

From the Department of Orthopedics, Institute of Surgical Sciences,  
Göteborg, Sweden

# **The acetabular component in total hip arthroplasty**

**Evaluation of different fixation principles**

**Jonas Thanner**

ACTA ORTHOPAEDICA SCANDINAVICA SUPPLEMENTUM NO. 286, VOL. 70, 1999

---

SCANDINAVIAN UNIVERSITY PRESS



Oslo - Copenhagen - Stockholm - Boston

Printed in Sweden  
Wallin & Dalholm, Lund  
1999

# Contents

## List of papers

### Introduction, 1

- History, 1*
- Polyethylene, 2*
- Ceramics, 3*
- Biodegradable materials, 4*
- Bone cement, 4*
- Cementless fixation, 5*
- Wear, 6*
- Osteolysis, 7*
- Aseptic loosening, 7*
- Clinical evaluation, 8*
- Radiography, 9*
- Radiostereometry, 9*
- Aims of the study, 12*

### Patients and methods, 13

- Implants, 13*
- Clinical evaluation, 16*
- Radiography, 16*
- Radiostereometry, 16*
- Scintimetry, 17*
- Atomic absorption spectrometry, 17*
- Characterisation of cement, 17*
- Statistics, 17*

### Results, 18

- Study I: Evaluation of Boneloc<sup>®</sup>—chemical and mechanical properties, and a randomized clinical study of 30 total hip arthroplasties, 18*
- Study II: Poor outcome of the PCA and Harris-Galante hip prostheses—a randomized study of 171 arthroplasties with a 9-year follow-up, 20*
- Study III: Migration of press-fit cups fixed with poly-L-lactic acid or titanium screws—a randomized study using radiostereometry, 21*
- Study IV: Porous cups with and without hydroxylapatite-tricalciumphosphate coating—23 matched pairs evaluated with radiostereometry, 23*
- Study V: Hydroxyapatite and tricalcium phosphate-coated cups with and without screw fixation—a randomized study of 64 hips, 24*

### Discussion, 26

- Study I: Fixation with different bone cements, 26*
- Study II: cementless fixation with different designs, 27*
- Study III: porous cups fixed with different screws, 28*
- Study IV: Porous cups with and without ceramic coating, 29*
- Study V: Porous cups with and without screw fixation, 30*
- Summary and future recommendations, 32*
- Conclusions, 33*

### Summary, 34

- Acknowledgements, 34*

### References, 35

# List of papers

This presentation is based on the following papers (roman capitals I–V):

- I Evaluation of Boneloc®. Chemical and mechanical properties, and a randomized clinical study of 30 total hip arthroplasties.  
*Thanner J, Freij-Larsson C, Kärrholm J, Malchau H, Wesslen B.*  
Acta Orthop Scand 1995 Jun; 66(3): 207-14.
- II Poor outcome of the PCA and Harris-Galante hip prostheses. Randomized study of 171 arthroplasties with 9-year follow-up.  
*Thanner J, Kärrholm J, Herberts P, Malchau H.*  
Acta Orthop Scand 1999 Apr; 70(2):155-162.
- III Migration of press-fit cups fixed with poly-l-lactid acid or titanium screws. A randomized study using radiostereometry.  
*Thanner J, Kärrholm J, Malchau H, Wallinder L, Herberts P.*  
J Orthop Res 1996 Nov; 14(6): 895-900.
- IV Porous cups with and without hydroxylapatite-tricalcium phosphate coating. 23 matched pairs evaluated with radiostereometry.  
*Thanner J, Kärrholm J, Malchau H, Herberts P.*  
J Arthroplasty 1999; 14(3): 266-280.
- V Hydroxyapatite and tricalcium phosphate-coated cups with and without screw fixation. A randomized study of 64 hips.  
*Thanner J, Kärrholm J, Malchau H, Herberts P.*  
Submitted 1999.

## Introduction

In Sweden, approximately 10,000 total hip arthroplasties are performed annually. The results have improved over time, as reflected by a relative decrease of clinical failures resulting in reoperation. However, such revision procedures constitute 7–20% of the total hip replacements performed in different Scandinavian countries. Previous investigations have shown that the pathophysiology and incidence of implant failure display important differences between the acetabular and the femoral components.

Numerous designs of acetabular components relying on either cemented or cementless fixation have been introduced. Furthermore, many compositions of bone cements have been tried at the same time as many uncemented fixation principles have been introduced with varying success. In the long term, failure of the acetabular component is the most common reason for revision surgery. Early micromotion or wear of the socket, not detectable by conventional radiography, usually precede these failures. After several years, these events may result in detectable radiographic changes, which finally may result in obvious clinical failure. Many implants or fixation principles with inferior performance are therefore still identified late in observational studies including large patient cohorts.

The aim of the present study was to investigate different fixation principles of the acetabular component, and to apply methods that permit early detection of implant properties assumed to be of importance for their long-term performance. The aim was also to provide a scientific basis for optimal implant selection and thereby reduce the number of patients subjected to the potential hazards of new implant designs or fixation principles.

### History

In 1939, Smith-Pedersen introduced the vitallium cup arthroplasty. The acetabulum was reshaped

using hand reamers and a moulded cup was inserted. Smooth surfaces both in the acetabulum and on the femoral head were considered to be important. They should ensure free movement of the vitallium mould on the femoral head and in the acetabulum. The Smith-Pedersen arthroplasty was used for several years, but long-term follow-up revealed unacceptably high revision rates (Law 1962). In 1956, McKee and Watson-Farrar introduced a hip replacement of ball and socket type with a metal-metal articulation (McKee and Watson-Farrar 1966). This implant was also made of chrome-cobalt alloy. The fixation of this cup was achieved by the attachment of a threaded peg, which was screwed into the acetabular roof. This concept was not sufficient to obtain reproducible and lasting fixation and the results were similar to those obtained with the cup interposition arthroplasty by Smith-Pedersen.

When Charnley (1960) described the use of methyl methacrylate to anchor femoral components within the femur, the McKee-Farrar cup was redesigned to permit cemented fixation. Despite the improved fixation, these all-metal prostheses with large (38 to 42 mm) femoral heads were associated with high friction in the socket, resulting in wear and greater strains on the bone-cement interface (Swanson et al. 1973). In 1973, McKee and Chen reported 6% revisions and 2% acetabular loosening after 2–3 years with this design. However, some long-term studies have shown encouraging results with the McKee-Farrar arthroplasty (Jacobsson et al. 1996, Schmalzried et al. 1996). Patient selection and technical factors possibly contributed to the long-term survival, and conversely to the failure of this design. The McKee-Farrar arthroplasty has not been used since the mid 1970s, because of frequent loosening and concerns about metal release. Metal-metal articulations manufactured with a more exact fit between the articulating surfaces have later been reintroduced, because of their high wear resistance. The absence of polyethylene material in

such a joint has also been considered advantageous (*vide infra*). The accumulating evidence of the central role of polyethylene particles in generation of periprosthetic bone resorption (Schmalzried et al. 1992a, 1992b) further explains the renewed interest in metal-metal bearings.

In the early 1960s, Charnley introduced the low friction arthroplasty, with a 22-mm stainless steel head and a plastic acetabular component. This design represented the start of a new era in the history of total hip arthroplasty (Charnley 1970). Both the acetabular and the femoral components were fixed with cement. The articulation with a small femoral head implied less friction torque. The Charnley prosthesis is still the gold standard among cemented prosthetic designs. Excellent results, with survival rates of 88% after 16 years on a national level (Herberts and Malchau 1997) and 84% after 20 years in special series, have been reported (Kavanagh et al. 1994). The early success with the Charnley prosthesis in the 1970s stimulated the evolution of numerous design variations, wider indications and an increasing frequency of operations.

Already in the mid 1970s, cementless implants were developed in France because of high rates of loosening of cemented sockets. (Judet et al. 1978, Lord et al. 1979). Both the acetabular and the femoral component in the Judet design had a rough-textured surface and the components were inserted with the press-fit technique. Lord introduced a prosthesis with a threaded ring and a femoral stem with a macroporous surface in 1975, and reported on 7-year results as early as in 1983 (Lord and Bancel).

In young and active patients, early studies reported poor results (Chandler et al. 1981). Dorr et al. (1983) called attention to the need to develop new implant designs and alternative solutions to bone fixation. Some attributed the failure exclusively to the cement itself and the term "cement disease" was popularised (Jones and Hungerford 1987). Thus, in the late seventies and early eighties many cementless hip systems were introduced, based on experimental studies of bony ingrowth into microporous surfaces (Galante et al. 1971, Pilliar et al. 1975, Pilliar 1987). During the last two decades several new uncemented implants with differences in design, material, surface tex-

ture and coating have been developed and used in clinical practice, often without any organised long-term follow-up.

Threaded acetabular cups in different materials (ceramic, chrome-cobalt or titanium) were introduced in the late 1970s. These implants had initially a smooth surface which did not integrate with the bone (Snorrason and Kärrholm 1990). The clinical results have been disappointing. Engh et al. (1990) reported radiographic signs of instability in 21% of the patients with smooth threaded acetabular components after 4 years and 25% had clinical symptoms. Malchau et al. (1996) reported on the Lord arthroplasty and the cup survival rate was only 70% at 10 years.

Press-fit hemispherical designs (second generation of cementless cups) with the possibility to achieve maximum contact against the bone have shown good fixation in clinical materials (Latimer and Lachiewicz 1996, Incavo et al. 1996, Berger et al. 1997, Dorr 1998). These cups have a porous or rough surface to achieve biological fixation. Addition of a thin layer of a calcium ceramic to this surface may further improve the fixation (Søballe 1993, Geesink and Hoefnagels 1995). Many of these sockets are used with additional screws, spikes or pegs to secure the initial fixation of the metal shell, but the need for these fixation devices has not been studied in randomised clinical trials until recently.

## Polyethylene

Polyethylene is a viscoelastic material formed by polymerisation of ethylene molecules under high pressure. Charnley (1962) was the first to use sockets made of high molecular weight polyethylene. Earlier he had discarded polytetrafluoroethylene (Teflon) as a bearing surface because of inadequate wear properties. Ultrahigh molecular weight polyethylene (UHMWPE) is currently used in orthopedic implants because of superior wear resistance. Nevertheless, improvements in design characteristics and material properties are desirable to further reduce wear. It is evident that polyethylene particles can initiate inflammatory reactions and bone resorption (Howie et al. 1988, 1990), phenomena which have been observed in associa-

tion with aseptic loosening (Santavirta et al. 1991, Schmalzried 1992a, 1992b, Harris 1994, McKellop et al. 1995).

Polyethylene plastics not only vary regarding molecular weight, crystallinity and degree of cross-linkage, but there are also other variations of the raw material caused by unintentional differences during the manufacturing process. These factors have been difficult to control, which may partly explain why the wear of one and the same implant can vary over time (Tanner et al. 1995). Manufacturing and sterilisation processes will influence physical properties important for wear behaviour. Polyethylene should not be autoclaved because high temperatures may cause softening and degradation. Ethylene oxide can be used for sterilisation, but most orthopaedic implants made of polyethylene are sterilised using high-energy electron beams or gamma-radiation. Gamma-radiation creates free radicals, which induce cross-linking of molecules. However, in the presence of air free radicals can also result in oxidation and degradation of the surface layer, thereby decreasing its wear resistance.

Satisfactory design of the polyethylene implant is crucial for long-term success. The thickness of the polyethylene has to exceed a minimum value. Modular components must have a safe liner locking mechanism and provide conformity between the liner and the metal shell, to minimise the risk of friction by motion.

## Ceramics

Calcium phosphate ceramics such as hydroxyapatite (HA) and tricalcium phosphate (TCP) are biocompatible and can become attached to bone with chemical bonds (Jarcho 1981). They are composed of the same ions as in natural bone mineral and participate in the equilibrium of calcium phosphate ions at the interface. Shortly after implantation a thin layer of newly formed apatite can be observed attached to the coating. These coating materials are bioresorbable, but the rate and degree of resorption vary between different calcium phosphates and are also related to the surface area. The resorption is solution or cell-mediated. Phagocytosis of coating material may occur,

which can initiate inflammatory reactions. TCP is resorbed more rapidly than HA and dense coatings with high crystallinity are less resorbable than porous structures with less crystallinity (Klein et al. 1983).

Retrieval studies have revealed that many porous coated implants are fixed by fibrous tissue (Bobyn et al. 1987, Cook et al. 1988) and interest has been focused on ceramic coatings to achieve enhancement of early bony ingrowth. HA cannot be used as an implant because of its brittleness. However, calcium phosphates can be applied to metallic surfaces. The most common method used today is the plasma spraying technique, developed in the 1980s (deGroot et al. 1987).

The quality of the coating depends on several factors, such as crystallinity, purity, density and thickness. Decreased thickness of the ceramic layer improves its fatigue strength. Thin coatings are also necessary to preserve a porous surface of an implant. A coating thickness of about 50–75  $\mu\text{m}$  has been recommended for clinical use (Geesink 1987). Thicker coatings may be brittle, due to decreased fatigue strength, and thinner coatings may resorb too quickly. HA particles can theoretically be responsible for third-body wear of the plastic liner and modern techniques try to attain thin ceramic applications. The bond strength between the HA and the substrate is related to the porosity and thickness of the coating, thereby limiting the possibility of decreasing the thickness. In the present study, we used ceramic coatings consisting of a combination of HA and TCP. The coating was plasma-sprayed on implants with a porous mesh made of pure titanium. Tricalcium phosphate is more bioresorbable than hydroxyapatite and is therefore more suitable to stimulate early ingrowth of bone into porous surfaces.

Animal studies have shown that HA enhances bone growth across gaps between the implant and bone in stable and unstable conditions (Søballe 1993). Applications of HA coatings in total hip arthroplasty are now well-documented and clinical and radiological results have been promising (Kroon and Freeman 1992, Kärrholm et al. 1994, Geesink and Hoefnagels 1995, Moilanen 1996, D'Antonio 1996 and Capello et al. 1997, 1998). Retrieval studies have also shown increased bone ingrowth into porous surfaces, confirming the os-

teoconductive properties of HA (Bauer et al. 1991, Bloebaum et al. 1991 and 1993).

## Biodegradable materials

Biodegradable screws and pins have been used to fix fractures and osteotomies. Polylactic acid is biodegraded by hydrolytic scission of the ester bonds in the polymer chain. The degradation products are ultimately eliminated as carbon dioxide and water. Rapid degradation may exceed the capacity of the tissue to phagocytise the polymer chains. This mechanism might explain the occurrence of osteolysis and sterile subcutaneous exsudations after use of polyglycolic acid rods to obtain internal fracture fixation (Böstman 1991). Poly-L-lactic acid (PLLA) degrades more slowly than polyglycolic acid. Pihlajamaki (1992) did not observe any complications after internal fixation with PLLA pins of small-fragment fractures and osteotomies. Biopsies in two patients, 20 and 37 months after implantation, did not reveal any remaining polymeric material, suggesting that PLLA is a safer material. In the early 1990s, PLLA seemed to be without adverse effects, suggesting that it could be safely used for implant fixation. No complications had been noted after insertion of such screws when used to treat femoral condylar fractures or to fix acetabular cups in the canine (Andersson 1992).

## Bone cement

### *Basic principles*

The main component of bone cement is polymethyl methacrylate (PMMA). Small amounts of substances, which stabilise the liquid during storage or initiate the polymerisation process, are added. Barium sulphate or zirconium oxide is mixed with the powder to make the cement radiopaque. Antibiotics and colour pigments are also commonly added.

Before insertion of the implant, the prepolymerised methyl methacrylate powder and liquid monomer are mixed, usually in a system, which reduces the aerial pressure, thereby reducing the number of voids. The polymerisation process gen-

erates heat. The temperatures generated at the bone-cement interface will vary depending on a number of factors, e.g. the composition of the cement, the initial temperature of the components, the amount of cement used, the interface geometry and the heat conductivity of the implant and the tissues. In total hip arthroplasty, temperatures between 40° and 70° have been recorded (Mjöberg 1986, Wykman 1992). Wykman (1992) noted that continuous water irrigation reduced the amount of heat at the acetabular bone-cement interface to median 41 (37–48) °C. The threshold temperature to impair bone regeneration has been determined to 44–47 °C during one-minute exposure (Eriksson 1983). The production of heat is proportional to the amount of monomer used (Debrunner et al. 1976). Not only heat (Feith 1985) but also the monomer itself can be toxic to the bone cells (Willert 1974, Linder 1976). Cell injury and necrosis initiate inflammatory reactions. The fibrous membranes commonly seen between the bone and the cured cement (Charnley 1970, Freeman et al. 1982, Linder and Carlsson 1986, Goodman et al. 1988) have been believed to be the result of injuries caused by heat (Mjöberg 1986) or monomer toxicity (Pedersen et al. 1983, Stürup et al. 1994). Porosity, due to entrapment of air during the mixing procedure, decreases the fatigue strength (Burke et al. 1984). This might facilitate the development of microfractures, which may be involved in the loosening process of the femoral component (Jasty 1991). Reduction of porosity by vacuum mixing (Lidgren et al. 1984) or centrifugation (Burke et al. 1984) will improve the mechanical properties of the cement, but it is still uncertain if these measures will have any positive influence on the fixation of the acetabular or femoral components in a clinical material.

Modern cementing technique also includes brushing, high-pressurised irrigation and pressurisation of the cement. These measures significantly reduce the mechanical failure rates (Herberts and Malchau 1997). Careful and precise surgical preparation of the bone is thus important. Several holes are drilled or punched in the acetabular roof to achieve cement-bone interdigitation. Close contact between bone and cement is dependent on clean and dry bony surfaces.

### **Fixation of implants with cement**

Charnley (1960) introduced the bone cement as the standard fixation for hip prostheses. Improvements of the cementing technique and not the cement itself have been the most important reason for reduction of the clinical loosening rate with time. Long-term follow-up of cups cemented with finger packing (first generation of cementing technique) showed a high rate of acetabular component failure (Stauffer 1982, Sutherland et al. 1982, Wroblewski 1986). Despite the use of newer cementing techniques, a high incidence of radiographic acetabular loosening (42%) has been reported after 10 years (Mulroy and Harris 1990). The same authors recently published 15-year results in younger patients. Acetabular loosening occurred in 50–79% depending on design (Mulroy and Harris 1997). However, these and other reports have clearly demonstrated that modern cementing techniques have resulted in improved long-term fixation of femoral stems.

In the study of Mulroy and Harris (1997) the number of patients was relatively small (40 patients, 47 hips) and different acetabular cups were included. Several recent studies have shown a significant improvement of fixation also of the acetabular component with the use of better cementing techniques (Malchau et al. 1993, Ranawat et al. 1997) and the question whether to use cement or not in the acetabulum is still controversial.

### **Cold-curing cements**

Heat generation during cementing of hip implants with a standard cement (Palacos<sup>®</sup> cum gentamicin, Schering-Plough) was measured by Toksvig-Larsen et al. (1991). They stipulated that bone necrosis could be expected in 10% of the cases. To reduce heat injury, cold-curing cements have been developed and used in clinical practice. Mjöberg (1986) used bone cement with polymer particles of different sizes, allowing use of a smaller amount of monomer. Radiostereometry revealed improved initial fixation compared to conventional cement but the follow-up was short, 4 months, and no further follow-up has been presented. Stürup et al. (1994) concluded that release of hot and toxic chemicals is more harmful to the interface than heat alone. Boneloc<sup>®</sup> cement was developed to reduce the leakage of monomer and curing

temperature (Jensen et al. 1991). The cement does not only contain methyl methacrylate but is a mixture of different polymers (methyl methacrylate/n-decyl methacrylate/isobornyl methacrylate). Boneloc cement was reported to diminish bone injury and to facilitate bone repair (Nimb 1993). This bone cement was widely used in Denmark and Norway during the early 1990s, but turned out to be a large scale clinical failure.

### **Cementless fixation**

In early cementless designs, implant fixation was achieved by impaction of the prosthesis into the bone (Moore 1943) or by mechanical internal fixation such as screws (Ring 1968). In the 1970s several screw-in cups were introduced, such as the Lord cup (1978), and they were widely used in Europe. Prostheses like these with smooth surfaces could not maintain their initial stability (Snorrason and Kärrholm 1990, Engh 1990). For long-term fixation, the use of surface structures that permit biological attachment is necessary. It was early shown that bone could grow into porous surfaces of different materials and designs (Jones 1960). Different heat sintering processes of metals and ceramics can be used to produce porous surfaces. Pores are applied by sintering microspheres, powders or beads to the substrate. In a clinical study, Cameron (1982) studied femoral components with a microporous surface consisting of sintered tiny cobalt-chrome beads (Pilliar et al. 1975), but bone ingrowth was not uniformly achieved.

Titanium has been used as a surface material in porous coatings because of its high biocompatibility and resistance to corrosion. In 1971, Galante described a porous mesh of sintered titanium fibres ( $\varnothing=0.2$  mm) with a porosity of 50%. When implants with this coating were inserted in rabbit femurs, bone had grown deeply into the mesh after 3 weeks. Similar observations were made in femoral components in dogs, supplied with the same type of mesh.

Later, Harris (1983) studied hemispheric acetabular cups with sintered chrome-cobalt balls on the outer surface in a canine study. All components were fixed rigidly, bony ingrowth covered

53% of the porous surface of the implant and bone grew into the porous layer.

The development of modern acetabular designs used in clinical practice today is based on these findings. In many cup designs the whole metallic part of the cup or its thicker and inner layer has been replaced by cobalt-chrome or titanium-vanadium-aluminum alloy (Ti-6Al-4V). Hemispherical porous-coated cups have displayed low complication rates up to 10 years (Berger 1996 and 1997, Latimer and Lachiewicz 1996) and bone ingrowth into the porous coatings does occur, but this process requires stability (Pilliar et al. 1986). Primary stability can be achieved with the press-fit technique (impaction, under-reaming) which has often been complemented with screw fixation.

## Wear

Wear of artificial hip joints depends on several factors, such as the surface finish, the material hardness, the type of lubricant, the femoral head diameter, the joint pressure and the number of gait or motion cycles. There are several ways in which wear occurs, but abrasive probably dominates over adhesive and corrosive wear. Pin-on-disc studies and joint simulator tests are examples of laboratory tests allowing evaluation of wear characteristics of different materials. In artificial hip joints, the sliding distance between head and socket is dependent on head size. The volumetric wear is directly related to the head size (Charnley et al. 1969b, Livermore et al. 1990, Kesteris et al. 1996). Smaller femoral heads result in higher local pressures and the cold flow and linear wear can be expected to be higher.

Many types of polymers, such as polyacetal (delrin), teflon, polyester and polyethylene have been tried as bearing surfaces in total hip arthroplasty. All but polyethylene have been abandoned due to excessive wear (Charnley 1962, Havelin 1986). This plastic, now modified into ultrahigh molecular weight polyethylene, has become the most common type of articulating material on the acetabular side. Modifications of the molecular size have resulted in improved wear properties. Nonetheless, annual wear rates of about 0.1–0.2 mm are reported (Livermore et al. 1990,

Schmalzried et al. 1992, Wroblewski 1992, Callaghan et al. 1995, Devane et al. 1995), indicating release of enormous amounts of submicron particles to the joint (McKellop et al. 1995).

To minimise wear, the femoral head must have optimum surface finish. The geometry of the femoral head and liner must be manufactured exactly to minimise generation of particles (Ritter et al. 1996, Livingston et al. 1997).

In modular components, motions of the polyethylene insert in relation to the metal shell can result in wear (Chen et al. 1995, Lieberman et al. 1997). Rocking and pistoning between nonconforming components during loading can be of importance (Kurtz et al. 1998). This wear probably contributes to secondary changes in the bone such as local resorption but the quantitative importance of this factor is not known. Rotations of the liner inside the shell and even liner extrusions observed with early designs of press-fit cups are, however, obvious signs of this problem (Retpen and Solgaard 1993, Astion et al. 1996). More recent cup designs have tried to address this problem by exact conformity between the insert and the shell, a secure locking mechanism, a polished surface of the metal against the polyethylene and exclusion of thin liners.

Fretting between the screw heads and the metallic shell is another source of particles and screw holes may facilitate transport of particles to the bone implant interface (Huk et al. 1994). Metal release from implants occurs in the form of ions and wear particles. It is inevitable that modern metal-metal articulations of cobalt-chrome alloy create particles, but the wear rates have been reported to be low (Streicher 1996, 1998). The number of wear particles seems to be lower in metal-metal articulations, but they are also smaller compared to polyethylene particles (Soh 1996, Walker 1998). Fretting and corrosion between the femoral head and the taper in modular designs are other sources of metal ions and particles and can possibly influence the amount of wear (Urban et al. 1994).

Significant metal release to local tissues and distant organ systems also takes place and might be potentially hazardous to the host (Woodman et al. 1988, Salvati et al. 1993, Urban et al. 1994).

## Osteolysis

Periprosthetic bone resorption or osteolysis is one of the major problems in hip replacement. Charnley observed osteolysis around sockets made of Teflon, but the failure mechanism and the relation to massive wear was not understood. Charnley also reported on osteolysis around cups made of ultrahigh molecular weight polyethylene but at that time sepsis was common, and these changes were believed to be of infectious origin despite negative cultures (Charnley et al. 1968). In 1977, Willert and Semlich described foreign-body reactions around hip components. They focused attention on particles and macrophages and were aware of the importance of the lymphatic system in transporting particles away from the joint.

Detailed analyses of membranes around loose implants revealed synovial-like cells adjacent to the cement layer, capable of generating high levels of prostaglandin E2 and collagenase. These substances were believed to initiate bone resorption (Goldring et al. 1983). Later, slowly progressive endosteal erosions were described around well-fixed and stable cemented implants (Jasty et al. 1986). These osteolytic lesions were by some believed to be a biological response to cement particles (Jones and Hungerford 1987). Identical tissue reactions were shown also to develop in cementless arthroplasties (Santavirta et al. 1990). What previously was claimed to be cement disease was given a new name, "particle disease" (Harris 1994). Histological evaluations of tissues around failed primary arthroplasties have revealed metal, cement and polyethylene particles (Nasser et al. 1990, Buly et al. 1992, Schmalzried et al. 1992), but it is generally believed that polyethylene wear debris is the major cause of osteolysis (Hirakawa 1996). At present, the upper limits for acceptable annual wear are supposed to be 0.1–0.2 mm and 80 mm<sup>3</sup> for linear and volumetric wear, respectively. Abrasive wear results in release of many polyethylene particles. Most of these particles are submicron (Campbell et al. 1995) and ingested by macrophages, which initiate a complex cellular response, including release of substances such as cytokines, growth factors and inflammatory mediators, ultimately resulting in bone resorption, mainly by osteoclasts.

## Aseptic loosening

Implant loosening is the commonest reason for revision surgery. It has been suggested that the loosening process differs between the femoral and acetabular components. On the femoral side, retrieval studies have shown cement fractures and local osteolytic lesions around defects in the cement (Maloney et al. 1990). These findings have supported the theory that this loosening process is initiated by a separation at the cement-implant interface. Primary loosening starting at the bone-cement interface is uncommon and mainly occurs in instances where the bone bed is compromised due to a previous loosening or the cementing technique has been inadequate.

On the acetabular side, poor initial stability caused by an inadequate cementing technique, poor implant design or, when using cementless cups, poor bone-implant contact may initiate the loosening process. A fibrous interface will develop, which will facilitate transportation of joint fluid and particles into the interface. Schmalzried et al. (1994) suggested that a progressive osteolytic process starting at the periphery would end up in clinical loosening, without focusing on the presence of micromotions. Findings of radiolucent lines and local areas of bone resorption close to the cup in seemingly stable implants support this theory.

Changes of the hydrostatic pressure, perhaps due to membranous tissue structures, which permit the flow of body fluids in one direction only, have been proposed as another mechanism of implant failure. Elevated intracapsular pressures have been seen in patients with aseptic loosening of acetabular and femoral components. The pressure has been reported to vary with different positions of the hip (Robertsson et al. 1997) and increased intraarticular pressure has been found to correlate with pain (Gosling 1988). Even if acetabular cups have intimate peripheral contact and seem to be stable, micromotions can induce pressure waves able to pump the joint fluid in and out of the interface (Franzén et al. 1993). Animal studies have shown that increased fluid pressure can induce bone resorption (Aspenberg et al. 1998). Further, wear debris is not always found in osteolytic lesions (Willert et al. 1990). It has also

been shown that the concentration of cytokines with the capacity to induce bone resorption will increase a few years after implantation, even in successful cases without signs of loosening or accelerated wear (Nivbrant et al. 1999). These findings indicate that the interfaces should be protected from intrusion of joint fluid, because of its ability to initiate bone resorption by chemical substances or high pressure. Avoidance of these side effects by primary stability is probably one of the most important factors to reduce the risk of implant loosening (Mjöberg 1994).

### Clinical evaluation

Preclinical testing is necessary before new implants and bone cements are introduced for clinical use. Mechanical and wear properties must be tested thoroughly. The clinical performance can only be evaluated in prospective, randomised studies in which new implants are compared with established concepts (Chalmers et al. 1983, Gross 1988, Keller et al. 1993, Cochrane collaboration: Mulroy and Oxman 1996).

Different score systems have been used to describe pain, motion and walking ability (d'Aubigne and Postel 1954, Charnley 1979). The Harris score was introduced in 1969 and included active daily living functions and deformity. This score system was originally designed to evaluate acetabular fractures but has later been widely used in hip arthroplasty. Specific pain drawings and visual analogue scales (Huskisson 1974) are other instruments used to describe pain. It is essential that the observer is independent as well as objective. Consequently, the surgeon must not be involved. Clinical outcome parameters are blunt instruments for detection of implant failures and long-term follow-up is needed, which is a disadvantage. Furthermore, replacement of the diseased joint with a prosthesis will in the majority of cases eliminate or markedly reduce the type of pain experienced before operation. Complications from the implant will only occasionally cause pain in the early phase. If present, this pain has another quality than experienced before the operation and may not be interpreted by the patient as hip or implant related.

There are also problems associated with the definition of various failure parameters. Failure can be defined in different ways, e.g. loosening or revision. Various statistical methods are used to calculate survivorship of implants. Life tables account for deceased patients and those lost to follow-up. The survival analysis according to Kaplan-Meier (1958) was originally developed for other research areas but has also become popular for evaluation of total hip arthroplasty. However, the use of these methods to describe the outcome of arthroplasties has been criticised (Murray et al. 1993). The choice of end-points is critical. Indications and resources for performing revisions vary as well as the definitions of radiographic loosening or migration. Another confounding factor is that minor changes of the surgical procedure and the implant design often occur over time. Further, the number of patients at risk also decreases with time. Presentation of confidence intervals is therefore mandatory. Nonetheless, the data will be less and less informative with increasing observation time.

Valuable information is obtained from observational studies such as the national hip arthroplasty registers in Sweden and Norway (Herberts et al. 1989, Anfeldt et al. 1990, Espehaug et al. 1995, Havelin et al. 1995). The Swedish register was initiated in 1979 and primary and secondary operations (revisions) are reported. This register contains data from more than 150,000 primary arthroplasties and makes it possible to study differences in choice of implant design, mode of fixation and surgical technique (Herberts and Malchau 1997). Because large patient cohorts are studied, small differences between different subgroups can be detected and the performance of hip replacements in Sweden has improved due to this effort. Usually, however, there is a long delay between implantation and clinical failure and large registers often have further delays due to administrative reasons. Many patients may therefore be treated with a new implant or surgical technique before the efficacy of these procedures can be evaluated. In these situations, other instruments have to be used to obtain a faster evaluation, which should also minimise the number of patients exposed to the potential hazards of the new technique.

## Radiography

Standard radiographic examinations are done in the supine position. The film-focus distance and the exposure rate should be as standardised as possible to allow comparisons between examinations done at increasing time intervals after implantation. To standardise the evaluation further, the interface around the cup is divided into three regions on the anteroposterior and the lateral view, respectively (DeLee and Charnley 1976). The femoral stem interface is analysed in seven regions in the frontal plane and seven in the sagittal plane (Gruen et al. 1979). The presence of postoperative radiographic findings such as bone-remodelling, radiolucent lines (zones), erosions, granuloma or osteolytic lesions is defined and described in the different areas.

Two-dimensional migration can be calculated from serial radiographs using reference points in the skeleton and implant landmarks. A precision of 1–3 mm for vertical migration has been reported (Freeman and Plante-Bordeneuve 1994, Walker et al. 1995), but it is uncertain if this accuracy can be achieved when anatomical landmarks are used in a prospective study. Plain radiographs can be digitised and stored in a computer and interpreted with unchanged accuracy (Malchau et al. 1995). These authors reported an accuracy of vertical cup migration between 4.4 and 6.6 mm. The corresponding values for the stem were 3.9 and 12.3 mm, depending on the choice of landmarks. The precision increased when implanted markers were used as reference points.

Radiographic follow-up should be done to detect early changes. In the standard case, this can rarely be done earlier than (1–) 2 years after the operation. Radiolucent lines (RLL) or zones correspond to bone resorption. New or increasing radiolucencies have been found to correlate with mechanical loosening (Hodgkinson et al. 1988, Strömberg et al. 1996). However, radiographic evaluation is subjective and there is considerable inter- and intraobserver variability when interpreting radiolucent lines (Brand et al. 1985, McCaskie 1996). In addition, there is an underestimation of radiographic signs compared with the clinical situation when implants are removed (Engh et al. 1993). It is generally accepted that radiographic

loosening should be defined as bone resorption (>1 mm) around the whole interface and/or significant migration. Fracture of the cement (Harris et al. 1982, Mulroy and Harris 1995) and in some studies also varus/valgus tilt of the stem has been interpreted as definite loosening (Gruen et al. 1979).

The amount of linear wear can be estimated from plain radiographs. Problems may arise when metal-backed cups or heads in alumina materials have been used, because of difficulties in visualising the contours of the femoral head. Charnley only measured vertical wear, assuming that this was the main direction. According to Livermore (1990), the thinnest part of the polyethylene should be measured and compared with the postoperative radiograph. The known head diameter is used to correct for magnification. The EBRA (Ein Bild Röntgen Analyse) method (Russe 1988, Krismer 1995) can be used for measurements of both migration and wear and this method is more accurate than the Livermore technique regarding wear (Ilchmann 1997). It is a computerised method, where changes of pelvic rotations can be compensated for, using positions of anatomical landmarks. This can be done up to a certain level of rotation, where the method becomes inaccurate (Krismer et al. 1995). More recently, another computerised system, allowing three-dimensional measurements based on coordinates from two-dimensional radiographs has been introduced by Devane et al. (1995). This method of measuring wear can be applied to metal-backed cups.

## Radiostereometry

The most accurate method of measuring both migration and wear is radiostereometric analysis (RSA). This method relies on implantation of small metallic markers for most of its applications. It also requires simultaneous exposure of two x-ray tubes and a calibration system.

In 1974, Selvik presented a method based on mathematical principles of rigid body fitting and calculation of three-dimensional motions, roentgen stereophotogrammetric analysis (RSA). This method, later named radiostereometric analysis, has become widely used. It has been continuously

developed to improve its applicability in a number of fields in orthopedic research, to increase its accuracy and to speed up and facilitate the evaluation procedure (Kärrholm 1989, Söderqvist and Wedin 1993, Nyström et al. 1994, Börlin 1997, Kärrholm et al. 1997, Valstar et al. 1997, Östgaard et al. 1997 and Vrooman 1998).

To obtain distinct anatomical landmarks, spherical tantalum markers with a diameter of 0.8 or 1.0 mm are inserted in the skeleton and in the implants. These types of tantalum markers have been used as skeletal markers for almost 30 years without any adverse reactions. The markers are easy to identify on radiographs due to the high density of tantalum. A steel cannula with piston or a spring-loaded piston in an insertion instrument is used to implant markers into the skeleton. Scattering of the markers in the bone is important. Up to 9 markers are often used in each segment to optimise the precision. In young bone, where the metabolism is rapid, the markers can be unstable initially but in the adult skeleton initial and lasting stability is usually obtained (Ragnarsson et al. 1989). Marking of implants is dependent on design and material. Acetabular cups made entirely of polyethylene and polyethylene inserts of cementless cups are supplied with tantalum balls around the opening of the cup. Markers can also be inserted into the dome, but in this study we avoided inserting such markers in cementless cups, due to concerns of wear and weakening of the polyethylene.

In RSA, migration of the femoral component can be measured as translations of the femoral head centre. Femoral components are, if possible, supplied with tantalum markers during manufacture. Additional marking can be done using small titanium pegs including tantalum balls, which are fixed with press-fit in pre-drilled holes. This will enable a more complete analysis to be made, including femoral component rotations and translations of different parts of the implant (e.g. shoulder and tip).

Synchronous exposures from two x-ray tubes with an angle of about 40° between them are used for the radiographic examination (Figure 1). High kilovoltage and low amperage facilitate the identification of markers on radiographs, especially if they are hidden behind a metal shell made of tita-

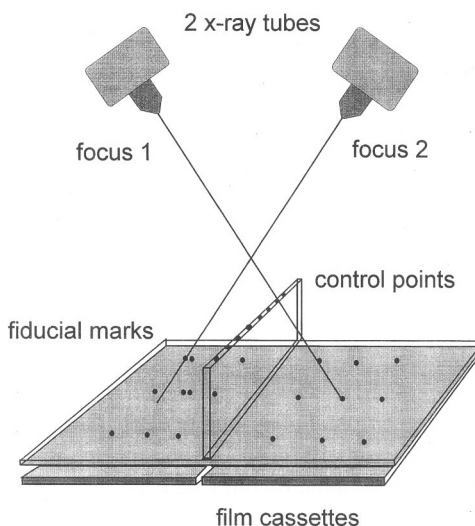


Figure 1. The calibration cage (uniplanar technique) used at the radiostereometric examinations.

niun alloy. Chrome-cobalt alloy is more radiopaque and it is difficult to visualise markers behind such metals.

In the present studies of migration and wear, the patients were examined in the supine position and a calibration cage including cassette holders was placed under the examination table (uniplanar technique, Figure 1). The calibration cage is supplied with markers with defined three-dimensional positions (fiducial marks and control points). In the majority of the examinations, the two-dimensional positions of all the markers were recorded manually on a measuring table, connected to a video camera for magnification, and stored in a computer. During the later part of the studies, a new method based on measurement of digitised radiographs was used (Börlin 1997). The software designed to measure digital images is partially automated to facilitate detection and measurements of predefined positions and geometric images such as the cage markers and the femoral head. To define the centre of the marker, the software utilises all available information in the pixels included in the markers and fits mathematical models corresponding to the continuous change of grey-scales from the periphery to the centre of the marker. Only a rough user-assisted approximation of the marker position has to be given. An automated algorithm iterates the calculations of the centre to optimise its identification. Poorly de-

finer markers are automatically discarded. To handle markers situated close to each other or close to an edge, specific mathematical models are used. If the marker image is seriously impaired, manual measurements based on fitting of a circle to the marker edge can be done.

Calculations of three-dimensional positions of cage and patient markers are performed in a computer software system (UMRSA<sup>®</sup>) which includes several programs. The precision of the calculations is dependent on the radiographic equipment, the quality of the cages and correct and accurate identification of the markers on the x-ray films. The user obtains information about the transformation of the film coordinates to the laboratory coordinate system by the size of the residuals from these calculations. In this first "quality control", the known coordinates of cage markers are compared with those that have been computed based on the pair of radiographs obtained. The position of the patient markers will be described in the coordinate system identified by the cage markers. The computer chooses the most probable couplings of patient marker positions from the two foci. Further computations are done when two or more examinations are available.

Tantalum markers in one segment form a geometric figure or a "rigid body". To test the identification and stability of these markers, the degree of deformation of each segment between two examinations is calculated and expressed as the "mean error of rigid body fitting" (Selvik 1974). The user can define the upper acceptable limit for this parameter. By correction of erroneously identified markers and exclusion of poorly defined or loose markers, the software will, if possible, identify a

segment that maintains its stability between subsequent examinations.

The accuracy of the calculations is also dependent on the configuration or scattering of markers. This scattering is described mathematically by the "condition number" (Söderqvist 1993). The condition number is low if the markers are well scattered and it is high if the markers are close to each other or situated along a line. The mean error of rigid body fitting and the condition number are crucial parameters in radiostereometric analysis and help the investigator to determine if the measurements are reliable.

The relative motions of the implant are calculated using the corresponding bone markers as a fixed reference segment. If at least three well-spaced markers are identified in the implant and in the bone, both translations and rotations can be measured. Motion of an implant during a time period is named migration. This motion is described in relation to 3 body fixed axes; the transverse (medial-lateral axis, x-axis), the longitudinal (proximal-distal, y-axis) and the sagittal (anterior-posterior, z-axis).

The precision of RSA is high. Under optimal conditions, one standard deviation of the error could be 0.01 mm for translations and 0.05° for rotations (Selvik 1974). In clinical practice, it will be higher, primarily because of difficulties in obtaining optimum marker configurations, high quality radiographs and measurements. The error can be estimated by performing double examinations of each patient in a study group on at least one occasion. Calculation of the 99% confidence intervals of the errors is used to determine the limits for significant motions in the individual case.

## AIMS OF THE STUDY

The aim of this study was to investigate different fixation principles with the main emphasis on the acetabular components. Laboratory tests of bone cement, standardised clinical evaluations, conventional radiography, radiostereometric analysis,  $^{99m}\text{Tc}$ -MDP scintimetry and atomic absorption spectrometry were used for the evaluation.

The specific aims were:

1. To study chemical and mechanical properties of a newly developed cold-curing bone cement and determine if this cement improved the fixation and the bone-implant interface in total hip arthroplasty compared with standard cement.
2. To compare the intermediate term results of two cementless designs, representing different design principles believed to solve the problems of cemented fixation in young patient populations during the early eighties.
3. To determine if biodegradable screws can replace titanium screws for adjunctive fixation of uncemented hemispherical porous cups, thereby reducing the risk of fretting corrosion and wear between screws and the metallic shell or the polyethylene liner.
4. To determine if addition of a HA/TCP coating on uncemented hemispherical cups with a porous titanium surface increases the early stability and influences the radiographic appearance of the bone-implant interface and the amount of wear.
5. To determine if additional screw fixation is necessary for optimum fixation when HA/TCP-coated porous cups are inserted with the press-fit technique and to study if the use of screws influences the amount of wear.

## Patients and methods

The patients in Studies I–V (Table 1) were selected from the waiting list at Sahlgrenska University Hospital, Gothenburg. In Studies III and IV, patients were also recruited from the Northern University Hospital, Umeå. The local ethics committees approved these studies.

The patients in Studies I–II and V were randomly assigned to different implant designs or modes of fixation. In Studies I, III and V, the patients were allocated and stratified by a computer program based on age, sex, weight and diagnosis. Closed envelopes were used in Study II.

In Study IV, 23 patients with hydroxyapatite and tricalcium phosphate coated porous cups were selected from two consecutive studies at Sahlgrenska University Hospital. The selection was based on presence of successful radiostereometric evaluation up to 2 years and presence of a matching partner in a database containing patients with a similar cup design, but without ceramic coating. The patients in this database were operated upon at either of the two hospitals.

59 patients entered Study III, but 16 patients were excluded because of absence of radiostereometric measurements.

One patient participated in two studies (III and V) because of bilateral hip procedures. 8 patients (8 hips) from Study III were also included in the control group in Study IV.

The mean follow-up was 9 years in Study II. In the other studies the follow-up was 1 (Study I) and 2 years (III, IV and V) respectively. Radiostereometric data up to 5 years are presented in the summary of Study I.

### Implants

All patients in Study I received a Reflexion® all polyethylene cup and a Spectron EF® stem (Smith & Nephew Inc, USA; Figure 2). The cup was sterilised in ethylene oxide. The Spectron EF stem is made of cobalt chrome alloy and has a grit-blasted ( $R_a = 112 \mu\text{m}$ ) proximal and bead-blasted ( $R_a = 26 \mu\text{m}$ ) distal surface finish. Femoral heads of cobalt-chrome alloy with a diameter of 28 mm were used in all hips.

The PCA® (Howmedica Inc, USA) and the Harris-Galante® I (Zimmer Inc, USA) cementless designs were used in Study II. The PCA prosthesis is made of cobalt-chrome (Figure 3). The porous coating consists of cobalt-chrome beads, which

Table 1. Summary of patients in Studies I–V.

Study	Patients	Age median (range)	Sex F/M <sup>c</sup>	Implants <sup>a</sup>		Acetabular fixation <sup>b</sup>			
				Group I	Group II	n	Group I	n	Group II
I	30	71 (63–76)	22/8	Spectron	Spectron	16	Palacos cement	14	Boneloc cement
II	155	50 (24–64)	78/77	PCA	HG I	84	Sintered beads Pegs	87	Titanium mesh Titanium screws
III	43	60 (44–68)	26/17	HG II	HG II	20	Titanium mesh Titanium screws	23	Titanium mesh PLLA screws
IV	46	53 (38–64)	26/20	HG II	HG I/II	23	Titanium mesh Titanium screws HA/TCP	23	Titanium mesh Titanium screws
V	62	56 (32–75)	32/30	Trilogy	Trilogy	30	Titanium mesh Titanium screws HA/TCP	34	Titanium mesh HA/TCP

<sup>a</sup> HG Harris-Galante; PCA Porous Coated Anatomic

<sup>b</sup> PLLA poly-L-lactic acid; HA/TCP hydroxyapatite-tricalcium phosphate

<sup>c</sup> F/M female/male.



Figure 2. The Reflexion all polyethylene cup and the Spector femoral stem.

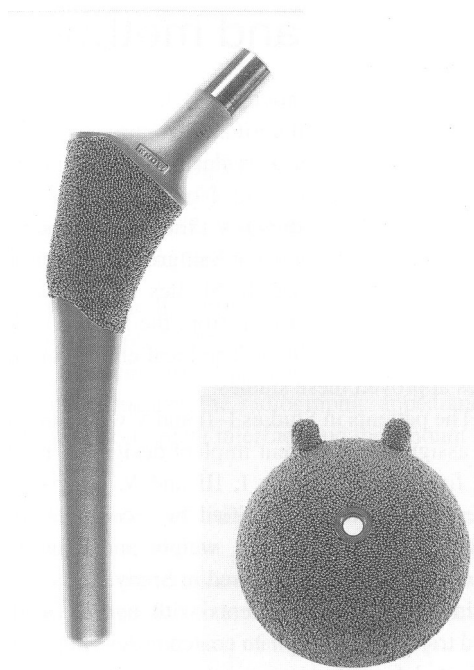


Figure 3. The PCA prosthesis.

are sintered to the surface layer. The fully porous coated cup has two stabilising pegs located superolaterally. The polyethylene liner was sterilised with gamma radiation in air. At the beginning of the study, the liner was assembled in the shell at delivery and it was stabilised with a central peg. During the study the design was changed and the liner was inserted with press-fit into the shell. To provide rotatory stability, the opening of the shell had an octagonal shape mating the liner rim. The stem is anatomically shaped and has a proximal and circumferential porous coating and modular 32 mm cobalt-chrome heads were used.

The Harris-Galante I cup is hemispherical, made of Ti-6Al-4V alloy (Tivanium®, Zimmer Inc.) and has a porous fibre mesh made of pure titanium (Figure 4). The cup has multiple holes for additional fixation with screws (5.1 mm). The liner was inserted with press-fit into a metal rim with three pairs of small tines. The insert was sterilised using the gamma radiation in air technique. The Harris-Galante stem is straight and has 3 proximal titanium pads for bone ingrowth (Figure 5). The porous coating is not circumferential. A 32 mm modular head was used in all hips except one (22 mm).

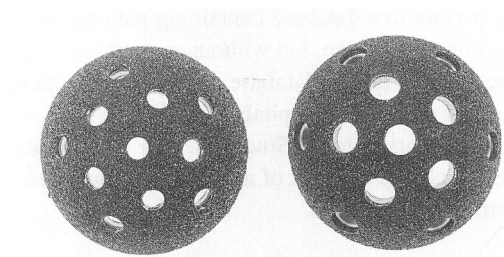


Figure 4. The Harris Galante I cup (to the left) and the Harris Galante II cup (to the right).

In Study III we used the Harris-Galante® II cup (Zimmer Inc, USA). Compared to the Harris-Galante I cup, this design has a 1 mm thicker metal shell, it does not represent a full hemisphere, wider screws are used (6.5 mm) and the liner locking mechanism consists of four or five pairs of tines instead of three (Figure 4). The holes in the cup and the screw heads have bevellings, which allow for more tilting of the screws at insertion. The poly-L-lactic acid (PLLA) screws had the same diameter as the titanium screws (Figure 6). However, the cores of the PLLA screws had to be made

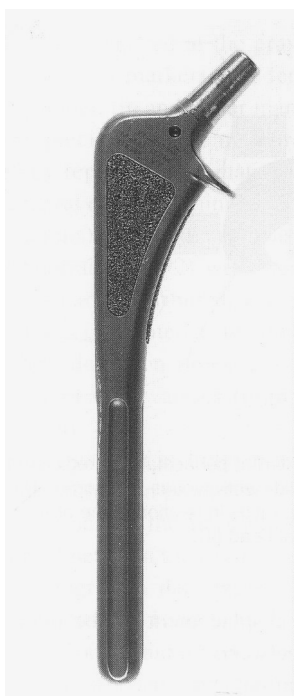


Figure 5. The Harris Galante I femoral stem.

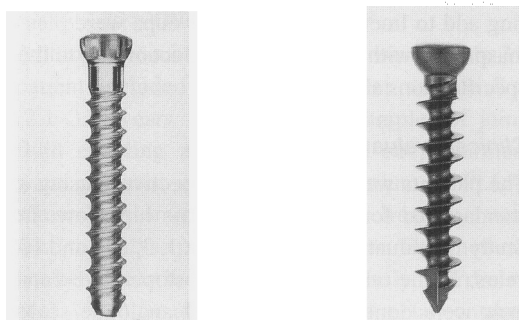


Figure 6. A poly-L-lactic acid (PLLA) screw to the left and a titanium screw to the right.

for additional fixation. In half of the cups the shell was plasmasprayed with a ceramic coating consisting of 70% hydroxyapatite (HA) and 30% tricalcium phosphate (TCP). The ceramic coating reduced the porosity of the titanium mesh to 35%. In the non-coated control group, 8 cups were of the Harris-Galante I design.

Trilogy® cups (Zimmer Inc, USA) with or without 3 cluster holes were studied in Study V

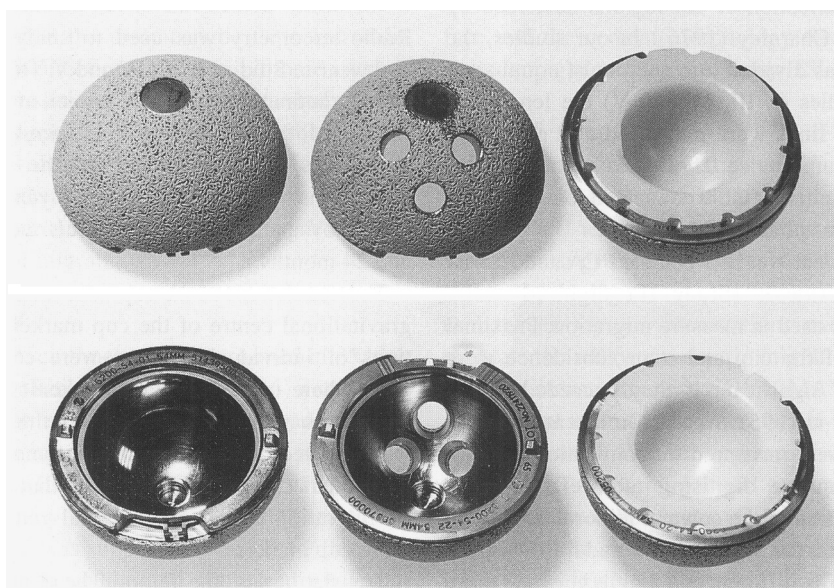


Figure 7. The Trilogy cup with and without cluster holes and with the liner assembled.

thicker (4.6 mm) to prevent breakage at insertion. The titanium mesh, with a porosity of 50%, was the same in all the Harris-Galante cups.

The same cup, Harris-Galante II, was used in 38 of 46 hips in Study IV. 6.5 mm screws were used

(Figure 7). These hemispherical sockets have the same type of porous titanium mesh as the two Harris-Galante designs. The inside is smooth and congruent to the liner, which is inserted with press-fit. Two anti-rotational tabs and a locking

ring add to liner stability. All the cups were plasmasprayed with HA/TCP coating according to the specifications above.

### Clinical evaluation

The patients were followed prospectively using a standardised form including Harris hip score. In Study II evaluations were made at 1, 3, 5, 7 and 10 years. In the other studies the postoperative controls were done yearly. A visual analogue scale was used to assess pain in Studies I, III and V.

### Radiography

The radiographic examination of hip arthroplasties included a minimum of 3 exposures; one pelvic view with the central beam projecting on the symphysis, one anteroposterior view centred on the inter-trochanteric area and one or two true lateral views visualising the bone-implant interfaces of both the cup and the stem. Examinations were performed regularly in all the five studies. Presence and extent of radiolucent lines at the acetabular interface were defined in different regions. We used a modification of the regions described by DeLee and Charnley (1976). In our studies, the interface was divided into sectors of equal size. In four studies (I, III, IV and V) the lengths of radiolucent lines were measured and related to the cup circumference. These measurements were done on a digitising table connected to a computer (Orthographics Inc, USA).

In the comparison between the PCA and Harris-Galante prostheses (Study II), digitised radiographs were used to measure migration. Proximal migration of the cup and stem subsidence were regarded as significant if they exceeded 5 mm (Malchau et al 1995). Wear, radiolucent lines and osteolysis were measured on conventional radiographs using the digitising table. To measure wear, the centre of the cup and femoral head were determined on the postoperative and follow-up radiographs. The difference in length between these two points along the longitudinal axis of the body was calculated and represented proximal wear. The metal backing hid the head in the majority of the PCA cups, necessitating use of an alternative method. A centreline through the neck of the femoral component and a line between the most lateral and medial edges of the opening of the cup was

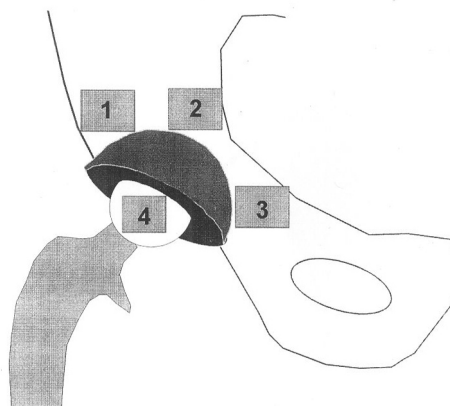


Figure 8. The three different periacetabular regions (1–3) in which the radionuclide activity was measured. The results were recorded as ratios in relation to the area corresponding to the femoral head (4).

reconstructed. The displacement of the intersection of these lines between 2 examinations (proximal–lateral penetration) was used to represent wear.

### Radiostereometry

Radiostereometry was used to study migration and wear in Studies I, III, IV and V. The postoperative examination was done 1 week after surgery. In Study I, the following examinations were done at 6 weeks, 6 months and 12 months. Further examinations were done at 2, 3 and 5 years. In Studies III, IV and V the time intervals were 3, 6, 12 and 24 months.

The translations of the cup were measured at the gravitational centre of the cup markers. Translations of individual markers were computed in cups where only 2 implant markers were available. This was only done when these markers were located on each side of the femoral head to obtain data comparable with those that were based on migration of the gravitational centre of 3 or more cup markers.

Translations of the femoral head centre using the cup markers as a fixed reference segment represented the penetration of the femoral head into the polyethylene cup or insert (Baldursson et al 1979). This motion, called femoral head penetration, is the combined effect of deformation of the polyethylene and wear.

The proximal-distal migration of the femoral

stem was measured at the gravitational centre of the four stem markers (the femoral head centre, the shoulder, tip and collar markers).

The precision of the measurements was calculated by repeated examination of the patient with an interval of 10–20 minutes (so called double examinations). Based on previous studies (Kärrholm and Snorrason 1992) we assumed that the error was normally distributed. The 99% confidence interval was calculated as the mean difference + the standard deviation times a *t*-value based on the number of observations (minimum *t*-value: 2.58 for  $n = \infty$ ).

Thus, this error includes all possible factors during the evaluation procedure including any inducible motions of the implants, which could have occurred between the examinations.

The migration data were presented as signed values in Studies I and V, and as absolute values in Studies II and IV. Signed values have the advantage of showing the direction of movements. The use of signed values also implies that the error of the measurements will have little or no influence on the calculated mean or median value for a group, because the error can be expected to be equal in both directions. However, if there are pronounced translations or rotations in a study group and in two opposite directions, the absolute mean or median values provide a better description of the magnitude of the motions.

In the diagrams in this summary, signed values are given for migrations.

### **Scintimetry**

<sup>99m</sup>Tc-MDP scintimetry was performed in 35 hips (Study III) after median 2.5 (2.0–3.6) years after surgery. The scintimetric activity (radionuclide uptake) was measured in the different periacetabular regions (DeLee and Charnley 1976; Figure 8). The activity corresponding to the area of the femoral head was supposed to be least influenced by the skeletal uptake and comparatively equal between the patients. Therefore, the numerical results were recorded as ratios between the mean activity in the different regions surrounding the cup and the femoral head.

### **Atomic absorption spectrometry**

Arthrocentesis of the operated hip was done in 31 patient included in Study III after median 2.6 (2.1–3.3) years. Representative samples of joint fluid enabling metal analyses to be performed were obtained in 16 hips (8 titanium, 8 PLLA screws). Atomic absorption spectroscopy was used to analyse presence of titanium. This method has been described in detail previously (Kärrholm et al. 1994). To minimise the risk of metal contamination, we used exactly the same type of sampling equipment as described in this study. The detection limit for titanium in synovial fluid was 2 ng/g (3 SD, Kärrholm et al 1998).

### **Characterisation of cement**

A tensile testing machine (JJ Instrument T 30 K) was used to determine the tensile and shear strength properties of different cements. The thermal properties of cured cement were evaluated using differential scanning calorimetry (DCS). Monomer release was calculated after extraction of cement samples in phosphate-buffered saline (pH 7.2) and in methanol. The bone-cement interface and the cement morphology were analysed by scanning electron microscopy (ISI-100A).

### **Statistics**

Differences were regarded as significant if the *p* values were less than 0.05. Generally, Mann-Whitney's U-test was used for comparisons of observations at given time intervals and Wilcoxon's matched pairs signed ranks test to evaluate changes between various observations over time. To evaluate the radiostereometric migration data, the repeated measurements ANOVA (MANOVA) was used except in Study III, where Mann-Whitney U-tests were used. Logistic regression was done to analyse if certain pre, per and postoperative factors influenced the results. Calculation of survivorship of the prosthetic designs and individual implants in Study II was done according to Kaplan-Meier. Evaluation of the differences in revision rates in the same study was done using Cox regression analysis.

## Results

### Study I: Evaluation of Boneloc®—chemical and mechanical properties, and a randomized clinical study of 30 total hip arthroplasties

Boneloc® cement was studied and compared with Palacos® cum gentamicin bone cement.

#### Laboratory study

Laboratory tests were done to study the tensile strength of the cement, adhesion of the cement to a metal surface (shear strength), glass transition temperature, curing temperature and release of monomer from samples of cured cement. Further, medullary cavities from fresh frozen bone (sheep; proximal humerus or proximal femur) were prepared and filled with the different cements. The bone-cement interface was studied with a scanning electron microscope (SEM). These studies were done in collaboration with the Department of Chemical engineering at Lund University.

#### Clinical study

30 patients with a mean age of 71 years were included and received a cemented total hip arthroplasty (Spectron EF®, Smith & Nephew). The patients were randomised to fixation with either of the two types of cement. The bone was prepared using brushes, high-pressure lavage, distal plugging of the femoral canal and adrenaline tamponades. Tantalum markers were implanted in the periacetabular bone, the femur and the implants. The Boneloc monomer and polymer were delivered and mixed in a closed plastic tube, made to fit into a cement gun. The Palacos cement was vacuum-mixed. The cement was pressurised into the bone and tantalum spheres (1 mm) were also placed into the cement surrounding the femoral component to allow evaluation of micromotions at the bone-cement and cement-implant interfaces.

Clinical, radiographic and radiostereometric examinations were done regularly. One patient in the Boneloc group died of a malignancy between the 6- and 12-month follow-up. One cup in the Pala-

cos group was excluded from the radiostereometric analysis due to poor marking. The migration data are presented as signed values.

#### Laboratory results

The curing temperature was 23° lower for the Boneloc cement. This cement also displayed reduced tensile strength, a lower elastic modulus and a lower glass transition temperature. The shear strengths of the cement-implant interface were similar for the two cements (Table 2). Scanning electron microscopy showed good adhesion between the two types of cement and cancellous bone, without any difference between the two groups.

#### Clinical results

Increased mean proximal migration of the cup was recorded in the Boneloc group during the postoperative year ( $p = 0.04$ , MANOVA). These cups migrated medially, in contrast to a small lateral migration in the Palacos group ( $p = 0.04$ , MANOVA). There was a distinct difference in proximal-distal stem migration between the two groups (Table 3). At 1 year the mean subsidence was close to zero (0.03 mm) in the Palacos group

Table 2. Characterisation of cements used in Study I, mean and SD

	Palacos®		Boneloc®	
Tensile strength at break, Mpa	33.4	2.2 <sup>b</sup>	15.2	3.0
Young's modulus, Mpa	579	51 <sup>a</sup>	426	96
Shear strength cement/metal	5.8	0.2	6.0	2
Curing temperature, °C	73	5	50	4
Glass transition temp., °C	119		74	
Weight loss				
21 days in PBS, %	1	0.3	1	0.2
21 days in methanol, %	3.8	0.1	5.0	0.1
MMA in methanol				
after 24 hours, %	0.01		0.01	
after 21 days, %	0.12		0.03	

<sup>a</sup>  $p < 0.05$ , <sup>b</sup>  $p < 0.01$ , Mann-Whitney U-test.

**Table 3. Study I. Migrations of the cup and stem in relation to the bone during the postoperative year, mean and SD**

	Palacos®		Boneloc®		p <sup>a</sup>
<b>Cup translations, mm</b>					
medial +, lateral -	-0.06	0.14	0.07	0.18	0.04
proximal +, distal -	0.14	0.17	0.26	0.20	0.04
anterior +, posterior -	0.10	0.32	-0.02	0.17	0.4
<b>Cup rotations, degrees</b>					
anterior +, post. tilt -	0.18	0.57	0.16	0.58	0.6
ante +, retroversion -	0.12	0.39	0.02	0.48	0.5
more +, less inclin. -	0.26	0.47	-0.10	0.74	0.4
<b>Stem translations, mm</b>					
proximal +, distal -	-0.03	0.12	-0.26	0.28	0.005
<b>Stem rotations, degrees</b>					
anterior +, post. tilt -	0.03	0.35	0.04	0.19	0.6
ante +, retroversion -	-0.64	0.69	-0.54	0.68	0.7
varus +, valgus tilt -	-0.04	0.16	0.03	0.16	0.2

<sup>a</sup> p-value (MANOVA).

and 0.3 mm in the Boneloc group ( $p = 0.005$ , MANOVA). An increased stem subsidence was recorded between 6 and 12 months ( $p = 0.002$ , Wilcoxon's signed ranks test) and 6 of 13 stems fixed with Boneloc cement had subsided more than 0.2 mm at the 1-year follow-up. The subsidence occurred mainly inside the cement mantle (Boneloc vs Palacos,  $p = 0.02$ , MANOVA). The mean subsidence at the cement-bone interface up to 1 year was small (Boneloc 0.1 mm and Palacos 0.04 mm) without any significant difference.

The extension of radiolucent lines around the acetabular cup was more pronounced in the Boneloc group after 1 year ( $p = 0.04$ , Mann-Whitney U test). The clinical results (Harris hip score, VAS) did not differ.

### 5-year results

Radiostereometric analysis was done in 21 patients (10 Boneloc, 11 Palacos) up to five years after surgery (Table 4). Four patients had died, two patients were revised (1 in the Boneloc, cup and stem, and 1 in the Palacos group, cup only) and three patients refused further examinations. One patient in the Boneloc group was scheduled for revision surgery because of loosening of the acetabular cup.

The mean proximal cup migration was 0.77 mm in the Boneloc group, compared to 0.20 mm in the Palacos group, but this difference was not signifi-

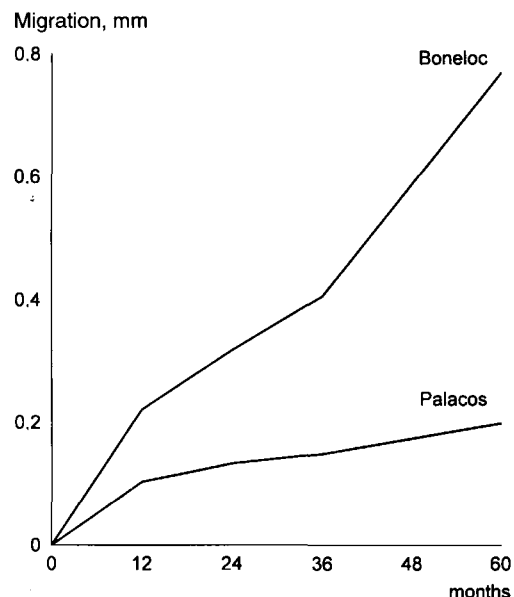
**Table 4. Study I. Migrations of the cup and stem in relation to the bone at 5 years. Signed values, mean and SD**

	Palacos®		Boneloc®		p <sup>a</sup>
<b>Cup translations, mm</b>					
medial +, lateral -	0.05	0.08	0.13	0.62	0.5
proximal +, distal -	0.20	0.27	0.77	1.25	0.1
anterior +, posterior -	0.06	0.32	-0.05	0.18	0.1
<b>Cup rotations, degrees</b>					
anterior +, post. tilt -	-0.20	0.60	0.51	1.55	0.5
ante +, retroversion -	0.04	0.60	-0.27	1.21	0.9
more +, less inclin. -	-0.45	0.71	-0.53	1.51	0.2
<b>Stem translations, mm</b>					
proximal +, distal -	-0.10	0.16	-0.58	0.59	0.03
<b>Stem rotations, degrees</b>					
anterior +, post. tilt -	0.03	0.40	0.08	0.16	0.7
ante +, retroversion -	0.63	0.91	0.27	1.15	0.8
varus +, valgus tilt -	0.10	0.18	-0.02	0.22	0.2

<sup>a</sup> p-value (MANOVA).

cant (Figure 9). Stem subsidence was more pronounced in the Boneloc group (mean 0.58 mm; Palacos: 0.10 mm;  $p 0.03$ , MANOVA; Figure 10).

There was no difference in wear (Boneloc/Palacos: 0.58/0.73 mm; Figure 11).



**Figure 9. The mean proximal cup migration up to 5 years in Study I.**

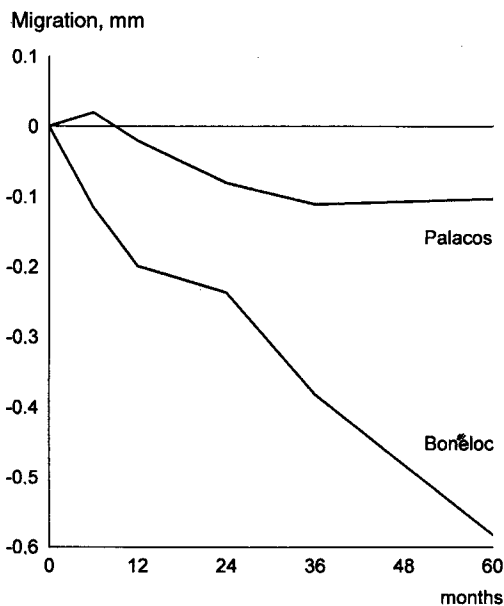


Figure 10. The mean stem subsidence up to 5 years in Study I.

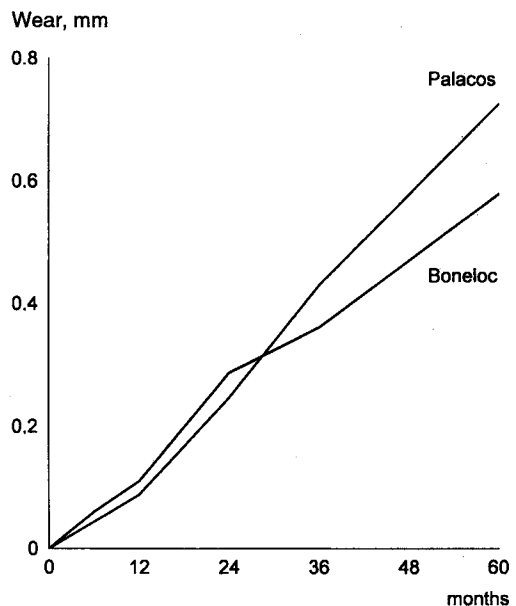


Figure 11. The mean wear (femoral head penetration) up to 5 years in Study I.

### Conclusions

The Boneloc cement provided inferior fixation of both the acetabular and femoral components. The early and frequent acetabular radiolucencies indicate cup failure at the bone-cement interface. Subsidence of femoral components occurred mainly inside the cement mantle, consistent with the findings of reduced tensile strength and increased elasticity of Boneloc. The lower glass transition temperature of Boneloc cement indicates that this cement, at body temperature, is closer than conventional cements to the point where cements become semifluid.

Because of inferior mechanical and chemical properties verified in the clinical study, Boneloc cement should not be used in total hip arthroplasty.

### Study II: Poor outcome of the PCA and Harris-Galante hip prostheses—a randomized study of 171 arthroplasties with a 9-year follow-up

#### Patients and methods

155 patients (171 hips) with a mean age of 50 years were included in the study. They were oper-

ated upon with uncemented total hip arthroplasties and randomised to either the PCA<sup>®</sup> design (n 84, Howmedica Inc, USA) or the Harris-Galante<sup>®</sup> type I design (n 87, Zimmer Inc, USA). The implants were inserted using specific instruments provided by the manufacturers. All cups were inserted with line to line reaming.

Clinical and radiographic examinations were done regularly (1, 3, 5, 7 and 10 years). The average follow-up was 9 years.

#### Results

13 hips in the PCA and 16 in the Harris-Galante group were revised because of mechanical failures and after a mean follow-up of 9 (8–11) years. The 10-year survival rates, based on revision as the endpoint, were 85% and 99% for the PCA and Harris-Galante cups, respectively ( $p = 0.02$ , Cox regression analysis; Figures 12, 13). In contrast, the survival rate for the PCA stem was higher than that observed for the Harris-Galante design (96% and 86%;  $p = 0.02$ , Cox regression analysis). The annual wear did not differ between the two groups (PCA/HG: 0.15/0.16 mm). Osteolytic lesions were commonly seen around the Harris-Galante stems ( $p < 0.001$ ). When radiographic failures were added to the survival curves, the 10-year sur-

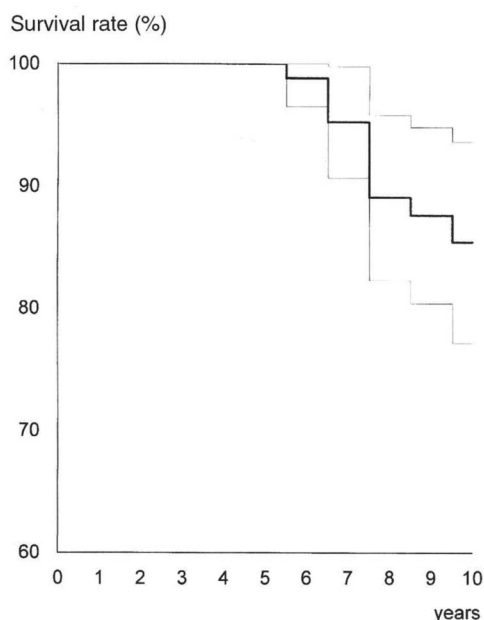


Figure 12. The survival rate for the PCA cup in percent and with 95% confidence intervals (Study II).

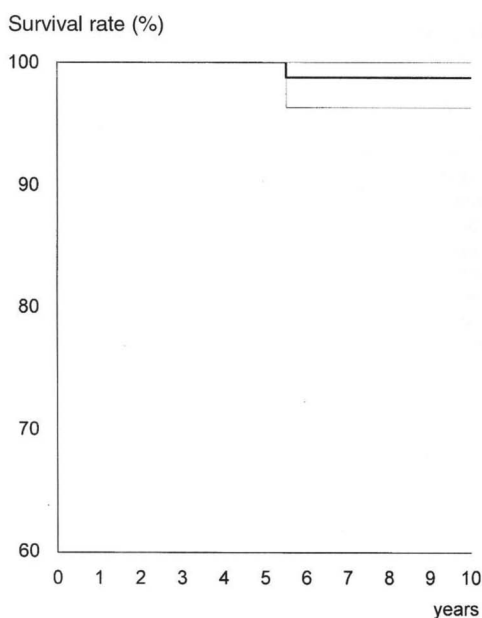


Figure 13. The survival rate for the HG I cup in percent and with 95% confidence intervals (Study II).

vival dropped to 68% for the PCA and 69% for the Harris-Galante designs.

### Conclusions

The 10-survival rates for the PCA and Harris-Galante designs were unsatisfactory. The Harris-Galante cup was the only individual component, which showed an acceptable survival rate. However, even with this cup, wear of the polyethylene liner remains a problem. The comparatively young patient population and the use of relatively thin polyethylene inserts can partly explain this observation. Osteolysis is a major complication. It is often asymptomatic and continuous radiographic follow-up is necessary to enable revision to be performed before severe bone destruction has occurred.

The chosen representatives of the second generation of cementless designs displayed a high rate of unexpected failures when tested in a young patient population. New hip implant designs without long-term documentation must be regarded as experimental.

### Study III: Migration of press-fit cups fixed with poly-L-lactic acid or titanium screws—a randomized study using radiostereometry

#### Patients and methods

43 patients with a mean age of 60 years received uncemented press-fit acetabular cups with a porous titanium mesh (Harris-Galante type II<sup>®</sup>, Zimmer Inc, USA). The patients were randomised to additional fixation of the cup with either biodegradable screws made of poly-L-lactic acid (n 23, PLLA) or metallic screws (n 20, titanium). 2–4 screws were used and tightened similarly (1.6 Nm) using a torque-wrench. The periacetabular bone and the polyethylene liner were marked with tantalum markers. All femoral stems were cemented using either a Spectron EF<sup>®</sup> (n= 26, Smith & Nephew Inc, USA) or a Lubinus SP 2<sup>®</sup> stem (n=17, Link, Germany).

There was one revision, 7 months after the primary operation, due to a ceramic head fracture. Clinical, radiographic and radiostereometric examinations were done regularly up to 2 years. The migration data are presented in absolute values.

**Table 5. Study III. Migration at the 2-year follow-up. Absolute values, median and (range)**

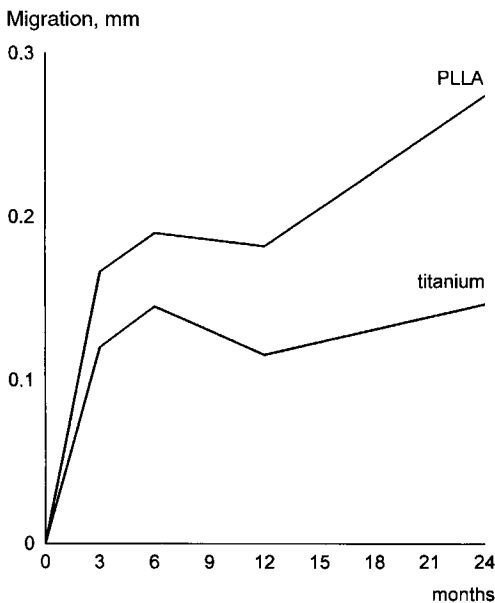
	PLLA screws	Titanium screws	p-value <sup>a</sup>
Translations, mm			
transverse axis	0.25 (0.01–0.86)	0.08 (0.00–0.93)	0.04
longitudinal axis	0.27 (0.02–1.53)	0.15 (0.01–0.59)	0.02
sagittal axis	0.29 (0.00–1.40)	0.45 (0.01–1.16)	0.3
Rotations, degrees			
transverse axis	0.46 (0.08–1.18)	0.51 (0.03–1.73)	0.9
longitudinal axis	0.45 (0.01–1.13)	0.73 (0.05–2.75)	0.04
sagittal axis	0.40 (0.02–3.17)	0.31 (0.03–1.40)	0.4

<sup>a</sup> Mann-Whitney U-test.

### Results (Table 5)

At 2 years increased proximal-distal migration was seen in the PLLA group (median 0.27 mm) compared with the titanium group (0.15 mm,  $p = 0.02$ , Mann-Whitney U test; Figure 14). Medial-lateral translations were also more pronounced in the PLLA group (median 0.25 vs 0.08 mm,  $p = 0.04$ ; Mann-Whitney U-test). Less median rotation around the longitudinal axis was recorded in the PLLA group (0.45 vs 0.73°,  $p = 0.04$ , Mann-Whitney U-test).

The total extension of radiolucent lines in relation to the interface did not differ postoperatively,



**Figure 14.** The median proximal cup migration up to 2 years for porous cups additionally fixed with different type of screws (Study III).

but in the PLLA group there were more patients with central gaps ( $p < 0.05$ ; Mann-Whitney U-test). This difference had disappeared at the 2-year follow-up. Instead, the PLLA group displayed more radiolucencies anteriorly at 2 years. There were no differences in the Harris hip score and pain assessment (Harris pain, VAS) at the 2-year follow-up.

### Results, <sup>99m</sup>Tc-MDP scintimetry

35 of the 43 patients evaluated with RSA were examined with <sup>99m</sup>Tc-MDP scintimetry at median 2.5 (2.1–3.6) years after surgery (16 titanium screws, 19 PLLA screws). We could not see any difference in radionuclide uptake in the periacetabular bone between the groups (Table 6).

### Results, atomic absorption spectrometry

Arthrocentesis was performed in 43 of the 59 hips initially included in the study. It was possible to analyse the presence of metal in synovial fluid from 16 hips (8 with titanium and 8 with PLLA screws) median 2.6 (2.1–3.3) years after surgery. Titanium could not be detected in 14 of the hips. Low levels of titanium were seen in 1 patient with titanium screws (4.9 ng/g) and in 1 patient with PLLA screws (12.4 ng/g). Analyses of blood and urine did not reveal presence of titanium in any of the 16 patients.

**Table 6. Study III. Radionuclide uptake in the different acetabular regions (DeLee and Charnley) expressed as ratios in relation to the femoral head, median and (range)**

	PLLA screws	Titanium screws	p-value <sup>a</sup>
Anterior			
A	2.83 (1.63–4.17)	2.83 (1.63–4.30)	0.1
B	2.97 (2.31–5.14)	2.87 (1.61–4.30)	0.3
C	2.95 (2.39–4.85)	2.80 (1.81–4.06)	0.3
Posterior			
A	2.02 (1.54–2.80)	1.83 (0.85–2.83)	0.4
B	2.17 (1.47–2.97)	2.05 (0.34–3.57)	0.4
C	2.23 (1.45–3.58)	2.28 (0.33–3.66)	1.0

<sup>a</sup> Mann-Whitney U-test.

### Conclusions

The PLLA-fixed cups displayed inferior bone-implant contact postoperatively and more pronounced medial-lateral and proximal translations up to 2 years. Poly-L-lactic acid is a bioresorbable material and it might be that degradation products influence the bone quality negatively. Alternative modes of fixation should be used until more is known about the biological response to degradation products of poly-L-lactic acid. Increased rotations around the longitudinal axis were seen in the titanium group. Randomised studies comparing press-fit cups with and without screw fixation are needed to elucidate if metallic screws constrain the migration in a certain direction.

### Study IV: Porous cups with and without hydroxylapatite-tricalciumphosphate coating—23 matched pairs evaluated with radiostereometry

46 patients with uncemented porous acetabular cups (Harris-Galante® type II, Zimmer Inc) with additional screw fixation were studied. In the study group of 23 cups, the titanium mesh was plasmasprayed with a 40 µm layer of hydroxyapatite and tricalcium phosphate coating (HA/TCP). The control group consisted of cups without coating. They were pairwise matched with the study group based on sex, age, weight, diagnosis and cup size. Tantalum markers were inserted into the bone and polyethylene liner.

Clinical, radiographic and radiostereometric examinations were done regularly up to 2 years. The femoral head centre could be calculated in 12 pairs, allowing wear measurements. The migration data are presented in absolute values.

### Results

Decreased rotations around the horizontal axis were recorded in the HA/TCP group up to 2 years ( $p < 0.01$ , MANOVA). There was also a tendency to decreased rotations around the longitudinal axis

Table 7. Study IV. Migration at the 2-year follow up. Absolute values, mean and (range).

	HA/TCP coating	Uncoated	p-value <sup>a</sup>
Translations, mm			
transverse axis	0.16 (0.01–0.82)	0.25 (0.03–0.68)	0.2
longitudinal axis	0.15 (0.01–0.36)	0.17 (0.02–0.59)	0.9
sagittal axis	0.28 (0.00–1.30)	0.47 (0.01–1.35)	0.1
Rotations, degrees			
transverse axis	0.38 (0.00–1.74)	0.94 (0.03–3.10)	<0.01
longitudinal axis	0.47 (0.07–3.07)	0.72 (0.05–2.75)	0.07
sagittal axis	0.33 (0.03–1.88)	0.36 (0.02–1.00)	0.5

<sup>a</sup> MANOVA.

( $p = 0.07$ ) in this group. There were no significant differences in translations along the three axes, but the numerical values were smaller in the HA/TCP group (Table 7). The median proximal migration is shown in Figure 15. The wear did not differ between the groups.

More pronounced radiolucencies (anteroposterior view) were seen in the HA/TCP group postoperatively ( $p < 0.01$ , Mann Whitney U-test). At the 2-year follow-up the situation was the reverse ( $p < 0.01$ , Mann Whitney U-test). Postoperative central gaps were more frequently seen in the HA/TCP group (AP/lateral:  $p < 0.01$ /  $p < 0.05$ ), but

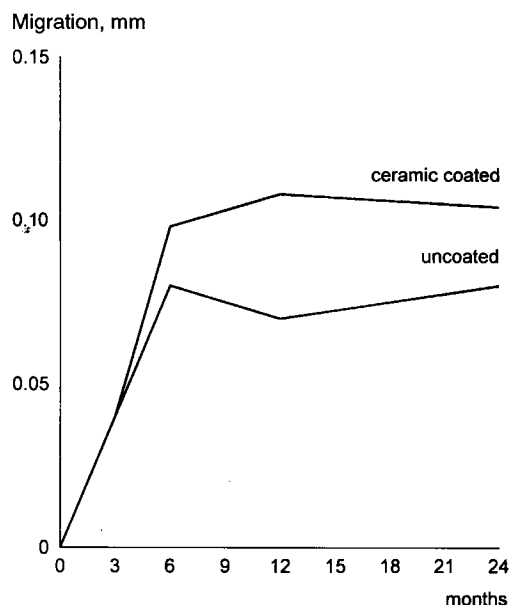


Figure 15. The median proximal cup migration up to 2 years for porous cups with and without ceramic coating (Study IV).

Table 8. Study V. Cup migrations at 2-years. Signed values, median and (range)

	Screws	No screws	p-value <sup>a</sup>
Translations, mm			
medial +, lateral -	-0.08 (-0.45–0.96)	0.04 (-0.36–0.91)	0.8
proximal +, distal -	0.12 (-0.55–0.79)	0.10 (-0.13–1.55)	0.9
anterior +, posterior -	-0.02 (-1.00–0.54)	0.06 (-0.73–0.79)	0.3
Rotations, degrees			
anterior +, posterior tilt -	0.15 (-2.85–1.42)	-0.05 (-0.82–4.27)	0.9
ante +, retroversion -	-0.14 (-4.55–1.09)	0.11 (-0.92–6.52)	0.2
more +, less inclination -	-0.09 (-0.54–1.95)	0.17 (-0.57–2.49)	0.4

<sup>a</sup> MANOVA.

Table 9. Study V. Wear at 2 years. Signed values, median and (range)

	Screws	No screws	p-value <sup>a</sup>
Wear, mm			
medial +, lateral -	-0.07 (-0.41–0.52)	-0.08 (-0.25–0.12)	0.6
proximal +, distal -	0.22 (0.03–0.67)	0.24 (-0.18–0.44)	0.7
anterior +, posterior -	0.07 (-0.29–0.42)	0.04 (-0.39–0.75)	0.8
vectorial sum (3D)	0.33 (0.14–0.95)	0.31 (0.06–0.75)	0.9

<sup>a</sup> Mann-Whitney U test.

they diminished over time. The magnitude of migration did not influence the disappearance of these gaps (logistic regression analysis). The clinical results did not differ at 2 years.

### Conclusions

The addition of HA/TCP coating improved the fixation of porous cups up to 2 years in terms of smaller rotations around the horizontal axis. Furthermore, the cups in this group displayed closer bone-implant contact at 2 years. These findings suggest that HA/TCP contributes to a high-quality interface, perhaps more resistant to loosening and osteolysis.

### Study V: Hydroxyapatite and tricalcium phosphate-coated cups with and without screw fixation—a randomized study of 64 hips

#### Patients and methods

Trilogy<sup>®</sup> cups (Zimmer Inc, USA) were inserted in 64 hips (62 patients). The porous titanium fibre mesh was plasma-sprayed with a coating consist-

ing of 70% hydroxyapatite and 30% tricalcium phosphate (HA/TCP). The patients were randomised to a cup with cluster holes for additional screw fixation (n 30), or to a cup without holes (n 34). The periacetabular bone and the polyethylene liner were marked with tantalum pellets. All cups were inserted with the press-fit technique (1–2 mm).

Clinical, radiographic and radiostereometric examinations were done regularly up to 2 years. Two patients died during the follow-up (1 hip with and 2 hips without screw fixation). One patient was excluded because of inability to achieve press-fit stability during surgery. The migration data are presented in signed values.

#### Results

Up to 2 years, the median translations and rotations were below 0.2 mm and 0.2° in both groups, without any difference between them (Table 8, Figure 16). The median annual proximal wear was 0.11 mm in the group with and 0.12 mm in the group without screw fixation (Table 9, Figure 17).

Postoperative radiolucencies were frequently seen in the separate regions, but without any sig-

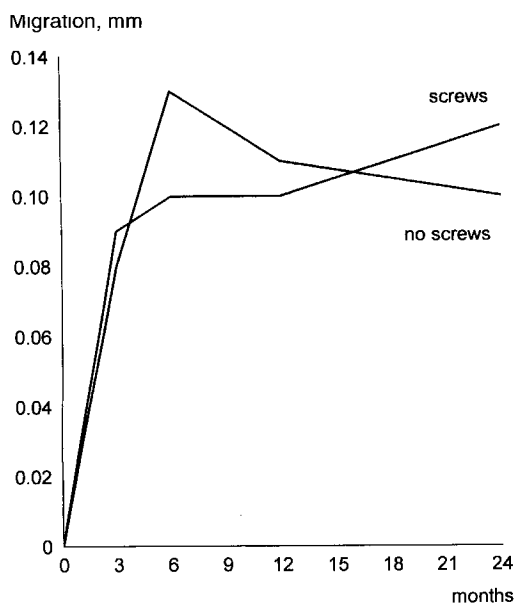


Figure 16. The median proximal cup migration up to 2 years for HA/TCP-coated porous cups with and without additional screw fixation (Study V).

nificant differences between the groups. These gaps had diminished in both groups at the 1-year follow-up (AP and lateral:  $p < 0.01$ , Wilcoxon's signed ranks test). There was no correlation between the extent and change of radiolucencies and the recorded migrations. The clinical results did not differ up to 2 years.

### Conclusions

Additional screw fixation is not necessary to obtain initial fixation of porous acetabular cups with

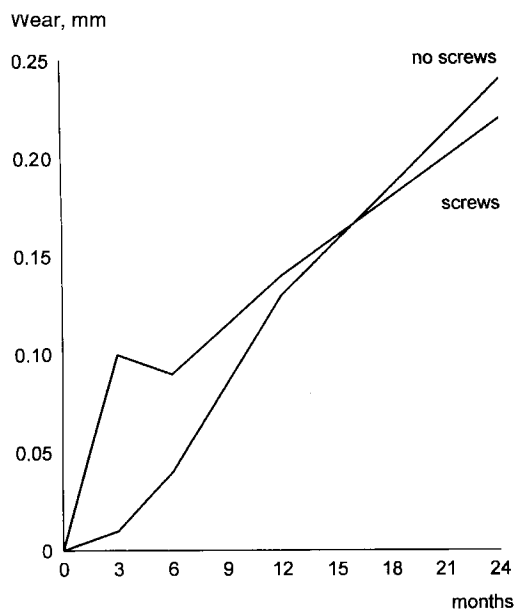


Figure 17. The median wear up to 2 years for the different cups used in Study V.

HA/TCP coating. Screw fixation can be avoided in cups of the same design as in this study. This will result in lower costs, shorter operating time and a decreased risk of perioperative complications. However, adjunctive screw fixation should be considered if the bone quality is poor or the press-fit stability achieved at surgery is uncertain. Despite the use of ceramic coating, the amount of wear was within the expected range, indicating that hydroxyapatite particles do not influence the wear rate in the short term.

## Discussion

Fixation with bone cement is the most common method used for both the components of a total hip arthroplasty in Sweden. For most implants, the results have shown a continuous improvement over time (Herberts and Malchau 1997). The most successful designs display 9-year survival rates around 95% when inserted with modern cementing technique. Other studies have also documented the importance of the cementing technique (Mulroy and Harris 1990, 1995). In a comparison between first and second generation cementing techniques, Mulroy and Harris (1997) found dramatically improved results in the latter group after 15 years in younger patients. This improvement was valid mainly for the femoral component. The revision rate for aseptic socket loosening remained high and increased with time. Even for the Charnley cup, long-term studies have shown increased rates of aseptic cup loosening (Madey 1997, Callaghan 1998) and progression of radiolucent lines (Garcia et al. 1997). These findings indicate that cement fixation is more reliable for the femoral, compared to the acetabular component. However, there are so far no available results from long-term studies in which the third generation cementing technique has been used. The dubious results for cemented acetabular cups in the long term have popularised the use of different cementless designs. In fact, there are no prospective randomised studies today, which have been able to demonstrate the superiority of either cemented or cementless cups. The Norwegian arthroplasty register makes it possible to differentiate between cup and stem failures, but this register has also been unable to identify differences between the different modes of fixation (Havelin et al. 1994).

### Study I: Fixation with different bone cements

Initial implant stability is mandatory for long-term survival of cemented cups. This can be

achieved by interdigitation between the cement and the bone during surgery, which also prevents or reduces penetration of particles into the interface. The surgical technique necessary to produce such an interface is difficult. The periacetabular bone has to be reamed properly to allow proper cement interdigitation. Multiple small holes must be drilled and the bone surface must be dry when the cement is introduced. Repeated training programmes are mandatory to maintain the surgeons' skill both for cemented and for cementless techniques, but the many steps included in cemented fixation require a longer learning time. Careful cementing is also more time-consuming than many cementless techniques.

Conventional cement relies on the formation of an interlock. There is no biological or chemical bonding between the cement and the bone, which is a disadvantage from a theoretical point of view. In addition, the bone at the interface is subjected to high temperatures and toxic chemicals during curing of the cement (Toksvig-Larsen et al. 1991, Stürup et al. 1994). According to Toksvig-Larsen et al, bone necrosis could be expected in 10% of the cases. Mjöberg addressed this problem with cold-curing cement. Nivbrant and Kärholm (1997) studied a similar bone cement (Cemex Rx<sup>®</sup>, Tecres, Italy) using radiostereometry. This cement has the same chemical formula (PMMA) as Palacos but contains less monomer and the curing temperature is reduced. They found no difference in cup migration at 2 years when this cement was compared with Palacos. The stem subsidence was small in both groups, but almost all of the stem migration occurred at the cement-implant interface. This and our findings in combination with the excellent clinical results observed with conventional cement for femoral fixation suggest that heat-induced bone necrosis has little clinical relevance in primary total hip arthroplasty, at least when performed in the standard case.

Boneloc is another cement which was claimed to solve this problem. It should be associated with

decreased release of hot monomers, which were thought to be of crucial importance in initiating a loosening process (Jensen 1991). This cement was reported to diminish bone injury in the canine tibial diaphysis (Nimb 1993). Boneloc became popular in many European countries and was widely used when our study was initiated. Our laboratory results could confirm the low curing temperature, but otherwise the results indicated inferior chemical and mechanical properties. The reduced tensile strength, the low elastic modulus and the low glass transition temperature are the most worrying findings, and probably explain the poor clinical results reported during recent years (Riegels et al. 1995, Suominen 1995, Nielsen and Wiig 1996). As a natural effect of the composition of Boneloc, the release of methylmethacrylate was reduced but the total amount of monomers extracted from this cement was larger. Thus, we could not verify one of the basic advantages claimed for this product. Impaired fixation of both acetabular and femoral components was seen in the Boneloc group. Weightman et al. (1987) tested a new cement containing butylmethacrylate, a polymer also used in Boneloc. These authors reported increased stem subsidence with this cement in the laboratory, which supports our findings. The increased incidence of radiolucencies in the Boneloc group indicated cup failure at the bone-cement interface and further supports the theory that heat necrosis is not a major problem in total hip arthroplasty. The potential problem of monomer leakage remains to be studied clinically.

Alternative factors such as poor interlock and fatigue failure of the interface are probably more important reasons for increased accessibility to the interface, radiolucencies and clinical loosening. Previous RSA studies (Mjöberg et al. 1986) have indicated that the loosening process starts early. It might be that the poor fixation of the cup in the Boneloc group was caused by insufficient penetration of a weak and compliant cement into the bone, facilitating penetration of joint fluid into the interface and early development of radiolucent lines. The stems in the Boneloc group migrated mainly inside the cement mantle, which can be directly related to the inferior mechanical properties of this cement.

The poor performance of Boneloc has been well

documented in clinical studies. Nilsson and Dalén (1998) observed increased migration of the tibial component in knee arthroplasty in a randomised comparison with Palacos cement. In the Norwegian arthroplasty register, higher revision rates have been shown for implants fixed with Boneloc cement compared to fixation with high viscosity cement (Furnes et al. 1998). The difference in revision rate was less pronounced for Exeter stems. This is logical because this stem is designed to subside inside the cement mantle if the cement weakens.

The Boneloc cement has caused worse clinical problems than the Christiansen total hip arthroplasty did during the 1970s (Havelin 1995, Linder 1995). The lesson learned from the Christiansen experience was that new concepts should not be marketed without clinical documentation. Despite this, the Boneloc cement was introduced on a large scale without documentation regarding clinical performance. This product would most probably not have passed the first step in an appropriate clinical trial. In our study, concerns arose in the laboratory evaluation but these tests were done late in the evaluation process. 14 patients were sufficient to verify the inferior fixation properties of Boneloc after only 6 months follow-up by means of the very precise RSA technique. At that time, thousands of patients had been operated upon with this cement. The Boneloc experience again emphasises the importance of stepwise introduction of new concepts in total hip arthroplasty (Malchau 1995).

## Study II: Cementless fixation with different designs

Inferior clinical results with cemented hip replacements in Europe stimulated interest in macroporous cementless fixation in the late 1970s (Judet 1978, Lord 1979). In the USA, the poor results described in younger populations in the early 1980s (Chandler et al. 1981, Dorr et al. 1983) were also related to the cement and interest was focused on cementless fixation using microporous surfaces.

The first generation of cementless acetabular cups, such as the Lord and the Mecron ring, were

threaded, the surface layers smooth and the results were disappointing (Eng et al. 1990, Malchau et al. 1996). However, threaded cups with other surface textures and hydroxyapatite coating are currently used and they seem to be functioning well so far (Manley et al. 1998). The second generation of uncemented cups had porous surfaces intended to facilitate micro-interlocking, primary fixation and bone ingrowth.

Several authors have reported high failure rates for the PCA cup (Heekin et al. and Callaghan 1993, Malchau et al. 1997). In our study, too, the revision rate was unacceptably high. Loose chrome-cobalt beads in the surroundings of the cup were frequently seen. This finding is probably an effect of micromotions in combination with an insufficient porous layer. It is unlikely that the design, with two superolateral pegs, provided adequate initial stability. The cup was inserted with line to line reaming and the pegs could only prevent rotations, without adding to central or medial stability. Besides, the liner locking mechanism was insufficient in the PCA design (Astion 1996). The design of the liner insert was changed in the beginning of 1987, but this difference did not influence the results.

The liners were all sterilised with gamma radiation in air. Nonetheless, there was a wide variation in wear of the PCA liner in our study. Different levels of activity could partly explain this observation, but other reasons such as different qualities of the polyethylene are probably more important. The pronounced early wear seen in several patients compared to practically no wear in others at the 13-year follow-up strengthens this theory. Varying quality of the polyethylene is probably still an unsolved problem for many manufacturers.

The Harris-Galante cup was designed for bone ingrowth, which at least to a certain extent occurs according to retrieval studies (Sumner et al 1993). The long-term results have been excellent regarding revision rates of the metal shell and our findings correspond to other reports (Incavo 1996, Berger et al. 1996 and 1997, Tompkins et al. 1997 and Clohisy and Harris 1999). However, the liner locking mechanism is vulnerable and disassembly has been described in case reports (Retpen and Solgaard 1993, Han et al. 1998). The liner can ro-

tate in relation to the shell, which will generate particles (Kärrholm and Snorrason 1992, Kärrholm et al. 1994, Önsten and Carlsson 1994). Tompkins (1997) reported 4% osteolysis after 7–10 years for the Harris-Galante cup, which is comparable to our findings. Berger et al. (1997) reported an increasing incidence of osteolysis after 7 years and concluded this to be the greatest problem at 11 years. Despite the low revision rates so far reported for the Harris-Galante I cup, the increasing problem with osteolysis is an ominous sign and indicates that this implant is not successful in a young patient population in the long term.

The mean wear rates for the Harris-Galante I and PCA cups were equivalent to results reported earlier (Woolson and Murphy 1995, Berger et al. 1997). There were no differences in wear or presence of acetabular osteolysis between the two designs in our study. Polyethylene wear debris is probably not responsible for the increased revision rates among the PCA cups. It is reasonable to believe that the Harris-Galante cup was more securely fixed to the bone due to differences in surface texture, material and type of fixation.

Femoral osteolysis was more pronounced and frequently seen around Harris-Galante stems compared with the PCA stems. This relationship is probably design-related. The Harris-Galante stem has a non-circumferential proximal coating and joint fluid and wear particles can easily get access to the femoral canal. (Tanzer et al 1992, Urban et al. 1996).

### Study III: Porous cups fixed with different screws

Although it is generally agreed that polyethylene particles have an important role in the development of osteolysis, other types of particles can also cause this phenomenon. Corrosion and wear induce the release of metal ions and particles. Chrome-cobalt particles are toxic and induce proliferation of macrophages (Howie 1990, Haynes et al. 1993). Hip prostheses with metal-metal articulations and of chrome-cobalt alloy have been reintroduced on the market and the wear rates described are very low (Schmidt and Weber 1996). In contrast, Saikko et al. (1998) noted substantial

metal release in cobalt-chromium articulations in a hip simulator study and concluded that this type of articulation hardly solved the wear problem. Titanium is regarded as an inert material but as a particle it can activate macrophages (Bennet 1991). These particles may be responsible for bone resorption seen around screws made of titanium alloy. Titanium particles have also been found to increase the wear of metal femoral heads in laboratory tests (McKellop and Röstlund 1990).

Kärrholm et al. (1994) investigated the titanium levels in the synovial fluid 2 years after surgery. All 19 hips had a Harris-Galante cup (I or II), whereas cemented or cementless stems made of titanium had been inserted in the femur. Titanium levels between 12 and 56 ng/g were noted in the hybrid implants, whereas most of the totally uncemented hips had levels below the detection limit. We could only detect titanium in synovial fluid in 2 patients and the levels were low. These findings indicate that the release of titanium from Harris-Galante cups is low in the short term. However, increasing wear of the polyethylene liner will increase the stresses on the metal shell and it is possible that the levels of titanium will be elevated with time.

Micromotions of screws in relation to the metal screw heads generate particles which can be transported to the bone-implant interface (Huk 1994). Avoidance of metallic screws would eliminate this type of wear. Schmalzried et al. (1992) reported clinical and radiographic results regarding Harris-Galante cups inserted with the press-fit technique with a mean follow-up of five years. They recommended fixation without screws. However, initial migration of Harris-Galante cups fixed with screws has been described (Kärrholm and Snorrason 1992, Önsten 1994) and we believed that this concept needed additional screws to obtain a reproducible degree of stability.

The choice of biodegradable screws was an attempt to utilise the supposed early stabilising effect of screws and avoid disadvantages in the long term. The increased translations observed with this fixation could be explained by the screw design. However, a more probable explanation for the increased proximal migration is that the degradation products of poly-L-lactid-acid (PLLA) soften the bone. Neither the rate of degradation of

PLLA implants *in vivo* nor the biological responses of the bone tissue to degradation products are fully understood.

Absorbable implants, for internal fixation of fractures, were introduced on a large scale in the late 1980s. It was found that internal fixation devices made of polyglycolic acid were occasionally associated with bone resorption and subcutaneous sterile exsudations (Böstman 1991). These findings were then regarded as benign and transient. Longer experience with these types of implants, and above all observations of ankle arthritis caused by foreign-body reactions to polymer material from osteolytic lesions, has changed this opinion (Böstman et al. 1998). On the other hand, the authors found no articular damage in patients who had exclusively PLLA devices. Development of osteolysis has been thought to be unusual in association with PLLA screws and pins, because of the slower degradation of this material. The degradation rate of PLLA implants varies but could be several years, depending on the polymeric structure, molecular weight and implant design and probably also the local metabolism of the bone.

Pihlajamäki et al. (1992) analysed biopsies from 2 patients who had been treated with poly-L-lactic pins. After 2 and 3 years postoperatively, no remaining material could be seen. Other reports in the literature do not support the contention that PLLA is a safe material, but foreign-body reactions seem to appear later compared to polyglycolide materials. Remnants of degraded PLLA surrounded by fibrous tissue were frequently seen 3 years after fixation of zygomatic fractures (Bergsma et al. 1993). Böstman and Pihlajamäki (1998) recently reported on a foreign-body reaction more than 4 years after insertion of a PLLA screw for fixation of an ankle fracture. The late appearance of these inflammatory reactions was related to the slow degradation of PLLA and to overload of polymer debris. The clinical use of various PLLA implants has increased during the last years and it might be that foreign-body reactions will be more commonly seen in the future.

According to the analysis of postoperative radiolucencies, these cups should have had a better press-fit stability but nevertheless displayed a higher rate of translation. It is possible that degradation products of PLLA influenced the interface

negatively. The increasing radiolucencies in a 2-year perspective indicate instability at the interface. Schmalzried et al. (1992) also reported increasing radiolucencies around Harris-Galante cups fixed with screws but inserted with the line to line reaming technique. It might be that the initial fixation was impaired in these cups despite the use of screws.

We could not see any difference in radionuclide uptake in the periacetabular bone between the groups. Negative effects of lactic acid products ought to have initiated an increased bone turnover. Thus, the equal isotope uptake in the two groups does not support the presence of foreign-body reactions at 2.5 years. Neither has further follow-up based on conventional radiography at 5 to 7 years revealed any osteolytic lesions in the patients treated with PLLA screws. A distinct osteolytic lesion was detected in one patient with titanium screws at 4 years, but it has not progressed since then.

The fact that cups fixed with titanium screws displayed more pronounced rotations around the longitudinal axis is hard to explain. Metallic wear debris can enter the articulation, causing friction and wear of the polyethylene, but the analyses of metal in synovial fluid do not support this theory. A less securely fixed liner can move in relation to the metal shell. Eccentric wear may also facilitate rotations of the liner. Another theory could be that the screws constrained the motions of the metallic shell by resisting proximal migration. Instead, they created fulcrums which facilitated tilting. The findings of low levels of titanium in both groups indicate that the second theory is more likely to explain the different patterns of rotation.

#### **Study IV: Porous cups with and without ceramic coating**

The Harris-Galante cups with ceramic coating (HA/TCP) showed minimum migration. Radiographic evaluation showed closer bone-implant contact, suggesting that the stability was an effect of more extensive bone ingrowth in these cups. Moilanen et al (1996) reported increased stability for hydroxyapatite-coated cups when compared with non-coated press-fit cups. In our study, the

differences between the implants with and without ceramic coating were small and only significant around the transverse axis. Rotatory movements indicate instability at the periphery, consistent with the increased incidence of peripheral radiolucencies seen in the non-coated group.

The addition of a ceramic coating slightly increases the diameter of the cup and probably improves the initial press-fit stability. These cups might therefore less frequently have reached the dome of the acetabulum during insertion, observed as central gaps postoperatively. Önsten et al. (1996) reported that the presence of central postoperative gaps was associated with smaller migration, indicating that peripheral contact is desirable. The central radiolucencies decreased or disappeared in HA/TCP-coated cups during the follow-up without signs of migration into these gaps. Søballe (1993) has reported that hydroxyapatite, in contrast to titanium, can induce bi-directional gap healing, which can explain the increased speed of bone formation seen around hydroxyapatite-coated implants. Beight et al. (1989) have suggested that the ceramic coating acts by providing a local source of calcium and phosphate ions essential for mineralisation of the surrounding tissue. The disappearance of central zones in our study must be related to formation of new bone, possibly due to the ossification process induced by the HA/TCP coating.

Despite the short follow-up, the radiostereometric and radiographic findings for our HA/TCP-coated cups are encouraging. A high-quality interface will prevent particle debris entering the bone-implant interface, thereby minimising the risk of development of osteolysis. Delamination of HA from the metal shell has been described in cups with ceramic coatings, but the risk is probably greater for implants with a smooth surface (Collier et al. 1993). Ceramic coatings could be a possible source of particles, which might increase third-body wear, but our findings do not support this theory. Neither did the observations of Moilanen et al. (1996) and Nivbrandt and Kärrholm (1997) indicate that cups with ceramic coatings are associated with increased wear.

The problems related to uncemented acetabular cups have been progressive radiolucent lines and development of osteolysis. To prevent these side

effects and to retain stability, the bone-implant interface must be of high quality and the wear must be minimised. This study shows that a ceramic coating contributes to such an interface. The main reason for this is the biological effects of hydroxyapatite and tricalcium phosphate.

### **Study V: Porous cups with and without screw fixation**

The previous studies in this thesis and other reports (Kärrholm and Snorrason 1992, Önsten et al. 1994) have demonstrated that porous press-fit cups fixed with screws are associated with micro-motions, which in some instances continue for at least 5 years (Kärrholm et al. 1995). This was the main reason for not using these implants without screws in our previous studies. There has, however, been concern about corrosion and abrasion of the metal shell and the polyethylene liner, which can result in particles capable of inducing bone resorption. According to clinical studies, porous coated cups without additional screw fixation have been successful up to 6 years (Schmalzried et al. 1994, Dorr et al. 1998). These reports and the favourable outcome of the HA/TCP-coated cups in Study IV warranted further evaluation of similar implants without screw fixation.

In implants with a grit-blasted surface, bone contact directly against the metal substrate has been shown when the HA coating has been resorbed, suggesting that the bone remodelling effectively fixes the implant (Bauer et al. 1991). Ceramic coatings on porous surfaces seem to be effective in clinical practice (Moilanen et al. 1996, Geesink et al. 1995). In a radiostereometric study of HA-coated cups, additional screw fixation did not influence the stability (Önsten et al. 1996). Our long experience with porous coated cups motivated the use of the same surface to reduce the risk of unexpected failures, not attributable to the use of screws or not. To our knowledge, no randomised study has previously evaluated this issue.

Up to 2 years there were no differences in migration, wear, radiographic findings or clinical outcome. According to *in vitro* tests, the influence of screws on primary stability is controversial. Some authors have reported improved stability

when screws are used (Stiehl et al. 1991, Perona 1992). In contrast, Kwong et al. (1994) and Won et al. (1995) did not find any beneficial effect of screws when the press-fit stability was adequate.

This study indicates that screws can be omitted when press-fit stability is achieved. Factors related to implant design, coating and surgical technique are probably more relevant. Even if the bone quality is adequate, the acetabulum is properly reamed and the cup is impacted with the press-fit technique, there will still be gaps at the interface. The gap-healing capacity is probably the most important property of hydroxyapatite. As also noted in Study IV, the cup will attain maximum stability and the radiographic signs indicate that the interface is better sealed.

So far, exclusion of additional screw fixation has not been associated with any advantages in terms of less migration or wear but the follow-up is short. Despite this, avoidance of screws will probably be beneficial in a longer perspective. The amount of particles ought to be reduced and absence of cluster holes will result in fewer pathways for the particles and the joint fluid to reach the interface.

To improve the long-term results, the production and biological effects of wear debris must be minimised (Goodman et al. 1998). It is obvious that insufficient liner locking mechanisms have contributed to wear and release of polyethylene particles (Dorr et al. 1997). This problem, seen in different uncemented acetabular cups, can contribute to the development of osteolysis. New designs have tried to address this issue by an improved locking mechanism, polished inside of the metal shell and improved congruency against the liner. It is reasonable to believe that these measures will have the expected effect of reducing the development of osteolysis, but this has to be demonstrated in clinical studies. It might be that modular metal-backed cups are still more prone to develop osteolysis than cemented polyethylene cups, because of lower elasticity, increased wear and other unknown factors.

The insert in this study was gamma radiated in nitrogen, in contrast to radiation in air, which earlier has been used for sterilisation of the Harris-Galante liner. However, the wear rates were not reduced. The present wear rates (0.11–0.12 mm/

year) are too high for successful long term results in active patients and further improvements to the wear resistance of polyethylenes are necessary. High doses of gamma radiation (10–20 MRad) increase the cross-linking of the polyethylene, which improves the wear resistance. However, the amount of free radicals also increases. These radicals facilitate oxidation of the polyethylene close to the surface and thereby decrease its resistance to wear. Free radicals can be removed using heat treatment. Machined cups of such polyethylenes have been shown to be highly resistant to wear and aging (McKellop et al. 1998), but they have not yet been evaluated in clinical practice. An important observation is that acetabular cups made of another polyethylene, subjected to very high doses of gamma radiation, display very low wear rates in clinical evaluations with long-term follow-up (Onishi et al. 1996).

Hydroxyapatite particles released from the coating can theoretically be responsible for third-body wear and ceramic-coated components have the potential to produce greater amounts of particulate debris. Bloebaum et al. (1997) analysed acetabular polyethylene components from patients with osteolysis. Third body particles were frequently seen and were supposed to contribute to the production of more particles, creating a vicious circle. In contrast, no radiostereometric study has so far demonstrated accelerated wear in cups coated with calcium ceramics (Önsten et al. 1996, Nivbrandt and Kärrholm 1997). These observations only embraced periods of about 2 years and it might be that particles from the coating do not influence the wear rates in the short term perspective. Although one might expect that much of the coating will have been absorbed at 2 years, further studies are necessary to elucidate the effects in a longer perspective.

We found that the use of additional fixation with screws can be omitted in hemispherical cups with a combination of porous and ceramic coating. This finding is probably applicable to other cups of similar design. Removal of screws has some obvious positive effects; lower costs, shorter operating time and decreased risk of injuring vital structures. We do not think reliance on only press-fit stability has any negative effects in the long term. The existence of further positive effects in

the long term, such as less wear or a lower incidence of osteolysis, has to be studied. At present, additional screw fixation can be restricted to cases with poor bone quality, revisions or primary cases where the press-fit stability obtained during surgery is judged to be inadequate. In a longer perspective, avoidance of screws will hopefully result in a reduced incidence of wear and osteolysis.

### Summary and future recommendations

The market has been flooded with new prosthetic hip devices at the same time as the expectations of the procedure have increased. During the last 10 years some implant designs used with a specific surgical technique and fixed with cement have shown excellent results (Herberts and Malchau 1997). As a minimum requirement, new implants must yield the same results as these designs. So far, many prostheses and fixation techniques have been used on a large scale without clinical documentation and in some cases at the cost of a number of costly revisions and unacceptable patient suffering.

Rapid development of new designs and modes of fixation offers a potential for further improvement of the results, however. This development should particularly address patient groups who still present inferior results compared to the average. Such patient categories are well documented in the literature (Ahnfelt et al. 1990). Careful pre-clinical research and stepwise introduction of the implants and fixation methods is necessary to detect unexpected properties of these new concepts early and minimise the patient population at risk (Malchau 1995).

Revision of the acetabular component is the most common reason for repeated surgery in total hip arthroplasty (Woolson and Murphy 1995, Dorr et al. 1998) and further research is essential to improve fixation and to reduce wear. Whether cemented or uncemented acetabular designs should be used is still under debate. It might be that the incidence of continuously migrating cemented cups is somewhat higher than observed for some designs of cementless cups. The RSA results at the 5-year follow-up of our control cases in Study I support this theory. Kärrholm et al. (1996) and

Önsten et al. (1998) also observed similar tendencies, but this hypothesis still has to be verified. On the other hand, complications such as liner disassembly and osteolysis have seriously impaired the results of many cementless cups.

This study has shown that satisfactory stability can be achieved using uncemented hemispheric porous cups with a titanium surface. Hydroxyapatite coating enhances the fixation and the quality of the interface. The fixation is probably more related to bone quality and surgical technique than to additional fixation with screws. It seems reasonable to believe that the efforts to improve the modular designs of uncemented cups will further improve their performance. The introduction of new polyethylenes with increased wear resistance has the potential to improve the results of both cemented and cementless designs. Both these fixation concepts will probably coexist in the future. If these new measures mean that cementless fixation will have at least as good long-term success rate as cemented, the use of uncemented implants will probably increase, due to the faster and, in the standard case, simpler surgical technique.

Continuous evaluation of different designs of cementless cups using techniques with high resolution has enabled us, during a comparatively short period of time, to identify designs with a potential for excellent long-term performance. The next step would be to initiate a prospective, randomised comparison between the most optimum designs of cemented and cementless cups in a comparatively young patient population. In addition, radiostereometric evaluation of the newly developed polyethylenes is essential to determine the wear properties of these materials.

## Conclusions

1. The use of Boneloc cement did not improve the fixation of a standard total hip arthroplasty. Instead, the fixation was impaired for both the cup and the stem. The stem subsidence occurred mainly inside the cement mantle and could be related to inferior mechanical properties of the Boneloc cement. Laboratory tests confirmed the low curing temperature of this cement but also showed a lower elastic modulus, reduced tensile strength and a lower glass transition temperature. The finding of high monomer release was contrary to earlier reports and implied that one of the basic advantages claimed for this cement not could be verified. Boneloc cement should not be used in total hip arthroplasty.
2. The PCA and the Harris-Galante I prostheses, representing the second generation of cementless prosthetic designs, did not fulfil the expectations when used in a relatively young patient population. The only individual component with an acceptable survival rate was the Harris-Galante I cup. However, even this component is associated with disadvantages, e.g. liner instability and polyethylene wear. The use of cementless implants must still be considered an experimental procedure, necessitating continuous radiographic follow-up to ensure early detection of implant loosening and osteolysis. Early revisions are recommended even if clinical symptoms are sparse or absent.
3. Increased translations up to 2 years were seen when porous cups were additionally fixed with biodegradable screws made of poly-L-lactic acid (PLLA) compared to titanium screws. Later reports have shown that PLLA material can initiate foreign-body reactions and softening of the bone, which possibly explains the increased proximal migration. Screws made of this type of polymeric material are not recommended for adjunctive fixation of acetabular cups.
4. The addition of a ceramic layer, HA/TCP, improved the fixation of porous cups up to 2 years. The radiographic appearance suggested a more pronounced bone ingrowth at the interface and the wear rate was not influenced.
5. There was no difference in early stability of porous acetabular cups with HA/TCP coating whether additional screw fixation was used or not. Nor did the wear rates or the radiographic findings differ. Screw fixation can be avoided in the majority of cases when cups with this or similar designs are used in primary hips. This can reduce costs, risks and operating time. The use of screws should be restricted to cases where the bone quality is poor or the press-fit stability is inadequate.

## Summary

Initial stability is necessary for permanent fixation of acetabular cups. Biologic reactions to submicron particles such as localized bone resorption may lead to implant failure. The aim of the study was to evaluate different fixation principles of acetabular components. Four randomized studies and one case-control study were performed to evaluate different bone cements, different cup designs, use of ceramic coating or not, different type of screws and the need of additional screw fixation or not.

Radiostereometry (RSA) makes it possible to analyze small translations and rotations of implants with a high accuracy. This method is suitable for evaluation of early stability and was used in four of the studies. Clinical and radiological follow-up were performed regularly. The cements were tested in the laboratory.

30 patients (mean age 71 years, range: 63–76) received total hip arthroplasties and were randomised to fixation with Boneloc (14) or Palacos cum gentamicin (16) bone cement. The curing temperature was 23° lower for the Boneloc cement but the tensile strength was reduced and the elastic modulus was lower compared to Palacos. The proximal cup migration was greater in the Boneloc group up to 12 months ( $p$  0.04) and these cups migrated medially in contrast to a small lateral migration seen in the Palacos group ( $p$  0.04). Radiolucencies were more pronounced in the Boneloc group at 12 months ( $p$  0.04).

155 patients (171 hips, mean age 50 years, range: 24–64) received uncemented hip arthroplasties. 84 hips were randomised to the PCA and 87 to the Harris-Galante I designs. The 10-year survival rates were 85% for the PCA and 99% for the Harris-Galante I cups (revision as end-point).

The wear and clinical results did not differ.

43 patients (mean age 60 years, range 44–68) received uncemented porous cups with a titanium mesh in pure titanium (Harris-Galante II) and were randomised to additional fixation with either biodegradable screws (23, poly-L-lactic acid, PLLA) or screws made of titanium alloy (20). Increased proximal and medial-lateral translations ( $p$  0.02, 0.04) but less rotation around the longitudinal axis ( $p$  0.04) were seen in the PLLA group up to 2 years. There were also more pronounced radiolucencies anteriorly in this group at 2 years. The clinical results did not differ.

23 uncemented porous cups (Harris-Galante II) with hydroxyapatite-tricalciumphosphate coating (HA/TCP) were pair-wise matched to uncoated cups. Up to 2 years, decreased rotations around the horizontal axis were recorded in the HA/TCP-coated cups. Central postoperative gaps were more frequently seen in the HA/TCP group ( $p$  < 0.01), but at 2 years radiolucencies were more pronounced in the uncoated group ( $p$  < 0.01). The wear and clinical results did not differ.

62 patients (64 hips, mean age 56 years, range: 32–75) were randomized to porous Trilogy cups with (30) and without (34) cluster holes for additional screw fixation. Up to 2 years there were no differences in migration, wear, radiographic findings or clinical results.

In conclusion Boneloc cement was associated with poor fixation due to inferior mechanical properties. The PLLA screws did not provide sufficient stability. Unacceptably high failure rates were recorded for the PCA cup. HA/TCP coating improved the fixation and the interface of porous cups. HA/TCP coated porous cups can be fixed without adjunctive screw fixation.

---

### Acknowledgements

The studies were supported by The Göteborg

Medical Society, Greta and Einar Askers Foundation and Hjalmar Svensson Foundation.

## References

- Anderson G, Greis PE, Klein AH et al: Alternative methods of acetabular fixation in a canine total hip replacement model. *Trans Orthop Res Soc* 17: 318, 1992
- Ahnfelt L, Herberts P, Malchau H: Prognosis of total hip replacement. A Swedish multicenter study of 4,664 revisions. *Acta Orthop Scand Suppl* 238, 1990
- Aspenberg P, Van der Vis: Migration, particles and fluid pressure. A discussion of causes of prosthetic loosening. *Clin Orthop* 352: 75, 1998
- Astion DJ, Saluan P, Stulberg BN: The porous-coated anatomic total hip prosthesis: failure of the metal-backed acetabular component. *J Bone Joint Surg (Am)* 78: 755, 1996
- Balderson H: Total hip replacement in rheumatoid arthritis. Thesis, University of Lund, Lund, Sweden 1979
- Bauer TW, Geesink RC, Zimmerman R et al: Hydroxyapatite-coated femoral stems. Histological analysis of components retrieved at autopsy. *J Bone Joint Surg (Am)* 73: 1439, 1991
- Beight J, Radin S, Cuckler J: Effect of solubility of calcium phosphate coatings on mechanical fixation of porous ingrown implants. *Trans Orthop Res Soc* 14: 334, 1989
- Bennet NE, Wang JT, Manning CA et al: Activation of human monocyte/macrophages and fibroblasts by metal particles; release of products with bone resorbing activities. *Trans Orthop Res Soc* 16: 188, 1991
- Berger RA, Jacobs JJ, Quigley LR: Primary cementless acetabular reconstruction in patients younger than 50 years old. 7- to 11-year results. *Clin Orthop* 344: 216, 1997
- Bergsma EJ, Rozema FR, Bos RR et al: Foreign body reactions to resorbable poly (L-lactide) bone plates and screws used for the fixation of unstable zygomatic fractures. *J Oral Maxillofac Surg* 51: 666, 1993
- Bloebaum RD, Merrell M, Gustke K et al: Retrieval analysis of a hydroxyapatite-coated hip prosthesis. *Clin Orthop* 267: 97, 1991
- Bloebaum RD, Bachus KN, Rubman MH et al: Postmortem comparative analysis of titanium and hydroxyapatite porous-coated femoral implants retrieved from the same patient. A case study. *J Arthroplasty* 8:203, 1993
- Bloebaum RD, Zou L, Bachus KN et al: Analysis of particles in acetabular components from patients with osteolysis. *Clin Orthop* 338: 109, 1997
- Boby JD, Engh CA, Glassman AH: Histological analysis of retrieved microporouscoated femoral prostheses. *Clin Orthop* 224: 303, 1987
- Brand RA, Yoder SA, Pedersen DR: Interobserver variability in interpreting radiographic lucencies about total hip reconstructions. *Clin Orthop* 192: 237, 1985
- Buly RL, Huo MH, Salvati E et al: Titanium wear debris in failed cemented total hip arthroplasty. An analysis of 71 cases. *J Arthroplasty* 7: 315, 1992
- Burke DW, Gates EI, Harris WH: Centrifugation as a method of improving tensile and fatigue properties of acrylic bone cement. *J Bone Joint Surg (Am)* 66: 1265, 1984
- Börlin N: High precision measurements in digital radiographs. Licentiate thesis, Umeå University, Umeå, Sweden, 1997
- Böstman OM: Osteolytic changes accompanying degradation of absorbable fracture fixation implants. *J Bone Joint Surg (Br)* 73: 679, 1991
- Böstman OM: Osteoarthritis of the ankle after foreign-body reaction to absorbable pins and screws: a three- to nine-year follow-up study. *J Bone Joint Surg (Br)* 80: 333, 1998
- Böstman OM, Pihlajamäki HK: Late foreign-body reaction to an intraosseous bioabsorbable polylactic acid screw. A case report. *J Bone Joint Surg (Am)* 80: 1791, 1998
- Callaghan JJ: The clinical results and basic science of total hip arthroplasty with porous-coated prostheses. *J Bone Joint Surg (Am)* 75: 299, 1993
- Callaghan JJ, Pedersen DR, Olejniczak JP et al: Radiographic measurement of wear in 5 cohorts of patients observed for 5 to 22 years. *Clin Orthop* 317: 14, 1995
- Callaghan JJ, Forest EE, Olejniczak JP: Charnley total hip arthroplasty in patients less than fifty years old. A twenty to twenty-five-year follow-up note. *J Bone Joint Surg (Am)* 80: 704, 1998
- Campbell P, Ma S, Yeom B et al: Isolation of predominantly submicron-sized UHMWPE wear particles from periprosthetic tissues. *J Biomed Mater Res* 29: 127, 1995
- Capello WN, D'Antonio JA, Feinberg JR et al: Hydroxyapatite-coated total hip femoral components in patients less than fifty years old. Clinical and radiographic results after five to eight years of follow-up. *J Bone Joint Surg (Am)* 79: 1023, 1997
- Capello WN, D'Antonio JA, Manley MT et al: Hydroxyapatite in total hip arthroplasty. Clinical results and critical issues. *Clin Orthop* 355: 200, 1998
- Chalmers TC, Celano P, Sacks HS et al: Bias in treatment assignment in controlled clinical trials. *N Engl J Med* 309: 1358, 1983
- Chandler HP, Reineck FT, Wixson RL et al: Total hip replacement in patients younger than thirty years old. *J Bone Joint Surg (Am)* 63: 1426, 1981
- Charnley J: Anchorage of the femoral head prosthesis to the shaft of the femur. *J Bone Joint Surg (Br)* 42: 28, 1960
- Charnley J, Eftekar N: Postoperative infection in total prosthetic replacement arthroplasty of the hip-joint. With special reference to the bacterial content in the air of the operating room. *J Bone Joint Surg (Br)* 56: 641, 1969

- Charnley J, Kamangar A, Longfield MD: The optimum size of prosthetic heads in relation to the wear of plastic sockets in total replacement of the hip. *Med Biol Eng* 7: 31, 1969
- Charnley J: The reaction of bone to self-curing acrylic cement. A long-term histological study in man. *J Bone Joint Surg (Br)* 52: 340, 1970
- Charnley J: Total hip replacement by low-friction arthroplasty. *Clin Orthop* 72: 7, 1970
- Charnley J: Low friction arthroplasty of the hip. Theory and practice. Springer-Verlag, Berlin Heidelberg, p 20, 1979
- Chen PC, Mead EH, Pinto et al: Polyethylene wear debris in modular acetabular prostheses. *Clin Orthop* 317: 44, 1995
- Clohisey JC, Harris WH: The Harris-Galante porous-coated acetabular component with screw fixation. An average ten-year follow-up study. *J Bone Joint Surg (Am)* 81: 66, 1999
- Collier JP, Surprenant VA, Mayor MB et al: Loss of hydroxyapatite coating on retrieved total hip components. *J Arthroplasty* 8: 389, 1993
- Cook SD, Thomas KA, Dalton JE: Histological analysis of retrieved human porous-coated total joint components. *Clin Orthop* 234: 90, 1988
- D'Antonio JA, Capello WN, Manley MT: Remodeling of bone around hydroxyapatite-coated femoral stems. *J Bone Joint Surg (Am)* 78: 1226, 1996
- D'Aubigné MR, Postel M: Functional results of hip arthroplasty with acrylic prostheses. *J Bone Joint Surg (Am)* 36: 451, 1954
- Debrunner HU: Temperature increase of bone cement in polymerisation. *Arch Orthop Unfallchir* 78: 309, 1974
- DeGroot K, Geesink RG, Klein CP: Plasma sprayed coatings of hydroxyapatite. *J Biomed Mater Res* 21: 1375, 1987
- DeLee JG, Charnley J: Radiological demarcation of cemented sockets in total hip replacement. *Clin Orthop* 121: 20, 1976
- Devane PA, Bourne RB, Rorabeck CH et al: Measurement of polyethylene wear in metal-backed acetabular cups. I. Three-dimensional technique. *Clin Orthop* 319: 303, 1995
- Devane PA, Bourne RB, Rorabeck CH et al: Measurement of polyethylene wear in metal-backed acetabular cups. II. Clinical application. *Clin Orthop* 319: 317, 1995
- Dorr LD, Takei GK, Conaty JP: Total hip arthroplasties in patients less than forty-five years old. *J Bone Joint Surg (Am)* 65: 474, 1983
- Dorr LD, Lewonowski K, Lucero M et al: Failure mechanisms of anatomic porous replacement I cementless total hip replacement. *Clin Orthop* 334: 157, 1997
- Dorr LD, Wan Z, Cohen J: Hemispheric titanium porous coated acetabular component without screw fixation. *Clin Orthop* 351: 158, 1998
- Engh CA, Griffin WL, Marx: Cementless acetabular components. *J Bone Joint Surg (Br)* 72: 53, 1990
- Engh CA, Zettl-Schaffer KF, Kukita et al: Histological and radiographic assessment of well functioning porous-coated acetabular components. A human postmortem retrieval study. *J Bone Joint Surg (Am)* 75: 814, 1993
- Eriksson AR, Albrektsson T: Temperature threshold levels for heat-induced bone tissue injury: a vital-microscopic study in the rabbit. *J Prosthet Dent* 50: 101, 1983
- Espehaug B, Havelin LI, Engesaeter LB et al: Early revision among 12,179 hip prostheses. A comparison of 10 different brands reported to the Norwegian Arthroplasty Register, 1987-1993. *Acta Orthop Scand* 66: 487, 1995
- Feith R: Side-effects of acrylic cement implanted into bone. A histological, (micro)angiographic, fluorescence-microscopic and autoradiographic study in the rabbit femur. *Acta Orthop Scand Suppl.* 161, 1975
- Franzen H, Mjöberg B, Rydholm U: Metal backing improves the survival of surface replacement of the hip. *Arch Orthop Trauma Surg* 112: 257, 1993
- Freeman MA, Bradley GW, Revell PA: Observations upon the interface between bone and polymethylmethacrylate cement. *J Bone Joint Surg (Br)* 64: 489, 1982
- Freeman MA, Plante-Bordeneuve P: Early migration and late aseptic failure of proximal femoral prostheses. *J Bone Joint Surg (Br)* 76: 432, 1994
- Furnes O, Lie SA, Havelin LI et al: Exeter and Charnley arthroplasties with Boneloc or high viscosity cement. Comparison of 1,127 arthroplasties followed for 5 years in the Norwegian Arthroplasty Register. *Acta Orthop Scand* 68(6): 515-20, 1997
- Galante J, Rostoker W, Lueck R et al: Sintered fiber metal composites as a basis for attachment of implants to bone. *J Bone Joint Surg (Am)* 53: 101-14, 1971
- Garcia-Cimbrelo E, Diez-Vazquez V, Madero R: Progression of radiolucent lines adjacent to the acetabular component and factors influencing migration after Charnley low-friction total hip arthroplasty. *J Bone Joint Surg Am* 79: 1373, 1997
- Geesink RG, deGroot K, Klein CP: Chemical implant fixation using hydroxyl-apatite coatings. *Clin Orthop* 225: 147, 1987
- Geesink RGT, Hoefnagels NHM: Six-year results of hydroxyapatite-coated total hip replacement. *J Bone Joint Surg (Br)* 77: 534, 1995
- Goddard NJ, Gosling PT: Intra-articular fluid pressure and pain in osteoarthritis of the hip. *J Bone Joint Surg (Br)* 70: 52, 1988
- Goldring SR, Schiller AL, Roelke M et al: The synovial-like membrane at the bone-cement interface in loose total hip replacements and its proposed role in bone lysis. *J Bone Joint Surg (Am)* 65: 575, 1983
- Goodman SB, Fourmasier VL, Kei J: The effect of bulk versus particulate polymethylmethacrylate on bone. *Clin Orthop* 232: 255, 1988
- Goodman SB, Lind M, Song Y et al: In vitro, in vivo, and tissue retrieval studies on particulate debris. *Clin Orthop* 352: 25, 1998
- Gross M: A critique of the methodologies used in clinical studies of hip-joint arthroplasty published in the English-language orthopaedic literature. *J Bone Joint Surg (Am)* 70: 1364, 1988

- Gruen TA, McNeice, Amstutz HC: "Modes of failure" of cemented stem-type femoral components. A radiographic analysis of loosening. *Clin Orthop* 141: 17, 1979
- Han CD, Choe WS, Yoo JH: Late dissociation of the polyethylene liner from a modular acetabular metal shell after primary total hip arthroplasty—a report of five cases. *Yonsei Med J* 39: 277, 1998
- Harris WH: Traumatic arthritis of the hip after dislocation and acetabular fractures: Treatment by mold arthroplasty. An end-result study using a new method result evaluation. *J Bone Joint Surg (Am)* 51: 737 1969
- Harris WH, Schiller AL, Scholler JM et al: Extensive localized bone resorption in the femur following total hip replacement. *J Bone Joint Surg (Am)* 58: 612 1976
- Harris WH, McCarthy JC Jr, O'Neill DA: Femoral component loosening using contemporary techniques of femoral cement fixation. *J Bone Joint Surg (Am)* 64: 1063, 1982
- Harris WH, White RE, McCarthy JC et al: Bony ingrowth fixation of the acetabular component in canine hip joint arthroplasty. *Clin Orthop* 176: 7, 1983
- Harris WH: Osteolysis and particle disease in hip replacement. A review. *Acta Orthop Scand* 65: 113, 1994
- Harris WH: The problem is osteolysis. *Clin Orthop* 311: 46, 1995
- Havelin LI, Gjerdet NR, Lunde OD et al: Wear of the Christiansen hip prosthesis. *Acta Orthop Scand* 57: 419, 1986
- Havelin LI, Espehaug B, Vollset SE et al: Early failures among 14,009 cemented and 1,326 uncemented prostheses for primary coxarthrosis. The Norwegian Arthroplasty Register, 1987-1992. *Acta Orthop Scand* 65: 1, 1994
- Havelin LI, Espehaug B, Vollset SE et al: The effect of the type of cement on early revision of Charnley total hip prostheses. A review of eight thousand five hundred and seventy-nine primary arthroplasties from the Norwegian Arthroplasty Register. *J Bone Joint Surg (Am)* 77: 1543, 1995
- Haynes DR, Rogers SD, Hay S et al: The differences in toxicity and release of bone-resorbing mediators induced by titanium and cobalt-chromium-alloy wear particles. *J Bone Joint Surg (Am)* 75: 825, 1993
- Heekin RD, Callaghan JJ, Hopkinson WJ et al: The porous-coated anatomic total hip prosthesis, inserted without cement. Results after five to seven years in a prospective study. *J Bone Joint Surg (Am)* 75: 77, 1993
- Herberts P, Ahnfelt L, Malchau H et al: Multicenter clinical trials and their value in assessing total joint arthroplasty. *Clin Orthop* 249: 48, 1989
- Herberts P, Malchau H: How outcome studies have changed total hip arthroplasty practices in Sweden. *Clin Orthop* 344: 44, 1997
- Hirakawa K, Bauer TW, Stulberg BN et al: Characterization and comparison of wear debris from failed total hip implants of different types. *J Bone Joint Surg (Am)* 78: 1235, 1996
- Howie DW, Vernon-Roberts B, Oakeshott R et al: A rat model of resorption of bone at the cement-bone interface in the presence of polyethylene wear particles. *J Bone Joint Surg (Am)* 70: 257, 1988
- Howie DW: Tissue response in relation to type of wear particles around failed hip arthroplasties. *J Arthroplasty* 5: 337, 1990
- Huk OL, Bansal M, Betts F et al: Polyethylene and metal debris generated by non-articulating surfaces of modular acetabular components. *J Bone Joint Surg (Br)* 76: 568, 1994
- Huskisson EC: Measurement of pain. *Lancet* 9: 1127, 1974
- Ilchmann T: Radiographic assessment of cup migration and wear after hip replacement. *Acta Orthop Scand Suppl.* 276: 1, 1997
- Incavo SJ, Ames SE, DiFazio FA et al: Cementless hemispherical acetabular components. A 4- to 8-year follow-up report. *J Arthroplasty* 11: 298, 1996
- Jacobsson SA, Djerf K, Wahlstrom O: Twenty-year results of McKee-Farrar versus Charnley prosthesis. *Clin Orthop* 329: 60, 1996
- Jarcho M: Calcium phosphate ceramics as hard tissue prosthesis. *Clin Orthop* 157: 259, 1981
- Jasty MJ, Floyd WE, Schiller AL: Localized osteolysis in stable, non-septic total hip replacement. *J Bone Joint Surg (Am)* 68: 912, 1986
- Jasty M, Maloney WJ, Bragdon CR: The initiation of failure in cemented femoral components of hip arthroplasties. *J Bone Joint Surg (Br)* 73: 551, 1991
- Jensen JS, Sylvest A, Trap B: Genotoxicity of acrylic bone cements. *Pharmacol Toxicol* 69: 386, 1991
- Jones WD: Fundamental principles of powder metallurgy. London, Edw. Arnold, Ltd, 1960
- Jones LC, Hungerford DS: Cement disease. *Clin Orthop* 225: 192, 1987
- Judet R, Siguier M, Brumpt B et al: A noncemented total hip prosthesis. *Clin Orthop* 137: 76, 1978
- Kaplan EL, Meier P: Nonparametric estimation from incomplete observation. *J Am Stat Assoc* 53: 457, 1958
- Kavanagh BF, Wallrichs S, Dewitz M et al: Charnley low-friction arthroplasty of the hip. Twenty-year results with cement. *J Arthroplasty* 9:229, 1994
- Keller RB, Rudicel SA, Liang MA: Outcomes research in orthopaedics. *J Bone Joint Surg (Am)* 75: 1562, 1992
- Kesteris U, Ilchmann T, Wingstrand H et al: Polyethylene wear in Scanhip arthroplasty with a 22 or 32 mm head: 62 matched patients followed for 7-9 years. *Acta Orthop Scand* 67: 125, 1996
- Klein CP, Driessen AA, de Groot K: Biodegradation behavior of various calcium-phosphate material in bone tissue. *J Biomed Mater Res* 17: 769, 1983
- Krismer M, Bauer R, Tschupik J et al: EBRA: a method to measure migration of acetabular components. *J Biomech* 28: 1225, 1995
- Kroon PO, Freeman MA: Hydroxyapatite coating of hip prostheses. Effect on migration into the femur. *J Bone Joint Surg (Br)* 74: 518, 1992

- Kurtz SM, Ochoa JA, White CV et al: Backside nonconformity and locking restraints affect liner/shell load transfer mechanisms and relative motion in modular acetabular components for total hip replacement. *J Biomech* 31: 431, 1998
- Kwong LM, O'Connor DO, Sedlacek RC et al: A quantitative in vitro assessment of fit and screw fixation on the stability of a cementless hemispherical acetabular component. *J Arthroplasty* 9: 163, 1994
- Kärrholm J: Roentgen stereophotogrammetry. Review of orthopedic applications. *Acta Orthop Scand* 60: 491, 1989
- Kärrholm J, Snorrason F: Migration of porous coated acetabular prostheses fixed with screws: roentgen stereophotogrammetric analysis. *J Orthop Res* 10: 826, 1992
- Kärrholm J, Borssen B, Löwenhielm G et al: Does early micromotion of femoral stem prostheses matter? 4-7 year stereoradiographic follow-up of 84 cemented prostheses. *J Bone Joint Surg (Br)* 76: 912, 1994
- Kärrholm J, Malchau H, Snorrason F et al: Micromotion of femoral stems in total hip arthroplasty. A randomized study of cemented, hydroxyapatite-coated, and porous-coated stems with roentgen stereophotogrammetric analysis. *J Bone Joint Surg (Am)* 76: 1692, 1994
- Kärrholm J, Frech W, Nilsson KG et al: Increased metal release from cemented femoral components made of titanium alloy. 19 hip prostheses followed with radiostereometry (RSA). *Acta Orthop Scand* 65: 599, 1994
- Kärrholm J, Herberts P, Hultmark P et al: Radiostereometry of hip prostheses. Review of methodology and clinical results. *Clin Orthop* 344: 94, 1997
- Kärrholm J, Snorrason F, Carlsson L: Migration of porous coated press-fit acetabular cups. *Trans Orthop Res Soc* 20: 244, 1995
- Kärrholm J, Frech W, Nivbrant B: Fixation and metal release from the Tifit femoral stem prosthesis. 5-year follow-up of 64 cases. *Acta Orthop Scand* 69: 369, 1998
- Latimer HA, Lachiewicz PF: Porous-coated acetabular components with screw-fixation. *J Bone Joint Surg (Am)* 78: 975, 1996
- Law WA: Late results in vitallium-mold arthroplasty of the hip. *J Bone Joint Surg (Am)* 44: 1497, 1962
- Lidgren L, Drar H, Möller J: Strength of polymethylmethacrylate increased by vacuum mixing. *Acta Orthop Scand* 55: 536, 1984
- Lieberman JR, Kay RM, Hamlet WP et al: Wear of the polyethylene liner-metallic shell interface in modular acetabular components. An in vitro analysis. *J Arthroplasty* 11: 602, 1996
- Linder L, Carlsson ÅS: The bone-cement interface in hip arthroplasty. A histologic and enzyme study of stable components. *Acta Orthop Scand* 57: 495, 1986
- Linder L: Bone cement monomer. Thesis, University of Göteborg, Göteborg, Sweden, 1976
- Linder L: Boneloc—The Christiansen experience revisited. *Acta Orthop Scand* 66: 205, 1995
- Livermore J, Ilstrup D, Murray B: Effect of femoral head size on wear of the polyethylene acetabular component. *J Bone Joint Surg (Am)* 72: 518, 1990
- Livingston BJ, Chmell MJ, Spector M et al: Complications of total hip arthroplasty associated with the use of an acetabular component with a Hylamer liner. *J Bone Joint Surg (Am)* 79: 1529, 1997
- Lord GA, Hardy JR, Kummer FJ: An uncemented total hip replacement: experimental study and review of 300 madreporique arthroplasties. *Clin Orthop* 141: 2, 1979
- Lord G, Bancel P: The madreporic cementless total hip arthroplasty. New experimental data and a seven-year clinical follow-up study. *Clin Orthop* 176: 67, 1983
- Madey SM, Callaghan JJ, Olejniczak JP: Charnley total hip arthroplasty with use of improved techniques of cementing. The results after a minimum of fifteen years of follow-up. *J Bone Joint Surg (Am)* 79: 53, 1997
- Malchau H: On the importance of stepwise introduction of new hip implant technology. Thesis, University of Göteborg, Sweden, 1995
- Malchau H, Herberts P, Ahnfelt L: Prognosis of total hip replacement in Sweden. Follow-up of 92,675 operations performed 1978–1990. *Acta Orthop Scand* 64: 497, 1993
- Malchau H, Kärrholm J, Wang YX et al: Accuracy of migration analysis in hip arthroplasty. Digitized and conventional radiography, compared to radiostereometry in 51 patients. *Acta Orthop Scand* 66:418, 1995
- Malchau H, Herberts P, Wang YX et al: Long-term clinical and radiological results of the Lord total hip prosthesis. A prospective study. *J Bone Joint Surg (Br)* 78: 884, 1996
- Malchau H, Wang YX, Kärrholm J et al: Scandinavian multicenter porous coated anatomic total hip arthroplasty study. Clinical and radiographic results with 7- to 10-year follow-up evaluation. *J Arthroplasty* 12: 133, 1997
- Maloney WJ, Jasty M, Rosenberg A: Bone lysis in well-fixed cemented femoral components. *J Bone Joint Surg (Br)* 72: 966, 1990
- Manley MT, Capello WN, D'Antonio JA et al: Fixation of acetabular cups without cement in total hip arthroplasty. A comparison of three different implant surfaces at a minimum duration of follow-up of five years. *J Bone Joint Surg (Am)* 80: 1175, 1998
- McCaskie AW, Brown AR, Thompson JR: Radiological evaluation of the interfaces after cemented total hip replacement. Interobserver and intraobserver agreement. *J Bone Joint Surg (Br)* 78: 191, 1996
- McKee GK, Watson-Farrar: Replacement of arthritic hips by the McKee-Farrar prosthesis. *J Bone Joint Surg (Br)* 48: 245, 1966
- McKee GK, Chen SC: The statistics of the McKee-Farrar method of total hip replacement. *Clin Orthop* 75:26, 1973 McKellop HA, Röstlund TV: The wear behavior of ion-implanted Ti-6Al-4V against UHMW polyethylene. *Biomed Mater Res* 24: 1413, 1990
- McKellop HA, Campbell P, Park SH et al: The origin of submicron polyethylene wear debris in total hip arthroplasty. *Clin Orthop* 311: 3, 1995
- McKellop H, Shen FW, Salovey R et al: Extremely low wear of gamma-crosslinked/remelted UHMW polyethylene acetabular cups. *Trans Orthop Res Soc* 23: 98, 1998

- Mjöberg B: Loosening of the cemented hip prosthesis. The importance of heat injury. *Acta Orthop Scand Suppl.* 221: 1, 1986
- Mjöberg B: Theories of wear and loosening in hip prostheses. Wear-induced loosening vs loosening-induced wear—a review. *Acta Orthop Scand* 65: 361, 1994
- Moilanen T, Stocks GW, Freeman MA et al: Hydroxyapatite coating of an acetabular prosthesis. Effect on stability. *J Bone Joint Surg (Br)* 78: 200-205, 1996
- Moore AT, Bohlman HR: Metal hip joint. A case report. *J Bone Joint Surg* 25: 688, 1943
- Mulroy RD Jr, Harris WH: The effect of improved cementing techniques on component loosening in total hip replacement. An 11-year radiographic review *J Bone Joint Surg (Br)* 72: 757, 1990
- Mulroy WF, Estok DM, Harris WH: Total hip arthroplasty with use of so-called second-generation cementing techniques. A fifteen-year-average follow-up study. *J Bone Joint Surg (Am)* 77: 1845, 1995
- Mulroy WF, Harris WH: Acetabular and femoral fixation 15 years after cemented total hip surgery. *Clin Orthop* 337: 118, 1997
- Mulrow CD, Oxman AD: Cochrane collaboration handbook. In *The Cochrane Library. The Cochrane Collaboration.* Oxford, 1996
- Murray DW, Carr AJ, Bulstrode CJ: Which primary total hip replacement? *J Bone Joint Surg (Br)* 77: 520, 1995
- Nasser S, Campbell PA, Kilgus D et al: Cementless total joint arthroplasty prostheses with titanium-alloy articular surfaces. A human retrieval analysis. *Clin Orthop* 261: 171, 1990
- Nilsen AR, Wiig M: Total hip arthroplasty with Boneloc: loosening in 102/157 cases after 0.5-3 years. *Acta Orthop Scand* 67: 57, 1996
- Nilsson KG, Dalen T: Inferior performance of Boneloc bone cement in total knee arthroplasty: a prospective randomized study comparing Boneloc with Palacos using radiostereometry (RSA) in 19 patients. *Acta Orthop Scand* 69: 479, 1998
- Nimb L, Sturup J, Jensen JS: Improved cortical histology after cementation with a new MMA-DMA-IBMA bone cement: an animal study. *J Biomed Mater Res* 27: 565, 1993
- Nivbrant B, Kärrholm J: Migration and wear of hydroxyapatite-coated press-fit cups in revision hip arthroplasty: a radiostereometric study. *J Arthroplasty* 12: 904, 1997
- Nivbrant B, Kärrholm J: Migration of hip prostheses fixed with a standard or a cold curing bone cement. *Trans Orthop Res Soc* 22: 309, 1997
- Nivbrant B, Karlsson K, Kärrholm J: Cytokine levels in synovial fluid from hips with well-functioning or loose prostheses. *J Bone Joint Surg (Br)* 81: 163, 1999
- Nystrom L, Söderkvist I, Wedin PA: A note on some identification problems arising in roentgen stereo photogrammetric analysis. *J Biomech* 27: 1291, 1994
- Onishi H, Kuno M, Ikada Y et al: Super low wear cross-linked UHMWPE by heavy high-dose gamma irradiation. Proceedings from the 2nd congress of hip section of western pacific orthopaedic association. 1996:4
- Pedersen JG, Lund B, Reimann I: Depressive effects of acrylic cement components on bone metabolism. Isotope release and phosphatase production studied in vitro. *Acta Orthop Scand* 54: 796, 1983
- Perona PG, Lawrence J, Paprosky et al: Acetabular micromotion as a measure of initial implant stability in primary hip arthroplasty: An in vitro comparison of different methods of initial acetabular component fixation. *J Arthroplasty* 7: 537, 1992
- Pihlajamäki H, Bostman O, Hirvensalo E et al: Absorbable pins of self-reinforced poly-L-lactic acid for fixation of fractures and osteotomies. *J Bone Joint Surg (Br)* 74: 853, 1992
- Pilliar RM, Cameron HU, Macnab I: Porous surfaced layered prosthetic devices. *J Biomed Eng* 10: 126, 1975
- Pilliar RM, Lee JM, Maniopoulos C: Observations on the effect of movement on bone ingrowth into porous-surfaced implants. *Clin Orthop* 208: 108, 1986
- Pilliar RM: Porous-surfaced metallic implants for orthopaedic applications. *J. Biomed. Mater Res* 21: 1, 1987
- Ragnarsson JI, Hansson LI, Kärrholm J: Spontaneous compression in femoral neck fractures. *Acta Orthop Scand* 60: 283, 1989
- Ranawat CS, Peters LE, Umlas ME: Fixation of the acetabular component. The case for cement. *Clin Orthop* 344: 207, 1997
- Retpen JB, Solgaard S: Late disassembly of modular acetabular components. A report of two cases. *Acta Orthop Scand* 64: 193, 1993
- Riegels-Nielsen P, Sorensen L, Andersen HM et al: Bone-loc cemented total hip prostheses. Loosening in 28/43 cases after 3-38 months. *Acta Orthop Scand* 66: 215, 1995
- Rimnac CM, Wright TM, McGill DL: The effect of centrifugation on the fracture properties of acrylic bone cements. *J Bone Joint Surg (Am)* 68: 281, 1986
- Ring PA: Complete replacement arthroplasty of the hip by the Ring prosthesis. *J Bone Joint Surg* 50: 720, 1968
- Ritter MA, Meding JB, Faris PM: Femoral head size: variation among manufacturers. *Orthopedics* 19: 877, 1996
- Robertsson O, Wingstrand H, Kesteris U et al: Intracapsular pressure and loosening of hip prostheses. Preoperative measurements in 18 hips. *Acta Orthop Scand* 68: 231, 1997
- Russe W: Roentgen photogrammetry of the artificial hip joint acetabulum. *Aktuelle Probl Chir Orthop* 32: 1, 1988
- Saikko V, Nevalainen J, Revitzer H et al: Metal release from total hip articulations in vitro: substantial from CoCr/CoCr, negligible from CoCr/PE and alumina/PE. *Acta Orthop Scand* 69: 449, 1998
- Salvati EA, Betts F, Doty SB: Particulate metallic debris in cemented total hip arthroplasty. *Clin Orthop* 293: 160, 1993
- Santavirta S, Hoikka V, Eskola A et al: Aggressive granulomatous lesions in cementless total hip arthroplasty. *J Bone Joint Surg (Br)* 72: 980, 1990

- Santavirta S, Konttinen YT, Hoikka V et al: A Immunopathological response to loose cementless acetabular components. *J Bone Joint Surg (Br)* 73: 38, 1991
- Selvik G: Roentgen stereophotogrammetry. A method for the study of the kinematics of the skeletal system. Thesis, University of Lund, Lund, Sweden 1974. (Reprinted Acta Orthop Scand Suppl 232, 1989)
- Schmalzried TP, Kwong LM, Jasty M et al: The mechanism of loosening of cemented acetabular components in total hip arthroplasty. Analysis of specimens retrieved at autopsy. *Clin Orthop* 274: 60, 1992
- Schmalzried TP, Jasty M, Harris WH: Periprosthetic bone loss in total hip arthroplasty. Polyethylene wear debris and the concept of the effective joint space. *J Bone Joint Surg (Am)* 74: 849, 1992
- Schmalzried TP, Harris WH: The Harris-Galante porous-coated acetabular component with screw fixation. Radiographic analysis of eighty-three primary hip replacements at a minimum of five years. *J Bone Joint Surg (Am)* 74: 1130, 1992
- Schmalzried TP, Wessinger SJ, Hill GE et al: The Harris-Galante porous acetabular component press-fit without screw fixation. Five-year radiographic analysis of primary cases. *J Arthroplasty* 9: 235, 1994
- Schmalzried TP, Szuszczewicz ES, Akizuki KH: Factors correlating with long term survival of McKee-Farrar total hip prostheses. *Clin Orthop* 329: 48, 1996
- Schmidt M, Weber H, Schon R: Cobalt chromium molybdenum metal combination for modular hip prostheses. *Clin Orthop* 329: 35, 1996
- Smith-Pedersen MN: Arthroplasty of the hip. A new method. *J Bone Joint Surg* 21: 269, 1939
- Snorrason F, Kärrholm J: Primary migration of fully-threaded acetabular prostheses. A roentgen stereophotogrammetric analysis. *J Bone Joint Surg (Br)* 72: 647, 1990
- Soh EW, Blunn GW, Wait ME: Size and shape of metal particles from metal-on metal total hip replacements. *Trans Orthop Res Soc* 21: 462, 1996
- Stauffer RN: Ten-year follow-up study of total hip replacement. *J Bone Joint Surg (Am)* 64: 983, 1982
- Stiehl JB, MacMillan E, Skrade DA: Mechanical stability of porous-coated acetabular components in total hip arthroplasty. *J Arthroplasty* 6: 295, 1991
- Streicher RM: Metal-on-metal articulation in total hip arthroplasty: the case for using metal-on-metal. *J Arthroplasty* 13: 343, 1998
- Streicher RM, Semlitsch M, Schon R et al: Metal-on-metal articulation for artificial hip joints: laboratory study and clinical results. *Proc Inst Mech Eng (H)* 210: 223, 1996
- Stürup J, Nimb L, Kramhoft M et al: Effects of polymerization heat and monomers from acrylic cement on canine bone. *Acta Orthop Scand* 65: 20, 1994
- Sumner DR, Jasty M, Jacobs JJ et al: Histology of porous-coated acetabular components. 25 cementless cups retrieved after arthroplasty. *Acta Orthop Scand* 64: 619, 1993
- Suominen S: Early failure with Boneloc bone cement. 4/8 femoral stems loose within 3 years. *Acta Orthop Scand* 66: 13, 1995
- Sutherland CJ, Wilde AH, Borden LS et al: A ten-year follow-up of one hundred consecutive Muller curved-stem total hip-replacement arthroplasties. *J Bone Joint Surg (Am)* 64: 970, 1982
- Swanson SA, Freeman MA, Heath JC: Laboratory tests on total joint replacement procedures. *J Bone Joint Surg (Br)* 55: 759, 1973
- Søballe K, Hansen ES, Brockstedt-Rasmusson H et al: Hydroxyapatite coating enhances fixation of porous-coated implants. *Acta Orthop Scand* 61: 299, 1990
- Søballe K, Hansen ES, Brockstedt-Rasmusson H et al: Tissue ingrowth into titanium and hydroxyapatite coated implants during stable and unstable conditions. *J Orthop Res* 10: 285-99, 1992
- Søballe K: Hydroxyapatite ceramic coating for bone implant fixation. Mechanical and histological studies in dogs. *Acta Orthop Scand Suppl* 255: 1993
- Søballe K, Overgaard S: The current status of hydroxyapatite coating of prostheses. *Bone Joint Surg (Br)* 78: 689, 1996
- Söderqvist I: Computing parameters in nonlinear least squares models. Thesis, University of Umeå, Sweden 1993
- Tanner MG, Whiteside LA, White SE: Effect of polyethylene quality on wear in total knee arthroplasty. *Clin Orthop* 317: 83, 1995
- Tanzer M, Maloney WJ, Jasty M et al: The progression of femoral cortical osteolysis in association with total hip arthroplasty without cement. *Bone Joint Surg (Am)* 74: 404, 1992
- Toksvig-Larsen S, Franzen H, Ryd L: Cement interface temperature in hip arthroplasty. *Acta Orthop Scand* 62:102, 1991
- Tompkins GS, Jacobs JJ, Kull LR et al: Primary total hip arthroplasty with a porous-coated acetabular component. Seven-to-ten-year results. *J Bone Joint Surg (Am)* 79: 169, 1997
- Urban RM, Jacobs JJ, Gilbert JL: Migration of corrosion products from modular hip prostheses. Particle microanalysis and histopathological findings. *J Bone Joint Surg (Am)* 76: 1345, 1994
- Urban RM, Jacobs JJ, Sumner DR et al: The bone-implant interface of femoral stems with non-circumferential porous coating. *J Bone Joint Surg (Am)* 78: 1068, 1996
- Valstar ER, Spoor CW, Nelissen RG: Roentgen stereophotogrammetric analysis of metal-backed hemispherical cups without attached markers. *J Orthop Res* 15: 869, 1997
- Vrooman HA, Valstar ER, Brand GJ: Fast and accurate automated measurements in digitized stereophotogrammetric radiographs. *J Biomech* 31: 491, 1998
- Walker PS, Mai SF, Cobb AG et al: Prediction of clinical outcome of THR from migration measurements on standard radiographs. A study of cemented Charnley and Stanmore femoral stems. *J Bone Joint Surg (Br)* 77: 705, 1995
- Walker PS, Blunn GW: Metal-on-metal articulation in total hip arthroplasty: the case for improving metal- or ceramic-on-polyethylene. *J Arthroplasty* 13: 339, 1998

- Weightman B, Freeman MA, Revell PA: The mechanical properties of cement and loosening of the femoral component of hip replacements. *J Bone Joint Surg (Br)* 69: 558, 1987
- Willert HG, Ludwig J, Semlitsch M: Reaction of bone to methacrylate after hip arthroplasty. A long-term gross, light microscopic, and scanning electron microscopic study. *J Bone Joint Surg (Am)* 56: 1368, 1974
- Willert HG: Reactions of the articular capsule to wear products of artificial joint prostheses. *J Biomed Mater Res* 11: 157, 1977
- Willert HG, Bertram H, Buchhorn GH: Osteolysis in alloarthroplasty of the hip. The role of ultra-high molecular weight polyethylene particles. *Clin Orthop* 258: 95, 1990
- Won C-E, Hearn TC, Tile M et al: Micromotion of cementless hemispherical acetabular components. *J Bone Joint Surg (Br)* 77: 484, 1995
- Woodman JL, Jacobs JJ, Galante JO: Metal ion release from titanium-based prosthetic segmental replacements of long bones in baboons: a long-term study. *J Orthop Res* 1: 421, 1984
- Woolson ST, Murphy MG: Wear of the polyethylene of Harris-Galante acetabular components inserted without cement. *J Bone Joint Surg (Am)* 77: 1311, 1995
- Wroblewski BM: 15-21-year results of the Charnley low-friction arthroplasty. *Clin Orthop* 211: 30, 1986
- Wroblewski BM, Taylor GW, Siney P: Charnley low-friction arthroplasty: 19- to 25-year results. *Orthopedics* 15: 421, 1992
- Wykman AG: Acetabular cement temperature in arthroplasty. Effect of water cooling in 19 cases. *Acta Orthop Scand* 63: 543, 1992
- Önsten I, Carlsson AS, Ohlin A et al: Migration of acetabular components, inserted with and without cement, in one-stage bilateral hip arthroplasty. A controlled, randomized study using roentgenstereophotogrammetric analysis. *J Bone Joint Surg (Am)* 76: 185, 1994
- Önsten I, Carlsson ÅS: Cemented versus uncemented socket in hip arthroplasty.: A radiostereometric study of 60 randomized hips followed for 2 years. *Acta Orthop Scand* 65: 517; 1994
- Önsten I, Carlsson ÅS, Sanzen L et al: Migration and wear of a hydroxyapatite-coated hip prosthesis. A controlled roentgen stereophotogrammetric study. *J Bone Joint Surg (Br)* 78: 85, 1996
- Önsten I, Carlsson ÅS, Besjakov J: Wear in uncemented porous and cemented polyethylene sockets: A randomized, radiostereometric study. *J Bone Joint Surg (Br)* 80: 345, 1998
- Østgaard SE, Gottlieb L, Toksvig-Larsen S et al: Roentgen stereophotogrammetric analysis using computer-based image-analysis. *J Biomech* 30: 993, 1997