

Hydroxyapatite-coated uncemented hip stems and bone remodeling

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Hydroxyapatite-coated uncemented hip stems and bone remodeling

Hydroxyapatiet gecoate ongecementeerde heupprotheses en botremodellering

(met een samenvatting in het Nederlands)

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Chapter 1

General Introduction and thesis outline

General Introduction

Osteoarthritis of the hip is one of the most common joint disorders in the world, which is treated by total hip arthroplasty (THA) as one of the most cost-effective surgical procedures.¹

In the mid-nineteenth century the ankylosed hip joint was resected to produce extraarticular pseudarthrosis. But lasting mobility in a functional range could not be obtained with this approach.

In 1885 Ollier performed an early form of hip joint reconstruction with interpositional arthroplasty using soft tissue of the body. Later, other materials like muscle, joint capsule, fat, skin and fascia lata were tried.

In 1923 Smith-Petersen introduced the concept of "mould" arthroplasty as an alternative to the interpositional membrane. A piece of glass was moulded into the shape of a hollow hemisphere which could fit over the ball of the hip joint and provide a new smooth surface for movement. The glass could not withstand the stress of walking and quickly failed. After the development of Vitallium by Venable and Stuck in 1937, implants of sufficient durability became available. During the 1940's, mould arthroplasty was considered "state of the art."

However, this resurfacing technique provided insufficient pain relief and hip movement remained limited for many patients.

The Judet brothers (1952) used an acrylic material to replace arthritic hip surfaces, but fragmentation of the acrylic with wear resulted in severe tissue reaction, including bone destruction.²

Both Thompson and Moore developed metallic femoral head prostheses with medullary stems.³ Fixation of these implants was more or less by press-fit, resulting in severe bone resorption. The results remained unpredictable and arthritic destruction of the socket persisted, which focused attention on the need for resurfacing the acetabulum.

The metal-on-metal total hip arthroplasties that Urist, Ring, McKee-Farrar, and others designed were not satisfactory because friction and metal wear resulted in an unacceptably high incidence of loosening and pain.^{4,5}

Sir John Charnley was a pioneer in the development of all aspects of total hip arthroplasty. Charnley replaced an arthritic hip socket with a plastic cup and replaced the femoral head with a metal prosthesis and he introduced bone cement fixation for prostheses.⁶ This cold-curing acrylic bone cement (polymethylmethacrylate, or

PMMA) represented a major advance in fixation of the components. The method of allowing the metal femoral head component to slide smoothly inside the plastic cup surface worked rather well, with a long term survival rate that set a new standard in total hip replacement surgery.^{7,8}

Early cementing techniques involved finger-packing of a medullary cavity that was largely unprepared, but the current cementing technique includes the use of bone lavage, vacuum mixing during the preparation of bone cement, and femoral plugging with pressurization during the injection of bone cement. Significantly better, and even excellent, mid-to long- term results with these so called third generation cementing techniques have been reported in the literature.^{9,10,11}

Cementless total hip arthroplasty was introduced partly in the belief that periprosthetic osteolysis was mainly caused by “the cementing disease” and therefore could be eliminated by eliminating the need for cement.^{12,13}

But osteolysis is not unique to cemented femoral components, since in uncemented hip prosthesis polyethylene particles have been shown to be capable of causing resorption of bone and this may be the initiator of osteolysis. These particles cause a local macrophagic or sensitivity reaction, leading to the production of osteolytic mediators or local necrosis. (also called particle disease)¹⁴⁻¹⁷

In the 1980s non-cemented implants designed for immediate fixation with press-fit, macrofit, and porous-surface technology were developed.¹⁸⁻²⁰

These first-generation stems were designed for biological fixation at the diaphysis of the femur, but were associated with high rates of thigh pain, subsidence of the femoral component, aseptic loosening, and bone loss based on proximal stress shielding.^{21,22-30}

A second-generation cementless femoral component with a more anatomical metaphyseal fit and distal tapered design was developed.

Clinical results improved and in a meta-analysis of published reports on uncemented tapered stems, with a minimum of five year follow-up, an overall aseptic revision rate of 0.8% was documented.³¹ But also long term good survival rates have been reported (94.5% survival rate for the femoral component after 17 years³² and 87% after 22 years³³).

Bone and bone remodeling

Bone is a well organized and dynamic tissue. Bone presents in two forms: woven and lamellar bone. Immature woven bone is remodeled and structurally organized into

mature lamellar bone. Depending on the location in the skeleton and the loading pattern, lamellar bone presents as trabecular bone or cortical bone. Metabolic turnover of trabecular bone is eight times greater than that of cortical bone because it has a much larger surface area for cellular activity.^{34,35}

Trabecular bone has a mass four times lower than cortical bone and is also much less stiff. Chemically, bone consists of minerals, proteins, water, and other macromolecules. The inorganic or mineral phase of bone is composed of a calcium phosphate mineral analogous to crystalline calcium hydroxyapatite, and accounts for 60% to 70% of the tissue. Water accounts for 5% to 8% of the volume, and the organic matrix makes up the remainder.

Structural, mechanical and biochemical properties of bone are determined by the organic phase of the extracellular matrix. The organic matrix of bone mainly consists of type I collagen (90%). Other factors, like growth factors, cytokines and proteins have a large influence on the biological function and metabolism of bone.³⁶⁻⁴⁰ Cortical and trabecular bone are constantly remodeled to renew old bone and to reorganize trabecular structures to achieve the maximum strength obtainable with the bone mass available. Calcium homeostasis is also maintained by the remodeling process.⁴¹ With increasing age, bone mass diminishes as a result of negative bone remodeling balance. Formation rates remain constant while resorption rates increase, especially over the age of 40. Osteoclasts and osteoblasts work closely together in time and space, and these units are called Bone Multicellular Units (BMU).⁴²

Bone remodeling is influenced by patient factors like type-I diabetes, liver disease, kidney disease, a family history of osteoporosis or hyperthyroidism⁴³, while corticosteroids, various anti-seizure medications, certain barbiturates and high-dose thyroid replacement drugs are known to cause bone loss.⁴⁴⁻⁴⁶

So also in total hip arthroplasty it has been shown that gender influences the bone remodeling process⁴⁷ and that following cemented total hip arthroplasty, postmenopausal women loose more periprosthetic bone than men of the same age.⁴⁸

In the 19th century a theory of bone remodeling was developed by the German Anatomist/Surgeon Julius Wolff (1835-1902). Wolff's law states that bone in a healthy person or animal will adapt to the loads placed on it. If loading on a particular bone increases, the bone will remodel itself by the BMU's over time to become stronger to resist this loading (positive bone remodeling). In areas with diminished load the

skeleton retains only the amount of bone tissue necessary to sustain the diminished load (negative bone remodeling). The skeleton in the unloaded areas becomes weaker. This last process is called stress shielding or stress protection induced bone resorption. So when a prosthetic stem is inserted into a femur this will affect bone remodeling, because new stress patterns are created by the implant. Force or stress transmission depends on the shape of the bone cavity and design (geometry and stiffness) of the implant.⁴⁹⁻⁵¹ Immediately after total hip arthroplasty, periprosthetic bone resorption is noted for all kinds of implant designs. This behavior is typically observed during the first 6 months post-operatively or even later. Such early bone loss is probably due mainly to surgical trauma and reduced weight bearing during the post-operative and rehabilitation periods.^{48,52-56}

Stem design and bone remodeling

Proximal bone remodeling after insertion of a femoral stem is a complex phenomenon. It depends mainly on the mechanical properties of the bone and the geometry and stiffness of the stem as well as the fixation technique, stem size and length.⁴⁹

The role of stem design in cemented implants is different to that in uncemented stems since the bone-cement interface allows for full implant-bone force transmission according to the fit and fill principle.⁵⁷ The relatively thick cement mantle allows thinner and more flexible stems to be used.

Cementless fixation requires immediate press-fit stability of the implant to allow the osseointegration that will provide durable biological fixation.

The (thin) coating and need for direct press-fit stability requires a thicker (and stiffer) stem compared to cemented stems.

Stress shielding is caused by all stems, particularly in the calcar region, and its effects are in general more severe in fully ingrown stems, less severe in proximally ingrown stems and even milder in cemented stems because of the differences in stem rigidity and pattern of offloading.^{49,51,58,59} In general, after several years, proximally coated femoral components achieve a mid-stem fixation.⁶⁰⁻⁶²

The extent of bone remodeling also depends on the stem elasticity. The stiffer and larger the stem, the greater the bone resorption.⁴⁹⁻⁵⁰ Titanium stems have a lower modulus of elasticity, which is approximately one-third to one-half that of stainless steel and cobalt-chromium.⁶³ Stiff uncemented stems, especially those made of cobalt-chrome, cause more stress-shielding of the bone and tend to be associated with progressive bone loss proximally.⁶⁴

Short stem prostheses have therefore been designed, to provide the advantage of a bone-sparing technique of implantation, and with the expectation that the higher proximal load transfer will be beneficial.⁶⁵

Hydroxyapatite coating

Since the 1980s plasma-sprayed hydroxyapatite (HA) coatings have been introduced in orthopedics as surface coatings on metallic implants.^{66,67}

Plasma-sprayed hydroxyapatite coatings are able to bond directly to bone, promote fixation and enhance bone ingrowth.^{68,69} This may lead to a better and more reliable biological fixation and better sealing of the implant-bone interface against wear particles, increasing long-time survival.

The most widespread and successful use of hydroxyapatite-coated implants in arthroplasty has been with titanium, its alloy Ti-6Al-4V, and cobalt chrome alloy. Compared with cobalt chrome alloy, titanium demonstrated a 33% increase in bonding strength to a hydroxyapatite coating in vitro.⁶⁹

Provided that there is good overall implant stability, hydroxyapatite-coated implants can bridge bone deficiencies as wide as 2 mm, which is important since initial fit can never be complete.⁶⁶ In contrast, uncoated porous implants have demonstrated a fibrous interface in clinical retrieval studies.⁷⁰⁻⁷²

Studies have reported good to excellent results with hydroxyapatite-coated femoral stems with high survival rates and a low prevalence of thigh pain.⁷³⁻⁷⁶

However, in a prospective trial porous-coated stems with and without additional HA coating were compared and it was shown that a hydroxyapatite coating on a porous surface did not improve or diminish the results of total hip arthroplasty after mid-term follow-up.⁷⁷

Cemented and proximal HA-coated stems both provide secure fixation, but a trend in favor of HA in terms of fewer radiolucent lines, fewer lytic lesions, less proximal osteopenia, and longer survival has been published.⁷⁸ This should be especially important for young patients.

Anatomical, uncemented proximally HA-coated stem

The stems used in these studies are the ABG-I and ABG-II implant. The ABG-I implant® (Stryker, USA) is of anatomical design and made of the titanium alloy Ti-6Al-4V (E-Modulus 110 GPa) with a cervical diaphyseal angle of 135°. The proximal third is coated with a plasma-sprayed hydroxyapatite (HA) layer of $60 \pm 10 \mu\text{m}$ (Avg. \pm SD)

thickness with a maximum porosity of 2% and a shear strength of 62-65Mpa. The HA is meant to promote osseointegration in the proximal part. A macro-relief scaled surface on the HA-coated proximal third is designed to encourage stress transfer from implant to bone. There is 7° anteversion in the stem's metaphyseal portion and 5° anteversion of the neck, giving a total of 12° anteversion in the coronal plane. The stem is not polished distally but has a grit-blasted surface texture and tapers very slightly distally.

The ABG-II stem® (Stryker,USA) design (Fig.1.) is an evolutionary development to further enhance proximal stress transfer to reduce stress shielding in this critical region to favour improved bone remodeling. The ABG-II stem is made of a different titanium alloy (TMZF with E-Modulus 85 GPa instead of 110 GPa; ABG-I) and for a given size its length is shorter and the distal end polished to reduce or prevent distal stem osseointegration and consequent distal load transfer, as was observed with the ABG-I stem. The cervical-diaphyseal angle is reduced to 130° and some extra HA coating is added most proximally on the lateral shoulder.

Radiographic studies

The radiographical study of the hip consists of an anteroposterior (AP) and either a cross-table or externally rotated frog-leg lateral view.⁷⁹ For the AP radiograph the leg is internally rotated to accommodate femoral anteversion and to bring the femoral neck into a plane perpendicular to the anteroposterior x-ray beam.

Analysis of radiographs in patients who have an uncemented prosthesis is an important tool for investigating the response to the altered patterns of stress created by the device. To locate the periprosthetic bone changes evaluated by radiographs or DEXA, the Gruen zones are used.⁸⁰

Standard radiographs also allow the analysis of areas of stress shielding and transmission by monitoring radiographic phenomena associated with bone remodeling such as resorption, bone thickening or reactive line formation.⁸¹

DEXA

Measurement of bone mineral density (BMD) with central dual-energy X-ray absorptiometry (DEXA) is the current gold standard for diagnosing osteoporosis. DEXA measures the bone mineral content: (i.e.) the mass of mineral in a volume of bone, but not bone density (mass/volume). In the DEXA-scan, BMD is measured in gram/cm².

With DEXA bone densitometry the effectiveness of medical treatment of osteoporosis can be estimated, but it is also important and more precise for monitoring the bone remodeling process than on serial X-rays.⁸²

DEXA can quantify periprosthetic bone density changes with ca.5% error, but only if the areas under examination have a certain minimum size.⁸³ DEXA may identify bone loss at an earlier stage (>4.5% bone loss) and can also provide more quantitative information than conventional radiographs.

Prospective DEXA studies of bone remodeling around uncemented stems have revealed a rather consistent pattern. Bone mineral is lost in all Gruen zones but especially in the proximal Gruen regions up to six months or one year after the operation.^{49,84}

Using DEXA, higher bone mineral density values are seen around hydroxyapatite-coated implants compared with porous-coated stems of the same geometry, after 5 to 7 years.⁸⁵ The effect of bone loss secondary to remodeling is not yet clear, especially in the long term. Continuous bone resorption may jeopardize the ingrowth and stability of the implant.

Preoperative bone quality has been shown to be a major factor influencing bone loss around a newly inserted femoral stem.⁴⁷ Patients with a low preoperative BMD risk more bone loss near the prosthesis. Women have an increased risk of losing periprosthetic bone compared to men.^{47,86} To prevent bone loss, medication like biphosphonate drugs may play a role in the future, since it has been shown that biphosphonate drugs can reduce or even avoid periprosthetic bone loss following THA.⁸⁷

Histology

Hydroxyapatite (HA) coatings on stems for uncemented total hip arthroplasty (THA) promote the ongrowth of bone through osteoblasts, but at the same time is also exposed to osteoclastic resorption driven by stress shielding.^{66,88-90}

However, these two opposite processes do not work in the same postoperative period. While the in growth is immediate postoperatively and of short duration, the stress shielding induced bone resorption starts only after the biological fixation of the implant and is longstanding.

There are two different types of retrieval studies of hydroxyapatite-coated femoral stems: revision and autopsy. Stems acquired during revision surgery have shown dissolution and delamination of the hydroxyapatite coating.⁶⁸ It has been suggested that hydroxyapatite particulate material could cause an inflammatory tissue response

and osteolysis.⁹¹ However, Bauer et al showed that the problem of third body wear is not greater with hydroxyapatite coated implants than with porous coated implants or with implants inserted with cement.⁹²

On the contrary, retrieval studies on autopsy-retrieved stems showed a uniform coating of hydroxyapatite on the stem with extensive direct apposition of the bone. In these post-mortem retrieval studies there was no evidence of delamination of the hydroxyapatite coating, formation of a fibrous membrane, inflammation or necrosis.^{67,93-96} Divers histological studies showed that resorption of the HA-coating is cell-mediated and dependent on bone remodeling processes.⁹⁷⁻⁹⁹

Revision

Aseptic loosening and dislocation are still the two primary reasons for revision of implanted components.

Periprosthetic fractures (PPF) have become the third most common reason for revision after total hip arthroplasty,¹⁰⁰ since periprosthetic femoral fractures have become more common as the population of at risk patients with joint arthroplasty has increased. The number of PPF is somewhat elevated in uncemented hip prostheses.¹⁰¹ The estimated prevalence of post-operative periprosthetic femoral fractures in the literature ranges from 0.1 to 2.1%, but this usually concerns cemented hip prostheses.^{102,103}

Research questions and approach

Mechanical properties of the bone, fixation technique, geometry and stiffness of the stem, stem size and length, fit of the prosthesis and patient factors are all known to influence the periprosthetic bone remodeling process after total hip arthroplasty. Proximal bone resorption in uncemented stems has been described which may lead to a higher revision rate and a more difficult revision because of the lack of bone stock. These are the reasons to analyze the bone remodeling process and the factors influencing into more detail.

Therefore we formulated the following questions, which will be addressed in this thesis:

Question 1) What are the characteristics of the bone remodeling pattern around a hydroxyapatite-coated hip prosthesis and can the theoretical benefits of the design changes in the successor generation (ABG-II), aimed at improving proximal bone preservation, be validated clinically?

Question 2) Does preoperative bone quality significantly influence the bone remodeling around a specific HA-coated hip prosthesis?

Question 3) Is the fit and fill ratio of a HA-coated hip implant a critical factor concerning bone remodeling and clinical results?

Question 4a) Is the resorption of HA coating and bone ongrowth mainly correlated with time in vivo or with demographics, and when time in vivo is predominant, at which point can we expect that all HA is gone?

Question 4b) Are HA resorption and/or the amount of bone ongrowth correlated with each other or rather related to the metaphyseal stem level?

Question 4c) What happens to the implant-bone interface when all hydroxyapatite coating is resorbed?

Question 5a) Bone remodeling patterns have been shown to differ between cemented and uncemented implants. Does this difference in bone remodeling pattern also influence the morphology of fractures around this uncemented stem?

Question 5b) Is there an increased periprosthetic femoral fracture rate for this hydroxyapatite-coated hip prosthesis compared to the cemented stems?

Question 5c) Does the diagnostic and treatment protocol established for periprosthetic fractures of cemented stems (Vancouver classification) also apply to uncemented stems?

Approach

In **chapter 2** a prospective study is presented in which 51 patients were randomized to either the ABG-I or ABG-II hip prosthesis. Periprosthetic bone loss around ABG-I was compared with that around ABG-II, and periprosthetic BMD change at various time-points was measured using DEXA.

In **chapter 3** a retrospective study was performed in which patients were matched for preoperative bone quality. 24 ABG-II patients were compared with two different ABG-I groups: A) 25 patients from our earlier prospective study and B) 24 patients selected to match perfectly the ABG-II group for gender, age and preoperative bone quality. Post-operative changes in periprosthetic bone mineral density (BMD) were quantified at 2 years post-operative using DEXA.

In **chapter 4**, we analyzed a consecutive series of 64 patients with an ABG-II stem, to see whether the relation of fit and fill of the prosthesis affected bone remodeling and clinical results.

In **chapter 5**, a histological and histomorphometrical study is presented which evaluates bone ongrowth and HA residue on hip stems of one single design (ABG-I) retrieved at post mortem.

To evaluate this interface, a histological and histomorphometric examination of the femoral components and the surrounding bone was performed in thirteen cadaver specimens, which had been recovered between 3.3 to 11.2 years after primary total hip arthroplasty using a proximal hydroxyapatite (HA)-coated titanium alloy implant of a single design.

In **chapter 6**, a retrospective study was done: In a series of 619 HA-coated hip implants (ABG-I), carried out between 1990 and 1997, 14 periprosthetic fractures were encountered. Fracture patterns are described and compared to cemented implants and other uncemented stems. The fracture rate is compared to the literature for cemented and uncemented stems. Our treatment is retrospectively compared to the treatment protocol established for periprosthetic fractures of cemented stems (Vancouver classification).

In **chapter 7**, the questions are answered and in **chapter 8** a summary of this thesis is given and the results are being discussed.

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Chapter 2

The influence of implant design on periprosthetic bone remodeling of two types of uncemented HA-coated hip stems. A two-year follow-up study using DEXA.

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Abstract

Proximal bone resorption and an increased fracture rate in the ABG-I stem has been shown. These were reasons why ABG-I stem design was changed into ABG-II. In this study periprosthetic bone loss around ABG-I vs. ABG-II is compared to verify if the design changes resulted in improved proximal bone preservation.

51 patients were randomized to either the ABG-I or ABG-II hip prosthesis. Periprosthetic BMD change at various time points was measured using DEXA. Between the two groups (age, gender, weight etc) no statistical difference was encountered.

Compared to the baseline at 2 years ABG-II preserved bone better proximally (e.g. zone 7: ABG-II: -3.7%, ABG-I:-11.9%, $p=0.05$) than ABG-I. Distally, the trend was opposite and less bone loss was measured for the ABG-I than the ABG-II in zones 3, 4 and 5 (n.s.).

This study confirms the philosophy behind the design changes from the ABG-I to ABG-II-stem where increased elasticity, more proximal HA-coating, a shorter and distally polished stem, was meant to reduce proximal bone resorption. In future this might lead to less periprosthetic fractures and to less complicated revision surgery.

Introduction

Immediately after THA surgery periprosthetic bone resorption is noted for all implant designs, a typical behavior commonly observed during the first 6 months postoperatively or even longer.^{1-4,5-10} Such early bone loss is probably mainly due to the surgical trauma and the reduced weight bearing during the post-operative time and rehabilitation.¹¹ After 6 months, it must be assumed that only the design of the prosthesis will determine the intensity and location of the bone remodeling.

The stress-related changes in bone mass of the proximal femur following cementless total hip arthroplasty, and especially stress shielding phenomenon, have already been recognized a long time by Engh and Bobyn.¹¹ To reduce stress shielding and periprosthetic bone loss, proximal fixation and load transfer are indicated.¹² Therefore second-generation cementless femoral components were designed in this way to provide more reliable ingrowth and to limit distal osteolysis by incorporating circumferential proximal ingrowth surfaces.

The Anatomic Benoist Girard (ABG-I) is a proximally hydroxyapatite (HA)-coated uncemented hip prosthesis designed for proximal stem fixation and stress transfer. Despite reliable proximal osseointegration¹ there is evidence for augmented distal load transfer manifested by distal cortical thickening in the ABG-I. This has been demonstrated in clinical series as well as by histological analysis and scintigraphy studies.^{1,13,14 15-17}

Proximal bone resorption may not pose a problem to the prosthetic's short-term stability, but a somewhat elevated periprosthetic fracture rate in ABG-I stems has already been shown.¹⁸ Also it may render a potential revision surgery more difficult. However most osteolysis is particle induced and this is still by far the most important factor in long term aseptic loosening, especially for the acetabular component. These observations together with the unusual taper design of ABG-I, led to the decision to modify ABG-I. The aim of this study was to compare the periprosthetic bone loss around ABG-I and ABG-II stem over a 2 year period, to verify if the design changes did result in improved proximal bone preservation as intended.

Material and Methods

Patients

This study was approved by the medical ethical committee of the Atrium Medical Center Heerlen, the Netherlands. Informed consent was obtained from all patients and they were randomized to either ABG-I or ABG-II. Patients were blindly randomized and before operation they had to retrieve one of the envelopes. In the operation

theatre the envelope was opened at the morning of the operation and accordingly either an ABG-I or ABG-II stem was implanted.

Fifty-one patients (22F, 29M, mean age: 60.8 years, range: 46-68 years) undergoing primary THA were included. The ABG-I group consisted of 8F/17M with a mean weight of 77.5 kg and mean age of 61.7 years, while the ABG-II group consisted of 14F/12M with a mean weight of 82.8 kg and mean age of 60.1 yrs. The mean Merle d'Aubigne (MdA) hip score of the ABG-I group was 10.5 pre-operatively and 10.0 for the ABG-II group. MdA scores were acquired at the outpatient center by an orthopaedic surgeon or a resident in orthopaedic surgery.

There were no significant differences between the groups comparing age, gender weight and preoperative MdA score. Index diagnosis for the ABG-I group was osteoarthritis in 22 patients, avascular head necrosis in one patient, rheumatoid arthritis in one patient and morbus Paget in one patient. Index diagnosis for the ABG-II group was osteoarthritis in 22 patients, post-traumatic arthritis in 2 patients and rheumatoid arthritis in 2 patients. Co morbidity in the ABG-I group consisted of 7 patients having a cardiac disease and 2 patients having an endocrine disease. In the ABG-II group co morbidity consisted of 4 patients having a cardiac disease, one patient having an endocrine disease and 5 patients having a hepatic disease. None of all these patients used medication affecting bone metabolism.

The prosthesis

The ABG-I implant® (Stryker, from Caen, France) is of anatomical design (Fig.1.) and made of the titanium alloy Ti-6Al-4V (E-Modulus 110 GPa) with a cervical diaphyseal angle of 135°. The proximal third is coated with plasma sprayed hydroxyapatite (HA) layer of $60 \pm 10 \mu\text{m}$ (Avg. \pm SD) thickness with a maximum porosity of 2% and a shear strength 62-65Mpa. The HA is meant to promote osseointegration in the proximal part and therefore mainly proximal stress transfer. A macro-relief scaled surface present on the HA coated proximal third was designed to encourage stress transfer from implant to bone via vertical compression instead of shear. There is an area of transition between the coated metaphysis and the non-coated diaphysis of the stem to prevent chipping of the HA during insertion. In order to obtain proximal rotational stability, regardless of diaphyseal fill, there is 7° anteversion in the stem's metaphyseal portion and 5° anteversion of the neck, giving a total of 12° anteversion in the coronal plane. The stem is not polished distally but has a grit-blasted surface texture and tapers very slightly distally to transmit compression forces to the bone.

The ABG-II stem® (Stryker, from Caen, France) design (Fig. 1) is an evolutionary development to further enhance proximal stress transfer to reduce stress shielding in this critical region in favor of improved bone remodeling. The ABG-II stem is made of a different titanium alloy (TMZF with E-Modulus 85 GPa) and for a given size its length is shorter and the distal end polished to reduce or prevent distal stem osseointegration and by that distal load transfer as was observed with the ABG-I stem. The cervical-diaphyseal angle is reduced to 130° and the taper is standardized to V40. Some extra HA coating is added most proximally on the lateral shoulder.



Fig. 1: Stryker ABG-I (left) in comparison to the Stryker ABG-II (right) implant made of a low modulus titanium alloy and having a shorter, small diameter polished stem, increased proximal HA coating and neck lateralization (135° vs. 130°)

Surgery

Patients were operated by either an orthopaedic surgeon or an orthopaedic surgeon in training. At least 5 different surgeons performed operations within the study. The surgical approach was straight lateral in all cases and reaming was not done, since the ABG-stem has an anatomical press fit. Preoperatively templating had been performed in all cases and broaching with increasing stem sizes was done until there was a good fixation of the stem. Bone defects which needed allografting were not encountered in this series.

BMD measurements

Using dual energy radiographic absorptiometry (DEXA), even small changes in bone mineral density (BMD) can be accurately detected near the prosthesis.³

BMD measurements were performed using a QDR-2000plusDXA bone densitometer (Hologic Inc, Bedford, Mass., USA). Preoperative scans were acquired of the posteroanterior (PA)(L1-L4) and lateral (L2-L4) lumbar spine, the contralateral hip (femoral neck, trochanter, intertrochanteric, total hip and Ward's triangle sites) and the non-dominant distal forearm (ultra-distal, mid-, one-third and total radius sites). Postoperative DEXA scans were performed to measure BMD in periprosthetic bone at 10 days (treated as baseline for subsequent follow-up), six weeks, and 3, 6, 12, and 24 months after THA. The patient's leg was positioned in a foam bag to control rotation.¹⁹ The scans were analyzed using the manufacturer's metal exclusion software with a template to create seven Gruen zones that was manually adjusted to the anatomy of each individual. BMD was measured laterally (Gruen zones 1, 2 and 3) and medially (Gruen zones 5, 6 and 7) around the stem of each prosthesis, and also 1 cm distally to the tip of the stem (Gruen zone 4). The seven Gruen zones are widely accepted for the radiological and densitometric evaluation of THA.²⁰ Measurements of all seven Gruen zones were combined to give the total periprosthetic BMD. The manufacturer's scan comparison software was used to transfer the Gruen zones regions of interest (ROIs) onto the follow-up scans of each individual with care taken in patient positioning and scan analysis to ensure that the area measured coincided as closely as possible with the baseline postoperative scan. The coefficient of variation (CV) of the BMD measurements varied between 1.4% and 4.1% according to the Gruen zone assessed, with an overall figure of 2.4%.¹⁹ Results were expressed as the percentage change from baseline and the data examined for the differences in bone loss between the different Gruen zones, between the ABG-I and ABG-II stems and the relationship with preoperative BMD.

Follow-up

Clinical Merle d'Aubigne (Mda) hip scores were evaluated at the same moment of BMD measurements, while postoperative X rays were measured for stem position. The position of the stem was considered to be in varus or valgus when it showed a deviation of $> 2^\circ$ from the anatomic axis of the femur.

Postoperatively patients were allowed partially weight bearing with crutches during the first 4 weeks, and then to progress to full weight bearing over the next 8 weeks. Migration of the femoral component was measured as the change in vertical distance

between the lateral shoulder of the stem to the most medial point of the lesser trochanter and noted when exceeding a value of 5mm.

No subsidence at two years was encountered in this series. In the ABG-I group 8 patients had a leg length difference preoperatively ranging from 10 mm to 25 mm. In all cases this was restored to zero, as measured on the postoperative X-rays. Only one patient in this group had a leg length difference postoperatively (7 mm). In the ABG-II group 5 patients had a leg length difference preoperatively ranging from 8 mm to 30 mm. In 4 patients leg length was completely restored and in one patient leg length difference was decreased from 30 mm to 8 mm. Three patients had a postoperative leg length difference: 3 mm, 5 mm and 8 mm respectively.

Results

A total of 51 patients (25 ABG-I, 26 ABG-II) completed the study. The mean Merle d'Aubigne (Mda) hip score of all patients combined was 10.3 pre-operatively and increased to 17.1 one year post-operatively and 17.2 two years post-operatively. There was no statistically significant difference between the ABG-I and ABG-II groups with regards to pre-operative Mda (10.5 and 10.1), the one year post-operative score (17.0 and 17.1) and two year post-operative score (17.0 and 17.4). The average improvement of the Mda from the pre-operative level to the 2 year data was higher for ABG-II (7.5) than for the ABG-I (6.5) but not significantly different in a two-tailed student t-test ($p=0.15$).

The mean stem size used for the ABG-I implant was 3.6 (range 2-5) and 3.5 (range 1-5) for the ABG-II ($n.s.p>0.05$), implying that the fit/fill configuration was of the same size and order for both stems. Stem alignment of both implants were also not significantly different with varus positions ($>2^\circ$) recorded in 48.0% for the ABG-I stems and 46.1% for the ABG-II stems ($p>0.05$). None of the stems showed subsidence during the postoperative radiographic control and stem alignment was the same at the two year follow up as it was at the first postoperative radiographs.

The average BMD decline during the first three months post-operatively was steep and very similar for most patients for all Gruen zones and for both implant types (Fig. 2, Fig. 3). The mean drop in total BMD during the first 3 postoperative months was -5.6% for the ABG-I patients (1.555 g/cm² to 1.469 g/cm²) and -5.2% for the ABG-II patients (1.502 g/cm² to 1.423 g/cm²) with no statistically significant difference between the implants ($p=0.37$). The standard deviations calculated for BMD measurements at three months were relative to the mean values only half as low as calculated at the two year follow-up point.

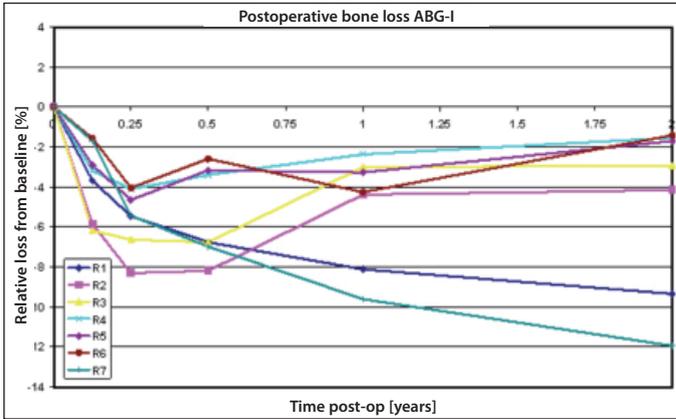


Fig. 2: Mean periprosthetic bone loss from baseline for each Gruen zone (ABG-I stem).

R1 = Gruen zone 1, R2 = Gruen zone 2 etc.

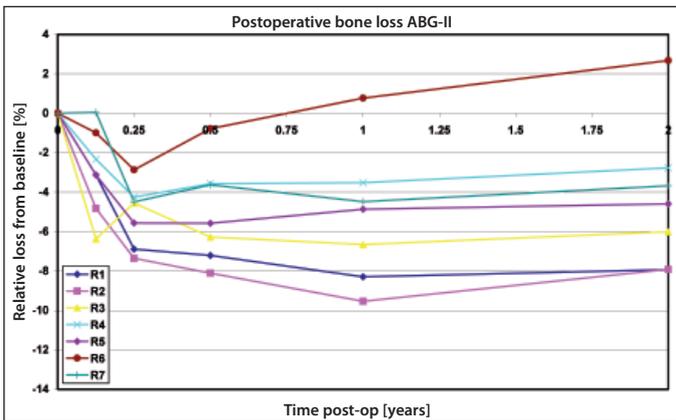


Fig. 3: Mean periprosthetic bone loss from baseline for each Gruen zone (ABG-II implant).

R1 = Gruen zone 1, R2 = Gruen zone 2 etc.

Analyzing the Gruen zones individually (Fig. 4) revealed that the regions of maximum and minimum BMD decline during the first three months were the same for both implants with the highest BMD losses recorded for zone 2 (ABG-I: -8.3%, ABG-II: -7.4%, $p=0.39$, n.s.) and the lowest BMD losses seen in zone 6 (ABG-I: -4.0%, ABG-II: -2.9, $p=0.31$, n.s.).

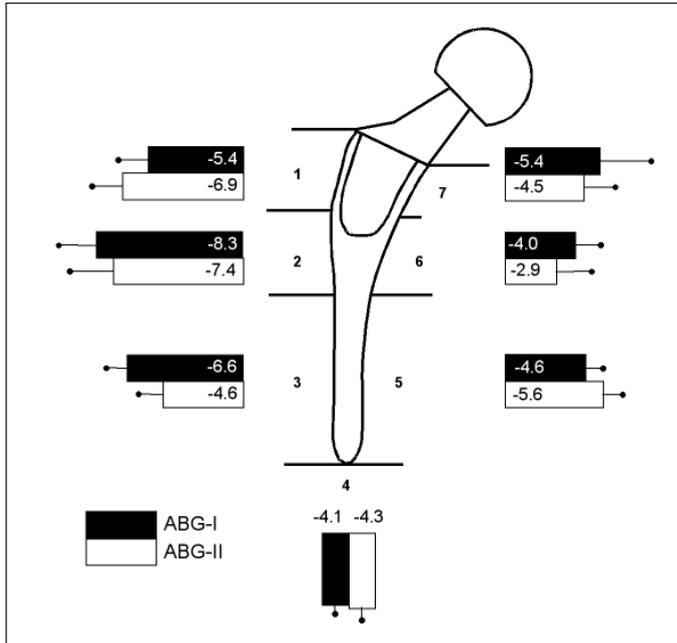


Fig. 4: Percentage bone loss from baseline at 3 months post-op (mean \pm SEM)

After 3 months and up to 24 months post-operatively, in the mid-stem Gruen zones 2 and 6 and the distal zones 3, 4 and 5, the BMD decline either stopped and formed a plateau or even showed some recovery in both the ABG-I and II groups (**Fig. 2, Fig. 3**). Only in the proximal Gruen zones 1 and 7 a continuous decline beyond 6 months post-operatively was measured for both implants. However in the ABG-II group this BMD decline seemed to form a plateau after one year, while for the ABG-I implant the decline continued towards the two year follow-up.

Like at three months follow-up, at two years the total BMD decline for all Gruen zones combined was not different between both ABG implants (ABG-I: -4.0%, ABG-II: -4.1%, $p= 0.47$, n.s.). However analyzing the distal and proximal Gruen zones separately clearly showed different bone preserving potentials for the two ABG hips.

In the proximal Gruen zones 1 and 7 bone mineral density around the ABG-II implant developed a plateau or even showed some recovery at one year post-op while BMD in the ABG-I group continued to decline in regions 1 and 7 (**Fig. 2 vs. Fig. 3, Fig. 5**).

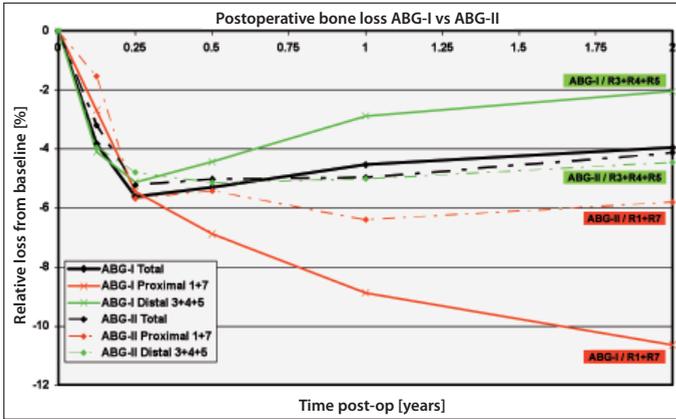


Fig. 5: Mean periprosthetic bone loss from baseline for distal, proximal and all Gruen zones combined.

R1 = Gruen zone 1, R2 = Gruen zone 2 etc.

While bone loss at two years post-op was only -3.7% for ABG-II in zone 7, it was for -11.9% for the ABG-I ($p=0.05$). In Gruen zone 1 the difference was not as pronounced but the trend of better proximal bone preservation of the ABG-II stem was confirmed with a BMD loss of -7.9% for the ABG-II and -9.3% for ABG-I ($p=0.35$, **Fig. 6**).

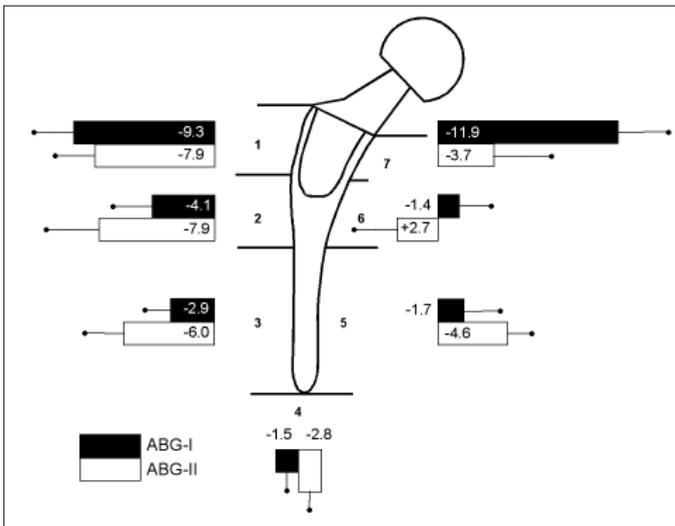


Fig. 6: Percentage bone loss from baseline at 2 years post-op (mean ± SEM)

In the distal Gruen zones 3, 4 and 5 comparing bone loss between ABG-I and II revealed the opposite trend. The reduction in BMD at two years post-op was less in ABG-I than ABG-II in all distal regions. In Gruen zone 3 BMD loss in the ABG-I group was only -2.9% but -6.0% with the ABG-II ($p=0.16$). In zone 4 the difference was not as high (ABG-I: -1.5% vs. ABG-II: -2.8%, $p=0.25$), but in zone 5 the difference was again more pronounced favouring the ABG-I (ABG-I: -1.7% vs. ABG-II: -4.6%, $p=0.15$, **Fig. 6**)

In the mid-stem zones 2 and 6 (**Fig. 7**) ABG-I showed better bone preservation than ABG-II in the lateral Gruen zone 2 (ABG-I: -4.2% vs. ABG-II: -7.9%, $p=0.19$, Fig. 6) but in the medial zone 6 ABG-II preserved bone better with the only positive BMD change from baseline observed (ABG-I: -1.4% vs. ABG-II: +2.7%, $p=0.13$, **Fig. 6**).

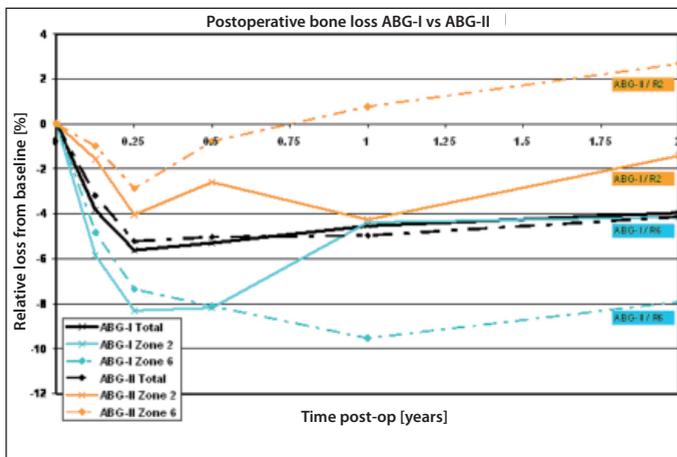


Fig. 7: Mean periprosthetic bone loss for the mid-stem Gruen zones 2 and 6 in comparison to the total BMD loss

In all zones, the proximal, mid-stem and distal regions the relative standard deviations at two-year follow-up were nearly twice as high as at three months.

In short, ABG-I loses most bone proximally (most medial at the calcar region), whereas ABG-II loses most bone laterally midstem.

Discussion

Cortical stress shielding as a qualitative phenomenon is caused by all stems, particularly in the calcar region. Quantitatively, stress shielding effects differ with each type of fixation used. Stress shielding effects are severe in fully ingrown stems and less in proximally ingrowth stems because of the differences in stem rigidity.^{12, 21-23}

Stress shielding induced bone resorption in uncemented THA is mainly observed proximally and has been described in the ABG-I hip prosthesis by several authors.^{1, 13-17}

However these descriptions were based on serial X-ray interpretations, which are by no means accurate, but a rather crude way to interpret BMD changes.

While radiographically it looks as if bone condensation or new bone formation takes place even before bone resorption is noted, we know now from DEXA studies that periprosthetic bone resorption occurs in all Gruen zones early postoperatively.^{1-3, 24}

These stress induced changes of the periprosthetic bone mostly occur during the first two to three years. Long term bone loss after THA is mainly influenced by particulate induced osteolysis, which is morphologically a total different process.

Other factors which influence the bone remodeling process are patient-related factors like sex, quality of bone and preoperative BMD², but also the extent of HA-coatings have their influence.^{23, 25}

The extent of bone remodeling also depends on the stem elasticity. The stiffer and larger the stem, the greater the bone resorption, as described in an experimental canine model using DEXA²¹ and several clinical studies using stems with large difference of rigidity.^{22, 26}

Our study was undertaken to investigate the differences in regional adaptive femoral bone remodeling between the ABG-I and ABG-II hip design. Because remodeling of the proximal femur after a cementless hip arthroplasty mainly takes place during the first two postoperative years²⁷, we report our first results after a two year follow-up.

The different patient groups were randomized regarding the clinical parameters and the groups did not significantly differ regarding gender, age, weight and the MDA score preoperatively, at one and at two years postoperatively. Also the mean stem size, the fit and fill configuration and the alignment did not differ significantly for both groups. Despite of different starting BMD, the total BMD change of all zones combined (percentage decline from baseline) was the same for ABG-I and ABG-II at three months and notably also at 2 years. The steep BMD decline at three months was even the same

for both implants regarding each zone individually. This confirms the statement that the remodeling during the first three months is most probably determined by the surgical trauma and restricted weight bearing than to the altered local patterns of stress transfer.

However, beyond three months, when hip function is restored bone resorption and new bone formation depend on the mechanical stimulus caused by different implant designs as verified in this study for even relatively small but specific design differences. The ABG-II preserves the BMD better proximally (Gruen zones 1 and 7) though at the expense of higher distal bone loss (Gruen zones 3,4,5) where the ABG-I preserves bone better.

The mid-stem region was noticed as a transition zone between the better proximal bone preservation of the ABG-II and the better distal bone preservation of the ABG-I. However, patients were not matched by preoperative bone quality so that the starting BMD of the patient groups were different with higher mean densities recorded for the ABG-I (1.555g/cm^2) than for the ABG-II (1.502g/cm^2) partly due to different gender (M/F) ratios between both groups (ABG-I: 2.1, ABG-II: 0.9). While this study was going on our research group discovered that preoperative BMD is a major factor influencing bone loss around a newly inserted uncemented femoral stem.²

However, prosthetic design remained a statistically significant factor influencing periprosthetic bone loss even after controlling for the effects of preoperative BMD and gender.

In this study patients were not matched for preoperative BMD and gender, which may explain our high standard deviations and lack of significance at $p=0.05$.

Although in this study the patients had lower values of initial bone loss at three months compared to a previous study², the trend in bone loss per zone is the same after 3 months and after two years. The less BMD loss at three months in this series can be explained by a different gender distribution and by the fact that patients have not been matched by preoperative bone quality and starting BMD.

While the ABG-II is made of a titanium alloy TMZF (E-Modulus 85 GPa), the ABG-I[®] (Stryker, from Caen, France) is made of the titanium alloy Ti-6Al-4V (E-Modulus 110 GPa). Decreasing material modulus, thereby increasing elasticity, enhances implant-to-bone stress loading and can minimize bone atrophy due to stress shielding.²¹ This reduced Young's modulus is one factor which might be responsible for the decreased proximal bone loss for the ABG-II stem.

The proximal third of ABG-I and II both are coated with a plasma sprayed hydroxyapatite (HA) layer. However the ABG-II has some extra HA coating added most proximally on the lateral shoulder. This might cause a better osseointegration in the proximal part and therefore better proximal stress transfer.

Assuming that the type of periprosthetic fractures encountered in the ABG-II stem is the same as the ABG-I stem, the increased proximal bone preservation in the ABG-II stem might lead to a lower periprosthetic fracture rate compared to the ABG-I stem. Although the ABG-I stem has an excellent survival rate after 10 years¹³, the process of stress shielding induced proximal osteopenia together with the inevitable senile osteoporosis will weaken the bone substantially in the long term.

If particle induced osteolysis is even added leading to aseptic loosening of the stem revision surgery will be a major challenge.

This study has several drawbacks, like a different gender distribution between the groups (due to the blinded randomization), different preoperative starting BMD and a lack of statistical power. That's why we will follow up these two groups and will combine them with older ABG series which were measured for BMD² in order to get a better match for pre-operative BMD to enhance statistical power.

The distinct differences in the effect on BMD confirms the philosophy behind the design changes from the ABG-I to ABG-II where a shorter, distal polished stem with additional proximal HA coating was meant to enhance load transfer in the proximal region. This shift in load transfer and stress shielding did not affect total BMD change. Proximal bone quality increased, which may lead to better biological fixation proximally and a better sealing of the implant for wear particles increasing long-time survival. These findings suggest that it might be beneficial to develop even a shorter stem. But we realize that by doing this, interface stresses may augment to unacceptable levels. Although we have only presented our two-years result, we expect less proximal bone resorption in the ABG-II on conventional X-rays and measured by DEXA-scans in future.

In conclusion: prosthetic design can influence the loading pattern to periprosthetic bone and consequently affect periprosthetic bone remodeling. However, recently it was shown that preoperative bone quality is a major factor influencing bone loss around the femoral stem.² Future studies comparing the effects of design change on BMD should therefore match patient series for pre-operative bone quality and gender to enhance statistical power, especially in case of femoral stems which are only slightly different in design.

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Chapter 3

Preoperative bone quality as a factor in dual-energy X-ray absorptiometry analysis comparing bone remodeling between two implant types

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Abstract

Recently it was shown that the design changes from the ABG-I to ABG-II hip stem resulted in a better, although not significant, proximal bone preservation. Our hypothesis was that by matching patients for preoperative bone quality statistical power would increase and that the trend of better proximal bone preservation in ABG-II might become significant.

24 ABG-II patients were compared to two different ABG-I groups: A) 25 patients from our earlier prospective study and B) a group of 24 patients selected to perfectly match the ABG-II group for gender, age and preoperative bone quality. Postoperative changes in periprosthetic bone mineral density (BMD) was quantified at 2 years postoperative using DEXA.

Bone preservation (less BMD loss) was better for the ABG-II than the ABG-I (all two groups) in the proximal zones 1 & 7. In Gruen zone 7 a statistically significant difference was found for group B ($p=0.03$).

By matching patients for preoperative bone quality and gender a statistical significant difference was found in proximal bone preservation in favor of ABG-II. In future comparative bone remodeling studies using DEXA, patients should be matched for preoperative bone quality and gender.

Introduction

In 1989 the the Anatomic Benoist Girard (ABG-I) stem was developed, a cementless anatomic stem, made from Ti6Al4V (Young's Modulus 110 GPa).

Uniform and satisfactory radiological and clinical outcomes with a ten-year follow-up have been reported for the ABG-I stem by several authors^{1,2}, but also proximal bone resorption due to stress shielding has been observed.¹⁻⁶ Stress shielding and bone resorption can be decisive for determining the long-term prognosis of prosthesis.^{7,8}

Therefore the ABG-II femoral stem was developed and introduced in 1996 as a successor the ABG-I, in an effort to reduce proximal bone loss.



Fig. 1: Stryker ABG-I (left) in comparison to the Stryker ABG-II (right) implant made of a low modulus titanium alloy and having a shorter, small diameter polished stem, increased proximal HA coating and neck lateralization (135° vs. 130°)

The ABG-II (Fig. 1) stem is made of a special less stiff titanium alloy (TMZF, Young's Modulus 85 GPa) and for a given size its length is shorter and the distal end is polished. Some extra HA coating is added most proximally on the lateral shoulder.⁴ The cervical-diaphyseal angle is reduced to 130° compared to a cervical diaphyseal angle of 135° of the ABG-I and the taper is standardized to V40 to allow for modern bearing surfaces. In a prospective randomized trial it was shown that the design changes from the ABG-I to ABG-II-stem result in a trend towards better proximal bone preservation.⁹ However,

differences in bone mineral density failed to become statistically significant. Recently it was shown that preoperative bone quality is a major factor influencing bone loss around a newly inserted femoral stem.¹⁰ Thus it was hypothesized that different preoperative bone quality between both groups may have reduced statistical power of this original study and that matching patient groups for preoperative bone quality would increase statistical power and lead to significant differences between the implants.

Material and Methods

Hip arthroplasty patients (n=24) having received the Stryker ABG-II total hip were compared to two different patient groups having received the ABG-I total hip system:

- A) 25 patients from a prospectively randomized comparison previously published⁹,
- B) a group of 24 patients selected from the randomized comparison previously published⁹ and of another study¹⁰ to perfectly match the ABG-II group for gender, age and preoperative bone quality.

Preoperative bone quality was measured using preoperative dual energy x-ray absorptiometry (DEXA) scans and defined as normal, osteopenic or osteoporotic bone using the WHO classification.¹¹

The ABG-II group consisted of 11 males and 13 females with a mean weight of 83.0 kg and mean age of 60.0 yrs. The mean Merle d'Aubigne (MdA) hip score of the ABG-II group was 10.0 preoperatively. Index diagnosis for the ABG-II group was osteoarthritis in 20 patients, post-traumatic arthritis in 2 patients and rheumatoid arthritis in 2 patients. Three patients were classified as having normal bone (3/24=13%), 16 patients had osteopenic bone (16/24=67%) and 5 patients had osteoporotic bone (5/24 = 21%, Table 1).

Group A consisted of 17 males and 8 females with a mean weight of 77.5 kg and mean age of 61.7 years. The mean Merle d'Aubigne (MdA) hip score of the ABG-I group was 10.5 pre-operatively. Index diagnosis for group A was osteoarthritis in 22 patients, avascular head necrosis in one patient, rheumatoid arthritis in one patient and morbus Paget in one patient. Three patients were classified as having normal bone (3/25 = 12%), 15 patients had osteopenic bone (15/25 = 60%) and 7 patients had osteoporotic bone (7/25 = 28%).

The matched group B consisted of 11 males and 13 females with a mean weight of 75.0 kg and mean age of 60.0 yrs. The mean Merle d'Aubigne (MdA) hip score of the ABG-I group was 10.0 preoperatively. Index diagnosis for group B was osteoarthritis

in 21 patients, avascular necrosis in one patient and rheumatoid arthritis in 2 patients. Three patients were classified as having normal bone ($3/24 = 13\%$), 16 patients had osteopenic bone ($16/24 = 67\%$) and 5 patients had osteoporotic bone ($5/24 = 21\%$). There were no significant differences between all three groups comparing age, weight and preoperative MdA score. The ABG-II group and group B were also not different regarding gender ratio and preoperative bone quality. The surgical approach was straight lateral and the surgical technique (no reaming) was the same for all series. Bone defects which needed allografting were not encountered in this series.

		ABG-I	
	ABG-II	Group A	Group B
Male/Female	11/13	8/17	11/13
Mean weight	83	77.5	75
Mean age	60	61.7	60
Preop MdA	10	10.5	10
Osteoarthritis	20	22	21
Posttraumatic arthritis	2		
Avascular necrosis		1	1
Rheumatoid arthritis	2	1	2
m Paget		1	
Normal bone	3	3	3
Osteopenic	16	15	16
Osteoporosis	5	7	5

Table 1: Patient demographics

BMD measurements

Bone mineral density (BMD) measurements were performed using a QDR-2000plus bone densitometer (Hologic Inc, Bedford, Mass., USA). Preoperative scans were acquired of the posteroanterior (PA) (L1-L4) and lateral (L2-L4) lumbar spine, the contralateral hip (femoral neck, trochanter, intertrochanteric region, total hip and Ward's triangle sites) and the non-dominant distal forearm (ultra-distal, mid-, one-third and total radius sites). Based on these measurements patients were categorized for bone quality using the T-score and the WHO classification (normal, osteopenic or osteoporotic bone).

The patients leg was positioned in a foam bag to control rotation.¹² The scans were analyzed using the manufacturer's metal exclusion software with a template to automatically create seven Gruen zones¹³ which were manually adjusted to the anatomy of each individual. BMD was measured laterally (Gruen zones 1, 2 and 3) and medially (Gruen zones 5, 6 and 7) around the stem of each prosthesis and 1cm distally to the tip of the stem (Gruen zone 4). The manufacturer's scan comparison software was used to transfer the Gruen zones regions of interest (ROI) onto the follow-up scans of each individual with care taken in patient positioning and scan analysis to ensure that the area measured coincided as closely as possible with the baseline postoperative scan. The coefficient of variation (CV) for BMD measurements using this technique has previously been established at 2.4% overall with a range of 1.4% to 4.1% depending on the Gruen zone assessed.¹²

Postoperative DEXA scans were performed to measure BMD in periprosthetic bone at 10 days (treated as baseline) and at 2 years to compare the results of the bone remodeling process. Results were expressed as the percentage change from baseline and the data examined for the differences in periprosthetic bone loss between the ABG-I and ABG-II stems for each of the different Gruen zones (unpaired, double-sided student t-test). Clinical Merle d'Aubigne (Mda) hip scores were evaluated at the same moment of BMD measurements and the stem position was defined on postoperative x-rays. The position of the stem was considered to be in varus or valgus when it showed a deviation of $>2^\circ$ from the anatomic axis of the femur.

Results

The mean Merle d'Aubigne (Mda) hip score of group A was 10.5 pre-operatively and increased to 17.0 two years post-operatively. The mean Merle d'Aubigne (Mda) hip score of group B and the ABG-II group was 10 pre-operatively and increased to 17.0 two years post-operatively.

The mean stem size used for group A was 3.6 (range 2-5), and group B 3.4 (range 2-5). The mean stem size used for the ABG-II group was 3.3 (range 1-5), ($p>0.05$, n.s.), implying that the fit/fill configuration was the same for all three groups.

Stem alignment of both implants also was not significantly different in the three groups with varus positions ($>2^\circ$) recorded in 45.8 % for the ABG-II stems. In group A, varus position was recorded in 48% of the stems and in group B 37.5% ($p>0.05$, Table 2).

	ABG-II	ABG-I	
		Group A	Group B
Preop MdA	10	10.5	10
Postop MdA	17	17	17
Mean stem size	3.3	3.6	3.4
Stem alignment varus %	45.8	48	37.5

Table 2: Clinical scores and stem characteristics

Bone preservation (less BMD loss) was better for the ABG-II than the ABG-I (both groups) in the proximal zones 1 & 7 but also in the mid-stem zones 2 & 6 (Table 3). In Gruen zone 6 the ABG-II even recorded an increase in BMD. In zone 7 BMD loss at 2 years for the ABG-II was only -4.1% but between -11.9 (group A) and -14.5% (group B) for the ABG-I. In Gruen zone 1 BMD loss was also less for the ABG-II (-7.9%) than the ABG-I (-9.3% to -11.3%) depending on the group. In the distal zones 3-5 the BMD loss was slightly less for the ABG-I than the ABG-II (except Gruen zone 4 for group B).

Relative BMD loss 2 years post-op [%]						
Gruen zone	ABG-I		ABG-I		ABG-II	
	Unmatched ⁹ Group A		Matched Group B		Reference	
	Mean	SEM	Mean	SEM	Mean	SEM
R1	-9.3	2.6	-11.3	3.2	-7.9	2.5
R2	-4.1	2.6	-7.8	3.3	-3.5	2.0
R3	-2.9	1.7	-4.0	2.0	-5.9	2.5
R4	-1.5	1.3	-3.8	1.6	-2.8	1.2
R5	-1.7	2.4	-3.6	1.9	-4.5	1.5
R6	-1.4	2.2	-2.6	2.2	+2.8	2.8
R7	-11.9	3.3	-14.5	3.0	-4.1	3.7

Table 3: Relative BMD loss from baseline 2-years post-op [mean \pm SEM] per ABG-I/II group (grey to emphasize increase in BMD)

All these distinct differences between both ABG stems became more pronounced when the ABG-II was compared to the matched group (group B) than the unmatched group (group A) (Table 4). In Gruen zone 7 the positive difference in BMD preservation increased from +7.9% (group A; unmatched ABG-I) to 10.4% (group B; matched

ABG-I). These difference became also statistically significant at $p=0.03$. The same was observed in Gruen zone 1, where the difference (ABG-II minus ABG-I) increased from +1.4% to 3.3% (group B, fig 2). The p-value went down but the comparison remained statistically non significant. The same trend of increasing BMD advantage for the ABG-II combined with lower p -values applied to mid-stem Gruen zones 2 and 6 (Table 4).

Difference BMD loss (ABG-II minus I) [%]				
Gruen zone	Unmatched ¹ Group A		Matched Group B	
	II-I	<i>p</i>	II-I	<i>p</i>
R1	+1.4	0.70	+3.3	0.42
R2	+0.7	0.84	+4.3	0.28
R3	-2.9	0.34	-1.9	0.56
R4	-1.2	0.49	+1.0	0.62
R5	-2.8	0.33	-0.8	0.72
R6	+4.2	0.24	+5.4	0.14
R7	+7.9	0.12	+10.4	0.03

Table 4: Difference in BMD loss between ABG-II and ABG-I groups (grey = $p < 0.05$)

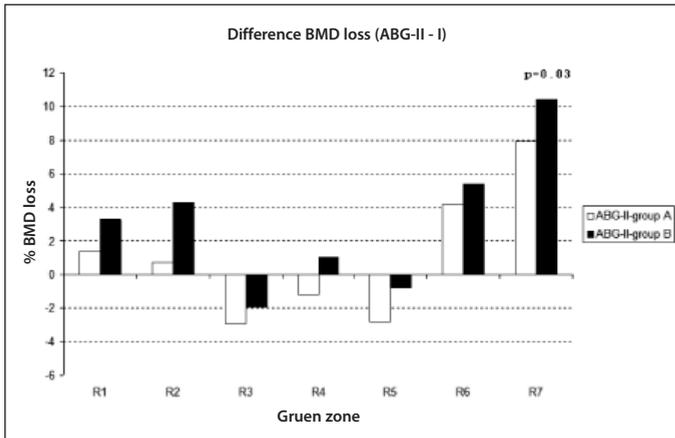


Figure 2: Graphical representation of difference in BMD loss between ABG-II and ABG-I

The previously reported influence of preoperative bone quality on bone remodeling⁹ which led to matching our patients for normal, osteopenic and osteoporotic bone was also confirmed in our study (Table 5). Patients with normal bone had less bone loss than osteopenic and osteoporotic patients especially in the critical proximal zone (Zone1: -5.4% vs -10.5% and -9.5%, Zone7: -6.5% vs -9.4% and -10.7%, $p > 0.05$).

Gruen zone	Percentage Bone loss per bone quality category					
	Normal		Osteopenia		Osteoporosis	
	Mean	SEM	Mean	SEM	Mean	SEM
R1	-5.4	4.7	-10.5	2.5	-9.5	4.9
R2	-4.5	3.4	-3.3	2.1	-13.9	5.9
R3	-4.3	1.1	-2.2	1.6	-6.9	3.4
R4	-1.4	1.0	-1.8	0.9	-8.9	3.3
R5	-3.3	1.3	-2.3	1.2	-9.9	3.6
R6	-0.8	1.5	1.2	1.9	-2.8	6.5
R7	-6.5	4.9	-9.4	3.1	-10.7	5.8

Table 5: Difference in percentage bone loss per bone quality category

Discussion

Uncemented, HA-coated anatomic stems like the ABG have been proven as reliable implants and several studies with a long term follow-up revealed excellent and consistent results for the ABG-I hip prosthesis.^{1,2} Stress shielding induced bone resorption in the proximal Gruen zones and distal cortical thickening leading to pedestal formation is not uncommon in hip arthroplasty in general^{14,15} and has also been described for the ABG-I hip prosthesis by several authors.¹⁻⁶ These studies of bone density changes in the ABG-I series were based on serial x-ray interpretations which are not as accurate in describing BMD changes as DEXA studies. Nevertheless, recently it was shown that even with conventional radiography statistically significant differences in bone remodeling quality could be detected between two implant variants (Zweymuller stem; cementless, straight tapered femoral stem) following a small design change of an original stem design.¹⁶

Using dual energy radiographic absorptiometry (DEXA) even smaller changes in bone mineral density (BMD) can be accurately detected near the prosthesis¹⁷ so that a bone remodeling comparison between two generations of the ABG seemed feasible.

Confirming this assumption, a first investigation comparing the ABG-I with the ABG-II in a prospectively randomized study showed different BMD developments over a two-year period with an advantage for the ABG-II especially in the proximal Gruen zones.⁹ However, the strong influence of preoperative bone quality on bone remodeling¹⁰ was not known at the initiation of the study so that the two patient groups differed significantly with regards to the preoperative T-scores and thus

confounded the study. In this retrospective study it was shown that by matching the patients for preoperative bone quality, statistical power could be improved and a statistically significant difference could be validated for zone 7 in favor of the ABG-II. At the same time the advantage of the ABG-II over the ABG-I with regards to better bone preservation increased also in Gruen zones 1, 2 and 6 while the p-values for the comparison decreased. Thus the statistical power of comparing DEXA values could be increased by matching the patients for preoperative bone quality.

The effect of matching the patients for preoperative bone quality can also be confounded by patients' gender. The ABG-II group and group B were also matched for gender as it has been suggested that postmenopausal women lose more periprosthetic bone than men of the same age.¹⁷ Patients with a low preoperative BMD risk more bone loss near the prosthesis and women seem to be at an ever higher risk. It has been shown that bisphosphonate drugs can reduce or even avoid periprosthetic bone loss following cemented or uncemented THA,¹⁸ which suggests that especially female arthroplasty patients with a low preoperative T-score may benefit from a bisphosphonate therapy.

Several factors might be responsible for the significantly better proximal bone preservation in favor of ABG-II. The increased elasticity of the ABG-II stem (TMZF versus Ti6Al4V) enhances the implant-to-bone load transfer and induces a more physiological stress pattern in the periprosthetic bone which may lead to reduced bone atrophy due to stress shielding.⁷

HA-coatings have shown to reduce the bone loss in general,¹⁹ because such a coating increases the speed, strength, and amount of bony ingrowth, which may lead to better biological fixation proximally and a better sealing of the implant against wear particles increasing long-time survival.¹⁹⁻²¹ The ABG-II has some extra HA coating most proximal on the lateral implant shoulder and this may have maintained higher proximal BMD as found in this study. While the distal 2/3 of the ABG-I stem has a grit-blasted surface texture, the ABG-II stem is distally polished, shorter and thinner to counteract distal bone ongrowth which can reduce or prevent distal off-loading and with it cortical thickening and pedestal forming as frequently observed for the ABG-I. The slightly lower distal BMD loss measured for the ABG-I may thus not be a sign of superior bone preservation of the old stem design but an indication that distal bone ongrowth which expresses itself in locally higher BMD values does happen less with the ABG-II as intended by the design change. The design changes from ABG-I to ABG-II

have led to the desired clinical effects but based on this study it cannot be identified which of the individual factors was most influential.

It was shown that implant design can improve periprosthetic bone preservation at two years postoperative from when according to literature²² BMD changes less and becomes steady. In the long term the influence of implant design on periprosthetic bone remodeling will be less as other factors such as wear particle induced osteolytic effects may dominate the bone remodeling process and eventually initiate failure. However, periprosthetic bone density which is well preserved by implant design features during the initial postoperative period may reduce or delay late osteolysis by sealing the bone implant interface against wear particles. In addition, increased proximal bone preservation in the early postoperative phase may also provide long-term benefits by reducing the periprosthetic fracture rate as indicated by a slightly elevated periprosthetic fracture rate reported for the less proximal bone preserving ABG-I.²³

In conclusion, in future studies using DEXA to compare the effects of different implant designs or treatments on periprosthetic bone remodeling patients should be matched for preoperative bone quality and gender to limit the number of patients while maintaining maximum statistical power.

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Chapter 4

Femoral fit in ABG-II hip stems: Influence on clinical outcome and bone remodeling; a radiographic study

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Abstract

In a consecutive series of 64 patients with an ABG-II stem, we analyzed if tightness of the fit of the prosthesis affected bone remodeling and if there is a relation between clinical and radiological results.

Radiographic analysis of bone remodeling in different Gruen zones was done.

Bone density changes were graded as present or absent in the AP and lateral radiographs as compared with the previous sets of radiographs.

Bone remodeling was compared to literature values of the ABG-I stem. Three stem levels were defined. The proximal level was set at the upper border of the lesser trochanter, mid stem level halfway the stem and distal level 1 cm above the tip of the prosthesis. Femoral fit was defined as tight when the ratio of the fit was ≥ 0.8 and as non-tight if the fit was < 0.8 . The incidence of thigh pain was scored using the Merle d'Aubigne (Mda) hip score.

Proximal bone resorption in Gruen zone 1 was 26.6% and in zone 7 34.4% compared to 48% and 45% for the ABG-I stem after 5 years. No correlation was found between femoral fit and radiological changes. Proximal and distal fit was significantly lower for patients with thigh pain than without thigh pain. Patients with a non-tight proximal fit produced significantly more varus (17/30=56.7%) than patients with a tight proximal fit (2/34=5.9%, $p < 0.01$).

Femoral fit in ABG-II does not predict certain radiological changes, but less proximal bone resorption confirms the design changes from ABG-I to ABG-II. A non-tight proximal fit is correlated with varus position of the stem. Thigh pain is correlated with a poor fit and fill of the femoral stem.

Introduction

Following primary total hip replacement standard radiographs are mostly used to evaluate implant position and stability against migration in the long term. Bone is known to adapt and remodel in response to applied stress. Standard radiographs also allow the analysis of areas of stress shielding and transmission by monitoring radiographic phenomena associated with bone remodeling such as resorption, reactive line formation or bone thickening. Stem sizing, intra-operative canal preparation and implant insertion influence the stress transfer into bone and thus its remodeling response and clinical outcome. Kim and Kim¹ performed a prospective study in which patients were followed for a minimum of six years after primary total hip arthroplasty using an uncemented porous coated hip. They found that a poor (non-tight) initial fit and fill of an anatomic stem has been associated with thigh pain and component loosening.¹

Oosterbos et al. reported that there is a correlation between the stem filling the medullary canal completely in the AP radiograph and the presence of symmetrical cortical thickening in the ABG-I hip prosthesis. In the study of Laine et al.² subsidence of the femoral stem was associated with significantly less metaphyseal fill than the stems which did not subside.

Thigh pain after total hip arthroplasty has been described in several studies and a high incidence of thigh pain (up to 27 %) with proximally porous coated anatomic stems has been reported.³⁻⁵ Danesh-Clough et al.⁶ reported a much lower incidence of thigh pain (2.7%) for a tapered uncemented stem, designed for proximal in-growth.

Anatomic stems such as the Anatomique Benoist Girard stem (ABG) are designed to accommodate the natural geometry of the proximal femur and are expected to show some different correlations between fit and fill, clinical outcome and radiographic signs of bone remodeling than straight stems.

For the first generation ABG (ABG-I) proximal bone resorption due to stress shielding has been observed.⁷⁻¹²

In this study we analysed for the second generation of the ABG (ABG-II) how tightness of stem fit did affect bone remodeling and clinical results at 5 years follow-up. Since the bone remodeling changes were scored by the same observer as in a previous study⁹, a comparison to this study did allow the effect of design changes between both stem generations to be analysed.

Patients and methods

A consecutive series of 64 patients, out of a prospectively followed group of patients, who had a primary total hip arthroplasty and a completed five year follow-up were included in this retrospective analysis of conventional radiographs and clinical follow-up forms. A cementless proximal hydroxyapatite (HA) coated stem (Stryker ABG-II, Caen, France) was used in all patients and matched to a HA coated ABG-II cup. The ABG-II femoral stem was developed and introduced in 1996 as a successor of the ABG-I. The ABG-II stem is made of a special titanium alloy of lower stiffness (TMZF, Young's Modulus 85 GPa) and for a given size its length is shorter and the distal end is polished. Some extra HA coating is added most proximally on the lateral shoulder. The cervical-diaphyseal angle is reduced to 130° compared to a cervical diaphyseal angle of 135° of the ABG-I and the taper is standardised to V40.

Patients included 19 males and 45 females with a mean weight of 79.5 kg and mean height of 163 cm. Mean age at operation was 68.3 years (range 41-84 yrs) and the mean Merle d'Aubigne (Mda, 0-18) hip score was 9.6 pre-operatively (range 4-14).

Index diagnosis was osteoarthritis in 58 patients, rheumatoid arthritis in 3 patients, avascular necrosis in 2 patients and fracture of the collum femoris in one patient. Preoperative radiographs were graded for osteoporosis using the scale of Singh et al.¹³ Surgery was performed in a standard operating theatre by (or under the supervision of) three different surgeons (senior consultants). The surgical approach was straight lateral in all cases and reaming was not done since the ABG-II stem is meant to be implanted by an anatomical press fit. In the comparative study of Oosterbos the approach was also straight lateral (Hardinge approach) in 191 cases and anterolateral in 59 cases (Watson-Jones), but the distal femur was reamed to a diameter slightly greater (1-1.5mm) than the diameter of the prosthesis that was to be inserted.

In our study routine treatment included 24 hours of systemic antibiotic prophylaxis and subcutaneous anticoagulation for 6 weeks. Postoperatively, direct full weight bearing with crutches was allowed. All patients were included in a prospective follow-up schedule and were evaluated preoperatively and postoperatively at 6 weeks, 3, 6 and 12 months and yearly thereafter using the Merle d'Aubigne (Mda) hip score and radiographs. Mean follow up time for all patients was 6.3 years (range 5-6.8 yrs). For all patients we reviewed the clinical and radiographic findings at the five year follow-up. Stem position was measured on the direct postoperative radiographs and considered to be in varus or valgus when it showed a deviation of 3° or more from anatomic axis of the femur.

Femoral fit was measured on the direct postoperative radiographs (AP view) calculating the ratio of stem width to cavity diameter as defined by Kim and Kim.¹

These stem levels were defined: proximal, mid stem and distal. The proximal level was set as a line parallel to the upper border of the lesser trochanter. The mid stem level was defined halfway the stem. The distal level was defined as 1 cm above the tip of the prosthesis.

The femoral fit was considered as tight when this ratio of the fit was ≥ 0.8 and as non-tight when the fit was < 0.8 . Fit was measured at the proximal, mid stem and distal stem level (Figure 1).



Fig. 1: Measuring femoral fit at proximal level, mid-stem and distal level using the method of Kim & Kim¹

At the same time the morphometric features of the femur (CC-ratio) were described using the method described by Dorr et al¹⁴ and classified using the Canal Flare Index according to Noble¹⁵ as being either “champagne flute”, normal or “stove pipe”. Patients with an index between 0.50-0.55 were classified as champagne-flute, 0.56-0.75 as normal and 0.76-0.90 as stove-pipe femora. 81.2% of patients had a normal femur, 9.4% a champagne-flute femur and also 9.4% a stove pipe femur. The classification which was made on the first postoperative X-ray was supposed not to be influenced seriously by the operative procedure as no electric reaming of the cavity was applied.

All measurements were performed by one independent observer (B.W.) using the Roman V 1.70 software on images calibrated on the femoral head diameter.

A detailed radiographic analysis of the bone remodeling was performed by one independent observer (W.V.) at the five year follow-up. Bone remodeling changes were assessed in both the AP and lateral views, but for simplicity they were combined and reported in the AP zones only.

The following morphologic features were analyzed per Gruen zone:¹⁶ cancellous densifications, cortical densifications, cortical thickening, pedestal formation, reactive line formation and bone resorption.¹⁷ These bone remodeling changes were assessed on the 5 years follow-up X-rays and compared to the direct postoperative X-rays.

Bone loss was considered present if the bone of the femur showed evidence of cortical thinning, increased porosity, or decreased density (either cortical or trabecular) compared to the direct postoperative X-ray. The degree of stress shielding, as defined by Engh¹⁸ was not classified.

Resorption or densification of bone was not quantified but graded as present or absent. A bone pedestal was defined as a shelf of endosteal new bone either partially or completely bridging the intramedullary canal in an apparent attempt to support the tip of the prosthesis. Osteolysis was defined as a scalloped erosion of greater than 2 mm in diameter at the bone-prosthesis interface.

Heterotopic ossification was assessed according the classification system of Brooker et al.¹⁹ Migration of the femoral component was measured as the change in vertical distance between the lateral shoulder of the stem to the most medial point of the lesser trochanter 20 and noted when exceeding a value of 5mm.

Clinical outcome and bone remodeling at 5 years was correlated with fit and fill. Statistical analysis was performed using SPSS 10.0 software (SPSS, Chicago, IL). The

influences of clinical and radiographic values were studied using the Fisher exact test and the student T-test. Statistical significance was set at $p < 0.05$. Thigh pain was defined as present or not present based on the Merle d'Aubigne (Mda) hip score.

Results

The mean preoperative Mda increased from 9.6 to 17.1 postoperatively for all patients. No periprosthetic fractures were encountered in this series, nor infections. One cup was revised 4 years after the initial operation because of recurrent dislocations. Stem position on the first postoperative radiographs was found to be neutral in 44/64 patients (68.8%), varus in 19/64 patients (29.7%) and valgus in 1/64 patients (1.6%). The varus/valgus positions did not change significantly during the follow-up. Small cyst formation (<5mm) was observed in Gruen zone 7 in only one patient. However, no radiolucent lines around the hydroxyapatite-coated parts of any femoral component were noted and there were no signs of impending failure of any ABG-II stem. Only one patient showed migration of the femoral component exceeding a value of 5mm or more (7mm).

Radiological changes after 5 years

The radiological changes for all ABG-II implants independent of fit and fill are tabulated below (Table 1) and compared to equivalent values for the ABG-I from a previously published study.⁹

No significant relationship could be established between the radiologic findings between the ABG-I and ABG-II stem. However, several trends could be observed.

Proximal bone resorption in ABG-II was noted in 26.6% of the stems in zone 1 and 34.4% of the implants in zone 7.

In the mid-stem zones 2 and 6, the ABG-II showed a higher percentage of cancellous densifications (83-88% vs 65-70%) and a lower percentage of cortical densifications (5-9% vs 12-14%). Regarding rate of cortical thickening in the distal zones 3 (9% vs 7%) and 5 (4.7% vs 5%) no difference in remodeling response was measured. Reactive line formation at the stem tip (zone 4) was also frequent with the ABG-II (73%).

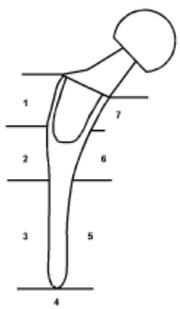
					
		Zone 1	Zone 7		
Proximal resorption	ABG-I	48%	45%		
	ABG-II	26.6%	34.4%		
		Zone 2	Zone 6	Zone 3	Zone 3
Cancellous densification	ABG-I	65%	70%	51%	49%
	ABG-II	82.8%	87.5%	43.8%	25%
Cortical densification	ABG-I	14%	12%	7%	3%
	ABG-II	9.4%	4.7%	9.4%	1.6%
Cortical thickening	ABG-I	9%	6%	7%	5%
	ABG-II	7.7%	3.1%	9.4%	4.7%
		Zone 4			
Reactive line Formation	ABG-I	82% 3yrs			
	ABG-II	43% 10yrs 73.4% 5yrs			
Pedestal	ABG-I	not reported			
	ABG-II	18.8%			

Table 1: Bone remodeling patterns ABG-I vs. ABG-II

Femoral fit and clinical results

Femoral fit was measured at three stem levels and proximally, the average fit was 0.79 with approximately half of the patients (34/64) recording a tight fit (≥ 0.8). At the mid stem level the average fit was 0.72 and only 13/64 (20%) patients had a tight fit. Distally, the average fit was 0.78 and again approximately half of the patients (33/64) had a tight fit (Table 2).



	Fit ≥ 0.8	Fit < 0.8	Average Fit
Proximal	34	30	0.79
Mid stem	13	51	0.72
Distal	33	31	0.78

Table 2: Femoral fit at three stem levels for ABG-II stem

Postoperatively, all patients had less pain in the operated hip but there was a prevalence of 15.6% (10 patients) of thigh pain after 5 years. Severity of the thigh pain was scored by using the MdA hip score: seven of them reported mild thigh pain, two patients reported moderate pain and one severe thigh pain, the latter three necessitating analgesics.

Since the ABG-II stem is an anatomic stem which is designed for proximal fixation and loading the proximal fit and its correlation with clinical outcome was analysed in more detail (Table 3).

	preop MdA	Postop MdA	thigh pain	Varus $>3^\circ$
All patients	9.6	17.1	10	19
prox fit ≥ 0.8 (n=34)	9.3	16.9	4	2
prox fit < 0.8 (n=30)	9.9	17.3	6	17*

P <0.01 (Fisher exact test)

Table 3: Clinical outcome for tight and non tight proximal fit (ABG-II)

The mean MdA score for the group with a tight proximal fit was 9.3 preoperatively and 16.9 postoperatively compared to 9.9 and 17.3 for the group with a non-tight proximal fit ($p>0.05$). A non-tight proximal fit did not significantly increase the risk of thigh pain (non-tight vs tight = 20% vs 12%).

Patients with a non-tight proximal fit produced significantly more varus (17/30=56.7%) than patients with a tight proximal fit (2/34=5.9%) when both groups were compared (Fisher exact test, $p<0.01$).

Also, when implants were grouped into stems with non-tight fit at all three levels (18/64) and patients with a tight fit at one or more levels (46/64), a non-tight fit showed to produce varus positions significantly more frequently (13/18=72.2%) than with a tight fit at one or more stem levels (6/46=13%) ($p<0.001$; Fisher exact test).

The average proximal and distal fit (0.75 and 0.72) in the group of patients with thigh pain was significantly lower than for patients with no thigh pain (proximal 0.80, distal 0.79, $p<0.05$, one-sided Student T-test, table 4). The same applied for the total fit (average of all three levels, $p=0.043$).

	Average fit proximal	Average fit mid stem	Average fit distal
Thigh pain	0.75	0.69	0.72
No thigh pain	0.80	0.73	0.79
p-value	0.049	0.088	0.032

Table 4: Correlation between femoral fit and thigh pain (ABG-II)(Student T-test)

No significant relationship could be established for the average stem size for the group of patients with thigh pain (average stem size 3.3) and without thigh pain (average stem size 3.7). Despite these differences, the overall clinical result for patients with and without thigh pain was similar with the preoperative MdA score improving from 9.5 to 16.5 postoperatively for the group of patients with thigh pain and from 9.6 to 17.2 for the group without thigh pain ($p>0.05$). There was no correlation between varus position of the stem and the occurrence of thigh pain.

Femoral fit and bone remodeling at 5 years

The correlation between the tightness of proximal fit and fill and radiographic bone remodeling is investigated in table 5 for the proximal level only, as this is the most relevant area of fixation for an anatomic stem, such as the ABG-II.

Radiologic reaction	prox fit ≥ 0.8	prox fit <0.8	P =	All pts
Cancellous densification	97%	90%	n.s.	94%
Cortical densification	18%	13%	n.s.	15.6%
Cortical thickening	14.7%	6.7%	n.s.	10.9%
Reactive lines	76.5%	76.7%	n.s.	78.1%
Pedestal formation	14.7%	23.3%	n.s.	18.8%

Table 5: Correlation between femoral fit and bone remodelling (n.s.: $p>0.05$) (**Fisher exact test**)

Comparing patient groups with tight and non-tight proximal fit no statistically significant difference between the groups could be measured. The same was true when the comparison was made for different fit at the mid-stem and distal level (Fisher exact test). Distally, some differences, which were non-significant trends, between tight and non-tight stems were noted such as cortical densifications (tight: 25%, non-tight: 6%, $p=0.07$) and cortical thickening (tight: 16%, non-tight: 6%, $p>0.05$). The pre-operative quality of bone stock was considered good in 53.1 %, fair in 37.5 % and poor in 9.4% of the patients according to the modified Singh index. No correlation was found between quality of bone stock and the presence of any of the radiographic changes (Fisher exact test).

36 patients developed no heterotopic ossification, heterotopic ossification grade I was found in 24 patients, 3 patients developed ossification grade II and one patients grade III.

Femur shape fit and bone remodeling

Patients with a champagne-flute femur showed a higher percentage of tight distal fit and less frequent tight proximal fit than patients with a normal or stovepipe femur. (Table 6). Patients with a champagne-flute femur and a tight distal fit showed proximal bone resorption in 60% of cases (vs. 48% overall) and pedestal formation in 40% (vs. 19% overall). (n.s. Fisher exact test).

		Prox fit ≥ 0.8	Mid stem fit ≥ 0.8	dist fit ≥ 0.8
Champagne 0.5-0.55	9.4%	33.3%	33.3%	83.3%
Normal 0.56-0.75	81.2%	55.8%	21.2%	50%
Stovepipe 0.76-0.90	9.4%	50%	0%	33.3%

Table 6: Femoral fit and shape of the medullary canal

Discussion

Although dual energy radiographic absorptiometry (DEXA) is an important and more precise tool to monitor the total loss or gain of bone as a sequel of the bone remodeling process,²¹ analysis of radiographs in patients who have an uncemented prosthesis gives more differentiated information about the morphology and location of the bone remodeling features than DEXA. While DEXA cannot differentiate if bone augmentation comes from cancellous or cortical densification, X-ray analysis can. The same is valid for resorption, pedestal formation and reactive line formation.

The stem survival rate of the ABG-II is comparable to previous published studies regarding the same prosthesis and other proximally porous coated cementless stems.^{9,11,22-24} However, the clinical results concerning thigh pain were considerably worse than most other studies of straight uncemented stems, designed for proximal in-growth,²⁵⁻²⁸ but less than the study of Bourne²⁸, which reported a percentage of 27% for a proximally porous coated anatomic stem.

The grading of osteoporosis did not significantly influence the bone remodeling process, which is in a way contradictory to previous published studies.^{29,30} However the grading of osteoporosis according to Singh¹³ is not as reliable as other measures such as the T-score and might explain the lack of influence of the preoperative bone quality on outcome in this study.

The Singh grading of osteoporosis was chosen for this study, since preoperative DEXA-scans were not available for this patient group.

The rate of reactive line formation at five years follow up was similar to other studies and thus seems typical for the ABG stem regardless of its generation.^{2,22} Proximal bone preservation was superior for the ABG-II stem, which is in agreement with results from shorter follow-up studies.³⁰ Although visual assessment of bone resorption has been reported to be reproducibly recognized only at levels of 70% of bone loss and

thus to be prone to interobserver error, this study and the literature referred to were assessed by the same single observer (W.V.), thus benefiting from the much higher intraobserver reliability reported before. The intra-observer reproducibility of bone loss between the initial evaluation and second evaluation is the same for 90% of the zones.¹⁸ Proximal bone loss was noted in 26.6% of the stems in zone 1 and 34.4% of the implants in zone 7 in ABG-II and 48% and 45% in ABG-I stems.

When accounting for a 90% reproducibility for both implants, in theory the smallest differences for proximal bone loss would still be 15% for zone 1 and 3% for zone 7 in favor of ABG-II.

The high percentage of cancellous densification in zone 2 and 6 and the low percentage of proximal bone resorption in the ABG-II stem after 5 years suggests mainly proximal stress transfer and proximal osseointegration of the stem. These findings confirm the original concept of the implant which should guarantee mainly metaphyseal load transfer.

In this study only 53.1% of patients had a tight proximal femoral fit. This was probably caused by the fact that the senior author (AT) preferred the smallest stem size already stable. That may have been the reason why no periprosthetic fractures during surgery or postoperatively were encountered compared to a 1-3.5% fracture rate reported for uncemented stems.^{31,32}

Fit and fill may influence the bone remodeling response, but at 5 years an effect could not be measured with the conventional methods. A longer follow up may reveal a difference. A non-tight fit both either proximal or all three levels combined was associated with an increased incidence of a varus stem position. Peroperatively, the surgeon may think that the stem is canal filling while instead it is undersized and in varus position. The high percentage of varus position of the stem might be correlated with the straight lateral approach used in all cases. As the straight lateral approach gives somewhat less exposure of the proximal femur than the posterolateral approach, a stem may go into varus and give the impression of good fit while in fact being undersized. Although in the study of Oosterbos a straight lateral or antero-lateral approach was used, a much lower percentage of varus stem position is reported.

The reason may be that while the ABG-II stem is inserted without reaming, for the ABG-I stem the medullar cavity is reamed. Thereby the surgeon is more aiming at distal fit which will give a more anatomical alignment of the femoral stem.

A non tight proximal fit did not predict the development of thigh pain. This might be caused by a lack of statistical power since the group of patients with thigh pain did have a significantly smaller proximal and distal fit. Whiteside³³ found a relation

correlating a tight femoral canal fit with the absence of pain in a larger patient group.

The exact cause of thigh pain in uncemented arthroplasty is still not well understood.

All our patients with thigh pain reported pain at the lateral side of the hip. The thigh pain with the ABG-II prosthesis is probably located more proximally because the stem is relatively short. The direct lateral approach used in our study might be partly responsible for the relatively high percentage of thigh pain, since the incidence of lateral trochanteric pain with the posterior approach has been reported only at 1.2% compared to the direct lateral approach at 4.9%.³⁴ However, clinically it is difficult to discern thigh pain from lateral trochanteric pain.

Several studies about uncemented anatomic stems using the method of Kim and Kim¹ have been published.^{2,35} The average proximal femoral fit (0.78) of this study was the same as in the study of Laine et al. with the ABG-I stem.² In this study on the ABG-II a tight or non-tight femoral fit did not predict different radiological changes while Gosens et al. found such a correlation for the Mallory-Head stem.³⁶ This indicates that fit and fill have different effects in straight stems than in anatomic stems. So fit and fill is only one factor influencing the bone remodeling, while design (straight or anatomic) is another.

Although the ABG is an anatomic stem optimised for proximal fit, patients with a champagne-flute femur showed a high percentage of tight distal fit but a low percentage of a tight proximal fit. This will lead to distal off loading paired with proximal stress shielding. The finding of the high percentage of proximal resorption and pedestal formation observed for this group supports this assumption. Our data further suggest that the anatomic ABG fits best in normal and stovepipe femora, in which the cancellous bone is less strong and the medulla is not narrow.

In conclusion, fit and fill configuration of the ABG-II stem in our hands did not predict certain radiological changes. However patients without thigh pain showed a better proximal and distal fit. A non-tight fit both either proximal or all three levels combined was correlated with varus position of the stem. In this study the high percentage of varus, the high percentage of non-tight proximal fit and the high percentage of thigh pain was comparatively high. These findings suggest the change of the operation technique for the better, for example by reaming the medullar cavity again, like in the ABG-I, to provide more frequent tight fit at all three levels.

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Chapter 5

Bone Remodeling and Hydroxyapatite Resorption in Coated Primary Hip Prostheses

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Abstract

Hydroxyapatite coatings for THA promote bone ongrowth, but bone and coating are exposed to stress shielding-driven osteoclastic resorption. We asked the following questions: (1) is the resorption of hydroxyapatite coating and bone ongrowth correlated with demographics? (2) Is the resorption related to the stem level? And (3) what happens to the implant-bone interface when all hydroxyapatite coating is resorbed? We recovered 13 femoral components from cadaveric specimens 3.3 to 11.2 years after uneventful primary THA. Three cross sections (proximal, medial, distal) of the hydroxyapatite-coated proximal implant sleeve were analyzed by measuring the percentage of residual hydroxyapatite and bone ongrowth on the implant perimeter. Hydroxyapatite resorption was independent of patient age, but increased with time in vivo and was mostly gone after 8 years. Bone ongrowth was independent of time in vivo but decreased with aging patients. Only in the most proximal section did less residual hydroxyapatite correlate with less bone ongrowth. Hydroxyapatite resorption, which was more proximal than distal showed no adverse effects on the implant-bone interface.

Introduction

The use of hydroxyapatite (HA) has been advocated to provide rapid and reliable attachment of bone to metal implants.¹⁻⁹ Augmented bone ongrowth has been documented as early as 3 weeks and as persisting for some years.^{1,9-13} However, as much as 20% to 30% of bone loss at the proximal femur has been reported after THA for the same period as a consequence of proximal stress shielding.^{7,14,15} It also is expected and observed that the HA coating resorbs with time,^{6,10,11,13,16-18} although it is unknown whether this adversely influences the amount of long-term bone ongrowth. Apart from time in vivo and new stress patterns, do other factors influence long-term ongrowth and HA resorption?

Based on short-term bone density studies using DEXA, gender, age and bone stock are believed to influence ongrowth and resorption.^{15,19} While age is certainly related to bone stock quality, direct correlation between age and bone ongrowth onto implants such as uncemented HA-coated hip stems has not yet been proven. However in longer-term human histomorphometric retrieval studies,^{12,13,16,18,20} the influence of demographics on bone ongrowth and HA resorption could not be studied because of the low number of retrievals or heterogeneity of the described implant designs.

HA coating loss can be caused by several mechanisms such as osteoclastic resorption during bone remodeling, abrasion, chemical dissolution or delamination. The theory that HA resorption is mainly cell mediated through bone remodeling^{6,10,18} could be supported if a correlation could be found between HA resorption and stem level. Since the introduction of HA-coated implants prospectively controlled clinical studies could prove ongoing implant fixation, but the above questions regarding bone ongrowth and HA resorption at the stem-bone interface could not be answered.^{2,5,7}

We therefore addressed three questions: First, is the resorption of HA coating and bone ongrowth mainly correlated with time in vivo or with demographics and if time in vivo is predominant, at which time can we expect that all the HA is gone? Second, are HA resorption and/or the amount of bone ongrowth correlated or rather related to the stem level? Third, what happens to the implant-bone interface when all HA coating is resorbed? Is there still bone ongrowth left to maintain fixation? What levels of bone ongrowth can be associated with clinically stable stem fixation?

Materials and Methods

At autopsy, we performed histomorphometric examination of metaphyseal surfaces of femoral stems from 13 cadavers by measuring the extent of residual HA coating and the amount of bone ongrowth to find correlations between these histomorphometric parameters and patient demographics (time of implantation, age, height, weight, and clinical score). Values for residual HA and bone ongrowth were measured at three metaphyseal levels, first to correlate the two measures and then to correlate them to the different metaphyseal stem levels. Since all stems were mechanically well fixed at the time of retrieval, we assessed the status of HA resorption and the percentage of bone ongrowth in relation to stable stem fixation as expressed in percentage of bone ongrowth.

Thirteen patients from a prospectively followed series of more than 750 consecutive patients receiving primary ABG®-I (Stryker, Caen, France) prostheses provided written consent for retrieval of the prostheses postmortem. All 13 patients (10 women, three men; age at the time of the surgery, 58–86 years) had uneventful THAs and died from causes unrelated to their hip disease (Table 1).

<i>Patient Number</i>													
	1	2	3	4	5	6	7	8	9	10	11	12	13
Parameter													
Gender	F	F	M	F	M	M	F	F	F	F	F	F	F
Age at THA (yrs)	63	86	65	81	58	72	66	86	65	73	60	69	66
Diagnosis	OA	OA	OA	OA	OA	OA	OA	OA	Fract	RA	RA	OA	OA
Time from implantation (yrs)	3.3	4.5	5.2	5.4	5.7	6.1	6.2	6.6	8.0	8.3	8.1	10.5	11.2
Weight (kg)	85	65	65	52	50	65	75	65	60	50	57	103	70
Height (m)	1.39	1.62	1.69	1.60	1.52	1.66	1.63	1.60	1.71	1.55	1.60	1.64	1.68
Merle d'Aubigné-Postel score	18	18	18	18	15	18	18	18	18	18	15	13	14
Harris hip score	100	100	100	97	90	100	100	95	100	100	76	73	75
Alignment stem	Neutral	Neutral	Neutral	4°valgus	Neutral	4°varus	2°varus	Neutral	Neutral	Neutral	Neutral	Neutral	3°varus
Cause of death	cardiac arrest	cardiac arrest	cerebral hemorrhage	cardiac arrest	cardiac arrest	cerebral hemorrhage	acute aneurysm	pancreatitis	cardiac arrest	lung carcinoma	foramen magnum trapping	cardiac arrest	subdural haematoma

Table 1: Patient demographics

The time from implantation (stem in vivo) ranged from 3.3 to 11.2 years. The femoral stems were made of titanium alloy (Ti6Al4V) with the proximal third HA-coated by plasma spray onto a macro relief surface. The titanium substrate had a roughness of

3 to 4 μm Ra. The coating had a HA content greater than 90% and porosity less than 10%. Crystallinity was 100% before coating and greater than 75% thereafter. The grain size was 20 to 50 μm , and the strength of the tensile bond was 62 to 65 MPa. The thickness of the HA layer was $60 \pm 15 \mu\text{m}$.

The prostheses and surrounding bone were collected postmortem, immersed in buffered formalin for 7 days, and then immersed in 70% ethanol for 24 hours. Three cross sections were cut from the metaphyseal femur proximal to a line separating proximal Gruen Zones 1 and 7 (regions with HA coating) from the distal stem (Fig. 1). The three metaphyseal sections were proximal (A), medial (B), and distal (C).

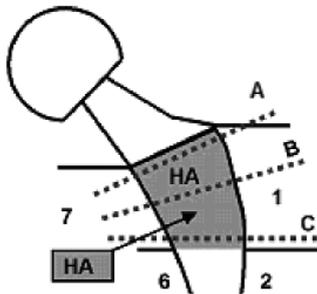


Fig. 1: Three cross sections were cut from the metaphyseal femur proximal to a line separating proximal Gruen Zones 1 and 7 (regions with HA coating) from the distal stem. The three levels were proximal (A), medial (B), and distal (C)

Each segment was embedded in a polymethylmethacrylate resin and a representative section (approximately 20 μm thick) was cut from each segment using a microcutting and grinding technique adapted from a technique described by Donath and Breuner.²¹ The sections underwent paragon staining (a combination of basic fuchsin and toluidine blue) for qualitative histology and quantitative histomorphometry.

A Polyvar microscope (Reichert-Jung, Vienna, Austria) was used for qualitative analysis; quantitative analysis was performed on an Axioskop[®] microscope (Carl Zeiss, Jena, Germany) equipped with a color image analyzing system (SAMBA technology; Alcatel, Paris, France).

The pathologists (MT, AA) were blinded to all clinical information, except for patient identification and cause of death. They successively identified regions of implant, bone, and lacunae, including all soft tissues. The methods used were described previously.¹⁸

For each section, the total implant perimeter and the percentage of implant perimeter covered by bone and/or by residual HA coating were measured. Bone-implant contact was defined as direct ongrowth of bone to the HA coating or to the titanium surface after HA resorption and represented the amount of osseointegration. The lengths of bone or HA contact were divided by the length of the implant interface to provide a parameter illustrating the percentage of the implant covered by bone or HA. Means and standard deviations were calculated for each section. The percentages of bone ongrowth and residual HA coating were compared among the three section levels (A, B, and C) and correlated to the total time in vivo and patient demographics (gender, age, diagnosis, time in vivo, weight, height, clinical score, and stem position).

The histomorphometric parameters for the femoral components of Cases 1, 3, 4, 5, and 7 were reported previously,¹⁸ but because of the small data sample, correlations between the histomorphometric and demographic data were not reported but rather the study focused on histological findings. In another histomorphometric study,¹³ nearly total resorption was observed after more than 6 years implantation. Therefore, we used a 6-year cutoff after implantation to compare amounts of HA coating resorption between two groups with time of implantation before and after this threshold (Group I existing of Cases 1-6 and Group II –existing of Cases 7-13)

To answer our first question, we used linear regression to correlate HA-resorption and bone ongrowth with time in-vivo and patient demographic factors such as age. In addition, based on the threshold value of 6-years in-vivo, we compared two groups above and below this threshold using the unpaired student t-test. To answer our second question, we used linear regression to correlate HA resorption with bone ongrowth and to correlate these two parameters with the three metaphyseal levels. The paired Student's t-test was used to compare the differences between these three levels.

The assumptions regarding linearity (correlation testing) and normality (comparisons) were confirmed using the runs test (linearity) and Kolmogorov-Smirnov test (normality). Trends and evidence levels (p values) also were validated using nonparametric test alternatives. To answer our third question we used only descriptive statistics.

Results

HA resorption (total of three stem levels) increased ($r = -0.775$; $p = 0.002$) with time in vivo as measured by the residual HA (Fig. 2).

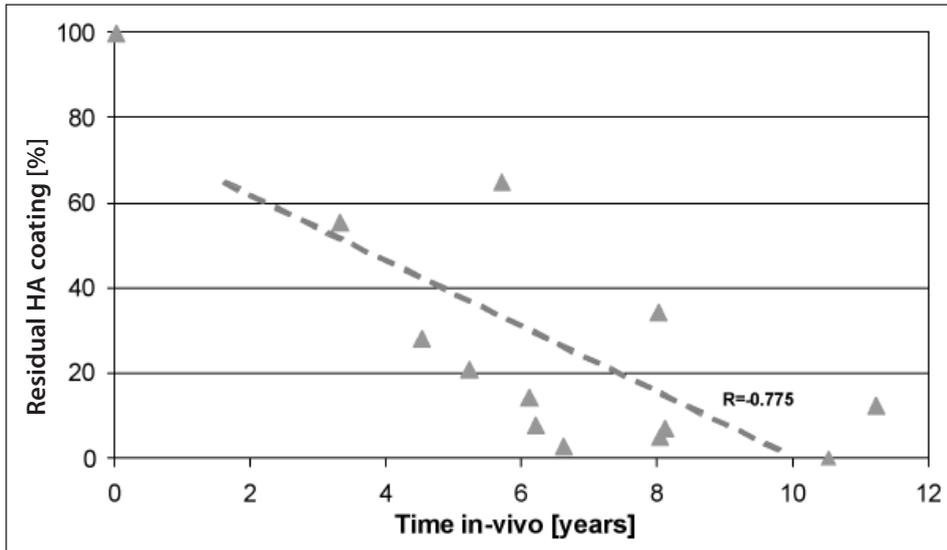


Fig. 2: A graph shows the correlation between residual HA coating and time in vivo ($r = -0.775$; $p = 0.002$)

Less residual HA and thus increased resorption with time in vivo was observed for each section (A: $r = -0.709$, $p = 0.007$; B: $r = -0.779$, $p = 0.002$; and C: $r = -0.756$, $p = 0.003$). Also, the average residual HA level was higher ($p = 0.02$) when time in vivo was less than 6 years ($36.7\% \pm 22.2\%$ [$n = 6$]) than when it was more than 6 years ($10.1\% \pm 10.0\%$ [$n = 7$]). Beyond 8 years, the HA was almost gone (Fig. 2). Overall bone ongrowth ranged between 18% and 56% and was independent ($r = 0.221$; $p = 0.46$) of the time in vivo (Fig. 3).

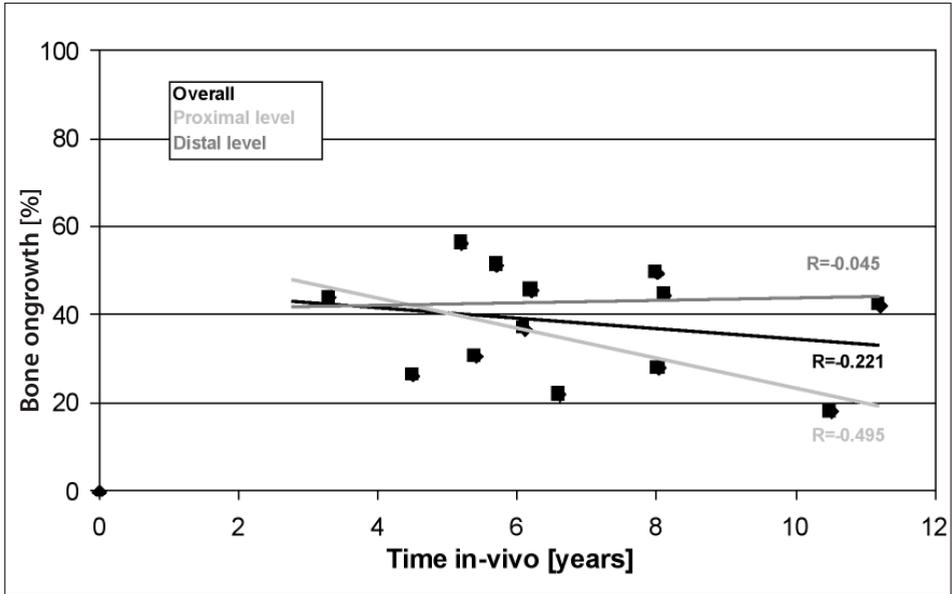


Fig. 3: A graph shows the correlation between bone ongrowth and time in vivo overall ($r = -0.221$; $p = 0.46$) and for the proximal ($r = -0.495$; $p = 0.085$) and the distal ($r = -0.045$; $p = 0.88$) levels

At the proximal level (A), bone ongrowth decreased somewhat ($r = -0.495$; $p = 0.085$) with time in vivo beyond 3 years, while the bone ongrowth remained flat at the medial B ($r = 0.044$; $p = 0.89$) and distal C ($r = 0.045$; $p = 0.90$) levels (Fig. 3). Bone ongrowth correlated ($r = -0.817$; $p = 0.0007$) with patient age, with younger patients having higher bone ongrowth than older patients (Fig. 4).

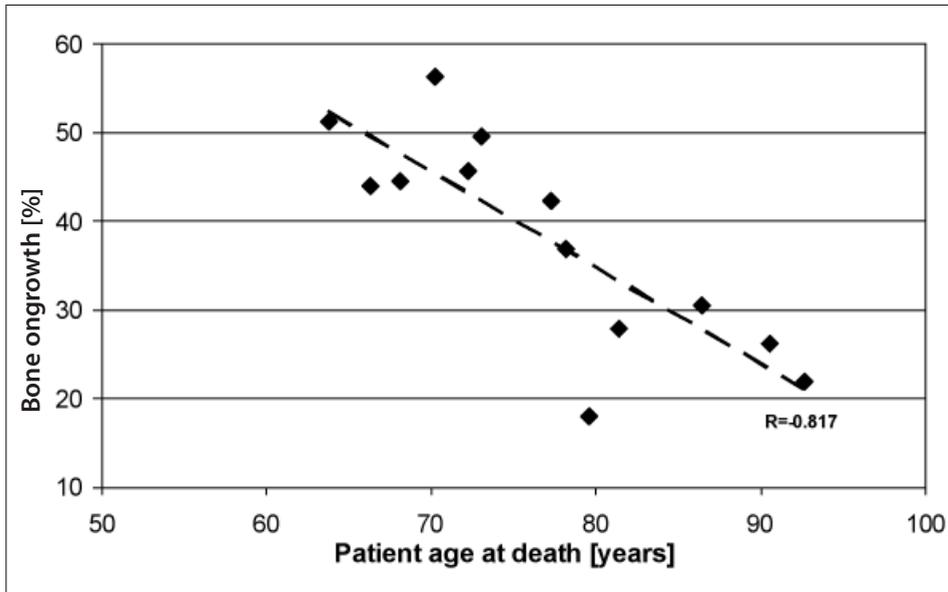


Fig. 4: A graph shows the correlation between patient age and overall bone ongrowth ($r = -0.817$; $p = 0.0007$).

HA resorption however did not correlate ($r = -0.396$; $p = 0.20$) with patient age. Patient height, weight, and body mass index had no influence on either residual HA ($p = 0.13$ – 0.86) or bone ongrowth ($p = 0.51$ – 0.93).

Bone ongrowth and HA resorption correlated ($r = 0.716$; $p = 0.009$) only in the most proximal zone, with lower bone ongrowth associated with lower levels of residual HA. We observed no correlation for the medial ($r = 0.265$; $p = 0.41$) or distal ($r = 0.200$; $p = 0.53$) stem level or for overall values ($r = 0.519$; $p = 0.08$). HA resorption was highest ($p = 0.045$) most proximally, with less residual HA in the proximal level ($13.0\% \pm 14.9\%$) than in the medial ($22.6\% \pm 23.1\%$) and distal ($28.1\% \pm 27.3\%$) levels (Fig. 5).

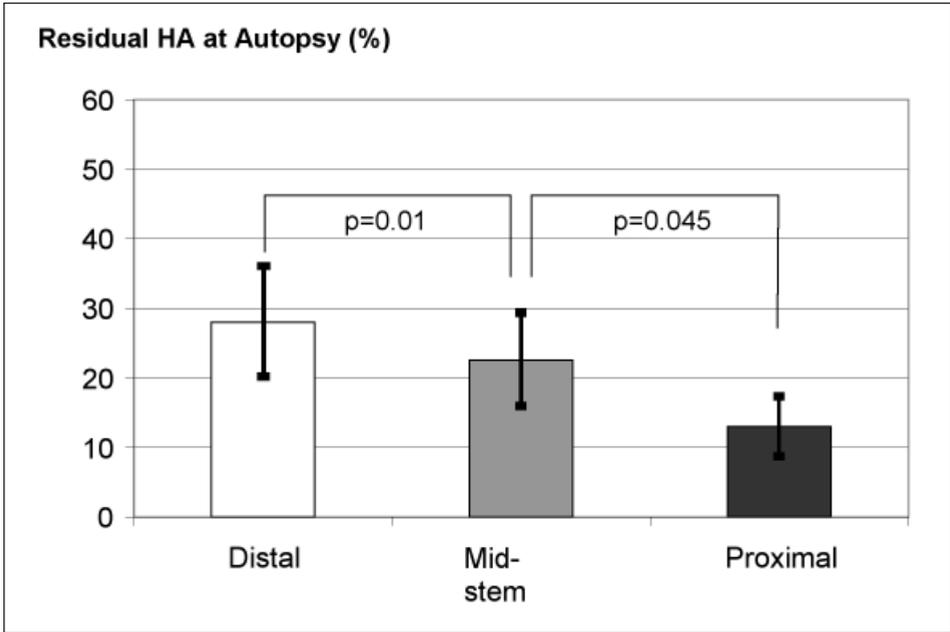


Fig. 5: A comparison between residual HA values measured at the different stem levels shows HA resorption was highest ($p = 0.045$) in the most proximal section. Data are expressed as means with standard errors of the mean

Bone ongrowth was not correlated ($p = 0.07-0.53$) with the metaphyseal stem levels (A: $34.1\% \pm 15.6\%$; B: $37.2\% \pm 14.9\%$; C: $42.7\% \pm 13.2\%$) (Fig. 6).

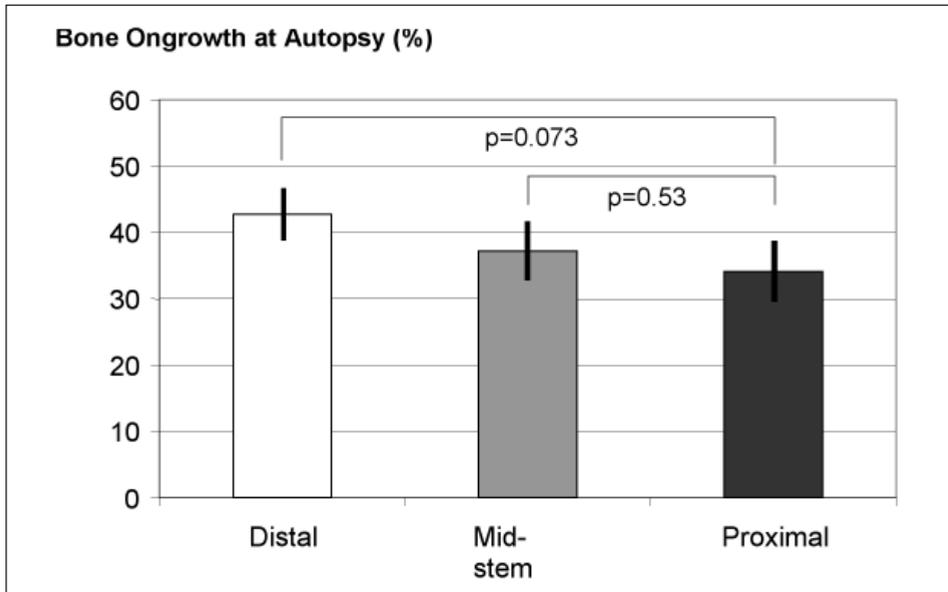


Fig. 6: A comparison between bone ongrowth levels measured at the different stem levels shows bone ongrowth was not correlated ($p = 0.07-0.53$) with the metaphyseal stem levels. Data are expressed as means with standard errors of the mean

All stems were well fixed at retrieval and the ranges of residual HA and bone ongrowth were 0% to 55% and 18% to 56%, respectively. The three lowest levels of residual HA still showing stable stem fixation were 0%, 3%, and 5%, respectively, whereas the three lowest levels of bone ongrowth that secured stem fixation were 18%, 22%, and 26%, respectively (Table 2).

	Patient number												
	1	2	3	4	5	6	7	8	9	10	11	12	13
Bone ongrowth [%]													
1A-7A	51	34	48	25	61	37	36	33	40	6	24	9	40
1B-7B	40	18	54	25	45	35	52	12	55	40	54	19	35
1C-7C	39	27	67	42	48	37	49	21	54	36	56	27	52
Mean	44	26	56	31	51	37	46	22	50	28	45	18	42
Residual HA [%]													
1A-7A	15	2	12	n.a.	50	11	5	3	31	0	2	0	6
1B-7B	68	3	20	n.a.	68	18	7	2	31	10	10	0	11
1C-7C	83	4	31	n.a.	77	14	11	8	41	6	11	0	20
Mean	55	3	21	n.a.	65	14	8	3	34	5	8	0	12

n.a.= not applicable

Table 2: Percentages of bone ongrowth and residual hydroxyapatite coating

Discussion

HA coating accelerates early bone ongrowth whereas proximal stress shielding-induced periprosthetic bone resorption seemingly plays a contrary role during the local bone remodeling process. One relates to initial repair primarily in cancellous bone while the other relates to long-term adaptation which radiographically seems to occur in the proximal cancellous areas as in the cortical areas.^{2,5,8,15,19,22,23} However, these opposing processes of bone gain and bone loss do not work at the same time, but whether they persist and to what degree are unknown. Although short-term retrieval studies report the HA coating after 2 to 4 years implantation is partly broken down through osteoclastic resorption,^{4,6,10-13,17,20} none of these studies reported whether patient demographics might influence residual HA coating or bone ongrowth.

Therefore, we asked three questions: (1) Is the resorption of HA coating and bone ongrowth mainly correlated with time in vivo or with demographics, and when time in vivo is predominant, at which point can we expect that all HA is gone?; (2) Are HA resorption and/or the amount of bone ongrowth correlated with each other or rather related to the metaphyseal stem level, and (3) What happens to the implant-bone interface when all of the HA coating is resorbed, how much bone ongrowth is left, and which minimum levels can be associated with clinically stable fixation?

Our study has some limitations. First, the quality of the initial bone stock and exact parameters of patient activity level were not known and these two factors have a major influence on general bone remodeling.^{17,19,24} Second, we did not study interobserver variability, although the two pathologists who performed the measurements were from a dedicated professional laboratory specializing in histology and histomorphometry. Third, with only three patients showing nonneutral stem alignment, we could not examine the influence of varus or valgus positioning on the histomorphometric bone remodeling parameters. Positioning might well influence long-term bone remodeling and we could not account for these influences. On the other hand, we studied retrievals from patients having only one femoral stem design. The harvesting, preparation, and analysis were the same for all specimens and the pathologists were blinded to all clinical data, except for cause of death.

We observed HA coating was increasingly resorbed with time from implantation and was nearly completed at 8 years. No other demographic factor showed any correlation. Bauer et al.^{10,11} and Hardy et al.¹² did not report a correlation between the extent of residual HA and duration in vivo but their series are too small (3 to 7 cases) and the follow-up was too short (25 months) to document substantial HA resorption. However, longer follow-up^{13,16,18} or animal experiments¹⁷ indicate a tendency toward total HA coating resorption with increased time of implantation. The only demographic factor that influenced the amount of bone ongrowth was age, with younger patients having higher bone ongrowth percentages than older patients. This may relate to greater initial bone stock in younger people but also can be explained by the fact that in older patients the resorptive component of the remodeling process is more prominent, especially in patients with senile osteoporosis. Our data do not support those of Linder et al.²⁵ showing inferior bone ingrowth in patients with osteopenic rheumatoid arthritis as compared with patients with osteoarthritis. Søballe et al.²⁶ also did not observe less bone fixation of HA-coated implants in osteopenic versus normal bone after 4-weeks implantation, but with titanium porous implants bony fixation was less in osteopenic bone. Also Shih et al.²⁷ observed significant impaired bone ingrowth of porous cobalt/chromium plugs in areas with cancellous bone in ovariectomized dogs compared with female controls. Therefore, it appears percentages of long-term bone ongrowth are affected mainly by the individual bone stock quality, which is intimately related to the age of the patient. The observation that HA resorption is independent of age supports this conclusion, but also indicates that older age is not a contraindication for the use of HA-coated implants.

Only the most proximal stem level showed a correlation between lower bone ongrowth and lower levels of residual HA. Both values decreased from distal to proximal but the effect and evidence were stronger for HA resorption. Thus the extent and metaphyseal location of the HA resorption strongly resembled the new postoperative proximal stress shielding patterns,²⁸⁻³⁰ as they can be qualitatively predicted for hip stems in general showing highest stress shielding most proximally and a rapid reduction in stress shielding going more distally. In other words, when we presume a relationship between the amount and location of resorption of the HA and the known pattern of progressing load transfer from proximal to distal, our histomorphometric results suggest that the bone remodeling process (as dictated by

the local stress-shielding patterns, which are described for instance in finite-element studies²⁸⁻³⁰) is a major regulating factor in HA resorption. Bauer et al.¹⁰ also reported a general increase of bone apposition from proximal to distal (in the coated portion of the stem). Coathup et al.²⁰ compared bone remodeling around one femoral stem design with three different proximal coatings in 21 post-mortem cases and observed a larger amount of bone ingrowth into the surface of the plain porous implants at the most distal metaphyseal level compared with the two proximal levels. However, bone ongrowth into the porous HA-coated regions was more evenly distributed without large differences. As they also noted more ingrowth and ongrowth of bone to the porous HA-coated surface, it is thought the HA counteracts the bone resorptive action of the local stress shielding, at least during the early postoperative years.

Since bone ongrowth was independent of implantation time *in vivo* and independent of HA resorption on the medial and distal parts of the coated stem, we presume the long-term implant fixation is not disturbed by ongoing HA-coating resorption. This means, during the remodeling process, part of the resorbed HA-coating layer will be replaced by bone. This has been observed in numerous experimental and retrieval studies.^{13,16-18} In a dog study using weight bearing implants, Overgaard et al.¹⁷ reported completely resorbed HA coating was replaced by $36\% \pm 6.0\%$ (range, 26%–42%) bone in direct contact with the implant surface, suggesting the implant was firmly fixed despite loss of the ceramic coating. Aebli et al,¹⁶ in a single human retrieval study, noted complete HA coating resorption after 9.5 years of good function, with a 34% average bone-implant contact at the originally coated part. We also observed retrieved specimens with little HA coating (0%–8%) remaining but with bone ongrowth percentages between 18% and 45%. These data indicate a lack of correlation between HA coating resorption and the amount of bone ongrowth; suggesting, after an initial burst of accelerated bone ongrowth with all its positive effects,^{1,2,7} HA has no additional beneficial or negative role during the middle to long-term for implant fixation or for the bone remodeling process.

We found the HA coating layer was slowly resorbed and was almost completely resorbed after 8 years of implantation. Age or other patient factors such as gender, height, and weight had no apparent influence on this process. The amount of bone ongrowth to the stem observed at postmortem, however, was related to the age of the patient at time of death but not to the time period of implantation. The extent and metaphyseal location of the HA coating resorption reflected the ongoing proximal

stress-shielding patterns after THA. These findings suggest the amount of HA coating resorption has no influence on the amount of bone ongrowth and therefore will not disturb long-term fixation of the implant.

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Chapter 6

Periprosthetic fractures around cementless hydroxyapatite-coated femoral stems

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Abstract

We studied 14 periprosthetic femoral fractures out of a series of 619 hydroxyapatite coated hip implants and compared the outcome to published treatment algorithms using the Vancouver classification. There were five type A fractures, six B1, two B2, and one type B3 fracture. All but one type A fractures were treated conservatively. Compared with the Vancouver classification, we observed a different fracture type in the type B fractures. No fractures at the tip of the stem were seen, as in cemented implants. Three B1 fractures were treated operatively due to fracture displacement, and three were treated conservatively. The B2 and B3 fractures were managed with long, uncemented, revision stems because of a disrupted bone-prosthesis interface. All fractures healed well. This study confirms that the modified algorithm of management of periprosthetic fractures, using the Vancouver classification, is a simple, reproducible, classification system for uncemented prostheses. Conservative treatment is a valid option if the implant is stable whilst surgical intervention is mandatory if the implant is loose.

Introduction

Periprosthetic femoral fractures have become more common as the population of at risk patients with joint arthroplasty has increased.^{1,2} These fractures pose a therapeutic challenge for the orthopaedic surgeon. The choice of treatment depends on the location of the fracture relative to the implant³, the fixation of the implant⁴ and patient factors such as deficient bone stock.^{5,6} The management of periprosthetic femoral fractures around cemented hip prostheses has been extensively described, but reports on femoral fractures around cementless femoral implants are scarce.⁷ Periprosthetic fractures around cemented femoral components mostly occur around the tip of the prosthesis. In cementless hip prostheses with a different pattern of bone remodeling⁸ different locations of stiffness gradients develop with consequently also different locations of periprosthetic fractures.⁹ This phenomenon has implications for fracture type and management of periprosthetic fractures around uncemented stems.

The Vancouver classification, originally mainly based on periprosthetic fractures in cemented prostheses, provides guidelines for classification and management of periprosthetic fractures.⁵ Type A fractures occur in the proximal Gruen (1 and 7) zones; type B fractures are diaphyseal, but not extending into the distal diaphysis. Type B fractures are subdivided; Type B₁ includes fractures in which the femoral component is still solidly fixed, while type B₂ includes fractures in which this component is loose. In case of a loose prosthesis and severe loss of bone stock the fracture is classified as type B₃. Periprosthetic fractures in which the implant is stable can be treated conservatively and in unstable implants surgery is mandatory.

Type C fractures occur well below the stem tip, and are in fact distal femur fractures. Recently a modified algorithm of management of periprosthetic fractures has been published by Learmonth et al.¹⁰ and Masri.¹¹ The latter has also expanded this system to cover intraoperative fractures.

In this study 14 cases of periprosthetic femoral fractures around one type of a cementless stem are described. Our treatment is compared to the most recent management algorithm of periprosthetic fractures using the Vancouver classification.^{10,11}

Patients and methods

From January 1990 to December 1996 619 consecutive total hip prostheses (ABG-I) have been implanted at our institution. The hip prosthesis used has a proximal coating

of plasma sprayed hydroxyapatite (ABG[®], Stryker Howmedica, UK) and is extensively described in former studies.^{8,12,13} Both the acetabular and femoral components are implanted in a cementless press fit manner.

Patients receiving such hip prostheses were followed-up annually and were examined using the Merle d' Aubigne hip score together with a physical examination. In addition radiographic analysis was performed on the implants annually to measure stem position and bone remodeling processes around the prostheses. The position of the femoral stem was judged as normal when the position was within 2°valgus>stem<2°varus.

Fourteen patients have presented a fracture around the femoral component after an adequate trauma, mostly a fall at home (14/619= 2.26%). These patients and the whole group were analysed demographically.

Of the 619 ABG hip prostheses 155 were implanted in men and 464 in women; the PPF-group consisted of 11 women and 3 men. 11/464 women (2.4%) sustained a periprosthetic fracture and 3/155 men (1.94%) (n.s.). Mean age at operation in the whole group was 67.6 yrs and 72.6 yrs in the PPF-group (periprosthetic fracture group) (n.s. p=0.05).

Mean BMI at operation was 26.8 and in the PPF-group 24.8 (n.s. p=0.1). Of the 619 ABG femoral implants 59 were placed in varus and 4 in valgus. In the group with the periprosthetic fractures all femoral implants were placed in neutral position. (n.s., varus p=0.26, valgus p=0.76, neutral p=0.24).

Mean stem size in the whole group was 4.6 and in the group with a periprosthetic fracture was 5.5 (p=0.005). The average interval since the index hip operation was 6.9 years (range 2.0 to 13.7 years).

The average age at the time of the fracture was 79 years (range 65 to 92 years). Until the time of fracture all 14 patients showed an uneventful postoperative course. Mean follow-up after the periprosthetic fracture was 3.2 yrs.

Fractures were classified using the Vancouver classification and treatment of these fractures was retrospectively compared with the recently published management algorithm of periprosthetic fractures.^{10,11}

Statistical analysis

Groups were analyzed using the unpaired t-test or Chi-square test. P values <0.05 were considered to be statistically significant.

Results of fracture treatment

In Table I the 14 cases are listed and grouped by type of fracture.

Thus, five type A fractures, six B₁, two B₂ fractures, one B₃-fracture and no type C fractures were seen.

	A	B	C	D	E	F	G	H	I	J
1	F	OA	23	69	7	Fall	69	2	B1	Traction 6 weeks
2	F	OA	25	81	6	Fall	86	5	AG	Bed rest 4 weeks
3	F	OA	27	83	6	Fall	88	5	B1	Traction 6 weeks
4	M	OA	33	68	5	Fall	73	5	B1	Cable grip wiring
5	F	OA	23	78	4	Fall	80	6	AG	Bed rest 10 days
6*	F	RA	21	59	6	Fall	64	6	B2	Long stem revision, plate, cerclage
7	M	RA	28	70	7	Fall	78	8	B1	Gradual weight bearing
8	F	OA	23	80	5	Fall	87	7	B2	Long stem revision + cerclage
9	F	OA	23	82	3	Fall	91	10	B1	Zimmer-trochanterplate, cerclage
10	F	AN	25	65	6	Fall	71	5	AG	Gradual weight bearing
11	F	OA	23	70	5	Fall	81	11	AG	Zimmer-trochanterplate, cerclage
12	M	RA	19	63	6	Fall	69	6	AL	Gradual weight bearing
13	F	OA	26	73	5	Fall	87	13	B3	Long stem revision + Zimmer-trochanterplate + cerclage + femoral allograft
14	F	OA	25	70	6	Fall	82	11	B1	3 cerclage wires, 6 weeks no weight bearing
	11F/3M		25.0	70.0	5.5			6.9		

* sustained a new periprosthetic fracture 53 months after the revision operation

A = sex

B = primary diagnosis; OA= osteoarthritis, RA= rheumatoid arthritis AN= avascular necrosis

C = BMI

D = age at first surgery (THA)

E = stem size

F = cause of fracture

G = age at second surgery (PPF)

H = years until fracture

I = fracture type

J = type of treatment

Table 1: Diagnosis, treatment and follow-up of periprosthetic femoral fractures

Type A: Three patients sustained a fracture of the greater trochanter without significant displacement and a stable stem (Type A_G fractures). The fractures occurred in the area between the proximal (1) and middle (2) lateral Gruen zones in which an acute bone density gradient was seen on the X-ray. Two cases were managed by simple bed rest for respectively 28 and 10 days after which gradual weight bearing was begun. The other case was managed by direct gradual weight bearing. One patient sustained a fracture of the lesser trochanter, which was also managed by direct gradual weight bearing. Treatment in these cases was uneventful with no complications. At follow-up these patients were satisfied and showed adequate hip functions. Radiographically consolidation was observed at six weeks. One patient sustained a fracture of the greater trochanter with severe displacement, which had to be operated. Fixation was achieved by a trochanter plate and 4 cerclage wires. See figure 1.



Figure 1: Patient with a fracture of the greater trochanter with severe displacement (left)
Fixation was achieved by a trochanter plate and 4 cerclage wires (right)

Type B: Nine patients sustained fractures through the diaphyseal area around the stem (Type B fractures). The fractures occurred also in the area between the proximal (1 and 7) and middle (2 and 6) Gruen zones in which an acute bone density gradient was seen on the X-ray.

Stable implants: in six of these fractures (6/9) the stem was considered stable, thus they were classified as type B₁ fractures. Closed treatment was carried out in three patients (3/6). Traction provided healing after 6 weeks in two cases, whereas one case was managed by gradual weight bearing. These patients showed uncomplicated recovery with radiographically consolidated fractures after three months. In the other three type B₁ fractures (3/6 stable implants) osteosynthesis with cable wiring with or without a trochanteric plate was needed because of severe displacement of the loose proximal fragments. During surgery it was confirmed that the stem was still fixated. In two of these cases immediate full weight bearing with crutches was allowed leading to fast recovery and proximal reosseointegration within three months. In the other case only partial weight bearing was allowed during the first six weeks after the surgery.

Unstable implants: three patients (3/9) were classified as type B₂- B₃ fractures because they sustained fractures in the diaphyseal area around the stem, which did not show osseointegration in the distal Gruen zones 3-5. These stems therefore were completely loose and had to be revised with a long revision stem and plating with cerclage wiring. One of these patients (B₃-fracture) had very poor bone stock and received a femoral allograft as well. See figure 2. One patient (B₂-fracture) sustained a second periprosthetic fracture distal to the revision stem after 4 years later. Fracture stabilisation was achieved by plate and cerclage wiring.



Figure 2: Patient with an unstable fracture and completely loose stem with also a poor bone stock. (B_3 -fracture). This stem had to be revised with a long revision stem and plating with cerclage wiring. This patient received a femoral allograft as well (right)

In summary: type A fractures were all but one treated conservatively. Three B_1 fractures were operated because of fracture displacement and three were treated conservatively. The B_{2-3} fractures were managed operatively with long revision uncemented femoral components.

Discussion

In this article fourteen cases of postoperative fractures around one special type of femoral component of an uncemented HA coated hip prosthesis, 2 to 13.7 years after implantation, are described. The estimated prevalence of postoperative periprosthetic femoral fractures in the literature ranges from 0.1 to 2.1%¹¹, however, this usually concerns cemented hip prostheses.^{1,9} An increased risk with uncemented implants has been reported.¹⁴ Our fracture rate of 2.26% confirms these findings. In the retrospective study of Wu¹⁵ a postoperative periprosthetic fracture rate in uncemented hip implants of 3.5% was reported.

The cause of periprosthetic fractures is usually a minor episode of trauma.⁴ The patients described in this study all suffered a minor episode of trauma.

Major risk factors for periprosthetic fractures include osteoporosis, osteolysis and revision arthroplasty.¹⁴ The increased risk for fracture after revision total hip arthroplasty is probably due to compromised bone quality and focal bone deficiencies.¹ Periprosthetic stress fractures can occur spontaneously in areas of high stress¹⁶ as in osteopenia in combination with varus angulation of the femur.^{3,4, 17} No varus angulation of the femur was encountered in our series, indicating that this factor did not influence the fracture rate. A slight preponderance of periprosthetic fractures in women is noted¹ as in our series (2.37% vs. 1.94%), although the difference was not significant. There was also no significant difference in BMI between both groups. Furthermore, particulate debris-induced osteolysis also has been shown to be a risk factor for periprosthetic fractures.¹⁸ No specific period after total hip arthroplasty has been reported to elevate the risk for a periprosthetic fracture.

However, the mean stem size in our patients with a periprosthetic fracture was significant larger than for the whole group. This larger stem size might influence the fracture rate, because a greater stiffness increases stress shielding and the subsequent bone resorption is a risk factor for a periprosthetic fracture. The larger stem size in the PPF-group might be due to the higher age of these patients at the index operation, although the difference was not significant.

The site of the fracture in our series was always localized in an area where an acute bone density gradient in the cortex had developed, between the proximal and the middle Gruen zones. The ABG-I is a proximally hydroxyapatite (HA)-coated hip prosthesis designed for proximal stem bonding and stress transfer. Indeed this process does occur, as was shown in retrieval histological studies and finite element studies^{13,19}, but DEXA studies pointed to general periprosthetic bone resorption in all Gruen zones during the first half year after operation, which was most prominent for the proximal Gruen Zones 1 and 7.²⁰ After that time, a balance between bone resorption and bone formation occurred between 12 and 24 months after operation, suggesting that the load transfer in that area was sufficient to prevent any further postoperative bone loss. In comparison, the periprosthetic bone loss in Gruen zones 2-6 stabilized by 3 months. In Gruen zone 6, BMD increased progressively after the 3-month time point and the total recovery of 5% at the end of 3 years was statistically significant.²⁰ These findings suggest that in the ABG-1 stem the load transfer occurred mostly distally to Gruen zones 1 and 7 after the initial proximal osseointegration, which is acknowledged by radiographic analysis and histological studies.^{8,12,13} So, in time there develops a rather acute gradient in bone density at the transition zone of

Gruen zone 1-7 and Gruen zone 2-6 acting as a local stress raiser with an increased risk for fracture. When the patient falls on the operated hip a local fissure or fracture can develop at that particular location. This fracture may propagate as a transtrochanteric fracture (Type A) or, when the impact of energy is even larger, may propagate further distally (Type B). So there is always a local or more extensive debonding of the proximal osseointegration and depending on the status of the stem, distally bonded or not, the stem remains fixed or not. For similar reasons most fractures around cemented prostheses occur in the area around the tip of the prostheses since that is the area where an acute gradient in stiffness is present between the cemented part of the femur and the uncemented part.

The Vancouver classification system provides a clear assistance in formulating the strategy for management of a periprosthetic fracture and an algorithm of management of periprosthetic fractures has recently been published.^{10,11}

In our study we have seen five type A fractures, six B₁, two B₂ fractures and one B₃ fracture.

The type A fractures were managed conservatively except for one, which showed severe displacement of the greater trochanter. This is in accordance with the management algorithms of periprosthetic fractures.^{10,11}

Compared to the Vancouver classification we observed a different fracture type in the type B- fractures. No fractures at the tip of the stem were seen as in cemented implants.

The treatment of B₁-fractures around in-growth prostheses essentially differs from the cemented counterpart since in the latter treatment would mainly be operatively.^{21,22}

Although in the recently published management algorithm of periprosthetic fractures by Masri¹¹ open reduction and internal fixation with or without strut allograft is advised for B₁-fractures, we rather agree with the management algorithm of Learmonth¹⁰ that in case of a stable prosthesis conservative treatment is a good option. Two patients were treated by traction for six weeks. However, traction treatment and bed rest in the elderly patient bears the risk of the development of airway and thromboembolic complications and decubitus ulcers. One can speculate that these patients would perhaps have been better treated by gradual weight bearing.

In three type B₁ fractures osteosynthesis was needed because of severe displacement of the loose proximal fragments. Although Masri and Learmonth^{10,11} propagate ORIF with cerclage and struts or a plate for unstable B₁-fractures, we have used in two patients only cerclage wiring with good results. However, Mont et al.⁷ showed that

in mid stem and distal stem fractures, cerclage cables and bone graft or revision to a longer stem were superior to screw-plate fixation or traction. Only cerclage cables seem to be a good option, although one of these patients was not allowed to start weight bearing directly. This patient could probably have been mobilized earlier in case struts or plates with cerclage wiring were used.

The two B₂ fractures and one B₃-fracture in our series were treated with a long uncemented revision stem (DPM® Stryker Europe). Treatment by special designed revision stems is clearly indicated in any periprosthetic fracture in which the implant is loose. Type B₃-fractures are fractures with unstable implants associated with deficient bone stock and they need some sort of additional bone augmentation.^{21,22} In the literature some controversy exist whether cemented or uncemented long stemmed implants should be used in B₂ or B₃-fractures.^{21,23} On one hand sufficiently long stemmed porous coated prostheses achieving distal fixation seem adequate treatment. On the other hand the use of cement bears a risk of cement interposition between fracture fragments. However, this is probably technique related and special care is needed to expose the diaphysis avoiding cement interposition. In case of a B₃-fracture in the elderly patient it is advised by Learmonth¹⁰ and Masri et al.¹¹ to perform a prosthetic proximal femoral replacement or even a tumor prosthesis. In our series we used a long stem revision implant, together with a plate and cerclages and a femoral allograft to augment the bone stock. So, except for the B₃-fracture our treatment algorithm did follow the management algorithm of Learmonth¹⁰ and Masri et al.¹¹ See Figure 3.

The incidence of periprosthetic fractures around non cemented prostheses probably will form an increasing therapeutic problem.¹⁰ Fracture patterns differ essentially from those seen in cemented hip prostheses, as has been shown in our study. This study also confirms that the algorithms of management of periprosthetic fractures by Learmonth¹⁰ and Masri et al.,¹¹ based on the Vancouver classification, are adequate for the uncemented treatment modality. Conservative treatment is a valid option in case of a stable implant, unless fracture displacement is too large, while in case of a loose implant surgical intervention is always mandatory.

The goal of operative treatment is to return the patient to pre-morbid activity level. Careful preoperative planning based on the status of the prosthetic interfaces and fracture types will increase the chance of a favourable outcome.

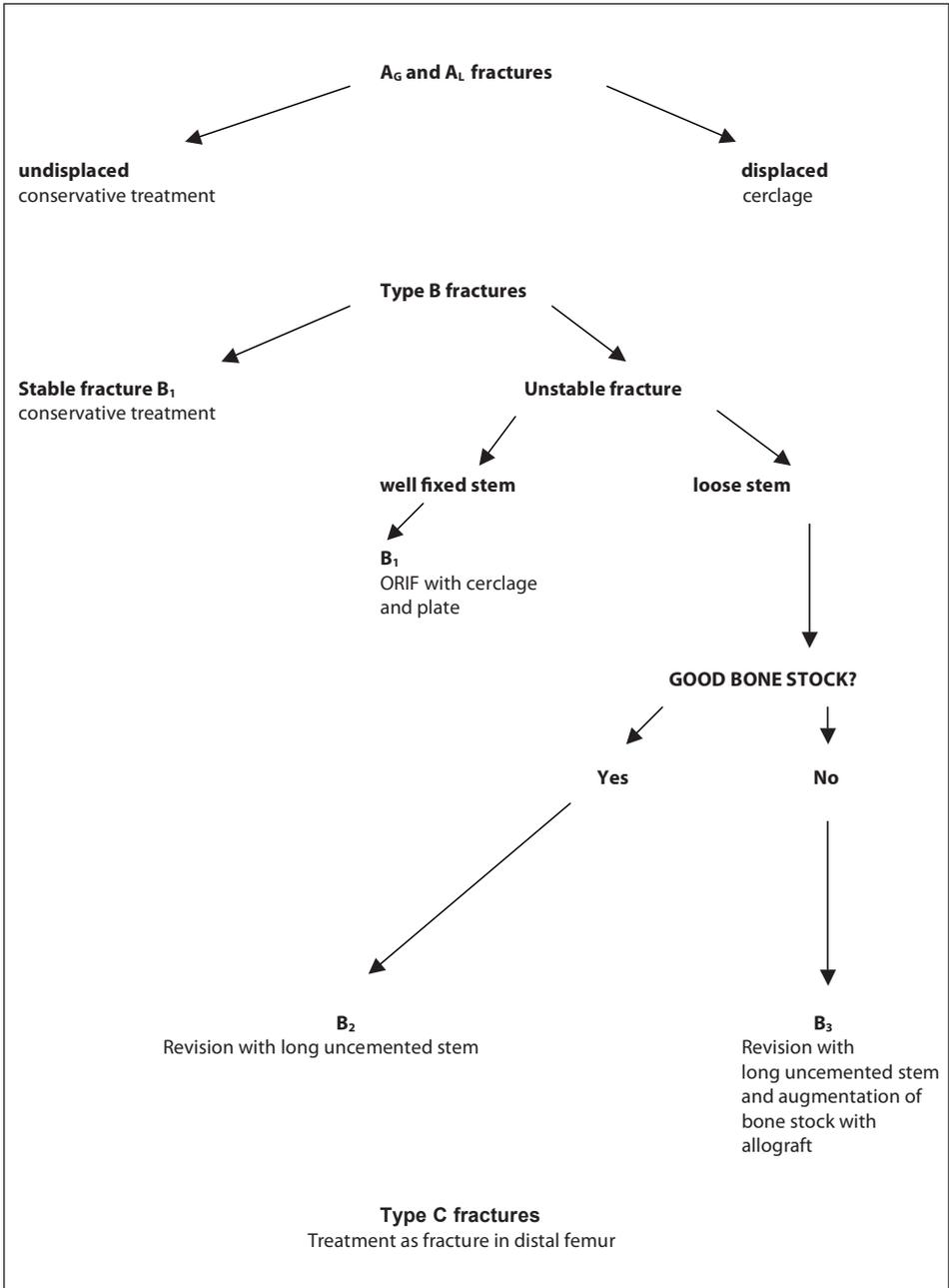


Figure 3: Our management algorithm of postoperative periprosthetic fractures in uncemented femoral implants

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Chapter 7

Answer to the questions

Question 1) What are the characteristics of the bone remodeling pattern around a hydroxyapatite-coated hip prosthesis and can the theoretical benefits of the design changes in the successor generation (ABG-II), aimed at improving proximal bone preservation, be validated clinically?

Answer 1) The DEXA-study described in chapter 2 shows that in both implants there was proximal bone loss after 2 years. A different bone remodeling pattern was shown: ABG-II preserved bone better proximally than ABG-I. Distally, the trend was the opposite and less bone loss was measured for the ABG-I than the ABG-II. However, these differences were not statistically significant.

Question 2) Does preoperative bone quality significantly influence the bone remodeling around a specific HA-coated hip prosthesis?

Answer 2) The DEXA-study described in chapter 3 shows that by matching patients for preoperative bone quality and gender a statistically significant difference was found in proximal bone preservation in favor of the uncemented hydroxyapatite-coated hip prosthesis, designed for more proximal loading.

Question 3) Is the fit and fill ratio of a HA-coated hip implant a critical factor concerning bone remodeling and clinical results?

Answer 3) The study described in chapter 5 shows that a tight or non-tight fit of the ABG-II stem is not associated with certain radiological changes, but there is correlation with clinical results. A non-tight proximal fit is correlated with varus position of the stem. Thigh pain is correlated with a poor fit and fill of the femoral stem.

Question 4a) Is the resorption of HA coating and bone ongrowth mainly correlated with time in vivo or with demographics, and when time in vivo is predominant, at which point can we expect that all HA is gone?

Answer 4a) Hydroxyapatite resorption was independent of patient age, but increased with time in vivo and was mostly gone after 8 years. Bone ongrowth was independent of time in vivo but decreased with aging patients.

Question 4b) Are HA resorption and/or the amount of bone ongrowth correlated with each other or rather related to the metaphyseal stem level?

Answer 4b) Only in the most proximal section did less residual hydroxyapatite correlate with less bone ongrowth. Hydroxyapatite resorption, which was more proximal than distal showed no adverse effects on the implant-bone interface.

Question 4c) What happens to the implant-bone interface when all hydroxyapatite coating is resorbed?

Answer 4c) The amount of HA coating resorption has no influence on the amount of bone ongrowth and therefore will not disturb long-term fixation of the implant.

Question 5a) Bone remodeling patterns have been shown to differ between cemented and uncemented implants. Does this difference in bone remodeling pattern also influence the morphology of fractures in the uncemented stem?

Answer 5a) This uncemented hydroxyapatite-coated hip prosthesis does indeed show different fracture patterns compared to the cemented implants. The site of the fracture in our series was always localized in an area where an acute bone density gradient in the cortex had developed, between the proximal and the middle Gruen zones. No fractures at the tip of the stem were seen as in cemented implants.

Question 5b) Is there an increased periprosthetic femoral fracture rate for this hydroxyapatite-coated hip prosthesis compared to the cemented stems?

Answer 5b) The study described in chapter 6 describes how the periprosthetic femoral fracture for this uncemented hydroxyapatite coated hip prosthesis ABG-I is comparable to other uncemented total hip implants. Our PPF-rate does indeed show an increased risk compared to cemented implants.

Question 5c) Does the diagnostic and treatment protocol established for periprosthetic fractures of cemented stems (Vancouver classification) also apply to uncemented stems?

Answer 5c) This study confirms that the modified algorithm of management of periprosthetic fractures, using the Vancouver classification, is a simple, reproducible classification system also suitable for the uncemented treatment modality.

Antwoorden op de vragen

Vraag 1) Wat zijn de karakteristieken van het patroon van botremodelling rondom een hydroxyapatiet gecoate heupprothese en kunnen de theoretische voordelen van de veranderingen in het ontwerp van de nieuwe generatie femursteel (ABG-II), gericht op het verbeteren van proximale botpreservatie, klinisch worden gevalideerd?

Antwoord 1) De DEXA-studie beschreven in hoofdstuk 2 toont aan dat na 2 jaar bij beide prothesen sprake is van proximale botresorptie. Een verschil in het patroon van botremodelling was waarneembaar: ABG-II preserveerde het bot proximaal beter dan ABG-I. Distaal was de trend precies tegenovergesteld: bij de ABG-I was het botverlies distaal minder dan de ABG-II. Echter, deze verschillen waren statistisch niet significant.

Vraag 2) Wordt botremodellering rondom een hydroxyapatiet gecoate heupprothese beïnvloed door de preoperative botkwaliteit van de patiënt?

Antwoord 2) De DEXA-studie, welke wordt beschreven in hoofdstuk 3, toont aan dat door groepen patiënten te vergelijken van gelijk geslacht en overeenkomstige preoperatieve botkwaliteit een significant verschil wordt gevonden voor proximale botpreservatie ten gunste van de HA-gecoate heupprothese, welke ontworpen is voor een betere proximale belasting.

Vraag 3) Is de juiste fit van een HA-gecoate heupprothese in het medullaire kanaal een kritieke factor wat betreft botremodellering en klinische resultaten?

Antwoord 3) De studie beschreven in hoofdstuk 5 toont aan de fit van de steel in het medullaire kanaal geen correlatie toont met bepaalde radiologische veranderingen, maar er is wel een correlatie met de klinische resultaten. Een niet nauwsluitende proximale fit is gecorreleerd met een varus positie van de femursteel. Pijn in het bovenbeen is gecorreleerd met een slechte fit van de femursteel.

Vraag 4a) Is de resorptie van de hydroxyapatiet coating en bot ingroei ter plaatse van de femursteel met name gecorreleerd met de tijd in vivo of met patiënt gerelateerde factoren, en indien de tijd in vivo de belangrijkste factor is, op welk tijdstip kan verwacht worden dat al het hydroxyapatiet is geresorbeerd?

Antwoord 4a) De resorptie van de hydroxyapatiet is onafhankelijk van de leeftijd van de patiënt, maar de resorptie van de hydroxyapatiet neemt toe met de tijd in vivo en de HA was bijna geheel geresorbeerd na 8 jaar. Bot ingroei is onafhankelijk van de tijd in vivo, maar is minder naarmate de patiënt ouder is.

Vraag 4b) Is de resorptie van de hydroxyapatiet en/of de mate van bot ingroei onderling gecorreleerd of alleen gerelateerd aan het metafysaire niveau van de steel?

Antwoord 4b) Alleen in het meest proximale gedeelte van de steel is een grotere resorptie van de hydroxyapatiet gecorreleerd met minder botingroei. Resorptie van de hydroxyapatiet is proximaal meer dan distaal, echter dit veroorzaakte geen negatief effect op de interface tussen het bot en de femursteel.

Vraag 4c) Wat gebeurt er met de interface tussen het bot en de femursteel als al het hydroxyapatiet is geresorbeerd?

Antwoord 4c) De hoeveelheid resorptie van de HA-coating heeft geen invloed op de mate van bot ingroei en zal daarom op de lange termijn de fixatie van de steel niet nadelig beïnvloeden.

Vraag 5a) Het is aangetoond dat het patroon van bot remodelering verschillend is voor gecementeerde heupprothesen in vergelijking met ongecementeerde heupprothesen. Beïnvloedt dit verschil van botremodellering ook de morfologie van de fracturen rondom een ongecementeerde steel van een heupprothese?

Antwoord 5a) Deze ongecementeerde hydroxyapatiet gecoate heupprothese toonde inderdaad een ander patroon van fracturen rondom de steel in vergelijking met een gecementeerde heupprothese. De plaats van de fractuur rondom de steel was altijd gelocaliseerd daar waar een afname van botdichtheid in de cortex was ontstaan, op de overgang tussen de meest proximale en middelste Gruen zones. In tegenstelling tot de gecementeerde heupprothese toonde deze studie geen fracturen ter plaatse van de tip van de steel.

Vraag 5b) Is het aantal periprothetische fracturen verhoogd voor deze hydroxyapatiet gecoate heupprothese in vergelijking met de gecementeerde heupprothese?

Antwoord 5b) De studie in hoofdstuk 6 beschrijft dat het aantal periprothetische fracturen rondom deze ongecementeerde hydroxyapatite gecoate femursteel (ABG-I) vergelijkbaar is met andere ongecementeerde femorale componenten. Het aantal periprothetische fracturen rondom deze ongecementeerde femursteel is inderdaad verhoogd in vergelijking met een gecementeerde heupprothese en derhalve is ook het risico op een periprothetische fractuur verhoogd.

Vraag 5c) Is het diagnostische en behandelingsprotocol vastgesteld voor periprothetische fracturen rondom gecementeerde femurstelen (Vancouver classificatie) ook toepasbaar op de ongecementeerde femurstelen?

Antwoord 5c) Deze studie bevestigt dat een gemodificeerd algoritme van de behandeling van periprothetische fracturen, met als uitgangspunt de Vancouver classificatie, een eenvoudig reproduceerbaar classificatie systeem is, welke ook toepasbaar is voor de behandeling van periprothetische fracturen rondom een ongecementeerde totale heupprothese.

Chapter 8

Summary and conclusions

In this thesis the clinical results, the periprosthetic bone remodeling and histological analysis of an anatomical designed proximally hydroxyapatite-coated hip prosthesis were investigated to answer several research questions.

In **chapter 1** a short overview of the history of total hip arthroplasty is presented. Terms such as bone remodeling and stress shielding are introduced and explained. The influence of patient factors, disease, medication, total hip arthroplasty and different kinds of stem design on bone remodeling is discussed. The properties of a hydroxyapatite coating and its biological impact are described for the uncemented femoral stem. The uncemented, anatomical designed proximal HA-coated stem used in these studies (ABG-I, Stryker, USA) is described in detail and also its successor (ABG-II). Special attention is also given to post-operative implant evaluation by the use of serial X-rays, DEXA scans and post-mortem histological analysis.

Several questions are formulated that should elucidate which factors are responsible for proximal bone resorption, and the approaches that lead to answer these questions are outlined.

In **chapter 2** a two year prospective study was performed to see whether the stem design changes for ABG-I to ABG-II resulted in improved proximal bone preservation. Fifty-one patients were randomized to either the ABG-I or ABG-II stem. For the clinical evaluation, the Merle d'Aubigne (MdA) hip score was used. Post-operative X rays were measured for stem position (varus $>2^\circ$, neutral or valgus $>2^\circ$). Periprosthetic BMD change at various time points was measured using DEXA. Post-operative DEXA scans were performed to measure BMD in periprosthetic bone at 10 days (treated as the baseline for subsequent follow-up), six weeks, and 3, 6, 12, and 24 months after total hip arthroplasty.

All patients showed less pain in the operated hip, and no statistically significant differences were found between the preoperative and postoperative MdA scores for the ABG-I and ABG-II implant. The mean stem size and stem alignment of both implants were not significantly different either.

The average BMD decline during the first three months post-operatively was steep and very similar for most patients for all Gruen zones and for both implant types.

After 3 months and up to 24 months post-operatively, in the mid-stem Gruen zones 2 and 6 and the distal zones 3, 4 and 5, the BMD decline either stopped and formed a plateau or even showed some recovery in both the ABG-I and ABG-II groups. In the proximal Gruen zones 1 and 7 bone mineral density around the ABG-II implant

developed a plateau or showed some recovery at one year post-op while BMD in the ABG-I group continued to decline in regions 1 and 7. However the differences between the two stem designs (ABG-I and ABG-II) were not statistically significant.

In **chapter 3** a retrospective study was performed in which patients with an ABG-II hip implant were compared with two different groups of patients with an ABG-I hip implant. Patients were matched for preoperative bone quality and gender, because recently it was shown that preoperative bone quality is a major factor influencing bone loss around a newly inserted femoral stem. Thus it was hypothesized that different preoperative bone quality between the two groups evaluated in chapter 2 may have reduced the statistical power of the study and that using patient groups matched for preoperative bone quality would increase statistical power for other parameters such as stem design. Twenty-four ABG-II patients were compared with two different ABG-I groups: A) Twenty-five patients from our earlier prospective study and B) twenty-four patients selected to match the ABG-II group for gender, age and preoperative bone quality.

The ABG-II group consisted of eleven males and thirteen females. Three patients were classified as having normal bone, sixteen patients had osteopenic bone and five patients had osteoporotic bone. Group A consisted of seventeen males and eight females. Three patients were classified as having normal bone, fifteen patients had osteopenic bone and seven patients had osteoporotic bone. The matched group B consisted of eleven males and thirteen females. Three patients were classified as having normal bone, sixteen patients had osteopenic bone, and five patients had osteoporotic bone. Post-operative changes in periprosthetic bone mineral density (BMD) were quantified at two years post-operative using DEXA. Bone preservation (less BMD loss) was better for the ABG-II than the ABG-I (both groups) in the proximal zones 1 & 7. In Gruen zone 7 a statistically significant difference was found for group B at two years follow-up.

In **chapter 4** a consecutive series of sixty-four patients, out of a prospectively followed group of patients, with an ABG-II stem is presented. In this study we analyzed whether the tightness of fit of the prosthesis affects bone remodeling and whether there is a correlation between clinical results and radiological features. In addition, a comparison with the literature allowed us to establish whether there are different bone remodeling patterns between both stem generations. The follow-up period was five years and for the clinical evaluation the Merle d'Aubigne (MdA) hip score was used. Femoral fit was measured on the direct post-operative radiographs (AP view). The femoral fit was defined as tight when this ratio of the fit was ≥ 0.8 and as non-tight when the fit was

<0.8. Fit was measured at the proximal, mid stem and distal stem level. Radiographic evaluation comprised a meticulous description of all changes of the bone around the implant and changes in the position of the implant. Bone remodeling was compared with literature values of the ABG-I stem. Clinical outcome and bone remodeling at 5 years was correlated with fit and fill.

Proximal bone resorption in the proximal Gruen zones was more frequent for the ABG-I than the ABG-II implant. No correlation was found between femoral fit and radiological features, but a non-tight proximal fit was correlated with varus position of the stem. Thigh pain was correlated with a poor fit of the femoral stem.

In **chapter 5** a histological and histomorphometrical study is presented which evaluates the normal tissue reactions around an hydroxyapatite coated hip implant (ABG-I) retrieved at post-mortem.

From a series of over 750 consecutive primary total hip arthroplasties, thirteen femoral stems could be examined after retrieval at autopsy 3.3 to 11.2 years after implantation. All 13 patients had uneventful THA procedures and died from causes unrelated to hip diseases. The prostheses and surrounding bone were prepared for qualitative histological and quantitative histomorphometric analysis. Three cross sections were cut from the metaphyseal femur proximal to a line separating the proximal Gruen zones 1 and 7 (regions with HA coating) from the distal stem. The three sections were A (proximal), B (mid-part) and C (distal). The percentage of bone growth onto the implant (bone-implant contact), the relative bone area around the implant, the extent of residual hydroxyapatite coating, and the thickness of the coating were measured.

Hydroxyapatite resorption was independent of patient age, but increased with time in vivo and was mostly gone after 8 years. Bone ongrowth was independent of time in vivo but decreased with aging patients. Only in the most proximal section did less residual hydroxyapatite correlate with less bone ongrowth. Hydroxyapatite resorption, which was more proximal than distal showed no adverse effects on the implant-bone interface. The amount of HA-resorption in relation to its metaphyseal level is suggesting the remodeling bone process as the principal actor of the HA coating resorption.

In **chapter 6** a retrospective study was performed. From January 1990 to December 1996 619 consecutive total hip prostheses (ABG-I) have been implanted at our hospital. Fractures were classified using the Vancouver classification and treatment of these fractures was retrospectively compared with the recently published management algorithm of periprosthetic fractures. Fourteen patients presented with a fracture

around the femoral component after an adequate trauma (14/619= 2.26%), mostly a fall at home. Mean age at operation in the whole group was 67.6 yrs and 72.6 yrs in the PPF-group ($p=0.05$). Mean stem size in the group with a periprosthetic fracture was significantly larger than the stem size for the whole group ($p=0.005$). The average interval since the index hip operation was 6.9 years (range 2.0 to 13.7 years). The average age at the time of the fracture was 79 years (range 65 to 92 years).

Five type A fractures, six B₁, two B₂ fractures and one B₃-fracture were seen. The site of the fracture in our series was always localized in an area where an acute bone density gradient in the cortex had developed, between the proximal and the middle Gruen zones.

All type A fractures except one were treated conservatively. Using the Vancouver classification we observed different fracture types in the type B fractures. No fractures at the tip of the stem were seen as in cemented implants. Three B₁ fractures were operated because of fracture displacement, while three could be treated conservatively. The B₂ and B₃ fractures were managed with long uncemented revision stems because of a disrupted bone-prosthesis interface. All fractures healed well. Mean follow-up after the periprosthetic fracture was 3.2 yrs.

The larger stem size in the PPF-group might influence the fracture rate, because greater stiffness increases stress shielding and the subsequent bone resorption is a proven risk factor for a periprosthetic fracture.

Periprosthetic bone remodeling following the insertion of a cementless femoral stem can be attributed to mechanical and biological factors in response to the new biomechanical situation created by the prosthesis.

In this thesis bone remodeling is investigated by several methods.

In our first prospective study the characteristics of the bone remodeling pattern around an uncemented anatomical, proximally coated stem (ABG-I) and its successor (ABG-II) were described using DEXA. ABG-II showed less bone loss proximally, especially in zone 7, which is also described in the 5-year prospective study from Panisello et al.¹ However, the difference found for the proximal zone 7 was not significant. In the study of Panisello¹ this difference was significant, but these patients were preoperatively matched for bone quality.

In our second study, patients were retrospectively matched for preoperative bone quality and gender. Now, a statistically significant difference was found in proximal bone preservation in favor of ABG-II for zone 7. These findings and the above mentioned study¹

support our conclusion that in comparative bone remodeling studies for prosthetic design using DEXA, patients should be matched for preoperative bone quality and gender to limit the number of patients while maintaining maximum statistical power.

Bone remodeling can also be influenced by tightness of stem fit,²⁻⁵ and therefore we assessed the radiological changes five years after implantation of the stem (third study). We investigated if there was a correlation between a tight fit and the bone remodeling pattern. In addition, bone remodeling for the ABG-II stem was compared with values for the ABG-I stem taken from the literature.

In this study there was no correlation between fit and radiological changes, as in a straight stem study,⁶ but there was a correlation between a poor fit and thigh pain for the ABG-II stem.

When comparing the bone remodeling pattern between ABG-II and the literature values of the ABG-I it was noted that ABG-II showed less proximal bone loss after five years. The clinical results concerning thigh pain for the ABG-II stem were considerably worse than in other studies with straight uncemented stem designs.⁷⁻¹⁰

A better fit of the ABG-II stem is important since this might decrease the incidence of thigh pain.

In the fourth study bone remodeling was assessed by histomorphometric analysis of a proximally HA-coated stem (ABG-I).

In this study the HA residue was measured histomorphometrically on hip stems of one single design (ABG-I) retrieved at post-mortem, and the long-term performance of the HA coating and the effects of resorption were investigated.

HA resorption increased significantly with the time in vivo as measured by the residual HA. Beyond 8 years HA was almost gone. HA resorption was significantly more proximal than distal, an effect which was less strong with bone ongrowth.

This study shows the influence of stress shielding, since the amount of resorption of HA-coating after THA is more or less a replica of the new stress patterns as expressed in finite element studies. The amount of HA-resorption in relation to its metaphyseal level is suggesting the remodeling bone process as the principal actor of the HA-coating resorption.

Bone ongrowth was statistically independent of the time in-vivo. Bone ongrowth was significantly less with older patients.

Another interesting finding of this study is that although bone ongrowth was less in older patients, all stems were well fixed at the time of retrieval.

This supports the finding that uncemented implants also show good results in older patients.

In the fifth and last study periprosthetic fractures around an uncemented proximally coated stem are described. The fracture patterns were analyzed by reviewing the X-rays in detail and the modified Vancouver classification (originally designed for cemented implants) was retrospectively applied for these fractures.

An increased number of periprosthetic fractures for the ABG-I stem compared to the cemented stem was shown. The site of the fracture in our series was always localized in an area where an acute bone density gradient in the cortex had developed, between the proximal and the middle Gruen zones.

The retrospectively applied Vancouver classification turned out to be a simple, reproducible classification system for the uncemented treatment modality, which will make clinical decision-making easier.

We do not yet know whether the number of periprosthetic fractures for the ABG-II stem will be less than for the ABG-I. Theoretically you might argue that because of less proximal bone resorption the number of PPF will decrease, however the bone remodeling process in ABG-II is only gradually different and the fracture rate for the ABG-II is as yet unknown.

The higher incidence of PPF of uncemented stems is of concern since more patients are undergoing THA, and patients are also becoming older, indicating that the number of PPF will probably increase. Research should focus on an uncemented stem with minimum to zero stress shielding and patient characteristics should be analyzed to identify patients with an increased risk of sustaining a periprosthetic fracture. Perhaps for these patients a cemented stem is the best option.

All studies performed point in the same direction: proximal bone loss for the ABG stem and less proximal bone loss for the ABG-II stem compared to the ABG-I stem. Despite this proximal bone resorption, clinical follow up shows excellent results after ten years for the ABG-I stem.^{11,12}

Its successor (ABG-II) shows less proximal bone resorption, but a relatively high percentage of thigh pain. Long term follow-up studies should provide more information as to whether less proximal bone resorption (ABG-II) will also lead to better clinical performance.

Stress shielding is and will remain an important issue in total hip arthroplasty for the long term.

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Chapter 9

Samenvatting en conclusies

In dit proefschrift worden de klinische resultaten van een anatomische hydroxyapatiet gecoate heupprothese, de periprothetische botremodellering rondom deze steel en de histologische analyse hiervan onderzocht om verscheidene onderzoeksvragen te beantwoorden.

In **hoofdstuk 1** wordt een kort overzicht gegeven van de geschiedenis van de totale heuparthroplastiek. Termen zoals “botremodellering” en “stress shielding” worden geïntroduceerd en nader toegelicht.

De invloed van patiëntgerelateerde factoren, medicatie en de verschillen in het ontwerp van de femursteel op de botremodellering worden besproken.

De karakteristieken van een hydroxyapatiet coating en zijn biologische werking worden beschreven met betrekking tot de ongecementeerde femursteel.

De ongecementeerde, anatomische proximale hydroxyapatietgecoate femursteel, welke wordt gebruikt in deze studies (ABG-I, Stryker, USA) en zijn opvolger (ABG-II), worden gedetailleerd beschreven.

Bijzondere aandacht wordt besteed aan de postoperatieve evaluatie van de femursteel door het analyseren van de elkaar opeenvolgende röntgengeno's, DEXA scans en de histologie post-mortem.

Verscheidene vragen worden geformuleerd, zodat de factoren welke verantwoordelijk zijn voor de proximale botresorptie kunnen worden geïdentificeerd. De methodes om deze vragen te beantwoorden worden uiteengezet.

In **hoofdstuk 2** wordt een prospectieve studie met een follow-up van 2 jaar beschreven, waarbij wordt onderzocht of de veranderingen in het ontwerp van de ABG-I femursteel in de ABG-II femursteel resulteren in een betere proximale botpreservatie.

51 patiënten werden gerandomiseerd om of de ABG-I steel danwel de ABG-II steel geïmplanteerd te krijgen. Om de patiënten klinisch te evalueren werd gebruik gemaakt van de Merle d'Aubigne (Mda) heupscore. Op de postoperatieve röntgengeno's werd de positie van de steel gemeten (varus $>2^\circ$, neutraal of valgus $>2^\circ$).

Periprothetische botmineraaldichtheid (BMD) werd op verschillende tijdstippen gemeten door het maken van DEXA scans, om te beoordelen of hierin veranderingen optraden. Postoperatieve DEXA scans werden 10 dagen postoperatief (deze waarde is de uitgangswaarde voor de verdere follow-up), 6 weken, 3,6,12 en 24 maanden na de totale heuparthroplastiek gemaakt.

Alle patiënten hadden minder pijn aan de geopereerde heup en er werden geen significante verschillen gevonden tussen de pre- en postoperatieve Mda scores voor de ABG-I of ABG-II prothese.

De gemiddelde grootte van de steel en de positie van de steel toonden geen significante verschillen.

De gemiddelde BMD toonde een afname gedurende de eerste drie maanden postoperatief en deze afname was gelijk voor de meeste patiënten in alle Gruen zones en voor beide femurstenen (ABG-I en ABG-II).

Na 3 maanden en tot 24 maanden postoperatief, in de Gruen zones 2 en 6 (halverwege de steel) en de distale Gruen zones 3,4, en 5, stopte de afname in de BMD of vormde een plateau of toonde zelfs enig herstel voor zowel de patiënten in de ABG-I groep, als de ABG-II groep.

In de proximale Gruen zones 1 en 7 bereikte de botmineraaldichtheid een plateau of toonde zelfs enig herstel een jaar na de operatie (ABG-II). Terwijl de BMD in de ABG-I groep bleef afnemen in de zones 1 en 7. Echter, de verschillen in BMD tussen de verschillende ontwerpen van de femursteel (ABG-I en ABG-II) waren statistisch niet significant.

In **hoofdstuk 3** wordt een retrospectieve studie beschreven, waarbij patiënten met een ABG-II femursteel worden vergeleken met twee verschillende groepen patiënten met een ABG-I femursteel.

Patiënten moesten preoperatief overeenkomen voor botkwaliteit en geslacht, omdat onlangs is aangetoond dat preoperatieve botkwaliteit een belangrijke factor is, welke het botverlies beïnvloedt rondom een pas geplaatste femursteel.

De hypothese was dat het verschil in preoperatieve botkwaliteit tussen de twee groepen, beschreven in hoofdstuk 2, de statistische kracht heeft doen verminderen en door het gebruik van twee groepen patiënten welke overeenkomen voor preoperatieve botkwaliteit, het statistisch vermogen toeneemt voor andere factoren, zoals het ontwerp van de femursteel.

24 ABG-II patiënten werden vergeleken met twee verschillende groepen ABG-I patiënten: A) 25 patiënten van onze eerdere prospectieve studie en B) 24 patiënten welke waren geselecteerd om overeen te komen wat betreft geslacht, leeftijd en preoperatieve botkwaliteit met de groep ABG-II patiënten.

De groep ABG-II patiënten bestond uit elf mannen en dertien vrouwen. Drie patiënten hadden normaal bot, zestien patiënten hadden osteopeen bot en vijf patiënten hadden osteoporotisch bot.

Groep A bestond uit zeventien mannen en acht vrouwen. Drie patiënten hadden normaal bot, vijftien patiënten hadden osteopeen bot en zeven patiënten hadden osteoporotisch bot.

Groep B bestond uit elf mannen en dertien vrouwen. Drie patiënten hadden normaal bot, zestien patiënten hadden osteopeen bot en vijf patiënten hadden osteoporotisch bot.

Postoperatieve veranderingen in de bot mineraaldichtheid rondom de prothese werden gequantificeerd twee jaar na de operatie door middel van DEXA scans.

Botpreservatie (minder verlies van BMD) was beter voor de ABG-II dan de ABG-I (beide groepen) in de proximale zones 1 en 7. In Gruen zone 7 werd een statistisch significant verschil gevonden in BMD afname ten opzichte van de ABG-I groep (groep B).

In **hoofdstuk 4** wordt vanuit een prospectief gevolgde groep een opeenvolgende serie van 64 patiënten met een ABG-II femursteel beschreven. In deze studie wordt onderzocht of een nauwsluitende fit van een HA-gecoate heupprothese in het medullaire kanaal een correlatie heeft met klinische resultaten en radiologische kenmerken.

Aanvullend wordt er een vergelijking gemaakt tussen de twee generaties femurstelen of zij verschillen in botremodelleringspatronen. Deze vergelijking is mogelijk aangezien de botremodelleringspatronen van de ABG-I steel uit de literatuur bekend zijn.

De follow-up periode was 5 jaar en voor de klinische evaluatie werd de Merle d'Aubigne (MdA) heupscore gebruikt. De fit van de femursteel in het medullaire kanaal werd gemeten op de direct postoperatieve röntgenfoto's (AP -opname).

De fit van de femursteel in het medullaire kanaal werd gedefinieerd als nauwsluitend indien de ratio van de fit ≥ 0.8 was en als niet nauwsluitend als de fit < 0.8 was. De fit van de femursteel in het medullaire kanaal werd op drie niveaus gemeten: proximaal, halverwege de steel en distaal.

Radiologische evaluatie bestond uit een nauwkeurige beschrijving van alle veranderingen van het bot rondom de femursteel en van de positie van de femursteel. Daarnaast werd de botremodellering rondom de ABG-II steel vergeleken met de eerder beschreven waarden in de literatuur voor de ABG-I steel. Klinische resultaten en botremodellering na 5 jaar werden gecorreleerd met de fit van de femursteel in het medullaire kanaal. Botresorptie in de proximale Gruen zones was vaker aanwezig bij de ABG-I steel dan de ABG-II steel.

De fit van de femursteel in het medullaire kanaal toont geen correlatie met bepaalde radiologische veranderingen, maar een niet nauwsluitende proximale fit is gecorreleerd met een varus positie van de femursteel. Pijn in het bovenbeen is gecorreleerd met een slechte fit van de femursteel.

In **hoofdstuk 5** wordt een histologische en histomorfometrische studie beschreven, waarin de normale reacties van het bot rondom een hydroxyapatiet gecoatete heupprothese post mortem worden onderzocht.

Uit een serie van 750 opeenvolgende primaire totale heup arthroplastieken, konden dertien femurstelen worden onderzocht, welke werden verkregen tijdens autopsie. De tijd van overlijden na de primaire totale heup arthroplastiek varieerde van 3.3 tot 11.2 jaar. Alle 13 patiënten hadden een ongecompliceerd beloop tijdens en na de primaire totale heup arthroplastiek en overleden aan een oorzaak die geen relatie had met de operatie.

De prothesen en het omliggende bot werden geprepareerd voor kwalitatieve histologische en histomorfometrische analyse.

Drie dwarsdoorsnedes werden verkregen van de metafyse van het femur, proximaal van een lijn die de proximale Gruen zones 1 en 7 (zones met HA-coating) scheidt van het distale gedeelte van de steel. De drie doorsnedes waren A (proximaal), B (middengedeelte) en C (distaal).

Het percentage botingroei ter plaatse van de femursteel (bot-femursteel contact), het relatieve botoppervlak rondom de femursteel, de hoeveelheid residu van de hydroxyapatiet coating, en de dikte van de coating werden gemeten.

De resorptie van de hydroxyapatiet is onafhankelijk van de leeftijd van de patiënt, maar de resorptie van de hydroxyapatiet neemt toe met de tijd in vivo en de HA was bijna geheel geresorbeerd na 8 jaar. Botingroei is onafhankelijk van de tijd in vivo, maar is minder naarmate de patient ouder is.

Alleen in het meest proximale gedeelte van de steel is een grotere resorptie van de hydroxyapatiet gecorreleerd met minder botingroei.

De resorptie van HA was proximaal significant meer dan distaal en toonde geen negatief effect op het contactoppervlak tussen de femursteel en het bot.

De hoeveelheid resorptie van hydroxyapatite in relatie tot het metafysaire niveau suggereert dat het botremodelleringsproces hierin de grootste rol speelt.

In **hoofdstuk 6** wordt een retrospectieve studie beschreven. In de periode van januari 1990 tot december 1996 zijn 619 totale heupprothesen (ABG-I) geplaatst in ons ziekenhuis.

Fracturen werden geclassificeerd met behulp van de Vancouver classificatie en de behandeling van deze fracturen werd retrospectief vergeleken met het recent gepubliceerde behandelingsprotocol voor periprotetische fracturen.

Veertien patiënten presenteerden zich met een fractuur rondom de femursteel na een trauma (14/619= 2.26%), meestal een val binnenshuis.

De gemiddelde leeftijd ten tijde van de operatie voor de hele groep was 67.6 jaar en 72.6 jaar in de groep met een periprothetische fractuur (PPF-groep). De gemiddelde grootte van de steel in de PPF-groep was significant groter dan de grootte van de steel voor de hele groep ($p=0.005$).

De gemiddelde tijdsduur vanaf de primaire operatie tot de fractuur was 6.9 jaar (range 2.0 tot 13.7 jaar). De gemiddelde leeftijd ten tijde van de fractuur was 79 jaar (range 65 tot 92 jaar).

Vijf patiënten hadden een type A fractuur, zes patiënten een type B₁ fractuur, twee patiënten een type type B₂ fractuur en één patiënt een type B₃-fractuur.

De plaats van de fractuur rondom de steel was altijd gelocaliseerd daar waar een afname van botdichtheid in de cortex was ontstaan, op de overgang tussen de meest proximale en middelste Gruen zones.

Met uitzondering van één patiënt werden alle patiënten met een type A fractuur conservatief behandeld.

Met als uitgangspunt de Vancouver classificatie, observeerden we een andere morfologie van de fractuur bij de type B fracturen. In tegenstelling tot de gecementeerde heupprothese toonde deze studie geen fracturen ter plaatse van de tip van de steel. Drie patiënten met een type B1 fractuur werden geopereerd vanwege verplaatsing van de fractuurfragmenten, terwijl drie patiënten conservatief konden worden behandeld.

Patiënten met een type B2 of B3 fractuur werden geopereerd en vanwege het verstoorde contactoppervlak tussen het bot en de prothese werd een lange ongecementeerde revisiesteel ingebracht.

Alle patiënten met een periprothetische fractuur herstelden goed en de gemiddelde follow-up tijd na de fractuur was 3.2 jaar.

De grotere maat van de steel in de groep patiënten met een PPF heeft mogelijk het aantal fracturen beïnvloed, aangezien een afname in elasticiteit stress shielding doet toenemen en de botresorptie die hierdoor ontstaat, een bewezen risicofactor is voor het ontstaan van een periprothetische fractuur.

Periprothetische botremodelling na het inbrengen van een ongecementeerde femursteel kan worden toegeschreven aan mechanische en biologische factoren in antwoord op een nieuwe biomechanische situatie gecreëerd door de prothese.

In dit proefschrift wordt botremodellering op verschillende manieren onderzocht. In de eerste prospectieve studie worden de karakteristieken van het patroon van botremodellering rondom een ongecementeerde, anatomische, hydroxyapatite gecoate heupprothese (ABG-I) en zijn opvolger (ABG-II) beschreven. Om dit patroon te onderzoeken en beschrijven wordt gebruik gemaakt van DEXA-scans. De ABG-II steel preserveerde het bot beter proximaal dan ABG-I steel, met name in Gruen zone 7. Panisello et al.¹ beschrijven ditzelfde fenomeen in hun 5-jarige prospectieve studie. Echter, het verschil dat gevonden werd voor Gruen zone 7 in deze studie was niet significant, i.t.t. de studie van Panisello¹, waarvan de patiëntengroep wel een overeenkomstige preoperatieve botkwaliteit had.

In de tweede studie werden patiënten retrospectief gematched voor preoperatieve botkwaliteit en geslacht.

Deze studie toonde een significant verschil aan voor proximale botpreservatie ten gunste van de ABG-II (Gruen zone 7).

De bevindingen in de studie van Panisello et al.¹ ondersteunen de conclusie dat in studies naar de invloed van het ontwerp van de prothese op de botremodellering, patiënten overeen moeten komen voor geslacht en preoperatieve botkwaliteit om het aantal patiënten dat nodig is voor een studie te beperken, terwijl er een maximaal statische vermogen behouden blijft.

Botremodellering kan worden beïnvloed door het wel of niet nauwsluitend passen van de steel in in het medullaire kanaal,²⁻⁵ en daarom hebben we de radiologische veranderingen beoordeeld 5 jaar na het implanteren van de femursteel om te onderzoeken of er een correlatie was tussen de fit van de femursteel en het patroon van botremodellering (hoofdstuk 4).

Daarnaast werd de botremodellering rondom de ABG-II steel vergeleken met de eerder beschreven waarden in de literatuur voor de ABG-I steel.

Deze studie toonde aan dat er geen correlatie is tussen de fit van de ABG-II steel in het medullaire kanaal en bepaalde radiologische veranderingen, maar pijn in het bovenbeen is wel gecorreleerd met een slechte fit van de femursteel.

Indien het patroon van botremodellering wordt vergeleken tussen ABG-I en ABG-II 5 jaar na implantatie van de femursteel, toont de ABG-II steel minder proximaal botverlies rondom de prothese dan ABG-I.

De klinische resultaten wat betreft pijn in het bovenbeen voor de ABG-II steel zijn slechter dan de meeste andere studies voor rechte ongecementeerde stelen.⁶⁻⁹ Een

betere fit voor de ABG-II steel is belangrijk omdat dit de incidentie van pijn in het bovenbeen kan verminderen.

In de vierde studie wordt botremodelling beschreven en beoordeeld door histomorfometrische analyse van een proximale hydroxyapatiet gecoate femursteel (ABG-I steel).

In deze studie wordt het residu gemeten van de hydroxyapatietcoating op femurstelen van één design (ABG-I), welke zijn verkregen na het overlijden van de patiënt. Het biologisch gedrag van de hydroxyapatietcoating op lange termijn en de effecten van de resorptie van de HA werd onderzocht.

De resorptie van het hydroxyapatiet was onafhankelijk van de leeftijd van de patient, maar de resorptie van nam toe met de tijd in vivo en de HA was bijna geheel geresorbeerd na 8 jaar. De resorptie van HA was proximal significant meer dan distaal. Botaangroei echter, toonde geen duidelijke relatie met het metafysaire niveau.

Deze studie toont de invloed van stress-shielding aan, aangezien de resorptie van de HA-coating na een totale heuparthroplastiek min of meer een replica is van het nieuwe belastingspatroon, zoals dit beschreven wordt in eindige element studies. De hoeveelheid resorptie van hydroxyapatite in relatie tot het metafysaire niveau suggereert dat het botremodellingproces hierin de grootste rol speelt. Botingroei is onafhankelijk van de tijd in vivo maar, maar is minder naarmate de patient ouder was.

Een andere interessante bevinding in deze studie is dat hoewel de botaangroei rondom de prothese minder is in de oudere patiënt, alle femurstelen goed gefixeerd zijn ten tijde van verwijderen van de prothese bij de overleden patiënt.

Dit ondersteunt de bevinding dat ongecementeerde stelen ook goede klinische resultaten hebben bij oudere patiënten.

In de vijfde en laatste studie worden periprothetische fracturen rondom een ongecementeerde, proximale gecoate steel onderzocht.

De morfologie van de fractuur wordt geanalyseerd door het beoordelen van de röntgenfoto's en de gemodificeerde Vancouver classificatie (oorspronkelijk bedoeld voor het classificeren van fracturen rondom gecementeerde totale heupprothesen) wordt retrospectief toegepast voor deze fracturen.

Het aantal periprothetische fracturen rondom deze ongecementeerde femursteel is verhoogd in vergelijking met een gecementeerde heupprothese.

De plaats van de fractuur rondom de steel was meestal gelocaliseerd ter plaatse van

een afname van botdichtheid in de cortex, op de overgang tussen Gruen zones 1-2 en 6-7.

Deze studie bevestigt dat een gemodificeerd algoritme van de behandeling van periprothetische fracturen, met als uitgangspunt de Vancouver classificatie, een eenvoudig reproduceerbaar classificatie systeem is, geschikt voor de toepassing bij de behandeling van periprothetische fracturen rondom een ongecementeerde heupprothese. Dit classificatie systeem is klinisch goed toepasbaar en is een eenvoudige leidraad voor de behandeling van deze fracturen.

Onbekend is nog of het aantal periprothetische fracturen voor de ABG-II steel lager zal zijn dan voor de ABG-I steel.

De ABG-II steel toont minder proximale botresorptie; een voordeel waardoor een lager aantal periprothetische fracturen verwacht kan worden. Echter het patroon van botremodellering rondom de ABG-II steel toont slechts een graduueel verschil i.v.m. de ABG-I steel en de incidentie van periprothetische fracturen rondom de ABG-II steel is vooralsnog onbekend.

De toename van de incidentie van periprothetische fracturen rondom ongecementeerde heupprothesen is zorgwekkend, aangezien het aantal patiënten dat geopereerd wordt vanwege coxarthrosis toeneemt en de patiënten ook gemiddeld ouder worden. Hierdoor zal het aantal periprothetische fracturen waarschijnlijk toenemen.

Onderzoek moet zich met name richten op het ontwerpen van een ongecementeerde steel met minimale stress shielding. Patiënten die een verhoogde kans hebben op een periprothetische fractuur zouden geïdentificeerd moeten worden.

Misschien dat voor de patiënten met een verhoogd risico een gecementeerde steel de beste optie is.

De studies beschreven in dit proefschrift wijzen alle naar dezelfde richting: minder botverlies proximaal rond de ABG-II steel in vergelijking met de ABG-I steel.

Ondanks de botresorptie tonen klinische follow-up studies uitstekende resultaten voor de ABG-I steel na tien jaar.^{10,11}

De opvolger van de ABG-I (ABG-II) toont wel minder proximale botresorptie, maar een relatief hoog percentage patiënten heeft bovenbeenspijn.

Lange termijn follow-up studies moeten meer gegevens verschaffen om te kunnen beoordelen of minder proximale botresorptie rond de ABG-II-steel ook leidt tot betere klinische resultaten.

Stress shielding is en blijft een belangrijk onderwerp bij totale heup prothesiologie op de lange termijn.

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Curriculum vitae

The author of this thesis was born April sixth, 1973 in Lisse, The Netherlands. He spent a happy childhood in Lisse with his brother, sister and parents. He attended Gymnasium β at the Fioretti College in Lisse and after graduation he commenced Medical School in 1991 at the University of Leuven. After a year he returned to the Netherlands and started his medical studies at the Erasmus University Rotterdam. In December 2003 he started his orthopedic training under supervision of dr. I.C. Heyligers at the Atrium Medical Center Heerlen. In October 2005 his training as an orthopaedic surgeon went on at the Academic Medical Center Maastricht under supervision of dr A.van Ooij for a year. In 2007 he finalized his training as an orthopaedic surgeon at the Atrium Medical Center Heerlen.

During his residency he started his research project entitled "Hydroxyapatite-coated uncemented hip stems and bone remodeling". This work has led to a nomination for the William Harris award at the ORS in Washington in 2004, several publications and this thesis.

Currently he is working as an orthopaedic surgeon at Meander Medical Centre, Amersfoort and lives together with Jeanne and his daughter Kim.

