

#### ANNA-KATRIINA HIMANEN

# AGC Endoprosthesis in Total Knee Arthroplasty of Patients with Rheumatic Diseases and Arthrosis

#### ACADEMIC DISSERTATION

To be presented, with the permission of the Faculty of Medicine of the University of Tampere, for public discussion in the Jarmo Visakorpi Auditorium, of the Arvo Building, Lääkärinkatu 1, Tampere, on December 19th, 2009, at 12 o'clock.

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## **ABSTRACT**

The aim of this study was to analyse the results of primary total knee arthroplasty (TKA) in patients with rheumatoid arthritis (RA). The main data consisted of 751 knees of 586 patients of the Rheumatism Foundation Hospital (RFH) operated on during the period 1985 and 1995 (original Reports II and III). Anatomically Graduated Components (AGC) knee endoprosthesis was used during the study period at RFH. The survival of AGC prosthesis on national level was analysed using the Finnish Arthroplasty Register of National Agency for Medicines (original Report I) database. One study was made of aspects of demanding primary and revision surgery of patients with rheumatic diseases (original Report IV). The survival of the prosthesis was used as the most important indicator of results of the TKAs.

The first study (I) presented the results of the survival of AGC knee endoprostheses in Finland 1985-1999. There were two patient groups, RA and osteoarthrosis (OA) for comparison. In the RA group the 5-year survival rate was 96.9% and 10 years 95.5, in the OA group the respective percentages were 96.4 and 94.1. Sex and age appeared to be significant determinants for the prosthetic survivorship. Both among RA and OA patient groups men had a higher cumulative revision rate than women, and 10-year survival rates were significantly better in older patients.

The survival of two different tibial components used in RFH during the study period 1985-1995 was analysed in the second study (II). Of 751 TKAs, a total of 256 tibial components were of the moulded design and 495 of the modular design. The mean follow-up of the moulded subgroup was 9.6 years, and that of the modular group 7.0 years. The groups compared differed significantly in Larsen grade, cementing of components and patellar resurfacing, but no statistically significant difference in survival was found. Survival rates for both components were good: the cumulative success rate of the moulded group was 96.8% at five years and 94.4% at ten years, and of the modular group 96.2% and 93.6% respectively.

The material of the third study (III) was a smaller subgroup of the data of the second study. Survival of unresurfaced (n=82 knees) and resurfaced patella (n=152) in 234 TKAs of 224 patients with RA was analysed. Radiological and clinical outcome as well as Kaplan-Meier survival was studied. The cumulative success rate of the unresurfaced group was 92.8% at 10 years and of the metal-backed patella group 92.0% respectively (probability value=not significant, p=NS). Patellar resurfacing yielded slightly more favourable results with respect to anterior knee pain.

In the fourth study (IV) of this dissertation four primary and 21 revision TKAs made with Dual Articular Knee prosthesis in RFH during 1992-1999 were analysed. There were 25 knees in 24 patients, among whom 20 patients had RA. In all cases there was a demanding preoperative situation with bone defects, instability or fixed deformity. In follow-up examination no progression of radiolucent lines was observed, and no instability was noticed. Complications were related to the extensor mechanism, with four patellar tendon ruptures. Subjective satisfaction was excellent in 18 cases, and no patients reported of severe pain. The prosthesis proved to be suitable for bone grafting and also for bone packing.

In conclusion, despite challenging pre- and peroperative situations, knee arthroplasties of rheumatoid arthritis patients with AGC prosthesis yielded good results as measured in prosthesis survival both in a sample of RFH patient material and in national wide scale.

## TIIVISTELMÄ

Tutkimuksessa analysoitiin primaarien polvitekonivelleikkausten tuloksia nivelreumaa sairastavilla potilailla. Tutkimuksen pääaineisto koostui Reumasäätiön sairaalassa (RSS) vuosina 1985-1995 tehdyistä 751 polven tekonivelen asennuksesta 585 potilaalla (osatyöt II ja III). Anatomically Graduated Components (AGC) polven tekonivel oli tutkimusajankohtana käytössä RSS:ssa. AGC tekonivelen kansallisen survivalia (pysyvyyttä) tutkittiin käyttämällä Lääkelaitoksen ylläpitämän Endoproteesirekisterin tietokantoja (osatyö I). Osatyössä IV tarkasteltiin lisäksi vaativia ensi- ja uusintaleikkauksia reumasairauksia sairastavien potilaitten hoidossa. Proteesin pysyvyyttä käytettiin tärkeimpänä tulosmittarina.

AGC Ensimmäisessä osatyössä (I) tarkasteltiin tekonivelen pysyvyystuloksia Suomessa aikavälillä 1985-1999. Aineistossa verrattiin kahta potilasryhmää, nivelreumaa ja nivelrikkoa sairastavia. Nivelreumaa sairastavien ryhmässä tekonivelen pysyvyysluku oli viiden vuoden kohdalla 96.9 prosenttia, ja kymmenen vuoden vastaava luku 95.5 prosenttia. Nivelrikkoa sairastavilla vastaavat luvut olivat 96.4 ja 94.1. Ikä ja sukupuoli olivat merkittäviä tekijöitä tekonivelen pysyvyydessä. Sekä nivelreumaa että nivelrikkoa sairastavien potilaitten ryhmissä miehien kumulatiiviset tekonivelten uusintaleikkausmäärät olivat suuremmat kuin naisilla, ja kymmenen vuoden pysyvyysluvut olivat tilastollisesti merkitsevästi paremmat vanhemmilla potilailla.

Ajanjaksolla 1985-1995 RSS:ssa oli käytössä kaksi erilaista tekonivelen säärikomponentin mallia. Näiden pysyvyyttä verrattiin toisiinsa II osatyössä. Yhtenäiseksi valettua säärikomponenttia oli käytetty 256 polvileikkauksessa ja modulaarista säärikomponenttia 495 leikkauksessa. Valetun komponentin ryhmässä seurannan keskiarvo oli 9.6 vuotta, ja modulaarisen säärikomponentin ryhmässä 7.0 vuotta. Vertailtavat ryhmät erosivat toisistaan tilastollisesti merkitsevästi komponenttien sementoinnin, nivelen tuhoutumisen vaikeusasteen (Larsen) ja polvilumpion pinnoittamisen suhteen, mutta tilastollisesti merkitsevää eroa ryhmien pysyvyyslukujen välillä ei havaittu.

Pysyvyysluvut kummankin komponentin ryhmässä olivat hyvät: kumulatiivinen pysyvyysprosentti oli valetun säärikomponentin ryhmässä 96.8% viiden vuoden kohdalla ja 94.4% kymmenen vuoden kohdalla, modulaarisessa ryhmässä vastaavasti 96.2% ja 93.6%.

Kolmas osatutkimus (III) koostui osasta II työn aineistoa, 224 potilaan 234 polvitekonivelleikkauksesta. nivelreumaa sairastavan Työssä analysoitiin polvilumpion pinnoittamisen merkitystä tekonivelen pysyvyyteen. Pinnoittamattomien polvilumpioiden ryhmässä oli 82 polvea, ja metallipohjaisella patellakomponentilla pinnoitettujen polvien ryhmässä oli 152 polvea. Kaplan-Meier –menetelmällä arvioidun pysyvyystuloksen lisäksi tarkasteltavana olivat myös radiologiset ja kliiniset tulokset. Kumulatiivinen pysyvyysprosentti oli kymmenen vuoden kohdalla pinnoittamattoman polvilumpion ryhmässä 92.8% ja vastaavasti pinnoitetun patellan ryhmässä 92.0%. Ryhmien välinen ero ei ollut tilastollisesti merkitsevä. Pinnoitetun polvilumpion ryhmässä tulokset olivat kuitenkin hieman paremmat polven etuosan kivun suhteen.

Neljännessä osatyössä (IV) analysoitiin RSS:ssa vuosina 1992-1999 Dual Articular Knee –proteesilla tehtyjen neljän primaarileikkauksen ja 21 revisioleikkauksen tuloksia. Nivelreumaa sairastavia potilaita oli 20. Kaikissa tapauksissa preoperatiivinen tilanne oli vaativa mm. instabiliuden, luupuutosten tai deformiteettien vuoksi. Seurannassa ei havaittu tekonivelen irtoamiseen viittaavaa kirkastumalinjojen etenemistä tai instabiliutta. Komplikaatiot liittyivät polven ojentajamekanismiin, ja neljässä tapauksessa todettiin patellajänteen repeämä. Valtaosa potilasta (18) oli erittäin tyytyväinen tulokseen, eikä yksikään potilas ilmoittanut vaikeaa kipua. Dual Articular Knee osoittautui käyttökelpoiseksi kun tarvittiin luun siirteitä tai luunpakkausmenetelmää vaihtoleikkauksessa.

Huolimatta pitkäaikaisen reumasairauden mukanaan tuomista erityishaasteista polven tekonivelleikkauksissa, osoittautui AGC-proteesin pysyvyys hyväksi sekä RSS:n potilasaineistossa että valtakunnallisessa rekisteriaineistossa.

## **ABBREVIATIONS**

ACL anterior cruciate ligament

AGC Anatomically Graduated Components
AIMS Arthritis Impact Measurement Scales

CAS computer assisted surgery
CCK Constrained Condylar Knee

CI confidence interval CRP C-reactive protein

DA Dual Articular

DMARD disease-modifying antirheumatic drug

EULAR European League Against Rheumatism

GEE generalising estimating equations
HAQ Health Assessment Questionnaire
ICLH Imperial College/London Hospital

KSS Knee Society Score

LCL lateral collateral ligament

LPD lateral patellar displacement

MCL medial collateral ligament

MIS minimally invasive surgery

MRI magnetic resonance imaging

NS not significant

NSAID non-steroidal anti-inflammatory drug

OA osteoarthrosis probability value

PCL posterior cruciate ligament

PS posterior stabilised RA rheumatoid arthritis

RCT randomised controlled trial

RFH Rheumatism Foundation Hospital

 $\mathsf{RHK}^{\mathsf{TM}} \qquad \mathsf{Rotating\text{-}Hinge}\;\mathsf{Knee}^{\;\mathsf{trade}\;\mathsf{mark}}$ 

RSS Reumasäätiön sairaala

SD standard deviation

TKA total knee arthroplasty
TNF tumour necrosis factor

TNF-α tumour necrosis factor alfa

VAS visual analogue scale

## LIST OF ORIGINAL PUBLICATIONS

This thesis is based on the following original communications, referred to the text by Roman numerals I-IV:

- Himanen A-K, Belt E, Nevalainen J, Hämäläinen M and Lehto MUK: Survival of the AGC total knee arthroplasty is similar for arthrosis and rheumatoid arthritis. Acta Orthop 2005; 76:85-88.
- Himanen A-K, Belt EA, Lehto MUK and Hämäläinen MMJ: A comparison of survival of moulded monoblock and modular tibial component of 751 AGC total knee replacements in the treatment of rheumatoid arthritis. J Bone Joint Surg Br 2007; 89-B:609-614.
- III Himanen A-K, Belt EA, Kautiainen H, Lehto M and Hämäläinen MMJ: Patellar resurfacing had no influence on the survival of TKA in rheumatoid arthritis. Submitted.
- IV Himanen A-K, Mäenpää HM, Lehto MUK, Hämäläinen MMJ and Belt EA: Dual Articular Knee in demanding primary and revision replacements in patients with rheumatic diseases. Int Orthop 2002; 26:92-97.

## 1. INTRODUCTION

Rheumatoid arthritis (RA) is a chronic systemic autoimmune disease. The aetiology of RA is unknown. RA involves joints and extra-articular sites. Many factors, like environmental triggers and genes, have been thought to be implicated in the onset of the disease (Klareskog et al. 2004, Firestein 2005.)

Studies of prevalence and incidence of RA show slightly different outcomes depending on population, time period and the definition of RA. The prevalence of RA in the adult population has been estimated to vary 0.5-1.0% in Western countries (Kvien 2004). In a study of a population based cohort of subjects in Finland, prevalence was estimated to be 0.8% (Hakala et al. 1993a). Annual age-adjusted incidence of RA in Finland was 32/100 000 in 1995 and in 1990, and incidence has declined by 14% from 1980 and 1985 (Kaipiainen-Seppänen and Aho 2000). The typical onset of RA is now found in older age groups. The mean age at diagnosis was 59 years in 1995, and it has risen by 8.8 years from 1975. (Kaipiainen –Seppänen et al. 1996, Kaipiainen-Seppänen and Aho 2000).

The purpose of treatment is to achieve remission of RA and to minimise the consequences of the systemic and chronic disease. In order to maintain daily functional ability in patients with RA, the treatment should be started proactively from the very start of the disease aiming at early remission (Puolakka et al. 2005). Together with antirheumatic treatment, attention should be paid to preventing osteoporosis in RA patients (Deodhar and Woolf 1996).

Medical treatment of RA has improved remarkably in recent decades. Conventional drugs like glucocorticoids are still in use, but disease-modifying antirheumatic drugs (DMARDs) and biological agents like inhibitors of tumour-necrosis factor  $\alpha$  (TNF- $\alpha$ ), and the possibilities of combination pharmacotherapy have led to promising results (Möttönen et al. 1999, Combe et al. 2007).

RA demands effective co-operation between patient and the health-care system, and also between all professionals in the care chain (Sculco 1998). Rehabilitation, for instance physical therapy and different modes of psychosocial support, is also crucial to maintain the quality of functioning of the patient – including working ability (American College of Rheumatology Subcommittee on Rheumatoid Arthritis Guidelines 2002, Combe et al. 2007).

RA often begins in the small joints of the hands and feet (Belt 1998), but especially in the progression of the disease, large joints like hip and knee may be involved (Scott et al. 1986, Isacson et al. 1988, Lehtimäki et al. 1998). In the treatment of severe knee joint destruction total knee arthroplasty (TKA) is needed, if pain or deformities of the knee threaten patient's coping with daily activities. The prevalence of knee and hip joint replacements increased 2 to 10-fold in patients without RA, but not in patients with RA between 1986 and 2003 in central Finland (Sokka et al. 2007).

On a nationwide scale the number of primary TKAs of patients with RA increased during the period 1980-1999, and remained almost constant in the 2000's; in 2004 there were 65 TKAs performed on men and and 330 on women. The number of knee rearthroplasties has increased over time in Finland as the number of primary TKAs has increased: In 2004 there were 582 revision TKAs, whereas in 1980 there were 27 registered revisions (Rantanen et al. 2006.)

Knee arthroplasty in patients with RA is challenging because of medical, anaesthetic and global musculoskeletal problems. Bone quality can also be expected to be suboptimal. Bone may be replaced by inflammatory granulation tissue, the integrity of subchondral bone may be affected by osteopenia, and cyst formation is more frequent in patients with RA than with osteoarthrosis (OA) (Chmell and Scott 1999.)

The aim of the present study was to analyse the outcome of knee arthroplasty in patients with RA treated with Anatomically Graduated Components (AGC) knee prosthesis.

## 2. REVIEW OF THE LITERATURE

## 2.1. Rheumatoid Arthritis (RA)

#### 2.1.1. Aetiology and pathogenesis of RA

RA begins long before physical signs and symptoms can be noticed, and the aetiology of the disease is multifactorial, including genetic risk and environmental factors (Majka and Holers 2003). Cascade of cellular and immunological mechanisms of the inflammatory process in RA is responsible for tissue alterations. Different mediators of inflammation, cytokines, like tumour necrosis factor (TNF), as well as growth factors, chemokines, adhesion molecules and matrix metalloproteinases appear to be involved in the pathogenesis of RA (Cooke and Scudamore 1989a, Cooke and Scudamore 1989b, Harris 1990, Roberts and McColl 2004, Khurana and Berney 2005).

Immune cells are activated, and mediators also play a part in the activation, proliferation and transformation of the synoviocytes to form active pannus. Pannus is like a local invasive tumour, which invades and erodes articular cartilage, subchondral bone, tendons and ligaments. Rheumatoid synovial cells have a highly destructive potential (Harris 1990, Khurana and Berney 2005.)

#### 2.1.2. Diagnosis and assessment of RA

There is no single RA-specific test or a clinical sign for diagnostic purposes. Widely accepted classification of RA is based on the American College of Rheumatology criteria formulated in 1987. There are seven criteria, of which four have to be present. Morning stiffness, arthritis of three or more joint areas, arthritis in the area of the hand joints, and symmetric arthritis should be present for at least six weeks. Rheumatoid nodules, serum rheumatoid factor and radiographic changes typical for RA, i.e. particular osteoporosis and erosions are the other criteria (Arnett et al. 1988.)

Rheumatoid factor-positive RA has mostly been connected to destructive disease (Kaarela et al. 1993). In the evolution of the disease symmetric articular manifestations occur, mostly beginning in the small peripheral joint as stiffness, swelling and tenderness (Belt et al. 1998). Multiple joints and synovial sheets of tendons may be affected during the progression of RA, and the disease may manifest in other organs like skin, eyes, lungs etc (Turesson et al. 2002, Turesson et al. 2003).

In the diagnostic phase and also in monitoring the treatment the number of swollen joints should be measured as well as the level of markers of systemic inflammation and radiographic erosions (Combe et al. 2007.) C-reactive protein (CRP) and erythrocyte sedimentation rate are widely used to indicate the severity of general inflammation in RA and can be connected to functional outcome (Smedstad et al. 1996, Devlin et al. 1997).

Imaging is a significant tool in the diagnosis and in monitoring of RA. At the early stage of RA, alterations of the joints can be seen in radiographs as tissue swelling and periarticular osteoporosis, and in later stages large osseous erosions and complete obliteration of the articular space can be noticed (Resnick and Kransdorf 2005). In order to describe

and to analyse the progression of RA, radiologic scoring systems have been developed. Widely used radiologic scoring methods are the Sharp and the Larsen methods, which are used to quantify the joint damage (Sharp et al. 1971, Larsen et al. 1977) based on plain radiographs. These scoring systems can be used to analyse the differences between changes over time within one patient or groups of patients (Scott et. al 1986, Bruynesteyn et al. 2004).

Imaging techniques, like ultrasound and magnetic resonance imaging (MRI) can be used in the early phases of disease to show synovitis and small erosions (Farrant et al. 2007). In later phases of RA after arthroplasties, metal implants interfere with the quality of MRI scans. Therefore triple-phase bone scintigraphy can be used in the differential diagnosis as a tool for the detection of periprosthetic infection (Nagoya et al. 2008).

Patient's symptoms and ability to perform activities must be evaluated in a standardized way by self-administered questionnaires during the process of the disease. The Stanford Health Assessment Questionnaire (HAQ) (Fries et al. 1980) and Arthritis Impact Measurement Scales (AIMS) (Meenan et al. 1980) are widely used. Self-reported functional ability assessed by the questionnaires among Finnish RA patients correlates well with physical impairment (Hakala et al. 1993b). The visual analogue scale (VAS) can also be used to evaluate pain and subjective satisfaction after surgical procedures (Bullens et al. 2001).

#### 2.1.3. Conservative treatment of RA

The European League Against Rheumatism (EULAR) sums up recommendations based on recent studies of treatment of RA. Joint erosions occur early in RA, and a "window of opportunity" for effective treatment has been highlighted. Patients at risk of developing persistent and/or erosive arthritis should be started on DMARDs as early as

possible, and the main goal of DMARD treatment is to achieve remission. For reducing pain and swelling of the joints non-steroidal anti-inflammatory drugs (NSAIDs) and intra-articular glucocorticoid injections can be used. Regular monitoring of the activity of RA is essential in choosing and changing treatment strategy (Combe et al. 2007.)

Among the DMARDs, methotrexate is often considered the anchor drug, and systemic glucocorticoids can be considered as an adjunct to the DMARD system. In the early and aggressive treatment of RA, combination therapy of DMARDs (see Möttönen et al. 1999) seems to increase the efficacy of the treatment compared to that of single-drug treatment. However, doubts about the superior efficacy of combination therapy have also been expressed (Smolen et al. 2005).

New drugs called biological agents have been available in Finland since 1999, when infliximab entered the market. Nowadays etanercept, adalimumab and anakinra have also been added to the list of anti-TNF agents. These drugs are used mostly in such cases of RA in which achieving remission has not been successful with DMARDs and glucocorticoids. One problem of anti-TNF agents is the high price of the treatment (Koski-Pirilä 2007.)

Intra-articular glucocorticoid injections are nowadays a widely used form of local treatment of RA, and they have been used since the 1950's (Hollander et al. 1951). Although the effectiveness of glucocorticoids in relieving the symptoms of a joint has been seen for decades, the importance e.g. of a clinical routine of a postinjection rest has been questioned. In randomized controlled trial (RCT) it was noticed that a 24-hour rest after an intra-articular injection of a knee joint might result in prolonged clinical response duration (Chakravarty et al. 1994). In another RCT intra-articular glucocorticoid treatment of knee synovitis was observed to reduce cartilage breakdown, and when postinjection immobilisation of 24 hours was used, the reduction was even more pronounced (Weitoft et al. 2005).

Radiation synovectomy can also be performed. It is undertaken by injecting the appropriate carrier-labeled radioisotope into the diseased joint. Yttrium silicate is the most commonly used agent (Vuorela et al. 2003). In an RCT where efficacy between radiation synovectomy combined with glucocorticoids and glucocorticoids alone was compared, the patients with marked synovial inflammation benefited from intra-articular treatment, and no significant difference between treatments was found (Jahangier et al. 2006). In a meta-analysis the method showed better results in RA than in OA (Kresnik et al. 2002).

## 2.2. Knee joint in RA

#### 2.2.1. Anatomy and biomechanics of the knee joint

The knee joint is the largest human joint. The stability of the normal knee joint is a result of a complex interaction of the joint surfaces, ligaments and muscles. It comprises two joints, the patellofemoral and tibiofemoral joints. Knee stability is achieved by four major ligaments, the anterior and posterior cruciate ligament (ACL and PCL) as well as medial and lateral collateral ligaments (MCL and LCL). The quadriceps muscle is the main extensor of the knee, and the hamstrings are the main flexors. In extension tensor fascia lata stabilises the knee in the lateral side and at the end of extension. In flexion the gastrocnemius, sartorius and gracilis muscles contribute to stability. Medial rotation of the knee in flexion is controlled by the medial hamstrings, popliteus, sartorius and gracilis. The biceps femoris controls lateral rotation. Tendons, ligaments, capsular structures and bursae also take part in strengthening and smooth movement of a knee (Fairclough and Graham 2003.)

In the arthritic knee the musculature is often weak, but the MCL, LCL and the PCL are usually mostly intact. The condition of PCL especially is important because it stabilises the knee in both active and passive states (Sledge and Walker 1984.) However, the condition of posterior cruciate ligament has also been reported to be markedly weakened in RA compared to OA (Hagena et al. 1989), leading to a high rate of posterior instability and recurvatum deformity in a knee after knee replacement (Laskin and O´Flynn 1997).

The biomechanics of the patellofemoral mechanism is complicated. The contact point of the patellar fulcrum shifts constantly during flexion of the knee. The patellofemoral contact stress also differs, and the maximum contact pressure is achieved at 80-90° flexion. Situations like mediolateral patellar malpositioning due to lateral retinacular tightness or insufficiency of the medial retinacular and muscular structures cause increased contact stress. It may predispose towards rapid cartilage degeneration and pain. In the treatment of a patient with knee problems, restoration of patellofemoral balance is essential (Bellemans 2003, Frankel 2003.)

## 2.2.2. Examination of the knee joint

Proper physical examination is essential in estimating the problems of the knee joint, in both pre- and in postoperative phases. In a review article on the physical examination of the knee (Malanga et al. 2003) multiple tests in knee examination are presented. The importance of an original description or agreed standards for each test is emphasised. For the evaluation of ACL the Lachman test seems to be very sensitive and highly specific, and for PCL tears the posterior drawer test as well. Common tests for patellofemoral pain (grinding test and patellofemoral compression test) lack sensitivity when correlated with pathologic operative findings (Malanga et al. 2003.)

Special rating systems have been developed to evaluate the clinical success of TKA postoperatively. One of the most used is the knee rating system of the Knee Society, Knee Society Score (KSS). In the KSS range of motion as well as stability of the knee is evaluated. The final score is reduced if flexion contracture, extension lag or alterations of ideal alignment occur. The functional score in daily activities is also analysed. With Unlimited walking ability and normal stair climbing full points are gained. Using canes, crutches or a walker causes deductions from the final score. Pain is also evaluated and included in the score (Insall et al. 1989, Crockarell and Guyton 2007.)

The assessment forms by EULAR have been used in pre- per- and postoperative clinical studies in the Rheumatism Foundation Hospital (RFH) (Hämäläinen 1985). The EULAR knee assessment chart includes the same information as the KSS, but also general information on disease history, medication and general locomotor status. The EULAR assessment also includes radiologic evaluation, which is not as detailed as in the Knee Society TKA roentgenographic analyses and scoring system (Ewald 1989). The results of arthroplasty surgery are usually estimated radiologically, mainly by observing radiolucencies adjacent to the prosthetic components and alterations in component positioning. Usually the contours of femoral, tibial and patellar components are divided into zones to localise possible radiolucencies (Ewald 1989).

## 2.2.3. Manifestations of RA in the knee joint

In the progression of RA different joint groups are involved. Metatarsophalangeal (Belt 1998) and hallux interphalangeal joints are examples of early involvement. Larger joints, like knees, are more often damaged in the later course of RA, or at least remain asymptomatic longer than smaller joints (Harris 2005). The knee joint is frequently damaged in progressive RA, and knee symptoms can be the greatest hindrance to walking (Scott et al. 1986, Isacson et al. 1988). It has been

estimated that the knee joint is affected in nearly 90% of patients with long-standing RA (Fleming et al. 1976).

At the beginning of RA, involvement of the knee joint may be joint swelling without cartilage damage. In the progression of RA, chronic proliferative synovitis can lead to mechanical dysfunction of the knee and chronic pain. The cartilage may be destroyed, and subchondral bone will be also damaged by pannus-like granulation tissue and activated osteoclasts (Sculco 1998, Okada 2005.)

Bone loss leads to progressive joint deformity, which also includes the soft tissues. Especially valgus deformity with or without flexion contracture is typical to RA patients (Sculco 1998, Chmell and Scott 1999). Restriction of mobility, ligamentous laxity and quadriceps atrophy are frequently observed (Khurana and Berney 2005), and extreme weakness of the cancellous bone poses challenges for the surgeon (Sledge and Walker 1984).

Often within a week of the onset of symptoms, quadriceps atrophy is already noticeable. Muscle weakness leads to the application of more force than usual through the patella to the femoral bone surface. Loss of full extension is one of the early manifestations of the knee being affected. Flexion of the knee with large effusion increases the intra-articular pressure, which may lead to outpouching of posterior components of the knee joint called popliteal or Baker's cyst (Harris 2005.)

## 2.3. Surgical treatment of the knee in RA and in OA

In progressive RA multiple joints may be severely affected, and surgical treatment has to be considered to minimise pain and to improve function. Buckwalter et al. (2003) sums up the current surgical procedures for the treatment of patients with RA. Tenosynovectomy and joint synovectomy can be used to reduce pain as well as joint fusion and joint replacement. Tendon, ligament and joint capsule reconstruction can improve joint stability and alignment. Peripheral nerve decompression as well as spinal cord and nerve decompression may be needed (Buckwalter et al. 2003.)

Total joint arthroplasty can be said to represent the failure of medical treatment, and the rate at which operations are performed is a measure of RA progression. In a 25-year follow-up study of a cohort of 103 RA patients, large joint replacement was needed in 27% of patients, and 41% of them needed more than one replacement (Palm et al. 2002). In a 23-year prospective, longitudinal study by Wolfe and Zwillich (1998) it was estimated that 25% of RA patients will undergo total joint arthroplasty within 21.8 years of disease onset. Over a mean disease duration of 15.9 years total joint arthroplasty was performed on nearly 18% of 1 600 patients. TKA accounted for 57% of total joint arthroplasties and total hip arthroplasties accounted for 34% of the operations (Wolfe and Zwillich 1998.)

## 2.3.1. Characteristics of surgery in the treatment of RA

Compared to general population, patients with RA have an increased risk of many surgical complications. RA has been estimated to be a risk factor for prosthetic joint infections (Maderazo et al. 1988, Blackburn and

Alarcón 1991, Luessenhop et al. 1996, Jämsen et al. 2009). Particularly knee operations have been historically reported to be associated with higher incidence of postoperative infection compared to other locations of surgery among patients with RA (Hämäläinen et al. 1984). However, in a more recent study, TKA patients with RA were reported to have lower risk of prosthetic joint infections than total hip arthroplasty patients (Bongartz et al. 2008).

Long-term use of corticosteroid therapy has been reported to be a risk for postoperative wound healing (Garner et al. 1973). Treatment with biological agents has been reported to cause more skin and soft tissue infections than DMARD treatment, suggesting an important physiological role of TNF in host defence (Dixon et al. 2006). The type of antirheumatic medication used in 1975-1978 (corticosteroids, gold, penicillamine, antimalarial drugs, cytotoxic agents) has been reported to have no influence on the incidence of postoperative infections (Hämäläinen et al. 1984).

Besides skin problems, overall immunologic alterations of patients with RA may cause problems. Patients with RA are at increased risk of developing infections (Doran et al. 2002). They even have higher mortality because of infections compared to the general population (Myllykangas-Luosujärvi et al. 1995, Sihvonen et al. 2004). Skin and blood vessels as well as bone quality require extreme caution in the physical handling of RA patients to avoid skin ulcerations, haematomas and fractures postoperatively (Buckwalter et al. 2003). Patients with multiple joint involvements, as in RA, may require bilateral joint replacement sequentially or simultaneously or they may need treatment of the upper extremity before surgery of the lower extremity to enable effective rehabilitation (Chmell and Scott 1999, Buckwalter et al. 2003).

#### 2.3.2. Synovectomy and arthodesis of the knee

In the early phases of joint destruction, synovectomy, in which the chronically inflamed synovial membrane of a knee joint is removed, has sometimes been used in order to delay the progression of destruction and deformation (Jensen et al. 1991). In RA synovitis occurs in the whole intra-articular area, which imposes demands on the skills of the surgeon (Kim et al. 2006). Open synovectomy of the knee has been the traditional procedure in treating RA patients, today replaced by arthroscopic synovectomy. Open synovectomy usually requires extensive knee joint debriment, and the recovery tends to be slow (Sculco 1998.)

Although the validity of synovectomy has also been questioned (Doets et al. 1989), in most studies the results of synovectomies have been encouraging, at least in the short term. Before the development of modern medical treatment of RA, synovectomy was often used, and good long-term results were reported (Brattström et al. 1985). Synovectomy can at least reduce pain, and swelling of knee in RA (Ogilvie-Harris and Basinski 1991), but the question of the effects on the destructive process in cartilage remains open. Synovectomy in the early phase of RA is indicated when medical treatment has failed, and in a later stage of RA synovectomy should be regarded as a palliative procedure in order to postpone TKA (Jensen et al. 1991).

Klug et al. (2000) studied clinical outcome of arthroscopic synovectomies of patients with early stage of RA (≤Larsen grade 2). In short term follow-up (average 33 months) there was clinical improvement, especially in patients who had received additional radiation synovectomy. Carl et al. (2005) recommend additional treatment such as radiation therapy combined with arthroscopic synovectomy in order to gain more thorough elimination of the synovitis. In their study the reduction of

inflammatory infiltrates was found to be dependent on the anatomic region of the joint. In the areas where resection of synovial tissue was incomplete, chronically inflamed synovial tissue persisted (Carl et al. 2005.)

However, in some studies even long-term results of arthroscopic synovectomies for RA have been encouraging. Gibbons et al. (2002) found out that arthroscopic synovectomy in patients with early RA (≤ Larsen grade 2) can be beneficial regarding clinical and functional outcome, although secondary degenerative changes were noticed in radiographic follow-up. In a follow-up study of open synovectomies in later cases of RA, a delay in the need for TKA was reported in nearly three-quarters of 93 knees studied (Jüsten et al. 1999).

Arthrodesis has been a treatment of choice, especially before effective TKA (Raunio 1985). Nowadays knee arthrodesis is seldom performed as a primary procedure, and the most frequent indication for knee arthrodesis is salvage surgery of a failed total knee arthroplasty (Vlasak et al. 1995, Conway et al. 2004, Pickering 2007). In knee fusion numerous techniques have been described. Both external fixation and intramedullary nailing can be used, although the latter appears to be the method of choice for most patients (Puranen et al. 1990, Wilde and Stearns 1989, Vlasak et al. 1995, Crockarell and Mihalko 2005, Panagiotopoulos et al. 2006, Bargiotas et al. 2007). However, intramedullary nailing has also been reported to carry a higher risk of recurrent infection than external fixation knee arthrodesis (Mabry et al. 2007). Despite fusion technique, knee arthrodesis following failed total knee arthroplasty in RA has been reported to have problems with persistent sepsis and bone stock losses in a study of 27 knees of which nineteen cases fused promptly (Figgie et al. 1987).

#### 2.3.3. Knee replacement surgery in RA and in OA

#### 2.3.3.1. Surgical decisions in primary knee arthroplasty

Various incisions have been used for primary TKA. The most commonly used is an anterior midline incision (Harwin 2005, Crockarell and Guyton 2007), but a subvastus approach (Hofman et al. 1991, Schutte 2005) or lateral approach (Keblish 1991, Keblish 2005) can be used. The standard retinacular incision is medial parapatellar (Crockarell and Guyton 2007). However, the target is to gain optimal access to the joint without causing too much soft tissue damage. Especially good care should be taken not to endanger patellar blood supply, because surgery may increase the risk of osteonecrosis, stress fracture and loosening, all of which are factors contributing to patellar complications in TKA (Brick and Scott 1989). In an RCT the avoidance of patellar eversion enhanced the return of quadriceps function and enabled a shorter length of stay at hospital (Walter et al. 2007).

There have been several modifications of the standard surgical technique, like mini midvastus approach (Karachalios et al. 2008, Laskin 2007). Minimally invasive surgical (MIS) techniques have received extensive attention lately (Pagnano and Meneghini 2006, Chin et al. 2007, Kolisek et al. 2007).

Accurate prosthetic alignment is essential to prevent polyethylene wear and deviation of mechanical axis of the limb (Matsuda et al. 1999). The mechanical axis of the lower limb (the line connecting the centre of the hip, knee and ankle joints) is usually referred to in TKA, and normal knee alignment corresponds to 0° of mechanical axis and femorotibial angle of 5°-7° of valgus (Insall et al. 1985). Traditionally intramedullary guides for femoral preparation and extramedullary guides for tibial preparation have been used, but computer-assisted surgery (CAS) with navigation devices has been developed to improve implant positioning

(Crockarell and Guyton 2007, Haider et al. 2007). Many recent studies recommend the use of computer navigation surgery to make sure of correct placement of the tibial and femoral components (Chin et al. 2005, Jenny et al. 2005, Ensini et al. 2006) – but doubtful comments have also been made on of the benefits of CAS (Callaghan et al. 2006).

Instability of the knee, fixed valgus or varus deformities and flexion contractures need ligamentous balancing together with preparation of bone cuts. In RA valgus knee alignment is most common (Chmell and Scott 1999). Flexion contracture involves contracture of the PCL, posterior capsule and hamstring musculature, and the goal of the surgery is to bring the knee to full extension (Scuderi and Kochhar 2007). Excessive valgus knee alignment sometimes necessitates release of the lateral supporting structures to various extents (Miyasaka et al. 1997, Clarke et al. 2005, Bottros et al. 2006). Lateral release has been questioned due to increased risk of complications related to it, e.g. patellar fractures (Windsor et al. 1989a, Ritter et al. 1996, Ritter et al. 1999), poor pain scores (Elson and Brenkel 2006) as well as peroneal nerve palsy (Krackow et al. 1991) and increased rate of patellar component loosening (Berend et al. 2001). Adequate surgical techniques especially in component positioning in TKA reduce the need for lateral release (Sodha et al. 2004, Kelly et al. 2006, Newbern et al. 2006).

In postoperative care after total joint arthroplasty in the lower extremity adequate thromboembolic prophylaxis, monitoring of cardiovascular and metabolic status as well as signs of infection must be taken care of to avoid complications. Therefore early discharge of patients from the hospital has not been recommended (Parvizi et al. 2007).

In RFH postoperative hospital stays of patients with RA after total knee arthroplasty have shortened from the 80's and 90's, when typical length of stay was from one to two weeks. Nowadays it is from three to eight days, depending on the postoperative situation. Patients recieve intensive physiotherapy on the ward after surgery, continuous passive

motion device is used, and mobilisation with crutches usually begins on day 1 or 2 postoperatively. Full weight-bearing is normally allowed, except if bone transplantation or peroperative fracture complication restrict it. Wound healing is monitored, and if necrotic areas are observed at the margins of the wound, surgical excision is considered at an early phase. Postoperative monitoring of CRP for several days has been found to be useful in order to detect postoperative infections (Mäenpää et al. 2002). Adequate and proactive treatment of postoperative pain is also essential. Follow-up is arranged at the outpatient clinic a few months after surgery, and then one and four years postoperatively.

#### 2.3.3.2. First steps of TKA

The earliest surgical attempts to treat arthritic knees were as early as 1861, when Ferguson reported resection arthroplasty. In 1863 Vernuil performed the first interposition arthroplasty of the knee, in which he inserted a flap of joint capsule between two resected joint surfaces to prevent them from growing together. Later the success of various interposition materials was poor. Major advances in prosthetic arthroplasties began in 1940's. First metallic hemiarthoplasty of the femur and later of the tibia were performed. The first attempts to replace both femoral and tibial articular surfaces were made in the 1950's with hinged prostheses. The earliest models were prone to loosening and infection (Crockarell and Guyton 2003.)

The first knee arthroplasty in Finland was probably performed by Raunio at RFH in the 1950's, but no confirmation of this statement could be found. The first documented knee arthroplasties in RFH were done in the 70's, and results of the early designs were reported in 1985 (Hämäläinen 1985). In a retrospective part of that study, two series of TKAs performed from 1973 to 1978 with two designs, Freeman-Swanson and Geometric Knees, were compared. Failure rates were 16.9% for the Freeman-Swanson Knees (mean follow-up 5.0 years) and 30.2% for the

Geometric Knees (mean follow-up 6.1 years). In a randomised, prospective study of Hämäläinen's thesis ICLH (Imperial College/London Hospital), Townley and Anametric designs were compared. At one-year follow-up one patella was excised in ICLH series – the patella was not resurfaced in any arthroplasty in that series - but no rereplacements were done (Hämäläinen 1985.)

Modern endoprosthesis evolution began in the 1970's by bi- and tricompartmental designs. Total condylar prosthesis can be said to mark the beginning of the modern era of TKAs. The total condylar prosthesis was influenced largely by previous ICLH design. The femoral component had a symmetrical anterior flange for patellar articulation and symmetrical femoral condyles. The tibial component was originally all-polyethylene. The patellar component was a domeshaped and all-polyethylene. Many of the previous design characteristics are retained in currently used endoprostheses (Crockarell and Guyton 2003, Crockarell and Guyton 2007.)

#### 2.3.3.3. Constraint in current designs

The amount of constraint in a modern knee endoprosthesis varies from PCL-retaining models with minimal constraint to the maximal constraint of rigid, hinged prostheses. Constraint can be slightly increased in PCL-retaining designs by the geometry of articulating surfaces. PCL substituting models (or posterior-stabilised (PS) designs) have a little more constraint, the articulating surfaces are often more concave, and there is a cam mechanism between the femoral and tibial components. Even more stability can be achieved by constrained condylar and total condylar prostheses. Rotating hinge and rigid hinge prostheses give maximal constraint in cases of severe bone loss and global instability (Crockarell and Guyton 2007.)

Usually in the PCL retentive prosthesis the articulating surfaces of femur and tibia have to be less congruent, "flat-on-flat", in order to allow the femoral roll-back and to accommodate kinematics of the PCL (Fetzer et al. 2002). Concern about high contact stresses on the flat surface causing wear and delamination of the polyethylene insert has been expressed, and severe polyethylene wear has been reported to be one of the main problems of PCL preserving models (Blunn et al. 1991, Feng et al. 1994, Toksvig-Larsen et al. 1996). The polyethylene for a PCL-preserving total knee prosthesis needs to have fewer voids and more strength, and the importance of direct compression moulding of polyethylene in the manufacturing process has been emphasised (Ritter et al. 1995, Ritter et al. 2001). Bartel et al. (1986) have mentioned that the increased conformity required in PS designs may decrease the stresses in the polyethylene and at the bone-cement interface.

In a Cochrane review of randomised controlled trials of PCL retention versus resection in total knee replacement (Jacobs et al. 2005), no solid criteria of either retaining or resection of the PCL with or without use of PS design in knee arthroplasty were given. In a retrospective study two groups of patients with RA receiving either posterior ligament retentive design or resecting model were compared (Laskin and O'Flynn 1997). The study ended up to recommend PCL resecting prosthesis rather than PCL preserving prosthesis in treatment of RA knee, in light of the problems with posterior instability and recurvatum deformity in the PCL preserving model. However, in a study of anteroposterior instability following cruciate-retaining knee arthroplasty in patients with RA, no patients developed posterior instability (Niki et al. 2008). Favourable results have been achieved in PCL-retaining knee replacement both in mid-term studies (Knutson et al. 1986, Thomas et al. 1991) and in longer follow-ups (Schai et al. 1999, Archibeck et al. 2001, Gill and Joshi 2001, Meding et al. 2004). However, the follow-up results of knee arthroplasties with PCL resected are also good (Scott et al. 1988, Stern and Insall 1992).

If persistent laxity occurs despite proper tissue balancing, implants with greater constraint than standard implants have to be used (Sculco 2006). The constrained condylar designs with non-linked, semiconstrained design may be useful in a TKA of severe valgus knee with marked medial laxity or in revision procedures (Lachiewicz and Falatyn 1996, Easley et al. 2000). The Constrained Condylar Knee (CCK) was first developed by Insall and others from the PCL-substituting design by enlarging the central post of the tibial polyethylene insert and deepening the central box of the femoral component (Crockarell and Guyton 2007). In a retrospective study of demanding primary knee arthroplasties of 61 knees (in 27 knees OA as diagnosis, in 15 knees RA) treated with modular PS constrained implant (Biomet), wear and failure due to modularity were not a problem, but revisions were due to infection, problems with the extensor mechanism and recurrent instability (Lombardi et al. 2007a). In cases of marked bone loss and absence of ligamentous support, a rotating-type hinged prosthesis allowing some amount of external and internal rotation may be used (Draganich et al. 1999, Sculco 2006, Pour et al. 2007). Rigid hinged prostheses were commonly used from the 1950s to the 1970s in TKA, and they may still be needed in knees with severe instability or deformity (Bohm and Holy 1998).

#### 2.3.3.4. The variety of tibial designs

Early tibial design was made of only polyethylene, and in the 1980's metal backing of the tibial component was introduced, and it opened a way for modular designs (Bartel et al. 1982, Hyldahl et al. 2005). All-polyethylene tibial design has been reported to have quite a high success rate (Ranawat and Boachie-Adjei 1988, Lee et al. 1990, Adalberth et al. 2000, Pavone et al. 2001, Rodriguez et al. 2001, Gioe et al. 2006, Muller et al. 2006, Gioe et al. 2007). However, Faris et al. (2003) have reported a ten-year survival rate of only 68% with AGC all-polyethylene flat-on-flat

tibial design, when aseptic loosening or revisions were included as failures.

Whether a moulded or modular tibial component should be used has been debated. Modularity, in which the metal tray and the polyethylene insert are separate, gives more options during surgery both in primary and in revision TKA (Takahashi and Gustilo 1994), and good radiological as well as clinical results have been reported (Lachiewicz et al. 2004). However, wear of the polyethylene has been identified to be a major source of polyethylene debris contributing to tibial osteolysis, to early revisions and together with metallic wear particles even causing a systemic increase of wear particles (Wasielewski et al. 1997, Urban et al. 2000, Mikulak et al. 2001, Jacobs et al. 2006, Purdue et al. 2006). The use of metal-backed tibial plates in total knee replacement prostheses can result in the flow of ultra-high molecular weight polyethylene from the tibial insert into a cavity on the metal tray surface, so-called cold flow deformation (Cuckler et al. 2003). Moderate to severe backside wear of nonarticulating surfaces was reported in a study of twelve different modular tibia designs (Conditt et al. 2004).

Micromotion between the tibial insert and the baseplate has been noted, and improvement of the locking mechanisms has been recommended to control this (Parks et al. 1998, Rao et al. 2002). Many studies have focused on the bone-cement interface, focusing on preparation of the bone-surface and cementing techniques (Ritter et al. 1994), but in addition, the microstructure of contemporary tibial baseplates may also have an influence on the strength of the metal-cement interface contributing to early tibial component failures (Pittman et al. 2006).

On the other hand, in a moulded design, in which polyethylene insert is directly moulded to the metal tray, delamination produced large wear particles in a follow-up study by Ritter (2001). The dominant failure

mechanisms of the moulded design have been preoperative deformity, technical factors of component alignment and ligamentous imbalance (Berend et al. 2004).

Whether a mobile bearing or a fixed bearing of the polyethylene insert should be used has also been discussed. In mobile-bearing models the polyethylene component can rotate but in the fixed-bearing designs it cannot. The mobile bearing insert can be a rotating platform or a meniscal bearing, which both rotates and glides (Jacobs et al. 2001, Crockarell and Guyton 2007). Fixed bearing knee designs have relatively low tibio-femoral conformity, which decreases contact area and increases contact stresses compared to rotating-bearing designs, in which lesser contact stresses on polyethylene articular surface can result in reduced polyethylene wear (D´Lima et al. 2001, Dennis and Komistek 2006).

In a Cochrane review (Jacobs et al. 2001) no evidence of the superiority for one of the two types was found, but only two acceptable randomised studies were found. Better methodological quality was found in the study by Price et al. (2003), in which a fixed tibial component (AGC, Biomet-Merck) was compared with a mobile one (TMK, Biomet-Merck) in bilateral procedures, and a slightly better clinical outcome for mobile bearing knee replacement was found, but no difference in range of motion. The other study was by Kim et al. (2001) and no difference between the mobile bearing (LCS, DePuy) and fixed models (AMK, DePuy) was found. In addition, in a longer follow-up (mean 13.2 years) no evidence of the superiority of one design over the other was found either (Kim et al. 2007a).

#### 2.3.3.5. "Prostheses families"

Manufacturers have developed several options for the surgeon to choose from among different types of components of knee implants. In "prostheses families" there is a range from minimal to maximal constraint

to suit the preoperative situation (Crockarell and Guyton 2003). Preoperative degree of severity addresses the demand for prosthetic constraint, in minimal deformity PCL-retaining devices can be used, while in severe cases a constrained condylar prosthesis with augments and wedges or even a rotating or a rigid hinge model may be needed (Lombardi et al. 2007a).

The AGC knee endoprosthesis has been used at RFH since 1985. In the material of the present study PCL-retaining design was used in primary cases. A more constrained model, AGC Dual Articular (DA) Knee, was also used in demanding primary and in revision knee arthroplasties. DA Knee is a semiconstrained prosthesis, which is a modular design having a bihelical tibial bearing to allow rotation at the articulation. It is posterior stabilized and there is a central keel on the tibial bearing. A PS design as well as hinged models are available. Different degrees of constraint are offered in the continuum of designs; for example, a rotating-hinge prosthesis (RHK<sup>TM</sup>), which has been directly evolved from the custom DA RHK<sup>TM</sup>, can be used if a hinged prosthesis is not needed (see Biomet Inc. 2009.)

Conventional AGC endoprosthesis is usually used in primary TKAs. It is a non-constrained PCL-retaining design with flat-on-flat articulating surfaces, Femoral component is made from cobalt-chromium, and it has a universal design with no spesific geometry for the right or left side. Two kinds of tibial components are available. One is a moulded tibia component which has compression-moulded ultra-high molecular weight polyethylene directly attached by the manufacturer to a cobalt chrome metal tray with a central stem.

The other is a modular component, in which there is a baseplate of titanium, and a separate modular power-milled polyethylene component. The patellar component is nowadays all-polyethylene, but in 1980's a component with metal-backed polyethylene was also used.



Figure 1. Components of the modular AGC knee endoprosthesis.



Figure 2. Femoral components with different designs by the manufacturer of the AGC endoprosthesis (Biomet).

Figures 1 and 2 printed with kind permission of Biomet

In the course of time the AGC prosthesis has been redesigned, and nowadays designs called Maxim and Vanguard are available. They are based on the principles of the AGC prosthesis, but there are small modifications e.g. in the femoral component (from universal model of the original AGC to right-left differentiation) and in the tibial stem design.

#### 2.3.3.6. Cementing in TKAs

Fixation of the components has been discussed. In support of cementless fixation is ease of revision surgery and shorter operation time (Hungerford and Kenna 1983). In a study by Armstrong and Whiteside (1991) in older patients with RA (mean age 62 years) the early clinical results of cementless TKA were good, and the authors emphasised preservation of bone stock if revision was subsequently needed. Good clinical results with a 99% survival at five years were achieved with 584 cementless TKA (mixed diagnosis in patient material), and the author emphasised proper patient selection as a basis for success in cementless fixation (Bassett 1998). In a mid-term follow-up of 51 posterior cruciate ligament retaining AGC prosthesis cementless knee arthroplasty in RA patients, the clinical results were good and the cumulative survival rate was 97% at five years (Schrøder et al. 1996). In a longer follow-up of PCL-retaining cementless arthroplasty in OA and in RA patients, poor bony ingrowth was observed as radiolucent lines in radiography, but survival was 100% at ten years (Watanabe et al. 2004).

The gold standard in the fixation of TKA seems to be the use of cementing. In five-year follow-up of cemented versus cementless TKA in a randomised and prospective study by McCaskie et al. (1998), a significantly greater number of radiolucent lines was observed in the cemented group, although there was no difference in the clinical results. The authors elected not to support cementless fixation, because they could not explain the significance of their radiological results and because cementless fixation was more expensive. In an RCT comparing

hydroxyapatite-coated tibial implants and cemented tibial fixation, no difference was found five years postoperatively in pain, function, complications or radiographic scores (Beaupré et al. 2007).

In an update of the Swedish Knee Arthroplasty register it was pointed out that tibial components without cement fixation had an increased risk of revision (Robertsson et al. 2001). In a study by Fehring et al. (2001), 13% of early failures were revisions for lack of bony ingrowth, and the authors recommended routine use of cement in TKA. An analysis of survival of 11,606 primary TKAs at ten years showed that the survival of prostheses fixed with cement (92%) was significantly greater than the survival of cementless fixation (61%, p<0.0001) (Rand et al. 2003). Cemented implantation of knee arthroplasties in treatment of RA has also been recommended, because frequent upper extremity involvement in RA makes the use of crutches impossible and full weight-bearing must be tolerated postoperatively (Elke et al. 1995).

#### 2.3.3.7 Resurfacing the patella - or not?

The use of patellar resurfacing has varied over the years. Patellar resurfacing in TKA means replacing the worn articular surface of the patella with a patellar component. In the early models of knee prostheses only tibial and femoral component were used, and the patella was left unresurfaced. Early designs without patellar resurfacing were associated with high rates of patellofemoral problems, especially with RA (Insall et al. 1976).

The materials and geometry of the patellar component have also varied. In order to achieve optimal patellar tracking and patellofemoral contact, the designs of both the femoral and the patellar components have to be compatible (Burnett and Bourne 2003). In 1974 the first patellar component was dome-shaped and made of polyethylene (Aglietti

et al. 1975). Since then polyethylene has been combined with metal, and nowadays all-polyethylene patella is again favoured.

After the development of the patellar component, patellar resurfacing was preferred, especially around the 1980's, by many surgeons as a routine in TKA (Insall et al. 1979, Ranawat 1986, Aglietti et al. 1988). However, the number of complications was reported to rise together with the increasing patellar resurfacing. Problems with patellar fractures, maltracking, "overstuffing" of the patellofemoral joint, aseptic loosening, extensor mechanism complications, patellar clunk syndrome and polyethylene wear were detected (Lynch et al. 1987, Rand 1990, Boyd et al. 1993, Rand 1994, Healy et al. 1995).

In RA some authors have recommended resurfacing because of the risk of persistent synovitis in the patellar cartilage (Sledge and Walker 1984, Boyd et al. 1993, Kajino et al. 1997). Patellar resurfacing has been reported to reduce the incidence of knee pain including in patients with juvenile rheumatoid arthritis (Lybäck et al. 2004). In a prospective study of 80 patients with RA, arthroplasty without resurfacing yielded satisfactory results in a mid-term follow-up, and routine patellar resurfacing could not be recommended (Bhan et al. 2006).

The controversy concerning patellar resurfacing has persisted in the treatment of OA as well. In a systematic review where three RCTs of patellar resurfacing in knee arthroplasties for OA were analysed, no midto long-term benefit was found from leaving the patella unresurfaced (Forster 2004). In two RCTs comprising 89 patients (Barrack et al. 1997) and 142 patients with OA (Smith et al. 2008), no significant difference was found between the resurfaced and non-resurfaced groups in clinical assessment. According to an RCT of knee arthroplasties of OA in patients with a minimum of 10 years of follow-up (Burnett et al. 2004), and in a study of 32 patients with OA with bilateral procedures (Burnett et al. 2007) and in an RCT with ten-year follow-up of OA patients (Campbell

et al. 2006) no difference between resurfaced and nonresurfaced groups was found.

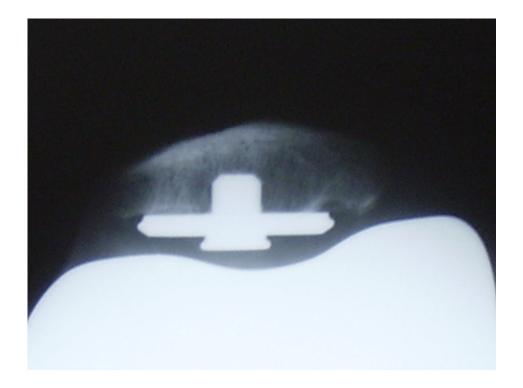


Figure 3. A tangential, "sky-line" patellofemoral radiograph with a metal-backed patella component 16 years postoperatively.

### 2.3.3.8 Revision knee arthroplasties

Osteolysis as a result of a foreign body response to wear debris is one of the leading causes for late revisions of TKA (Gupta et al. 2007). In many studies the most usual complication of primary TKA has been periprosthetic osteolysis and aseptic loosening (Knutson et al. 1986, Moreland 1988, Purdue et al. 2006). Infection has also been mentioned to be one of the major causes of failure in TKA (Windsor et al. 1989b), and infection has appeared to be a risk to the longevity of TKA, especially with RA patients. In follow-ups (from 10 to 15 years) the reported prevalence of infection has been 7% in deep infection (Kristensen et al.

1992) and from 4.1% (Rodriguez et al. 1996) to 6.3% (Laskin 1990) in delayed sepsis.

Mechanical arthroplasty component failures have become less common than in earlier studies of TKA but infections and periprosthetic fractures have increased (Robertsson et al. 1997, Vessely et al. 2006). Instability after TKA may result from component loosening, bone loss, prosthetic breakage, and collateral ligament failure, and revision surgery must eliminate deforming forces (Vince et al. 2006). Stiff or painful postoperative outcome has been reported to be associated with factors like female sex, high body mass index, diabetes, previous knee surgery and depression (Fisher et al. 2007). The aetiology of pain after TKA must be carefully evaluated with clinical examination, imaging and laboratory investigations before the decision on revision procedure (Mandalia et al. 2008).

According to the endoprosthesis register of National Agency for Medicines there were 584 TKA revisions in Finland in 2004. Infection was the most common reason for revision (26% of revisions). Malposition of the components (10%) and patellar complications (10%) were followed by loosening of tibial or both tibial and femoral component as the reason for revision in 9% of the cases (Rantanen et al. 2006.)

Revision TKA requires preoperative assessment to determine the mechanism of failure of the initial arthroplasty (Dennis 2007). Revisions include surgical challenges like restoration of the anatomical joint line (Partington et al. 1999, Laskin 2002, Hofmann et al. 2006), management of bone loss (Dorr et al. 1986, Windsor et al. 1986, Backstein et al. 2006, Bush et al. 2006,) and soft tissue balancing in flexion and extension (Krackow 2002, Ries et al. 2004).

In patients with RA the density of trabecular bone is significantly lower than in patients with OA or normal bone (Yang et al. 1997). Problems

with bone quality already appear in primary TKA, but especially in revision. Bone defects can be managed by metal augments, cement with screws, autografts, allografts and tumour prostheses (Backstein et al. 2006). Bone grafting has been seen as an alternative to using custom tibial prostheses or excess cement (Dorr et al. 1986, Windsor et al. 1986). Prosthetic shims or wedges are recommended in large fragment defects (Laskin 1989), and calcium phosphate ceramic coatings on implant surfaces have been used to enhance bone ingrowth (Kienapfel et al. 1999).

Revision as well as complex primary TKA may need implant design with more constraint, like condylar constrained prostheses (Hartford et al. 1998). Nonconstrained implants have also been used in revisions of OA, RA and posttraumatic knees, with satisfactory results in average follow-up of 20 months (Takahashi and Gustilo 1994). Polyethylene insert exchange in revision is possible, but in that case a careful assessment of delamination of the articulating surface and backside wear of the primary insert should be made (Engh et al. 2000).

### 2.3.4. Results of TKA

#### 2.3.4.1. Effects of TKA on individual level

Successful surgery can have a positive influence on the entire functioning ability of the patient. In a study by Johnsson and Larsson (1990) the overall locomotion score measured from pre- to postoperative improved in 75% of all cases after a single joint replacement in RA. Together with pre- and postoperative levels of function, patient expectations for TKA have been observed to influence ultimate satisfaction after TKA (Noble et al. 2006). In a review of studies of health-related quality of life in total hip arthroplasty and TKA, both procedures were found to be quite effective in

terms of improvement in health-related quality of life dimensions, but in patients with RA, these interventions may provide limited restoration in health status because of disabilities in the upper extremities (Ethgen et al. 2004). Kaneko et al. (2004) compared postoperative life expectancies of patients with RA, who had undergone either hip arthroplasty or TKA from the 1970's to the 1990's. Although the follow-up was shorter in a group of joints operated on in the 1990's, the results showed both the life expectancy and cumulative survival rates to be better in the 1990's group. The authors speculated that the improvement of RA treatment in recent decades, the increase in life expectancy of Japanese population and well-timed application of arthroplasty to be the factors involved in the improvement (Kaneko et al. 2004.)

#### 2.3.4.2. Results of TKA in the treatment of RA compared to OA

Although knee arthroplasty in the treatment of RA is slightly more challenging than in the treatment of OA, the results have been encouraging. The results of TKA in patients with RA have been reported in to be good in short and medium-time follow-ups (Riley and Hungerford 1978, Sledge and Walker 1984, Hvid et al. 1987, Stuart and Rand 1988, Thomas et al. 1991, Ebert et al. 1992.) Survival rates of TKA with RA patients in longer follow-ups have been reported to be good, especially when revision alone has been considered to be the endpoint of failure. Variation from 80% (Laskin 1990) to 95% (Robertsson et al. 1997) at ten years, and from 91% (Rodriguez et al. 1996) and 93% (Meding et al. 2004) to 94% at 15 years (Ito et al. 2003) have been observed.

On the other hand, problems with wound healing have been reported in TKA in patients with RA (Laskin 1981, Boegård et al. 1984). Furthermore, Böhm et al. (2000) reported higher mortality rate in RA patients compared to general population after TKA in their study of 422 primary knee arhtroplasties with a hinged prosthesis in 330 patients (208 patients with OA, 122 patients with RA). Moreover, in a study of patient

survival after TKA Schrøder et al. (1998) found patients with RA to have increased mortality compared to general population, the difference being significant in the age group 65-74 years. After TKA a longer survival than in general population has been found and in the group of women aged over 75 years the difference was statistically significant. The authors speculated that the improvement of mobility might be the reason for the better life expectancy (Schrøder et al. 1998.)

In a study by Rand and Ilstrup (1991) - data from 1971 to 1987 with 9200 TKAs (patients with OA 68%, with RA 31%), significantly lower risk of failure was associated with variables like primary TKA, diagnosis of RA, age of sixty years or more and use of a condylar prosthesis with a metal-backed tibial component. Sledge and Walker (1984) reported in their short-term follow-up of 798 TKAs comparable results in RA and OA groups, with regard to range of motion and pain relief. In an analysis of 11,606 primary TKAs (Rand et al. 2003) the survival was 91% at ten years, 84% at fifteen years and 78% at twenty years, and primary TKA can be expected to succeed better in patients with inflammatory arthritis (survival 95% at ten years) than in patients with OA (survival 90%, p<0.005). However, in a follow-up study of 61 patients, Hanyu et al. (1997) reported lower survival rate in patients with RA than in general population.

# 3. PURPOSE OF THIS STUDY

The aim of this study was to analyse the results of AGC total knee arthroplasties in the treatment of rheumatoid arthritis.

The specific aims for the present study were:

- I To assess the survival of AGC knee endoprostheses in the treatment of rheumatoid arthritis and osteoarthrosis nationwide.
- II To evaluate the survival of moulded monoblock and modular tibial components of the AGC total knee arthroplasties in patients with rheumatoid arthritis.
- III To compare the results of unresurfaced and metal-backed resurfaced patellas in total knee arthroplasties in patients with rheumatoid arthritis.
- **IV** To analyse the results of DA Knee in demanding primary and revision knee replacements in patients with rheumatic diseases.

# 4. PATIENTS AND METHODS

The main data consisted of 751 knees and 586 patients with rheumatoid arthritis, who were operated on in RFH during the period 1985-1995 (original Studies II and IIII). AGC knee endoprostheses were used during the study period at RFH. The data was based on patient documents, and it was analysed both from radiological and clinical point of view. Data collection began in 1999 with radiological analysis.

The survival of AGC prostheses on national level was analysed using the databases of the Finnish Arthroplasty Register of National Agency for Medicines (original Study I). In Study IV the results of demanding primary and revision surgery of patients with rheumatic diseases were reported (original Study IV).

Methodologically all four studies were retrospective. Survival analysis was performed in the data on RFH (Studies II, III and IV) and the Finnish Arthroplasty Register (Study I). In Study IV, subjective satisfaction of the patients was elicited. In Study II, III and IV radiological follow-up data was analysed as well as clinical data based on follow-up results of the EULAR data base in RFH.

### 4.1. Patients

In this thesis four different patient groups are included. In Study I the focus was on the national scale of knee arthroplasties. In Study II there were RA patients of RFH, and a smaller subgroup was included in the third article. In Study IV, 24 patients of RFH were analysed.

### 4.1.1. Study I

In the first study survival of 8,467 AGC knee arthroplasties in 7,209 patients was analysed according to the data of the Finnish Arthroplasty Register. Two different patient groups were included, 5,470 patients with OA and 1,739 patients with RA. There were 1,254 males and 4,216 females in the OA group, and 332 males and 1,407 females in the RA group. The mean age was higher in the OA group than in the RA group at the time of knee replacement, 69 among men and 71 years for women in the OA group, and in the RA group 60 and 61 years respectively.

### 4.1.2. Study II

In the second study there were 586 patients (106 males, 480 females) with rheumatoid arthritis who had undergone arthroplasty using AGC knee endoprosthesis in RFH during 1985-1999. During the study 165 patients had bilateral knee replacements, giving a total of 751 TKAs. There were two study groups. In group A, moulded design of the tibial component was used, and in group B, a modular tibia component was used. In group A the mean age of the patients was 58 years, and in group B it was 60 years. The mean weight of the patients was 66 kg and 68 kg, respectively.

# 4.1.3. Study III

In the third study, a smaller subgroup of the patients in Study II was selected. In this study there were 234 knee arthroplasties in 224 patients with RA. Survival and results of two subgroups was based on whether the patella was resurfaced or not. The number of patients in the group with unresurfaced patella was 80, and number of TKAs was 82. In the group

with metal-backed resurfaced patella there were 144 patients and 152 TKAs. There were 68 women (85% of the patients in the group) in the unresurfaced patella group, and 118 women (82%) in the metal-backed patella group. The mean age of the patients was 60 years in the unresurfaced group, and 58 in the metal-backed patella group. The mean weight of the patients was 66 kg and 65 kg, respectively.

### 4.1.4. Study IV

In the fourth study there were 24 patients with rheumatic diseases (20 patients had RA, 23 juvenile chronic arthritis and one patient had psoriatic arthropathy). There were 25 TKAs, of which four were primary and 21 revisions. Mean age at the time of the operation was 56 years in the primary knee replacement group and 60 years in the revision knee replacement group, and the mean duration of the disease was 23 and 31 years, respectively. All patients used corticosteroids and six patients received cytotoxic agents.

### 4.2. Methods

### 4.2.1. Retrospective study design

In all studies the design of the study protocol was retrospective. There was no randomisation of the patients to the groups to be compared. The data of Studies II, III and IV were based on the patient documents in RFH, which is an institution with expertise in the orthopaedic treatment of rheumatoid diseases. The costs of treatment at RFH are met by the patients' home municipalities.

The prosthesis used in TKAs (Studies II, III and IV) was based on the endoprosthesis selection policy of RFH at the time of the operations. The use of more constrained prosthesis in Study IV was based on the choice of the operating surgeon. The allocation of the patients of Study II also depended on the year of operation and the tibial component available to the surgeon at that time. At the beginning (1985-1989) and at the end of the study period only moulded design was used at RFH. Only for a short overlapping period were both moulded and modular components available for the surgeon to choose from. In terms of resurfacing of the patella (Study III), there was no randomisation of the patients to the unresurfaced and metal-backed resurfaced groups. The decision on resurfacing was made by the operating surgeon based on the preoperative clinical and radiological examination of the knee.

### 4.2.2. Register study

In Study I data from the Finnish Arthroplasty Register maintained by National Agency for Medicines was used. In Study III dates of deaths of the patients and survival of the prostheses were collected from the National Agency for Medicines database.

### 4.2.3. Statistical analyses

The results were expressed as means with standard deviations (SD). The most important descriptive values were expressed with a 95 per cent confidence interval (95% CI). Statistical comparison between the groups in Study II was performed by t-test or chi-square test.

In Studies I, II and III Kaplan-Meier curves were used to illustrate information on the cumulative proportions of survival, and log rank test to compare the groups. The prognostic factors predicting the duration of the

survival time were analysed using univariate and multivariate proportional hazard regression models, called Cox´s regression models. The endpoint of follow-up in this study was revision arthroplasty defined as the removal, exchange or addition of a prosthetic component, death of a patient or the year 2000. The data of the National Agency for Medicines endoprosthesis register was used to find the withdrawn cases. Success was defined as a prosthesis still in situ at the end of follow-up, regardless of clinical or radiological findings (Studies II and III).

In Study III the repeated measures were analysed using either generalising estimating equations (GEE) models with exchangeable correlation structure (binary or ordinal type variables) or mixed models with unstructured correlation structure (continuous type variables).

### 4.2.4. Surgical techniques in RFH (Studies II, III and IV)

All patients were operated on using insertion of an AGC prosthesis. In Studies II and III the prosthesis was nonconstrained design AGC, and in Study IV AGC Dual Articular Knee was used. At the beginning of the study period (Studies II and III) only moulded tibial component was used, and modular design was available after 1989. For a short time both designs were used concurrently. The patellar component was mainly metal-backed design. The decision on resurfacing the patella was made by the operating surgeon. In most procedures an anteromedial approach was used. Whether cement was used or not was dependent on the operating protocol at the time of TKA and whether peroperative circumstances required it.

Prophylactic antibiotics was used preoperatively. The operations were performed under general or spinal anaesthesia. A tourniquet was used and was released after wound closure and dressing. A modified Robert Jones bandage was used, and at the ward continuous passive movement -machines were used for mobilisation of the knee.

### 4.2.5. Follow-up procedure in RFH

In RFH EULAR pre-, per- and postoperative knee charts have been used to assess detailed symptoms, general locomotor status, functional ability and the findings of the physical examination. Patients in RFH were invited to a postoperative checkup after TKA at least a few months, 1 year, 2 years, 4 years, 8 years and 12 years after surgery. The protocol could be different if more follow-up was needed, but in this study the radiological findings at the time points mentioned above were estimated as a basis for Studies II and III. On a visit to RFH, full-length, sagittal and sky-line (tangential) patellar projection radiographs of the operated knee were taken. In clinical examination both subjective satisfaction and functioning ability were elicited and the status of the knee was assessed. Clinical parameters were noted on EULAR forms.

Clinical data were evaluated from EULAR databases (Studies II and III), and from patients' documents (Studies II, III and IV). Pre- and postoperative radiographic data were analysed by a researcher (A-K Himanen). For the radiological analysis an assessment form was constructed and it was tested in an intraobserver analysis in 1999 for Studies II and III. In radiological analysis the incidence of radiolucent lines was recorded as millimetres by zone. The position of the components and the use of bone blocks were also estimated. The radiological assessment form was slightly modified for Study IV. In addition, for Study IV, a telephone interview with 22 patients was arranged in 2000, 1-8 years after surgery, and the subjective satisfaction of the patients and also the functioning ability were registered.

# 4.3. Ethical considerations

The study protocol was approved by the institutional review board of RFH.

### 5. RESULTS

# 5.1. Study I

The survival of AGC knee endoprosthesis on national level during the period 1985-1999 was analysed in Study I. Data was collected from the Finnish Arthroplasty Register maintained by National Agency for Medicines. Two patient groups, RA and OA, were compared. During study period there were 8,467 primary AGC knee arthroplasties performed on 7,209 patients. In the RA group there were 2,161 knees and in the OA group 6,306 knees. Operations took place in 54 hospitals, the median number of operations per unit being 43. Mean follow-up period was 5.2 years in the RA group and 3.2 years in the OA group.

In a survival analysis with revision as an endpoint similar survival rates were found in both groups. In the RA group the 5-year survival rate was 97% and the 10-year survival rate was 96%, and in the OA group the rates were 97% and 94% respectively. (Table 1 and 2.)

**Table 1**. Demographic and clinical variables and prosthetic survival in arthrosis of the knee.

Variable		5-year	10-year	p-value*
		% (95% CI)	% (95% CI)	
Sex				0.011
femal	e(n=4871)	97.7 (97.1 to 98.2)	94.4 (92.3 to 96	.0)
male	(n=1435)	96.1 (94.5 to 97.3)	92.9 (87.5 to 96	.0)
Age (yea	ars)			< 0.001
-60	(n=570)	95.9 (93.3 to 97.5)	84.2 (72.6 to 91	.2)
>60	(n=5736)	97.5 (97.0 to 98.0)	95.3 (93.7 to 96	.5)
Cementing				0.43
used	(n=1103)	97.5 (96.8 to 98.0)	93.5 (87.6 to 96	.6)
not used (n=5203)		97.6 (95.9 to 98.0)	93.6 (91.6 to 95	.6)
Time period of operation		on		0.63
1985-	-89 (n=252)	98.3 (95.6 to 99.4)	95.1 (91.0 to 97	.4)
1990-	-94 (n=1432)	97.5 (96.5 to 98.2)	94.4 (91.9 to 96	.2)
1995-	-99 (n=4622)	97.2 (96.4 to 97.9)	-	•

<sup>\*</sup> Log-Rank test for difference in survival curves between groups

**Table 2**. Demographic and clinical variables and prosthetic survival in rheumatoid arthritis.

Variable		5-year	10-year	p-value*
		% (95% CI)	% (95% CI)	
Sex				0.004
femal	le (n=1757)	97.5 (96.5 to 98.2)	96.1 (94.7 to	97.1)
male	(n=404)	94.0 (90.4 to 96.2)	92.6 (88.4 to	95.3)
Age (yea	ars)			0.007
-60	(n=913)	95.8 (94.1 to 97.0)	93.9 (91.7 to	95.6)
>60	(n=1248)	97.9 (96.7 to 98.6)	97.1 (95.6 to	98.1)
Cementi	ng			0.5
used	(n=827)	97.0 (95.6 to 97.9)	96.5 (95.0 to	97.6)
not us	sed (n=1334)	96.9 (95.4 to 97.9)	94.9 (92.9 to	96.4)
Time period of operation		on		0.7
1985	-89 (n=446)	97.4 (95.3 to 98.5)	96.0 (93.5 to	97.5)
1990-	-94 (n=845)	97.0 (95.6 to 98.0)	95.7 (93.8 to	97.0)
1995	-99 (n=870)	96.7 (94.6 to 97.9)	-	·

<sup>\*</sup> Log-Rank test for difference in survival curves between groups

Sex and age appeared to be significant for the prosthetic survivorship; the revision rates were higher in men and in younger patients. Use of cement or time of operation had no effect on the risk of loosening (Table 3.)

**Table 3**. Proportional hazard model to determine the effect of variables on risk of loosening.

Relative risk (95% CI)	p-value
1.25 (0.87 to 1.80)	0.2
1.66 (1.22 to 2.24)	0.001
0.97 (0.96 to 0.99)	< 0.001
0.89 (0.62 to 1.26)	0.5
·	0.4
1.0 (indicator)	
1.28 (0.81 to 2.03)	
1.47 (0.86 to 2.52)	
	(95% CI) 1.25 (0.87 to 1.80) 1.66 (1.22 to 2.24) 0.97 (0.96 to 0.99) 0.89 (0.62 to 1.26)  1.0 (indicator) 1.28 (0.81 to 2.03)

# 5.2. Study II

The survival of a moulded and a modular design tibial component of the AGC knee arthroplasties in patients with RA were evaluated in the second study. During the period 1985-1995 a total of 751 knees were replaced at RFH, a subgroup (= group A) with moulded design included 356 and in a subgroup with modular design (= group B) there were 495 arthroplasties. The groups differed significantly from each other in Larsen grade (p<0.001), mean weight (p=0.018), cementing of components (p=0.019) and patellar resurfacing (p<0.001) (Table 4). These and other clinical and demographic variables, however, had no statistically significant influence on the risk of loosening (Table 5).

**Table 4**. Demographics and clinical data of 586 patients undergoing AGC knee arthroplasty.

Variables	Moulded	Modular	P-value
	N=256	N=495	
Demographics:			
Number of females, (%)	215 (84)	406 (82)	0.50
Mean age,years,(range)	58 (23 to 80)	60 (11)	0.098
Mean weight, kg, (range)	66 (36 to 101)	68 (13)	0.018
Clinical:			
Number of Larsen grade 5, (%)*	186 (74)	288 (62)	<0.001
Number of cemented, (%)	142 (55)	318 (64)	0.019
Patella resurfaced, n (%)	04 (00)	000 (70)	<0.001
None Metal-backed	81 (32) 170 (66)	360 (73) 81 (16)	
All-polyethylene	5 (2)	54 (11)	

<sup>\*</sup> There were 32 anteroposterior radiographs missing from the study group, so there were only 253 in group A and 466 in group B

**Table 5**. Proportional hazard model to determine the effect of variables on risk of needing revision of the AGC arthroplasties in RA.

Variable	Hazard Ratio (95% Cl <sup>†</sup> )	P-value
Female sex	0.64 (0.29 to 1.42)	0.27
Age (per year)	0.98 (0.95 to 1.01)	0.24
Weight (per kg)	1.01 (0.99 to 1.03)	0.45
Larsen grade 5	1.30 (0.59 to 2.86)	0.64
Cemented Patella resurfaced	1.52 (0.56 to 4.14)	0.41
None	Reference ‡	
Metal-backed	1.52 (0.70 to 3.31)	0.29
All-polyethylene	1.95 (0.60 to 6.33)	0.27
Modular type of tibia component	1.15 (0.51 to 2.57)	0.74

<sup>&</sup>lt;sup>†</sup> Calculated using robust estimate of variance.

<sup>&</sup>lt;sup>‡</sup> Denominator of hazard ratio.

There was no statistically significant difference between the cumulative success rates of the two groups (Log-Rank, p=0.91). The cumulative success rate of the moulded group was 96.8% (95% CI 93.6% to 98.4%) at five years and 94.4% (95% CI 90.4% to 96.7%) at ten years. In the modular group the survival rate was 96.2% (95% CI 94.0% to 97.6%) at five years and 93.6% (95% CI 89.7% to 96.0%) at ten years. (Figure 4.)

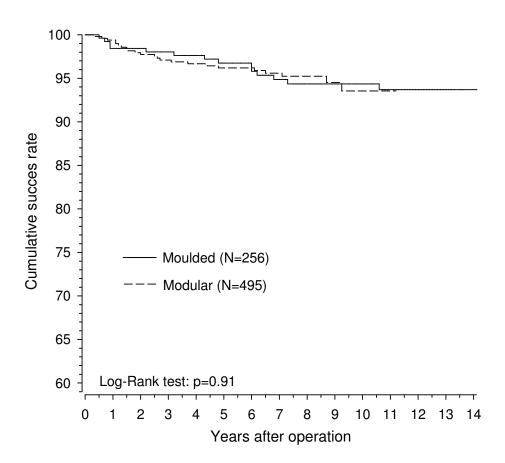


Figure 4. Cumulative success rate of moulded and modular subgroups of the AGC knees.

The clinical outcome did not differ significantly between the groups when estimated at the four-year post-operative evaluation by the subjective assessment of severity of pain, the uninterrupted walking ability and the ability to ascend and descend stairs. In the radiological follow-up there was no statistically significant difference between the groups with respect to the radiolucent lines estimated from the anteroposterior translucencies. More radiolucent lines were found in the moulded group when sagittal zones indicating anterior and posterior translucencies were examined.

# 5.3. Study III

In the third study the survival of the unresurfaced patellas (group A) and metal-backed resurfaced patellas (group B) were compared in mid-term follow-up. The studied groups differed significantly (p<0.001) from each other in two clinical factors, i.e. Larsen grading and use of different tibial component designs. Larsen grade 5 indicating severe destruction of the joint were found in 46 knees in group A, and in 118 knees in group B. Modular design of tibial component was used in 40 knees in group A and in 35 knees in group B. Moulded design was used in 42 knees and 117 knees respectively. No statistically significant differences between the groups were noticed in the mean weight or the mean age of the patients, or in the use of lateral release.

Based on a national register data maintained by National Agency for Medicines, there was no statistically significant difference between the survival of the groups at a 10 year follow up. The cumulative success rate in group A at ten years was 92.8% (95% CI: 83.5% to 97.0%), and in the group B 92.0% (95% CI: 86.0% to 95.5%). There were 27 revision cases, eight in group A and nineteen in group B.

Lateral patellar displacement (LPD) was analysed on radiographs, and there was a statistically significant difference between the groups (p<0.001). LPD was greater in the non-resurfaced group at every radiologically studied time-spot after TKA (postoperative, 1 year and 4 years). One possible explanation for this is, that resurfacing the patella serves to better regulate the movement of the patella in the femoral groove.

The number of painless knees was significantly higher at four years postoperatively in the metal-backed group than in the unresurfaced group (p=0.03). However, there was variation in the results: the number of knees with no reported pain was higher in the unresurfaced group at the first postoperative, 1-year and 4-year follow-ups. Clinical estimation was also carried out at 2 years postoperatively, and at that point there were more painless knees in the unresurfaced group. The ability to walk more than 1 km did not differ significantly between the groups. Besides painlessness, ability to walk over 1 km was counted a sign of clinical success, and no significant difference between the groups was found. At the mid-term follow-up the results of TKAs were good whether the patella was resurfaced or not.

# 5.4. Study IV

In the fourth study short-term results of semiconstrained DA Knee prostheses in demanding primary and revision replacements was analysed. There were 25 knee arthroplasties (four primary and 21 revision procedures) of 24 patients (22 women) with rheumatic diseases during the period 1992-1999 at RFH. One case was bilateral. Mean follow-up was 2.3 years (range 1-8 years). The prosthesis used was DA Knee, which is a modular design belonging to the AGC Total Knee System with a bihelical bearing and a large central keel in the tibial component.

In both groups instability was the most frequent indication for the procedure. In all cases there was a demanding preoperative situation with bone defects, fixed deformity or instability. Bone grafts had to be used in many cases, morselised in 12 knees, combined morselised and blocks in six, and a massive solid grafting in one knee. Tibial resection line in the primary group was from -5 to +16 mm above the line of the fibular head and in the revision group from -19 to +10 mm.

Complications were related to the extensor mechanism. There were four patellar tendon ruptures, and in one patient the rupture was bilateral. In the radiological analysis there was no progression of radiolucent lines, although these occurred fairly frequently. In the interview measuring subjective satisfaction and functioning ability, 18 patients reported the results to be excellent and most of the patients (14) needed no aid in walking (Table 6). At the most recent follow-up examination mean flexion was 94°.

**Table 6.** Subjective satisfaction and functioning ability of 22 patients after DA Knee TKA.

Questions asked/response alternatives	Patients (n)
Subjective satisfaction	
Excellent	18
Fair	2
Poor	2
Pain at rest	2
Pain in movement	
No pain	20
Mild pain	2
Severe pain	0
Mobility aids	
No aid	14
Crutches or stick	4
Wheelchair	4
Ability to climb stairs	
Normal	3
One step at a time	14
Cannot use stairs	5

# 6. DISCUSSION

# 6.1. Study I

In the first study of this dissertation, long-term survival of the knee replacements in patients with RA or with OA was compared on national level. No significant differences between two groups were found, and the results seem to be in line with most other studies. In a retrospective study by Scuderi et al. (1989) the success rate was comparable between knee arthroplasties of OA and RA patients, and the same was reported in a 15-year observational study of 4,390 patients with 4,606 TKAs (Roberts et al. 2007). In a register based study of revision TKAs in Finland, no difference was found between the survival of revisions in patients with OA or RA (Sheng et al. 2006a). However, Nafei et al. (1996) in a longer follow-up (up to 12 years) reported significantly poorer survival of knee arthroplasties in the RA group (87%) comparing to the OA group (97%).

The results of Study I resemble Swedish arthroplasty register material – sex and age have an effect on the survival of the prosthesis (Robertsson et al. 1997). However, slight differences also occur in the comparison; based on a study of the Swedish Knee Arthroplasty Register (Robertsson et al. 2001), OA patients had a 1.3 times greater risk of revision than patients with RA (p=0.003). The risk of revision because of infection was higher in RA than in OA with a risk ratio 1.4. (Robertsson et al. 2001.)

The use of cement in fixation had no effect on the survival of TKAs in this study. As discussed earlier, cementing seems to be the gold standard of fixation – regardless of prosthesis design. Survival of 81.7% at 15 years of cemented press-fit condylar prostheses (DePuy) was reported in a prospective study by Attar et al. (2008). Retrospective follow-up studies of cemented TKA have shown good results - 94.1% clinical survival at 15 years of Total Condylar knee prostheses (Ranawat et al. 1993), a ten-year success rate of 97% with a PS design with an allpolyethylene design (Scuderi et al. 1989) and 95% survival at 15 years with PCL-retaining prostheses with a modular tibial component (Vessely et al. 2006). With the cemented PCL-retaining AGC prosthesis, 95% survival was found at 11-year follow-up (Emerson et al. 2000), and even 98.9% survival at 15 years (Keating et al. 2002). In a study with a minimum 2-year postoperative follow-up, no significant difference in absolute or relative periprosthetic bone mineral density between cemented and cementless TKAs was found, and the authors questioned the use of more expensive cementless components (Abu-Rajab et al. 2006).

# 6.2. Study II

No significant difference between two different tibial components of AGC prosthesis, moulded and modular, could be found in Study II. However, according to many studies moulded design seems to be slightly better than modular design. In a survival analysis of 11,606 primary TKAs a survival of 92% of the nonmodular metal-backed tibial components compared to a survival of 90% of modular metal-backed tibial components was reported, and the difference was statistically significant (p<0.0001) (Rand et al. 2003). In a series of 1,071 primary TKAs with AGC prostheses, better radiological and clinical results were reported with a moulded monoblock than with a modular tibial design (Weber et al.

2002). Typical problems after knee arthroplasty, such as wear of polyethylene and osteolysis, have not been reported to be a problem in some follow-ups of moulded design either in a PS knee prosthesis (Thadani et al. 2000) or in a PCL-retentive model (Ritter 2001).

Although AGC prostheses are now "old-fashioned" with a flat-on-flat articulating design, the survival results were good. In the survival analysis of AGC prostheses with PCL sparing and geometry of nearly flat-on-flat articulating surfaces (87% of 3054 patients had OA), Ritter et al. (2001) reported over 98% survival at 15 years. Fetzer et al. (2002) with press-fit condylar prostheses with relatively flat joint surfaces likewise, reported of 93% survival at 12 years (OA as diagnosis in 85% of material). Furthermore, clinical outcome has been reported to be similar with flat or concave inserts (Uvehammer et al. 2001, Saari et al. 2006).

The design of the AGC prosthesis in this study is PCL-retaining with a fairly low amount of constraint. No clear difference between the results of PCL substituting and PCL retaining designs in knee arthroplasties of rheumatoid arthritis patients could be found in the literature. Survival has been reported to be 97% at 5 years (Hvid et al. 1987) and 96% at 13 years in PCL substituting design (Aglietti et al. 1995). With PCL-retaining designs survival has been reported to be 97% at 13 years (Schai et al. 1999) and 90.7% at 19 years (Gill and Joshi 2001). In a five-year follow-up of 44 knee arthroplasties with five different prostheses no difference between the survival of PCL substituting and PCL sacrificing designs could be found (Stuart and Rand 1988). In a prospective study with a mean follow-up time of 10.5 years, PCL-retaining prostheses yielded satisfactory clinical and radiological results, and a survival rate of 81% at ten years with any reoperation as the endpoint (Archibeck et al. 2001).

# 6.3. Study III

The superiority of designs and materials of patellar components has been debated in the literature, likewise whether to resurface the patella or not. No difference between resurfacing the patella or not was found in the third study - this result was found even though old-fashioned metalbacked patella was used in the material. In metal-backed patellas wear and fracture of polyethylene, and separation of polyethylene bearing of the metal counterpart has been reported (Bayley et al. 1988, Lombardi et al. 1988, Stulberg et al. 1988), likewise metallosis of the knee joint (Crites and Berend 2001). These observations have lead to a recommendation to avoid of metal-backed patella components (Burke et al. 2005). In an analysis of factors affecting the durability of primary TKAs, survival at ten years was significantly better (p<0.03) for knees with an all-polyethylene patella component (93%) than it was for those of no resurfacing (87%), and metal-backed components had 76% survival (Rand et al. 2003). However, metal-backed patellas have also been reported to survive quite well when compared to all-polyethylene designs (Braakman et al. 1995). The design of the metal-backed patella component may also be of importance: in a retrospective follow-up study of a metal-backed mobile bearing patella survival was 97% at a maximum of 19 years (Jordan et al. 2005).

In this study most of the patients – as usual in RA, were women. Preoperative factors like male gender and body mass index greater than 30 kg/m²have been reported to be associated with patellar fractures (Meding et al. 2008). The importance of peroperative factors has also been stressed in avoiding patella problems (Barrack et al. 2001). "Overstuffing" of the patellofemoral joint should be avoided, and postoperative thickness of the resurfaced patella should be as near the original thickness as possible (Hsu et al. 1996, Ritter et al. 1999). Optimal even thickness of the patella has been estimated to be from 1 to 1.5 cm (Windsor et al. 1989a). However, in a retrospective study of 800 primary

TKAs, overstuffing of the patellofemoral joint was surprisingly reported not to have adverse outcomes after TKA (Pierson et al. 2007).

In this study patella resurfacing had no influence on the survival of TKA in patients with RA in a retrospective mid-term follow-up. The need for patellar resurfacing in TKA of patients with RA has been questioned, as discussed in Chapter 2.3.3.7. Based on this study, it is hard to make recommendations, whether to resurface the patella in RA or not.

# 6.4. Study IV

In rereplacement cases the constraint of the prosthesis has to be estimated according to the reasons for the failure of the primary TKA. In this study good results were achieved with a semiconstrained prosthesis, DA Knee, in the treatment of demanding primary and revision knee arthroplasties of RA patients. In a follow-up of revisions with an unlinked, semi-constrained model too, patients with inflammatory arthritis had similar results to OA patients (Sheng et al. 2006a). In an average follow-up of 9.8 years after revisions porous-coated revision prostheses with constraint in tibiofemoral articulation yielded good clinical results in the treatment of patients with OA, RA and haemophilic arthropathy (Mow and Wiedel 1998).

Lack of bone due to e.g. fracture or large resections in primary operation can cause major problems in revision. In Study IV bone grafts and bone packing were used to resolve the problems of bone deficiency, and all bone grafts were preserved in short-term follow-up. However, long-term comparative studies are needed to determine the superiority of different surgical options in the treatment of severe bone deficiencies (Mabry and Hansen 2007).

In Study IV short-term results were presented, but longer follow-ups of revisions in general, as well as comparative studies of different solutions are needed. In an analysis of revision TKAs between 1990 and 2002 based on the nationwide Finnish Arthroplasty Register, the survival of revisions proved to be good: 95% at two years, 89% at five years and 79% at ten years when 2637 revision TKAs were studied. Reduced activity level seemed to protect against repeat revisions (Sheng et al. 2006b.)

The importance of surgical interventions in the extensor mechanism was stressed in Study IV, where all complications were related to the extensor mechanism. The importance of skilful management of patella and surrounding tissues cannot be overemphasised, and the question of patella resurfacing remains topical.

### 6.5. General discussion

It has been observed, that there are regional differences in the incidence and prevalence of RA in Finland (Kaipiainen-Seppänen et al. 2001, Korpilähde et al. 2003). It was not possible with this study to analyse to what extent the patients of RFH reflect RA patients of Finland as a whole or the local distribution of RA in Finland.

The remarkable advances in the conservative treatment of RA may hopefully lead to a decrease in the need for surgery in RA. However, the number of TKAs in patients with RA has recently remained almost at the same level. In general, the number of primary TKAs in Finland has increased in Finland; in 1997 there were 4.277 primary TKAs and in 2006 10.411 TKAs (National Agency for Medicines 2008). Furthermore, the number of both primary and revision TKAs will increase in the near future

due to aging of the population: e.g. in the USA the demand for primary TKAs is expected to grow by 673% from 2005 to 2030 (Kurtz et al. 2007).

All the patients included in Studies II, III and IV had RA, and one strength of this dissertation is the consistent bases for the diagnosis of RA. As the major diagnostic group for TKA from the epidemiologic point of view is OA, many studies have focused in it, as in the doctoral dissertation of factors related to the early outcome of surgery of knee replacements of patients with OA (Niskanen 2006). In many orthopaedic studies patients with RA are a minority compared to the number of patients with OA, and possibly therefore the number of RA patients has tended to be quite small in many studies (see Riley and Hungerford 1978, Boegård et al. 1984, Stuart and Rand 1988, Schrøder et al. 1996, Gill and Joshi 2001). However, in a doctoral dissertation studying knee arthroplasties of patients with RA or OA, the number of rheumatic patients was quite comparable, but no clear difference in the outcomes of TKAs was found (Partio 1995).

In the data of RFH the primary number of TKAs studied was high, but the number of patients declined mainly due to death, but also because of missing follow-up data. In the 1980's and 1990's most of the patients operated on in RFH were also followed up in RFH. Nowadays many patients have their post-operative controls in their home districts, not in RFH, which is naturally a problem for clinical follow-up study in RFH. However, standardised and continuous evaluation of replaced knees is essential, and thus effective co-operation between operating centres and basic health care would also be desirable in orthopaedic research. The importance of effective follow-up arrangements is emphasised especially in the treatment of patients with RA, who may have had several arthroplasties.

Survival analysis has the advantage of including all cases included in the study, but also limitations – one might ask, what the results were of the patients who have been lost to follow-up or who have died, and how these results might have differed from the results of the patients who have been followed up (Rand et al. 2003).

The success and the pitfalls of TKAs can be analysed e.g. based on the data of various nationwide registers, RCTs or longitudinal studies. RCT seems nowadays to be the gold standard in the evaluation of orthopaedic surgery as well. However, for determination of the long-term or rare outcome, the number of patients needed in the study is high, which causes difficulties in the study procedure. An arthroplasty register or administrative data might be used to retrieve the relevant information (Boutron et al. 2007.)

Since the introduction of the first national arthroplasty register of TKAs in Sweden in 1975, nationwide registers have been established in many other countries - in Finland in 1980 (Paavolainen et al. 1991, Kolling et al. 2007). Registers can provide methods of follow-up to provide nationwide feedback and quality control from an epidemiological point of view of widely used surgical tehniques like total hip arthroplasties (Herberts and Malchau 2000, Eskelinen 2005), but comparisons between registers in different countries of the use of certain prosthesis is difficult (Labek et al. 2008). A registry provides the nationwide mean for the outcome, for example, of revision TKAs as well (Sheng 2006b). As Robertsson (2007) has stated, registers may supply prospective follow-up of patients, but they cannot give detailed information nor replace the RCT. However, RCTs are quite laborious and costly processes and are not suitable for large studies over a long period of time (Robertsson 2007).

A nationwide epidemiological view can be reached by using adequate registers instead of studies of one centre. In this thesis, Study I was based on National Agengy for Medicines registers, and in Study III survival data was also collected from it. The endoprosthesis registers are based on the information supplied by hospitals. In each hospital reliable

databases depend ultimately on adequate completion of forms. Further, reporting schema should be the same in each hospital in order to provide reliable data on a nationwide scale. Problems in comparing the incidence of infected knee replacements between hospitals were noticed, when the data sources of the Finnish Arthroplasty Register and the Finnish Hospital Discharge Register were used, and the retrospective method may have problems with the quality of the data (Jämsen 2009). Further quality management in the registering chain is needed.

Study III encountered the problems of retrospective method. The number of cases in the groups differed, loss in follow-up was seen, and the results of old-fashioned design of patella component appeared not to be of interest in the orthopaedic study field. In prospective works the number of cases may be smaller than in retrospective studies, but the control over the variables may also be better.

In this study a fairly "old generation" model of TKA prosthesis was evaluated. On national level the survival of the prosthesis was perceived to be good, as reported in Study I. Two tibial components with varying materials and design were analysed in Study II, and no superiority of either model, modular or moulded, could be established. In Study III, on the analysis of patella resurfacing surprisingly good results were found in a mid-term follow-up with an old-fashioned metal-backed patella component. However, in a longer follow-up of AGC knee prosthesis failure of metal-backed patella has been reported (Emerson et al. 2000). In many studies, as discussed earlier, wear of polyethylene part of prosthesis has been reported to be a problem. In this study polyethylene wear was not estimated, because adequate measuring of wear, based on plain radiographs, appeared too challenging.

The development in the design of knee endoprosthetics continues, and prospective, randomised studies are needed to evaluate the various solutions. Modern TKA designs modified to achieve high degrees of flexion have been reported to achieve improved tibiofemoral contact biomechanics in high flexion when conventional and high-flexion cruciate-retaining models were compared in a cadaver study (Most et al. 2006). Weeden and Schmidt (2007) in a randomised, prospective study compared standard PS implant and a PS implant designed for increased flexion. After one year follow-up there was an improved degree of flexion in TKAs where implants designed for increased flexion were used. (Weeden and Schmidt 2007). In an in vivo radiographic study comparing PS tibial inserts and inserts designed to allow more flexion, the latter group achieved a wider range of motion (Coughlin et al. 2007). However, in a prospective randomised double-blind study no difference was found in functional outcome and range of flexion when standard and high flexion components were compared in a short term follow-up (Nutton et al. 2008).

Current issues in TKA studies have also included the kinematics of the components - fixed versus mobile-bearing - as well as the materials of the components. In a mid-term follow-up (mean 7.3 years) of TKAs with the Rotaglide mobile-bearing total knee system, functional, radiological and survival results were good both in the treatment of young patients with OA (74% of knees) as well as patients with RA (25% of knees) (Morgan et al. 2007). Mobile-bearing designs vary; increased backside wear of anterior-posterior-glide model compared to rotating platform design in the long run has arisen, although short-term results were similar (Kop and Swarts 2007).

In a review of trends in manufacturing polyethylene it was pointed out that new sterilization techniques and the use of more highly cross-linked polyethylene has to suit the whole range of design goals - questions of function, fixation and wear (Wright 2005). Highly crosslinked ultrahigh molecular weight polyethylene materials were introduced in late 1990's in total hip arthroplasty bearing surfaces, and they have also achieved good results in TKA designs in simulator testings (Kester et al. 2007, Wang et

al. 2008). Bioceramic models of TKA designs and in cemented ceramic design (Yokohama Medical Ceramic Knee) results in patients with RA in middle-term follow-up have been satisfactory with a survival rate of 99.1% at 8 years (Koshino et al. 2002). In the development of cementless implants porous metal devices have been produced. However, cemented fixation is still claimed to be the gold standard in fixation in TKA (Lombardi et al. 2007b).

Plain radiographs have often been used in monitoring the results of TKAs, as in Studies II, III and IV. The accuracy of standard radiographs – usually anteroposterior and sagittal views – is essential, otherwise radiolucency lines associated with loosening cannot be reliably interpreted (Lundberg-Jensen et al. 2002). Smith et al. (1999) concluded in their study of tibial radiolucent lines, that radiolucencies noticed in radiological follow-ups can be divided into two categories. The first type is nonprogressive, partial and thin. It is related to preoperative sclerosis and does not precede loosening. The other type of radiolucency is progressive, it occurs only when wear rate is greatly increased and expands quickly to indicate obvious areas of osteolysis (Smith et al. 1999.)

A radiostereophotogrammetric analysis has also been used to evaluate the micromotion of a prosthesis predicting mechanical failure (Lindstrand et al. 1999, Muller et al. 2006). Migration of the components measured by radiological follow-up of tantalum markers of bone and components indicates mechanical loosening, which has been reported to occur one or two years after TKA and before the onset of symptoms (Ryd et al. 1995). However, the radiostereophotogrammetric analysis method is not available for routine and extensive use in follow-up of TKA in Finland, and plain radiographs without detailed three-dimensional analysis of coordinating markers are likely to retain their position in postoperative assessments of TKAs – as in routine follow-ups of patients in RFH.

During this study, conventional jigs and manual instrumenting techniques in the alignment of TKA components were used in RFH. However, in the development of surgical techniques of total knee replacements, CAS is an emerging area, and a robot-assisted TKA is already available (Bargar 2007, Bellemans et al. 2007, Park and Lee 2007). Concerns about extra time consumption and prolonged operating time, training of personnel and accuracy of CAS have emerged, likewise doubts about the effect on revision and loosening rates (Callaghan et al. 2006).

On the other hand, CAS has been seen e.g. as a potential tool in intraoperative feedback and in surgical training (Stulberg et al. 2006, Cobb et al. 2007) as well as in improving the alignment of components (Confalonieri et al. 2007, Mullaji et al. 2007). In short-term follow-ups better component alignment has been reported with CAS (Ensini et al. 2006), but not in all studies; in an RCT of 100 patients with OA, computer-assisted navigation did not result in more accurate alignment of the components than with conventional knee replacement (Kim et al. 2007b). Furthermore, in the clinical outcomes no significant difference between computer navigation versus conventional manual methods were found (Spencer et al. 2007), and in a meta-analysis the clinical benefits of navigated TKA were reported to be unclear and remained to be defined on a larger scale (Bauwens et al. 2007). Both CAS and conventional alignment jig techniques rely on the accurate identification of bony morphology in orientating the prosthesis (Middleton and Palmer 2007).

However, CAS will also be a challenge in the orthopaedic treatment of RA patients, and it remains to be seen how CAS can help the surgeon in cases of fairly severe multiple joint deformities of RA. Longer follow-ups are still needed to estimate the effects of CAS on survival in knee arthroplasties.

In this dissertation some traditional questions of the orthopaedic research of TKA were analysed. Controversy over tibial designs and whether or not to resurface the patella remained. In the comparison of the success of total knee replacements between patients with RA and OA, no difference was found. This study presents no absolute solutions for the guidance of future treatment protocols. However, the results of total knee arthroplasties in treatment of surgically challenging RA knees with AGC prosthesis were good.

# 7. SUMMARY AND CONCLUSIONS

I The survival of AGC knee endoprostheses in total knee arthroplasties during the period 1985-1999 in the treatment of RA and OA patients were similar according to the data of the Finnish Arthroplasty Register. The revision rates were found to be higher in men and in younger patients.

II There was no difference in the survival of moulded monoblock and modular tibial components of the 751 AGC total knee arthroplasties in patients with rheumatoid arthritis treated in RFH during 1985-1995.

III Patellar resurfacing had no influence on the survival of TKA in patients with RA. In the short term resurfacing in TKA yielded slightly more favourable results with respect to anterior pain.

IV The AGC Dual Articular Knee prosthesis proved to be suitable for demanding primary and revision TKA in patients with rheumatic diseases with or without bone grafting and bone packing. Special attention should be paid to the patella area during surgery.

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# 10. ORIGINAL COMMUNICATIONS

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# Survival of the AGC total knee arthroplasty is similar for arthrosis and rheumatoid arthritis

Finnish Arthroplasty Register report on 8 467 operations carried out between 1985 and 1999

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ABSTRACT We report the survival of AGC knee endoprosthesis from the Finnish Arthroplasty Register for 2 indications, osteoarthrosis (OA, 6 306 knees) and rheumatoid arthritis (RA, 2 161 knees) during 1985–1999. Survivorship analysis was performed with revision as an endpoint. We found similar survival rates. In the OA group, survival after 5 years was 97% and it was 94% after 10 years. In the RA group the corresponding figures were 97% and 96%, respectively. There was no significant difference in survival whether or not cement was used for fixation. The revision rates were higher in men and in younger patients.

This report is based on data collected from the Finnish Arthroplasty Register, which is maintained by the National Agency for Medicines. The number of total knee arthroplasties (TKA) in Finland has increased during 1980–1999 from 295 to 4 380 operations per year, from 6/100 000 inhabitants to 85/100 000 (Nevalainen et al. 2000). During the same period, the number of hospitals performing TKA has risen from 19 to 64.

We report the survival of the AGC endoprosthesis which is used for the treatment of osteoarthrosis (OA) and rheumatoid arthritis (RA). This was one of the commonest implants used in Finland during 1985–1999, which is when the data used in the cur-

rent study were collected. We evaluated the effect of different demographic and clinical variables.

#### Patients and methods

From 1985 through 1999, 8 467 primary AGC (Anatomically Gratuated Component, Biomet, Warsaw, IN, USA) knee arthroplasties were performed on 7 209 patients. Of these, 1 102 patients died during the study. The operations took place in 54 hospitals. The median number of operations per unit was 43 (1–1269). We performed Kaplan-Meier survivorship analysis with an endpoint of revision defined as removal, exchange or addition of a prosthetic component. We used the proportional hazard model and Log-Rank test to test the survival curves, with a significance level of 0.05.

Prosthetic survival was studied separately in patients with OA and in patients with RA. In the OA group, the number of knees operated was 6 306, and the corresponding figure in the RA group was 2 161. The follow-up averaged 3.2 (0–14) years in OA and 5.2 (0–15) years in RA. The mean age was higher in the OA group than in the RA group: 69 years for males and 71 years for females, compared to 60 and 61 years in the RA group (Table 1). We also analyzed the effect of cement fixation, and when the operation was performed.

	Osteoarthr Men / Women		Rheumatoid a Men / Women	
Number of patients Number of knees Mean age in years (SD)	1 254 / 4 216 1 435 / 4 871 69 (8) / 71 (7)	5 470 6 306	332 / 1 407 404 / 1 757 60 (11) / 61 (13)	1 739 2 161

Table 1. Patient demographics

#### Results

In the OA group, survival after 5 years was 97%, and after 10 years of follow-up it was 94%. In the RA group, the corresponding figures were 97% and 96%, respectively (Figures 1 and 2). In both groups, men had a higher cumulative revision rate than women. In the OA group, survival was 94% for women after 10 years, as compared to 93% for men (p = 0.01). In the RA group, the 10-year survival rates were 96% and 93%, respectively (p = 0.004) (Tables 2 and 3).

83% of the patients were over 60 years of age (n = 6 984). The 10-year survival rates were better among older patients (p < 0.001 for the OA group, p = 0.007 for the RA group). In patients with arthrosis, 10-year prosthetic survival was 95% for patients older than 60 years, and 85% for patients younger than this. In the RA group, the corresponding figures were 97% and 94%, respectively (Tables 2 and 3).

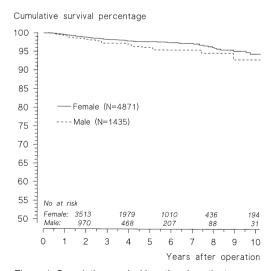


Figure 1. Cumulative survival in arthrosis patients.

In a proportional hazard model determining the effect of different variables on risk of loosening, diagnosis had no effect on the risk of loosening (relative risk (RR) = 1.25, 95% CI: 0.87–1.80, p = 0.2), nor had the use of cement (RR = 0.89, CI: 0.62–1.26, p = 0.5) or the time period of operation (p = 0.4). Gender and age were of importance: the relative risk for men was 1.66 (CI: 1.22–2.24, p = 0.001). With respect to the age factor, relative risk per year was 0.97 (CI: 0.96–1.26, p = <0.001). Younger patients had a higher risk for revision (Table 4).

#### Discussion

In our study, and most other studies, comparing the long-term survival of the TKA in patients with RA and patients with OA, no significant differences between the groups have been found (Scuderi et al. 1989, Elke et al. 1995). Surprisingly, in their 12-

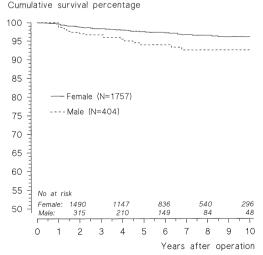


Figure 2. Cumulative survival in rheumatoid arthritis patients.

Table 2. Demographic	and	clinical	variables,	and	prosthetic	survival	rates	in
osteoarthrosis								

Variable	n	5-year survival % (95% CI)	10-year survival % (95% CI)	P-value <sup>a</sup>
Sex				0.01
female	4 871	97.7 (97.1-98.2)	94.4 (92.3-96.0)	
male	1 435	96.1 (94.5–97.3)	92.9 (87.5–96.0)	
Age (years)				< 0.001
≤ 60	570)	95.9 (93.3-97.5)	84.2 (72.6-91.2)	
> 60	5 736	97.5 (97.0-98.0)	95.3 (93.7-96.5)	
Cement				0.4
used	1103	97.5 (96.8-98.0)	93.5 (87.6-96.6)	
not used	5203	97.6 (95.9-98.0)	93.6 (91.6-95.6)	
Year of operation				0.6
1985-1989	252	98.3 (95.6-99.4)	95.1 (91.0-97.4)	
1990-1994	1 432	97.5 (96.5-98.2)	94.4 (91.9-96.2)	
1995–1999	4 622	97.2 (96.4–97.9)	_	

<sup>&</sup>lt;sup>a</sup> Log-Rank test for difference in survival curves between groups.

Table 3. Demographic and clinical variables, and prosthetic survival rates in rheumatoid arthritis

Variable	n	5-year survival % (95% CI)	10-year survival % (95% CI)	P-value <sup>a</sup>
Sex				0.004
female	1 757	97.5 (96.5-98.2)	96.1 (94.7-97.1)	
male	404	94.0 (90.4–96.2)	92.6 (88.4-95.3)	
Age (years)				0.007
≤ 60	913	95.8 (94.1-97.0)	93.9 (91.7-95.6)	
> 60	1 248	97.9 (96.7-98.6)	97.1 (95.6-98.1)	
Cement				0.5
used	827	97.0 (95.6-97.9)	96.5 (95.0-97.6)	
not used	1 334	96.9 (95.4-97.9)	94.9 (92.9-96.4)	
Year of operation				0.7
1985-1989	446	97.4 (95.3-98.5)	96.0 (93.5-97.5)	
1990-1994	845	97.0 (95.6-98.0)	95.7 (93.8-97.0)	
1995–1999	870	96.7 (94.6–97.9)	_	

<sup>&</sup>lt;sup>a</sup> Log-Rank test for difference in survival curves between groups.

Table 4. Proportional hazard model to determine the effect of variables on risk of loosening

Variable	Relative risk (95% CI)	P-value
Diagnosis (OA) Sex (male) Age (per year) Cementing Year of operation 1985–1989 1990–1994 1995–1999	1.25 (0.87–1.80) 1.66 (1.22–2.24) 0.97 (0.96–0.99) 0.89 (0.62–1.26) 1.00 (indicator) 1.28 (0.81–2.03) 1.47 (0.86–2.52)	0.2 0.001 < 0.001 0.5 0.4

year follow-up, Nafei et al. (1996) reported 87% survivorship in patients with RA as compared to 97% survivorship in patients with OA. On the other hand, Rand and Ilstrup (1991) documented better survival rates in patients with RA than in patients with OA (83% vs. 80%) in a 10-year follow-up.

We found no difference in the survival of TKAs whether or not cement was used. The outcome of cemented and cementless arthroplasties has been discussed in many studies. Lybäck et al. (2000) documented 99% overall survival after up to 13 years of AGC knee endoprosthesis in juvenile

chronic arthritis, and found cementless fixation to be better. Nielsen et al. (1992) studied cementless fixation of AGC TKAs in unselected cases of OA and RA. Their results favored the use of cementless fixation, but the authors emphasized the importance of good fit of the tibial component. Bassett (1998) reported excellent clinical results with cementless fixation in the treatment of osteoarthrotic knees, and Nafei et al. (1996) observed a 92% overall survival rate for the cemented TKA at 12 years.

During the time period of 1980–1999, the 9-year-survival rate in the Finnish Arthroplasty Register was 93% for the 3 most used cemented knee prostheses in the OA group, and the 13-year-survival rate was 76% for the three most used uncemented endoprostheses. In RA, the 15-year-survival rate was 84% for the three most used cemented prostheses, and for the uncemented models the 14-year-survival rate was 82% (Nevalainen et al. 2000). Comparing AGC prostheses with the three models combined, AGC gave better survival rates. Although the AGC prostheses have an "old-fashioned" flat-on-flat design, the results can be considered to be good.

The most common indication for revision knee arthroplasty in 1999 in Finland was patellar complications (Nevalainen et al.2000). Primary resurfacing can cause complications such as wear, patellar fractures and dislocation. Non-resurfacing, on the other hand, can lead to anterior knee pain, and finally to secondary resurfacing. Some studies have shown resurfacing to be better (Wood et al. 2002, Enis et al. 1990), but in some studies the outcome has been just the opposite (Bourne et al. 1995). The question of whether to resurface the patella or not in total knee arthroplasty is still unresolved. Our register study does not provide enough data to answer this question.

Our findings have similarities with the report from the Swedish Knee Arthroplasty Register of primary operations in patients with RA (1985–1995). Both in Finland and in Sweden, sex and age had an effect on prosthetic survival. Women and older patients (> 55 years) had better survival rates (Robertsson et al. 1997). The natural consequence of the ageing of the population is that the number of patients treated for OA is increasing with time (Knutson et al. 1994, Robertsson et al. 2000).

No competing interests declared.

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# A comparison of survival of moulded monoblock and modular tibial components of 751 AGC total knee replacements in the treatment of rheumatoid arthritis

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From Rheumatism Foundation Hospital, Heinola, Finland We evaluated the survival of moulded monoblock and modular tibial components of the AGC total knee replacement in patients with rheumatoid arthritis. Between 1985 and 1995, 751 knees with this diagnosis were replaced at our institution. A total of 256 tibial components were of the moulded design and 495 of the modular design. The mean follow-up of the moulded subgroup was 9.6 years (0.5 to 14.7), and that of the modular group 7.0 years (0.1 to 14.7).

The groups differed significantly from each other in Larsen grade, cementing of components and patellar resurfacing, but no statistically significant difference between the survival of the components was found (Log rank test, p = 0.91). The cumulative success rate of the moulded group was 96.8% (95% confidence interval 93.6% to 98.4%) at five years and 94.4% (95% confidence interval 90.4% to 96.7%) at ten years, and of the modular group 96.2% (95% confidence interval 94% to 97.6%) and 93.6% (95% confidence interval 89.7% to 96%), respectively. Revision was required in 37 total knee replacements, the main causes were infection, pain, loosening of the tibial component and patellar problems. Survival rates for both components were satisfactory.

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J Bone Joint Surg [Br] 2007;89-B:609-14. Received 27 March 2006; Accepted after revision 11 January 2007 Total knee replacement (TKR) usually provides good results in patients with rheumatoid arthritis, but can be technically difficult owing to the poor quality of the bone and the surrounding soft tissues. <sup>1-3</sup> High levels of satisfaction for relief of pain and range of movement with low rates of revision have been reported. <sup>4-7</sup> A significantly lower risk of failure in TKR has been associated with rheumatoid arthritis as the underlying diagnosis. <sup>8</sup> However, some studies have reported worse outcomes in rheumatoid arthritis than in osteoarthritis. <sup>9,10</sup>

Flat-on-flat total condylar knee prostheses were developed in order to achieve a low rotational constraint and to preserve posterior femoral rollback and normal knee joint function. 11 In the evaluation of 34 000 TKRs, the AGC knee (Anatomically Graduated Components, Biomet Inc., Warsaw, Indiana) had a lower revision rate than any other design.<sup>12</sup> The prevention of tibial loosening and polyethylene wear have been challenging in the development of the tibial component of flaton-flat designs. Problems have been encountered with thin polyethylene with a flat surface, resulting in line contact rather than area contact, which produces high contact stresses and accelerated rates of wear. 11,13-15

Modular tibial components have been widely adopted, offering the intra-operative option of changing the thickness of the polyethylene components. Additionally, at revision the possibility of an isolated tibial insert exchange while retaining well-fixed components is available. However, disadvantages of modularity include breakage of modular couplings, fretting and corrosion of the modular baseplate, and backside wear of the polyethylene insert. <sup>17</sup>

The purpose of this study was to evaluate differences in the survival of moulded and modular AGC tibial components in patients with rheumatoid arthritis at mid-term follow-up.

#### **Patients and Methods**

Between September 1985 and December 1995 a total of 586 patients (106 males, 480 females) with rheumatoid arthritis underwent TKR using the AGC prosthesis. Of these, 165 patients had bilateral replacements during the study, producing a total of 751 replacements. The surgery involved 12 surgeons at our institution (Rheumatism Foundation Hospital). The TKRs were performed using non-constrained, posterior cruciate-retaining flat-on-flat components. Two versions of tibial component were used: the moulded tibial component, in which compression-moulded ultra-high-

Table I. Demographics and clinical data of the 586 patients who had AGC total knee replacement

	Group A	Group B	
Variables	(Moulded n = 256)	(Modular n = 495)	p-value
Demographics			
Number of females (%)	215 (84)	406 ( <i>82</i> )	0.50
Mean age in yrs (range)	58 (23 to 80)	60 (24 to 84)	0.098
Mean weight in kg (range)	66 (36 to 101)	68 (37 to 125)	0.018
Clinical			
Number of Larsen grade 5 (9	%) <sup>*</sup> 186 ( <i>74</i> )	288 ( <i>62</i> )	< 0.001
Number cemented (%)	142 ( <i>55</i> )	318 ( <i>64</i> )	0.019
Patella resurfaced (%)			< 0.001
None	81 ( <i>32</i> )	360 ( <i>73</i> )	
Metal-backed	170 ( <i>66</i> )	81 ( <i>16</i> )	
All-polyethylene	5 ( <i>2</i> )	54 ( <i>11</i> )	

\*there were 32 anteroposterior radiographs missing from the study group, so there were only 253 in group A and 466 in group B

molecular weight polyethylene (UHMWPE) was attached directly to a cobalt chrome metal tray with a central stem by the manufacturer; and the modular design, in which there was a baseplate of titanium into which the surgeon inserted a modular power-milled polyethylene component at operation. The moulded model was the original AGC design, and the modular model was introduced in 1989. A total of 256 tibial components were of the moulded design (group A) and 495 of the modular design (group B). The patients were allocated depending on the year of the operation and the component available to the surgeon at that time. The differences between groups in component fixation (cemented/cementless) were also analysed (Table I). If cement was used, all components were cemented; there were no hybrids. Whether cement was used was dependent on the operating protocol at the time of operation and whether intra-operative circumstances required it.

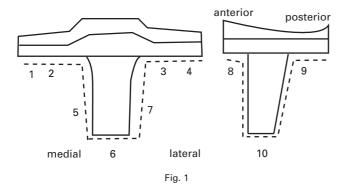
Clinical and radiological data were collected from the patient documents, radiographs and European League against Rheumatism (EULAR) charts<sup>18</sup> by the surgeons. Deaths and causes for revision surgery were gathered from the National Arthroplasty Register. Pre-operative details, including the patient's age, gender, weight and the Larsen, Dale and Eek<sup>19</sup> grade of the arthritic change ranging from 0 to 5 points, in which 0 is a normal knee and 5 represents severe destruction are also shown in Table I.

The two groups differed significantly with regard to the number of knees assessed as Larsen grade 5, the numbers of cemented components and patellae resurfaced, and also the mean weight. There were 186 Larsen grade 5 knees in group A, and 288 in group B. Cementing was the most common form of fixation. A total of 142 TKRs (55%) were cemented in group A and 318 (64%) in group B. The femoral component was made of cobalt-chromium, and the design was universal with no specific geometry for the right or left side. The contact between the femoral and tibial component was of a non-constrained line-type. The patella was resurfaced in 310 cases, of which 59 were all-polyethylene components (5 in group A, 54 in group B) and 251 were of a metal-

backed design (170 in group A and 81 in group B). In group A 175 (68%) of the patellae were resurfaced. In group B the patella was resurfaced only in 135 (27%) of the knees. The mean weight of the patients was 66 kg (36 to 101) in group A, and 68 kg (37 to 125) in group B, and the mean age of the patients in group A was 58 years (23 to 80), and in group B 60 years (24 to 84) (Table I).

The incidence of radiolucent lines at the bone-cement or bone-implant interfaces was determined by examination of orthogonal anteroposterior and lateral radiographs. The results were recorded as millimetres by the zone of the tibial component<sup>20</sup> (Fig. 1) by a researcher (A-KH). Radiolucent lines were defined as any parallel-sided gap greater than 1 mm in width at the interface. The position of the tibial component was measured on plain radiographs relative to the long axis of the tibia in both sagittal and coronal planes, by analysing the anteroposterior slope of the tibial component from a lateral projection, and the tilt of the component from an AP projection. The accuracy of the measurements was within 1°. Clinical outcome was estimated according to the EULAR post-operative assessment chart, which assesses general locomotor status, detailed symptoms, functional ability and the findings of the physical examination.<sup>21</sup> Ability to climb stairs with a reciprocating gait without using a hand rail, to walk more than 1 km without interruption and the absence of pain were regarded as signs of clinical success. Clinical and radiological parameters were followed up for four years post-operatively.

Kaplan-Meier<sup>22</sup> survival analysis was applied to the tibial component. Death of the patient, the end of the year 2000, or revision surgery with removal, exchange or addition of any prosthetic component, served as end-points. The mean follow-up was 7.9 years (0.1 to 14.7). For group A alone the mean follow-up was 9.6 years (0.5 to 14.7) and for group B, follow-up was 7 years (0.1 to 14.7). At the start of our study only the moulded tibial component was implanted, and from 1989 both moulded and modular models were used. At the beginning of the 1990's the modular design was favoured, especially in younger patients,

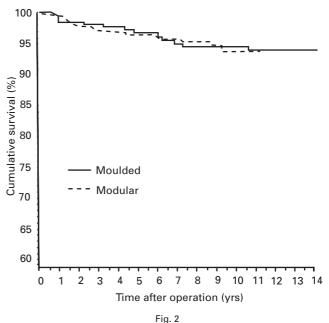


Tibial zones in radiological analysis of radiolucent lines.

**Table II.** Proportional hazard model to determine the effect of variables on the risk of revision of the AGC prostheses in rheumatoid arthritis

Variable	Hazard ratio* (95% CI†)	p-value
Female gender	0.62 (0.29 to 1.42)	0.27
Age (per year)	0.98 (0.95 to 1.01)	0.24
Weight (per kg)	1.01 (0.99 to 1.03)	0.45
Larsen grade 5	1.30 (0.59 to 2.86)	0.64
Cemented	1.52 (0.56 to 4.14)	0.41
Patella resurfaced		
None	Reference <sup>‡</sup>	
Metal-backed	1.52 (0.70 to 3.31)	0.29
All-polyethylene	1.95 (0.60 to 6.33)	0.27
Modular type of tibia component	1.15 (0.51 to 2.57)	0.74
Tibial tilt	1.10 (0.47 to 2.58)	0.83
Tibial slope		
Neutral	Reference <sup>‡</sup>	
Anterior	3.06 (0.68 to 13.71)	0.14
Posterior	1.93 (0.44 to 8.46)	0.38

<sup>\*</sup> calculated using robust estimate of variance



Cumulative survival of moulded and modular subgroups of the AGC knees (please see text for information on confidence intervals).

**Table III.** Percentages of radiolucent lines in the tibial zones of the moulded and modular tibial designs of AGC knee prosthesis

	Four years cumulativ		
Zone	Group A (moulded) (95% CI*)	Group B (modular) (95% CI)	p-value
1	17 (11 to 26)	17 (12 to 24)	0.98
2	11 (7 to 20)	7 (4 to 13)	0.27
3	7 (4 to 15)	7 (4 to 13)	0.90
4	13 (8 to 22)	12 (8 to 19)	0.92
5	6 (2 to 13)	4 (2 to 8)	0.75
6	1 (0 to 8)	3 (1 to 8)	0.40
7	6 (3 to 14)	3 (1 to 8)	0.24
8	36 (28 to 46)	20 (15 to 27)	0.002
9	26 (19 to 36)	14 (10 to 21)	0.011
10	4 (2 to 10)	5 (2 to 10)	0.96

<sup>\* 95%</sup> CI, 95% confidence interval

but no formal process of randomisation was applied for this study.

**Statistical analysis.** The results were expressed as the mean, range, and 95% confidence intervals (CI). Statistical comparison between the groups was performed using the t-test or the chi-squared test. A p-value < 0.05 was considered statistically significant. The prognostic factors predicting the duration of the revision-free survival time were analysed using Cox's multivariate proportional hazard regression models. Cumulative success rate was constructed using the Kaplan-Meier<sup>22</sup> method, and differences between the groups was tested by using the permutation type log-rank test. Success was defined as a prosthesis still *in situ* at the

end of the follow-up, regardless of clinical score or radiological findings.

#### Results

The Cox's proportional hazard regression analysis assessing the effect of variables on the risk of revision of the AGC prostheses found that the demographic variables of gender, age and weight, and clinical variables, including Larsen grading, use of cement, resurfacing of the patella, type of tibial component or its post-operative positioning, had no statistically significant influence on the risk of revision (Table II).

<sup>† 95%</sup> CI, 95% confidence interval

<sup>‡</sup> denominator of hazard ratio

Table IV. Clinical results at the four year post-operative followup of AGC total knee replacements

	Tibial component			
	Group A (moulded)	Group B (modular)	p-value*	
Pain (%)				
No	78	75	0.61	
Yes	22	25		
Walking ability (%)				
> 1 km	50	40	0.15	
< 1 km	50	60		
Ascending etc (%)				
Reciprocating gait	21	29	0.24	
Non-reciprocating gait	79	71		

<sup>\*</sup> chi-squared test

Table V. Causes for revision surgery of the AGC in rheumatoid arthritis

	Group A	Group B
Variables	(Moulded n = 14)	(Modular n = 23)
Pain	2	5
Poor range of movement	0	1
Instability	2	0
Migration of component		
Tibial	2	5
Femoral	1	0
Patellar	0	1
Fracture of patellar component	1	2
Fracture		
Femur or tibia	1	2
Patella	0	1
Infection	5	5
Audible patellar crepitus	0	1

<sup>\* 95%</sup> CI, 95% confidence interval

There was no statistically significant difference between the cumulative success rates in the two groups (Log rank, p =0.91). The cumulative success rate in group A at five years was 96.8% (95% CI 93.6% to 98.4%) and 94.4% at ten years (95% CI 90.4% to 96.7%). In group B the survival rate was 96.2% (95% CI 94.0% to 97.6%) at five years and 93.6% (95% CI 89.7% to 96.0%) at ten years (Fig. 2).

Cumulative success rates for the femoral component at five years and ten years in group A were 98.0% (95% CI 95.2% to 99.1%) and 96.6% (95% CI 93.2% to 98.3%), respectively. The cumulative success rates for the femoral component at five and ten years in group B were 98.7% (95% CI 97.2% to 99.4%) and 97.7 (95% CI 94.8% to 99.0%), respectively. The cumulative success rates for the tibial component in group A were 98.0% (95% CI 95.1% to 99.1%) at five years and 95.6% (95% CI 91.9% to 97.6%) at ten years and in group B were 97.5% (95% CI

95.6% to 98.6%) and 96.4% (95% CI 93.5% to 98.0%), respectively.

On radiological follow-up there was no statistically significant difference between the groups with respect to the radiolucent lines in the zones estimated from the anteroposterior radiographs (zones 1 to 7). Surprisingly, there were more radiolucent lines in the moulded group when sagittal zones indicating anterior and posterior translucencies were examined (chi-squared test, zone 8, p = 0.002; zone 9, p = 0.011) (Fig. 1, Table III). The clinical outcome did not differ significantly between the groups, judged by the subjective assessment of the severity of pain, the uninterrupted walking ability and the ability to ascend and descend stairs at the four-year post-operative evaluation (Table IV).

At the end of the survey, 37 knees had undergone revision; for infection in ten, pain in seven and loosening of the tibial component in seven. Revision was undertaken in six knees because of patellar problems: a fracture of the patella had occurred in one knee, and a fracture of the patellar component in three, audible crepitus was heard from the patella in one knee, and migration of the patellar component occurred in one case. Migration of the femoral component occurred in one case. Instability caused revision in two cases, and fracture of the femur in two and of both the tibia and femur in one, and one knee with a poor range of movement accounted for the remaining revision. Pain was mostly located anteriorly, suggesting a patellar origin. Accordingly, in six knees the patella was resurfaced at revision (Table V). Subsidence or change in the position of the tibial component indicating aseptic loosening was slightly more common in the modular group (two in group A and five in group B).

#### **Discussion**

This study is one of the largest series of TKRs in patients with rheumatoid arthritis. The AGC prosthesis has given good results in difficult cases of juvenile chronic arthritis<sup>23</sup> as well as in treating patients with osteoarthritis or rheumatoid arthritis.<sup>24</sup> In the latter condition TKRs tend to survive longer than in osteoarthritic patients,<sup>8</sup> possibly because of the reduced activity levels. A study examining outcome of patients with rheumatoid arthritis treated with a posterior cruciate ligament (PCL)-retaining prosthesis identified a high rate of posterior instability and recurvatum deformity, resulting in revision at which the PCL was found to be absent and synovial reaction was present. A posterior stabilised prosthesis was thought to be the preferred choice in these circumstances.<sup>25</sup> However, in our patients this was not a major cause of revision.

We found no significant difference between the survival of moulded and modular tibial components. In most other studies a slight superiority of the moulded design has been noted. In a series of 4583 AGC TKRs, a survival rate of 98.86% at 15 years was found with 36 knees at risk. The advantage of the moulded design in eliminating back-sided

wear of the polyethylene component was emphasised.<sup>26</sup> A 90% survival at ten years for modular metal-backed tibial components and 92% survival for the non-modular design has been reported in another study.<sup>27</sup> In a series of 1071 primary AGC TKRs, better clinical and radiological results were achieved with a compression-moulded monoblock than with a modular design.<sup>28</sup> A study involving 3152 AGC prostheses with moulded tibial components identified 41 tibial failures (1.3%).<sup>29</sup> The main mechanisms of failure for moulded tibial components with cemented fixation was collapse of the medial tibial plateau, ligamentous imbalance, progressive radiolucencies and pain.<sup>29</sup>

The difference between the groups in the incidence of radiolucencies noticed in anterior and posterior zones raised questions about the significance of the I-beamshaped tibial stem in the moulded tibia and the fluted stem in the modular design. Peters et al,<sup>30</sup> in their biomechanical study on cadavers mentioned no differences in tibial component motion between I-beam and cruciate-shaped stemmed components fixed with the surface-cemented technique in a limited loading protocol, which did not include testing with torsion or shear. The clinical relevance of the radiolucencies noticed can also be debated. Smith, Naima and Freeman<sup>31</sup> found early-onset radiolucent lines beneath the tibial cement to be related to the presence of pre-operative sclerosis, and to be non-progressive and having no effect on fixation. In our study, neither the different tibial stem designs nor the differences between cemented zones were analysed.

In this study revision surgery was the end-point, not the radiological changes. The polyethylene wear was not analysed, but backside wear and cold flow are concerns in modular tibial designs.<sup>32</sup> Micromotion causing fretting at the modular interface has been reported, and improvements in locking mechanisms have been recommended.<sup>32</sup> In an analysis of different modular inserts, wear of the non-articulating surface of the tibial insert occurred frequently, independently of the capture mechanism.<sup>33</sup> From this point of view, the moulded component, in which UHMWPE has been compression moulded directly to the baseplate, might offer advantages in avoiding the production of polyethylene debris and osteolysis.<sup>26,34-36</sup>

The mid-term mean follow-up of 7.9 years may be too soon for backside wear of the modular design to be apparent. Additionally, the follow-up of the modular group was shorter than that of the moulded group.

There was a statistically significant difference in the number of knees graded as Larsen 5 between the moulded and modular groups. Despite the severity of the rheumatoid process, surprisingly few revisions were due to problems with the patella, even with the old-fashioned, metal-backed design, which was mainly in use at the beginning of the study.

Our mid-term follow-up results using the AGC prosthesis in TKRs in patients with rheumatoid arthritis are satisfactory using either the moulded or the modular tibial

component. Neither fixation of the tibial and femoral components (cemented/cementless), resurfacing of the patella, or the type of patellar component had an impact on survial. It may be that a longer follow-up will be required to reveal any difference in outcome for the two types of tibial component.

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#### **Supplementary Material**

A further opinion by Dr K Trieb is available with the electronic version of this article on our website at www.jbjs.org.uk

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