 while the other groups had median age of 65. Additionally, 37% of patients in the  $\leq 10$  group were  $\leq 60$  years of age compared to 28% in the highest volume group  $>40$ . This was supported by Liddle et al. who found younger patients in the low volume group (104). All registers report poorer results in young patients (53, 62, 160, 161). Liddle et al. also found age to be an important predictive factor (105). As previously discussed, age is an independent risk factor.

Male sex was more common in UKA patients compared to the TKA population in paper I; between 43-47% men in the 4 UKA volume groups versus 29-37% men in the 5 TKA volume groups respectively. 47% male patients was registered in the lowest volume group of  $\leq 10$  a year, whereas 43% were in the group with yearly procedure volume of  $>40$  UKA.

OA was registered in 94% of the cases in the highest volume group versus 91% in the  $\leq 10$  UKA a year group.

### **6.2.2.2 Survival Analyses**

The risk of revision was assessed in comparison with the results for the lowest volume procedure group 1-10. In the unadjusted analysis, the 11-20 group had a lower risk of revision; RR=0.77 (0.62-0.96),  $p=0.02$ , the 21-40 group had RR=0.78 (0.62-0.97),  $p=0.03$  and the  $>40$  group had RR=0.53 (0.35-0.81),  $p=0.003$ . Risk of revision were similarly analysed with adjustments for sex, age and diagnosis. Patients in the hospital volume group of  $>40$  had the lowest risk of revision; RR=0.59 (0.39-0.90),  $p=0.01$  compared to the lowest volume group. We also found a linear trend between the groups; increasingly better results with increasing hospital volume.

As in paper I, a limitation to this study was the lack of information on surgeon UKA caseload. We did however assess the approximate number of TKA and UKA performing

surgeons in each hospital by the previously mentioned survey (appendix 3). 39 of the 42 performing orthopaedic departments responded, and the enquiry suggested a high number of low-volume surgeons equally distributed among the volume groups. This can make the interpretation of hospital volume somehow uncertain, since high volume hospitals theoretically could have only low-volume surgeons and low-volume hospitals could have only one surgeon performing all the UKA procedures.

Hospitals with the lowest procedure volume, having the highest rates of revision, implanted UKAs in younger patients than high volume hospitals. This could represent patients with partial thickness disease and poor indication for arthroplasty surgery. However, the register does not provide radiographic information.

Our analysis was limited to the cemented medial Oxford III UKA implant, which may limit the generalizability of the findings, as the influence of hospital volume appeared to be implant dependent in the study from Robertsson et al. (97). They suggested that technically demanding implants were more susceptible to the influence of procedure volume. Whether or not the Oxford III UKA is more technically demanding than other UKA implants remains to be studied further.

The common denominator in all UKA volume studies is the low caseload both regarding surgeon and hospital caseload over the years. The increasing focus from joint registries regarding the influence of caseload may improve UKA results in the coming years. 5 hospitals had a yearly volume of >40 Oxford III UKAs in our study, and they had superior results compared to the lower volume centers. This could be an indication that the hospitals involved have dedicated UKA surgeons with proper knowledge of indications for primary and revision surgery as well as proper surgical technique.

The comparison against TKA is difficult since the disease pattern with isolated medial OA and the preoperative functional status of the patients' knees is different from the typical TKA candidate. Nevertheless, UKA has inferior results compared the TKA even for the highest volume hospitals in our study. We found 89% survival after 7.6 years for the +40 UKA



hospitals compared to 92.5% 10 year survival for the lowest TKA hospital volume group (<25) in paper I.

In view of the literature, both Baker et al. (102) and Liddle et al. (104) suggested that surgeon caseload was an important measure regarding Oxford UKA. The correlation between hospital caseload and the risk of revision in UKA has been supported by Robertsson et al. (97) in the Swedish registry study. They found worse results with less than 23 UKA procedures a year. Baker et al. concluded with a minimum procedure number of 13 (102) and the New Zealand registry reported poorer results with less than 10 UKA a year REF. The study from the NJR of England and Wales concluded with optimal usage between 40-60% UKA usage, and acceptable results with usage more than 20% UKA REF. In another paper, Liddle et al. found the revision rate after UKA to drop steeply until it reached 10 cases a year, plateauing at 30 cases (104).

### ***6.2.2.3 Revision Causes***

We analysed the distribution of revision causes for 514 revisions among the hospital volume groups. The main finding, was a higher proportion of revisions for pain alone in the high volume group >40, but this was not statistically significant (Pearson p-value =0.1). Revision causes like instability, fractures, malalignment and dislocation were more common in the lower volume groups than in the high volume group. These causes of revision could be considered technical errors during surgery. However, log-rank tests did not show any statistically significant differences between the groups. Additionally, the numbers of revision were small, and therefore, we recommended cautious interpretation of those findings. Liddle et al. found that reasons for revision differed among the volume groups, where low-volume surgeons were more likely to revise due to aseptic loosening, unexplained pain or malalignment (104).

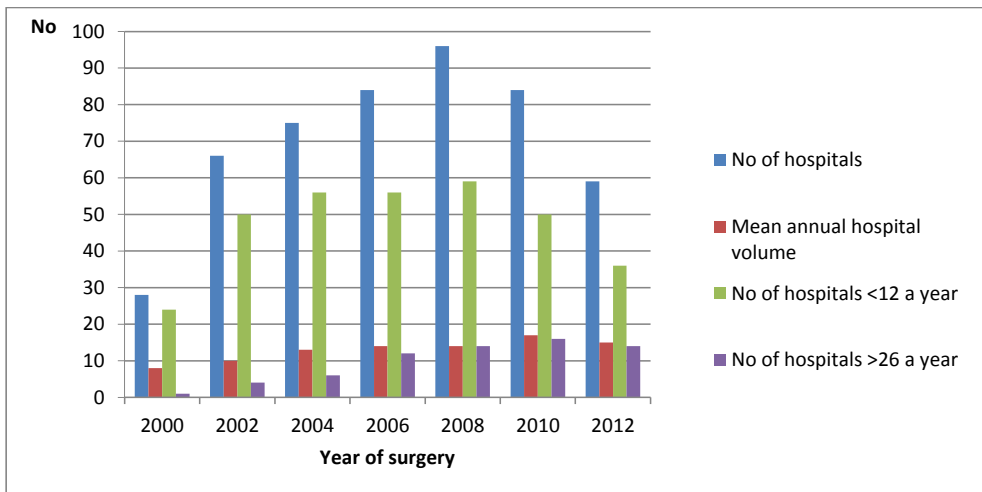
Other outcome measures such as risk of postoperative complications or readmission post-surgery and patient-reported outcome should also be taken into consideration in decision-making on whether to choose UKA or TKA. In a propensity-score matched study, UKA had better short-term patient-reported outcome for the best outcomes and excellent results (136). Lygre et al. found similar results, however small, in a Norwegian registry study (117). Complications and readmissions were more common after TKA in the NJR study. The use of unicompartmental knee replacement was associated with substantially lower mortality than was TKA in another study from the NJR of England and Wales (135). Comparing matched patients in a study from the NJR of England and Wales, TKA patients had a higher risk of mortality, readmissions and complications than UKA patients. In the same study UKA had worse results regarding revision than TKA at 8 years (162). This had also been stated in the observational study by Hunt et al.; measuring the 45-day mortality after 467,779 knee replacements for osteoarthritis from the National Joint Registry for England and Wales. The use of unicompartmental knee replacement was associated with substantially lower mortality than was total knee replacement (hazard ratio [HR] 0.32, 95% CI 0.19-0.54,  $p < 0.0005$ ) (135).

## 6.2.3 Paper III

### 6.2.3.1 Patient and Procedure Characteristics

Our study included data from 4 different national registers with multiple surgeons and hospitals with varying experience and caseload, suggesting high external validity. It reflects the current practice in 4 different countries.

NARA data showed that 126 different hospitals performed 12 986 cemented medial Oxford III UKA during 2000-2012. There was a substantial increase in numbers of hospitals performing Oxford III UKAs from 2002 to 2008, and then again the number of hospitals decreased. The increase in performing hospitals was not due to an increase in numbers of UKA, meaning lower volumes in more hospitals (Fig.21).



**Fig.21** Bar graph showing the change in number of hospitals performing Oxford III UKA (blue), the mean procedure volume per year (red), numbers of hospitals operating upon <12 patients a year (51) or >26 patients a year (purple).

There were also a large proportion of young patients; 18% were younger than 55 years, whereas only 13% were more than 75 years old. Other studies have shown that young patients experience an increased risk of revision after UKA compared to older patients (56, 105, 161, 163). W-Dahl et al. and Liddle et al. (105, 161) also found that older patients had the greatest benefits and the lowest revision rates. The increase in younger patients operated upon despite the knowledge of higher revision rate could be important explanation mechanisms for poor results. UKA has been associated with lower rates of morbidity and mortality compared to TKA (105, 135, 164, 165), and could therefore be a safer option for the elderly population, contrary to current practice

We found that 43% of the patients were male. Gender was not found to influence the results in our study.

We found that even though Denmark had the highest proportion of procedures in the annual volume groups in method 1, they only had 18% of high-users >20% in method 3. Finland had a majority of low-volume hospitals in method 1 and correspondingly only 10% high-user hospitals. Norway similarly had most patients in the low-volume hospitals in method 1, whereas 34% were high-users in method 3. Sweden had an even distribution in all volume groups in method 1, while 20% were high-usage hospitals in method 3. Denmark had statistically significant higher risk ratio compared to Sweden as reference; RR=1.4 (95% CI 1.2-1.6,  $p<0.001$ ). Similarly, Norway had RR=1.2 (95% CI 1.0-1.5,  $p=0.02$ ). Finland had RR=1.2 (95% CI 1.0-1.4,  $p=0.06$ ). Why Sweden had the best implant survival of all the 4 countries could be a result of longer period of training and experience, starting unicompartamental knee arthroplasty surgery and a knee arthroplasty register before the other Nordic countries, and thereby gaining more experience. In the Swedish Knee Arthroplasty Register, medial UKA was a popular procedure until 1995. Due to inferior results with high revision rates, a gradual drop in usage has been observed since then, and is now 3% of the total usage of knee replacements (63). Sweden differs from the other nations with only 50% of the implanted UKAs being Oxford and thus their learning curve could be improved by surgical experience performing other types of UKA.

### 6.2.3.2 *Survival Analyses*

We studied the annual hospital procedure volumes in detail and found great variability from one year to the next, probably due to changing surgeon availability and surgeons' method of choice for the treatment of knee osteoarthritis. A hospital with a high volume of 40 for 2-3 years could suddenly have 5 procedures the next year, and in method 1, this particular hospital would be evaluated both in the high and the low volume group, respectively. The reason for the change in yearly hospital volume is probably due to a change in available surgeons or a sudden change of practice or political decisions. Using <13 Oxford III UKA annual hospital volume as reference in method 1, all the higher volume groups had a lower risk of revision.

Average volume over the whole time period resulted in an annual upper caseload threshold at >26 to get equal groups for comparison, which is a low volume compared to method 1. This corresponds to the Swedish study where 75% of the units performed less than 23 UKA per year (97). Baker used the total volumes over an 8-year time-span, and therefore had less than 50 as the lowest volume and more than 400 as the highest volume in his study from 2014. A volume of 100 procedures therefore equated approximately 13 procedures a year (102). We found a 30% increased risk of revision in hospitals with an average annual hospital caseload of <26 UKA.

The usage or percentage method (method 3) added an interesting aspect to the procedure-outcome relationship. Only 20.4% of the patients were operated at hospitals with a recommended Oxford III usage of >20%. RR was 1.4 (95% CI 1.2-1.7, p<0.001) for the patients operated upon by low-usage hospitals  $\leq$ 20% compared to the hospitals with higher usage percentage >20%. The method suggests more dedication to the indications and procedures when performing for instance 100 total knee arthroplasties and 30 unicompartmental knee arthroplasties in an institution versus a hospital with a caseload of 200 TKA and 20 UKA. If some hospitals have 30% of the available patient population suitable for UKA and other hospitals only find 10% of patients suitable for Oxford UKA, there is a substantial difference in preference/indications and knowledge among surgeons.

In addition to using Kaplan-Meier survival analysis and adjusted Cox regression models, we expanded the statistical analyses by adding fitting linear regression models. This enabled the study to visualize the distribution of procedure volume among the hospitals as well as achieving a more accurate threshold value regarding recommended UKA usage.

We limited the analyses to the latest time period from 2000 excluding older implants and techniques. A limitation to the study could be unmeasured factors such as primary indication (166) as patients with full cartilage loss at the time of surgery are most likely to have relief of pain and improved function after knee arthroplasty, and thereby avoid the “pain alone” indication for revision surgery (67). Only hospital procedure volume was available for analysis in the NARA database, surgeon caseload and experience were not available. Ideally a high volume surgeon in a high volume center would gain the best results according to a systematic review regarding surgery volume (167). They stated, however, that the volume of a center had an equal if not greater effect on patient outcome than surgeon volume. We consider it a strength to the study limiting the analysis to one implant brand in the purpose to exclude possible confounder of implant type. Others have found surgeon volume to be volume-dependent in comparison to hospital volume (102).

Analyzing the combined Cox model previously described, with the risk of revision as a function of the annual hospital volume, patients operated at hospitals with a hospital volume of between 25 (median value) and 53, had a lower risk than the median patient. Inferior implant survival was found in hospitals with annual volumes of less than 25 UKAs and more than 53. The results were however not statistically significant, and the differences could only be interpreted as tendencies of improved or poorer results, as opposed to the single analyses.

The 3-year moving average model was constructed to smooth out year-by-year fluctuations in annual procedure volume. This was done in order to prevent bias regarding surgeons leaving the hospital leading to a sudden decrease in volume and also a drop in experience. The results indicated that hospitals with consistent high volume over a 3 year period had improved results compared to lower volume units. Adding the prior years of experience in the moving average, fell favorably for high volume hospitals. Hospitals with continuous high volume over time seemed to improve their results, diminishing the revision rate gradually

from 25 procedures per year. The term ‘consistent’ high hospital volume used in the results and discussion section refers to hospitals performing high volumes of Oxford III UKA for more than 1 random year of high volume. We examined all hospitals with procedure volumes >50 per year and found that 8 hospitals had 1 random year of high volume with various revision numbers. 7 hospitals had consistent high volume over a 5-6 years period, where the numbers of revisions decreased during the observed time period.

### *6.2.3.3 Revision Causes*

The interpretation of the differences found among the different volume groups regarding the causes of revision is difficult. There were statistically significant differences between the groups for some causes of revision. Pain alone in addition to loosening and wear were more common reasons for revision in the lowest volume group. These could be explanations to the differences in revision rates, suggesting a lower revision-threshold in low-volume users. However, the >45 group in method 1 had similar results as the <13 group regarding revisions due to aseptic loosening. This could explain why some high volume hospitals have inferior results in the combined Cox model. The group “other” was heterogeneous, consisting of both fractures, progression of osteoarthritis and malalignment, so to draw any certain conclusions on this matter could be biased. Similar results were found in our previous NAR study, however without statistical significance, probably due to smaller numbers of revision (168). In this study there were 1344 revisions after Oxford III UKA and they were evenly distributed among the volume groups.

## 7. CONCLUSION

### *Paper I*

- We found a gradual increase in the number of TKA registered in the NAR during the study period. 17% of the included TKAs were operated in hospitals with an annual hospital volume <25 TKA, 28% were operated in hospitals with 25-49 procedures annually, 40% in hospitals with 50-99 TKA per year, 8% in hospitals with 100-149 per year and 7% in hospitals with more than 150 TKA procedures per year.
- In this study, we found a significantly higher risk of revision following knee arthroplasties performed in low-volume hospitals as compared with high-volume hospitals with better prosthesis survival at hospitals performing >100 TKA per year.

### *Paper II*

- We found consistent low numbers of UKA registered in the NAR during the study period; approximately 10% of all knee replacements. 22% of UKAs were operated in hospitals with <10 procedures per year, 34% in hospitals with 11-20 per year, 37% in hospitals with 21-40 per year and 7% in hospitals with more than 40 UKA per year.
- This registry-based study confirmed that the risk of revision was significantly higher for hospitals performing less than 10 Oxford III UKA procedures a year than for those performing more than 40 Oxford III UKA procedures a year in Norway between 1999 and 2012.
- Low-volume hospitals appeared to have a higher risk of revision due to dislocation, instability, malalignment, and fracture than high-volume hospitals.



### *Paper III*

- We identified 4131 (31.6%) Oxford III implants in Denmark in 32 different hospitals: 2180 (16.8%) in Sweden distributed among 18 hospitals, 3826 (29.6%) in Finland in 41 hospitals and 2849 (21.9%) in Norway in 35 hospitals.
- A minimum hospital volume of at least 25 Oxford III UKA a year seemed to improve the implant survival in this study. A consistent high volume over years showed a tendency of improved results, lowering the risk of revision.
- This study identified hospital volume as an important predictor affecting implant survival of the cemented medial Oxford III UKA utilizing different statistical methods of measurement. We recommend a combined use of methods to evaluate procedure volume as they separately add valuable information.
- Revision for pain alone was lower in all higher volume hospital groups as compared to low volume hospitals.

National registries should discourage hospitals from performing UKA at low numbers as the risk of revision increases for all causes at low-volume hospitals. In our studies we found improved results when performing >100 TKA per hospital per year, >25 UKA per hospital per year and thus a usage of >20% UKA appears to be a reasonable measure achieving acceptable results. Nevertheless, risk of revision is higher for UKA than for TKA in most nation registries (62, 169), and the reason for this is probably multifactorial.

## 8. IMPLICATIONS AND FUTURE RESEARCH

Knee replacement surgery is increasing worldwide as an increasingly younger and more obese population has painful joints due to osteoarthritis. The current population is probably a more demanding group of patients to satisfy in terms of function, pain and expectations than previous generations with more advanced chronic disease. Thus the largest increase in patients receiving knee arthroplasty is the elderly patients. Satisfaction after total knee replacement has been reported in large study populations of no more than 80% (28). The survival of the prosthesis has been the main goal for surgeons for years and has reached a satisfactory level in national registers. The goal to achieve a forgotten joint a year after surgery remains unachievable for a large number of patients (170). However, total knee replacement has proved to improve outcome compared to nonsurgical treatment (30).

Aseptic loosening, malalignment, instability, fracture and pain are reasons for early revisions that could represent technical failures. Regarding alignment, there is increasing interest in restoring the patient's normal kinematics as opposed to mechanically aligned TKA, suggesting a higher proportion of satisfaction in the kinematically aligned group (29, 171) . The complexity of total knee arthroplasty regarding successful outcome, includes positioning and sizing of the implants in addition to ligament balancing and limb alignment.

All these factors are dependent on surgeon experience, but total knee arthroplasty is a common procedure bypassing hip replacement in volume in some countries, thus the volume effect will decline as time goes by and most surgeons and centers are categorized as high volume. Nevertheless, a new study with expanded numbers of years with additional high volume TKA hospitals could be recommended.

UKA has worse implant survival than TKA. However mortality and complication rates are higher for TKA than for UKA (135, 162, 164). The inferior implant survival should be addressed continuously by registers worldwide with emphasis on the large population of low-volume surgeons and units. In a recent study from the UK, 81.4% of the surgeons performed less than 10 UKA annually and more than 50% less than 5 a year, which is an

unacceptable high number of low-volume performance. Less than 10% of knee arthroplasties are UKAs in national registers (53, 62, 160, 172), so the caseload is basically low. Registers should continue to monitor the UKA volume and to encourage low volume hospitals to refer their UKA cases to higher volume units for improved results (61, 168). The NAR has encouraged surgeons through the annual reports to limit this procedure to a few dedicated surgeons in as few hospitals as possible, to achieve revision risk that is comparable with that of the TKA procedure. This seems to have had effect, as the latest report from 2015 showed an increase in UKA to 746 compared to earlier years with between 400-500 UKA annually. Fewer hospitals now perform UKA procedures (33) and there seems to be a larger amount of higher volume hospitals, as 9 of the 33 hospitals performed more than 30 UKA in 2015.

Future research regarding the effect of volume on results should focus on the possible differences in patient selection, differences in causes of revisions, differences in revision threshold and differences in surgical skills. Revision causes such as early aseptic loosening, fractures and development of lateral OA should be prevented to achieve results comparable to TKA (56). Patient selection is important in UKA as a typical misapprehension is to choose UKA for younger patients with early-stage disease. Revisions without a certain cause such as pain alone specified as the main factor is also more common in low-volume units (paper III). Concomitantly, UKA revisions might be more straightforward than TKA revisions, which could lower the revision threshold for some surgeons. This could be examined by a review of previous pre-UKA revision radiographs. This would be a highly interesting but time-consuming study. Knee revision surgery is also widespread low-volume surgery. A study to assess the volume-effect on revision surgery with concomitant assessment of method of choice and implant constrained among hospitals could reveal the risk of re-revision. For the Nordic countries numbers of revisions are low, so a NARA study could facilitate higher number of cases.

In the NAR and NARA, only hospital volume data is obtainable for analysis. There are pros and cons to this matter. For the surgeons, they can operate without the stress and insecurity of how the data of surgeon results will be handled by the government and by the media. The risk of introducing and ordering surgeon data is possible under-reporting to the register. The

advantage is the opportunity to use the surgeon data in research for more accurate estimates of results in the hospitals. Learning curves for new implants and methods introduced can also be monitored in more detail.

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## 10. PAPERS





## PAPER I

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# Influence of Hospital Volume on Revision Rate After Total Knee Arthroplasty with Cement

Mona Badawy, MD, Birgitte Espehaug, PhD, Kari Indrekvam, MD, PhD, Lars B. Engesæter, MD, PhD, Leif I. Havelin, MD, PhD, and Ove Furnes, MD, PhD

*Investigation performed at Kysthospital in Hagavik, Hagavik, and Norwegian Arthroplasty Register, Bergen, Norway*

**Background:** The number of total knee replacements has substantially increased worldwide over the past ten years. Several studies have indicated a correlation between high hospital procedure volume and decreased morbidity and mortality following total knee arthroplasty. The purpose of the present study was to evaluate whether there is a correlation between procedure volume and the risk of revision following total knee arthroplasty with use of hospital volume data from the Norwegian Arthroplasty Register.

**Methods:** Thirty-seven thousand, three hundred and eighty-one total knee arthroplasties that were reported to the Norwegian Arthroplasty Register from 1994 to 2010 were used to examine the annual procedure volume per hospital. Hospital volume was divided into five categories according to the number of procedures performed annually: one to twenty-four (low volume), twenty-five to forty-nine (medium volume), fifty to ninety-nine (medium volume), 100 to 149 (high volume), and  $\geq 150$  (high volume). Cox regression (adjusted for age, sex, and diagnosis) was used to estimate the proportion of procedures without revision and the risk ratio (RR) of revision. Analyses were also performed for two commonly used prosthesis brands combined.

**Results:** The rate of prosthetic survival at ten years was 92.5% (95% confidence interval, 91.5 to 93.4) for hospitals with an annual volume of one to twenty-four procedures and 95.5% (95% confidence interval, 94.1 to 97.0) for hospitals with an annual volume of  $\geq 150$  procedures. We found a significantly lower risk of revision for hospitals with an annual volume of 100 to 149 procedures (relative risk = 0.73 [95% confidence interval, 0.56 to 0.96],  $p = 0.03$ ) and  $\geq 150$  procedures (relative risk = 0.73 [95% confidence interval, 0.54 to 1.00],  $p = 0.05$ ) compared with hospitals with an annual volume of one to twenty-four procedures. Similar results were found when we analyzed two commonly used prosthesis brands.

**Conclusions:** In the present study, there was a significantly higher rate of revision knee arthroplasties at low-volume hospitals as compared with high-volume hospitals.

**Level of Evidence:** Therapeutic Level III. See Instructions for Authors for a complete description of levels of evidence.

Total knee arthroplasty is now a common and increasingly used surgical procedure that, in some countries, has bypassed total hip arthroplasty in terms of the number of procedures performed<sup>1</sup>. It is an established procedure with a high rate of patient satisfaction for the treatment of knee osteoarthritis<sup>2</sup>. There are multiple factors that may affect the outcome of total knee arthroplasty<sup>3-5</sup>. Patient characteristics and surgical indications, surgical technique, the quality of the implant and the bone cement, and implant-specific education

are all factors that affect surgical quality. Hospital and surgeon volume are also considered to be important factors<sup>6,7</sup>, but not all studies have demonstrated an association between surgeon volume and implant survival after total knee arthroplasty<sup>8</sup>. There have been reports of higher risks of perioperative and postoperative complications and higher rates of mortality following procedures performed at low-volume hospitals<sup>9-11</sup>. Some studies have shown a correlation between higher procedure volume and shorter length of hospital stay after total

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knee arthroplasty<sup>12,13</sup>. Others have shown that there is coherence between low volume and inferior functional outcome after total knee arthroplasty<sup>14</sup>. A higher short-term risk of complications after total knee arthroplasty has been associated with lower hospital and surgeon volumes, but very few studies have proven a relationship between procedure volume and implant survival. A study from the United States involving Medicare data suggested that procedures performed at low-volume hospitals are associated with a greater risk of revision at the time of intermediate-term follow-up (five and eight years)<sup>8</sup>. To our knowledge, there have been no studies involving national implant registry data that have investigated a possible correlation between hospital volumes and the rate of revision following total knee arthroplasty. Because of the large number of hospitals and procedures involved<sup>15</sup>, the Norwegian Arthroplasty Register provides valuable and dependable measures that can be used to analyze different volume-groups in order to evaluate the association between volume and the rate of revision.

The purpose of the present study was to evaluate whether there is a correlation between procedure volume and the risk of revision following total knee arthroplasty with use of hospital volume data from the Norwegian Arthroplasty Register.

### Materials and Methods

The Norwegian Arthroplasty Register was established in 1987 and initially included only hip arthroplasties. In 1994, the register started to include knee arthroplasties. The Norwegian Arthroplasty Register includes 99% of primary knee arthroplasties and 97% of revisions when checked against the Norwegian Patient Register<sup>15</sup>.

### Hospital Volume

The Norwegian Arthroplasty Register contains data on 37,381 primary total knee arthroplasties that were performed during the time period from 1994 to 2010. Thirty-three thousand, three hundred and seventeen (89%) of these total knee arthroplasties were performed without a patellar component, and, among these, 84% were performed with cement. To examine the annual surgery volume per hospital, we analyzed registry data for total knee arthroplasty procedures that were performed with cement and without a patellar component from 1994 to 2010. We selected this implant group because cemented implants without a patellar component are preferred at the majority of hospitals in Norway. We excluded implant brands that are rarely used, such as posterior stabilized designs (1180 implants) and hinged prostheses (sixty-five implants). After these exclusions, a total of 26,698 total knee arthroplasty procedures were analyzed (Fig. 1).

Hospital volume was categorized into five volume-groups (one to twenty-four, twenty-five to forty-nine, fifty to ninety-nine, 100 to 149, and  $\geq 150$ ). These cut-points were based on the mean annual numbers of total hip arthroplasties for the years 1994 to 2010 as reported in other similar studies<sup>9,16,17</sup>.

Because of the small number of revision arthroplasties, adjustment for prosthesis brand could not be done in the Cox model. We therefore performed a subanalysis on the AGC (Biomet, Warsaw, Indiana) and LCS (DePuy, Warsaw, Indiana) implants combined as these implants are commonly used and are well represented in all of the volume groups (with 1630 such implants in the one to twenty-four-procedure group, 2239 in the twenty-five to forty-nine-procedure group, 2250 in the fifty to ninety-nine-procedure group, 955 in the 100 to 149-procedure group, and 172 in the  $\geq 150$ -procedure group).

### Statistical Analysis

Descriptive analyses were used to assess patient characteristics for the different hospital and surgeon volume categories. Survival analyses were performed with

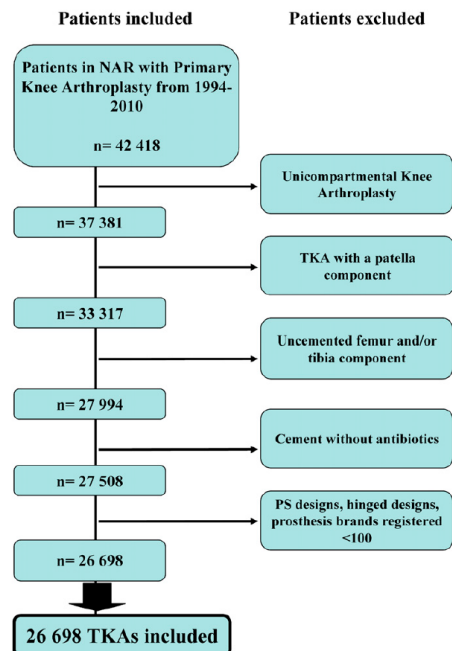


Fig. 1  
Twenty-six thousand, six hundred and ninety-eight total knee arthroplasties (TKA) were selected for inclusion in this study. Knees that were treated with unicompartamental knee arthroplasty, uncemented total knee arthroplasty, total knee arthroplasty with a patellar component, cement without antibiotics, and uncommon designs and brands were excluded. NAR = National Arthroplasty Register, PS = posterior stabilized.

revision of the prosthesis for any reason as the end point. Information on deaths and emigrations was retrieved from the National Population Register until December 31, 2010. The survival times of unrevised implants were censored at the date of death or emigration or at the last date of observation (December 31, 2010). Kaplan-Meier estimated survival curves were constructed for hospital volume categories, and the survival percentages at ten years are reported. To evaluate the effect of volume on prosthetic survival, we used the Cox regression model to calculate risk ratios (RR). These values are presented with 95% confidence intervals and p values relative to the lowest-volume group.

The Cox regression results regarding hospital volume were adjusted for age, sex, and diagnosis. Cox regression analyses with volume group as a stratification factor were used to construct adjusted survival curves. As many prosthesis brands had been used in small numbers and were associated with few revisions, adjustment for brand was not feasible in the Cox analyses. We therefore performed a subanalysis with the AGC and LCS implants combined.

### Source of Funding

There was no external funding source.



TABLE I Patient and Procedure Characteristics\*

	Annual Hospital Volume				
	<25 Procedures	25 to 49 Procedures	50 to 99 Procedures	100 to 149 Procedures	≥150 Procedures
No. of procedures	4685	7497	10,551	2131	1834
Male sex (%)	29	31	33	37	32
Age† (yr)	72 (20 to 93)	72 (22 to 92)	71 (26 to 96)	71 (22 to 92)	70 (31 to 91)
Osteoarthritis (%)	81	85	88	90	87
Common implants‡ (%)					
Profix (7002 implants)	23	30	33	6	0
LCS Complete (5501 implants)	8	8	26	22	80
AGC (3759 implants)	20	15	11	15	8
LCS (3511 implants)	15	14	10	30	2
Genesis I (2049 implants)	12	15	3	0	0
Duracon (1945 implants)	6	7	7	19	0
Cement with antibiotics (%)	96	98	99	100	100

\*Patient and procedure characteristics for 26,698 total knee arthroplasties performed with cement and without patellar resurfacing from 1994 to 2010 in Norway for five different hospital volume categories. †The values are given as the median, with the range in parentheses. ‡The values are expressed as the percentage of implants in each volume group. The most commonly used implants are shown. (A total of twenty-three different implant brands were registered in the Norwegian Arthroplasty Register. The six brands listed above constituted 89% of the total number of implants.)

## Results

The registration form in the Norwegian Arthroplasty Register includes information on patient characteristics, diagnosis, previous surgery on the knee, implant brand and type, fixation method, and other relevant data. Revision was defined as partial or complete removal or exchange of one or more implant components and was linked to the primary surgical procedure by the unique national identification number of the patient.

The patient and procedure characteristics according to hospital volume are shown in Table I.

### Hospital Volume

The hospitals with an annual volume of one to twenty-four procedures accounted for 4685 implants (17.5%), those with an annual volume of twenty-five to forty-nine procedures accounted for 7497 implants (28.1%), those with an annual volume of fifty to ninety-nine procedures accounted for 10,551 implants (39.5%), those with an annual volume of 100 to 149 procedures accounted for 2131 implants (8.0%), and those with an annual volume of ≥150 procedures accounted for 1834 implants (6.9%). The higher-volume group did not have the highest number of patients because higher-volume hospitals were uncommon during the first years of registration (Fig. 2).

The majority of hospitals had a gradual increase in annual hospital volume over time, but a few hospitals continued to be low-volume units and some stopped performing this procedure.

The percentage of hospitals performing fewer than twenty-five total knee arthroplasties per year decreased, and the percentage of hospitals performing ≥100 total knee arthroplasties per year increased. In 1995, 88% of the hospitals per-

formed fewer than fifty procedures annually. In 2010, 84% of the hospitals performed at least fifty procedures annually (Fig. 2).

The rate of prosthetic survival at ten years was 92.5% (95% confidence interval [CI], 91.5 to 93.4) for hospitals with an annual volume of one to twenty-four procedures and 95.5% (95% CI, 94.1 to 97.0) for hospitals with an annual volume of ≥150 procedures (Table II).

The risk of revision was assessed in comparison with the results for the low-volume hospitals (one to twenty-four procedures annually). Compared with knees that had been treated at hospitals with an annual volume of one to twenty-four procedures, those that had been treated at hospitals with an annual volume of twenty-five to forty-nine and fifty to ninety-nine procedures had lower risks of revision, but the differences

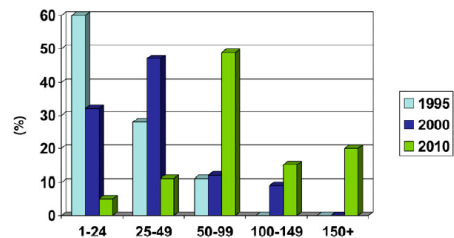


Fig. 2  
Bar graph showing the change in hospital volumes over time, with the three columns indicating the years of 1995, 2000, and 2010.

TABLE II Cox Regression Analysis

Annual Hospital Volume	No. of Total Knee Arthroplasties	No. of Revisions	Kaplan-Meier Estimated Cumulative Survival Rate at 10 Years* (%)	Adjusted RR <sup>†</sup>	P Value
<25 procedures	4685	280	92.5 (91.5 to 93.4)	1	
25 to 49 procedures	7497	373	93.1 (92.3 to 93.9)	0.94 (0.80 to 1.09)	0.40
50 to 99 procedures	10551	405	93.0 (92.0 to 94.0)	0.93 (0.80 to 1.08)	0.35
100 to 149 procedures	2131	64	94.7 (93.0 to 96.3)	0.73 (0.56 to 0.96)	0.03
≥150 procedures	1834	47	95.5 (94.1 to 97.0) <sup>‡</sup>	0.73 (0.54 to 1.00)	0.05

\*The 95% CI is given in parentheses. <sup>†</sup>Estimated risk ratio with adjustment for age, sex, and diagnosis. <sup>‡</sup>Estimated survival at five years (last revision).

were not significant (RR = 0.94 [95% CI, 0.80 to 1.09],  $p = 0.40$  and RR = 0.93 [95% CI, 0.80 to 1.09],  $p = 0.35$ , respectively). There was a significant difference between the hospitals with an annual volume of 100 to 149 procedures and the low-volume units (RR = 0.73 [95% CI, 0.56 to 0.96],  $p = 0.03$ ). The hos-

pitals with an annual volume of ≥150 procedures had the lowest risk of revision compared with the other groups (RR = 0.73 [95% CI, 0.54 to 1.00],  $p = 0.05$ ) (Table II). These numbers indicate an influence of hospital volume on the risk of revision in favor of the high-volume hospitals (Fig. 3).

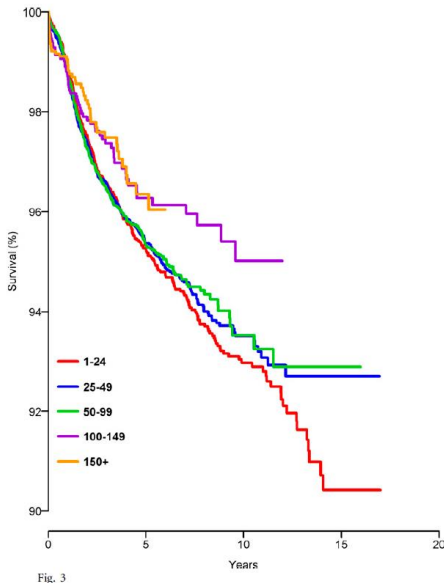


Fig. 3

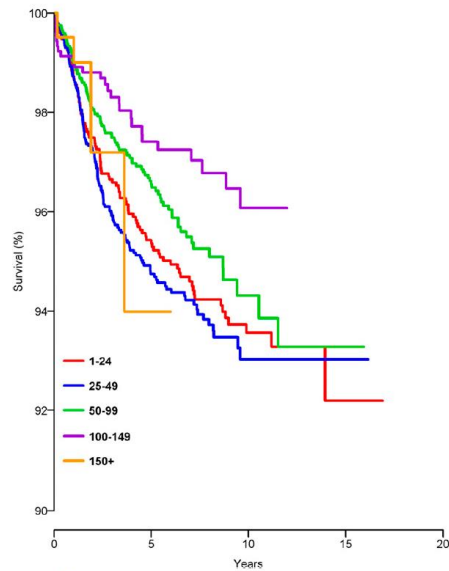


Fig. 4

**Fig. 3** Kaplan-Meier survival curves for total knee arthroplasties performed with cement and without patellar resurfacing in Norway from 1994 to 2010, with revision for any reason as the end point. The results of Cox regression analysis were adjusted for age, sex, and diagnosis. The results are shown for the five different hospital volume groups described in the text. **Fig. 4** Kaplan-Meier survival curves for total knee arthroplasties performed with cemented AGC and LCS implants without patellar resurfacing from 1994 to 2010, with revision for any reason as the end point. The results of Cox regression analysis were adjusted for age, sex, and diagnosis. The results are shown for the five different hospital volume groups described in the text.

In the subanalysis of AGC and LCS implants, we observed similar and corresponding results. Compared with knees that had been treated at hospitals with an annual volume of one to twenty-four procedures, those that had been treated at hospitals with an annual volume of twenty-five to forty-nine and fifty to ninety-nine procedures had lower risks of revision, but the differences were not significant (RR = 1.10 [p = 0.49] and RR = 0.82 [p = 0.17], respectively). A significant difference was found between the hospitals with an annual volume of 100 to 149 procedures and the low-volume hospitals (RR = 0.56; p = 0.007). The hospitals with an annual volume of  $\geq 150$  procedures had a low number of procedures and revisions compared with the other volume groups for these specific implant brands and did not have significant improvements regarding the risk of revision (RR = 0.81; p = 0.68) (Fig. 4).

### Discussion

This register-based study indicates that there was significantly better prosthetic survival following procedures performed at higher-volume hospitals as compared with low-volume hospitals during 1994 to 2010. However, these results might be influenced by several other factors<sup>8,19</sup>.

To study the influence of annual hospital volume on prosthetic survival, we used registry data from the Norwegian Arthroplasty Register to estimate the proportions of procedures without revision and relative differences in the risk of revision. Although the registry data do not include functional outcome after this procedure, the revision rate is an important measure of the clinical outcome of total knee arthroplasty.

### Comparison with Relevant Studies

The implants that were used in the later years may have been of better quality, and the surgical technique has improved, as has been shown for total hip arthroplasties with cement<sup>20</sup>. Styron et al. demonstrated that the annual volume of total knee arthroplasty procedures performed by the surgeon and hospital had a greater impact on the length of hospital stay than patient-related characteristics did<sup>13</sup>. The gradual improvement of the survival curve following total knee arthroplasty might be multifactorial, but the impact of volume probably is a crucial contributor. The benefits of high volume probably include not only improved surgical technique but also a better understanding of the importance of patient selection and the indications for surgery.

A higher short-term risk of complications such as wound infection after total knee arthroplasty has been associated with lower hospital and surgeon volume<sup>21</sup>. There also have been reports of higher risks of perioperative and postoperative complications and adverse outcomes (including pneumonia, acute myocardial infarction, pulmonary embolus, and deep infection) and higher rates of mortality in low-volume hospitals<sup>9,11</sup>. Other reports have indicated that there is coherence between low volume and inferior functional outcome following total knee arthroplasty<sup>14</sup>. Widespread differences have been reported in hospital volume definitions, with between two

and five hospital volume categories being used. The volume groups also differ in size. These discrepancies limit the conclusiveness of results<sup>6</sup>.

### Strengths and Limitations

Arthroplasty registers offer the ability to analyze outcome and to provide early warnings of failing implants and methods<sup>22</sup>. Except for revision, the Norwegian Arthroplasty Register does not include any clinical outcome data, which is considered a disadvantage. However, the Norwegian Arthroplasty Register has registered knee arthroplasties since 1994 and provides reliable measures of the change in volume over time. We therefore consider the results for hospital volume to be accurate. However, we are aware of other relevant factors contributing to the improving results in total knee arthroplasty, such as improvements in surgical and cementing techniques, implants, and implant-specific education.

We did not adjust for prosthesis brand when analyzing hospital volume, which might be considered to be a weakness. However, we compensated for this by performing a separate analysis of two commonly used brands that were well represented in all volume categories and achieved corresponding results. A recent study from the Norwegian Arthroplasty Register evaluated the different knee prosthesis brands and demonstrated that the implant most commonly used in the high-volume centers (Table I) had an average result when compared with the other implant brands and was not among the implants with the lowest risk of revision<sup>23</sup>.

### Explanations and Mechanisms

Standardization of procedure and care is important<sup>4</sup> and is well established in our country as nearly all procedures involve the use of cemented implants, antibiotics in the cement, perioperative antibiotic prophylaxis, antithrombosis prophylaxis, and some kind of rehabilitation after surgery. All resident orthopaedic surgeons in Norway are required to complete a practical and theoretical prosthesis course, and a textbook has been written for this course<sup>24</sup>. Patient selection and indications also play an important role in the outcome of total knee arthroplasty. Survival curves from the different national arthroplasty registers show a gradual improvement over time from 1994 to 2010 for the results of total knee arthroplasty<sup>25,26</sup>. Some of this effect might be volume-related.

In conclusion, in the present study, we found a significantly higher rate of revision following knee arthroplasties performed in low-volume hospitals as compared with high-volume hospitals. ■

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## PAPER II

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## Higher revision risk for unicompartmental knee arthroplasty in low-volume hospitals

Data from 5,791 cases in the Norwegian Arthroplasty Register

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**Background and purpose** — Some studies have found high complication rates and others have found low complication rates after unicompartmental knee arthroplasty (UKA). We evaluated whether hospital procedure volume influences the risk of revision using data from the Norwegian Arthroplasty Register (NAR).

**Materials and methods** — 5,791 UKAs have been registered in the Norwegian Arthroplasty Register. We analyzed the 4,460 cemented medial Oxford III implants that were used from 1999 to 2012; this is the most commonly used UKA implant in Norway. Cox regression (adjusted for age, sex, and diagnosis) was used to estimate risk ratios (RRs) for revision. 4 different volume groups were compared: 1–10, 11–20, 21–40, and > 40 UKA procedures annually per hospital. We also analyzed the reasons for revision.

**Results and interpretation** — We found a lower risk of revision in hospitals performing more than 40 procedures a year than in those with less than 10 UKAs a year, with an unadjusted RR of 0.53 (95% CI: 0.35–0.81) and adjusted RR of 0.59 (95% CI: 0.39–0.90). Low-volume hospitals appeared to have a higher risk of revision due to dislocation, instability, malalignment, and fracture than high-volume hospitals.

and other database studies have also indicated that survival is higher in patients with TKA than in patients with UKA (Lyons et al. 2012, SKAR 2012).

High-volume centers and high-volume surgeons have reported excellent results in their studies and follow-up of UKA (Murray et al. 1998, Lisowski et al. 2011, Price and Svard 2011). Advantages of a unicompartmental knee arthroplasty over total knee arthroplasty, such as reduced risk of complications, faster recovery, and a more rapid discharge, have been described by some authors (Lombardi et al. 2009, Brown et al. 2012) but not by others (Lygre et al. 2010). Technical failures leading to malpositioning of the components (Argenson and Parratte 2006, Mercier et al. 2010) are associated with procedure volume. There is a learning curve with this procedure, as demonstrated by Hamilton et al. (2009), but the failure rate persisted despite modifications to improve surgical techniques.

The purpose of this study was to establish the numbers of UKA procedures performed annually at the different hospitals, to investigate a possible correlation between low hospital procedure volume and high risk of revision regarding the Oxford III unicompartmental knee arthroplasty using the data from the NAR, and to investigate possible variation in the reasons for revision. Our hypothesis was that technical errors would occur more often in the low-volume hospitals.

The Norwegian Arthroplasty Register (NAR) has been registering knee arthroplasties since 1994 and has a registration-completeness of 99% (Espehaug et al. 2006).

In a study from the NAR, the 10-year survival probability was 80% for unicompartmental knee arthroplasty (UKA), as compared to 92% for the TKA (Furnes et al. 2007). The Finnish Arthroplasty Register had an even worse result, presenting a 60% survival rate for the UKA at 15-year follow-up (Koskinen et al. 2008). The Swedish Knee Arthroplasty Register

### Method

The UKA procedure accounted for approximately 10% of the knee implants in Norway during the period of analysis (1999–2012). The number of surgeries has remained rela-



Table 1. Characteristics of patients and procedures <sup>a</sup>

	Annual hospital volume (no. of procedures)			
	< 10	11–20	21–40	> 40
No. of procedures	964	1,542	1,633	321
Male sex, %	47	45	46	43
Age <sup>b</sup> , years	62	65	65	65
age range	36–90	36–91	35–92	39–88
≤ 60 years, %	37	31	29	28
Osteoarthritis, %	91	92	94	94
Year of surgery <sup>c</sup> , %				
1999–2000	36	31	34	0.0
2001–2005	22	37	31	11
2006–2012	21	33	40	5.5
No. of hospitals	49	34	22	5

<sup>a</sup> Patient and procedure characteristics for 4 460 cemented medial Oxford III UKAs according to hospital volume categories, from 1999–2012.

<sup>b</sup> The values are given as median (range).

<sup>c</sup> The values are expressed as the percentage of implants in each volume group. The majority of hospitals, 36 of 51, contributed to more than one volume group.

tively unchanged from one year to the next. 447 UKAs were implanted in 2004, as compared to 458 in 2012, while numbers of TKA procedures have been constantly increasing. 51 hospitals performed UKAs in 2012. Annual hospital procedure volume was calculated for all hospitals as the number of cemented UKAs performed during a year.

We analyzed 4 hospital procedure volume groups using data from the NAR. Group 1 had a procedure volume of 1–10 UKAs annually, group 2 had 11–20, group 3 had 21–40, and group 4 had more than 40 UKA procedures annually. Any hospital with inconsistent procedure volume over time may have contributed to different volume groups, as patients were entered into the hospital volume groups according to the number of procedures at their hospital in the year of surgery. Thus, for every hospital each year was examined individually, and 36 of the 51 hospitals that performed the UKA procedure contributed to more than 1 volume group (Table 1).

UKA surgery has been registered in the NAR since 1994 (Figure 1). The Oxford III implant was first reported to the Norwegian Arthroplasty Register in 1999. Analyses were done only for this implant, since it is the most commonly used unicompartmental knee implant in Norway, constituting 77% of all UKAs during the whole period. 3,955 patients were included and 505 (13%) of these patients had UKA surgery in both knees (Table 1).

The 4 volume groups were compared for risk of revision. Cox regression was used to estimate proportions without revision and relative risk (RR). We also analyzed the reason for revision in all 4 volume groups.

Revision was defined as a partial or complete removal/exchange of implant component(s) and was linked to the primary surgery by the unique national identification number of the patient.

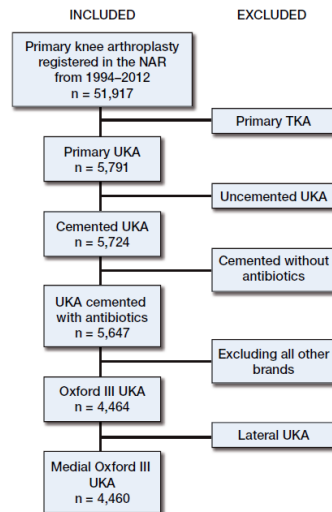


Figure 1. 4,460 unicompartmental knee arthroplasties (UKAs) were selected for inclusion in this study. Knees that were treated with total knee arthroplasty (TKA), lateral UKA, uncemented UKA, cemented UKA without antibiotics, and brands other than Oxford III were excluded.

## Statistics

Survival analyses were performed with any revision of the implant as endpoint. Information on deaths or emigrations was retrieved from the Norwegian Resident Registration Office until December 2012. Kaplan-Meier survival percentages at 10 years are reported. To evaluate the effect of volume on prosthesis survival, we used the Cox regression model to calculate risk ratios (RRs). These are presented with 95% confidence intervals (CIs) and p-values relative to the lowest-volume group.

Adjustments were made for sex, age and diagnosis. Age was divided into 4 groups (< 60, 61–70, 71–80, and > 80). Diagnoses were divided into 2 groups (osteoarthritis (OA) and others). Adjusted Cox regression survival curves were constructed for hospital volume categories with volume as stratification factor. In a material restricted to revised implants, the Pearson chi-square test was used to test whether proportions of specific revision causes differed among volume groups. The log-rank test was used to compare implant survival among volume groups with revision due to pain only, infection, loosening, dislocation, instability, malalignment, fracture, or to progression of osteoarthritis (OA) as endpoint.

The inclusion of bilateral knee arthroplasty may mean a violation of the assumption of independent observations in sur-



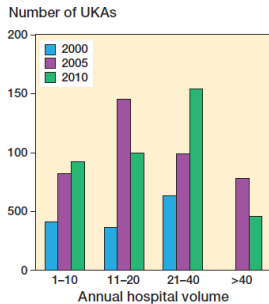


Figure 2. Bar graph showing the change in hospital procedure volumes over time, with the 3 columns indicating the years 2000, 2005, and 2010.

vival analyses. Studies have, however, shown that the effect on statistical precision is minor for survival analysis of knee replacements (Robertsson and Ranstam 2003). The proportional hazards assumption of the Cox model was tested based on scaled Schoenfeld residuals (Grambsch et al. 1995) and found to be valid for the factor annual hospital volume when investigated with the lowest-volume group as reference ( $p = 0.5$ ). SPSS versions 20.0 and 21.0 and R software version 2.15.1 were used.

## Results

In the first years of unicompartmental knee arthroplasty, none of the hospitals had the highest procedure volume (> 40 UKAs per year), but the number has slowly increased in the past 10 years (Figure 2). During the whole period, half of the hospitals contributed to the group of <10 procedures, one-third of the hospitals contributed to the 10- to 20-procedure group, one-fifth of the hospitals contributed to the 20- to 40-procedure group, and only 5 hospitals performed more than 40 UKAs

a year (Table 1). 36 of the 51 hospitals changed volume category during follow-up and therefore contributed to more than 1 volume group.

The annual hospital volume group of < 10 UKA procedures annually accounted for 964 implants over the whole time period from 1999 to 2012 (22%), the 11–20 volume group accounted for 1,542 implants (35%), the 21–40 group accounted for 1,633 implants (37%), and the > 40 group accounted for 321 implants (7.2%) (Table 1).

The percentage of male patients who received a UKA was higher than in the usual sex distribution for total knee arthroplasty (TKA) (NAR 2013). Additionally, the UKA patients tended to be younger than the TKA patients: median age was 64 (NAR 2013) (Table 1).

In the unadjusted analysis, comparing the risk of revision between the 4 volume groups, the knees in the 11- to 20-procedure group had a lower risk of revision (RR = 0.77, CI: 0.62–0.96) than those in the < 10-procedure volume group. This was also true of the 21- to 40-procedure group (RR = 0.78, CI: 0.62–0.97) and the > 40-procedure group (RR = 0.53, CI: 0.35–0.81) (Table 2). The risks of revision for the different volume groups were similarly analyzed with adjustment for age, diagnosis, and sex. The hospital group with an annual volume of > 40 procedures had the lowest risk of revision compared to the lowest-volume group (RR = 0.59, CI: 0.39–0.90). We also found a linear trend in the groups: there were increasingly better results with increasing annual hospital volume (Figure 3 and Table 2).

The distribution of causes of revision among 514 revised Oxford III implants from 1999 to 2012—according to hospital volume—is shown in Table 3. The main difference between the groups was a higher incidence of revisions for “pain alone” in the high-volume group (> 40 procedures annually), but this was not statistically significant. Technical errors such as instability, fractures, malalignment, and dislocation as the reason for revision were more common in the lower-volume groups (16–21%) than in the highest-volume group (7.7%). However, log-rank tests did not show any statistically significant differences between the groups and the number of revisions was small, so these findings must be interpreted with caution.

Table 2. Cox regression analysis

Annual hospital volume	No. of UKAs	No. of revisions	10-year survival <sup>a</sup> (95% CI)	Cox Regression Analyses			
				Unadjusted RR <sup>b</sup>	p-value	Adjusted RR <sup>c</sup>	p-value
< 10 procedures	964	147	78 (74–81)	1		1	
11–20 procedures	1,542	176	83 (81–86)	0.77 (0.62–0.96)	0.02	0.83 (0.66–1.03)	0.09
21–40 procedures	1,633	165	82 (79–85)	0.78 (0.62–0.97)	0.03	0.85 (0.68–1.06)	0.1
> 41 procedures	321	26	<sup>d</sup>	0.53 (0.35–0.81)	0.003	0.59 (0.39–0.90)	0.01
p-value for linear trend					0.002		0.02

<sup>a</sup> Kaplan-Meier estimated cumulative survival at 10 years (%)

<sup>b</sup> RR: risk ratio with the 95% CI in parentheses.

<sup>c</sup> Estimated risk ratio with adjustment for age, sex, and diagnosis with the 95% CI in parentheses.

<sup>d</sup> Last revision at 7.6 years (survival of 89, CI: 85–93).

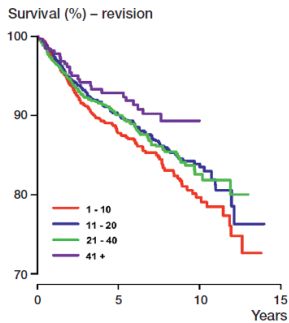


Figure 3. Cox-adjusted survival curve for cemented unicompartmental knee arthroplasty in Norway from 1999 to 2012, with revision for any reason as endpoint. The results of Cox regression analysis were adjusted for age, sex, and diagnosis. The results are shown for the 4 different hospital volume groups described in the text.

## Discussion

### Summary

This registry-based study confirmed that the risk of revision was significantly higher for hospitals performing less than 10 Oxford III UKA procedures a year than for those performing more than 40 Oxford III UKA procedures a year in Norway between 1999 and 2012.

### Comparison to other studies

The New Zealand Joint Registry reports are consistent with our study, indicating that the UKA procedure is volume-dependent (NZJR 2014). Robertsson et al. (2001) also related increased risk of revision to the number performed by the unit (more or less than 23 per year), and concluded that the

Oxford implant was more influenced by hospital volume than other commonly used brands. Baker et al. (2013) from the National Joint Registry of England and Wales (the NJR) recently reported that the risk of revision decreased as both center volume and surgeon volume increased for the Oxford implant most commonly used in England and Wales. Their study suggested a minimum annual procedure volume of 13—both regarding hospital volume and surgeon volume.

Some authors have suggested a lower threshold to revise a painful UKA to a TKA, claiming that revision rate is not an objective measurement for this particular implant (Goodfellow et al. 2010). A study from the NJR of England and Wales opposed this claim, suggesting a higher risk of revision for reasons other than pain compared to the TKA (Baker et al. 2012). This is supported by the study by Furnes et al. (2007).

Registry studies, as opposed to clinical studies, include all surgeons and all hospitals in the country. According to various registry reports, the average surgeon fails to achieve comparable results to those of surgeons in clinical studies conducted by inventor hospitals (Labek et al. 2011). This can be explained by factors such as lower surgical expertise regarding this particular procedure and implant.

UKA volume studies from the Swedish Knee Arthroplasty Register by Robertsson et al. (2001) and from the NJR of England and Wales by Baker et al. (2013) defined hospital procedure volume as the mean procedure volume for the hospital in a given period of time. We decided to measure hospital volume in a different way. The number of UKAs performed in each hospital each year was counted, and we compared the results for the annual hospital procedure volume groups accordingly. 36 of the 51 hospitals changed volume group during the study period. The advantage of this method of analysis is that if a hospital for 1 or more years belongs to the lowest-volume group, it actually reflects the rarity of the procedure that particular year. Less than 10 procedures a year means less than 1

Table 3. Reasons for revision <sup>a</sup>

	1–10	11–20	21–40	> 40	Pearson <sup>b</sup> p-value	Log-rank <sup>c</sup> p-value
No. of revisions	147	176	165	26		
Cause of revision, n (%)						
Infection (n = 20)	3 (2.0)	7 (4.0)	9 (5.5)	1 (3.8)	0.5	0.8
Loosening, PE wear (n = 178)	51 (35)	64 (36)	54 (33)	9 (35)	0.9	0.2
Dislocation, instability, malalignment, fracture (n = 89)	23 (16)	30 (17)	34 (21)	2 (7.7)	0.4	0.2
Progression OA (n = 62)	18 (12)	20 (11)	22 (13)	2 (7.7)	0.9	0.5
Pain only (n = 126)	40 (27)	40 (23)	35 (21)	11 (42)	0.1	0.1
Other (n = 39)	12 (8.2)	15 (8.5)	11 (6.7)	1 (3.8)	0.8	0.4

<sup>a</sup> 514 revisions with medial Oxford III UKA; distribution of reasons for revision by hospital volume groups. The reasons for revision are hierarchical from top to bottom. When more than one reason was reported, the top reason in the hierarchy was used as endpoint in the analyses. Pain as a cause of revision was used as endpoint in analyses and is shown in the table only when pain was the only reason reported.

<sup>b</sup> Pearson chi-square test of independence, p-value.

<sup>c</sup> Log-rank test to compare the survival distributions, p-value.

PE: polyethylene; OA: osteoarthritis.

procedure a month, and according to the authors' experience, even if a surgeon has had a reasonable surgery volume during previous years, continuous training in a technically demanding procedure is essential to achieve reproducible results. One could argue the opposite way, that mean volume over the whole time period is a more reliable method: if hospital A suddenly reduces its annual procedure volume to less than 10 but in the preceding 5 years has had a high annual procedure volume of > 40, it knows the procedure so well that one year with a low volume will not have an impact on the results.

### Strengths and limitations

One limitation of the present study was the lack of information on surgeon procedure volume, and there was no information regarding the correct/incorrect indication for the subsequent revisions and primary procedure. However, we know that surgeon procedure volume is generally low, and this could influence the hospital results.

Baker et al. (2013) investigated the surgeon volume in addition to the hospital volume, and suggested that surgeon volume was more important than hospital volume. We agree that this is probably a correct appraisal. In 2010, we sent a request to all 43 units performing UKA in Norway to manually count the surgeon volume for 2 specific years. We received an answer from 39 of the departments, and the enquiry suggested that the overall surgeon volume was low, even in the highest-volume hospitals. Thus, the distribution of low-volume surgeons was considered to be relatively equal in all the groups. This is, however, a limitation of the study, and makes interpretation of hospital volume difficult. Hospitals with a high procedure volume cannot guarantee their patients excellent results if they only provide low-volume surgeons.

### Explanations and mechanisms

There has been no overall improvement in UKA implant survival over time in Norway, in contrast to total knee arthroplasty (NAR 2013).

The total number of UKA procedures has not changed in the last 10 years in the NAR (447 UKAs in 2004 as opposed to 458 UKAs in 2013); it has not increased like the TKA procedure (Badawy et al. 2013). However, some hospitals have increased their annual procedure volume over the last 10 years (Figure 2).

Patient selection and indication for surgery are important factors that contribute to better results with the UKA procedure. In addition, standardization and procedure of care is important. The learning curve and improved surgical techniques are also probable reasons for better outcome. All these factors are possible explanations for better results in high-volume centers.

We found that a high hospital procedure volume was beneficial for survival of the Oxford III UKA implant. Analysis of the reasons for revision indicated that there was a higher number of dislocations, more instability, more malalignment, and a

greater number of fractures in the lower-volume groups support the statement regarding the Oxford III, as a possibly technically demanding implant. However, the numbers of revisions in each group were too small to allow us to make any conclusions regarding the differences between the groups. Whether or not this applies to all UKA brands remains to be investigated in registries that have other brands in sufficient volumes.

### Possible implications and future research

There is concern about the consistently inferior implant survival rates for the UKA compared to the TKA in the worldwide arthroplasty registries. The proportion of revisions and the reasons for failure must be addressed and investigated further. The UKA implants require thorough surgical technique, correct patient selection, and correct indication for surgery in addition to strict indications for revision. This can only be achieved through centralization of the procedure. The NAR has encouraged surgeons through the annual reports to limit this procedure to a few dedicated surgeons in as few hospitals as possible, to achieve revision risk that is comparable with that of the TKA procedure.

MB: study design, data collection, and drafting of manuscript. BE: data acquisition, data analysis, and revision of manuscript. KI: revision of manuscript. LIH: data collection and revision of manuscript. OF: study design, collection and interpretation of data, statistics, and revision of manuscript.

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