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Anatomy of the Proximal Femoral Medullary Canal and Fit and Fill Characteristics of Cementless Endoprosthetic Stems

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ABBREVIATIONS

HA	hydroxyapatite
CT	computed tomography
HU	Hounsfield unit
BMD	bone mineral density
ML	mediolateral
AP	anteroposterior
CFI	canal flare index
MCFI	metaphyseal canal flare index
DEXA	dual-energy X-ray absorptiometry
T	mid-point of lesser trochanter

DEFINITIONS

Fit = the ratio of endoprosthetic stem surface contacting endosteal cortical bone to the whole stem surface in the region studied

Fill = the ratio of the volume of stem to the volume of medullary canal in the region studied

INTRODUCTION

Total hip arthroplasty is apparently one of the most successful of orthopaedic procedures, providing relief of pain and restoring the daily activities of osteoarthritic patients. Cemented hip arthroplasty has proved its viability in a number of series with long-term follow-ups (Dall et al 1986, Eftekhar 1987, Malchau et al 1993, Neumann et al 1994, Sullivan et al 1994). The ultimate “golden standard” position of Charnley Low-Friction Arthroplasty is hardly open to question on statistical grounds (Herberts et al 1989).

Some 20 years ago porous coated cementless femoral stems were introduced (Lord et al 1979, Lord and Bancel 1983, Engh 1983). The number of cementless total hip replacements rapidly increased, as did the number of different cementless designs marketed in subsequent years (Huiskes 1993, Havelin et al 1995, Murray et al 1995). The disappointing results in a few cemented hip arthroplasty series with patients younger than fifty years (Chandler et al 1981, Collis 1984) were usually put forward as arguments for cementless fixation; lifelong durability of hip arthroplasty was sought (Amstutz 1985).

Tight fit in the diaphyseal canal was considered essential in the first-generation cementless designs (Lord et al 1979, Engh et al 1987). Noble and colleagues (1988) demonstrated the remarkable variability of the femoral canal shape. Improving the fit and fill of cementless stems in the femoral canal became an important topic (Robertson et al 1988), particularly in view of observations of proximal bone resorption due to stress by-passing, *i.e.* stress shielding (Engh and Bobyn 1988).

A number of innovations were introduced: custom-made systems to maximise fixation surface (Bargar 1989, Mulier et al 1989, Stulberg et al 1989, Reuben et al 1992), proximally limited porous coating (Callaghan et al 1988, Martell et al 1993, Hozack et al 1996), wedge-shaped press-fit stems (Pellegrini et al 1992, Morrey 1989), and isoelastic stems (Andrew et al 1986, Butel and Robb 1988) to avoid excessive stress shielding. Many innovations were utilised under inappropriate conditions of trial and error (Huiskes 1993).

In the 1990s the main topics pertaining to cementless arthroplasty were the modularity of components and polyethylene wear and osteolysis. However, there were articles which emphasised the fit and fill of cementless stems in the metaphyseal femoral canal (Burke et al 1991, Callaghan et al 1992, Hua and Walker 1994, Dujardin et al 1996). Articles dealing with the anatomy of the femoral canal and focusing on metaphyseal variation were published by Robertson et al (1996), Husmann et al (1997) and Massin et al (2000).

The purpose here was to study the anatomy of the proximal femoral canal by an appropriate method, and to evaluate the fit and fill characteristics and resulting bone remodeling patterns of two different cementless femoral stems.

REVIEW OF THE LITERATURE

Bone ingrowth and cementless fixation

Bone growth into the porous surface of the endoprosthetic component in the femoral canal is considered essential in cementless hip arthroplasty. Bone growth into porous implants was widely demonstrated from the early 1970s in a number of experimental series (Galante et al 1971, Nilles et al 1973, Cameron et al 1976, Lord et al 1979, Chen et al 1983). The minimum pore size for osseous fixation has been estimated at 50-100 μm (Hulbert et al 1970, Bobyn et al 1980 II). The relevance of this 'optimum' pore size, however, is questionable in clinical use, in view of the successful experience with solid fixation with pore sizes even up to 1-2 mm (Bobyn and Engh 1983, Malchau et al 1996).

In the bone ingrowth sequence three phases concomitant with primary fracture-healing can be seen to occur at the implant surface: 1) initial inflammatory phase, 2) reparative woven bone phase and 3) remodeling lamellar-bone phase (Galante et al 1971, Cameron et al 1976, Chen et al 1983, Sandborn et al 1988, Callaghan 1993). New-bone formation has been observed to start within ten days, and at twelve weeks thorough bone infiltration has been recorded in titanium implants in femoral canals of rabbits (Galante et al 1971). However, lamellar-bone can increase for at least 52 weeks, also resulting in increased attachment strength during that period (Sandborn et al 1995). In animal studies bone ingrowth has been verified with several porous-coated materials: ceramics (Welsh et al 1971, Nilles et al 1973), Vitallium (Welsh et al 1971), titanium (Galante et al 1971, Nilles et al 1973), stainless steel (Nilles et al 1973), carbon (Nilles et al 1973) and chrome-cobalt alloys (Lord et al 1979).

Galante and associates (1971) already mentioned that in some instances the ingrown bone trabeculae and the metal implant surface were separated by a very thin layer of fibrous tissue. Subsequently the interposition of such a fibrous tissue membrane was observed to be a fairly regular phenomenon in canine prosthesis models (Lord et al 1979, Chen et al 1983).

There are several factors governing the rate and quality of bone ingrowth. The type of tissue which grows into porous surfaces and the resulting fixation strength depend markedly on the relative initial motion between the implant and the bone (Cameron et al 1973). The exact threshold of micromotion for bone ingrowth has not been determined, but Pilliar and colleagues (1986) reported osseous fixation with relative motion of less than 28 μm and fibrous tissue fixation with 150 μm of motion. Likewise, in a study of Soballe and colleagues (1992, I) 150 μm of motion resulted a fibrous membrane around the implants. According to these findings a threshold between 40-50 μm of micromotion for bone ingrowth has been suggested (Callaghan 1993).

In stable conditions, *i.e.*, in experiments in which there are implants without direct loading in the reamed medullary canal, endosteal bone can grow into the porous surface over a gap of 2 mm, but the rate and degree of maturity and mineralisation is increased when the gap width is 0.5 mm or less (Bobyn et al 1981, Sandborn et al 1988, Dalton 1995). Sandborn and colleagues (1988) stated that the ability of bone to bridge a gap space and infiltrate a porous implant and especially the rate is more pronounced in the cortical than in the cancellous region. Contrary to this, Dalton and associates (1995) observed no significant differences between cortical and cancellous bone in gap filling, bone ingrowth or attachment strength. In their experiment implants with large initial gaps (1 or 2 mm) demonstrated even greater attachment strength in cancellous than in cortical bone.

The value of an osteoconductive hydroxyapatite (HA) coating in enhancing bone ingrowth has been widely documented (Cook et al 1988, Cook et al 1991, Soballe et al 1991, Soballe et al 1992 I, Soballe et al 1992 II, Soballe et al 1993, Dalton et al 1995). HA coating of unloaded titanium implants accelerates the rate of bone ingrowth and also increases fixation strength (Cook et al 1991, Soballe et al 1991, Dalton et al 1995). In the loaded model causing micromotion of 150 or 500 μm, both HA-coated and non-coated titanium implants were surrounded by fibrous membrane after 4 weeks of implantation, but the membrane was thinner, there was more fibrocartilaginous tissue instead of connective tissue, and the shear strength was significantly increased in the unstable HA groups (Soballe et al 1992 I, Soballe et al 1992 II). Obviously, HA coating has positive effects also in unstable conditions.

Endosteal bone grows into a porous coated implant in conditions in which the implant has adequate apposition to bone and initial stability. Retrieval analyses of cementless femoral components have demonstrated that bone ingrowth is limited. Obviously depending on methods and perhaps on stem designs, different extents of bone ingrowth have been reported (Galante and Jacobs 1992). Collier and associates (1988) observed bone ingrowth in only 27% of femoral components (the series also included loosened stems). Cook and associates (1988 I, II) reported that approximately one third of hip components had no bone ingrowth, one third had ingrown bone in less than 2% of the available surface area, and in one third there was ingrown bone in 2 - 10% of the available surface area. Engh and colleagues (1987) observed bone ingrowth in as much as 82% of femoral stems; they did not specify the extent of ingrowth. Jacobs and colleagues (1989) even found some degree of bone ingrowth in all of the 14 retrieved femoral components, the average extent of bone ingrowth reaching 45% of the available area. Bauer and group (1991) reported five retrieved proximally hydroxyapatite-coated stems with bone apposition of 32 - 78%. In stems with extensive porous coating most bone ingrowth is observed in the distal region, where the best contact is achieved between the implant and solid bone (Engh et al 1987, Haddad et al 1987). It has been surmised that a combination of limited ingrowth of bone and extensive ingrowth of fibrous tissue could be adequate for fixation (Haddad et al 1987).

Anatomy of the proximal femoral medullary canal

Research methods

The shape and size of the femoral medullary canal became a topic and interest, when the cementless endoprosthetic femoral stems were designed, but not until the studies by groups under Dai (1985) and Noble (1988) were any papers published dealing thoroughly and in detail with the subject. Noble and associates (1988) analysed 200 cadaver femora by standardised radiographs in perpendicular planes. Dai´s group had already performed computed tomography (CT) on 30 femora to examine the medullary canal in 1985. Woolson and group (1986) had described a difference of 1.6 – 3.0 mm between the CT-based measurement and actual femoral intramedullary dimensions. Later Rubin and associates (1992) established the superior accuracy of CT combined with image-processing methods compared with standard radiographs in studying the dimensions of the medullary canal. The mean difference was 0.8 ± 0.7 mm with CT and 2.4 ± 1.4 mm with standard radiographs. The main cause for this was the deficient information in standard radiographs in two perpendicular views compared to the information of series yielded by CT-slices across the femur. In addition to this, there are notable technical error sources in radiographs: inadequate control and determination of magnification (Knight and Atwater 1992) and the effect of different femoral rotation on measurement of the dimensions of the proximal metaphyseal canal (Eckrich et al 1994). Iguchi and colleagues (1996), on the other hand, presented a protocol in which they successfully predicted the shape and size of the proximal femoral canal from standard radiographs (less than 1 mm average difference from actual dimensions) with the aid of the average cross-sectional contours of the medullary canal from groups of cut and of CT sliced femora previously studied by Walker and Robertson (1988).

Three-dimensional anatomic reconstructions based on either actual cadaveric or CT scan cross-sections came into use as the basis for femoral component designing (Walker and Robertson 1988, Robertson et al 1988). Several series involving systems for individual optimal-fit component designing, *i.e.* custom-made stems, were published (Robertson et al 1987, Rhodes et al 1987, Bargar 1989, Stulberg et al 1989, Reuben et al 1992, Bougault et al 1993, Brien 1993, Essinger 1993, Hua and Walker 1993). Only few of these papers presented the accuracy of the system used (Robertson et al 1987, Bargar et al 1989, Hua and Walker 1993). Also only some described the actual image processing system in detail (Robertson et al 1987, Rhodes et al 1987) or referred to it appropriately (Reuben et al 1992). In a study of Rubin and colleagues (1992), which demonstrated CT to be superior to radiographs in evaluating endosteal dimensions, the authors actually compared the values from CT scanning to those obtained from the actual bone sections, which they photographed and processed by the same edge detection program as used on CT data. Also in this study the accuracy of the edge detection program was neither studied nor presented.

There is no general solution for digital image segmentation problems: the proposed methods are *ad hoc* solutions for particular problems (Kasturi and Jain 1991). CT images are gray scale images and both region- and edge-based segmentation methods can be used. Theoretically, the results of both methods will be equal. The simplest region-based method, thresholding, is widely used in image processing and there have been a number of proposals for calculating suitable threshold values for an image (Pun 1980, Sahoo et al 1988, Pal and Pal 1993). The idea underlying most edge detection techniques is the computation of a local first- or second-order derivative operator (Pratt 1991). After using the edge operators the filtered image is thresholded by a suitable value to determine the presence of an edge. With noise images, threshold selection becomes a trade-off between the missing of valid edges (gaps) and the creation of noise-induced false edges, and some post-processing is needed.

In several studies defining the femoral canal the border has been detected by a constant threshold value (Garg et al 1985, Alho et al 1989, Sumner et al 1989, Iguchi et al 1996, Aamodt et al 1999). The average density of cancellous bone in the metaphysis was 180/145 Hounsfield units (HU) (males/females), of cortical bone in the metaphysis 870/850 HU and of diaphyseal cortex 1661/1610 HU in the sample studied by Alho and associates (1989). The threshold value corresponding to the canal border has most often been selected as 500-600 HU (Alho et al 1989, Sumner et al 1989, Iguchi et al 1996, Aamodt et al 1999). Garg and group (1985) chose 275 HU as the border value of the femoral canal in their CT setting; this was based on their assumption that this would represent the femoral canal with 1 mm rim of cancellous bone. Aamodt and colleagues (1999) based their system of custom-made femoral stems on a constant threshold, 600 HU, which they found to be closest to the contour of the medullary canal after rasping of trabecular bone. Rasping was performed in order to determine the stabilising corticocancellous interface in the metaphyseal transitional zone from thin trabeculae to increasing density towards the cortical bone. Use of a constant threshold value may be questionable by reason of marked differences between CT equipments and imaging settings and of the variety of patient material and bone properties; at least a proper threshold value should be determined separately for each scanner and in certain conditions (Sumner et al 1989, Mankovich et al 1991).

Robertson and Huang (1986) demonstrated, how the accuracy of normal CT on femora was limited by spectral shift (beam hardening) artifacts: in the medullary canal CT values were significantly increased and external and internal bone edges thickened, resulting in cortical areas too large and medullary canal areas too small. They found that a second-order correction algorithm significantly improved the accuracy of the CT sizing methods for the medullary canal. Subsequently Mankovich, Robertson and Essinger (1991) appropriately presented an edge-detection method based on sampling of radial lines and spline interpolation. Dujardin and colleagues (1996) also studied grey level profiles of radial lines; the inner cortical point was selected separately for each radius, based on the ratio between the densities of cortical and cancellous bone. In a study concentrating on quantitative CT and bone mineral density (BMD) (Prevrhal et al 1999) radial profile was also used, from which threshold values were calculated by different methods to determine cortical thicknesses. The authors found accuracy to be strongly dependent on the properties of the CT scanner.

Descriptions of endosteal anatomy

Noble and associates (1988) convincingly demonstrated that there is no universal shape of the femoral canal and described substantial variability in femoral canal anatomy and poor predictability of dimensions characterising the endosteal surface. Typical correlation coefficients observed between endosteal dimensions ranged from 0.20 to 0.66. They had chosen the geometric center of the lesser trochanter as the reference point in vertical axis. The most predictable endosteal dimension was found to be the mediolateral (ML) width of the femoral canal at a level of 20 mm below the lesser trochanter mid-point (average 20.9 mm, S.D. 3.5 mm, range 11.0 – 29.5 mm). The overall correlations of this level with other levels were also the best (Noble et al 1988), as also previously observed by Dai and colleagues (1985). In the above-mentioned series studied by Noble´s group (1988) the average canal width at the level of neck osteotomy, 20 mm above the lesser trochanter mid-point, was 45.5 mm, S.D. 5.3 mm, range 31.0 – 60.0 mm.

In the same paper Noble and coworkers (1988) described femoral canal opening from isthmus to neck osteotomy level in the frontal plane by canal flare index (CFI). It was defined as the ratio of the mediolateral canal width at a level of 20 mm above the lesser trochanter mid-point and the canal isthmus. CFI ranged from 2.4 to 7.0 with an average of 3.8 (S.D. 0.74). The femora were divided according to their shape as stovepipe canals (CFI less than 3.0), normal canals (CFI 3.0 – 4.7) and canals with champagne-fluted appearance (CFI more than 4.7). In the material in question there were 9% stovepipe, 83% normal and 8% champagne-fluted canals.

CFI has since been used in all the series in which the morphology of the femoral canal has been studied. Massin and associates (2000) analysed 200 femora from pelvic radiographs of patients who had previously undergone hip arthroplasty of the contralateral hip. CFIs were much similar to those of Noble´s group (1988): ranging 2.1 – 7.5, average 3.6 (S.D. 0.8), and femora were distributed into stovepipe (16.5%), normal (72%) and champagne-fluted (11.5%) in the same way except for a slightly reduced number of normal type (Massin et al 2000). In contrast CFI were markedly smaller when 32 cadaver femora (average donor age 82 years) were studied by Rubin and colleagues (1992) using CT: CFI ranged from 2.37 to only 5.35, with an average of 3.36 (S.D. 0.75). Husmann and associates (1997) on the other hand presented higher CFI values than Noble and associates (1988). They examined 310 femora of candidates for hip arthroplasty by both standard radiographs and CT scanning. When CFI were measured from radiographs, the range was 2.3 – 7.2 and the average 3.81 (S.D. 0.83). When measurements were obtained from CT slices, CFI increased: range 2.3 – 8.3, average 4.32 (S.D. 1.05), and the percentage of champagne-fluted canals was over 20% (Husmann et al 1997). The main reason for these differences is probably technical, *i.e.* the limitations of standard radiographs (Husmann et al 1997). In addition, true variation in endosteal anatomy most probably exists between population groups.

Walker and Robertson (1988) modelled an average femur based on a three-dimensional analysis of sections of 26 cadaveric femora. They reported considerable variation in the shape and orientation of the femoral canal at neck osteotomy level. Equally, the correlation of the mediolateral (ML) and anteroposterior (AP) diameters of the canal of the metaphysis at the level of femoral neck osteotomy was only 0.40, indicating wide metaphyseal variability in the series studied by Noble and associates (1988). Walker and Robertson (1988) also reported that there is often a prominent calcar trabeculation in cross-sections at neck osteotomy level. Dai and colleagues (1985) had previously pointed out that the effective canal area is smaller than the actual canal size because of this calcar septum dividing the canal. The mechanical properties, stiffness and strength, of cancellous bone in the proximal femur correspond to the trabeculation system (Brown and Ferguson 1980). The bone strength is markedly elevated to the primary trabeculae especially under longitudinal load, but is notably reduced if loaded transversely (Brown and Ferguson 1980). Evaluation of cancellous bone strength from radiographs is, however, of limited predictive value (Rosson et al 1996).

Recent studies have focused on the variation in the femoral metaphysis and geometric parameters for characterising the shape of the metaphyseal canal have been determined (Robertson et al 1996, Husmann et al 1997, Massin et al 2000). Husmann and group (1997) calculated separately medial, lateral, anterior and posterior flare indices from the proportions of the vector lengths in CT slices 20 mm above and 40 mm below the lesser trochanter mid-point (310 femora). Considerable variation was observed: the medial flare indices ranged from 1.3 to 6.5 (average 3.65) and the anterior flare indices from 0.8 to 5.6 (average 2.24); the indices correlated rather poorly with each other and the femora were widely distributed into nine different femoral morphologies. Massin and colleagues (2000) selected a metaphyseal index which was calculated as a proportion between the mediolateral canal width at the level of 20 mm above and at the lesser trochanter mid-point (200 femora). This index, depicting only the canal shape of the uppermost 20 mm below the neck osteotomy, was found to range between 1.3 and 2.2. In this range, though it was smaller than that found by Husmann´s group (1997), the authors were able to identify numerous metaphyseal somatypes for femoral stem designing. Robertson and associates (1996) defined the medial cortex angle between the femoral shaft axis and the line passing the center of the femoral head and tangent to the medial inner cortex curvature. Thus the medial cortex angle is a parameter describing the metaphyseal canal opening and is not the same as the femoral neck-shaft angle. The material of the study in question consisted of patients with different classes of developmental hip dysplasia (24 hips); the medial cortex angle ranged from 151° to 167°.

The average cross-sectional shape of the femoral canal in metaphysis and diaphysis has been determined (Walker and Robertson 1988, Iguchi et al 1996), but it has not been considered necessary to describe its variation by any parameters, for instance using the ratio between ML and AP diameters of a level. Instead, the orientation of the canal has been a topic of interest (Robertson et al 1996, Husmann et al 1997). Husmann and colleagues (1997) distinguished extramedullary neck anteversion from intramedullary helitorsion at the level of the neck base in relation to the posterior bicondylar plane of the distal femur, because there was a difference of over 10° for a quarter of the femora studied, even if the average values were very similar (anteversion 24.7° ± 8.7° and helitorsion 24.0° ± 11.8°) and they correlated fairly closely (r = 0.66). Instead of helitorsion, Robertson´s group (1996) determined section angle, *i.e.* the deviation angle of the section´s long axis (fitting ellipse) from the femoral neck axis. They found in dysplastic femora that torsional deformity extended from the neck distally to the inferior portion of the lesser trochanter.

With aging the femur expands and the diameter of the medullary canal increases affecting canal shape (Smith and Walker 1964, Ruff and Hayes 1982). This natural phenomenon seems to continue with similar rate also after hip arthroplasty (Poss et al 1987, Comadoll et al 1988, Robinson et al 1994).

Fit and fill of cementless endoprosthetic femoral stems

The fit of the endoprosthetic stem in the femoral canal is determined as a proportion of stem surface in contact with endosteal cortical bone to the whole stem surface in the region studied. The fill of the endoprosthetic stem in the femoral canal is determined as the ratio of the volume of the stem to the volume of the canal in the region studied. From radiographs the canal fill is usually estimated from the ratio between the widths of the stem and the canal at a certain level. From a cross cut or a CT slice the sectional areas of the stem and the canal are used for calculating canal fill. The fit and fill can be determined for the whole stem, or separately for the metaphyseal and diaphyseal femoral regions, or divided into fourteen Gruen zones (Gruen et al 1973, Johnston et al 1990, Tonino et al 1995).

The postoperative fit and fill of cementless femoral stems has been evaluated from radiographs in a number of studies (Engh et al 1987, Kim and Kim 1993, Kärrholm and Snorrason 1993, Martell et al 1993, Mulliken et al 1996). Engh and associates (1987) assessed the fit on the isthmus region only, classifying cases into those without and those with contact to both endosteal cortices in AP radiographs. Kärrholm and Snorrason (1993) used both AP and ML views and measured contact between lesser trochanter and isthmus. Kim and Kim (1993) and groups under Martell (1993) and Mulliken (1996) used both views, but assessed several levels. Mulliken´s group (1993) evaluated separately the metaphyseal fit and diaphyseal fill.

Hayes and collegues (1991) demonstrated significant errors in radiological fit and fill estimations compared to cut cross-section and concluded that for research purposes the fit and fill data should be collected using cross-sections whenever possible. Robertson and collegues (1988) inserted different designs (straight, anatomic and custom-made) of plastic stems into plastic bone replicas, which were then cross-cut. The fit was defined as a distance of 1 mm or less between implant and inner cortex. The fill was determined from the areas of the implant and canal. The best fit and fill was obtained with custom-made stems, and the anatomic stems were better than straight ones.

Computed tomography performed on patients to assess the fit and fill of femoral stems has not been used routinely or even with large series of patients. When CT is performed through a femur carrying a metallic implant, the resultant artifact seriously lowers the accuracy of the data (Grelsamer et al 1993, Robertson and Taylor 1993). However, recent metal artifact reduction techniques in CT will obviously provide proper accuracy at least with titanium implants (Robertson and Taylor 1993, Feng et al 1996, Sutherland and Gayou 1996, Viceconti et al 1999).

Importance of fit and fill for micromotion

Two types of motion of the femoral endoprosthetic stem in femoral canal have been characterised: 1) a dynamic movement in response to one loading cycle, *i.e.* micromotion, and 2) irreversible displacement in the canal over time, *i.e.* migration or subsidence; these motions occur in three-dimensional manner (Schneider et al 1989, Buhler et al 1997).

Simple experiments with cadaver femora have demonstrated increased micromotion and subsidence of stems if the canal was prepared to provide a loose distal fit, and it was held that tight distal fit is essential (Noble et al 1988, Whiteside and Easley 1989, Sugiyama et al 1992). Whiteside and associates (1988) and Whiteside and Easley (1989) studied the effects of distal stem fit and use of a collared stem. The conclusion was that tight distal fit minimises micromotion, whereas subsidence is advantageously prevented by a collar.

The main load to on the hip is applied from an anterosuperior direction and force increases substantially during stair-climbing (Davy et al 1988). This causes a tendency for the femoral stem to rotate retroversion (Schneider et al 1989, Nunn et al 1989, Burke et al 1991, Buhler et al 1997). Cementless stems have seemed to be more susceptible to this torsional micromotion than cemented ones (Burke et al 1991).

The importance of metaphyseal fill in cementless stems to reduce torsional micromotion has been widely emphasised in strain-gauge studies on cadaver femora (Callaghan et al 1992, Ohl et al 1993, Hua and Walker 1994, Dujardin et al 1996). Proximal-filling anatomic stems have proved markedly more stable (average 26 ± 7 μm) under substantial torsional loads than straight stems (average 77 ± 58 μm), whose stability improves if cement is applied proximally (average 25 ± 27 μm) (Callaghan et al 1992). Hua and Walker (1994) compared symmetrical, asymmetrical and custom asymmetrical cementless stems. Axial subsidence was very similar in all three designs, but in torsional loading the symmetrical stem evinced some times more rotational motion than designs with greater metaphyseal fill. The custom asymmetrical design was, however, no better than standard asymmetrical one. Dujardin and colleagues (1996) compared an anatomic, custom-made and modified custom-made stem (distal part thinned out and tapered). The custom-made stem designs achieved initial stabilisation with fewer loading cycles and with less migration than the anatomic stem. The average torsional micromotion of the custom-made stems was significantly smaller than that of the anatomic stem. Thinning of the distal part of the custom stems did not significantly increase rotational motion, but instead anteroposterior and mediolateral pivoting were slightly increased in the metaphysis and clearly in the diaphysis. In all groups the average micromotions were however very small in metaphysis (8μm – 26 μm). In the metaphyseal region, the fill of stems was strongly correlated ($r = 0.89$) to rotational and also ($r = 0.87$) to vertical motion.

In a study in which the distal fit was set as the only variable, the best rotational stability was achieved in the group with tight distal fit made by underreaming (Sugiyama et al 1992). When both the metaphyseal and diaphyseal fit and fill have been properly evaluated, it has been obvious that avoidance of torsional micromotion is primarily dependent on the metaphyseal fit and fill and is only secondarily contributed to by the distal fit and fill (Ohl et al 1993, Whiteside et al 1994, Kendrick et al 1995). Torsional stability, which is provided by the tight distal fit, is markedly affected by the design of the distal part of the stem; the deeply fluted was superior to the porous-coated, to the finned and the slotted and narrowly fluted designs (Kendrick et al 1995).

In clinical series minute migration has been studied by roentgen stereophotogrammetric analysis. Immediate postoperative fit and fill parameters of non-porous macrolocking stems did not correlate with migration, which was mostly directed distally, in valgus and retroversion (Kärrholm and Snorrason 1993). Kärrholm and associates (1994) in a similar set-up compared different stem designs and also measured the fit and fill of the stems; they report no correlations between fit and fill and migration. Freeman and Plante-Bordeneuve (1994) and Kobayashi with coworkers (1997) observed from standard radiographs that early vertical migration of 2 mm or more of a femoral stem has a strong predictive value for late aseptic loosening. In those studies the effect of fit and fill of the stems was not assessed.

Effect of fit and fill on stress transfer and bone remodeling

If the load on the metaphyseal femur after hip arthroplasty is reduced, bone loss result: load values 20% to 100% of normal have generally been reported depending on measuring methods, design properties of endoprosthetic stems as well as fit and fill of stems (Oh and Harris 1978, Walker et al 1987, Jasty et al 1988, Walker and Robertson 1988, Hua and Walker 1995). Consequently, stress by-passing to the diaphysis causes considerably increased loads in the region of the stem tip (Walker et al 1987). This metaphyseal stress-shielding is greater in cemented than in cementless stems (Oh and Harris 1978, Walker et al 1987, Jasty et al 1994, Hua and Walker 1995). A collared design of the femoral stem (whether cemented or cementless) can minimise the phenomenon especially with loose distal fit (Indong et al 1978, Jasty et al 1988, Walker and Robertson 1988, Jasty et al 1994). However, if the diaphyseal fit is tight (underreamed canal of 0.5 mm), marked reduction in metaphyseal load occurs in spite of a collar (Jasty et al 1988). Tight distal fit and fill of the femoral stem indubitably entails disadvantageous load transmission (Jasty et al 1988, Walker and Robertson 1988, Jasty et al 1994), even though Jasty and collegues (1994) distinguished precise fit from tight press fit and from loose fit and concluded that precise fit results in the most normal strain pattern.

Hua and Walker (1995) compared custom-made, asymmetric and symmetric cementless stem designs. They observed that on the medial metaphysis the strains were closer to normal with symmetric than asymmetric (anatomic) stems, which distributed much of the load onto the anterior metaphysis and whose distribution also varied more. Evidently the asymmetric design could not match the range of metaphyseal geometries, whereas the load distribution of custom stems was more balanced and strain patterns were closest to normal.

The effects of different design properties of cementless stems on stress transfer have also been investigated by 3-dimensional computer simulations, finite element analyses, which seems to be of great value in predicting in vivo bone remodeling (Skinner et al 1994). In these models the observations and results have been in accord with stress transfer studies with cadaver femora. The more distally the porous coating extends and the more rigid the stem, the more stress by-passes the metaphyseal region (Huiskes 1990, Keaveny and Bartel 1993, Weinans et al 1994, Huiskes and van Rietbergen 1995). The axial load on the metaphysis could be preserved close to normal if the femoral stem has a collar with precise seating on the femoral neck, but the load is substantially reduced with loss of exact collar fit (Keaveny and Bartel 1993). In the model designed by van Rietbergen and group (1993) the wedging effect of a tapered implant initially generated high loads proximally, but gradually after elastic subsidence the loads were shifted distally, especially if the stem was not a perfect fit. Weinans and colleagues (1994) have demonstrated by finite element analysis how the metaphyseal load reduction could be avoided by distal overreaming of the femoral canal.

Remodeling of the proximal femur can be qualified radiologically as resorption (loss of cortical bone density or thickness) and hypertrophy (thickening of cortex) (Engh et al 1987, Engh et al 1990, Johnston et al 1990, Mulliken et al 1996, Vresilovic et al 1994). Despite the fact that these remodelings have been recorded in several series with different stem designs, remodeling changes have rarely been analysed in relation to the metaphyseal and diaphyseal parameters of the fit and fill of individual stems. In series of extensively porous-coated femoral stems with at least two-year follow-up, resorption of proximal bone, stress-shielding, was observed almost twice as often in cases with exact press fit of the distal stem compared with those without distal press fit (Engh et al 1987, Engh and Bobyn 1988). A similar observation has been made with proximally coated stems (Martell et al 1993). Whiteside (1989) studied the performance of a stem design with collar, whose bottom side and only the uppermost 1 cm of the stem surface was porous-coated. Exact seating of collar brought about metaphyseal cancellous hypertrophy, even if there was tight distal fit. In contrast, poor fit of collar was associated with calcar resorption under circumstances where tight distal fit often caused distal cortical hypertrophy. In series with proximally porous-coated femoral stems distal cortical hypertrophy has been observed most often in Gruen zones III and V in 25 - 35% of cases (Kim and Kim 1992, Martell et al 1993, Hozack et al 1996, Mauerhan et al 1997, Knight et al 1998). Groups under Martell (1993) and Knight (1998) found no correlation between the distal canal fit and fill and cortical hypertrophy. In contrast, Martell and associates (1993) were able to demonstrate a significant contribution of greater metaphyseal fill in preserving metaphyseal bone-stock.

To quantify bone remodeling around the femoral stem dual-energy X-ray absorptiometry (DEXA) is currently in use (Kröger et al 1998). Majority of the postoperative decrease in bone mineral density (BMD) occurs within the first 6 to 9 months (Rosenthall et al 1999 I), although minor progression can continue up to five to seven years after surgery (Kilgus et al 1993). The effect of the fit and fill of individual stems on bone remodeling has not been studied by DEXA. However, regional decreases in BMD apparently depend on femoral stem design; shape and extent of porous coating.

The greatest BMD decrease is usually found in the calcar region, Gruen zone 7. Retrospective studies with long and extensively porous-coated stems have revealed BMD loss averaging 35 – 45% in the proximomedial cortex (Engh et al 1992, Kilgus et al 1993). The BMD loss when proximally porous-coated stems, whether straight or anatomic, have been used has ranged 15 – 35% in the calcar region (Kiratli et al 1992, Hughes et al 1995, Kröger et al 1997, Rosenthall et al 1999 II). Using supermodular stems to match metaphyseal anatomy has attained a mean BMD decrease of 20% in Gruen zone 7; however no advantage over a standard proximally porous-coated stem was found (Rosenthall et al 1999 II). The respective BMD loss was only 12% with custom-made stems (Wixson et al 1997, Zerahn et al 1998), and even some increase in the BMD of the calcar has been reported with stemless femoral implants (Munting et al 1997).

Remodeling of the femur after hip arthroplasty is also affected by other stem-related factors than shape. Evidently, a hydroxyapatite surface on the proximal porous coating has a positive influence on BMD around the stem (Rosenthall et al 1999 II). Greater stiffness of the femoral stem disposes to bone loss: stems of larger diameter reduce BMD more than narrow ones (Engh et al 1993), cobalt-chrome more than titanium stems (Hughes et al 1995) and titanium more than isoelastic stems (Ang et al 1997).

Influence of fit and fill on clinical results

Inadequate canal filling has been considered to be the main cause of femoral stem failures, loosening and subsidence, both with extensively porous-coated (Engh et al 1990 I, Engh Jr et al 1997) and proximally porous-coated devices (Kim and Kim 1993, Martell et al 1993, Owen et al 1994, Malchau et al 1997). Engh and associates (1987) and Whiteside (1989) reported, that tight distal fit is associated with more complete pain relief in cementless hip arthroplasty, because in their series thigh pain was related to loose distal fit. Kim and Kim (1993) measured the initial fit and fill of proximally porous-coated stems from AP and lateral views at three levels; undersized components were related to thigh pain. Contrary to these findings, Campell and colleagues (1992) concluded that thigh pain would be a consequence rather of distal stress transfer in the absence of stable proximal fixation. Accordingly, with another proximally porous-coated stem design Kim and Kim (1992) have reported thigh pain in even 50% of patients; the metaphyseal fill of the stems was estimated to be poor.

The relation of fit and fill and clinical results was analysed in detail in a paper by Martell and associates (1993) dealing with a proximally porous-coated stem design. Aseptic loosening was related to lower fill in both the metaphyseal and the diaphyseal region, stem subsidence was inhibited by tight metaphyseal fill but more efficiently by diaphyseal fill, and a better clinical result was associated with better diaphyseal fill. A small series with a short follow-up showed that the relation between the fit and fill and clinical results is possibly not so clear with extensively porous-coated as with proximally porous-coated stems (Haddad et al 1990). Kim and Kim (1994) concluded likewise that results with extensively porous-coated stems were satisfactory if the stem had good fit either in the metaphyseal or the diaphyseal canal.

Despite the above, there are numerous publications on cementless femoral stems which do not deal with stem fit and fill in the canal at all; presumably no associations with clinical results have been found in studies with good or excellent overall results. Groups under Mauerhan (1997) and Knight (1998) found no relationship between fit and fill and clinical performance in their detailed analyses.

Results of cementless femoral stem designs

Extensively porous-coated stems

The Lord Madreporic femoral stem was a fully porous-coated long stem made of cobalt-chrome. The stem was seated tightly in the diaphyseal canal (Lord et al 1979). In a seven-year follow-up no loosening was observed (Lord and Bancel 1983). In a prospective study the Lord stem had a 98% clinical survival rate after ten years (Malchau et al 1996). These authors were concerned at the marked metaphyseal bone loss, especially in relation to future revisions. Lord and Bancel (1983) reported 3 cases of stem fatigue fractures, not encountered by Malchau´s group (1996).

The Anatomic Medullary Locking stem was designed and introduced under Engh (Engh et al 1990). It is also made of cobalt-chrome and sintered porosity extends over 80% of the stem surface. Despite its name “anatomic”, it is straight in the anteroposterior plane. This stem has also been manufactured with a smaller amount of porous coating, but Engh abandoned these designs in consequence of an increased incidence of thigh pain (Engh et al 1990). Long-term results with this design have been excellent, the ten-year stem survival being 97% (Sotereanos et al 1995, Engh Jr et al 1997). In keeping Kim and Kim (1994) reported that revision was performed on 1/50 stems (2%) during more than 7 years´ follow-up. The incidence of proximal bone resorption in radiological evaluation has varied considerably: from 18% to more than 50% (Engh et al 1987, Engh and Bobyn 1988, Engh et al 1990, McAuley et al 1998). The clinical insignificance of this phenomenon has been forcefully propounded (McAuley et al 1998). Some cases with stem breakage have been reported (Engh et al 1990, Sotereanos et al 1995).

Isoelastic stems

Stress transfer from femoral endoprosthetic stem to surrounding bone undoubtedly depends on the elasticity modulus of the stem (Bobyn et al 1990, Maistrelli et al 1991, Huiskes et al 1992). The concept of the isoelastic femoral stem was applied in several designs in about 1980 (Morscher and Dick 1983, Tullos et al 1984, Andrew et al 1986, Butel and Robb 1988). Preliminary results were reported to be encouraging (Andrew et al 1986), but predominantly the outcome has been disappointing: 33% failures in three years (Tullos et al 1984), 43% failures in four years (Jacobsson et al 1993) and 10% revisions after a 7-year follow-up, and only 44% of those not revised were graded excellent or good in clinical scoring (Niinimäki et al 1994).

Proximally porous-coated stems

The second-generation cementless femoral stems were designed with shorter stems, porous coating limited to the proximal part in order to achieve metaphyseal dominance in fixation and load transmission. Stem shape was either straight with more or less tapering, or anatomic with more or less increased stem volume and curve in the anteroposterior plane. The second-generation stems started to be implanted in large numbers at the beginning of the 1980s. Several short- and mid-term clinical series were published first and currently ten-year follow-up studies have also become available.

The Harris-Galante femoral stem is a straight titanium alloy stem with proximal porous titanium fibre mesh. Martell and colleagues (1993) presented a series with 97% 5-year stem survival, but other studies reported much inferior short-term results: 10% loosening in 5 years (Kim and Kim 1992), only 64% excellent or good in clinical scoring (de Nies and Fidler 1996), about 20% cortical osteolysis (Woolson and Maloney 1992, de Nies and Fidler 1996), and about 50% mid-thigh pain (Kim and Kim 1992, de Nies and Fidler

1996). In accord with these reports Harris-Galante stems have comprised only 81% (Clohisy and Harris 1999) and 86% (Thanner et al 1999) of 10-year survival rate.

The Tri-Lock femoral stem is a cobalt-chrome stem of flat wedge shape and porous coating of 60% proximally. In 5 to 8 years´ follow-up revision has been performed for one out of 57 patients and 70% of them were rated excellent or good in Harris hip score (Pellegrini et al 1992). Good results with the Tri-Lock stem have been reproduceable: no aseptic loosening of 60 stems in ten years (7 were revised because of acetabular failure) (Sakalkale et al 1999), and 10-year survival 95% (Burt et al 1998); in both studies the clinical ratings were also good and the prevalence of thigh pain low.

A family of straight and tapered titanium alloy stems with proximal porous coating of 30-50% have yielded excellent short- or mid-term results: Taperlock 0/105 revisions for aseptic loosening in 5 years, Mallory-Head 0/71 revisions in 4 years, Bi-Metric 1/50 revision in a minimum of 2 years, and Integral 0/170 revisions in 5-8 years (Hozack et al 1996, Mulliken et al 1996, Robertsen et al 1996, Mauerhan et al 1997), despite the problematic wear of the acetabular components with which these stems have been used (Hozack et al 1996, Puolakka et al 2000). The proportion of excellent and good ratings in Harris hip score was 94% for Integral (Mauerhan et al 1997) and 96% for Bi-Metric stems (Robertsen et al 1996).

The PCA is the most widely documented cementless femoral stem with anatomic design. It is made of cobalt-chrome and has proximal porous coating. Results of a consecutive series have been reported after two years (Callaghan et al 1988), after 5-7 years (Heekin et al 1993), and after a minimum of ten years (Xenos et al 1999). After two years 94% of cases had excellent or good rating in Harris hip score; thigh pain, however, was reported in 18% of cases, and there were radiographic signs causing concern, for example loosening of the beads (Callaghan et al 1988). After 5-7 years the clinical ratings were alike, and there was 5% femoral subsidence (Heekin et al 1993). After ten years the clinical rating had deteriorated (average Harris score from 92 to 84) and femoral osteolysis was observed in as many as 39% of cases, despite the fact that only 5% revisions for femoral components had been performed (Xenos et al 1999). In a Scandinavian multicenter study the results of 539 cases were documented (Malchau et al 1997): 7-year survival of the stems was 95.8%, the clinical rating was good and did not decrease after 5 years. However, the incidence of stem subsidence of more than 5 mm and the presence of femoral osteolysis was marked: if these were defined as the end point of stem survival after 7 years, it decreased to 61%. Young age and poor stem fill influenced stem failure, as well as factors related to acetabular wear. In a consecutive series of a minimum of six years´ follow-up 6% were revised or planned to revise, 25% had thigh pain, and osteolysis was observed in 33% of cases (Kim and Kim 1993). Likewise, Owen and associates (1994) reported a high incidence of wear and osteolysis and in consequence the disappointing results. Xenos and colleagues (1999) concluded, that femoral fixation can work properly, but more extensive porous coating could be beneficial to resist adverse effects of wear particles. Knight and colleagues (1998) had used a modified PCA femoral component with increased proximal volume and increased length; only 1/70 stem was revised, osteolysis was observed for some reason only in 2.8%, but thigh pain was present in 30% of the cases. Campell and associates (1992) concluded that the common thigh pain in PCA hips is caused by stem instability with distal stress transfer in the absence of stable metaphyseal fixation.

A proximally porous coated titanium alloy stem called Anatomic has also been designed to match the metaphyseal part of the femur (Ragab et al 1999). After a minimum follow-up of six years, 1/100 stems was revised because of loosening and there was thigh pain in 5/100 patients; femoral osteolysis was not detected. The two-year results of an other anatomic design, LSF, of cobalt-chrome with slightly longer porous coating were better than the AML or the PCA in a comparative study (Haddad et al 1990), but in a minimum follow-up of five years acetabular osteolytic changes were revealed and also on the femoral side there was 33% proximal osteolysis (Sharkey et al 1998).

Custom-made and supermodular stems

At the end of the 1980s several systems were introduced for custom-made femoral stem designing and manufacturing (Bargar 1989, Mulier et al 1989, Stulberg et al 1989, Reuben et al 1992). The purpose in these systems was to achieve better fit and fill of the stem in the femoral canal than with conventional cementless stems. In these early reports rather the rationales than the results were presented and the possibilities of these designs were discussed. Bargar (1989) mentioned that better pain scores were achieved with custom stems than conventional stems. The incidence of peroperative femoral fractures was quite high, 7-8% (Bargar 1989, Reuben et al 1992). Appropriate follow-up studies of custom-made stems with good results have not been published. On the other hand two series with inferior results have been presented: 28% failures before four years (Lombardi et al 1995) and an 80% survival rate at 43 months (Robinson and Clark 1996).

Another means of overcoming the metaphyseal-diaphyseal size mismatch has been the supermodular stems, in which the metaphyseal and the diaphyseal stem parts can be varied independently (Cameron 1994, Capello et al 1994, Chandler et al 1995). The S-ROM stem system consists of circular, distally split and fluted stems of varying sizes, and of metaphyseal sleeves with varying sizes and shapes. These titanium alloy parts are attached by a Morse taper. The S-ROM has had obvious benefits in revision hip surgery (Cameron 1994, Chandler et al 1995), but results in primary arthroplasties have not been published. The diaphyseal fit of the Omniflex titanium alloy stem is optimised by a cobalt-chrome modular tip, and a modular collar is also available (Capello et al 1994). Altogether 7% of Omniflex stems had been revised in a consecutive follow-up of 2-5 years (Capello et al 1994). There were as many as 7% major intraoperative fractures and in addition 10% minor ones.

Hydroxyapatite-coated and other third-generation stems

Furlong and Osborn (1991) began clinical trials with hydroxyapatite-coated femoral stems in 1985 and Geesink in 1986 (Geesink and Hoefnagels 1995). In the latter 1990s several well documented series of HA-coated stems were published.

The JRI-Furlong stem is straight, collared and fully HA-coated (Furlong and Osborn 1991). McNally and associates (2000) had followed 100 consecutive JRI Furlong stems for 9-12 years. One stem was revised because of infection; stem survival at 10 years was 99%. The average clinical ratings were good and anterior thigh pain was not recorded.

The Omnifit-HA stem is made of titanium and is of double wedge shape; the proximal surface has HA coating and relief of low steps (Geesink and Hoefnagels 1995). Six-year survival was 100%, and the average in Harris scoring was 98 points for the first 118

Omnifit-HA arthroplasties (Geesink and Hoefnagels 1995). In a prospective multicenter study 316 Omnifit-HA stems were followed for an average of 8 years; only one stem (0.3%) was revised because of aseptic loosening, but three more because of thigh pain and two because of infection (cumulatively 1.9% stem revisions) (Capello et al 1998). In the same study protocol there was a subgroup of 155 stems implanted for patients younger than 50 years of age; minimum follow-up was 5 years (D´Antonio et al 1997). In this high risk group two stems were revised for hip pain of undetermined origin and one for deep infection; the authors determined 1.9% as failure rate of the stems.

The ABG titanium alloy stem is proximally HA-coated with a scaled surface, has anatomic design proximally, is relatively short and it is sought to avoid distal stress transfer by overreaming of the diaphyseal canal (Tonino et al 1995). Results with the ABG stem have been assessed in a multicenter study reported by Tonino and colleagues (1995, 2000). After 5-7 years 3/398 (0.75%) stems had been exchanged (Tonino et al 2000). Clinical results were excellent and also bone remodeling changes, which often indicate successful proximal stress transfer, could be considered favourable. Also Rossi and associates (1995) and Garcia-Araujo and associates (1998) have published promising short-term results with the ABG stems.

Those series with HA-coated stems have so far yielded only excellent results. The advantage of HA coating has been established by groups under Donnelly (1997) and Kärrholm (1998) based on measurement of migration, and in these studies HA coating was also of clinical relevance. In contrast, groups of Cicotti (1994), Rothman (1996) and Yee (1999) found no significant clinical or radiological differences between stems with HA on porous coating or porous coating only.

Ultra-short femoral stems and stemless components represent innovations designed to preserve femoral bone stock maximally (Morrey 1989, Morrey et al 2000, Munting et al 1997). Morrey introduced the Mayo Conservative Hip in 1989: it is made of titanium alloy with a fibre mesh surface in the metaphyseal part, it is shaped as a double-tapered wedge, attaining multiple-point contact in the canal. A total of 159 hips with this stem were followed for 2 to 13 years; stem survival at both 5 and 10 years attained 98.2% and the average in Harris score exceeded 90 points (Morrey et al 2000). Munting and colleagues (1997) introduced a femoral implant with no medullary stem. The trunk of the component rests on the femoral neck resection surface and stability is ensured by lamellae penetrating into the metaphysis and by a transtrochanteric screw. The contact surface has HA coating. In a small series of 48 hips in patients below 50 years of age followed for 4-6 years, Munting and colleagues (1997) recorded 8 failures (17%); in all of the failed cases errors of implantation could be identified. The mean Harris score was 97.8 and the metaphyseal BMD was well preserved or in a couple of cases even increased.

AIMS OF THE STUDY

The aims of the present study were

1. to develop a image processing method for three-dimensional femoral canal shape modelling and to test the accuracy of this method appropriately (Study I)

2. to analyse the dimensions measured from the endosteal surface of the cadaver proximal femoral medullary canal in the diaphysis and in the metaphysis to determine whether it is rational to aim at perfect fit and fill in cementless femoral component fixation (Study II),

3. to evaluate anatomical basics for cementless femoral component design and for individual cementless femoral component selection (Study II)

4. to define the accuracy of postoperative radiographs in estimating the canal fill of cementless femoral stems (Study III),

5. to compare the fit and fill parameters of a straight and a proximally anatomic, HA-coated and distally over-reamed stem (Studies III, IV),

6. to compare the bone remodeling patterns induced by these two stem designs and fit and fill differences during a five-year follow-up (Study IV), and

7. to established whether the primary postoperative fit and fill of cementless stem affects mid-term clinical outcome (Study IV).

METHODS

Cadaver femora in studies I, II and III

Institutional Ethical Committee approval was obtained for the use of 50 cadaver femora. There were 21 left and 29 right femora, from 36 males and 14 females, who died at an average age of 70 years, ranged 38 to 87 years.

Computed tomography was performed on all femora (Study II). After CT ten femora were cut into slices in accuracy testing (Study I) and plastic replicas of cementless femoral stems were implanted in 20 femora (Study III).

Study I

Computed tomography of the femora

CT of the femora was performed with a Somatom CR scanner using settings of 125 kVp, 500 mAs with a matrix size of 256 x 256 and a pixel depth of 12 bits. Thus the physical size of the pixel was 0.83 mm x 0.83 mm.

Two femora were placed on plexiglass simultaneously so that their vertical axes were parallel to the table axis and the rotations neutral, the posterior surfaces of the distal femoral condyles on the table. The femora were placed so that the lesser trochanter mid-points (T) were at the same vertical level (the zero-level in vertical axis).

Thirty slices were taken from each femur, the lowest 160 mm below and the highest 60 mm above T. The interval between slices was shorter and slices thinner in the metaphyseal area. Sixteen horizontal 2-mm-thick slices at 5 mm intervals upwards from 20 mm below T (metaphysis) and fourteen 4-mm-thick slices at 10 mm intervals downwards from 20 mm below T (diaphysis) were taken.

Edge detection of femoral canal

When searching the femoral canal, a femur can be divided into three different parts depending on the structure of the cross-sectional slice. In the femoral diaphysis there is a clear border between the cortical and spongeous bone. Slices in the lesser trochanter area have posteromedially a calcar septum of nearly cortical density dividing the femoral cavity from the lesser trochanter. The uppermost part is above the lesser trochanter, where the septum is not detectable in cross-section, but the metaphyseal trabecular bone gradually transforms to cortical bone especially on the lateral side. The detectable lateral cortex normally extends 20 to 40 mm above the lesser trochanter mid-point. Different image analysis methods were used for femoral cavity detection depending on the structure of the slice under process.

The general procedure was as follows: search for the edge started from the lowest slice and passed upwards until the isthmus level was detected. The center of the isthmus level border data was subsequently used as reference point. The search was then resumed from the lowest slice upwards to the femoral neck. In principle each slice was processed separately, but the data of the identified border of the previous slice was employed with distance computation and for detection of the lesser trochanter and to check the validity of the proposed pixel.

A constant threshold value was not used because image gray-level values depend on the patient characteristics (*e.g.* thickness), on the local structure of the bone, and on the imaging parameters used (Sumner et al 1989, Mankovich et al 1991). The threshold value was thus computed for each slice separately. The original gray-level CT image was thresholded and the resulting binary image dilated. From this dilated image the thresholded image was subtracted and the result contour-tracked in order to collect the pixels of the border into a connected path.

The gray-level limits 1500 and 2000 used in the femoral shaft area were found by subjective evaluation. In slices at lesser trochanter level the image had to be processed in two or three parts (the lateral cortical bone area and the posteromedial calcar septum area and sometimes additionally the lesser trochanter area). Multiple problem areas were processed separately and linked together with the border previously found. If these methods did not identify the whole border some pixels in the problem area had to be approximated or pointed to by the mouse.

The results were saved in four output data files. In the text file the longest anteroposterior (AP), the longest mediolateral (ML) and the longest oblique diameters were saved. The second and third files were for 2D- and 3D-data, which can be used with CAD program. The last file was for center points of the slices.

Manual measurement of femoral canal and testing

Ten cadaver femora were sawn after CT into horizontal slices and used for testing. Each femur was so cut, that in the proximal area the intervals were 10 mm and in the distal area 20 mm corresponding to every other level in CT. A femur yielded ten slices for measurement. Prior to sawing medial and lateral lines were marked on the periosteal surface of each femur to ensure rotational alignment. In the vertical axis the lesser trochanter mid-point was the reference. The maximum AP and ML canal diameters of the slices were measured manually by caliper ruler. Each dimension was measured ten times and the average was calculated. Altogether 200 manually measured distances were obtained (10 femora x 10 slices x 2 directions). These were compared to the corresponding dimensions obtained from the image processing program of femoral canal.

Study II

Computed tomography was performed on 50 femora in order to study the anatomy of the femoral canal. CT and detection of the femoral canal proceeded as presented in Study I.

Variables of femoral canal

The longest *mediolateral, anteroposterior* and *oblique endosteal dimensions* of the slices were computed. The level of the slice (value given as distance below zero level) which had the narrowest ML diameter (*i.e.* the *isthmus width*) was defined as *isthmus level*. At the neck-osteotomy level (20 mm above T) the *endosteal neck anteversion* was defined as the angle between the longest oblique (*i.e*. the neck-oriented) diameter and the horizontal mediolateral diameter (**Fig. 1.**). The presence of a dense cortical-like septum in the *calcar femorale* area was studied.

Canal flare indices (CFI) were calculated as the ratio between the ML canal width at the neck-osteotomy level and the isthmus width (Noble et al 1988). *Anteroposterior CFIs* were calculated similarly from the AP dimensions. *Neck-oriented CFIs* were determined as the ratio between the longest oblique dimension at the neck osteotomy level and the isthmus width (**Fig 1**.). These figures were defined to describe the femoral canal opening from the isthmus to the neck osteotomy level.

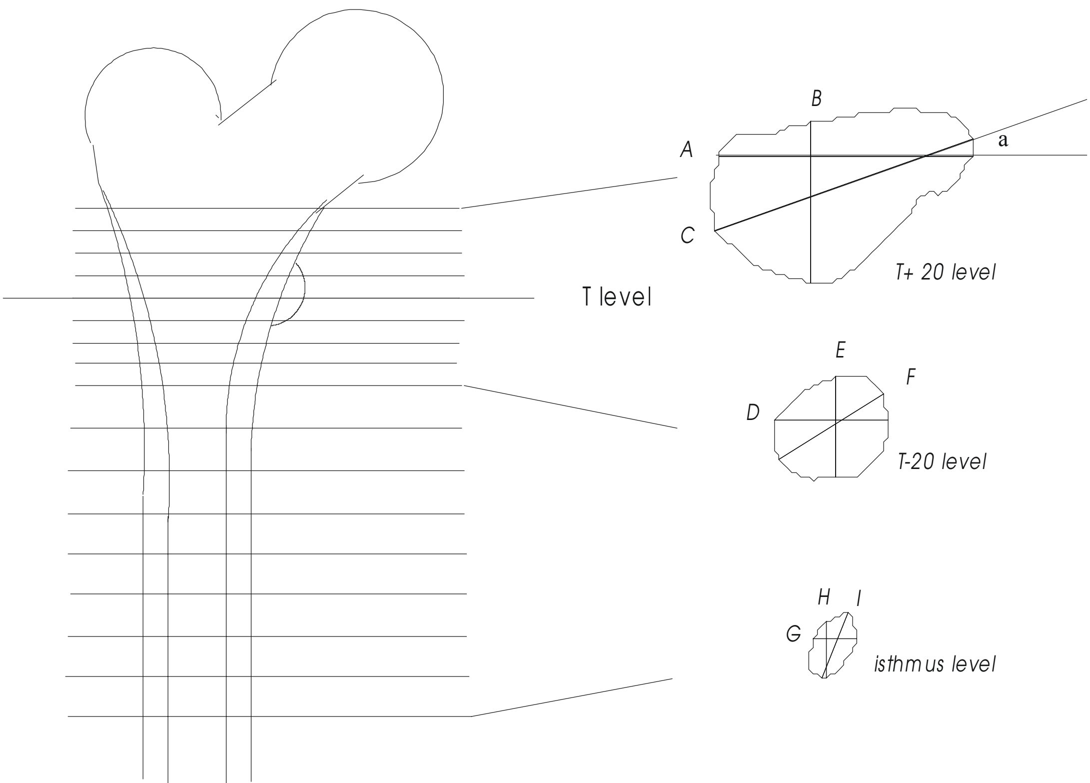
To ascertain the variability of the femoral metaphyseal opening a *metaphyseal canal flare index (MCFI)* was determined, *i.e.* the ratio between ML canal width 20 mm above and 20 mm below T. Correspondingly the *anteroposterior MCFIs* and the *neck-oriented MCFIs* were determined (**Fig. 1**.). To analyse the regularity of the shape of the metaphyseal femoral canal we calculated the bivariate correlations of the dimensions in metaphyseal slices (from 20 mm below to 20 mm above T).

In order to study the rate of opening from diaphysis to metaphysis, the *enlargement rate of the femoral cavity* was determined (*femoral cavity enlargement rate* = increase in mediolateral diameter *per* 10-mm slice interval).

Descriptive statistics, distribution graphics and Pearson linear correlations with scatter plots were used to observe the typical femoral endosteum and its variation.

Figure 1.

The longest mediolateral, anterioposterior and oblique diameters were computed for each slice. Canal flare indices (CFI) were calculated for each femur by the diameters of the isthmus-level slice and the osteotomy-level slice (20 mm above the lesser trochanter mid-point, T+20). Metaphyseal canal flare indices (MCFI) were calculated for each femur from the diameters of the slice 20 mm below (T-20) the lesser trochanter mid-point and the osteotomy-level slice (T+20). Endosteal neck anteversion angle (a) was measured from the osteotomy-level slice of each femur.



A = longest mediolateral diameter, T + 20 level B = longest anteroposterior diameter, T + 20 level C = longest oblique diameter, T + 20 level D = longest mediolateral diameter, T - 20 level E = longest anteroposterior diameter, T - 20 level F = longest oblique diameter, T - 20 level G = longest mediolateral diameter, isthmus level H = longest anteroposterior diameter, isthmus level I = longest oblique diameter, isthmus level	∠ AC = endosteal neck anteversion angle, a A / G = mediolateral canal flare index, CFI B / H = anteroposterior CFI C / G = neck-oriented CFI A / D = mediolateral metaphyseal canal flare index, MCFI B / E = anteroposterior MCFI C / D = neck-oriented CFI

Study III

Plastic replicas of ten straight Bi-Metric (Biomet) and ten anatomic ABG (Howmedica) cementless stems were planned to implant into twenty cadaver femora. The femora were preserved in alcoholic solution (2-6 weeks) before stem insertion. Preoperative radiographs (in neutral rotation, perpendicular AP and ML views, standard magnification 20%) were obtained to template the stems. Epoxyplastic was selected as the material for the stems in order to avoid the artefacting effect of metal implants in computed tomography. An epoxyplastic stem can also be appropriately inserted into the femoral canal and is clearly visible in radiographs. The stems were implanted in the femora by orthopaedic surgeons experienced in the clinical use of these designs; ABG stems were inserted after over-reaming of the canal as customarily. The standard instrumentation of both stems was used. One femur fractured during insertion of a Bi-Metric stem and was excluded. There were thus nine cases in the Bi-Metric group and ten cases in the ABG group.

Fill measurement from radiographs

Postoperatively the femora with implanted stems were radiographed in the same projections as preoperatively. Canal fill was measured in three manners: *(A)* from AP view only as the ratio of stem width to canal width, *(B)* by calculating the average of the fills in AP and ML view, and *(C)* by measuring stem and canal widths from AP and ML views and then calculating the hypothetical cross-sectional rectangle areas of stem and canal (**Fig.2.a and b**). Stem fill was studied at several levels: with 5-mm intervals in the metaphysis and 10-mm intervals in the diaphysis. The lesser trochanter mid-point (T) was the zero level of the bone vertical axis.

Fill in the computed tomography -based method

The femora with implanted stems were then studied with CT. Horizontal 2-mm thick slices were taken at 5-mm slice intervals from 20 mm above to 20 mm below the lesser trochanter mid-point (T). Distally 10-mm slice intervals were used down to the tip of the stem. Thus the levels studied were identical to radiographic measurement. The canal fill of the stem was studied by an image processing program using slice-dependent threshold values (Ahmad et al 2000). The fill was defined in a cross-sectional slice as the proportion of stem area to canal area.

The fill in CT was compared between straight stems and proximally anatomic stems, comparing means by t-test as statistical method. The accuracy of the radiographic fill was compared to the CT method at all separate levels and also when the levels were divided into metaphyseal and diaphyseal regions. This was studied by comparing means by paired-samples t-test and by Pearson linear correlation.

Study IV

Patients

During 1991 and 1992, 132 cementless Bi-Metric (Biomet) femoral stems (straight, proximally porous-coated, titanium) were implanted with cementless acetabular cups (Biomet Universal) at Tampere University Hospital. Of the 132 patients involved, 50 were selected randomly for the first study group. The second group consisted of the first 26 cementless ABG (Howmedica) arthroplasties performed during 1992 and 1993 at Tampere University Hospital (9 cases) and Jokilaakso Hospital (17 cases). The ABG titanium stem is proximally anatomic and hydroxyapatite-coated and is inserted after over-reaming of the diaphysis. A cementless ABG hydroxyapatite-coated cup was used in combination with all ABG stems. Patients with acetabular cup loosening or revision before 5 years were excluded (12 of the 132 Biomet Universal cups in the Bi-Metric series, but none in the ABG series), as were patients with either a previous proximal femoral fracture or a previous femoral osteotomy. Immediate postoperative radiographs were assessed retrospectively and structured clinical and radiographic data were collected

Figure 2a. Schematic illustration of radiographic measurements from AP and lateral views. The lesser trochanter mid-point (T) is the zero level in the vertical axis.

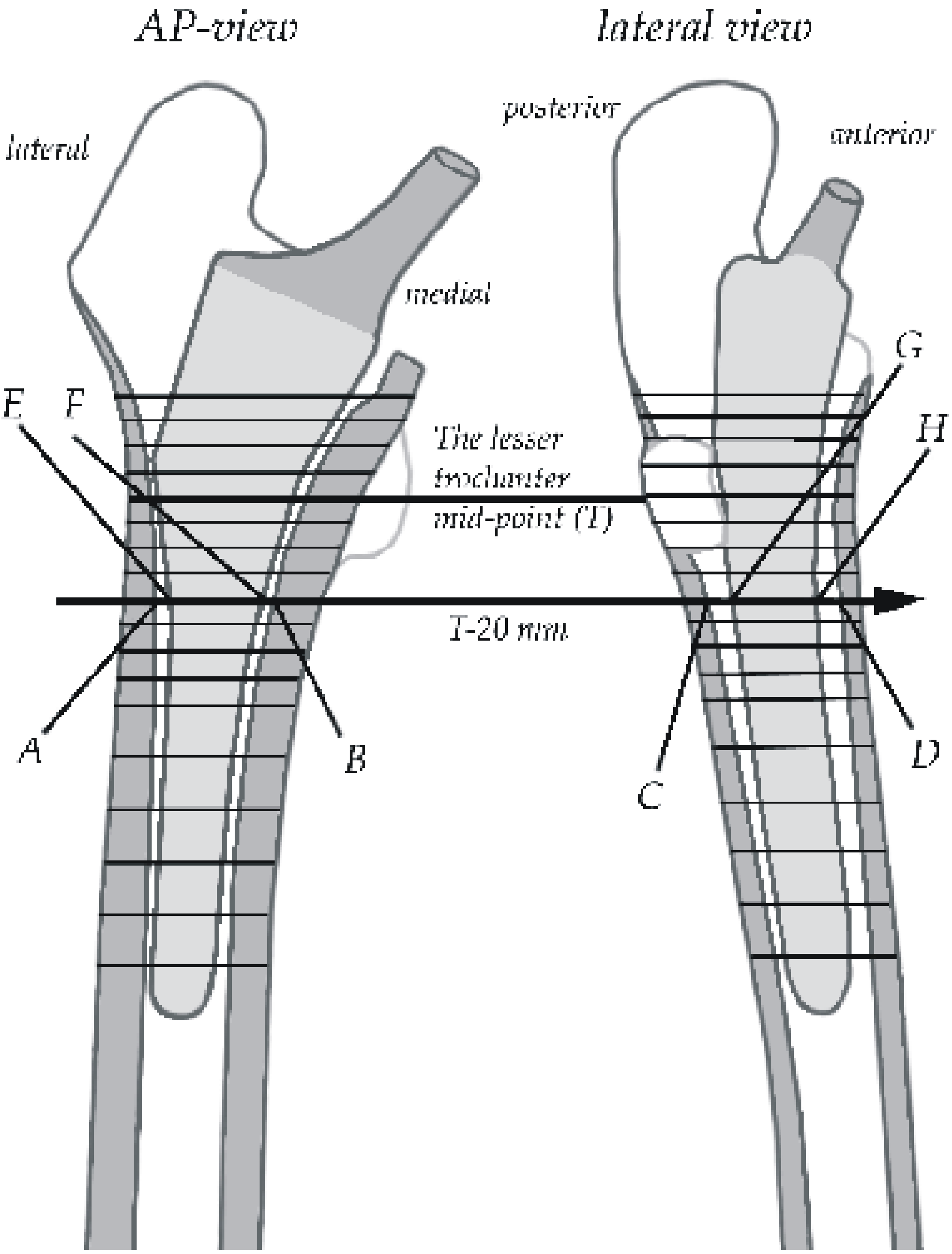
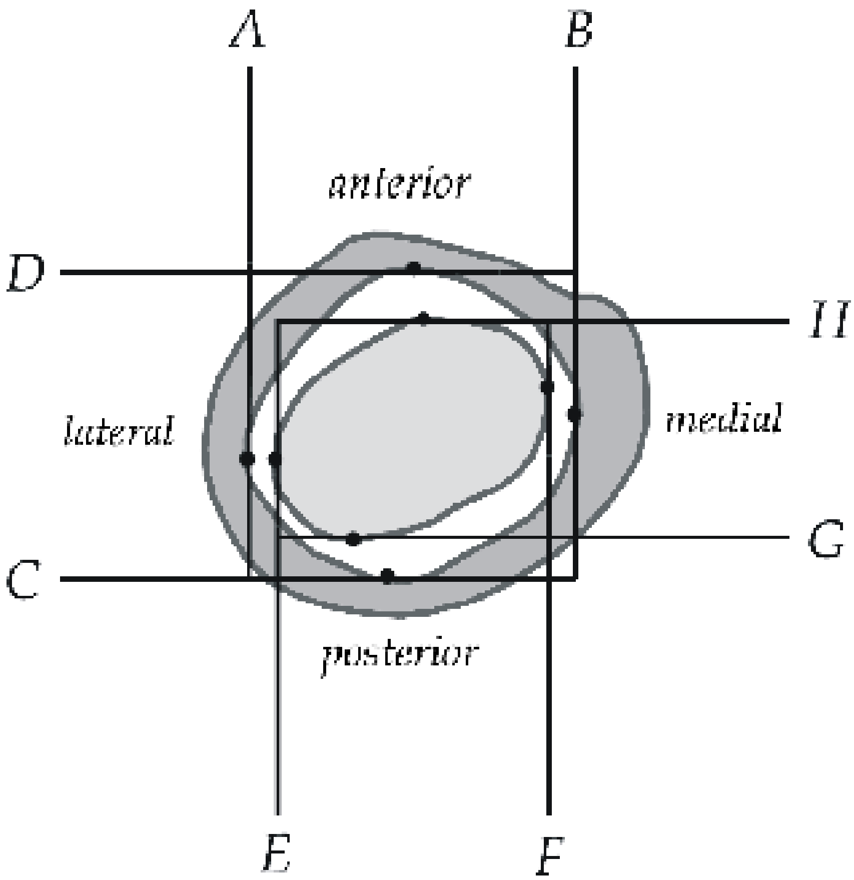


Figure 2b. An example of the measurement at a level 20 mm below T (T-20 mm): AB and CD refer to femoral canal width, EF and HG to stem width in AP and lateral views. The cross-section refers to the margins identified from the AP and lateral radiographs and explains the idea of hypothetical rectangular areas.

The canal fill according to AP view only $= \dfrac{EF}{AB}$

The canal fill as an average of the fills from AP and lateral views $= \left(\dfrac{EF}{AB} + \dfrac{GH}{CD} \right) : 2$

The canal fill from hypothetical rectangular areas $= \dfrac{EFxGH}{ABxCD}$.



during regular follow-up visits. There were no noteworthy differences between the study groups in patient demographics or operative indications.

Measurement of fit and fill

From the immediate post-operative radiographs (AP and lateral views) the fit of the stem was measured as the length of the stem in contact with cortical bone in proportion to the length of the stem surface in the region studied. It was measured for the whole stem as well as separately for the metaphyseal and diaphyseal regions, medially up to the margin of the stem and laterally up to the level of the clear lateral cortex in terms of Gruen zones (Gruen et al 1973, Johnston et al 1990). The fill was determined as the ratio of stem width to canal width. It was measured at five metaphyseal levels at 10-mm intervals from 20 mm above the lesser trochanter mid-point (T) to 20 mm below it. The diaphyseal levels were 50 mm below T and 10 mm proximal to the stem tip. The fill information from AP and lateral views was combined by calculating their average, corresponding to the method *(B)* used in Study III. Stem positions - varus or valgus and vertical position – were recorded. Magnification was calculated from femoral head diameter and this was taken into account in all measurements

Evaluation of clinical results

Clinical and radiological follow up were performed according to the routine of the surgical unit concerned. The average follow up of the Bi Metric group was 69.3 months (range 47 88) and that of the ABG group 59.4 months (range 49 66). Data were recorded with the The Finnish Arthroplasty Association proforma, which contains the details of a modified Harris hip score (Ilstrup et al 1973).

Assessment of migration, bone ingrowth and remodeling

Vertical migration of the femoral stem was assessed from 5 year AP radiographs by measuring the distance between the stem and the tip of the greater trochanter and the upper margin of the lesser trochanter. Vertical subsidence exceeding 2 mm (the mean change between the 2 distances) and a varus shift of 2° or more were considered significant (Engh et al 1990).

Bone ingrowth and qualitative remodeling were assessed from AP and ML radiographs (Engh et al 1990, Johnston et al 1990, Vresilovic 1994, Mulliken et al 1996). Determinants of bone ingrowth included spot welds (*i.e.* trabecular bridges between the stem and an endosteal surface) and intimate contact of the stem with the endosteal cortex in the absence of a radiolucent line. A reactive sclerotic line around the distal portion of the stem was considered evidence of motion at this interface, signifying proximal osseointegration. Bone resorption definitions included cortical thinning, marked loss of cortical density or corticocancellisation, and loss of calcar height or thickness. Calcar rounding off was not regarded as actual bone remodeling. Cortical hypertrophy, often spindle shaped around the distal portion of the stem, was also recorded.

The immediate postoperative fit and fill characteristics of the two different cementless stem designs and the 5 year bone remodeling patterns resulting from the use of these stems were compared. Special emphasis was placed on studying the predictive value of the primary postoperative fit and fill characteristics for the clinical result, for the radiological outcome, and for bone remodeling during the 5 year follow up period.

Differences in continuous variables between groups were tested by means of independent samples t test, or by analysis of variance for normally distributed variables. For variables with skewed distributions the Mann Whitney test, or Kruskall Wallis analysis of variance were used. Cross tabulation with the chi square test was used in studying categorised variables.

RESULTS

Study I

Accuracy of the computed tomography -based edge detection method

The standard deviations of the caliper ruler measurements of single dimensions were calculated to describe reproducibility of the measurements. The mean of the standard deviations of all measurements was 0.17 mm (= 0.8%). That of the standard deviations in diaphyseal slices was 0.12 mm (= 0.8%) and in metaphyseal slices 0.48 mm (1.6%).

The mean difference between the dimensions measured by the CT-based image processing method and manual measurements was 1.1 mm (S.D. 0.7 mm). The mean difference was slightly greater in the metaphyseal than in the diaphyseal slices, 1.2 mm (S.D. 0.9 mm) and 1.0 mm (S.D. 0.6 mm), respectively. The dimensions measured by the CT-based method were usually slightly smaller than those of the caliper ruler measurements, the peak of the distribution being about 1 mm negative (difference = CT - manual) (**Fig. 3**.).

Canal flare indices (CFI) (Noble et al 1988) were calculated to describe the canal shapes of the ten test femora. These were then divided into three groups according to their CFI. The mean differences were counted and studied in each group, and also separately for metaphyseal and diaphyseal slices (**Table 1**.). The differences were greatest in the metaphyseal slices of the three femora with the lowest CFI, group 1., 1.3 mm (S.D. 0.8 mm). In the diaphyseal slices the mean difference increased as CFI decreased. The difference was smallest in the diaphyseal slices of the femora with greatest CFI, group 3., 0.9 mm (S.D. 0.6 mm). In metaphyseal slices the change in the mean difference in relation to CFI was less obvious.

Figure 3.

The distribution of the difference between CT-based image processing program and the manual measurements of the femoral endosteum in all femora, and in diaphyseal and metaphyseal slices separately. Negative value means that a computed dimension was smaller than a manual measurement.

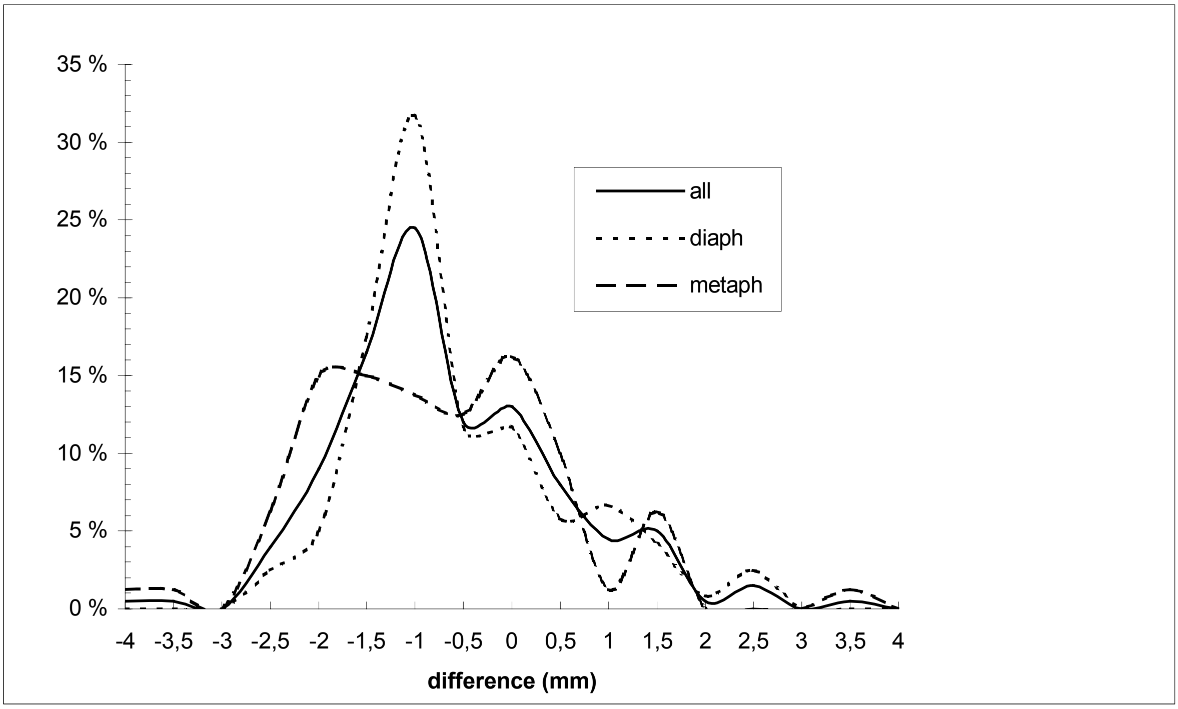


Table 1.

The mean difference (mm, ± S.D.) between the dimensions (n = number of measured dimensions) of the CT-based image processing program and the manual measurements of endosteum of the femora divided according to canal flare indices.

	Group 1., three femora CFI= 3.1, 3.5, 3.6	Group 2., four femora CFI = 3.7, 4.2, 4.3, 4.4	Group 3., three femora CFI = 4.6, 5.3, 5.5
All slices	1.2 (± 0.8) (n=60)	1.1 (± 0.7) (n=80)	1.0 (± 0.8) (n=60)
Metaphyseal slices	1.3 (± 0.8) (n=24)	1.2 (±1.0) (n=32)	1.1(±1.0) (n=24)
Diaphyseal slices	1.1(± 0.8) (n=36)	1.1 (± 0.5) (n=48)	0.9 (± 0.6) (n=36)

Study II

Femoral endosteal anatomy

The means and variations of the endosteal dimensions are presented in **Table 2.** The endosteal neck anteversion at the osteotomy level was on average 8° (range -19° to 39°, S.D. 12°). The average isthmus level was 110 mm (range 60 mm to 140 mm, S.D. 15 mm) below the lesser trochanter mid-point. In 78% of the femora the isthmus level was situated 100 mm - 120 mm below the lesser trochanter mid-point. In the calcar femorale region a trabecular ridge of nearly cortical density protruding endosteally from the posteromedial cortex was detectable in 96% of the femora.

Table 2.

Proximal femoral endosteal dimensions (mm) at different levels (n = 50).

	mediolateral dimensions		anterioposterior dimensions		longest oblique dimensions	
Level	Mean	S.D.	Mean	S.D.	Mean	S.D.
T+20	45.4	4.5	31.4	3.5	47.1	5.0
T+15	40.3	4.6	29.8	3.2	42.0	4.8
T+10	35.5	4.2	28.6	3.1	37.5	4.3
T+5	31.5	4.1	27.0	3.0	34.0	4.2
T	28.7	3.2	25.6	2.9	31.0	3.7
T-10	25.0	2.6	23.9	2.3	27.6	2.5
T-20	20.4	2.1	20.7	2.5	23.2	2.7
T-30	17.7	1.9	18.3	2.4	20.1	2.5
T-40	15.7	2.0	16.8	2.6	18.7	2.5
T-60	13.4	2.1	15.9	2.7	17.3	2.7
isthmus	11.0	1.9	14.1	2.8	14.8	3.0
T-150	12.7	2.0	14.8	2.6	15.6	2.7

The CFI and MCFI are presented in **Table 3.** According to Noble`s classification (Noble et al 1988) the percentage of “stovepipes“ (CFI < 3.0) was 6%, “normals“ (3.0 ≤ CFI ≤ 4.7) 68% and “champagne glasses“ (CFI > 4.7) 26%. Age of donor did not correlate with isthmus width, CFI or MCFI.

Table 3.

Femoral canal flare indices (n = 50)

		Mean	S.D.
Canal flare index (CFI)	mediolateral	4.2	0.88
	neck-oriented	4.3	0.93
	anterioposterior	2.3	0.51
Metaphyseal canal flare index (MCFI)	mediolateral	2.2	0.24
	neck-oriented	2.0	0.25
	anterioposterior	1.5	0.16

The femoral cavity enlargement rate was under 2.0 mm *per* 10-mm slice interval up to a level 40 mm below T in almost all femora (94%). Above the level T-20 the enlargement rate was over 2 mm in 95% of 10-mm slice intervals. Isthmus width correlated fairly well with mediolateral width at the level of T - 40 (r = 0.83) and T - 20 (r = 0.53) but poorly with the T + 20 level (r = -0.24). However, isthmus width correlated fairly well with MCFI (r = -0.72). The correlation between dimensions at the levels T - 20 and T + 20 was only 0.43 mediolaterally and 0.59 anterioposteriorly. It thus appeared that prediction of one dimension from another is unreliable between the levels T - 20 to T + 20 (the assumed bone ingrowth region of an endoprosthetic femoral stem).

Study III

The femoral canal fill of straight and anatomic stems

In Study III plastic stem copies were inserted into cadaver femora. There were 9 cases in the straight stem group (Bi-Metric) and 10 in the proximally anatomic stem group (ABG).

The average areal canal fill at the metaphyseal levels varied from 37% to 41% in the straight stem group and from 34% to 45% in the anatomic group as measured by CT method. Fill values were slightly greater with ABG stems above the lesser trochanter, albeit not significantly. At the border level between metaphysis and diaphysis (T – 20) straight Bi-Metric stems actually filled slightly more than ABG stems (41% versus 34%, $p < 0.05$).

In the diaphysis the Bi-Metric stems (average 42%) filled significantly ($p < 0.05$) more of the femoral canal than the ABG stems (average 36%), in which the canals were over-reamed prior to stem insertion. The difference between the stem designs was most marked at the levels T – 40 (45% versus 35%, $p < 0.01$) and T – 90 (42% versus 30%, $p < 0.01$).

The accuracy of radiographs compared to CT method in femoral canal fill measurement

All the radiographic methods resulted in markedly greater fill values than those by the CT method (**Table 4.**). When the fill was measured from the anteroposterior views only, the fill values were 1.9 - 2.1 times greater than those in CT. If the fill was calculated as an average of the fills in AP and lateral views, the values were still 1.7 - 2.0 times greater. When the radiological fill was estimated according to the hypothetical rectangle areas, the values were reduced to 1.2-1.6 times greater than those obtained with the CT method.

The radiological evaluations using both the AP and lateral views correlated well with CT scanning ($r = 0.76 – 0.80$) in the metaphyseal region, but in the diaphysis the correlations were lower ($r = 0.64 – 0.65$). If AP view measurement alone was used, the correlations were markedly reduced in the metaphysis ($r = 0.53 – 0.66$) and slightly in the diaphysis ($r = 0.59$). The errors with radiological methods and the correlations with CT values were similar for both stems, *i.e.*, the shape of the stem was not found to affect the accuracy of the methods.

Table 4.

Correlation of the different radiological calculations of fill with canal fill in CT (n=19). Statistical difference between the methods according to Pearson linear correlation ($p < 0.05$ = *, $p < 0.01$ = **, $p < 0.001$ = ***).

	Correlation between radiological methods and the CT scanning:		
Region	Square areas of AP and lateral views	Average of AP and lateral views	AP view only
metaphysis	0.76***	0.80***	0.66**
upper metaphysis	0.77***	0.77***	0.53*
lower metaphysis	0.80***	0.76***	0.60**
diaphysis	0.65**	0.64**	0.59**

Study IV

The postoperative radiological fit and fill of straight and anatomic stems

In Study IV 50 patients with straight stems (Bi-Metric) and 26 proximally anatomic stems (ABG) were evaluated: immediate postoperative fit and fill, clinical outcome and bone remodeling after 5 years.

The average overall fill of the anatomic ABG stems at metaphyseal levels was slightly but statistically significantly greater than that of the straight Bi Metric stems: 78% versus 74% (p = 0.025) if both AP (Gruen zones 1, 2, 6, 7) and lateral views (Gruen zones 8, 9, 13, 14) were included; and 79% versus 74% (p = 0.001) if only Gruen zones 1 and 7 were included (**Table 5**.). The diaphyseal cortical contact of the straight stems in Gruen zones 3 and 5 was significantly greater than that of the over reamed anatomic stems: 48% versus 24% (p < 0.001). In the lateral views there were no significant differences between the stems in their contact with either the diaphyseal anterior or posterior cortices. The diaphyseal fill of the straight stems slightly exceeded that of the over reamed anatomic stems: 90% versus 87% (n.s., p = 0.08).

The clinical outcome and its relation to the immediate postoperative fit and fill

There was no significant difference between the two groups in the Harris hip score after 5 years. Bi-Metric 94 (44 - 100) and ABG 95 (62 - 100), respectively. Any possible association between the postoperative fit and fill characteristics and the clinical outcome as expressed by the Harris hip score was analysed with Pearson's linear correlation and cross-tabulation, but no significant association was found in either the Bi-Metric or the ABG groups.

Table 5.

The immediate postoperative fit and fill of straight (Bi-Metric) and proximally anatomic (ABG) stems ($p < 0.05$ = *, $p < 0.01$ = **, $p < 0.001$ = ***).

Region		Fit, %	
		Bi-Metric	ABG
Metaphysis	Gruen 7	32	43
	Gruen 6	12	19
	Gruen 6 and 7	24	32
	Gruen 2	9	19
	Gruen 8 and 9	**36** **	25
Diaphysis	Gruen 3 and 5	**48** ***	24
	Gruen 10 and 12	33	30
	Gruen 3, 5, 10 and 11	**41** ***	26

Region		Fill, %	
		Bi-Metric	ABG
Upper metaphysis	Gruen 1 and 7	74	**80** ***
Lower metaphysis	Gruen 2 and 6	82	84
Metaphysis	Gruen 1, 2, 6, 7, 8, 9, 13 and 14	74	**78** *
Diaphysis	Gruen 3 and 5	90	87
	Gruen 10 and 12	83	84
	Gruen 3, 5, 10 and 11	86	86

The bone ingrowth, remodeling and stem subsidence of straight and anatomic stems

The straight Bi Metric stem had significantly more diaphyseal osseointegration around the stem tip (Gruen zones 4 and 11) and on the lateral distal part of the stem (Gruen zone 3). The anatomic and proximally hydroxyapatite coated ABG seemed to have significantly more osseointegration in the lower metaphyseal region (Gruen zones 2 and 6), but there was more spot weld formation between the Bi Metric stem and the anterior metaphysis (Gruen zone 8).

Subsidence of 2 mm or more was detected in two Bi Metric stems (4%, range: 3.5   3.8 mm) and in seven ABG stems (27%, range: 2.0   3.5 mm) ($p < 0.01$). Varus shift of 2° or more was found with two Bi Metric stems and with one ABG. Metaphyseal radiolucent lines, estimated as minor, were detected in one patient in both groups. These were not progressive and no stem was considered radiologically loose. Small femoral osteolytic changes were recorded in one subsided ABG stem, in which there was considerable wear of the acetabular polyethylene liner. In the Bi Metric group there were no osteolytic femoral lesions despite the fact that three acetabular revisions were scheduled due to wear of the liner.

The metaphyseal cortical resorption in the Bi Metric and ABG groups was similar: loss of calcar height, 0.7 mm versus 1.2 mm (n.s.); loss of calcar thickness, 1.1 mm versus 1.1 mm; marked loss of cortical density in Gruen 7 zone, 57% versus 50% (n.s.); marked loss of cortical density in more than one metaphyseal Gruen zone, 22% versus 35% (n.s.). However, metaphyseal cortical hypertrophy in Gruen zones 2 and 6 was observed in four ABG (15%, $p = 0.012$) but in none of the Bi Metric cases (0%).

There was diaphyseal cortical hypertrophy at the level of the tip of the stem (Gruen zones 4 or 11) in 12 cases (20%) in the Bi Metric group while no such remodeling was seen in any of the ABG stems ($p = 0.013$). In Gruen zones 3 and 5 the proportion of cortical hypertrophy was 27% and 33% around the Bi Metric stems and 19% and 23% around the ABG stems (n.s.). If all diaphyseal Gruen zones were included (*i.e.* Gruen 3, 4, 5, 10, 11, 12), there were hypertrophic signs in 49% in the Bi Metric group and 27% in the ABG group (n.s. $p = 0.065$). The reactive lines seemed to be typical findings around the distal portion of the ABG stems: 65% in Gruen zones 3, 4, 5, 10, 11, 12 and in over half of these cases the radiolucency extended over at least two zones. In contrast, in the Bi Metric group this was quite a rare finding, 12% ($p < 0.001$). Diaphyseal cortical thinning or marked loss of cortical density was observed in three ABG cases (11%) and in one Bi Metric (2%, n.s.).

Associations between postoperative fit and fill characteristics and 5-year radiological result

There was a significant ($p < 0.01$) but numerically quite small ($r = 0.32$) correlation between diaphyseal fit and radiological signs of diaphyseal bone ingrowth. No correlation was found between metaphyseal fit or fill and metaphyseal bone ingrowth. However, in the ABG group there was a moderate inverse correlation ($r =$ 0.57, $p < 0.01$) between the fit on the medial metaphyseal arc (Gruen zones 6, 7) and bone ingrowth at the stem tip in a lateral radiograph (Gruen zone 11).

The seven (27%) subsided ABG stems had significantly less metaphyseal fill than those which did not subside (73% versus 80%, $p < 0.01$). Likewise, poor calcar fit (Gruen zone 7) seemed to be associated with stem subsidence (19% versus 51%, $p = 0.056$). The diaphyseal fit or fill was not related to subsidence of the ABG stems.

The resorptive metaphyseal changes common in both stem groups could not be proved to be associated with the metaphyseal or the diaphyseal fit and fill parameters. However, the four ABG stems with metaphyseal cortical hypertrophy had a markedly greater metaphyseal fit on the medial cortex (Gruen zones 6, 7) than the other ABG stems: 64% versus 26% ($p < 0.01$).

The cortical hypertrophy around the tip of the 12 Bi Metric stems was strongly related to diaphyseal stem fill evaluated from anteroposterior radiographs (95% versus 85%, $p < 0.001$). Altogether 31 stems (41%) had diaphyseal hypertrophic signs after 5 years (all diaphyseal Gruen zones included). This remodeling was related to the diaphyseal fit (42% versus 31%, $p < 0.01$) and diaphyseal fill (88% versus 85%, $p < 0.05$) of the femoral stems. Distal reactive lines were observed in 30% of all stems and this seemed to be related to a lesser diaphyseal fit (19% versus 38%, $p < 0.05$). In the ABG group the incidence of distal reactive lines (65% of cases) was not associated with the magnitude of diaphyseal fit. In four ABG cases a distal reactive line was observed with cortical hypertrophy.

DISCUSSION

Detection of the femoral canal

A system for femoral canal anatomy searching was developed. There was a mean difference of 1.1 mm (± 0.7 mm) in measured femoral canal diameters between the CT-based image processing system and manual measurement with a caliper ruler. Accuracy would probably have been even better with a larger image matrix size and smaller pixel size in CT images; the system works independently of pixel size. The system should also be applicable and attain similar accuracy independently of the CT equipment and imaging parameters used. The distribution of the difference was adjusted to negative (program measurement < manual measurement, **Fig. 3**.) to avoid oversizing of the femoral canal, which kind of error might be a cause of the peroperative fractures reported to be unacceptably common in custom-made arthroplasties (Bargar 1989, Reuben et al 1992, Brien 1993, Christie 1993, Simonet et al 1993). Mankovich and associates (1991) reported a 4.6% (S.D. 2.9%) average error in the corresponding CT and edge detection system. However, in their study protocol testing was performed with plastic bone phantoms, and the difficulties of true trabecular bone segmentation and thresholding were thus not encountered. Rubin and associates (1992) compared CT and actual bone sections with an accuracy of 0.8 mm (± 0.7 mm). In that study the contours of both the CT and the cross-cut slices were extracted by the same image processing method; in point of fact the authors studied the accuracy of CT, not the accuracy of image processing.

During the early development phase of the edge detection system it was found that especially in osteoporotic femora with thin cortex the detected edge was prone to protrude into the cortex and diameters were computed too long. It seemed best that instead of a constant threshold value, a value be computed separately for every image, *i.e.* for every slice depending on its density and structure and additionally local thresholding of an image was used in problem areas. The threshold values normally ranged from 400 to 800 HU. With this solution the system became more independent of factors affecting absolute grey-level values of images (imaging parameters and patient properties), although these variables were eliminated in the study.

It may be questionable, whether there exists a clear and true border between cortical and trabecular bone in the metaphysis. Consequently, the term `accuracy´ may lose its meaning, and thus the importance of the reproducibility of the method has been emphasised (Prevrhal et al 1999). In the present study the reproducibility of the image processing was not properly assessed, which can be criticised.

In the present study the canal border was defined on a purely visual basis. In contrast Aamodt and colleagues (1999) first rasped the trabecular bone of the femoral metaphysis off and thus determined the corticocancellous interface, which could be strong enough to stabilize a cementless femoral stem. In that study a constant threshold of 600 HU was found to be closest to the contour of the medullary canal after rasping. A custom-made stem designed on their rationale may provide adequate metaphyseal fill for initial stability, in accord with one main conclusion of Study II. However, a constant threshold should properly be determined separately for each CT scanner (Sumner et al 1989, Mankovich et al 1991, Prevrhal et al 1999).

The object here was a fully automatic image processing program, but during its developing phase necessary interaction was allowed. If the program fails to visualize the whole border the missing part can be drawn by the mouse. This was never done in the diaphyseal slices. In the slices of the lesser trochanter region, however, the program detected the calcar septum border, and the septum peak was then connected to the posterior cortex. It was estimated that in slices from 10 mm below to 10 mm above the lesser trochanter mid-point (5 slices of the 30 per femur) about 10-15 % of the contours were the result of mousing, *i.e.*, about 3 % of the whole detected border of a femur. At this important level of bone ingrowth to the implanted endoprosthetic stem, extrapolation did not function appropriately and was therefore abandoned.

The accuracy of the CT-based image processing method was considered acceptable. It was assumed that if the threshold value computation is inappropriate and if the calcar femorale anatomy is not focused in the image processing protocol, a significant error may result. Three-dimensional femoral canal border data provided by the program could be used to produce a custom-made prosthesis.

Anatomy of proximal femoral canal

Details of the anatomy of the proximal femoral canal are essential for design components for hip arthroplasty. The number of published papers on the topic has nevertheless been small. The classical study by Noble and associates (1988) demonstrated the variability of the shape of the canal and the independence between the endosteal and periosteal dimensions; a total of 200 femora were studied from radiographs. The authors described the canal opening from the isthmus to the neck-osteotomy level by canal flare index. In the present study the average mediolateral CFI was larger (4.2 *vs.* 3.8) and the proportion of champagne-fluted femora was notably greater (24% *vs.* 8%) than the respective figures in Noble´s paper. The difference was even greater if the neck-oriented CFI (average 4.3, champagne-fluted propotion 32%) was compared with Noble's CFI. The main reason for the differences is obviously technical, *i.e.,* the limitations of standard X-rays, as concluded by Husmann and co-workers (1997). In their series 310 femora were studied with CT; the average CFI was similar to ours (4.3), as was the proportion of champagne-fluted femora (20%). In addition, true variation in endosteal anatomy most probably exists between population groups. In the present study there were more male than female donors (36/14). This could have caused the dimensions of the femora to be larger than in the studies with equal gender distribution. The average mediolateral widths of the femoral canal were, however, similar in the present study and in the study by Noble and associates (**Table 6**.). The gender has not been shown to affect the femoral shape.

Table 6.

The average (± S.D.) femoral canal width (mm) at different levels in the present study compared to the study by Noble et al (1988).

	present study	Noble et al
Canal width at level		
T + 20 mm	45.4 (± 4.5)	45.4 (± 5.3)
T	28.7 (± 3.2)	29.4 (± 4.6)
T - 20 mm	20.4 (± 2.1)	20.9 (± 3.5)
isthmus	11.0 (± 1.9)	12.3 (± 2.3)

A good metaphyseal fit and fill of the cementless stem in the femoral canal has proved to be of great benefit in eliminating micromotion of the stem and in achieving a favourable stress transfer (Walker and Robertson 1988, Burke et al 1991, Callaghan et al 1992, Hua and Walker 1994, Weinans et al 1994, Huiskes and van Rietbergen 1995, Dujardin et al 1996). Consequently, variation in proximal metaphyseal canal shape has become a topic of interest, and different geometric parameters have been determined to characterise the shape (Robertson et al 1996, Husmann et al 1997, Massin et al 2000). The approach in this respect has been quite similar in groups under Husmann (1997) and Massin (2000) as in the present study: metaphyseal flare indices have been defined. Incidentally these have been different. Husmann and associates (1997) chose an index interval from 40 mm below, in the present study from 20 mm below and Massin and associates (2000) exactly from the lesser trochanteric mid-point to 20 mm above it. The results of these studies are in good general accord: the shape of the proximal metaphyseal canal varies markedly. In the present study this is best demonstrated by the metaphyseal canal flare index distribution and the poor correlations between dimensions at T-20 and T+ 20 levels. The groups under Husmann (1997) and Massin (2000) sought to classify femora into metaphyseal somatypes and then determine the number of stem designs needed adequately to match the canal shape.

The present study demonstrated that a single design of cementless femoral stem will not match the variation in the shape of the metaphyseal femur, but the required number of different metaphyseal designs of the femoral component remained to be established. It was concluded that in order to achieve metaphyseal osseointegration and stress transfer, the suitable femoral stem for an individual patient should be selected according to the metaphyseal shape. This is described by the MCFI but not in fact by the CFI depicting the entire proximal bone. Thus the MCFI should have a greater influence than the CFI on stem selection. Primarily the different designs could respond to differences in the ML canal opening, because the metaphyseal opening (MCFI) in the ML and AP planes are well correlated ($r = 0.7$) and because the posterior metaphyseal fill may be less important than the ML fill in preventing rotational micromotion.

A dense calcar trabeculation has been observed in a CT study to modify the femoral canal in the trochanteric region (Dai et al 1985) and also in actual cross-sections (Walker and Robertson 1988). This dense calcar septum was observed in 96% of femora in the present study. During torsional loading of a hip implant, *e.g.* during stair-climbing, the femoral stem is forced into retroversion (Schneider et al 1989, Nunn et al 1989, Burke et al 1991, Chandler et al 1995, Buhler et al 1997). The calcar septum forms the posterior wall of the reamed canal in the metaphysis, and thus a well-preserved, strong calcar septum might reduce torsional micromotion. Furthermore, intimate stem-calcar contact may contribute to physiological-like load transmission.

The wide variation in the shapes and sizes of the proximal femoral medullary canal obviously means that it is impossible in practice to achieve 100 % cortical contact with the stem, especially in the metaphysis. The question can be raised whether this is necessary and could lead to a slightly different interpretation and conclusion. A good fill of the metaphysis of the femur undoubtedly increases primary stability, but on the other hand cancellous bone has superior healing capacity over cortical bone. Reliable ultimate bony union might thus be more easily attained in a region of good-quality cancellous bone. If so, “maximal“ metaphyseal fill may not be superior to “adequate“ fill, provided firm primary stability and good-quality cancellous bone next to the implant are achieved. In other words maximal cortical fit in the metaphysis may be incompatible with maximal osseointegration ability on the part of the metaphyseal trabecular bone. If this is the case, an optimal compromise between these two should be the design goal. One could also conclude that the problem of variability of metaphyseal canal should be solved with the use of cement. In that solution it might be optimal to limit the cement metaphysis only to achieve metaphyseal stress-transfer.

Measurement of canal fill of cementless femoral stems

Hayes and colleagues (1991) concluded that for research purposes fit and fill data on the femoral stems should whenever possible be collected using cross-sections. The recent progress in metal artifact reduction CT techniques has enabled to study femora with metallic implants (Robertson and Taylor 1993, Feng et al 1996, Sutherland and Gayou 1996, Viceconti et al 1999). However, since fit and fill data will mainly be obtained from radiographs in clinical work and also if large series of patients are studied in research work, it is advisable to establish the accuracy of standard radiographs with respect to fit and fill. To standardise the femoral rotation in radiographs is a difficult task and in assessment of the shape and dimensions of the femoral canal, this is the main cause of error (Eckrich et al 1994). Femoral rotation and especially anteversion of implanted stem strongly affect the radiological estimation of the cross-sectional area in the upper part of the stem. The variation in magnifications of radiographs also is of significance (Knight and Atwater 1992). The corticocancellous boundary observed in radiographs is obviously another main cause of error, but is reproducible corresponding to a CT density value somewhat more than 500 HU (Iguchi et al 1996).

In the present study plastic replicas of femoral stems were implanted in cadaver femora in order to compare radiographic and CT fill data. The image processing method used on CT data has been described in detail elsewhere (Ahmad et al 2000); this type of method is considered the most accurate (Prevrhal et al 1999). The purpose was also to evaluate the fit data of stems, *i.e.*, the amount of cortical contact. However, it emerged from CT images that real contact of the stems was inadequate for proper comparison and the analysis of fit was abandoned.

The fill values obtained by simple methods in conditions optimal for conventional radiographs were excessive, 1.7 – 2.1 times higher than those in CT. When the fill values are modeled to represent the ratio of cross-sectional areas of the stem and the canal (method based on hypothetical rectangles), the values are brought closer to the actual figures, 1.2 – 1.6 times higher than in CT. The correlations with values from CT were high (r = 0.76 – 0.80) if both radiographic views were used, which justifies use of radiographic methods for example in clinical studies comparing different stem designs and when the effect of canal fill on bone remodeling changes is to be assessed. If the fill is measured from normal radiographs, both the AP and lateral views must be used, and the calculation method based on hypothetical rectangles at each level would appear to provide the most reliable results.

Fit and fill of different femoral stem designs

The fit and fill of a straight Bi-Metric stem and a proximally anatomic ABG stem were examined from CT of cadaver femora in Study III and from radiographs of patients in Study IV. It was assumed that the anatomic design of ABG would have yielded significantly higher fill values than Bi-Metric in metaphysis; this was established in a clinical series (78% *v.* 74%, $p < 0.05$) but not in cadaver series (40% *v.* 40%). Both studies demonstrated the difference in fit and fill in diaphysis, which is purposely over-reamed before implantation of ABG stems: the diaphyseal fill of Bi-Metric stems in cadaver series and fit in clinical series were significantly higher. The initial stability of the Bi-Metric stem is evidently often provided by tight distal fit.

In the ABG concept the primary stability of the stem is attained by adequate support of the metaphyseal trabecular bone. In clinical series 7/26 (27%) stems subsided, and these had inferior and obviously insufficient metaphyseal fill. However, none subsided progressively or loosened.

It is often observed that the anterior curve of an anatomic stem matches nicely the anterior metaphyseal cortex. In Study IV, however, the fit on the anterior cortex in metaphysis (Gruen zones 8 and 9) was observed more with straight than with anatomic stems (36% *v.* 25%, $p < 0.01$). The explanation may be that when a straight stem is inserted in the femoral canal, it aligns itself with the femoral neck contacting on the anterior curve. An anatomic stem rather slopes along the curve but does not contact it.

Effect of differences in stem designs and in fit and fill on clinical results and bone remodeling

Proximally porous coated cementless stems have yielded excellent 5 10 year results in a number of series (Pellegrini et al 1992, Martell et al 1993, Hozack et al 1996, Mauerhan et al 1997, Burt et al 1998, Knight et al 1998, Ragab et al 1999, Sakalkale et al 1999, Xenos et al 1999). The straight proximally porous coated Bi Metric design is a second generation cementless femoral stem, while the proximally anatomical HA coated and distally over reamed cementless ABG can be considered a third generation stem. In the present study both the straight Bi Metric and the anatomical ABG stems had excellent clinical 5 year results, and this has been previously reported elsewhere (Robertsen et al 1996, Tonino et al 1995, Tonino et al 2000).

Inadequate canal fill has been considered an important reason for stem loosening and held to be detrimental to clinical results (Kim and Kim 1993, Martell et al 1993, Owen et 1994, Malchau et al 1997). In the present study the fit and fill did not influence clinical results. The number of patients in the series was perhaps too small to evince any minor difference, an aspect open to criticism. Harris hip score was used for clinical evaluation; a separate question on mid thigh pain should also have been included.

Bi Metric stems seemed to fit and fill the diaphyses rather than the metaphyses, and this resulted in diaphyseal hypertrophy in 50% of cases and marked loss of calcar cortical density in 59%. This remodeling indicates distal stress transfer. There was significantly more distal bone ingrowth with Bi Metric than with ABG stems. Even though no severe metaphyseal cortical resorption occurred, the desired succession of proximal porous coating, proximal osseointegration, optimal stress transfer and thus preservation of metaphyseal bone stock was not achieved with the second generation Bi Metric stems. Martell and associates (1993) reached the same conclusion using proximally porous coated straight Harris Galante cementless stems, with 36% of cases showing diaphyseal cortical hypertrophy and 85% loss of cortical density. In a previous Bi Metric report (Robertsen et al 1996) the proportion of distal cortical hypertrophy was identical to ours and calcar atrophy was observed in up to 88% of patients.

Tonino and colleagues (1995) observed bone remodeling changes around the ABG stems, indicating successful metaphyseal stress transfer. They reported an increase in bone density in the lower metaphysis in as many as 54% of cases, distal cortical hypertrophy in only 6%, and calcar resorption in 20%. In the present study the observations on bone remodeling were markedly inferior: only 15% metaphyseal cortical hypertrophy, as much as 50% metaphyseal cortical resorption and even 27% diaphyseal cortical hypertrophy. In both studies there were distal reactive lines in more than half of the cases, a phenomenon related to distal micromotion and a sign supporting the ABG concept. Also metaphyseal bone ingrowth was observed significantly more with ABG than with Bi Metric stems: 86% *v*. 64% in Gruen zone 2 and 90% *v*. 75% in Gruen zone 6. It must be emphasised that HA coating of ABG stem can apparently produce positive effects on bone remodeling and ingrowth. The value of HA coating has been demonstrated in comparative series of the same stem design with and without HA coating (Donnelly et al 1997, Rosenthall et al 1999 II).

Most often bone remodeling patterns have been reported as included in the radiographic results of different stem designs. In only rare cases has remodeling been studied in relation to the postoperative fit and fill parameters of the stems (Engh et al 1987, Engh and Bobyn 1988, Whiteside 1989, Martell et al 1993, Knight et al 1998), which is however one of the major factors for remodeling (Jasty et al 1988, Walker and Robertson 1988, van Rietbergen et al 1993, Jasty et al 1994, Weinans et al 1994, Hua and Walker 1995). In the present study thorough analysis was made of the way variations in the fit and fill parameters affected bone remodeling. The criteria of remodeling used were applied from several studies in conformity with each other (Engh et al 1990, Johnston et al 1990, Vresilovic 1994, Mulliken et al 1996). Assessment of bone remodeling from radiographs is a qualitative method; to quantify BMD around the femoral stems, the availibility of DEXA would have been most beneficial. Its appropriate use would however have demanded a prospective protocol (Kröger et al 1998).

Tight diaphyseal fit and fill of the Bi Metric stem led to hypertrophy of the diaphyseal cortex, whereas distal radiolucent lines were related to a lesser degree of diaphyseal fit. However, these effects were not seen in the series by Martell and colleagues (1993). Instead they observed that metaphyseal hypertrophy in Gruen zones 2 and 6 correlated with a higher degree of metaphyseal fill, whereas here this effect was found only with ABG stems.

CONCLUSIONS

1. An image processing method for three-dimensional femoral canal shape modelling was developed and its accuracy was tested and considered acceptable. During the development stage it became obvious that individual threshold value computation for each image is necessary. Three-dimensional femoral canal border data showed good accuracy and it could also be used to produce a custom-made prosthesis.

2. A detailed analysis of the dimensions and shape of the proximal femoral canal was undertaken. The shape of the metaphyseal canal was highly variable and there was a poor association between the dimensions of the diaphyseal and metaphyseal canal. This obviously means that it is impossible in practice to achieve 100 % cortical contact with the stem, especially in the metaphysis.

3. A suitable femoral stem for an individual patient should be selected according to the shape of the metaphyseal canal, which can be described by the metaphyseal canal flare indices (MCFI). Primarily different stem designs could respond to differences in the mediolateral canal opening because the MCFI in the mediolateral and anterioposterior planes are well correlated.

4. The radiographic fill obtained from both AP and lateral views correlated fairly well with the fill from CT, which justifies use of radiographic methods in clinical studies comparing different stem designs and when the effect of canal fill on bone remodeling changes is to be assessed. Both radiographic views must be used. The fill values from radiographs are excessive, but can be reduced closer to actuality by means of the method based on hypothetical rectangles.

5. The anatomic stems yielded slightly greater average fill in the metaphysis, but in subsided cases the fill was obviously inadequate to provide initial stability. Straight stems filled the diaphyseal canal more profusely than anatomic and over-reamed stems.

6. In the straight stem group (a second generation stem) there were bone remodeling signs indicating distal stress transfer in about half of the cases. In the group with

proximally HA-coated anatomic stems (a third-generation design) slightly more signs of metaphyseal stress transfer were observed than in the straight stem group, but the prevalence was markedly less than that reported in previous studies. Tight diaphyseal fit and fill were clearly related to cortical hypertrophy of the diaphysis. Resorptive changes in the metaphysis appeared independently of metaphyseal fill, but metaphyseal hypertrophy was related to greater metaphyseal fill.

7. The postoperative fit and fill of the cementless stem did not affect mid-term clinical outcome.

SUMMARY

Computed tomography (CT) was performed on 50 cadaver femora and an image processing program was developed to analyse the CT data. Ten femora were used for accuracy testing in Study I. The anatomy of the canal of 50 femora was examined in Study II. In Study III 20 cadaver femora were used; plastic replicas of the cementless femoral stem were implanted and the canal fill of the stems measured from standard radiographs and by CT method. The accuracy of radiographs was evaluated and at the same time two different stem designs were compared.

In Study IV two patient groups were analysed five years after cementless hip arthroplasty. The first group consisted of 50 patients with Bi-Metric stems (straight, proximal porous coating) and the second of 26 patients with ABG stems (anatomic, proximal HA coating, distal canal overreaming). The fit and fill were measured from immediate postoperative radiographs, bone ingrowth and remodeling was evaluated from 5-year postoperative radiographs and the clinical result was recorded with the Harris hip score. The stem groups were compared, and the influence of the fit and fill on bone remodeling and clinical result was assessed.

During the development stage of the image-processing method it became obvious that individual threshold value computation for each image is necessary. There was a mean difference of 1.1 mm (± 0.7 mm) in measured femoral canal diameters between the CT-based image processing system and manual measurement with a caliper ruler. This accuracy was considered acceptable for studying canal anatomy. Also custom-made prostheses could be produced with the three-dimensional data obtained on the femoral canal.

The femoral canal opening from isthmus to neck-osteotomy level has been described by the canal flare index (CFI). The average CFI was larger (4.2) and the proportion of wide champagne-fluted canals greater (24%) in this material compared to previous observations. The greatest variation in canal shape was observed in the metaphysis. The metaphyseal canal flare indices (MCFI) were determined to describe the shape of the metaphyseal canal, which should be considered in selecting a suitable femoral stem for an

individual patient together with the MCFI variation in designing cementless stems. A dense trabeculation in the calcar region modified the posteromedial canal shape in nearly all femora. This structure is obviously an important support against torsional motion of a femoral stem.

The fill values measured from conventional radiographs were excessive, 1.2 – 1.6 times higher than actual. However, the correlations between the values from CT and from radiographs were high ($r = 0.76 – 0.80$) if both radiographic views were used, which justifies using radiographic methods for example in clinical studies comparing different stem designs and when the effect of the canal fill on bone remodeling changes is to be assessed.

The anatomic design of the ABG yielded significantly higher fill values than the straight Bi-Metric in the metaphysis; this was established in the clinical (78% *v.* 74%, $p < 0.05$) but not in the cadaver series (40% *v.* 40%). Both studies demonstrated the difference of fit and fill in the diaphysis, which is purposely over-reamed before implantation of ABG stems: the diaphyseal fill of Bi-Metric stems in the cadaver series and fit in the clinical were significantly higher. In the ABG concept the primary stability of the stem is attained by adequate support of metaphyseal trabecular bone. In the clinical series 7/26 (27%) stems subsided, and these had inferior and obviously insufficient metaphyseal fill. However, none subsided progressively or loosened.

Fit and fill had no influence on the clinical results, but the fit and fill characteristics of the stem designs studied were different, as were the consequent bone remodeling changes. In the Bi Metric group (a straight second generation stem) there were signs of bone remodeling indicating to distal stress transfer in about half of the cases. In the ABG group (a HA-coated anatomic third-generation stem) slightly more signs of metaphyseal stress transfer were observed than in the straight stem group, but the prevalence was markedly lower than reported in previous studies. Tight diaphyseal fit and fill were clearly related to cortical hypertrophy of the diaphysis. Resorptive changes in the metaphysis appeared independently of metaphyseal fill, but metaphyseal hypertrophy was related to greater metaphyseal fill.

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REFERENCES

Aamodt A, Kvistadt KA, Andersen E, Lund-Larsen J, Eine J, Benum P, Husby OS (1999): Determination of the Hounsfield value for CT-based design of custom femoral stems. J Bone Joint Surg 81-B: 143-147

Ahmad I, Quddus A, Laine H-J, Yli-Harja O (2000): Image segmentation of the CT-scans of hip endoprostheses. Presented in 2000 IEEE Nordic Signal Processing Symposium, June 13 - 15, 2000, Norrköping, Sweden

Alho A, Hoiseth A, Husby T (1989): Bone-mass distribution in the femur. A cadaver study on the relations of structure and strength. Acta Orthop Scand 60: 101-104

Amstutz HC (1985): Arthroplasty of the hip. The search for durable component fixation. Clin Orthop 200: 343-361

Andrew TA, Flanagan JP, Gerundini M, Bombelli R (1986): The isoelastic, noncemented total hip arthroplasty. Preliminary results with 400 cases. Clin Orthop 206: 127-138

Ang KC, Das De S, Goh JCH, Low SL, Bose K (1997): Periprosthetic bone remodeling after cementless total hip replacement. A prospective comparison of two different implant designs. J Bone Joint Surg 79-B: 675-679

Bargar WL (1989): Shape the implant to the patient. A rationale for the use of custom-fit cementless total hip implants. Clin Orthop 249: 73-78

Bauer TW, Geesink RCT, Zimmerman R, McMahon JT (1991): Hydroxyapatite-coated femoral stems. Histological analysis of components retrieved at autopsy. J Bone Joint Surg 73-A: 1439-1452

Bobyn JD, Pilliar RM, Cameron HU, Weatherly GC (1980): The optimum pore size for the fixation of porous-surfaced metal implants by the ingrowth of bone. Clin Orthop 150: 263-270

Bobyn JD, Pilliar RM, Cameron HU, Weatherly GC (1981): Osteogenic phenomena across endosteal bone-implant spaces with porous surfaced intramedullary implants. Acta Orthop Scand 52: 145-153

Bobyn JD, Engh CA (1983): Biologic fixation of hip prostheses: Review of the clinical status and current concepts. Adv Orthop Surg 137-150

Bobyn JD, Glassman AH, Goto H, Krygier JJ, Miller JE, Brooks CE (1990): The effect of stem stiffness on femoral bone resorption after canine porous-coated total hip arthroplasty. Clin Orthop 261: 196-213

Bougault JJ, Argenson JN, Pizzetta M, Aubaniac JM (1993): A clinical and radiographic evaluation of 337 custom made prostheses: A one to six year follow-up study. J Bone Joint Surg 75-B (Suppl III): 258

Brien WW (1993): Design aspects of custom hips J Bone Joint Surg 75-B (Suppl III): 251

Brown TD, Ferguson AB (1980): Mechanical property distributions in the cancellous bone of the human proximal femur. Acta Orthop Scand 37: 429-437

Buhler DW, Berlemann U, Lippuner K, Jaeger P, Nolte LP (1997): Three dimensional primary stability of cementless femoral stems. Clin Biomech 12: 75-86

Burke DW, O´Connor DO, Zalenski EB, Jasty M, Harris WH (1991): Micromotion of cemented and uncemented femoral components. J Bone Joint Surg 73-B: 33-37

Burt CF, Garvin KL, Otterberg ET, Jardon OM (1998): A femoral component inserted without cement in total hip arthroplasty. J Bone Joint Surg 80-A: 952-960

Butel J, Robb JE (1988): The isoelastic hip prosthesis followed for 5 years. Acta Orthop Scand 59: 258-262

Callaghan JJ, Dysart SH, Savory CG (1988): The uncemented porous-coated anatomic hip prosthesis. Two year results of a prospective consecutive series. J Bone Join Surg 70-A: 337-346

Callaghan JJ, Fulghum CS, Glisson RR, Stranne SK (1992) The effect of femoral stem geometry on interface motion in uncemented porous-coated total hip prostheses. J Bone Joint Surg 74-A: 839-848

Cameron HU, Pilliar RM, MacNab I (1973) The effect of movement on the bonding of porous metal to bone. J Biomed Mater Res 7: 301-311

Cameron HU, Pilliar RM, MacNab I (1976): The rate of bone ingrowth into porous metal. J Biomed Mater Res 10: 295-302

Cameron HU (1994): The two- to six-year results with a proximally modular noncemented total hip replacement used in hip revisions. Clin Orthop 298: 47-53

Campbell ACL, Rorabek CH, Bourne RB, Chess D, Nott L (1992): Thigh pain after cementless hip arthroplasty. Annoyance or ill omen. J Bone Joint Surg 74-B: 63-66

Capello WN, Sallay PI, Feinberg JR (1994): Omniflex modular femoral component. Clin Orthop 298: 54-59

Capello WN, D´Antonio JA, Manley MT, Feinberg JR (1998): Hydroxyapatite in total hip arthroplasty. Clinical results and critical issues. Clin Orthop 355: 200-211

Chandler HP, Reineck T, Wixson RL, McCarthy JC (1981): Total hip replacement in patients younger than thirty years old. J Bone Joint Surg 63-A: 1426-1434

Chandler HP, Ayres DK, Tan RC, Anderson LC, Varma AK (1995): Revision total hip replacement using the S-ROM femoral component. Clin Orthop 319: 130-140

Chen P-Q, Turner TM, Ronningen H, Galante J, Urban R, Rostoker W (1983): A canine cementless total hip prosthesis model. Clin Orthop 176: 25-33

Christie M (1993): Pre and postoperative fit data of CAD-CAM hips J Bone Joint Surg 75-B Supp 251

Ciccotti MG, Rothman RH, Hozack WJ, Moriarty L (1994): Clinical and radiological evaluation of hydroxyapatite-augmented and nonaugmented porous total hip arthroplasty. J Arthroplasty 9:631-639

Clohisy JC, Harris WH (1999): The Harris-Galante uncemented femoral component in primary total hip replacement at 10 years. J Arthroplasty 14: 915-917

Collier JP, Mayor MB, Chae JC, Surprenant VA, Surprenant HP, Dauphinais LA (1988): Macroscopic and microscopic evidence of prosthetic fixation with porous-coated materials. Clin Orthop 235: 173-180

Collis DK (1984): Cemented total hip replacement in patients who are less than fifty years old. J Bone Joint Surg 66-A: 353-359

Comadoll JL, Sherman RE, Gustilo RB, Bechtold JE (1988): Radiographic changes in bone dimensions in asymptomatic cemented total hip arthroplasties. J Bone Joint Surg 70-A: 433-438

Cook SD, Barrack RL, Thomas KA, Haddad RJ (1988): Quantitative analysis of tissue growth into human porous total hip components. J Arthroplasty 3: 249-262

Cook SD, Thomas KA, Haddad RJ (1988): Histologic analysis of retrieved human porous-coated total joint components. Clin Orthop 234: 90-101

Cook SD, Thomas KA, Kay JF, Jarcho M (1988): Hydroxyapatite-coated porous titanium for use as an orthopedic biologic attachment system. Clin Orthop 230: 303-312

Cook SD, Thomas KA, Dalton JE, Volkman T, Kay JF (1991): Enhancement of bone ingrowth and fixation strength by hydroxylapatite coating porous implants. Orthop Trans 16: 550

Dai KR, An KN, Hein TJ, Nakajima I, Chao EY (1988): Geometric and biomechanical analysis of the human femur. Orthop Trans 10: 256

Dall DM, Grobbelaar CJ, Learmonth ID, Dall G (1986): Charnley low-friction arthroplasty of the hip. Long-term results in South Africa. Clin Orthop 211: 85-90

Dalton JE, Cook SD, Thompson KA, Kay JF (1995): The effect of operative fit and hydroxyapatite coating on the mechanical and biological response to porous implants. J Bone Joint Surg 77-A: 97-110

D´Antonio JA, Capello WN, Manley MT, Feinberg J (1997): Hydroxyapatite coated implants. Total hip arthroplasty in the young patient and patients with avascular necrosis. Clin Orthop 344: 124-138

Davy DT, Kotzar GM, Brown RH, Heiple KG, Goldberg VM, Heiple Jr KG, Berilla J, Burstein AH (1988): Telemetric force measurements across the hip after total arthroplasty. J Bone Joint Surg 70-A: 45-50

Donnelly WJ, Kobayashi A, Freeman MAR, Chin TW, Yeo H, West M, Scott G (1997): Radiological and survival comparison of four methods of fixation of a proximal femoral stem. J Bone Joint Surg 79-B: 351-360

Dujardin FH, Mollard R, Toupin JM, Coblentz A, Thomine JM (1996) Micromotion, fit, and fill of custom made femoral stems designed with an automated process. Clin Orthop 325: 276-289.

Eckrich SGJ, Noble PC, Tullos HS (1994): Effect of rotation on the radiographic appearance of the femoral canal. J Arthroplasty 9: 419-426

Eftekhar NS (1987): Long-term results of cemented total hip arthroplasty. Clin Orthop 225: 207-217

Engh CA (1983): Hip arthroplasty with a Moore prosthesis with porous coating: a five-year study. Clin Orthop 176: 52-66

Engh CA, Bobyn JD, Glassman AH (1987): Porous-coated hip replacement – The factors governing bone ingrowth, stress shielding, and clinical results. J Bone Joint Surg 69-B: 45-55.

Engh CA, Bobyn JD (1988): The influence of stem size and extent of porous coating on femoral bone resorption after primary cementless hip arthroplasty. Clin Orthop231: 7-28

Engh CA, Glassman AH, Suthers KE (1990): The case for porous-coated hip implants. Clin Orthop 261: 63-81

Engh CA, Massin P, Suthers KE (1990): Roentgenographic assessment of the biologic fixation of porous-surfaced femoral components. Clin Orthop 257: 107-128

Engh CA, McGovern TF, Bobyn JD, Harris WH (1992): A quantitative evaluation of periprosthetic bone-remodeling after cementless total hip arthroplasty. J Bone Joint Surg 74-A: 1009-1020

Engh CA, McGovern TF, Schmidt LM (1993): Roentgenographic densitometry of bone adjacent to a femoral prosthesis. Clin Orthop 292: 177-190

Engh Jr CA, Culpepper WJ, Engh CA (1997) Long-term results of use of the anatomic medullary locking prosthesis in total hip arthroplasty. J Bone Joint Surg 79-A: 177-184

Essinger JR (1993) A contourless custom hip designing process. J Bone Joint Surg 75-B Supp: 251

Feng Z, Ziv I, Rho J (1996) The accuracy of computed tomography–based linear measurements of human femora and titanium stem. Invest Radiol 31: 333-337

Freeman MAR, Plante-Bordeneuve P (1994): Early migration and late aseptic failure of proximal femoral prostheses. J Bone Joint Surg 76-B: 432-438

Furlong RJ, Osborn JF (1991): Fixation of hip prostheses by hydroxyapatite ceramic coatings. J Bone Joint Surg 73-B: 741-745

Galante J, Rostoker W, Lueck R, Ray RD (1971): Sintered fiber metal composites as a basis for attachment of implants to bone. J Bone Joint Surg 53-A:101-114

Galante JO, Jacobs J (1992): Clinical performance of ingrowth surfaces. Clin Orthop 276: 41-49.

Garcia-Araujo C, Fernandez Gonzales J, Tonino A and the International ABG Study Group (1998): Rheumatoid arthritis and hydroxyapatite-coated hip prostheses: five-year results. J Arthroplasty13: 660-667

Geesink RGT (1990) Hydroxyapatite-coated total hip prosthesis: 2-year clinical and roentgenographic results of 100 cases. Clin Orthop 261:39—58

Geesink RGT, Hoefnagels NHM (1995): Six-year results of hydroxyapatite-coated total hip replacement. J Bone Joint Surg 77-B: 534-547

Grelsamer R, Iorio R, Collier J, Haramati N, Williams I, Jensen R, Kidd K, Nercessian O, Eftekhar N (1993): The fit and fill of an intraoperatively customized stem – a CT and bone section analysis. J Bone Joint Surg 75-B (Suppl III): 252

Gruen TA, McNeice GM, Amstutz HC (1979): Modes of failure of cemented stem-type femoral components. Clin Orthop 141:17--27

Haddad RJ, Cook SD, Thomas KA (1987): Biological fixation of porous-coated implants. J Bone Joint Surg 69-A: 1459-1466

Haddad RJ, Skalley TC, Cook SD, Brinker MR, Cheramie J, Meyer R, Missry J (1990): Clinical and roentgenographic evaluation of noncemented porous-coated anatomic medullary locking (AML) and porous-coated anatomic (PCA) total hip arthroplasties. Clin Orthop 258: 176-182

Haddad RJ, Cook SD, Brinker MR (1990): A comparison of three varieties of noncemented porous-coated hip replacement. J Bone Joint Surg 72-B: 2-8

Havelin LI, Espehaug B, Vollset SE, Engesaeter LB (1995: Early aseptic loosening of uncemented femoral components in primary total hip replacement. J Bone Joint Surg 77-B: 11-17

Hayes DEE, Taylor JK, Paul HA, Bargar WL (1991): Errors of radiographic estimation of fit and fill of cementless femoral components. Orthop. Trans. 16: 533

Heekin RD, Callaghan JJ, Hopkinson WJ, Savory CG, Xenos JS (1993): The porous coated anatomic hip prosthesis, inserted without cement. J Bone Joint Surg 75-A: 77-91

Hozack WJ, Rothman RH, Eng K, Mesa J (1996): Primary cementless hip arthroplasty with a titanium plasma sprayed prosthesis. Clin Orthop 333: 217-225

Hua J, Walker PS (1993): A versatile hip design workstation-scientific rationale. J Bone Joint Surg 75-B Suppl: 251

Hua J, Walker PS (1994): Relative motion of hip stems under load. An in vitro study of symmetrical, asymmetrical and custom asymmetrical designs. J Bone Joint Surg 76-A: 95-103

Hua J, Walker PS (1995): Closeness of fit of uncemented stems improves the strain distribution in the femur. J Orthop Res 13: 339-346

Hughes SS, Furia JP, Smith P, Pellegrini VD (1995): Atrophy of the proximal part of the femur after total hip arthroplasty without cement. J Bone Joint Surg 77-A: 231-239

Huiskes R (1990): The various stress patterns of press-fit and cemented femoral stems. Clin Orthop 261: 27-38

Huiskes R, Weinans H, Rietbergen van B (1992): The relationship between stress shielding and bone resorption around total hip stems and effects of flexible materials. Clin Orthop 274: 124-134

Huiskes R (1993): Failed innovation in total hip replacement. Acta Orthop Scand 64: 699-716

Huiskes R, van Rietbergen B (1995) Preclinical testing of total hip stems. The effects of coating placement. Clin Orthop 319: 64-76

Hulbert SF, Young FA, Mathews RS, Klawitter JJ, Talbert CD, Stelling FH (1970): Potential of ceramic materials as permanently implantable skeletal prostheses. J Biomed Mater Res 4: 133-140

Husmann O, Rubin PJ, Leyvraz P-F, de Roguin B, Argenson J-N (1997) Three-dimensional morphology of the proximal femur. J Arthroplasty 12: 444-450

Iguchi H, Hua J, Walker PS (1996): Accuracy of using radiographs for custom hip stem design. J Arthroplasty 11: 312-321

Ilstrup DM, Nolan DR, Beckenbaugh RD, Coventry MB (1973): Factors influencing the results in 2012 total hip arthroplasties. Clin Orthop 95: 250-262

Jacobs JJ, Sumner DR, Caviglia HA, TM Turner, Urban RM, Galante JO (1989): A quantitative study of bone ingrowth into titanium total hip femoral components removed for reasons other than loosening. Orthop Trans 13: 524

Jacobsson S-A, Djerf K, Gillquist J, Hammerby S, Ivarsson I (1993): A prospective comparison of Butel and PCA hip arthroplasty. J Bone Joint Surg 75-B: 624-629

Jasty M, Henshaw RM, O´Connor DO, Harrigan TP, Harris WH (1988): Strain alterations in the proximal femur with an uncemented femoral prosthesis, emphasizing the effect of component fit. An experimental in vitro strain study. Orthop Trans 13: 335

Jasty M, O´Connor DO, Henshaw RM, Harrigan TP, Harris WH (1994): Fit of the uncemented femoral component and the use of cement influence the strain transfer to the femoral cortex. J Orthop Res 12: 648-656

Johnston RC, Fitzgerald RH, Harris WH, Poss R, Müller M, Sledge CB (1990): Clinical and radiographic evaluation of total hip replacement. J Bone Joint Surg 72-A: 161-168

Kärrholm J, Frech W, Nivbrant B, Malchau H, Snorrason F, Herberts P (1998): Fixation and metal release from the Tifit femoral stem prosthesis. 5-year follow-up of 64 cases. Acta Orthop Scand 69: 369-378

Kärrholm J, Malchau H, Snorrason F, Herberts P (1994): 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 76-A: 1692-1705

Kärrholm J, Snorrason F (1993): Subsidence, Tip, and Hump Micromovements of noncoated ribbed femoral prostheses. Clin Orthop 287: 50-60

Kasturi R, Jain R (1991): In: Computer Vision: Principles, pp. 65-76, IEEE Computer Society Press, Washington

Keaveny TM, Bartel DL (1993): Effects of porous coating and collar support on early load transfer for a cementless hip prosthesis. J Biomechanics 26: 1205-1216

Kendrick JB, Noble PC, Tullos HS (1995): Distal stem design and the torsional stability of cementless femoral stems. J Arthroplasty 10: 463-469

Kilgus DJ, Shimaoka EE, Tipton JS, Eberle RW (1993): Dual-energy x-ray absorptiometry measurement of bone mineral density around porous-coated cementless femoral implants. J Bone Joint Surg 75-B: 279-287

Kiratli BJ, Heiner JP, McBeath AA, Wilson MA (1992): Determination of bone mineral density by dual x-ray absorptiometry in patients with uncemented total hip arthroplasty. J Orthop Res 10: 836-844

Kim Y-H, Kim VEM (1992): Results of Harris-Galante cementless hip prosthesis. J Bone Joint Surg 74-B: 83-87

Kim Y-H, Kim VEM (1993): Uncemented porous-coated anatomic total hip replacement. J Bone Joint Surg 75-B: 6-14

Kim Y-H, Kim VEM (1994): Cementless porous-coated anatomic medullary locking total hip prostheses. J Arthroplasty 9: 243-252

Knight JL, Atwater RD (1992): Preoperative planning for total hip arthroplasty. J Arthroplasty 7: 403-409

Knight JL, Atwater RD, Guo J (1998): Clinical results of the midstem porous-coated anatomic uncemented femoral stem in primary total hip arthroplasty. J Arthroplasty 13: 535-545

Kröger H, Vanninen E, Overmyer M, Miettinen H, Rushton N, Suomalainen O (1997): Periprosthetic bone loss and regional bone turnover in uncemented total hip arthroplasty: A prospective study using high resolution single photon emission tomography and dual-energy x-ray absorptiometry. J Bone Miner Res 12: 487-492

Kröger H, Venesmaa P, Jurvelin J, Miettinen H, Suomalainen O, Alhava E (1998): Bone density at the proximal femur after total hip arthroplasty. Clin Orthop 352: 66-74

Lombardi AV, Mallory TH, Eberle RW, Mitchell MB, Lefkowitz MS, Williams JR (1995): Failure of intraoperatively customized non-porous femoral components inserted without cement in total hip arthroplasty. J Bone Joint Surg 77-A: 1836-1844

Lord GA, Hardy JR, Kummer FJ (1979): An uncemented total hip replacement. Clin Orthop 141: 3-16

Lord G, Bancel P (1983): The madreporic cementless total hip arthroplasty. New experimental data and seven-year clinical follow-up study. Clin Orthop 176: 67-76

MacAuley JP, Culpepper WJ, Engh CA (1998): Total hip arthroplasty. Concerns with extensively porous coated femoral components. Clin Orthop 355: 182-188

Maistrelli GL, Fornasier V, Binnington A, McKenzie K, Sessa V, Harrington I (1991): Effect of stem modulus in a total hip arthroplasty model. J Bone Joint Surg 73-B: 43-46

Malchau H, Herberts P, Ahnfelt L (1993): Prognosis of total hip replacement in Sweden. Acta Orthop Scand 64: 497-506

Malchau H, Herberts P, Wang YX, Kärrholm J, Romanus B (1996): Long-term clinical and radiological results of the Lord total hip prosthesis. J Bone Joint Surg 78-B: 884-891

Malchau H, Wang YX, Kärrholm J, Herberts P (1997): Scandinavian multicenter porous coated anatomic total hip arthroplasty study. J Arthroplasty 12: 133-148

Mankovich NJ, Robertson DD, Essinger J (1991): Measuring the accuracy of CT bone geometry for orthopedic implants. In: Computed Assisted Radiology, pp. 336-343. Ed. HU Lemke, Springer-Verlag, Berlin

Martell JM, Pierson RH, Jacobs JJ, Rosenberg AG, Maley M, Galante JO (1993): Primary total hip reconstruction with a titanium fiber-coated prosthesis inserted without cement. J Bone Joint Surg 75-A: 554-571

Massin P, Geais L, Astoin E, Simondi M, Lavaste F (2000): The anatomic basis for the concept of lateralized femoral stems. A frontal plane radiographic study of proximal femur. J Arthroplasty 15: 93-101

Mauerhan DR, Mesa J, Gregory AM, Mokris JG (1997): Integral porous femoral stem. 5- to 8-year follow-up study. J Arthroplasty 12: 250-255

McNally SA, Shepperd JA, Mann CV, Walczak JP (2000): The results at nine to twelve years of the use of a hydroxyapatite-coated femoral stem. J Bone Joint Surg 82-B: 378-382

Morscher EW, Dick W (1983): Cementless fixation of "isoelastic" hip endoprostheses manufactured from plastic materials. Clin Orthop 176: 77-87

Morrey BF (1989): Short-stemmed uncemented femoral replacement component. Clin Orthop 249:169-175

Morrey BF, Adams RA, Kessler M (2000): A conservative femoral replacement for total hip arthroplasty. A prospective study. J Bone Joint Surg 82-B: 952-958

Mulier JC, Mulier M, Brady LP, Steenhoudt H, Cauwe Y, Goossens M, Elloy M (1989): A new system to produce intraoperatively custom femoral prosthesis from measurements taken during the surgical procedure. Clin Orthop 249: 97-112

Mulliken BD, Nayak N, Bourne RB, Rorabeck CH, Bullas R (1996): Early radiographic results comparing cemented and cementless total hip arthroplasty. J Arthroplasty 11: 24-33

Munting E, Smitz P, Van Sante N, de Deuxchaisnes CN, Vincent A, Devogelaer J-P (1997): Effect of a stemless femoral implant for total hip arthroplasty on the bone mineral density of the proximal femur. J Arthroplasty 12: 373-379

Murray DW, Carr AJ, Bulstrode CJ (1995): Which primary hip replacement? J Bone Joint Surg 77-B: 520-527

Neumann L, Freund KG, Sorenson KH (1994): Long-term-results of Charnley total hip replacement J Bone Joint Surg 76-B: 245-251

Nies de F, Fidler MW (1996): The Harris-Galante cementless femoral components. Poor results in 57 hips followed for 3 years. Acta Orthop Scand 67: 122-124

Niinimäki TJ, Puranen JP, Jalovaara PKA (1994): Total hip arthroplasty using isoelastic stems. J Bone Joint Surg 76-B: 413-418

Nilles JL, Coletti Jr JM, Wilson C (1973): Biomechanical evaluation of bone-porous material interfaces. J Biomed Mater Res 7: 231-251

Noble PC, Alexander JW, Lindahl LJ, Yew DT, Granberry WM, Tullos HS (1988): The anatomic basis of femoral component design. Clin Orthop 235: 148-165

Noble PC, Kamaric E, Alexander JW (1988): Distal stem centralization critically affects the acute fixation of cementless femoral components. Orthop Trans 12: 383

Nunn D, Freeman MAR, Tanner KE, Bonfield W (1989): Torsional stability of the femoral component of hip arthroplasty. Response to an anteriorly applied load. J Bone Joint Surg 71-B: 452-455

Oh I, Harris WH (1978): Proximal strain distribution in the loaded femur. J Bone Joint Surg 60-A: 75-85

Ohl MD, Whiteside LA, McCarthy DS and White SE (1993): Torsional fixation of a modular femoral hip component Clin Orthop 287: 135-141

Owen TD, Moran CG, Smith SR, Pinder IM (1994): Results of uncemented porous-coated anatomic total hip replacement. J Bone Joint Surg 76-B: 258-262

Pal NR, Pal SK (1993): A review on image segmentation techniques. Pattern Recognition 26: 1277-1294

Pellegrini VD, Hughes SS, Evarts CM (1992): A collarless cobalt-chrome femoral component in uncemented total hip arthroplasty. J Bone Joint Surg 74-B: 814--821

Pilliar RM, Lee JM, Maniatopoulos C (1985): Observations on the effect of movement on bone ingrowth into porous-surfaced implants. Clin Orthop 208: 108-113

Poss R, Staehlin P, Larson M (1987): Femoral expansion in total hip arthroplasty. J Arthroplasty 2: 259-264

Pratt W (1991): Digital Image Processing. A Wiley-Interscience Publication, New York

Prevrhal S, Engelke K, Kalender WA (1999): Accuracy limits for the determination of cortical width and density: the influence of object size and CT imaging parameters. Phys Med Biol 44: 751-764

Pun T (1980): A new method for gray-level picture thresholding using the entropy of the histogram. Signal Processing 2: 223-237

Puolakka TJS, Laine H-J, Moilanen TPS, Koivisto A-M, Pajamäki KJ (2000): Alarming wear of the first generation polyethylene liner of cementless porous coated Biomet Universal cup. Acta Orthop Scand (in press)

Ragab AA, Kraay MJ, Goldberg VM (1999): Clinical and radiographic outcomes of total hip arthroplasty with insertion of an anatomically designed femoral component without cement for the treatment of primary osteoarthritis. J Bone Joint Surg 81-A: 210-218

Reuben J, Chang CH, Akin JE, Lionberger DR (1992): A knowledge-based computer-aided design and manufacturing system for total hip replacement. Clin Orthop 285: 48-56

Rhodes M, Kuo YM, Rothman S, Woznick C (1987): An application of computer graphics and networks to anatomic model and prosthesis manufacturing. IEEE Computer Graphics and Applications 7: 2-12

Rietbergen van B, Huiskes R, Weinans H, Sumner DR, Turner TM, Galante JO (1993): The mechanism of bone remodelling and resorption around press-fitted THA stems. J Biomechanics 26: 369-382

Robertsen K, Gaarden M, Teichert G, Langhoff O (1996): Results of the total Bi-metric cementless hip arthroplasty. Orthopedics 19: 673-674

Robertson DD, Essinger JR, Imura S, Kuroki Y, Sakamaki T, Shimizu T, Tanaka S (1996): Femoral deformity in adults with developmental hip dysplasia. Clin Orthop 327: 196-206

Robertson DD and Huang HK (1985): Quantitative bone measurements using x-ray computed tomography with second-order correction. Med Phys 13: 474-479

Robertson DD, Walker PS, Granholm JW, Nelson PC, Weiss PJ, Fischman EK, Magid D (1987): Design of custom hip stem prothesis using 3-D CT modelling. J Comput Assist Tomogr 11: 804-809

Robertson DD, Walker PS, Hirano SK, Zhou XM, Granholm JW, Poss R (1988): Improving the fit of press-fit hip stems. Clin Orthop 228: 134-40

Robertson DD, Taylor JK (1993): CT imaging of bone around metal implants: The state of the art. J Bone Joint Surg 75-B (Suppl III): 252-253

Robinson D, Hendel D, Halperin N (1994): Changes in femur dimensions in asymptomatic non-cemented hip arthroplasties. Acta Orthop Scand 65: 415-417

Robinson RB, Clark JE (1996): Uncemented pres-fit total hip arthroplasty using the Identifit custom-molding technique. A prospective minimum 2-year follow-up study. J arthroplasty 11: 247-254

Rosenthall L, Bobyn JD, Brooks CE (1999): Temporal changes of periprosthetic bone density in patients with a modular noncemented femoral prosthesis. J Arthroplasty 14: 71-76

Rosenthall L, Bobyn JD, Tanzer M (1999): Bone densitometry: influence of prosthetic design and hydroxyapatite coating on regional adaptive bone remodeling. Int Orthop 23: 325-329

Rossi P, Sibelli P, Fumero S, Crua E (1995): Short-term results of hydroxyapatite-coated primary total hip arthroplasty. Clin Orthop 310: 98-102

Rosson JW, Surowiak J, Schatzker J, Hearn T (1996): Radiographic appearance and structural properties of proximal femoral bone in total hip arthroplasty patients. J Arthroplasty 11: 180-183

Rothman RH, Hozack WJ, Ranawat A, Moriarty L (1996): Hydroxyapatite-coated femoral stems. A matched-pair analysis of coated and uncoated implants. J Bone Joint Surg 78-A: 319-324

Rubin PJ, Leyvraz PF, Aubaniac JM, Argenson JN, Esteve P, de Roguin B (1992): The morphology of the proximal femur. J Bone Joint Surg 74-B: 28-32

Ruff CB, Hayes WC (1982): Subperiosteal expansion and cortical remodeling of the human femur and tibia with aging. Science 217: 945-948

Sahoo P, Soltani S, Wong A (1988): A survey of thresholding techniques. Computer Vision, Graphics and Image Processing 41: 233-260

Sakalkale DP, Eng K, Hozack WJ, Rothman RH (1999) Minimum 10-year results of a tapered cementless hip replacement. Clin Orthop 362:138-144

Sandborn PM, Cook SD, Spires WP, Kester MA (1988): Tissue response to porous-coated implants lacking initial bone apposition. J Arthroplasty 3: 337-346

Schneider E, Kinast C, Eulenberger J, Wyder D, Eskilsson G, Perren S (1989): A comparative study of the initial stability of cementless hip prostheses. Clin Orthop 248: 200-209

Sharkey PF, Barrack RL, Tvedten DE (1998): Five-year clinical and radiographic follow-up of the uncemented Long-Term Stable Fixation total hip arthroplasty. J Arthroplasty 13: 546-551

Simonet JY, Argenson JN, Aubaniac JM (1993): The use of uncemented custom-made prostheses in high congenital dislocation of the hip. J Bone Joint Surg 75-B Suppl: 257

Skinner HB, Kilgus DJ, Keyak JS, Shimaoka EE, Kim AS, Tipton JS (1994): Correlation of computed finite element stresses to bone density after remodelling around cementless femoral implants. Clin Orthop 305: 178-189

Soballe K, Hansen ES, Brockstedt-Rasmussen H, Hjortdal VE, Juhl GI, Pedersen CM, Hvid I, Bünger C (1991) Gap healing enhanced by hydroxyapatite coating in dogs. Clin Orthop 272: 300-307

Soballe K, Brockstedt-Rasmussen H, Hansen ES, Bunger C (1992): Hydroxyapatite coating modifies implant membrane formation. Acta Orthop Scand 63: 128-140

Soballe K, Hansen ES, Brockstedt-Rasmussen H, Jorgensen PH, Bunger C (1992): Tissue ingrowth into titanium and hydroxyapatite-coated implants during stable and unstable mechanical conditions. J Orthop Res 10: 285-299.

Soballe K, Hansen ES, Brockstedt-Rasmussen H, Bunger C (1993): Hydroxyapatite coating converts fibrous tissue to bone around loaded implants. J Bone Joint Surg 75-B: 270-278.

Sotereanos NG, Engh CA, Glassman AH, Macalino GE, Engh Jr CA (1995): Cementless femoral components should be made from cobalt chrome. Clin Orthop 313: 146-153

Smith RW, Walker RR (1964): Femoral expansion in aging women: Implication for osteoporosis and fractures. Science 145: 156-157

Stulberg SD, Stulberg BN, Wixson R (1989): The rationale, design characteristics and preliminary results of primary custom total hip prosthesis. Clin Orthop 249: 79-96

Sugiyama H, Whiteside LA, Engh CA (1992): Torsional fixation of the femoral component in total hip arthroplasty. The effect of surgical press-fit technique. Clin Orthop 275: 187-193

Sullivan PM, MacKenzie JR, Callaghan JJ, Johnston RC (1994): Total hip arthroplasty with cement in patients who are less than fifty years old. J Bone Joint Surg 76-A: 863-869

Sutherland CJ, Gayou DE (1996): Artifacts and thresholding on X-ray CT of a cortical bone and titanium composite. J Comput Assist Tomogr 20: 496-503

Thanner J, Kärrholm J, Malchau H, Herberts P (1999): Poor outcome of the PCA and Harris-Galante hip prostheses. Randomized study of 171 arthroplasties with 9-year follow-up. Acta Orthop Scand 70: 155-162.

Tonino AJ, Romanini L, Rossi P, Borroni M, Greco F, Garcia-Araujo C, Garcia-Dihinx L, Murcia-Mazon A, Hein W, Anderson J (1995): Hydroxyapatite-coated hip prostheses. Early results from an international study. Clin Orthop 312: 211-225

Tonino AJ, Rahmy AIA and the International ABG Study Group (2000): The hydroxyapatite-ABG Hip System. 5- to 7-year results from an international multicentre study. J Arthroplasty 15: 274-282

Tullos HS, McCaskill BL, Dickey R, Davidson J (1984): Total hip arthroplasty with a low-modulus porous-coated femoral component. J Bone Joint Surg 66-A: 888-898

Viceconti M, Zannoni C, Pierrotti L, Casali M (1999): Spatial positioning of a hip stem solid model within the CT data set of the host bone. Comput Methods Programs Biomed 58: 219-226

Vresilovic EJ, Hozack WJ, Rothman RH (1994): Radiographic assessment of cementless femoral components. J Arthroplasty 9: 137-141

Walker PS, Schneeweis D, Murphy S, Nelson P (1987): Strains and micromotion of press-fit femoral stem prostheses. J Biomechanics 20: 693-702

Walker PS, Robertson DD (1988): Design and fabrication of cementless hip stems. Clin Orthop 235:25-34

Weinans H, Huiskes R, Grootenboer HJ (1994): Effects of fit and bonding characteristics of femoral stems on adaptive bone remodelling. J Biomech Eng 116: 393-400

Welsh RP, Pilliar RM, Macnab I (1971): Surgical implants. The role of surface porosity in fixation to bone and acrylic. J Bone Joint Surg 53-A: 963-977

Whiteside LA, Arima J, White SE, Branam L, McCarthy DS (1994): Fixation of the modular total hip femoral component in cementless total hip arthroplasty. Clin Orthop 298: 184-190

Whiteside LA, Easley JC (1989): The effect of collar and distal stem fixation on micromotion of the femoral stem in uncemented total hip arthroplasty. Clin Orthop 239:145-153

Wixson RL, Stulberg SD, Van Flandern GJ, Puri L (1997): Maintenance of proximal bone mass with an uncemented femoral stem analysis with dual-energy x-ray absorptiometry. J Arthroplasty 12:365--372

Woolson ST, Dev P, Fellingham LL, Vassiliadis A (1986): Three-dimensional imaging of bone from computerized tomography. Clin Orthop 202: 239-248

Woolson ST, Maloney WJ (1992): Cementless total hip arthroplasty using a porous-coated prosthesis for bone ingrowth fixation. J Arthroplasty 7: 381-388

Xenos JS, Callaghan JJ, Heekin RD, Hopkinson WJ, Savory CG, Moore MS (1999): The porous-coated anatomic total hip prosthesis, inserted without cement. J Bone Joint Surg 81-A: 74-82

Yee AJ, Kreder HK, Bookman I, Davey JR (1999): A randomized trial of hydroxyapatite coated prostheses in total hip arthroplasty. Clin Orthop 366: 120-132

Zerahn B, Storgaard M, Johansen T, Olsen C, Lausten G, Kanstrup I-L (1998): Changes in bone mineral density adjacent to two biomechanically different types of cementless femoral stems in total hip arthroplasty. Int Orthop 22: 225-229

ORIGINAL PUBLICATIONS (I – IV)