



TIMO PUOLAKKA

# Cementless Total Hip Prosthesis and Polyethylene Liner Wear

## A Study of the Finnish Arthroplasty Register, Clinical and Radiological Outcomes and Retrieval Analyses



ACADEMIC DISSERTATION

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## **ACADEMIC DISSERTATION**

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*In memory of my father*

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# 1. List of original communications

This dissertation is based on the following studies, referred to in the text by their Roman numerals I-V.

- I Puolakka TJS, Pajamäki KJJ, Halonen PJ, Pulkkinen PO, Paavolainen P, Nevalainen JK (2001): The Finnish Arthroplasty Register. Report of the hip register. *Acta Orthop Scand* 72:433-441.
- II Puolakka TJS, Pajamäki KJJ, Pulkkinen PO, Nevalainen JK (1999): Poor survival of cementless Biomet® total hip. A report on 1047 hips from the Finnish Arthroplasty Register. *Acta Orthop Scand* 70:425-429.
- III Puolakka TJS, Laine H-J, Moilanen TPS, Koivisto AM, Pajamäki KJJ (2001): Alarming wear of the first-generation polyethylene liner of the cementless porous-coated Biomet Universal cup. 107 hips followed for mean 6 years. *Acta Orthop Scand* 72: 1-7.
- IV Puolakka TJS, Laine H-J, Moilanen TPS, Pajamäki KJJ (2002): Resistance of the porous coated cementless Bi-Metric femoral stem against excessive polyethylene debris. Excellent clinical outcome, radiographic appearance and survival after 5 to 9 year follow-up. Submitted to *J Arthroplasty*.
- V Puolakka TJS, Keränen JT, Juhola KA, Pajamäki KJJ, Halonen PJ, Nevalainen JK, Saikko V, Lehto MUK, Järvinen M: Increased volumetric wear of polyethylene liners with more than 3 years of shelf-life time (2003). *Int Orthop*. 27:153-159. Epub 2003 Apr 01.

## 2. Abbreviations

AP	anteroposterior
ASTM	American Society for Testing and Materials
CAD	computer aided design
CEN	European Committee for Standardization
CMM	coordinate measuring machine
CoCr	cobalt-chrome
DSC	differential scanning calorimetry
EDS	energy dispersive X-ray analysis system
FDA	Food and Drug Administration
FTIR	Fourier transform infrared spectrometer
HHS	Harris hip score
HMWP	high-molecular-weight polyethylene
IGES	initial graphics exchange specification
ISO	International Organization for Standardization
OI	oxidation index
PTFE	polytetrafluoroethylene
RB	revision burden
RLL	radiolucent lines
SEM	scanning electron microscope
THA	total hip arthroplasty
THR	total hip replacement
UHMWPE	ultra-high-molecular-weight polyethylene

### 3. Introduction

Sir John Charnley initiated work in this field in 1962 with low-friction arthroplasty using a metal head and an ultra-high-molecular-weight polyethylene (UHMWPE) socket bearing couple (Charnley 1979). Eventually his concept of cemented low-friction arthroplasty became a worldwide success. UHMWPE has come to constitute the material of choice for bearing surfaces in total hip arthroplasties (THA) due to its high abrasion resistance, low friction, high impact strength, excellent toughness, low density, ease of fabrication, biocompatibility and biostability (Lewis 1997). Clinical results of THAs have been unique, excelling almost any other results in modern surgery. After THA patients almost invariably become painless and regain normal mobility of the joint (Charnley 1979). The median age of THA patients has been 70 years in Norway and Sweden (Havelin et al. 1993, Herberts and Malchau 2000). According to reports on this patient group there are good prospects of a lifelong solution using cemented THA, as the ten-year survival of THA has been over 90% (Herberts and Malchau 1997). This notwithstanding, an increasing number of aseptically loosened cemented hips, particularly among young patients (Chandler et al. 1981, Dorr et al. 1983), has prompted a search for other designs in order to ensure a permanent solution also among these. The early results with cementless designs were indeed promising (Lord and Bancel 1983, Callaghan et al. 1988, McKenzie et al. 1990), but unfortunately new problems arose especially in respect of polyethylene wear. Several reports of early UHMWPE wear have been published (Berry et al. 1994, Chmell et al. 1996) and nowadays osteolysis in reaction to polyethylene wear particles is regarded as the main long-term problem in THA (Santavirta et al. 1990b, Harris 2001).



The purpose of this study was to analyze factors related to the outcome of cementless total hip prostheses and especially to the wear of polyethylene liners and its influence on results of cementless THA.

## **4. Review of the literature**

### ***4.1. The evolution of total hip arthroplasty***

Smith-Petersen introduced his mould arthroplasty in 1923, experimenting with glass, pyrex and bakelite. These materials broke during use. He started with vitallium cup arthroplasty in 1938 (Smith-Petersen 1939). Although Law and Manzoni (1970) reported some satisfactory long-term results after 12-21 years, the use of vitallium mould arthroplasty was discontinued, because in general results were poor. In the long term the neck of the femur is absorbed and the mould falls into contact with the trochanters, preventing movement and causing pain. The first total hip arthroplasty was done in England in 1938, when Philip Wiles fitted six patients with cementless matched acetabular and femoral components made of stainless steel as hip replacements. The acetabulum was stabilized with screws and the head component with a bolt passing through the neck of the femur. Thirteen years later one patient was still alive, had no pain and could walk a little. Radiography revealed that both components were loose (Wiles 1958).

McKee and Watson-Farrar introduced a cementless hip replacement of ball and socket type. The fixation of this cup was achieved with a threaded peg screwed into the acetabular roof. For long-term performance this cementless fixation was found to be insufficient (McKee and Watson-Farrar 1966). It is nevertheless of note that cemented McKee-Farrar arthroplasty with metal-on-metal bearings subsequently had good twenty-year long-term results comparable to those with the Charnley low-friction prosthesis (Jacobsson et al. 1996). Visuri et al. (1987) did not report as good results in Finland.

In 1964 Peter Ring developed his own self-locking cementless design made of cobalt-chrome. The femoral component had a smooth surface and the socket was fixed to the ileum with a screw (Ring 1968). After eleven to fourteen years only 56% of cases gave satisfactory

results (Ring 1978). In Russia Sivash (1969) developed his own smooth-textured cementless design, which was widely used in Eastern Europe until the 1990s. All these early cementless designs had metal-on-metal bearings.

In view of the high friction inherent in metal surfaces, Charnley tested different bearing couples to solve the problem, starting with polytetrafluoroethylene (PTFE), which however evinced poor wearing properties. The first hips using high-molecular-weight polyethylene material (HMWP) were implanted in 1962 (Charnley 1979). Later Charnley's concept of the cemented low-friction arthroplasty with an HMWP cup and stainless steel femoral stem attained worldwide success.

Even though cemented low-friction arthroplasty proved superior to previous designs, the increasing number of aseptically loosened cemented hips, particularly among young patients (Chandler et al. 1981, Dorr et al. 1983), led to the development of the cementless fixation concept. The use of cementless prostheses was claimed to avoid "cement disease" (Jones and Hungerford 1987).

The cementless hip prosthesis with smooth surfaces has however yielded poor results (Tallroth et al. 1993, Fox et al. 1994, Savilahti et al. 1995, Malchau et al. 1996). Bone ingrowth into the porous surface of the endoprosthetic component is considered essential in cementless hip arthroplasty (Galante and Jacobs 1992, Laine 2001). Also textured surfaces (i.e., surfaces roughening by grit-blasting) provide an excellent surface for bone implant integration (Goldberg et al. 1995). The optimum pore size for osseous fixation has been estimated to be 50 $\mu$ m -400 $\mu$ m (Bobyne et al. 1980), but pore sizes of 1 to 2mm have also given good clinical results (Malchau et al. 1996). The clinical success of biologic fixation by bone ingrowth also requires a stable implant–bone interface (Cameron et al. 1973).

Several cobalt-chrome-molybdenum cementless prostheses have been developed. In Germany Mittelmeier (1974) introduced his cementless ceramic-on-ceramic Autophor

prosthesis with smooth stem and several macro holes. A very rough-surfaced porous metal femoral component with both macro- and microporosity was introduced by Judet and associates in 1976 (1978). Furthermore, to avoid stress shielding on the proximal femur an isoelastic prosthesis was introduced (Morscher and Dick 1983).

A great deal of research has been done to promote biologically more viable fixation by providing a stem with a porous surface and allowing for bone ingrowth (Bobyne et al. 1975, Bobyne et al. 1980). In France Lord (Lord et al. 1979) introduced a cementless femoral component with rough “madreporeque” surface. Small balls for bone ingrowth formed a coral-like surface. The socket was metal-backed and smooth threaded with polyethylene liner. In the USA Engh (1983) introduced a porous-coated cobalt-chrome-molybdenum femoral component and later an extensively porous-coated Anatomic Medullary Locking stem (Engh Jr et al. 1997). A titanium-fiber coated Harris-Galante prosthesis was correspondingly developed by William Harris and Jorge Galante (Martell et al. 1993). Likewise several porous coated titanium alloy prostheses have been introduced and used worldwide (Mallory and Mitchell 1990, Cautilli et al. 1994, Robertsen et al. 1996).

#### **4.2. Bearing materials**

In the first total hip replacement in 1938 stainless steel in a metal-on-metal bearing surface was used (Wiles 1958). Charnley introduced polytetrafluoroethylene (PTFE) as a bearing material in late 1950s. PTFE has a low coefficient of friction but poor wearing properties. With PTFE acetabular cups clinical failures occurred within a 1- to 2-year time period. After 300 operations PTFE was abandoned in 1961 (Charnley 1979). As noted at the outset, the first hips using high-molecular-weight polyethylene and stainless steel femoral component were implanted in 1962 (Charnley 1979).

Also other materials have been studied. Polyacetal, sometimes called polymethylene oxide, had the potential advantages of higher yield strength, higher crystallinity and ease of

manufacture. In pin-on-disk wear tests polyacetal had lower wear rates than polyethylene (Galante and Rostoker 1973). In clinical use, however, polyacetal sockets showed four times greater volumetric wear than Charnley polyethylene sockets in retrieval analyses (Mathiesen et al. 1986) and the revision rates for the polyacetal Christiansen devices were up to 7 times higher than for the Charnley prostheses (Sudmann et al.1983, Alho et al. 1984).

Polyester can be easily manufactured and successfully used in industrial bearing applications. Familiar polyesters are nylon and Dacron. However, polyester in bearing surfaces yielded poor results with progressive bone resorption. Over 50% of Weber-Huggler prostheses with rotational ball heads made of polyester had to be revised during a ten-year follow-up period (Willert et al. 1980)

In the late 1970s, efforts to reduce creep (cold flow) and wear of UHMWPE led to the development of a composite of carbon fibers and UHMWPE. The carbon-fiber-reinforced, high-molecular-weight polyethylene (Poly II) appeared to have increased resistance of the polyethylene-gliding surface in vitro testing. However, in clinical use its function proved unacceptable and its use was discontinued in view of fatigue resistance and wear (Li and Burnstein 1994, Korkala and Syrjänen 1998).

Ceramic materials used in the manufacturing of femoral heads have been either aluminium oxide or zirconium oxide. Ceramic materials evince a marked hardness and abrasion resistance. There are reports that ceramic-polyethylene bearing couples are less vulnerable to wear than chrome-cobalt–polyethylene bearings (Schuller and Marti 1990, Zichner and Willert 1992, Saikko 1995, Clarke and Gustafson 2000). However, in several recent articles both alumina- and zirconia-polyethylene pairings have failed to ensure benefits despite the theoretical advantages (Allain et al. 1999, Sychterz et al. 2000, Haraguchi et al. 2001a and b, Kim et al. 2001, Norton et al. 2002).

Ceramic-on-ceramic bearings have extremely low wear rates under ideal conditions. In addition they are harder and more resistant than metal alloys to damage by third-body particles (Schmalzried and Callaghan 1999). In the first generation alumina-on-alumina bearings the fracture risk was as high as 13% (Hamadouche and Sedel 2000), whereas the second- and third generation ceramics have involved lower fracture rates. Currently the failure rates of ceramic femoral heads are in the region of 0.004% (Bierbaum et al. 2002). In vivo studies after sixteen to twenty years have revealed low degrees of wear (Mittelmeier and Heisel 1992, Huo et al. 1996, Hamadouche et al. 2002). However, poor prosthesis design leading to impingement between neck and socket (Clarke IC 1992), lack of osteointegration with cementless hips (Garcia-Cimbrelo et al. 1996) and aseptic loosening of cemented cups (Hamadouche et al. 2002) have resulted in poor survival of early ceramic bearings. So far no better long-term results have been obtained with ceramic-ceramic THAs than with low-friction arthroplasty.

The first total hip arthroplasties had stainless steel metal-on-metal bearings (Wiles 1958). The McKee-Farrar total hip had cobalt-chromium on cobalt-chromium bearings. Cemented McKee-Farrar metal-on-metals have yielded low wear and twenty-year long-term results equal to the Charnley low-friction prosthesis (Jacobsson et al. 1996). Twenty-eight-year survival has been as good as 74% (Brown et al. 2002). However, results in Finland have been poorer than those (Visuri 1987, Turula 1989).

### **4.3. Polyethylene**

Polyethylene is made by polymerization of ethylene. Depending on the conditions of polymerization, different types of polyethylene can be prepared. In orthopaedics the material used is called UHMWPE. Synthesis of UHMWPE results in a fine granular white powder.

The basic resin has been produced by three resin suppliers: Himont (Montel, USA), Hoechst Celanese (Texas, USA) and Hoechst in Germany. Today Hoechst has assumed the name Ticona. Earlier the three most widely used resins in orthopaedic devices were GUR 412 and GUR 415 by Hoechst Celanese, and 1900 by Himont. The names of the basic resins have changed with time. GUR 415 is now GUR 4150 and further GUR 1150, and today GUR 1020 and 1120 comprise the most commonly used resins in Europe, and 1050 and 1020 in the United States. Also 1900 resin is currently in use (Li and Burstein 1994, Kurtz et al. 1999). There are three different means of preparing powder into an orthopaedic device. In direct compression moulding, powder is compressed into the final shape of the device. One advantage of this method is that the articulating surface is extremely smooth and free of machining marks. In ram-extrusion the UHMWPE powder is pushed into cylindrical bars and implants are machined from this cylindrical stock. This has been the most widely used stock shape for orthopaedic devices. The third method is to mould large sheets of UHMWPE. The powder is introduced into a heated container, and a plate large enough to cover the entire container is then applied with pressure, creating sheets from which implants can then be machined (Li and Burnstein 1994). There are several converters (Perplas Medical, Poly Hi Solidur Meditech, Westlake Plastics Company) who make UHMWPE from the basic resin for manufacturers of orthopaedic devices (Kurtz et al. 1999).

UHMWPE is a semicrystalline polymer, which means there are both crystalline and amorphous (noncrystalline) phases present. The average percentage of crystallinity in a sample can be determined by differential scanning calorimetry (DSC). The synthesized UHMWPE powders have crystallinity values from 58% to 75%, depending on the resin type (Li and Burnstein 1994). There have been marked differences in the degree of crystallinity of new polyethylene cups, figures ranging from 37% to 67% (Otfinowski and Pawelec 1995). In the early 1990s, a new form of UHMWPE, Hylamer, was introduced with higher

crystallinity. In vitro studies the potential clinical advantages for acetabular components made from Hylamer were identified. However, in clinical use, there was early failure of Hylamer acetabular inserts due to eccentric wear (Chmell et al. 1996).

Calcium stearate has been used as a scavenger and as a lubricant in UHMWPE production (Kurtz et al. 1999). However, this substance has negative effects on the properties of UHMWPE, being associated with fusion defects and the oxidation of UHMWPE, which further increases wear (Tanner et al. 1995).

The quality of polyethylene has been found to vary significantly (Tanner et al. 1995).

Components with unconsolidated UHMWPE particles leading to fusion defects could have increased wear (Wrona et al. 1994).

Oxidation of polyethylene leads to a chain scission of the large polymer chain into lower-molecular-weight units and the introduction of oxygen-containing groups into the polymer molecules. Oxidation involves changing of atoms of carbon from the  $-2$  oxidation state to higher oxidation states (Li and Burstein 1994).

Radiation improves the wear resistance of polyethylene by crosslinking (Grobbelaar et al. 1978), i.e. the formation of chemical bonds between molecular chains. Polyethylene crosslinking can be produced by high-level radiation energy. Crosslinked polyethylene has proved more resistant to abrasives in hip simulator studies (McKellop et al. 1999, Muratoglu et al. 2001a and b) and but so far there are no in vivo long-term data on this new product.

#### **4.4. Polyethylene wear**

Wear consists in the removal of material, which occurs as a result of motion between two surfaces under load. The wear of bearing materials was perceived early in the history of hip joint replacement. Prior to polyethylene, Charnley studied polytetrafluoroethylene (PTFE) as a bearing material in the late 1950s. However, PTFE proved to have poor wearing properties,



severe abrasive wear leading to clinical failures of PTFE acetabular cups within a 1- to 2-year period. After 300 operations PTFE was therefore abandoned in 1961 (Charnley 1979).

Although Charnley already observed wear in the early cemented polyethylene sockets (Charnley and Cupic 1973), this would appear to have been one of the less important issues in THA (Charnley 1979). The average polyethylene wear after ten years was 0,15mm/year (Charnley and Halley 1975).

There are three fundamental mechanism of wear: abrasion, adhesion and fatigue. Abrasive wear constitutes the main wear type in hip arthroplasty, abrasion being a process in which the harder surface cuts and ploughs the softer surface, removing material.

The conditions prevailing under the prosthesis where wear occurs are termed the wear modes (McKellop et al. 1995). In mode 1 particles are generated between motions of the femoral head against the polyethylene liner. In mode 2 the primary bearing surface moves against a secondary surface which it is not intended to contact, for example femoral head against acetabular shell. In mode 3 wear third-body particles between two primary surfaces cause three-body wear, for example hydroxyapatite particles between femoral head and polyethylene bearings. In mode 4 wear two secondary surfaces rub together, for example femoral neck against acetabular shell.

Mode 1 wear have greatest importance in THAs (Schmalzried and Callaghan 1999), but also mode 2 (Williams et 1997, Scott et al. 2000), mode 3 (Morscher et al. 1998) and mode 4 (Scott et al. 2000) have had marked effects in certain total hip designs.

The causes of polyethylene wear can be divided into endogenous and exogenous factors (Lewis 1997). Factors related to the material are termed endogenous and others exogenous.

The low molecular weight of the initial powder, the presence of calcium stearate, the inclusion of aluminum, calsium, silicon and titanium in the Ziegler-Nata catalyst, a high fraction of low-molecular-weight constituents and very high crystallinity may have an

adverse effect on the UHMWPE component (Wrona et al. 1994, Lewis 1997). There have been marked differences in the degree of crystallinity in new polyethylene cups, figures ranging from 37% to 67%, this possible leading to substantial individual differences in UHMWPE wear (Otfinowski and Pawelec 1995).

The manufacturing process may well influence the quality of polyethylene. The ram extrusion method is a semi-continuous process in the course of which inconsistencies could form in the extruded bar stock. There may also be microscopic shreds of UHMWPE on the surface of ram-extruded components (Lewis 1997). In contrast to this, direct compression moulding leaves the surface of the component extremely smooth (Kurtz et al. 1999). Thus direct compression moulded components have had less wear than ram-extruded components (Bankston et al. 1995, Tanner et al. 1995).

The commonest method of sterilizing UHMWPE components has been gamma radiation in air (Kurtz et al. 1999). Gamma sterilization in air was found, however, to promote oxidative chain scissions and long-term degradation of physical, chemical and mechanical properties of UHMWPE (Premnath et al. 1996). For this reason, UHMWPE is nowadays sterilized using gamma radiation in a reduced oxygen environment. Radiation can be carried out in a low-oxygen package, in a vacuum foil package or in nitrogen. UHMWPE can also be sterilized with ethylene oxide gas. In retrieval studies ethylene oxide gas-sterilized UHMWPE tibia components have shown less surface damage and delamination than gamma radiation-sterilized components (White et al. 1996). Gamma radiation-sterilized acetabular components have evinced rim cracking , while in contrast, ethylene oxide gas sterilized acetabular components show no rim cracking or delamination (Sutula et al. 1995). In new hip simulator studies, however, ethylene oxide sterilized cups have had more wear than gamma-sterilized cups (Ries et al. 2001, Affatato et al. 2002). Gas plasma sterilization is the third means of

sterilizing UHMWPE components. It does not affect the physical, chemical or mechanical properties of the device (Collier et al. 1996, Kurtz et al. 1999).

Poor design of the component could lead to excessively thin UHMWPE components, which leads increased stress and wear (Bartel et al. 1986, Saikko 1995, Lee et al. 1999).

In the computer simulation study it was found that there was not only one path, but rather many paths creating multidirectional shear forces on the polyethylene liner surface influencing to localization and amount of wear (Ramamurti et al. 1996).

The modularity of the prosthesis constitutes another factor which may increase UHMWPE wear. There is always motion between any type of modular liner and metal shell, leading to backside wear of the UHMWPE liner (Williams et al. 1997, Fehring et al. 1999).

Nonconformity between the polyethylene liner and the metal shell increases backside relative motion as well as load transfer at the liner/shell interface (Kurtz et al. 1998), this very possibly promoting the onset of surface fatigue failures and generation of UHMWPE wear. Screw holes also may distribute stresses unevenly (Kurtz et al. 1993), again possibly increasing UHMWPE wear.

A modular femoral head with an extended collar could likewise exacerbate UHMWPE wear. The presumed mechanism here is an increase in peripheral impingement of the flange-reinforced neck on the acetabulum due to a decrease in the ratio between the diameters of the femoral head and neck (Urquhart et al. 1998). The wear rates with 32mm femoral heads have been significantly greater than with 28mm heads in cemented arthroplasties (Livermore et al. 1990). The rate of volumetric wear and the radius of femoral head have a significant correlation. 22 mm heads have less volumetric wear than 28mm and 32mm heads (Hall et al. 1998). However, in a hip simulator with highly crosslinked UHMWPE the wear was seen to be independent of head size (Muratoglu et al. 2001a).

The roughness of the femoral head has been found to correlate with UHMWPE wear in hip simulators (Wang et al. 1998, Saikko et al. 2001), but in retrieval studies associations between roughness of femoral head and UHMWPE wear have been discrepant but usually indicative of poorer prognosis (Hall et al. 1997, Kusaba and Kuroki 1997, Elfick et al. 1999, Haraguchi et al. 2001b).

The wear rates of cementless metal-backed liners have been found to be significantly higher than those with cemented all-polyethylene components (Sychterz et al. 1996).

Several operative technique-related factors also influence UHMWPE wear. Femoral component offset is one such factor, use of a lateralized femoral component to restore preoperative hip biomechanics reduced UHMWPE wear significantly (Sakalkale et al. 2001). Too vertical a position of the cup increases UHMWPE wear at least in cementless THAs (Kennedy et al. 1998). In contrast it is reported that increased abduction of the acetabular component did not significantly increase UHMWPE wear in cemented THAs (Del Schutte et al. 1998).

If the hip joint is loose with telescopic movement between the bearings, separation during normal gait could also increase UHMWPE wear (Lombardi et al. 2000).

The effects of several patient-related variables on UHMWPE wear have been debated. Patient activity assessed by pedometer proved to be strongly correlated to wear (Schmalzried et al. 2000). The average walking activity has been calculated to be approximately 1 million cycles per year. However, there is a 45-fold range in patient activity (Schmalzried et al. 1998), a difference so substantial as to explain in part why there are hips which evince no measurable wear and hips with several times more wear than the average. Young patients (Shih et al. 1997) and men (Cates et al. 1993) have been observed to show more UHMWPE wear, and such subjects are usually more active than the average patient. Weight has no correlation with

UHMWPE wear (Charnley 1979), since true obesity is associated with reduced activity, which would if anything obviate wear.

An UHMWPE component could in the long run creep. This process is time-dependent, comprising plastic deformation, and the magnitude of the shift is difficult to quantify.

Femoral head penetration into the UHMWPE component constitutes the sum of wear and creep, and generally when we speak of UHMWPE wear, we in fact mean the sum of wear and creep.

#### ***4.5. Wear measurement***

The wear of UHMWPE has traditionally been assessed by radiography. In the uni-radiograph method, the width of the narrowest part of the socket in the weight-bearing area and the width of the widest part in the non-weight-bearing area are assessed and the difference is then halved (Charnley and Cupic 1973). Charnley and Halley (1975) introduced a duoradiographic technique which compares in the most recent radiographs to early postoperative radiographs. The magnification of radiographs was corrected by comparing the diameter of the femoral head on the radiograph with its known diameter. Charnley assessed the distance between a radiographic marker and the outline of the femoral head. The Livermore method is perhaps the most commonly used mode of analysis (Livermore et al. 1990), which in point of fact was first presented by Charnley's group (Griffith et al. 1978). Radiographs from the early postoperative phase and from the latest time available were studied, compasses being used to find the shortest distance from the center of the femoral head to a reference point on the acetabular cup in the follow-up radiographs. This measurement was then repeated with the initial postoperative radiograph. Two techniques use the opening face of the acetabular component as reference and calculate wear as the change in position of the femoral head relative to this acetabular face reference line. Dorr and Wan (1996) used a single radiograph

and Barrack and colleagues (1997) assessed duoradiographs comparing latest radiographs to early postoperative ones.

Ohlin and Selvik (1993) found all these methods to correlate with direct assessment of the internal deformity of 28 retrieved sockets by means of a coordinate measuring machine. The Livermore method was the most accurate. Also Ilchmann recommended this method for clinical purposes (Ilchmann et al. 1995). Comparing five manual techniques and two computer-assisted two-dimensional methods Barrack and colleagues (2001) found that computer assistance did not improve the accuracy of wear measurements.

These two-dimensional techniques have their limits; as multiple wear factors are involved, two-dimensional measurements may under estimate UHMWPE wear (Yamaguchi et al. 1997).

There are, however, more accurate three-dimensional computerized methods (Devane et al. 1995, Ilchmann et al. 1995, Shih et al. 1997, Chen and Shih-Shyn Wu 2002).

Radiostereometric analysis is the most accurate of them but can be employed only in prospective studies, because tantalum markers should be placed in the hip and the prosthesis (Franzen and Mjöberg 1990, Ilchmann 1997).

The correlation between single-plane radiographic measurements and direct wear measurements in retrieval studies has in fact been fairly good (Wroblewski 1985, Kabo et al. 1993, Jasty et al. 1997, Sychterz et al. 1997). Kabo and associates (1993) using a shadowgraph technique have compared linear wear measurements carried out on retrieved acetabular components with those obtained by measurements made on standard clinical radiographs of the same hips. There was a close correlation between the two, although the radiographic measurements slightly underestimated the linear wear measured on the retrieved implants. Also two-dimensional and three-dimensional measurements have been found to be more or less equal in 95% of patients (Sychterz et al. 1999).

The significance of weight bearing for measurement of UHMWPE wear has been a controversial subject. Smith and colleagues (1999) found the measured wear of the cemented UHMWPE acetabular component to be significantly greater when radiographs were taken under weight bearing rather than with the patient supine. Contrary to this Moore and associates (2000) found no significant differences between measured UHMWPE wear of cementless porous coated acetabular components, when radiographs were taken weight bearing or with the patient supine. The investigators stated that the tension of the hip capsule and the soft tissue surrounding the implant was sufficient to keep the femoral head in almost the same position whether the hip was loaded or not. The different acetabular components and fixation methods could be one reason for these different findings. Martell and coworkers (2000) concluded that weight bearing does not affect radiographic calculations of UHMWPE wear in any clinically important sense.

#### ***4.6. Osteolysis due to wear particles***

Osteolysis is bone resorption which occurs in association with a foreign-body response to particles from a prosthetic joint (Amstutz et al. 1992). Macrophages phagocytose small wear particles and may fuse foreign-body multinucleated giant cells, which could assimilate larger particles. Macrophages release cytokines, which stimulate bone resorption (Murray and Rushton 1990). Bone resorption is effected by osteoclasts. All foreign particles can induce an inflammatory foreign-body reaction if they are within a certain size range and present in sufficient numbers. The stimulatory effect of UHMWPE particles decreases when the particles are larger than about 7  $\mu\text{m}$  or smaller than about 0.2  $\mu\text{m}$  (Schmalzried and Callaghan 1999).

Osteolytic lesions can be viewed on radiographs. Femoral lesions are easily seen on plain radiographs, whereas acetabular lesions usually appear bigger on revision than on plain radiographs. Oblique radiographs could improve the detection of acetabular osteolysis

(Southwell et al. 1999, Zimlich and Fehring 2000). The average polyethylene wear rate of 0.1-0.2mm/year has been suggested as a threshold value for a significant association with osteolysis in clinical studies (Sochart 1999, Dowd et al. 2000). Cementless acetabular components evince osteolysis more commonly than cemented ones (Devane et al. 1997) Linear osteolysis is typically reported in association with cemented components. In 1976 Harris and associates reported non-linear localized bone resorption in the proximal part of cemented loose THA. They found osteoclastic bone resorption, a high concentration of macrophages and foreign-body giant cells with particles of polymethylmethacrylate. The condition was believed to be due to so-called cement disease. Cementless components are more likely to be associated with locally expansive lesions. Femoral osteolysis was subsequently also found around cementless components and was thought to be caused by UHMWPE particles (Maloney et al. 1990, Santavirta et al. 1990b). Femoral components with a smooth or noncircumferentially proximally coated surface have evinced distal osteolysis (Phillips and Messieh 1988, Duparc and Massin 1992, Maloney and Woolson 1996). On the other hand circumferential porous coating appears to prevent the distal migration of UHMWPE particles and distal osteolysis (McAuley et al. 1998, Emerson et al. 1999, Hellman et al. 1999, Sakalkale et al. 1999, von Knoch et al. 2000). Osteolysis around cementless acetabular components is typically of non-linear or expansive form (Santavirta et al. 1990a, Maloney et al. 1993).

As the biologic process of osteolysis is asymptomatic, so patients even with severe osteolysis are usually symptomless. Precisely secondary processes such as loosening of the component, mechanical failure of the component, UHMWPE wear throughout or fracture may give rise to actual symptoms, and osteolysis is commonly found only in late postoperative radiographs. Hence, regular radiographic follow-up is considered essential (Harris 2001).



#### **4.7. Arthroplasty registers**

The main purpose of arthroplasty registers is to chart the epidemiology of hip replacements and to identify risk factors for poor outcome related to the patient, to the implant and to surgical techniques (Herberts and Malchau 2000). Registers would appear to be a phenomenon typical of the Scandinavian countries. The first arthroplasty register was the Swedish Hip Register, set up in 1979 (Ahnfelt et al. 1990). Immediately thereafter the Finnish Arthroplasty register was established in 1980 (Paavolainen et al. 1991). Later, in 1987, national registers were started in Norway (Havelin et al. 1993) and in Denmark in 1995 (Lucht 2000).

Arthroplasty registers, acting as multicenter clinical trials, have an important role in the development and evaluation of total joint arthroplasty (Herberts et al. 1989). The epidemiology data and mortality associated with THAs can be described over time (Söderman et al. 2000). For instance, the risk of cancer after THA can be ascertained by matching data from arthroplasty registers and cancer registers (Visuri et al. 1996). The register can also reveal inferior implants and cement products only 3 years after their introduction (Havelin et al. 2000). Long-term registration can improve the quality of THAs by information on individualized patient risks, implant safety and improved techniques (Herberts and Malchau 1997). The need for THAs in the future can be estimated from data from national arthroplasty registers and other national registers (Ostendorf et al. 2002).

#### **4.8. Retrieval analyses**

The American Society for Testing and Materials (ASTM) standard for analysis of retrieved metallic orthopaedic implants (ASTM standard F 561-87) and the International Organization for Standardization (ISO) standard are designed for the retrieval and analysis of surgical

implants (ISO 12891), giving recommendations for the retrieval, handling and analysis of these devices.

Components can be removed in the course of a revision operation or post-mortem on autopsy (Sychterz et al. 1996). Failure analyses of orthopaedic implants may be divided into two parts: clinical and radiological and also technical analyses. Technical analyses comprise characterization of the material used and damage analyses of the components. Material analyses can be subdivided into non-destructive and destructive methods. First visual inspection and assessment under a stereomicroscope are undertaken. Structural defects such as white band or fusion defects in polyethylene components can be detected by optical microscopy. In dimensional analysis direct 3-D-measurements can be made using the optical fringe contour measurement technique or a contact probe stylus (Derbyshire et al. 1994). In the shadowgraph technique bone cement has been used to cast the worn area of a cup (Kabo et al. 1993). By means of scanning electron microscopy worn surfaces and the mechanism of the generation of wear particles can be studied. Elementary analysis can be done by energy-dispersive X-ray spectroscopy (EDS). Oxidation can be studied by infrared spectroscopy (Kurtz et al. 2002) and the crystallinity of polyethylene can be measured by differential scanning calorimeter (DSC) (Li and Burstein 1994). The surface roughness of implants can be assessed by contact or laser profilometer (Sychterz et al. 1999).

## 5. Aims of the present study

The aims of the present study were:

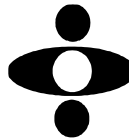
1. To analyse the results of total hip arthroplasties recorded in the Finnish Arthroplasty Register.
2. To report on survivorship analyses of the most commonly used implants in cementless arthroplasties in Finland.
3. To determine the wear of the polyethylene liner of the cementless Biomet Universal cup with a cobalt-chrome head and to analyse factors related to the wear rate measured.
4. To evaluate the radiographic appearance of osteolysis on the femoral side in a setting where the polyethylene liner has acted as a debris generator, and to report the consequent clinical and survival results.
5. To analyze material and design issues related to twenty retrieved Hexloc liners and to establish the reason for the poor clinical outcome of these bearings.

## **6. Materials and methods**

The material for studies I and II comprised THAs recorded by the Finnish Arthroplasty Register. Study III involved 132 cementless primary THAs in 130 patients and study IV 137 cementless THAs performed in Tampere University Hospital between 1991 and 1992. In study V, 20 Hexloc liners were retrieved in revision operations at Tampere University Hospital and retrieval analyses were made with the Institute of Materials Science, Tampere University of Technology.

### ***6.1. The Finnish Arthroplasty Register (Study I)***

Since 1980 the Finnish Arthroplasty Register has collected data on total hip replacements. In the case of a primary operation the operating hospital, date, personal number, indication for operation, implant design, method of fixation for each component and primary complications are recorded. In addition, for revision arthroplasty, date of the index operation, design of the revised prosthesis, indication for revision and the new prosthesis are recorded (Figure 1). Survival analysis between 1980 and 1999 according to Kaplan and Meier (1958) was made using revisions of any kind as end-point.



<b>Identity number of patient</b>	-									
<b>Date of operation</b>										
<b>Object of operation</b>	Joint <input type="checkbox"/> 1 Right <input type="checkbox"/> 2 Left									
	<input type="checkbox"/> 1 Hip	<input type="checkbox"/> 6 Shoulder	<input type="checkbox"/> 11 Cmc							
	<input type="checkbox"/> 2 Knee	<input type="checkbox"/> 7 Elbow	<input type="checkbox"/> 12 Mcp							
	<input type="checkbox"/> 3 Femoropatellar joint	<input type="checkbox"/> 8 Lunatum	<input type="checkbox"/> 13 Ip							
	<input type="checkbox"/> 4 Ankle	<input type="checkbox"/> 9 Scaphoideum	<input type="checkbox"/> 14 Temporomandibular joint							
	<input type="checkbox"/> 5 Mtp	<input type="checkbox"/> 10 Other structure **	<input type="checkbox"/> 15 Other **							
<b>Reason for operation</b>	<input type="checkbox"/> 1 Rheumatoid arthritis	<input type="checkbox"/> 5 Other **	<input type="checkbox"/> 9 Removal of previous prosthesis (Girdlestone)							
	<input type="checkbox"/> 2 Other arthritis	<input type="checkbox"/> 6 Replacement of prosthesis	<input type="checkbox"/> 0 Other revision (e.g. liner change)							
	<input type="checkbox"/> 3 Primary arthrosis	<input type="checkbox"/> 7 Removal of prosthesis								
	<input type="checkbox"/> 4 Congenital luxation of the hip	<input type="checkbox"/> 8 Secondary arthrosis								
<b>Type of implanted prosthesis (femoral and acetabular component)</b>	Brandname: femur *           acetabulum *									
	Femoral head <input type="checkbox"/> 1 Fixed <input type="checkbox"/> 2 Modular	Diameter of head _____ mm Type (Chrome, Titanium, Ceram. etc.) _____								
<b>Revision operation</b>	Reason for									
	<input type="checkbox"/> 1 Loosening (prox.comp.)	<input type="checkbox"/> 6 Fracture of bone								
	<input type="checkbox"/> 2 Loosening (dist. comp.)	<input type="checkbox"/> 7 Fracture of prosthesis								
	<input type="checkbox"/> 3 Infection	<input type="checkbox"/> 9 Patellar complication								
	<input type="checkbox"/> 4 Luxation	<input type="checkbox"/> 8 Other reason, please specify **								
	<input type="checkbox"/> 5 Malposition of prosthesis									
<b>Type of prosthesis to be replaced or removed, and date of previous operation</b>	Brandname: femur *           acetabulum *									
									Date 	
<b>Fixation method</b>										
			Hip prosthesis		Knee prosthesis		Patellar component	Other prosthesis		
	Cemented	<input type="checkbox"/> 1 femur <input type="checkbox"/> 3 acetabulum	<input type="checkbox"/> 5 femur <input type="checkbox"/> 6 tibia	<input type="checkbox"/> 7 <input type="checkbox"/> 8	<input type="checkbox"/> 9	<input type="checkbox"/> 10	<input type="checkbox"/> 11			
Uncemented	<input type="checkbox"/> 2	<input type="checkbox"/> 4								
	Cementing technique <input type="checkbox"/> 1 Ordinary <input type="checkbox"/> 2 Pressurized					Cement mixing technique <input type="checkbox"/> 1 Ordinary <input type="checkbox"/> 2 Centrifuge <input type="checkbox"/> 3 Vacuum				
<b>Brand of cement used</b>	Brandname									
<b>Bone graft</b>	<input type="checkbox"/> 1 Autograft	<input type="checkbox"/> 2 Allograft	<input type="checkbox"/> 3 Xenograft							
<b>Systemic antibiotic prophylaxis</b>	<input type="checkbox"/> 1 Yes <input type="checkbox"/> 2 No									
	Brand of antibiotics									
<b>Primary complications</b>	<input type="checkbox"/> 0 Anaesthetic	<input type="checkbox"/> 5 Luxation								
	<input type="checkbox"/> 1 Infection	<input type="checkbox"/> 6 Nerve injury								
	<input type="checkbox"/> 2 Haematoma	<input type="checkbox"/> 7 Other primary complication **								
	<input type="checkbox"/> 3 Tromboembolism	<input type="checkbox"/> 8 Death								
	<input type="checkbox"/> 4 Malposition of prosthesis	<input type="checkbox"/> 9 Wound necrosis								
<b>Name and telephone number of person in charge</b>										
<b>Comments **</b>										

**Please attach the prosthesis stickers on the reverse side !**

Figure 1. The notification form used by the Finnish Arthroplasty Register.

## **6.2. The most commonly used implants in cementless arthroplasties in Finland (Study II)**

Four different acetabular component designs were recorded as Biomet prostheses in the Finnish Arthroplasty Register. Information obtained from the supplier (Oy Kenn-Med Ab) on the number of prostheses sold was used to determine the reliability of the Register data. By comparing the exact number of implants sold with the data in the Register, it was possible to extract a reliable series for each of the four cup designs. The specific data concerned of 302 threaded smooth titanium cups (T-TAP), 148 plasma-sprayed partially threaded porous-coated titanium cups (Romanus) (also used with hydroxyapatite), 361 porous-coated cups of titanium alloy with four peripheral fins (Mallory-Head) and 236 porous-coated cups of titanium alloy (Universal). Survival analysis for the different designs according to Kaplan and Meier (1958) was done using revision as the end-point.

## **6.3 Wear of the polyethylene liner (Study III)**

Altogether 132 cementless primary THAs were done for 130 patients in Tampere University Hospital between 1991-1992. Twenty-five hips were excluded from the study (11 patient had died, five refused follow-up, and five early revision, in two only the other side of bilateral arthroplasties was included and two patients were lost to follow-up). Acetabular components were cementless porous-coated Biomet Universal cup with a Hexloc liner (Figure 2).



Figure 2. Retrieved Biomet Bi-Metric stem, Universal cup and Hexloc liner.

Modular liners were machined from extruded bar raw material and gamma-sterilized in air.

Radiographs of 107 primary hip arthroplasties were analysed retrospectively at a mean of 6 years (4-8) after the operation. Patients were classified in three groups (Charnley 1979).

Charnley class A patients have unilateral hip disease, class B bilateral hip disease and class C

systemic disease or other condition limits function. Radiographs from the early postoperative phase and from the latest time available were studied. The linear wear of polyethylene liners was assessed by a modification of the Livermore method (Livermore et al. 1990). The thinnest part of the polyethylene was measured in the latest follow-up radiographs and compared to the initial postoperative image. Magnification was calculated for each film based on the known head diameter. Volumetric wear was calculated by the formula  $v = \pi r^2 w$ , where  $v$  is the change in the volume of the bearing,  $r$  is the radius of the femoral head and  $w$  is the measured linear wear.

To define intraobserver reliability the same person repeated ten measurements twice and to define interobserver reliability two persons read the same ten radiographs independently. We measured the repeatability limit ( $1.96 \times \sqrt{\sum d^2/n}$ ,  $d$  = paired difference between repeated measurements of the same object,  $n$  = number of (pairs of) measurements) (Ranstam et al. 2000).

Measurements was made of the vertical migration of the acetabular component between the inferior margin of the component and the inferior margin of the ipsilateral teardrop.

Horizontal migration of the acetabular component was measured between Köhler's line and the margin of the acetabular shell (Callaghan et al. 1988).

RLL of at least 1 mm were estimated in the three zones of the acetabular interface (Delee and Charnley 1976). Calcar rounding was recorded simply as presence or absence of calcar rounding.

#### ***6.4 Osteolysis on the femoral side (Study IV)***

A total of 137 consecutive primary cementless Bi-Metric (Biomet, Warsaw, Indiana, USA) (Figure 2) femoral components with cementless porous coated titanium alloy Biomet Universal cups with a Hexloc liner (Biomet, Warsaw, Indiana, USA) were implanted at our institution in 134 patients during the period 1991 and 1992. The stem is straight, made of



titanium alloy with a plasma-sprayed porous coating circumferentially on the proximal third, thickness of coating ranging from 0.635 to 0.889mm. The pore size of the coating ranged between 100 and 1000 microns.

Fifteen patients (15 hips) died of unrelated causes before their follow-up examination; this group thus had no hip revisions. The early revisions comprised 2 peroperative femoral fractures (femoral component exchanged) and 3 early dislocations, which were treated by closed reduction. Five patients refused to attend the follow-up, but according to the telephone interview, their hips were giving no trouble. Only the first hip in bilateral arthroplasties was included (three patients). Two patients (2 hips) were lost to follow-up. Thus 107 patients with 107 hips comprised the cohort for the radiographic analyses.

The radiographs were analyzed by two orthopaedic surgeons not involved in surgery of these patients. AP radiographs of the pelvis and AP and lateral radiographs of the hip were used. Osteolysis around the stem and RLL wider than 1mm were assessed in 7 Gruen zones (Gruen et al. 1979) on AP views. Calcar rounding was recorded as reported in study III.

Vertical migration of the stem was measured between the superolateral extent of the porous coating and the tip of the greater trochanter and the superomedial extent of the porous coating and the upper margin of the lesser trochanter. Vertical subsidence of more than 5mm (the average of the two measurements) was defined as significant (Callaghan et al. 1988).

The wear rate was assessed by same modification of the Livermore method as in study III (Livermore et al. 1990).

Data on 106 patients for calculation of the modified HHS (Ilstrup et al. 1973) were recorded on the Finnish Arthroplasty Association form by a trained physiotherapist at the latest follow-up.

The life-table method of calculation for survival analysis was used (Murray et al. 1993).

Failure was defined as a performed or scheduled revision operation. Survival of the femoral component was studied separately.

### **6.5 Retrieval analyses (Study V)**

The twenty retrieved ultra-high molecular weight polyethylene (UHMWPE) liners analyzed were the so-called modular Hexloc<sup>®</sup> hi-wall design for use together with the Universal<sup>®</sup> acetabular shell (Biomet, Warsaw, Indiana, USA). Based upon information obtained from the manufacturer, UHMWPE liners were machined from extruded Hostalen GUR-415 (Hoechst AG/Aventis S.A., Strasbourg, France), except liner number 5, which was made of Hostalen GUR-412 or Hifax 1500 materials. The liners were gamma-sterilized in air at a dose of 25 to 30 kGy.

In three cases a zirconia ceramic head was used on the femoral side while in all other cases a cobalt-chromium alloy (CoCr) head was used. The size of the head was 28mm in 11 cases and 32mm in 9. The femoral component was a non-collared cementless Bi-metric<sup>®</sup> stem (Biomet, Warsaw, Indiana, USA).

The reason for revision was polyethylene wear in 13 cases, dislocation in 5 and infection in 2 cases.

All liners were subjected to initial visual inspection and assessment under a stereomicroscope. Volumetric measurements of the liners were carried out using a Faro Silver (FARO Inc., Lake Mary, Florida, USA) three-dimensional (3D) coordinate measuring machine (CMM) equipped with a mechanical stylus tip of 1.5 mm radius. Three-dimensional scanning allows accurate digitizing of the worn surface of an explanted liner. The worn interior surface of each liner was measured by taking data points around the inner surface of the liner. The AnthroCam programme (FARO Inc., Lake Mary, Florida, USA) was used to convert the scanned points to a 3D surface model using an initial graphics exchange

specification (IGES) file format. The IGES surface model was transferred to a Surfacer program (FARO Inc., Lake Mary, Florida, USA) and the changes in the internal volume of the liner were calculated using a standard computer aided design (CAD) program.

After the stereomicroscopic assessment and CMM measuring, the liners were cut into two halves perpendicular to the ridge area. One half of the sample was prepared for scanning electron microscopy (SEM) studies. The bearing surface morphology of worn liners was examined using a Philips XL 30 scanning electron microscope (FEI, Eindhoven, the Netherlands) equipped with an EDAX DX-4 energy dispersive X-ray analysis system (EDS) (EDAX Inc., Mahwah, New Jersey, USA). The other half of the liner was prepared for transmission light microscopy observation, crystallinity determination, and oxidation index measurements. Cross-section slices 200  $\mu\text{m}$  thick were cut from the liner perpendicular to the bearing surface using microtomy.

The crystallinity of samples was measured on a Perkin Elmer DSC 7 (PerkinElmer Inc., Wellesley, Massachusetts, USA) differential scanning calorimeter (DSC). Fourier Transform Infrared Spectrometry (FTIR) characterized oxidative degradation of the UHMWPE liners. A Perkin Elmer 1725X spectrometer (PerkinElmer Inc., Wellesley, Massachusetts, USA) was used and spectra were collected using eight-scan summations and a resolution of  $4.0\text{ cm}^{-1}$ .

Each liner was measured twice using different 200 $\mu\text{m}$ -thick microtomy samples.

The surface roughness of explanted femoral heads was measured with a UBM Microfocus COMPACT laser profilometer (NanoFocus Inc., Sunnyvale, California, USA) using a 1.75 mm evaluation length. The laser profilometer is a non-contact surface roughness measurement technique known to result in  $R_a$  values 4 to 6 times higher compared with the standard contact method (Sychterz et al. 1999). The laser profilometer was thus carefully calibrated with the known roughness standard in order to make roughness measurements in

this work comparable to values reported in the literature measured by a contact diamond stylus method.

## **6.6 Statistical analysis**

### **6.6.1 Studies I and II**

Standard Kaplan-Meier estimates were made for survival analysis (Kaplan and Meier 1958) with 95% confidence intervals.

### **6.6.2 Study III**

In view of the skewed distribution of the wear rate, it was described using medians and lower and upper quartiles. Mann-Whitney U-test was used to assess the statistical significance of differences in wear rates between groups. Spearman's correlation coefficient was used to evaluate the association between continuous variables. To analyze further the factors associated with the wear rate, logistic regression analysis was done. The wear rate was divided into normal ( $\leq 0.20$  mm/y) and excessive wear ( $\geq 0.20$  mm/y). The patient's gender, age and weight, size of the acetabular component, size of the femoral head, abduction angle of the acetabular component and the screw fixation of the acetabular component were included in the logistic regression analysis.

### **6.6.3 Study IV**

The life table method of calculation for survival analysis was used (Murray et al. 1993).

Fisher's exact, Pearson Chi-Square and Mann-Whitney U tests were used to study statistical significance.

#### **6.6.4 Study V**

Means and standard deviation were used with normally distributed variables and medians and range for variables with skewed distributions. Differences in continuous variables between groups were tested by means of independent samples t-test and for variables with skewed distributions the Mann-Whitney U test was used.

## 7. Results

### 7.1 The Finnish Arthroplasty Register (Study I)

Between 1980 and 1999, 62841 primary hip arthroplasties and 12224 revision hip arthroplasties were recorded in the Finnish Arthroplasty Register. Increasing numbers of both primary and revision hip replacements have been observed (Figure 3).

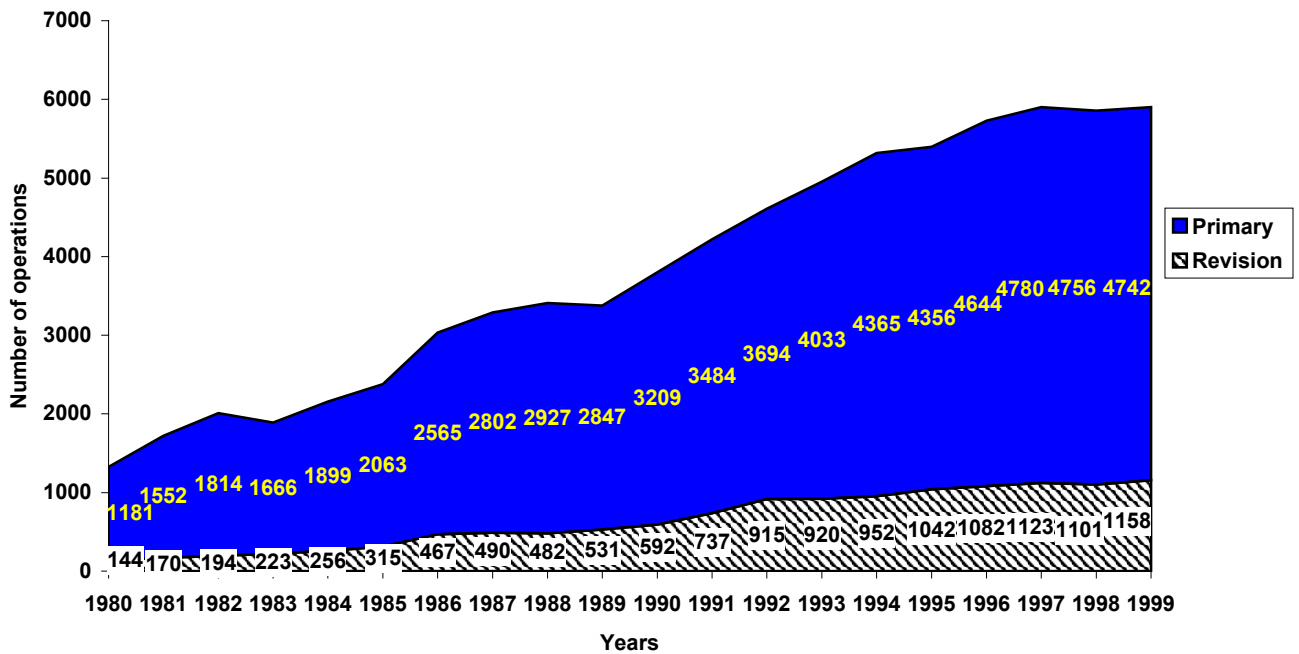


Figure 3. The annual number of primary and revision hip replacements.

A total of 4742 primary total hip replacements and 1158 revision hip replacements were performed in 1999. The incidence of primary hip arthroplasties was 93/100000 in 1999.

Some 40% of the femoral components and over 50% of the acetabular components have been cementless.

Survival of hip arthroplasties was clearly poorer in patients younger than 55 years compared to older patients. Ten years' survival was 72% (95% CI 67-76) in patients younger than 55 and 90% (95% CI 89-91) in those older than 70 years (Figure 4).

The survival of cemented hip arthroplasties has been consistent. Ten years' survival has been constantly approximately 88%. In contrast, the ten years' survival of cementless hip arthroplasties has improved from 71% to 81%, being nonetheless poorer than that of cemented replacements. During the last 5 years, however, survival was equal, 94% in cemented and 96% in cementless (Figures 5 and 6).

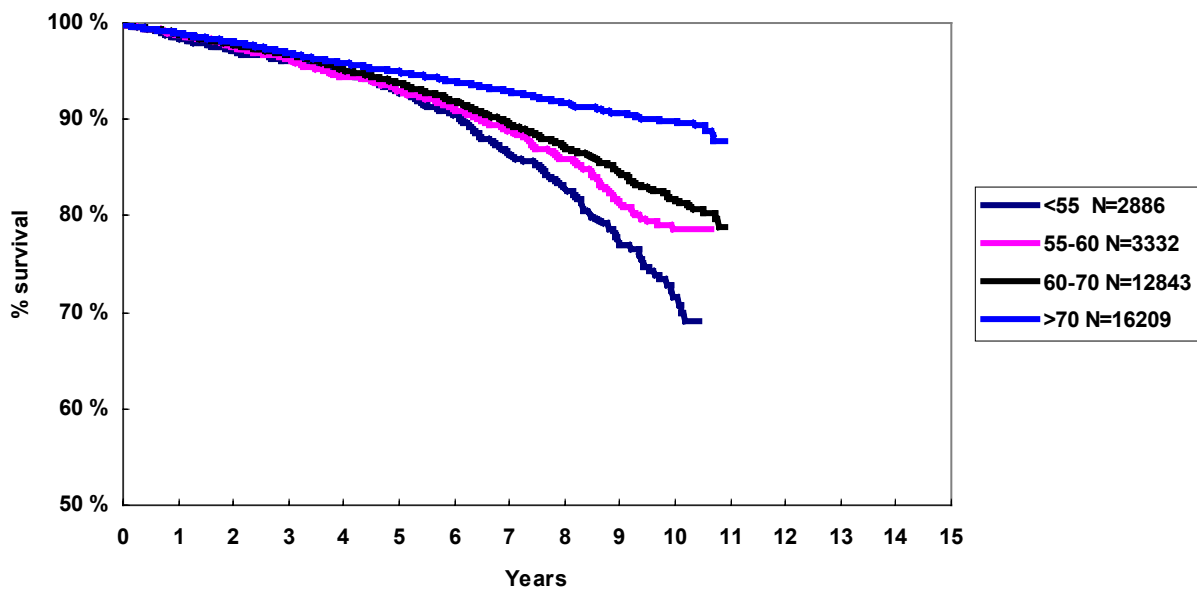


Figure 4. Survival rates in patients under 55 years, 55-59 years, 60-70 years and over 70 years from 1985-1999.

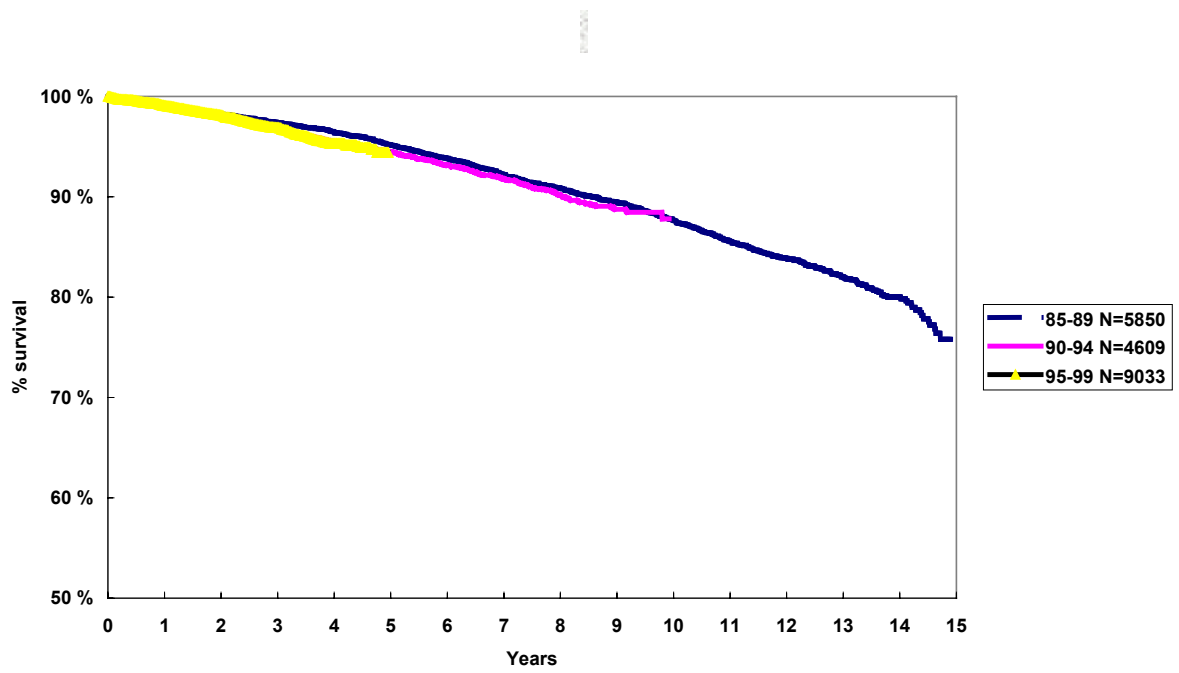


Figure 5. Survival rates of cemented hip arthroplasties in primary arthrosis from 1985-1999

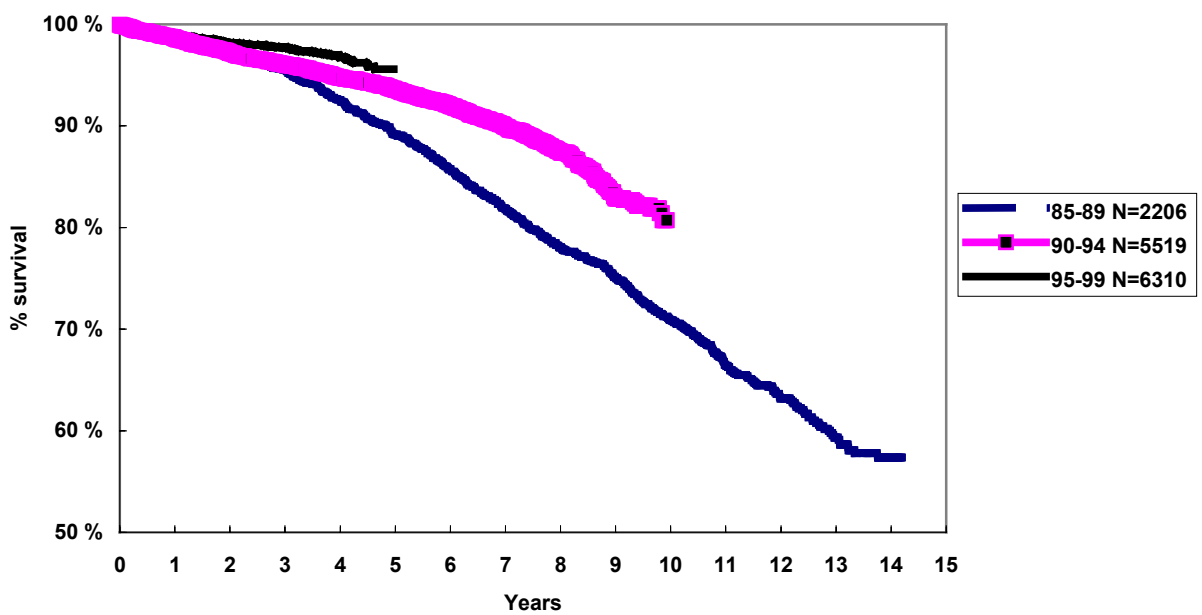


Figure 6. Survival rates of cementless hip arthroplasties in primary arthrosis from 1985-1999.



The commonest reason for revision in 1999 was aseptic loosening (Table 1).

Table 1.  
Reasons for hip revision in 1999

	%
Aseptic loosening	65
Infection	7
Luxation	9
Malposition of endoprosthesis	2
Fracture of bone	4
Fracture of endoprosthesis	2
Other reason	11

However, the other reasons than aseptic loosening formed 35% of the hip revision. Ten-year survival of revision arthroplasties was poorer than that of primary arthroplasties. Ten years' survival in cemented revisions was constantly approximately 77% while in cementless revisions it has improved from 65% to 76%.

## ***7.2 Survivorship analysis of the most commonly used implants in cementless arthroplasties in Finland (Study II)***

The number of cementless Biomet prostheses implanted for primary arthrosis was 4300. Altogether 76% of patients were 65 years and younger. The 9-year survival of arthroplasties using the T-TAP threaded cup was 58% (52-65). The 7.5-year survival of arthroplasties using Romanus cups was 85% (79-91); 5-year survival of arthroplasties using the Mallory-Head cup was 98% (97-100) and the 6-year survival of arthroplasties using Universal cups was 93% (88-98). Poor survival seems to be related to the poor survival of the cup.

## ***7.3 Wear of the polyethylene liner (Study III)***

The mean difference between two evaluations by the same person was 0.16mm, SD 0.17mm (range 0-0.45mm). The repeatability limit was 0.44mm (intraobserver reliability). The mean

difference between two evaluations by different persons was 0.57 mm, SD 0.32 mm (range 0.13-1.15). The repeatability limit was 1.26mm (interobserver reliability).

The average direction of wear was 1 degree laterally (SD 14°, range 29° laterally to 65° medially). The median liner wear was 1,04 mm and the median wear rate 0.17 mm/year.

There was no measurable wear at the latest follow-up in 21 cases and there was wear of 2 mm or more in 21 cases. The median volumetric wear was 640 mm<sup>3</sup> and the median volumetric wear rate 106 mm<sup>3</sup>/year. There were significant differences between the linear wear (p=0,02), the linear wear rate (p=0,03), the volumetric wear (0,002) and the volumetric wear rate (p=0,003) of the 28-mm and 32-mm femoral heads. Also cases with calcar rounding evinced significantly greater linear wear (p=0,009), linear wear rate (p=0,005), volumetric wear (p=0,01) and volumetric wear rate than those without rounding. The volumetric wear was greater (p=0,05) in the group with RLL than without it (Table 2).

In logistic regression analysis, the size of the femoral head (p=0,009) and the screw fixation of the acetabular component (p=0,03) were the only factors significantly related to wear rate.

In respect of patients' gender, age, weight, size of the acetabular component and abduction angle of the acetabular component no relation was found.

We found RLL in 19 cases and periacetabular osteolysis in 9. All the acetabular components were considered radiologically stable. Fourteen revisions have been done or are planned due to complications with the acetabular liner. In 2 cases a fractured rim of the worn liner led to repeated dislocations and in 12 cases the reason for revision has been wear of the polyethylene liner.

Table 2. The median, 25th and 75th percentiles of the volumetric wear and volumetric wear rate.

		n	Volumetric wear (mm <sup>3</sup> )				Volumetric wear rate (mm <sup>3</sup> /y)			
			median	25th	75th	p	median	25th	75th	p
All cups		107	640	215	1231		106	34	194	
Size of the femoral head	28	77	609	218	865	0.002	89	35	148	0.003
	32	30	1387	0	2331		228	0	355	
RLL	yes	19	1141	289	1801	0.049	157	46	304	0.081
	no	88	615	192	1045		96	27	183	
Screw fixation	yes	21	868	452	1292	0.138	153	79	222	0.080
	no	86	615	185	1164		92	30	192	
Calcar rounding	yes	74	730	298	1351	0.011	132	54	208	0.006
	no	33	474	0	865		75	0	137	
Revision	yes	14	1865	905	2668	<0.001	287	180	467	<0.001
	no	93	609	184	1015		89	29	158	
Charnley class	A	29	849	323	1457	0.1*	137	53	217	0.1*
	B	53	615	184	994		94	28	174	
	C	25	640	184	1516		105	29	251	

\*A versus B+C

#### ***7.4 Osteolysis on the femoral side in a setting where the polyethylene liner has acted as debris generator (Study IV)***

The nine years' survival of the Bi-Metric femoral stem component was 98,5%. Two patients underwent early exchange of the femoral component due to peroperative femoral fracture.

Three revisions were performed because of early dislocation. In 2 cases the femoral head was changed to a longer one and in one case a polyethylene liner with 15-degree elevated posterior rim and longer femoral head was changed. Twenty revisions of acetabular

components have been done or are planned due to excessive polyethylene wear or fracture of the polyethylene liner. No further revisions of femoral components have been undertaken.

We found neither osteolysis nor RLL in Gruen zones 2-6, not even in the cases with excessive liner wear and subsequent revision of the acetabular component. Four patients had osteolysis in

Gruen zone 1 and seven in zone 7. In two of these cases osteolysis was noted simultaneously in both of these Gruen zones (Figure 7).

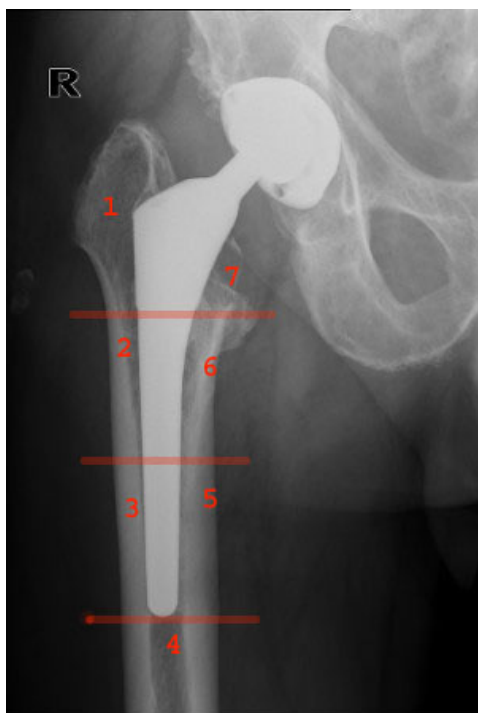


Figure 7. Osteolysis in Gruen zone 1 and in zone 7.

The group revised due to polyethylene wear had significantly more osteolysis in Gruen zones 1 (3/20 versus 1/87, Fisher's exact test,  $p=0.01$ ) and 7 (7/20 versus 0/87,  $p<0.001$ ) than the non-revised group (Table 3).

Calcar rounding or resorption was found in 73 cases (70%). The rounding was associated with revision due to polyethylene wear (Pearson Chi-Square,  $p=0.004$ ). No femoral stems subsided and they were considered stable.

The median HHS was 97. There were no significant differences in pain or HHS between revised and unrevised cases or those with and without proximal femoral osteolysis.

Table 3. Comparison of groups with revision and no revision due to polyethylene wear.

	Total n	Revision group	No revision group
Gender		20	87
	Male	10	36
	Female	10	51
Mean age (year)		54	58
Charnley class			
	A	7	18
	B	8	46
	C	4	23
Femoral osteolysis			
	zone 1	3	1
	zone 7	7	0
No femoral osteolysis		12	86

## 7.5 Retrieval analyses (Study V)

Visual inspection of the liner revealed burnishing on the back surface of the polyethylene and titanium particles some few hundred micrometers in size entrapped on the backside of the liner in all cases. Occasionally, a few titanium particles were also observed on the actual bearing surface of the liner but the number of visible particles was smaller than on the backside. The polyethylene tends to flow into the screw holes and form a 1-mm to 2-mm high node on the backside of the liner (Figure 9).

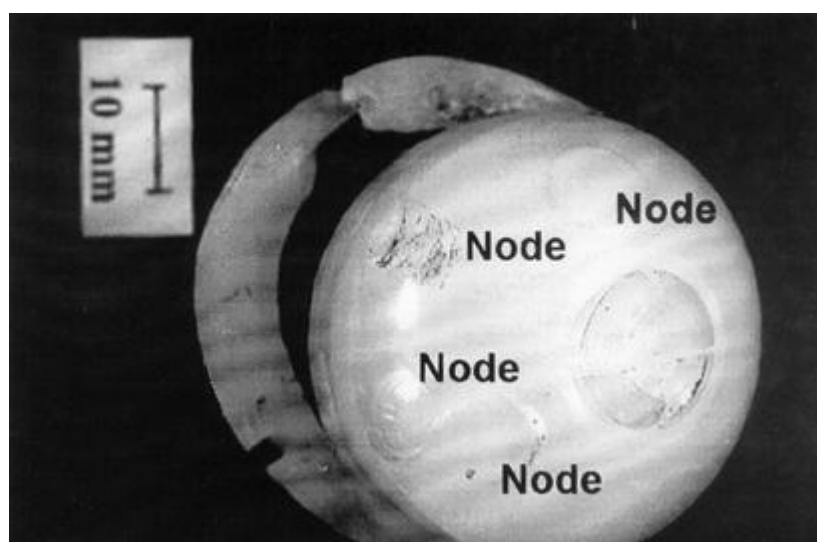


Figure 9. Backside of liner with nodes corresponding to polyethylene cold flow. (From Puolakka et al: Increased volumetric wear of polyethylene liners with more than 3 years of shelf-life time. *Int Orthop.* 2003;27:153-9).

Liners with a shelf-life time of three years or more had a significantly ( $p=0.002$ ) higher volumetric wear rate than those with a shelf-life time less than three years; average volumetric wear was  $535 \text{ mm}^3/\text{year}$  (SD 147) and  $214 \text{ mm}^3/\text{year}$  (SD 98), respectively. The Pearson correlation coefficient was 0.719, ( $p= 0.013$ ) (Figure 10).

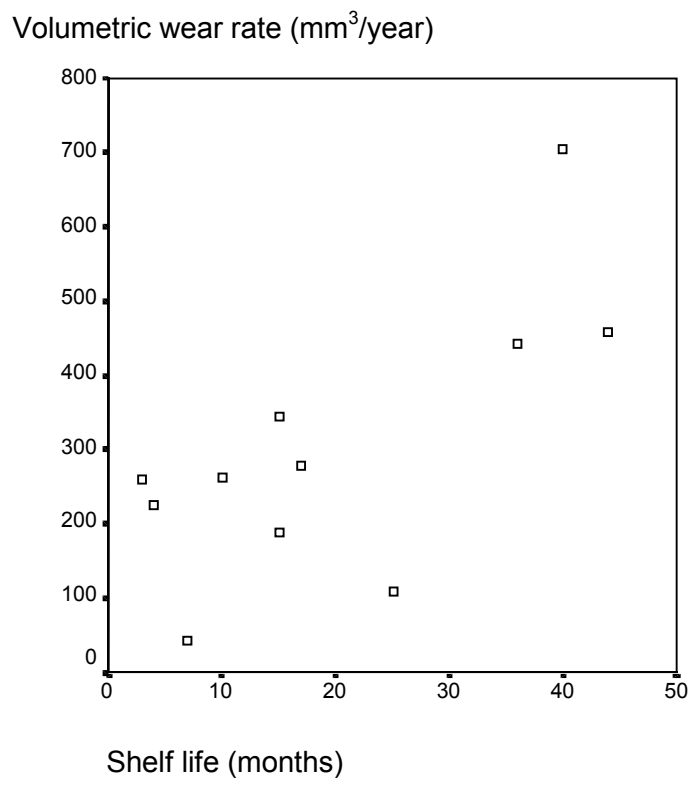


Figure 10. Increase in volumetric wear rate with increasing shelf-life time of the UHMWPE liner. The Pearson correlation coefficient was 0.719.

The median roughness of the explanted femoral heads was  $0.03\mu\text{m}$  (range  $0.01\text{-}0.29\mu\text{m}$ ). The roughness of the zirconia and CoCr heads was the same. Scanning electron microscopy examination of the liner revealed tearing, scoring and open porosity of bearing surfaces. Grooves and fringes were the most marked features in the load-bearing zone of the liner (Figure 11). The mean crystallinity of retrieved liners was 68% (SD 6) and the median oxidation index 0.86 (range  $0.56\text{-}1.03$ ). All retrieved liners showed evidence of a subsurface white band in the optical dark field micrographs (Figure 12).

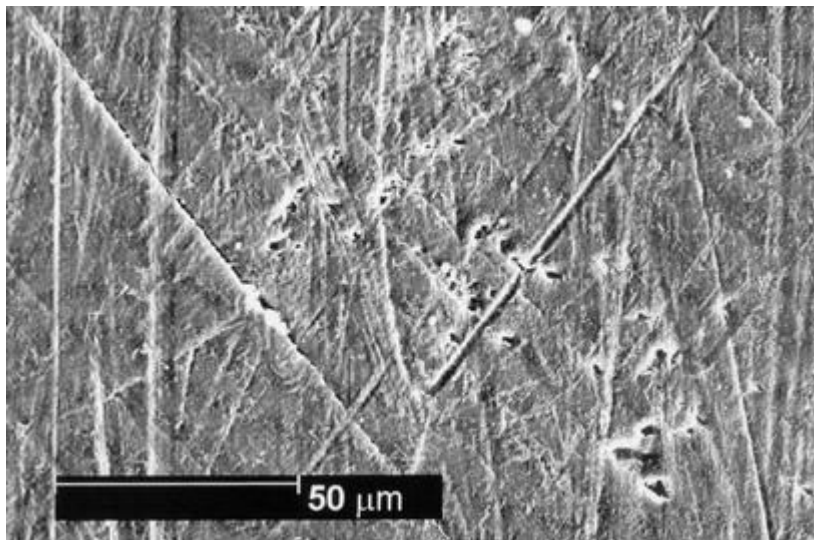


Figure 11. Grooves and fringes were the most marked features in the load-bearing zone of the liner. (From Puolakka et al: Increased volumetric wear of polyethylene liners with more than 3 years of shelf-life time. *Int Orthop*. 2003;27:153-9).





Figure 12. Subsurface white band in the optical dark field micrographs. (From Puolakka et al: Increased volumetric wear of polyethylene liners with more than 3 years of shelf-life time. *Int Orthop.* 2003;27:153-9).

## 8. Discussion

### 8.1. *The arthroplasty registers*

In Finland the incidence of THA operations almost doubled from 1988 to 1999. In 1999 the figure for primary THA was 93/100000. This is still, nevertheless, lower than in Norway and Sweden. In 2000 the incidence of primary THR was 120/100000 in Norway and 125/100000 in Sweden (Havelin et al. 2002, Malchau et al. 2002). It has been estimated that the annual number of total hip replacements by the year 2020 will increase by at least one fourth in Sweden; in other words the incidence of primary THR will be 140/100000 (Ostendorf et al. 2002). This will mean 7140 primary THR per year if the same estimate were borne out in Finland.

In the Finnish register data polyethylene wear is not separately recorded but appears in the group “other reasons”, which forms 11% of the reasons for revisions. In Finland more than 40% of hips were inserted without cement. In contrast, in Sweden less than 5% of primary arthroplasties have been cementless (Herberts and Malchau 2000). Polyethylene wear has been a rare indication for revision in Sweden, cases of revision on this indication constituting only 3% (Herberts and Malchau 2002). The Revision Burden (RB) is the fraction of revisions and the total number of primary and revision THRs. In Sweden the RB for cemented prostheses was 7,4% and for cementless ones 27,3% and for all prostheses 10% in 1998 (Herberts and Malchau 2002). In Finland the RB was 24,4% and 1158 revision hip operations were performed in 1999. If RB in Finland had been the same 10% as in Sweden, there would be only 472 revisions per year. The costs of a revision operation may be estimated at 15000 euros. This means that 686 fewer revision hip operations per year would save 10 million euros per year in Finland. We must thus acknowledge that the use of first- and second-

generation cementless implants has had poorer results than cemented devices and a negative effect on the ratio between primary operations and revision (Herberts and Malchau 2000).

Today we are able to offer life-long THA for almost all elderly people. In Finland the 10-year survival rate has been 90 % in patients older than 70 years. Results with younger patients are generally poorer; the 10-year survival was only 72% in patients younger than 55 years.

However, Lehtimäki (2001) have reported 92% 10-year survival in juvenile chronic arthritis patients performed with Charnley low-friction arthroplasty.

Especially in younger and active patients polyethylene wear has been a problem (Crowther and Lachiewicz 2002) and better solutions must be sought for these groups. Metal-on-metal (Brown et al. 2002) and ceramic-on-ceramic (Bierbaum et al. 2002) bearings could be one solution. Another alternative could be the new generation of resurfacing hips with metal on metal bearings. This is a bone-preserving procedure sparing bone stock for possible future revision. Also the large size of the femoral head could reduce the risk of dislocation. The short time follow-up of metal-on-metal resurfacing hips has been promising (McMinn et al. 1996), but long-term results are still awaited.

In Sweden long-term registration has improved the quality of hip replacement. The reason for that is continued improvement of cementing and surgical techniques as also the use of well-documented prostheses and bone cements (Herberts and Malchau 2000). In Finland the survival of cemented hip arthroplasties has remained constant over time. However, the results of cementless implants have improved with time, and in data concerning the years 1995-1999 the 5-year survival 96% was equal to or even better than that of cemented hip arthroplasties during the same period.

The poor survival of the most commonly used cementless components seems to be related to the poor survival of the cup. The main reason for revision has been aseptic loosening of the smooth first generation cups and polyethylene wear and osteolysis of the second-generation

porous coated cups. It has been difficult to perform detailed analyses of data concerning hip arthroplasties in the Finnish Arthroplasty Register, as acetabular and femoral components, as well as the material and size of the femoral heads, have been recorded separately only since 1996. In the future it will be possible to make more detailed analyses from the Finnish Arthroplasty Register.

## **8.2. Factors related to polyethylene wear**

The problem of wear of polyethylene-bearing surfaces was detected early in the history of joint replacement, but it appeared to be a matter of lesser importance in THA (Charnley and Cupic 1973, Charnley and Halley 1975). Problems arose precisely with modular metal-backed liners (Cates et al. 1993, Bono et al. 1994, Hernandez et al. 1994).

The reasons for polyethylene wear can be divided into endogenous and exogenous factors (Lewis 1997). In the present study several endogenous factors proved to be related to polyethylene wear. The ram extrusion method can create internal inconsistencies, manifested in incomplete fusion of polyethylene particles. A minimum thickness of 8mm polyethylene has been recommended (Bartel et al. 1986). In the present series all but one liner had a minimal thickness less than 5mm. In addition, sterilization was effected by gamma-irradiation in air, which together with long shelf-life time increases wear. Bohl and associates (1999) found the same adverse effect earlier with tibial components in knee arthroplasty, but we have seen no report on the effects of shelf-life time on clinical outcome in hip arthroplasty.

The design of bearing components, the level of conformity, the surface condition of the femoral head, and modularity comprise exogenous factors. The present study showed very high wear of the liner in the cementless Universal cup with cobalt-chrome femoral heads. Earlier Hozack and group (1996) demonstrated the same with titanium heads. Zirconia heads have commonly been recommended by reason of their favourable surface characteristics,

leading to less polyethylene wear in hip simulators (Saikko 1995, Smith and Unsworth 1999). In the small material in the present study as in several recent articles, both alumina- and zirconia-polyethylene pairings evinced no benefits despite the theoretical advantages (Allain et al. 1999, Sychterz et al. 2000, Haraguchi et al. 2001a, Kim et al. 2001, Norton et al. 2002). The size of the femoral head and screw fixation were the only exogenous factors significantly related to polyethylene wear. The wear rate in cases with 32mm heads was greater than that with 28mm femoral heads, as previously reported (Livermore et al.1990). Imperfect polyethylene conformity of the bearing surface due to screw holes may distribute stress unevenly, promoting the onset of surface fatigue failures and generation of debris. Increasing cross-linking has been shown in vitro and in vivo markedly to improve the wear resistance of UHMWPE, and the size of the femoral head has had no effect on polyethylene wear (Muratoglu et al. 2001a and 2001b). However, long-term clinical results are still lacking.

The Livermore technique to measure wear has been criticized because of the minor correlation between the results of two observers. This is the case when wear is less serious, because the reproducible defect has been 0.25mm (Devane and Horne 1999). In addition, according to the present study intraobserver and interobserver repeatability limits were quite high. However, Ohlin and Selvik (1993) and Ilchmann and colleagues (1995) recommended the Livermore method for clinical purposes. Sychters and associates (1999) state that for most patients two-dimensional measurements are sufficiently accurate. Comparing five manual techniques and two computer-assisted two-dimensional methods Barrack and colleagues (2001) found that computer assistance did not improve the accuracy of wear measurements. Also our own measurements comparing modified Livermore and CMM methods in retrieval study show sufficient accuracy (unpublished data).

### ***8.3. Clinical effect of polyethylene wear on the acetabulum component***

It is well documented that polyethylene particles may cause osteolysis (Harris 2001). The incidence of osteolysis increases concomitant with the rate of wear (Dowd et al. 2000). The literature indicates that osteolysis is rarely observed at a wear rate of <0.1 mm/y (Dumbleton et al. 2002). Osteolysis often comprises a localized, expansive lesion around cementless components. It is, however, not easy to detect on plain radiographs. Osteolysis behind the acetabulum is usually more extensive than expected. In the present series (study III) we found periacetabular osteolysis in only 9 % of cases despite the high wear rate. The lesions were usually around the screws and behind the screw-holes. We used only AP and lateral radiographs. Oblique radiographs could improve the detection of acetabular osteolysis (Southwell et al. 1999, Zimlich and Fehring 2000).

In addition we found RLL in 18% of hips on the acetabular side; in 2% of hips the RLL were in all three zones. Despite this all acetabular components were considered stable. The fixation of porous-coated acetabular metal shells was good in spite of high wear. Also in revision operations we found that even in cases with most serious osteolysis, acetabular components were well fixed to the bone and there was always good ingrowth to the porous-coated component.

Modular acetabulum components have always motion between liner and shell as noted in the present study; there was motion between the polyethylene liner and the acetabulum shell in every revision case. Pump-like motion between liner and acetabular shell could increase the effect of debris and may itself cause osteolysis (Aspenberg and Van der Vis 1998, Fehring et al. 1999). To avoid these disadvantages of modular acetabulum components cementless monoblock cups have been developed (Christie 2002).

In acetabulum wear could cause dislocations of the hip, when the rim of the liner has worn or fractured due to wear (Orozco and Hozack 2000, von Knoch et al. 2002). Similar occurred in 2 cases in our study III.

Wear debris may also cause other reactions besides osteolysis in the bone. Korkala and Syrjänen (1998) reported an intrapelvic mass caused by polyethylene. There was an extra-articular granulomatous tissue mass with fragments of the polyethylene liner among the contents in the cystic mass together with black metallic debris (Mak et al. 2001).

Wear through resulting metal-on-metal articulation between femoral head and acetabular shell may cause metallosis (Engh Jr et al. 2001). This could be detected in the bubble sign (Su et al. 2003). In a situation with metallosis, a revision operation is more difficult and it is almost impossible to clean out all metallic debris.

#### ***8.4. Effect of wear of polyethylene liners on the femoral side***

Femoral osteolysis is reported especially around smooth (Phillips and Messieh 1988) and noncircumferentially proximally coated cementless femoral components (Maloney and Woolson 1996). Circumferential porous coating seems to prevent the distal migration of polyethylene particles (von Knoch et al. 2000). Despite a marked debris challenge we found osteolytic lesions only in the most proximal part of the plasma-sprayed porous-coated Bi-Metric stem. This would indicate that circumferential plasma-sprayed porous coating forms a bone-implant interface tight enough to prevent the distal migration of polyethylene particles, as has previously been reported (Emerson et al. 1999). The beaded porous-coated stems have been shown to permit distal migration of polyethylene through interconnecting porous channels, resulting in distal intramedullary osteolysis (Kim et al. 1999).

## **8.5. Retrieval analyses**

We found the long-term durability of gamma-sterilized UHMWPE liners to vary significantly depending on shelf-life time before implantation. Liners with a shelf-life time of 3 years or more evinced significantly higher volumetric wear than those with a shelf-life time less than 3 years. Bohl and colleagues (1999) have previously observed earlier same adverse effect in tibial components. It is matter of concern that there is no standard for minimum shelf-life time, neither in the FDA protocol in the United States nor in the CEN/ISO standard in Europe. Many manufacturers have voluntarily limited stock shelf-life to 5 years. Orthopaedic surgeons should pay attention to the shelf-life time of THRs purchased.

Infrared spectroscopy and scanning calorimetry showed substantial *in vivo* oxidation and crystallization. The increase in OI is a direct consequence of radiation damage and shelf aging. Gamma radiation in air induces marked changes in the UHMWPE and the magnitude of aging increases with time (Kurtz et al. 2002). The energy of gamma radiation breaks the C-C and C-H bonds in the polyethylene, resulting in chain scission and the formation of free radicals. If oxygen is present, free radicals can react with it. Since free radicals may persist in UHMWPE for years, chain scission tends to increase concomitant with shelf storage. As oxidation and chain scission progress, the shortening of polymer molecules increases the density and crystallinity of UHMWPE. All retrieved liners showed an approximately 400- $\mu\text{m}$ -wide white band typically about half a millimetre below the surface. At higher magnification, the white band appeared as a trail of single particles adhering poorly to surrounding particles. SEM revealed open pores on the bearing surface, which is also related to incomplete fusion of polyethylene powder particles. Both microscopic findings also demonstrated the presence of degenerative aging in UHMWPE. Oxidative aging of polyethylene renders the polyethylene liner susceptible to severe wear. Poor acetabular design produces excessively thin liners, a substandard locking mechanism and backside wear



of the liner. The reason for the catastrophic wear of modular Hexloc liners was an unfortunate synergism of many inferior material and design factors.

## 9. Conclusions

1. Between 1980-1999 the ten-year survival of cementless hip arthroplasties was found to be improved from 71% to 81%, which is nonetheless still poorer than cemented devices with a constant 88% survival. However, more favourable prospect is shown at the latest in five years. The five years' survival was equal; 94% in cemented and 96% in cementless. Patients younger than 55 years evinced significantly poorer ten years' survival than patients older than 70 years, 72% and 90% respectively. The third-generation cementless implants are also promising in younger patients.
2. The poor survival of the most commonly used cementless implants seems to be related to the poor survival of the cup. This finding was common to all metal shell designs using Hexloc liners.
3. The median wear rate was 0.17 mm/year. The median volumetric wear was 640 mm<sup>3</sup> and the median volumetric wear rate 106 mm<sup>3</sup>/year. There were significant differences between linear wear ( $p=0,02$ ), linear wear rate ( $p=0,03$ ), volumetric wear (0,002) and volumetric wear rate ( $p=0,003$ ) in the respective femoral heads, the median linear wear being 0,28mm/year and 0.14mm/year for the 32mm and 28mm heads, respectively. In logistic regression analysis, the size of the femoral head and the screw fixation of the acetabular component were the only factors significantly related to wear rate.
4. We found neither osteolysis nor RLL in Gruen zones 2-6, not even in cases with excessive liner wear and subsequent revision of the acetabular component. Four patients had osteolysis in Gruen zone 1 and seven in zone 7. In two of these cases osteolysis was noted simultaneously in both of these Gruen zones. It seems that bone ingrowth on the proximal circumferential porous coating acts as an excellent barrier against polyethylene debris. The

nine years' survival of the Bi-Metric femoral stem component was 98,5% and the median HHS was 97.

5. Long-term durability varied significantly depending on shelf-life time before implantation. Liners with a shelf-life time of 3 years or more had significantly higher volumetric wear than those with a shelf-life time less than 3 years. Infrared spectroscopy and scanning calorimetry showed that all explanted devices underwent substantial in vivo oxidation and crystallization. The oxidative aging of polyethylene renders the polyethylene liner susceptible to severe wear. Poor acetabular design produces excessively thin liners, a substandard locking mechanism and backside wear of the liner.

## 10. Summary

The purpose of this study was to analyze the factors related to the outcome of cementless total hip prosthesis and especially to wear of the polyethylene liner and its influence on results obtained with cementless THA.

In the first study the results of total hip arthroplasties recorded by the Finnish Arthroplasty Register were analyzed. Increasing numbers of both primary and revision hip replacements have been noted. The incidence of primary hip arthroplasties was 93/100000 in 1999; 4742 primary total hip replacement and 1158 revision hip replacements were performed in that year. It is estimated that by 2020 there will be 7140 primary THRs per year in Finland.

The use of first- and second-generation cementless implants has yielded poorer results than cemented devices and has a negative effect on the ratio between primary and revision operations. The Finnish revision burden (RB) has been over double compared to that in Sweden. If RB in Finland had been the same 10% as in Sweden, we would have only 472 revisions per year. The costs of a revision operation may be estimated at 15000 euros. This means that 686 revision hip operations fewer per year would save 10 million euros per year in Finland.

The survival of cemented hip arthroplasties has remained consistent; ten-year survival was approximately 88% constantly. In contrast, the ten-year survival of cementless hip arthroplasties has improved from 71% to 81%, this being nonetheless inferior to that, of cemented ones. However, the last five years' survival was more or less equal, 94% in cemented and 96% in cementless. Survival of hip arthroplasties was clearly poorer in patients younger than 55 years compared to older patients. Ten years' survival was 72% in those under 55 and 90% in those older than 70 years. Today we are able to offer life-long THA for

almost all elderly people. The third-generation cementless arthroplasties appear to give better results than cemented devices, but long-term results are still lacking.

The poor survival of the most commonly used first- and second-generation cementless components seems to be related to the poor survival of the cup. The main reason for revision in the present series was aseptic loosening of the smooth first-generation cups and polyethylene wear and osteolysis of the second-generation porous coated cups.

An alarming degree of wear of the polyethylene liner of the cementless porous-coated Biomet Universal cup was noted. The median liner wear rate was 0.17mm/y, 32mm femoral heads showing significantly more wear than 28mm heads. The median linear wear was 0.28mm/year and 0.14mm/year for the 32mm and 28mm heads, respectively. In regression analyses the factors related to the wear rate were the 32mm size of the femoral head and screw fixation of the acetabular shell. In the present series we found periacetabular osteolysis in only 9 % of cases, despite the high wear rate.

Clinical results with cementless porous coated femoral stems seem to be excellent. The nine years' survival of the Bi-Metric femoral stem was 98.5%. The proximal circumferential plasma-sprayed porous coating acts as an excellent barrier against polyethylene debris and it could prevent distal osteolysis on the femoral side

In retrieval analyses liners with a shelf-life time of 3 years or more evinced significantly higher volumetric wear than those with a shelf-life time less than 3 years. Infrared spectroscopy and scanning calorimetry show substantial in vivo oxidation and crystallization. The increased OI is a direct consequence of radiation damage and shelf aging due to gamma radiation in air. SEM revealed open pores on the bearing surface related to incomplete fusion of polyethylene powder particles. Both microscopy findings also demonstrated the presence of degenerative aging in UHMWPE. Oxidative aging of polyethylene renders the polyethylene liner susceptible to severe wear. Poor acetabular design produces excessively

thin liners, substandard locking mechanisms and backside wear of the liner. The reason for the catastrophic wear of the modular Hexloc liners was an unfortunate synergism of many inferior material and design factors.

New innovations should be adopted for use only after close inquiry. To avoid poor results in the future we should use only prostheses with evidenced based results. Sufficient special training should be ensured before operating arthroplasties. Special qualification or special competence for arthroplasties should be developed. In future the need for joint replacements will increase, as a consequence of aging among the Finnish population. Local authorities should be prepared to cover increasing expenses for joint replacements.

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## **13. Original publications**