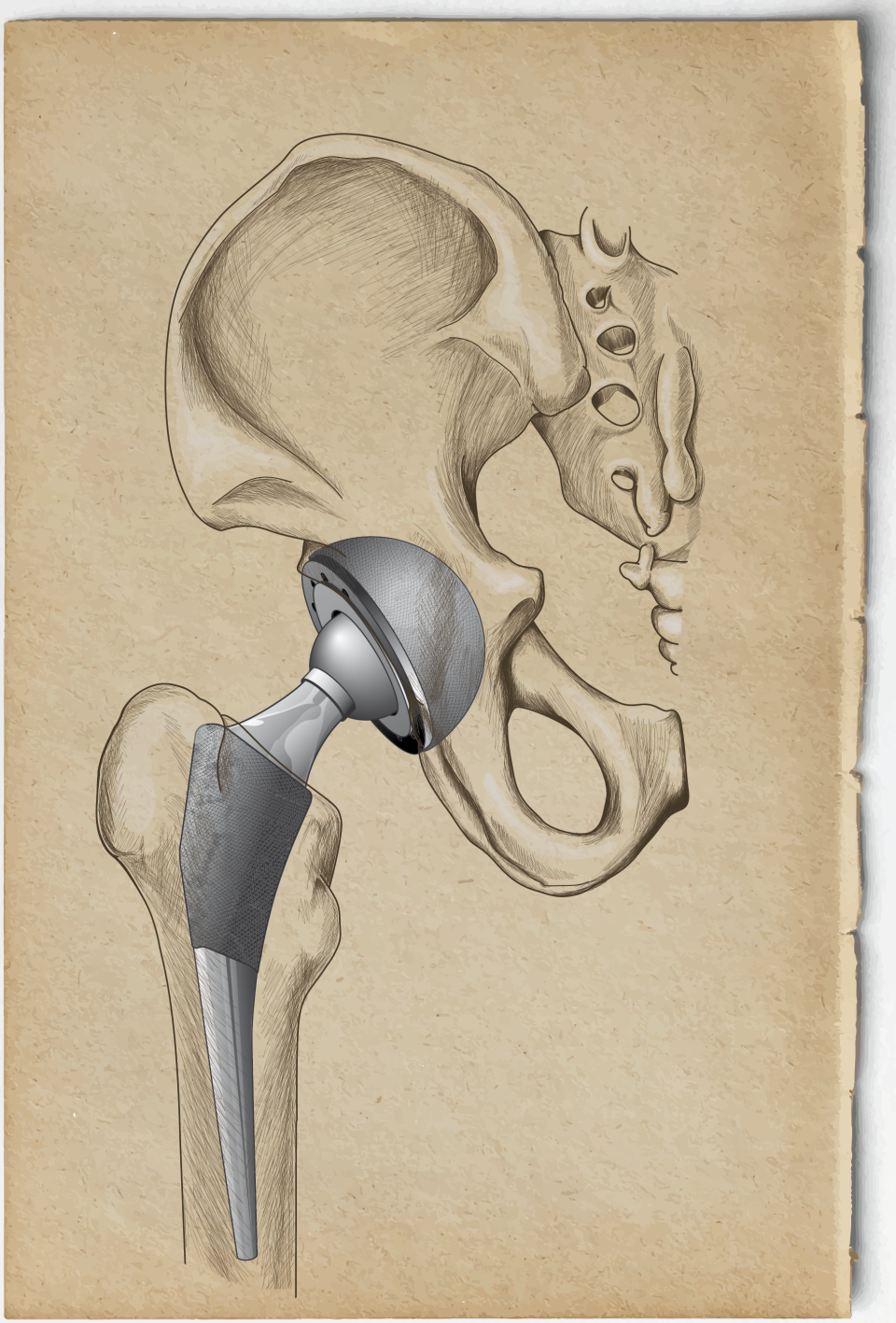
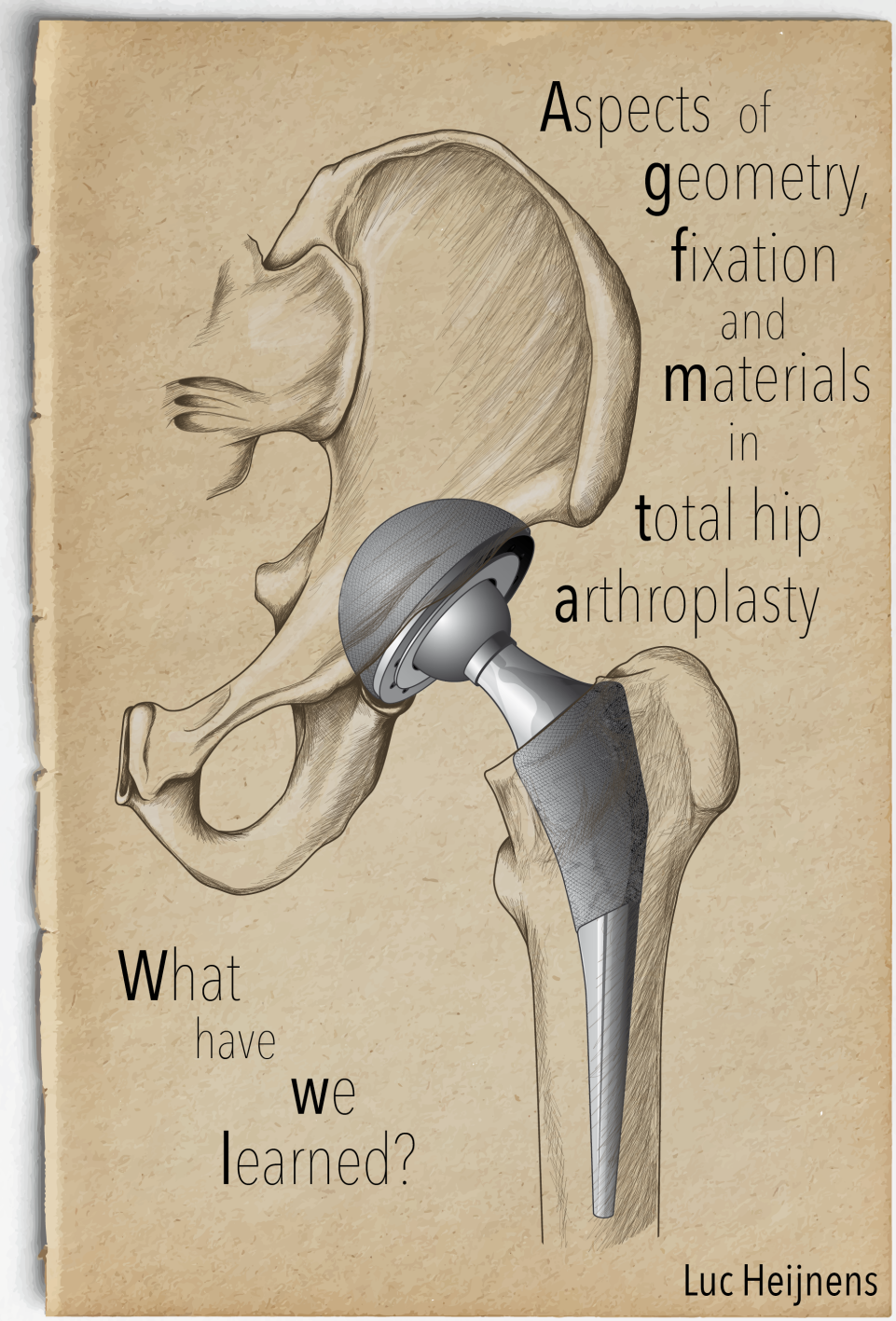


Luc Heijnens

Aspects of geometry, fixation and materials in total hip arthroplasty. What have we learned?



Aspects of geometry, fixation and materials in total hip arthroplasty. What have we learned?

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The printing of this thesis was financially supported by Nederlandse Orthopaedische Vereniging, Annafonds|NOREF, Smeets loopcomfort, Fit & Fysio, Penders voetzorg, Verloskundigen Praktijk Parkstad, Spronken orthopedie.

ISBN: 978-94-6361-851-9

Cover/Design: Myrthe Boymans
Layout and printed by: Optima Grafische Communicatie, Rotterdam

Online link: https://epubs.ogc.nl/?epub=lheijnens&k=b54fb9a4-cc36-4bdf-9eb8-900c82d0f134

Aspects of geometry, fixation and materials in total hip arthroplasty.
What have we learned?

PROEFSCHRIFT

ter verkrijging van de graad doctor aan de Universiteit Maastricht
op gezag van de Rector Magnificus, Prof. Dr. Pamela Habibović
volgens het besluit van het College van Decanen,
in het openbaar te verdedigen
op vrijdag **16 juni 2023** om **13:00** uur

door

Lucas Johannes Maria Heijnens

Geboren op 24 oktober 1988 te Veghel

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Voor Nele, Louve en Ine

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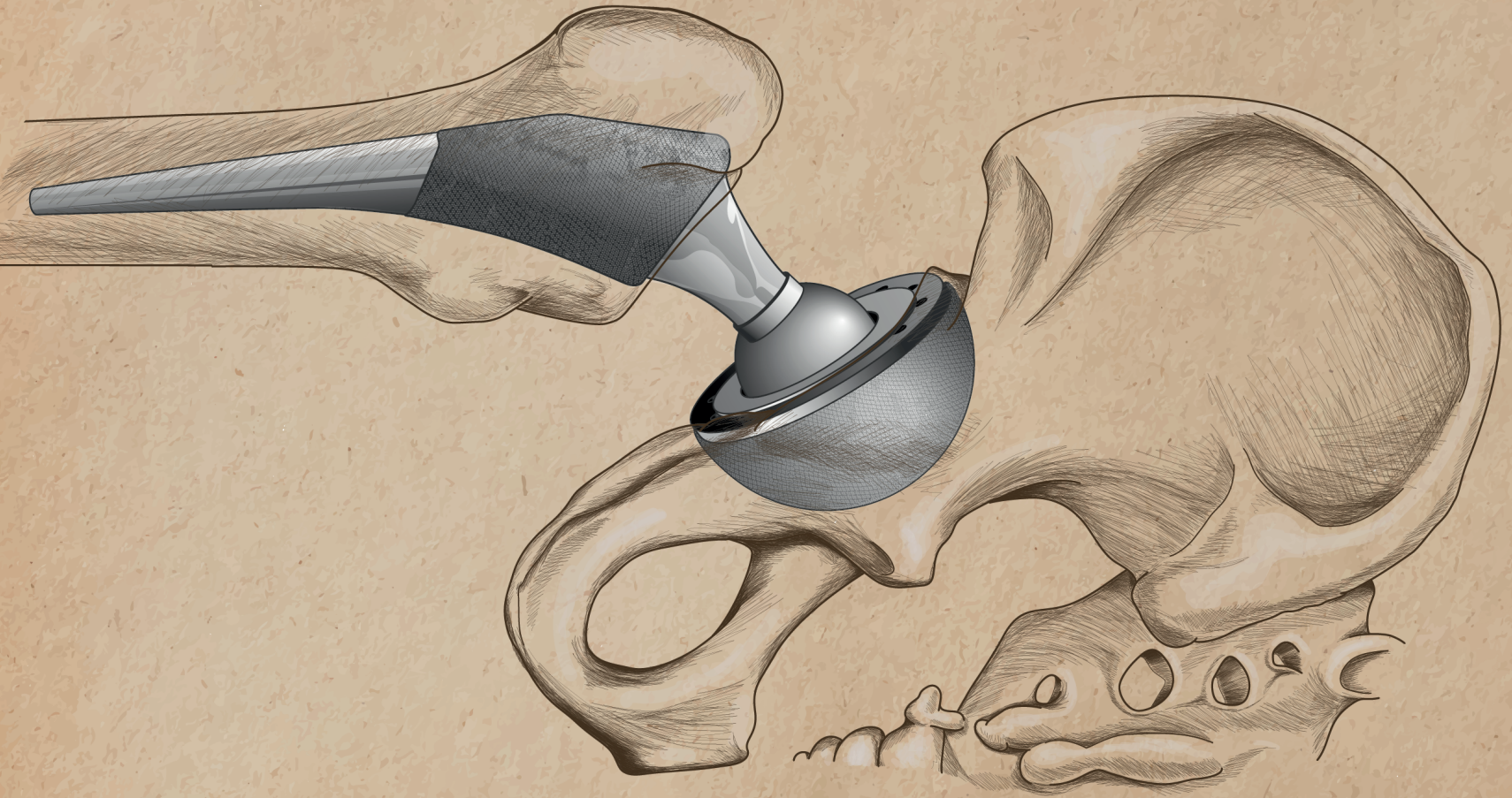


Chapter 1

General introduction and thesis outline

GENERAL INTRODUCTION

Osteoarthritis (OA) is a chronic degenerative joint disease affecting the cartilage and bone of the joint that may eventually result in pain and functional impairment. OA in general, and in particular OA of the hip and knee joint, is one of the leading causes of global disability of the musculoskeletal system worldwide [1, 2]. In literature, the prevalence of OA ranges from 12.3% to 21.6%, and specific for OA of the hip joint the prevalence is 6.2% [1, 3-5]. Aging, the increasing incidence of obesity and a sedentary lifestyle of the world's population will lead to a higher incidence of OA worldwide, but predominantly in the developed countries [6, 7]. This increasing incidence of OA is an economic burden, which is difficult to calculate, but is highly likely underestimated [8]. Various treatments are available at different stages of OA. For the early-stage OA, a non-surgical treatment can be effective with a (medical) treatment like non-steroid anti-inflammatory drugs (NSAIDs), physical therapy and lifestyle adjustments. However, with end-stage OA, a surgical total joint replacement (TJR) can be indicated. In orthopaedic surgery TJR of the hip, a total hip arthroplasty (THA) is the most performed and successful orthopaedic elective surgical procedure and is even entitled as 'the operation of the 20th century' [9, 10].

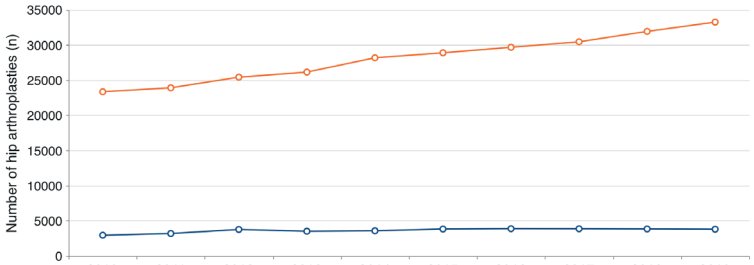
Surgical procedure

When a THA is performed, the damaged hip joint is replaced by artificial materials. THA can also be the treatment for a hip fracture, developmental hip dysplasia, post traumatic or post infectious OA. A THA consists of a femoral implant, an acetabular component with a bearing surface, and a femoral head. The femoral implant is fixed into the prepared femoral bone and the acetabular component is fixed into the prepared acetabular bone. This fixation can be achieved in two ways; either with bone cement (polymethylene-methacrylate (PMMA)) or without bone cement. In a cemented fixation the cement is situated as interface between the bone and the implant. In a cementless THA the primary fixation is achieved by a press-fit technique after which the cortical bone grows onto and/or into the special implant surface. The primary mechanical fixation is transformed into biological fixation. The implants in a cementless fixation need to be hammered into the prepared bone for optimal fixation. Age, medical history, bone quality, type/geometry of the implant and preference of the orthopaedic surgeon are all factors to choose for a cemented or cementless fixation [11, 12].

Patient demographics

In the Netherlands the number of THAs performed is still rising every year. In 2010, 23,350 primary THAs were performed, rapidly increasing up to 33,248 in 2019 and this number is still expected to increase (**Figure 1**) [13]. Due to the success of the THA, with decreasing revisions and higher patient's satisfaction, the indication for THA have broadened also including the younger aged patients (under 65 years of age). The indication for THA in these younger aged patients is not only primary OA but can also be due to avascular necrosis of the femoral head, post traumatic OA, Perthes disease, developmental dysplasia of the hip or post infectious OA. The proportion of patients under 65 years of age receiving a THA is expected to increase to the half of the total number THAs performed by the year 2030 [14]. These

patients are more physically active and have higher demands with regards to their function and mobility. Therefore, especially in this age group there must be a high reliability of survival and function of the THA with reliable long-term survival rates [15].



Year	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	Total
Type of procedure (n)											
Primary THA	23,350	23,914	25,420	26,144	28,180	28,890	29,671	30,453	31,931	33,248	**281,201**
Hip revision	2,952	3,198	3,770	3,517	3,583	3,834	3,882	3,870	3,845	3,804	**36,255**
Total:	**26,302**	**27,112**	**29,190**	**29,661**	**31,763**	**32,724**	**33,553**	**34,323**	**35,776**	**37,052**	**317,456**

Figure 1 Numbers of primary THA and hip revision surgeries in the Netherlands. Data collected by the LROI (Landelijke Registratie Orthopedische Interventies).

History of the total hip arthroplasty

Many attempts to treat OA of the hip came with failures and the road to the current THA was long. The first performed attempt to replace the damaged hip joint was reported in the last decade of the 19th century by Professor Glück in Germany [16]. At the 19th International Medical Conference in 1890 he presented the results of patients with severe damaged hip joints due to tuberculosis and were treated with an ivory hemiarthroplasty replacement of the femoral head [10, 16]. Because of the disappointing outcomes of this ivory hemiarthroplasty, Marius Smith-Petersen experimented in the late 19th and early 20th century with different types of hip operations. An interpositional or "Mould" arthroplasty with skin, pig bladder mucosa, glass, gold foil, or fascia lata tendon between the articulating surfaces of the hip joint was the first step [9]. The rehabilitation of this interpositional arthroplasty was time consuming and intense for the patients with post-operative traction for several weeks and high failure rate. These high failure rates asked for a more effective operative treatment of hip OA [17]. This search was continued between 1940-1950 by the French brothers Judet with the invention of a short stem hemiprosthesis made out of acrylic plastic [18]. The early results where promising, however the published 12-year results were disappointing with high loosening and prosthesis fracture rates as well as granuloma formations around the prosthesis [18]. And again, the search for a reliable hip implant continued, resulting in the first metal-on-metal (MoM) prosthesis made by the English surgeons George McKee and Watson Farrar in 1953. This one-piece cobalt-chrome prosthesis yielded an acceptable long-term survival at 28 years of 74%, however in the mid 1970s this prosthesis method became unpopular due to local effects of metal debris and metal particles [19, 20]. In 1960 Sir John Charnley introduced a revolutionary breakthrough

in orthopaedic arthroplasty with the 'low friction arthroplasty' which is still the blue-print of the THA designs used nowadays [21, 22]. The low friction arthroplasty was the first long lasting THA and consisted of a polyethylene (PE) acetabular implant, a femoral implant fixed with PMMA cement and a small femoral head made out of metal. Low friction arthroplasty became the standard care with reliable survival rates. Because of the good survival rates and satisfactory clinical results of the low friction arthroplasty design this type of THA became the standard care in THA. In 1971 the cemented THA lost popularity as the cementless THA was introduced by the brothers Judet with a surface roughness of the femoral and acetabular implant resulting in fixation by bone ingrowth [23]. However, loosening of these implants frequently occurred. Different types of metal alloys (i.e. titanium, stainless steel, cobalt/chrome) have been used for the femoral implants. The development of a titanium implant with a hydroxyapatite coating, an osteoconductive biological mineral, reduced these loosening rates [24-26]. One of the pioneers of the hydroxyapatite coated implants in THA was dr. Geesink of the department of orthopaedic surgery of the Maastricht University Medical Centre [27]. Hydroxyapatite coated implants are still widely used in cementless THA [28]. The use of cementless THAs is increasing, however, in patients aged over 65 years cementless THAs have lower implant survival than cemented THAs, which therefore remains the golden standard [29-32].

Biomechanics of the hip and total hip arthroplasties

Weight distribution from the acetabular bone to the proximal femur in the native hip joint is on the medial side mainly a compression force and on the lateral side mainly a tensile force. These forces occur according to a specific distribution pattern resulting in trabecular lines discovered by Julius Wolff in the late 19th century [33, 34]. In this 'Wolff''s law' bone is formed on sides with mechanical loading (**Figure 2**). This results in three groups of trabeculae in the native hip joint. One group formed by the combined tensile loading and compression forces forming an 'arch-work' between the medial and lateral cortex of the femur. A second group formed by forces running from the proximal end of the medial cortex and passing to the proximal pole of the femoral head. The final group of trabeculae run from the proximal medial cortex of the proximal femoral head to the lateral side of the femur, mainly supporting the tensile loading. Between these three groups of trabeculae formation a triangular area of very thin trabeculae exists; the Ward's triangle. This Ward's triangle is important for the strength of the proximal femur [35] (**Figure 2**). Understanding of the mechanisms of weight distribution in the hip joint is important for the geometry of the femoral implant in THA and for fixation. There are different geometries in both the cemented and cementless femoral implants all with the purpose to achieve a long-term fixation and near physiological situation of the THA [36-38].

Biomaterials and bearings in total hip arthroplasties

Biomaterials used for THA must be biocompatible, resistant to corrosion and degradation, must have adequate mechanical and wear properties and must be resistant for the high forces experienced [39]. The materials in THA experience continuous stress and strain forces. Stress is the intensity of an internal force and strain is a relative measure of the deformation of the material [40]. These stress and strain

capabilities of the material are expressed by the Young's modulus of elasticity (**Figure 3**). The Young's modulus is a measure of stiffness of a material in the elastic zone; in which the material will return to its original shape for a given amount of stress [39]. When too much stress is applied, the material will pass into the plastic zone, also referred as the Yield point, where the material will not return to its original shape for a given amount of stress [39, 40]. Due to repeating cycles and too much applied stress the material will eventually break. An increasing Young's modulus indicates an increase in stiffness of the material. An example of a material with a high Young's modulus is ceramic. Titanium, often used as vmetal in THA has a modulus that is comparable with the cortical bone in the human body. The Young's modulus of bone cement (PMMA) is lower compared to cortical bone, it is vulnerable for shear forces but can tolerate compression forces until a certain amount.

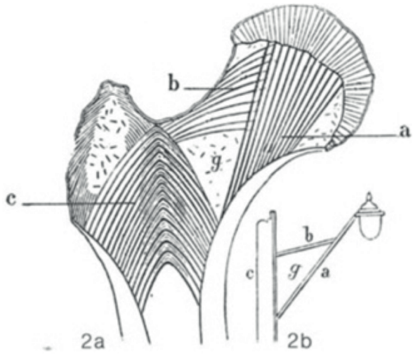


Figure 2 Weight distribution of the proximal femur. A: trabeculae from proximal to medial cortex. B: trabeculae from medial to lateral cortex. C: arch between lateral and medial cortex of femoral bone. G: Ward's triangle. Derived from Ward (1838).

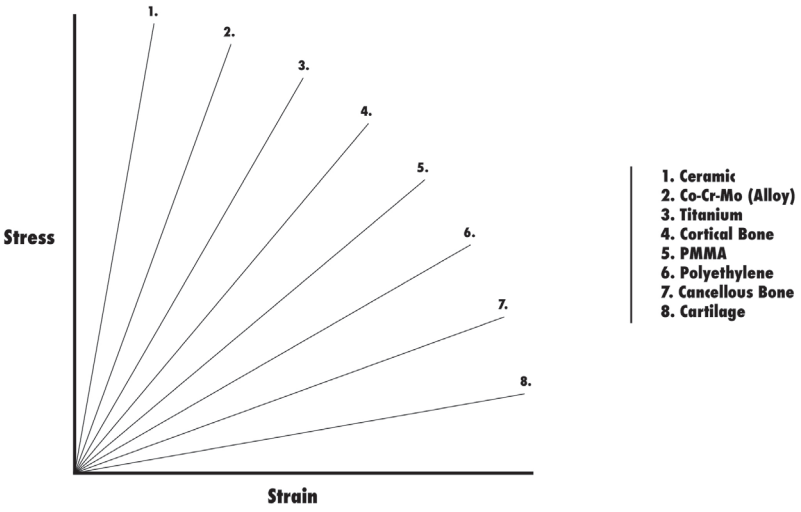


Figure 3 Stress and strain of different orthopaedic (bio)materials and human tissue. The Young's modulus is the measure of the stiffness in the elastic zone.

Bearing materials

In THAs bearing materials are used for the head and the acetabular insert liner. In 5% of the THAs failure of the articulating surfaces or articulating materials will occur over time, resulting in osteolysis in reaction to small wear particles and this eventually may lead to loosening and revision surgery [41]. The main reason for failure of the articulating surfaces is wear of the acetabular insert liner [41]. Therefore, the acetabular insert liner is a 'key' component of the THA which can determine the survival. In search for the most optimal wear resistible (bio)material for insert liners several options and combinations of bearings have been used. The most used acetabular insert liner in THA is polyethylene (PE). Nowadays cross-linked PE (XLPE) is used in 98% of the THA as acetabular insert liner [42, 43]. XLPE is an ultra-high molecular weight polyethylene (UHMWPE) that has been irradiated with 50 kilo Gray resulting in cross linking between the PE molecules which improves the wear resistibility [44]. Bearings with XLPE combined with a metal or ceramic head have as advantage that the wear rates are low, perhaps that low that PE-wear might be a historically problem. Long-term follow-up of XLPE will provide the answer [42, 45, 46]. On the other hand, XLPE has decreased mechanical properties and is therefore prone for breaking [42, 45, 46]. In addition to the PE bearing, a metal-on-metal (MoM) bearing was used in the middle of the 20th century mainly in hip resurfacing THA. The MoM bearing showed low wear rates, however it initiates adverse reactions to metal debris (ARMD), which is the reason for almost entirely abandoning of the MoM bearing. In search for perfection for the most suitable bearing in THA Carbon-Fiber-Reinforced Poly-Ether-Ether-Ketone (CFR-PEEK) was used as bearing surface in experimental studies only [47]. In vitro studies showed excellent wear resistance of CFR-PEEK, without the disadvantage of the MoM bearing [48].

Geometry and fixation in total hip arthroplasties

As stated previously, femoral implants can be fixated with bone cement (PMMA) and without cement. Both femoral implants have different geometrical properties and can be subdivided into different types of implants.

Cemented femoral implants

The cemented femoral implants can be classified based on shape, geometry and biomechanics. Classically resulting in two broad groups; force closed and shape closed femoral implants [49-51]. In the force closed femoral implants there is no direct fixation between the implant and the cement mantle. A regulated and controlled subsidence in the cement mantle is the mechanism of femoral-locking [52]. This locking-mechanism is mainly because of axial load and thereby compression of the cement mantle. In the shaped closed femoral implants, the fixation is between the implant and cement, and also between the cement and the bone [52]. However, a more comprehensive classification system, which classifies the femoral implants into four groups, would add even more meaning to the biomechanics of the femoral implants [51] (**Figure 4** and **Table 1**).

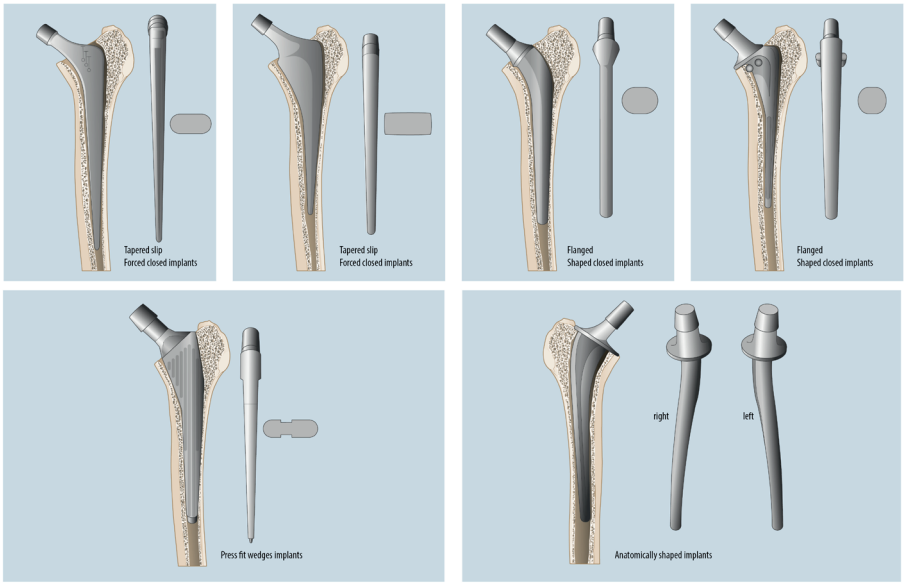


Figure 4 Classification of the cemented femoral implants [51].

Type	Geometry	Description	Fixation
1	Tapered	Polished, flat in AP plane and wide in ML plane. Tapers distally in two or three planes. Designed to load the cement by compression	Forced closed
2	Flanged	Round and minimal tapering distally, usually a collar. Narrowed in AP plane. Roughed surface.	Shaped closed
3	Wedged	Flat stem, thin in AP plane wide in ML plane. Roughed or polished surface.	Shaped closed
4	Anatomically	Curved, rounder and wider in ML than AP. Anatomically bowing. Inbuilt neck anteversion.	Shaped closed

Table 1 Classification of the cemented femoral implants. AP=anterior-posterior, ML=medial-lateral.

Tapered slip cemented implants

In the tapered slip, force closed, implants there is no direct fixation between the implant and the cement mantle. A regulated and controlled small subsidence (1-2 mm) in the cement mantle results in femoral locking [52]. The femoral locking in the tapered slip implants is mainly because of axial load and thereby compression of the cement mantle by the implant itself. In tapered slip femoral implants, the cement and bone are loaded in compression and shear forces are reduced because there is no cement bonding to the (smooth) surface of the femoral implant. The taper is mainly distally in the medial-lateral (ML) and/or anterior-posterior (AP) plane [53, 54]. Tapered slip femoral implants have mostly a polished surface to prevent cement fixation and are collarless with a centralizer at the distal end of the implant to allow a controlled subsidence of the femoral implant in the bone cement over time [55]. This controlled subsidence mechanism is mainly in the first two years after implantation, however, also lifetime subsidence of the femoral implant has been reported [56, 57] (**Figure 4** and **Table 1**).

Shaped closed cemented implants

In contrast to the tapered slip implants the shape closed/composite beam femoral implants have fixation between the implant and the cement mantle. Shaped closed implants are wider as the tapered slip implants in the AP plane and might have added design features (i.e. flanges, collars and flutes) that facilitate the rotational stability of the implant [51]. Also, in contrast of the tapered slip implants the shaped closed implants have a roughed surface to initiate cement fixation to the implant [58]. Subsidence of a shaped closed femoral implant is associated with implant loosening [50, 51]. The fixation of cement to the implant surface can be influenced by the surface, femoral collar and shape of the implant [52]. This is the opposite of the tapered slip femoral implants in which the femoral implants are polished and fixation of cement on the implants is not desired. These two philosophies are the cornerstones of the cemented femoral implants. The force closed implants results mainly in compression forces to the bone cement (PMMA) and the cortical bone and the shape closed implants results also in shear forces in the cement mantle (**Figure 4** and **Table 1**).

Press-fit wedged cemented implants

Press-fit wedged femoral implants are very similar to the shaped closed implants in the sense that these implants are also composite beam implants. However, the fixation of a press-fit cemented implant is achieved by a press-fit locking in the AP plane, with the absent of a subsidence mechanism [59]. Because of this press-fit locking the cement mantle around the femoral implant is thin (< 1mm) [60]. In some regions of the femoral cortical bone the femoral implant is in direct contact with the femoral bone without a cement interface [50]. As in the cementless femoral implants the press-fit cemented femoral implants need to hammered in the femoral canal to achieve the acquired position of the implant (**Figure 4** and **Table 1**).

Anatomically shaped cemented implants

Anatomically shaped femoral implants are curved in the same geometry as the femoral canal. A right/left version is available depending on the side of implantation [61]. Both a roughed and polished surface are available in anatomically shaped femoral implants. Using a taper in a three-dimensional fashion the femoral implant is locked in the femoral canal, without the ability to subside over time. An equally divided cement mantle around the full length of the femoral implant is seen in anatomically shaped implants, with a cement mantle of >2mm. Subsidence of the anatomically shaped femoral implant is associated with implant loosening [62, 63] (**Figure 4** and **Table 1**).

Cementless femoral implants

Fixation of a cementless femoral implant is based on primary mechanical fixation and secondary biological fixation; osseointegration. Osseointegration, with attachment of lamellar bone to the femoral implant without intervening fibrous tissue, was first described in 1981 by Abrektsson et al. [64]. Osseointegration is one of the keystones of the cementless femoral implants. Immediately after surgery, osseointegration will start and can take approximately four to twelve weeks after implantation, however the process

can also continue for many years after surgery [65]. Initial, primary, fixation of the cementless femoral implant is obtained in a press-fit manner, in which the femoral implant is hammered in the prepared femoral canal. With this press-fit fixation and the associated low micromotion of the femoral implant and the resulting hoop stresses, osseointegration (secondary biological fixation), is supported [66]. The primary press-fit fixation and stability of the femoral implant depends mainly on the geometry of the femoral implant and (anatomical) features of the femur [67]. Secondary biological fixation of the femoral implant depends on a number of factors like surface roughness, coating, plasma spraying, materials of the implant and bone quality. Porous (pore sizes of 50 – 400 μm) and trabecular metal are often used as surface treatment to facilitate the biological bone ingrowth [68]. Plasma spraying of the femoral implant, for example with a calcium phosphate compound (hydroxyapatite), promotes the ongrowth of bone on to the femoral implant. The combination of primary fixation (geometry and stiffness of the femoral implant, anatomical features and cortical contact of the femur) and secondary fixation (surface roughness and coating) determines the fixation of the cementless femoral implant.

Based on the geometry, design and place of surface coating the cementless femoral implants can be divided into six groups (**Figure 5** and **Table 2**) [38, 69]. Also, a seventh group can be distinguished, the short stem cementless femoral implants, with a separate classification [70]. Short stem femoral implants are designed to preserve femoral bone stock in the proximal side of the femur and have their fixation in the femoral neck. There is no universally accepted cutoff for the length of the short stem cementless femoral implants and the long-term outcomes remain unknown. The short stem cementless femoral implants are beyond the scope of this thesis.

The femoral implant geometry and shape determines the cortical contact and the initial stability of the implant. Based on this shape and geometry the cementless femoral implants can be classified as wedged, tapered, cylindric, modular and anatomic (**Figure 5** and **Table 2**) [38, 71]. All with other philosophies for stability and ways to achieve osseointegration.

Regarding the coating cementless femoral implants can be divided in proximally and fully (porous) coated implants. The (porous) coating is applied at an area where fixation is required to achieve fixation of the femoral implant in to the host bone. The combination of implant geometry and aspects (composition, thickness, location etc.) of the (porous) coating is essential for the fixation process of cementless femoral implants.

Single-wedged cementless femoral implants

Single-wedged cementless femoral implants are flat in the AP plane and are designed to achieve a wedged type fixation in the metaphyseal bone in the ML plane resulting in a "three-point fixation" (**Figure 5** and **Table 2**). A porous coating is used mostly in the proximal one-third of the femoral implant to achieve fixation. In single-wedged cementless femoral implants the flat shape results in a rotational stability [72-74].

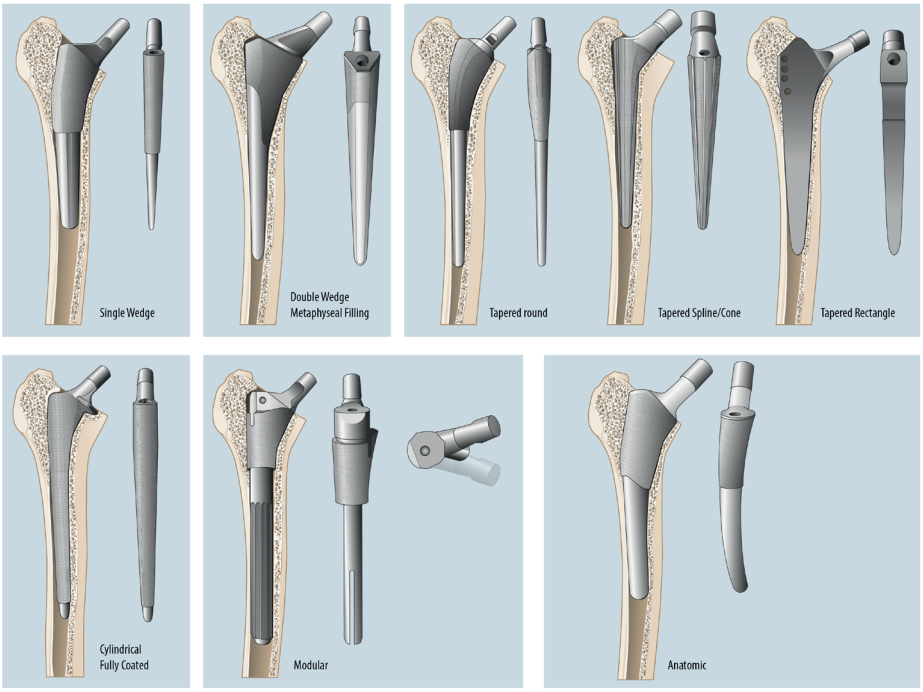


Figure 5 Classification of cementless femoral implants [38].

Double-wedged cementless femoral implants

Double-wedged cementless femoral implants are wedged in the AP and ML plane and are 'bulky' proximally (**Figure 5** and **Table 2**) [75]. The implant is metaphyseal filling and in this manner a fixation mainly in the proximal side of the femur is obtained.

Tapered cementless femoral implants

Tapered cementless femoral implants all have a tapered geometry in both the ML and in the AP plane (**Figure 5** and **Table 2**). Fixation of these tapered femoral implants is mainly in the metaphyseal-diaphyseal junction and not in the metaphysis like the single and double wedged cementless femoral implants. Cementless tapered femoral implants can be further subdivided into three subdivisions; tapered round implants, tapered conical implants and tapered rectangle shaped implants [38, 71].

Cylindric cementless femoral implants

Cylindric cementless femoral implants have a cylindric geometry and are mostly fully porous coated for an entire fixation of the femoral implant in the cortical bone of the diaphysis (**Figure 5** and **Table 2**). Most of the cylindric fully coated femoral implants have a proximal collar to achieve stability. This collar is thought to be responsible for transmitting the axial forces to the calcar of the proximal femur, although there is discussion on the function of the collar.

Modular cementless femoral implants

Modular cementless femoral implants are implants with different components for the metaphyseal and diaphyseal bone (**Figure 5** and **Table 2**) [76]. This type of femoral implant is mainly used for revision surgery, abnormalities in the femoral shape or in rotational abnormalities.

Anatomically cementless femoral implants

Anatomically cementless femoral implants are curved with an anatomically shape (**Figure 5** and **Table 2**). The anatomically shaped femoral implants have an anteversion of the neck and are therefore available in a right and left version depending the operation side [77]. With the anatomical shape the geometry of the proximal femur is matched to achieve a press-fit fixation established by a proximal 'bulky' geometry [77-80].

Type	Geometry	Description	Fixation
1	Single wedge	Flat AP plane, fixation in the ML plane, mainly proximal 1/3 coated	Metaphyseal
2	Double wedge	Narrows distally in the AP and ML plane, metaphyseal filling	Metaphyseal
3	Tapered	Tapered geometry in the AP and ML plane	Metaphyseal-diaphyseal
4	Cylindric	Fully porous coated, proximal collar to achieve stability	Diaphyseal
5	Modular	Separate metaphyseal and diaphyseal component to achieve fixation in both areas	Metaphyseal-diaphyseal
6	Anatomically	Wide 'bulky' proximal in AP and ML planes, anatomically bowing of the femoral implant	Metaphyseal

Table 2 Classification of the cementless femoral implants. AP=anterior-posterior, ML=medial-lateral.

RESEARCH QUESTIONS AND THESIS OUTLINE

The research described in this thesis mainly focussed on the medium- and long-term follow-up of the geometry, fixation and materials used in THA. The following research questions were postulated.

1. What are the survival outcomes of anatomically shaped cementless femoral implants, with a proximal hydroxyapatite coating, in THA?

Controversy exists about the most effective and reliable type of design/geometry in cementless femoral implants. So, there is no clear superior design. Optimal clinical outcomes and low revision rates are the most important parameters for patient satisfaction and implant survival. To this end, the long-term follow-up and clinical outcomes of different types of anatomically shaped cementless femoral implants were examined in **Chapter 2** and **Chapter 3**. In **Chapter 2** the survival and clinical outcomes of the OPTAN anatomically adapted femoral implants were examined with a medium-term follow-up. The purpose of this study was to evaluate the 5-year follow-up with general revision and revision because of (aseptic) loosening as endpoint.

In **Chapter 3** the survival and clinical outcomes of the Anatomic Benoist Gerard (ABG) I and II cementless femoral implants were examined with a long-term follow-up. The primary aim of this study was to evaluate the overall survival with revision for any reason and (aseptic) loosening as endpoint. The secondary aim was the clinical and radiological evaluation of both implants.

2. What are the survival outcomes of anatomically shaped femoral implants when cemented in THA?

In cemented femoral implants the design is important for the fixation in the cement mantle. Cemented femoral implants can be divided in to four subgroups as described before. The anatomically shaped cemented femoral implants have different fixation characteristics compared to the other types of cemented femoral implants. In **Chapter 4** the survival and clinical results of anatomically shaped cemented femoral implants (cemented ABG I and II) are presented in a retrospective cohort study with a long-term follow-up. The primary aim was to evaluate the overall survival with revision for any reason as endpoint. The secondary aim was the clinical and radiological evaluation of the femoral implants.

3. Is there a difference in survival outcome and reason for revision between cemented anatomically shaped and the cemented collarless, polished, tapered femoral implants in THA?

Should a cemented femoral implant be designed to subside over time? There is still controversy concerning this topic without a clear answer. The difference between the femoral implants that are designed to subside (collarless, polished, tapered) and the femoral implants that are designed not to subside (anatomically shaped/I-beam) might result in different survival outcomes. Therefore, the cemented femoral implants that subside over time are compared with cemented femoral implants with a design intended

not to subside. In **Chapter 5** the results of a large register-based study, in which these different types of cemented femoral implants are compared, is presented. In this study 60,655 I-beam femoral implants are compared to 15,626 tapered slip femoral implants. The aim of this national register-based study was to assess the survival and short-term complications of the implants not designed to subside compared with the implants designed to subside, in cemented THAs. We hypothesized that the implants designed to subside would outperform the implants who are designed not to subside, in survival for loosening.

4. Is CFR-PEEK a safe and effective material to use as insert liner in cementless THA in patients with end stage OA?

Cross-linked polyethylene, XLPE, is nowadays the most used bearing in THA. However, in search of the most optimal and reliable biomaterial CFR-PEEK was used as bearing surface in experimental studies. There are no clinical studies with CFR-PEEK used as bearing in THA. The results of a prospective single center study are presented in **Chapter 6**. In this study CFR-PEEK was used as insert liner in THA. In this study 29 patients (29 THAs) with end-stage OA received a cementless THA with CFR-PEEK used as insert liner. The results of 14.3-year follow-up are presented. The primary aim of this prospective study was to identify the potential benefit and the overall long-term survival rates of CFR-PEEK liners used in primary cementless THAs, and to evaluate the radiological and clinical results over time.

Finally, **Chapter 7** comprises a discussion of the main findings of the previous chapters, addresses the main limitations of the studies, provides final conclusions and recommendations and includes opportunities for future research. What have we learned?

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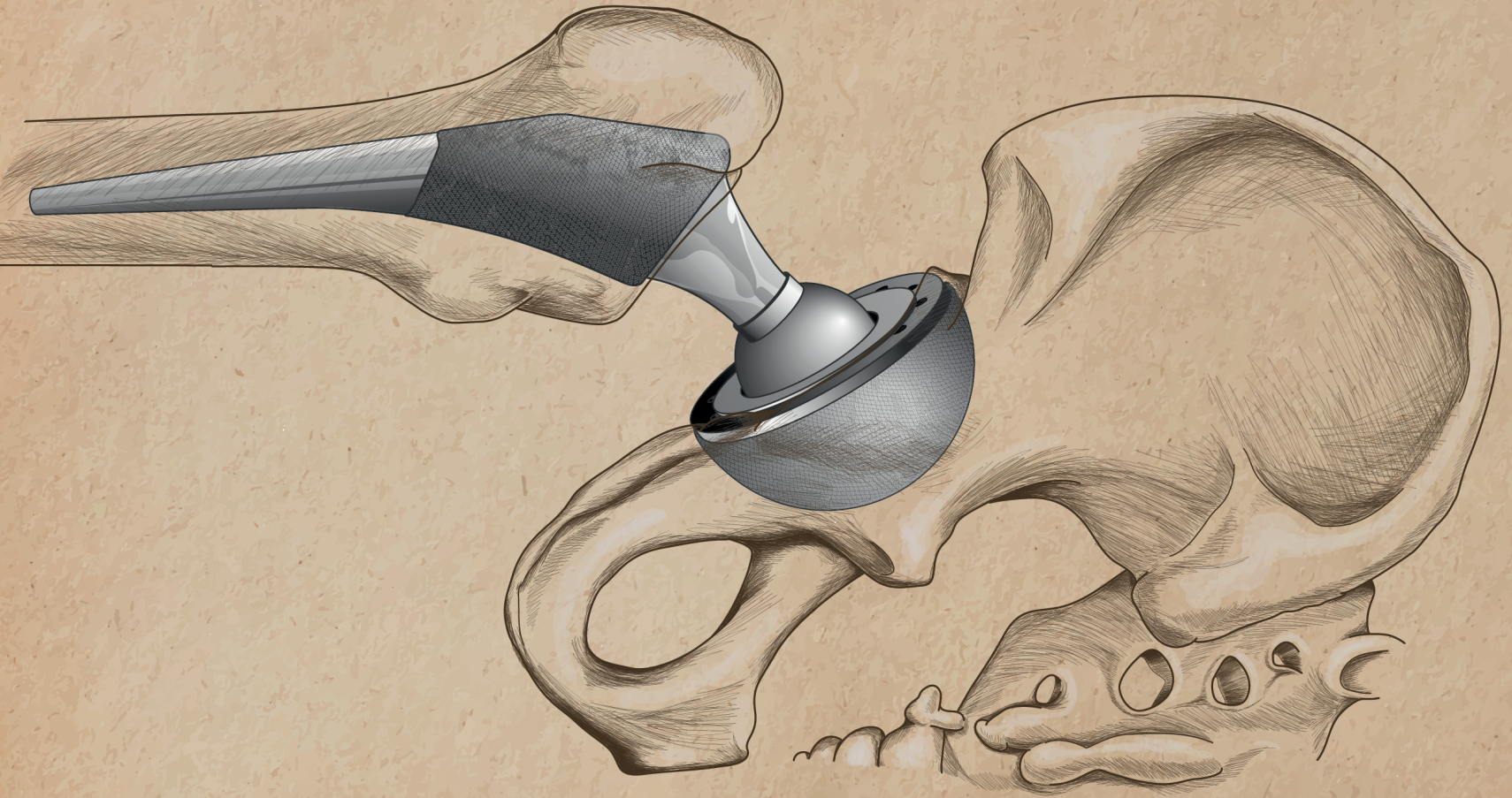

Chapter 2

Poor intermediate-term survival of the uncemented Optan anatomically adapted femoral component.

A retrospective study of 432 patients with a mean follow-up of 5 years.

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Acta Orthopaedica 2014 Aug;85(4):363-7. doi: 10.3109/17453674.2014.934185. Epub 2014 Jun 23. PMID: 24954492; PMCID: PMC4105766.

ABSTRACT

Purpose

We evaluated the 5-year survival of the cementless Optan anatomically adapted femoral implant, with revision for aseptic loosening as the endpoint.

Methods

Between January 2004 and March 2007, 432 total hip arthroplasties (THAs) were performed in 432 patients. After a follow-up for a mean time of 5 years, the patients were evaluated using the WOMAC questionnaire and plain radiography. Patients who were unable to attend the follow-up visit were contacted by telephone to determine whether they had had any revision surgery of their THA.

Results

Within 5 years, 39 patients (9%) had died of unrelated causes and 63 patients (15%) had been lost to follow-up. Of the remaining cohort, 224 patients (68%) had full follow-up while 88 patients (27%) were evaluated with WOMAC only and 18 patients (5%) were evaluated with radiography only. The mean WOMAC score of all evaluated patients was 21 (10 - 100). At 5-year follow-up, there were 26 femoral implant revisions reported (6%), 14 hips (3%) showed aseptic loosening, and 12 hips (3%) had had a periprosthetic femoral fracture. The 5-year survival to revision for any reason was 94%. Worst-case analysis yielded a 5-year survival of 79%.

Interpretation

The 5-year survival for aseptic loosening of the Optan anatomically adapted femoral implant was disappointing. Radiographic evaluation showed evidence of proximal radiolucencies and distal cortical bone hypertrophy, which we attribute to insufficient proximal bone in-growth and increased load transfer at the tip of the femoral implant. We do not recommend the use of the Optan femoral implant.

INTRODUCTION

The Optan femoral implant was designed to reduce proximal femoral bone loss after total hip arthroplasty (THA). It was designed with a specific geometry, stiffness, and surface roughness [1]. It is an anatomically shaped femoral implant in the sense that it has an anteversion similar to that of the native proximal femur. The cementless Optan femoral implant is made of a titanium-based alloy with a porous-coated proximal third. Furthermore, the femoral implant has a ventral rib that should prevent rotation. The distal narrowing, the anatomical shape, and the porous-coated proximal third of the implant are designed to lead to a physiological load transfer and therefore optimal bone in-growth of the femoral implant. Despite the theoretical advantages of the Optan femoral implant, no studies have been published on the survival of this cementless femoral implant. We evaluated the mean 5-years survival of the cementless Optan femoral implant used in primary THA.

PATIENTS AND METHODS

All 432 patients (303 women) who underwent primary THA and received a cementless Optan (**Figure 1**) anatomical adapted femoral implant (Zimmer Germany GmbH, Freiburg, Germany) and a Morscher monoblock cup (Centerpulse/Zimmer) between January 2004 and March 2007 were included (432 THAs). Patients aged 30 years or younger were not included. The most frequent diagnosis was primary osteoarthritis. The mean age at evaluation was 71 (32–92) years (**Tables 1 and 2**).

	Male	*Female*	*Total*
No. of THA	129 hips (30%)	303 hips (70%)	432
No. of patients	129	303	432
Age, mean (range)	69 (38-89)	72 (32-92)	71 (32-92)
Right:Left	63:66	154:149	217:215

Table 1 Patient demographics.

	Number of THAs
Primary osteoarthritis	405 (94%)
Post-fracture/AVN	22 (5%)
Secondary osteoarthritis	2 (0.5%)
Acute fracture	2 (0.5%)
Congenital Hip Dysplasia (CHD)	1 (0.2%)

Table 2 Primary diagnosis of patients.

The articulations used were either the 28-mm CoCr alloy metal-on-metal articulation (115 hips (27%)) or the ceramic-on-polyethylene articulation (317 hips (73%)). The operations were performed by 5 experienced orthopaedic surgeons who each perform over 150 arthroplasties per year at the same institution. All THAs were performed using a 28-mm femoral head. A lateral (trans gluteal) approach was used in all patients. They all received prophylactic antibiotics (cefazolin for 24 h perioperatively). At follow-up, the patients were examined with plain radiography and the Western Ontario and McMaster Universities index (WOMAC) questionnaire [2]. Radiographic evaluation was performed using Rogan software (Oldelft Benelux B.V., Veenendaal, the Netherlands). Patients who were not able to attend the follow-up visit were contacted by telephone and asked questions using the WOMAC questionnaire. Furthermore, we asked whether these patients had had any revision surgery. 63 patients whose telephone number was unknown or who did not respond to telephone calls were categorized as being lost to follow-up.

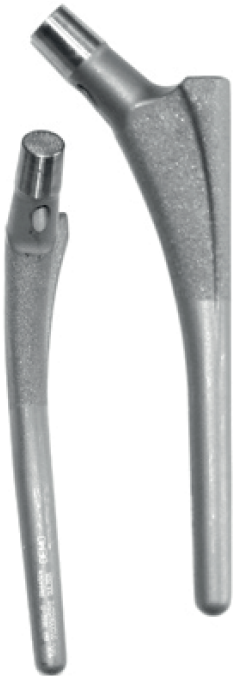

Figure 1 The Optan anatomically uncemented adapted femoral implant with a porous-coated proximal third and a ventral rib to prevent rotation. A left and right version is available.

Radiographical evaluation

Radiographs were assessed for periprosthetic osteolysis and/or radiolucencies. Radiolucencies were defined as a radiolucent line between implant and bone of 1 mm or more. The location of radiolucency was assessed according to the Gruen zones [3]. Radiographic evidence of cortical bone hypertrophy or resorption was also recorded. The first postoperative radiograph was also assessed for varus or valgus malpositioning, i.e. when the femoral implant had a varus or valgus orientation of 5 degrees or more on the anteroposterior pelvic radiograph. We also assessed whether the femoral implant was obviously undersized.

Statistics

Statistical evaluations and analysis were performed using SPSS version 19.0. This software was also used for Kaplan-Meier survivorship analysis for aseptic loosening of the femoral implant and revision for any reason. A worst-case survivorship analysis was performed in which all patients lost to follow-up were considered to be revised due to aseptic loosening. Welch's t-test was used to compare the mean WOMAC scores of the patients contacted by telephone with the patients who had had full follow-up. Furthermore, chi-square statistics was used to determine the factors that predisposed for periprosthetic fracture. The log-rank test (Mantel-Cox) was used to determine whether there was a significant difference in survival outcome in the different subgroups. We considered p-values of <0.05 to indicate significances.

RESULTS

The original cohort consisted of 432 THAs in 432 patients. At 5-year follow-up, 39 patients (9%) had died of unrelated causes. 63 patients (15%) did not respond for evaluation or could not be contacted and were categorized as being lost to follow-up. The remaining cohort consisted of 330 patients (76%). Of this remaining cohort, 224 patients (68%) underwent the full evaluation, 88 patients (27%) were evaluated with WOMAC only, and 18 patients (5%) were evaluated radiographically only (**Figure 2**). The mean duration of follow-up was 5.1 (3.7–6.6) years. At the end of follow-up, the femoral implant had been revised in 26 patients (6%), mainly because of aseptic loosening (14 THAs) and femoral fractures (9 THAs). Other reasons were infection (1 THAs) or recurrent dislocation (2 THAs). Altogether, 12 patients had had a periprosthetic fracture, leading to revision of the femoral implant in 9 cases. In 1 case, the fracture was managed with cerclage wiring. In another case, the fracture was treated with internal fixation with plate and screws. 1 fracture was treated non-surgically. Periprosthetic fractures had occurred at a mean of 1.6 (0.01–6.3) years after surgery. In 14 THAs, symptomatic aseptic loosening had occurred; these had undergone femoral implant revision surgery after a mean of 2.9 (0.02–6) years. 13 patients had had 1 or more dislocations (3%).

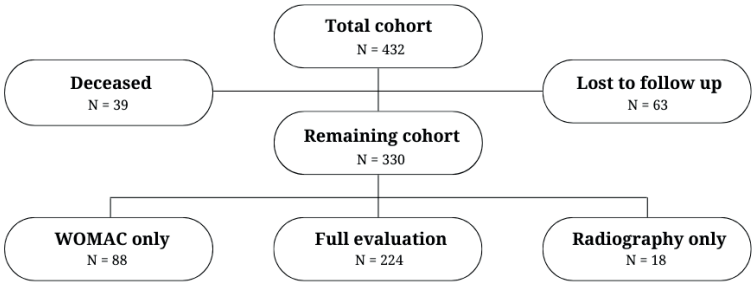

Figure 2 Flowchart of patients in this study.

The mean WOMAC score of all patients was 21 (10–100; median 15; 95% CI: 19–24). The patients who were evaluated by telephone had a statistically significantly better outcome than the patients with full follow-up regarding the WOMAC stiffness score and the WOMAC pain score. The mean WOMAC sum score and the mean WOMAC functional score were similar between the 2 groups (**Table 3**).

	Full follow-up (SD)	*Phone-contact only (SD)*	*p-value*	*95% CI*
WOMAC score	22 (21)	19 (20)	0.2	-1.9 – 8.2
WOMAC pain	15 (21)	8 (17)	0.007	1.7 – 11
WOMAC stiffness	26 (27)	14 (23)	<0.001	6.3 – 18
WOMAC functional	24 (23)	23 (23)	0.7	-4.7 – 7

Table 3 Comparison of the mean WOMAC scores of patients with full follow-up and patients who were enquired telephonically only.

Radiographic evaluation (n = 239) showed cortical bone hypertrophy at the distal end in 106 THAs (45%). In 17 THAs, there was radiolucency at the proximal end of the femoral implant. Of these cases, the radiolucency was located in Gruen zone 1 in 10 THAs and in 5 THAs a radiolucency was seen in Gruen zones 1 and 7. A pedestal, i.e. the formation of bone at the tip of the stem–which usually closes the medullary canal–was found in 18 THAs. In 47 THAs, there was an undersized femoral component; the femoral component was in varus malpositioning in 13 THAs and it was in valgus malpositioning in 5 THAs.

Survivorship analysis

Survivorship analysis with femoral implant revision for any reason as the endpoint revealed an overall survival of 94% at the 5-year follow-up (**Figure 3**). 5-years survival with aseptic loosening as the endpoint was 97% (**Figure 4**).

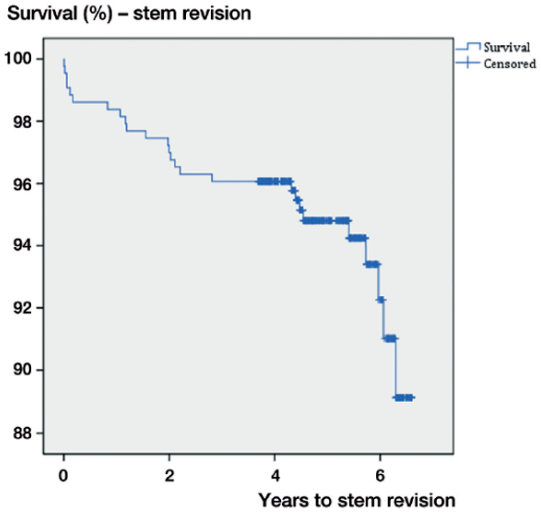

Figure 3 Kaplan-Meier survival analysis with revision for any reason as the endpoint.

The type of articulation (either ceramic-on-polyethylene or 28-mm metal-on-metal), age, varus/valgus malpositioning, or undersizing of the femoral implant did not significantly affect survival with implant loosening or implant revision for any reason as the endpoint (**Table 4**). Male patients had relatively more cases of aseptic loosening (survival 94%, p = 0.03). The worst-case scenario, in which all 63 patients who were lost to follow-up were considered to have had a revision of the femoral implant, would yield a survival rate of 79% with revision for any reason as the endpoint. With aseptic loosening as the endpoint, the survival rate would be 82%. Patient age, sex, varus or valgus malpositioning, and undersizing of the femoral implant did not significantly affect the frequency of periprosthetic fracture. The frequency of periprosthetic fracture was higher in the patients with a ceramic-on-polyethylene articulation (p = 0.03).

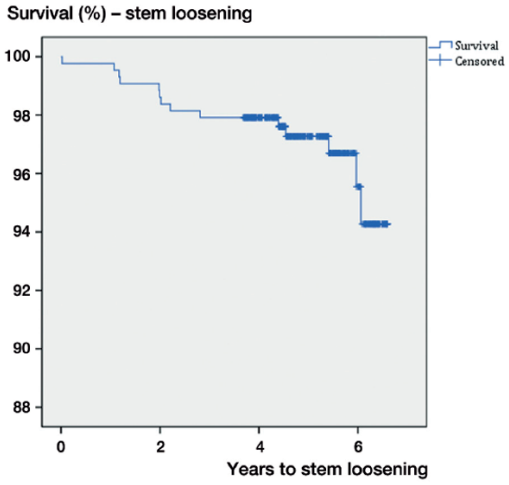

Figure 4 Kaplan-Meier survival analysis with revision due to aseptic loosening as the endpoint.

		Revision for any reason		*Revision for aseptic loosening*	
		Survival	*p*-value	Survival	*p*-value
Sex	Male	92%	0.3	94%	0.03
	Female	95%		98%	
Articulation used	Metal-on-Metal	97%	0.2	97%	0.6
	Ceramic-on-PE	93%		97%	
Undersized	Yes	87%	0.06	96%	0.8
	No	95%		97%	
Malpositioned	Varus	85%	0.7	92%	0.6
	Valgus	100%		100%	
Age	32 - 54	94%	0.6	97%	0.6
	55 - 74	93%		96%	
	75 - 92	95%		98%	

Table 4 Survival -to-revision for any reason and survival-to-aseptic loosening of the different subgroups categorized by sex, articulation, undersizing, varus/valgus malpositioning and patient age (Log rank/Mantel-Cox test).

DISCUSSION

The present study had several important limitations. Because of the retrospective design, it suffered from a substantial number of patients being lost to follow-up (63 patients, 15%), which could have influenced our results. The high number of patients who did not attend the full follow-up (106 patients, 25%) was also a limitation. Radiographic follow-up was completed in only 242 patients (56%). We believe,

however, that the telephone-based interview using the WOMAC questionnaire and determining whether patients had had any revision surgery of their THA was an adequate form of follow-up for patients who were unable to attend for full clinical follow-up. Furthermore, the WOMAC sum scores were similar in the full-evaluation group and the WOMAC-only group, indicating that these groups were comparable regarding clinical outcome.

Of the 432 patients, 115 (27%) received a metal-on-metal articulation. Thus, it is possible that patients who experienced pain after their THA actually had symptoms of pseudotumours or aseptic lymphocyte-dominated vasculitis-associated lesions (ALVAL) [4]. Advanced diagnostics in the form of ultrasonography, magnetic resonance imaging, or blood-cobalt screening were not routinely performed. Nevertheless, there were no signs of metal debris-induced pseudotumours or ALVAL–either clinically or by plain radiography–in our patients. Furthermore, in the present study the type of articulation did not significantly affect the survival rate of the femoral implant.

The overall survival rate of 94% for the Optan femoral implant at 5-year follow-up is a poor result. For reference, the tenth annual report of the National Joint Registry of England and Wales shows that cementless total hip implant combinations with a metal-on-polyethylene bearing have a mean 5-year all cause revision rate of 2.5% (CI: 2.4–2.7) [5]. We found 14 THAs with aseptic loosening (3.2%). Compared to other studies, the frequency of aseptic loosening after 5 years of follow-up in our study was high. For example, Wittenberg et al. reported a prevalence of 1.2% for aseptic loosening in cementless femoral implants [6]. Worst-case analysis of our cohort yielded a 5-year survival of 79% with revision for any reason as the endpoint and 82% with aseptic loosening as the endpoint. This indicates that the Optan femoral component may not be able to meet the NICE recommendations for THA.

The specific geometry of the Optan femoral implant, with a smooth surface at the distal end of the implant and a porous-coated proximal third, is designed to facilitate proximal bone in-growth. Nevertheless, we found radiolucencies in the proximal femur, Gruen zones 1 and 7, in 50% and 25% of cases. Other studies on the Optan stem have demonstrated bone loss medially and laterally in the proximal femoral regions, mainly affecting Gruen zones 1 and 7, and a progressive decline in bone mineral density (BMD) over the first 12 months after surgery [1, 7]. In the latter study, the most pronounced decrease in BMD, after 12 months, was found to be in Gruen zones 7 and 1 [1]. Furthermore, in a large number of patients (106 patients (45%)) we observed cortical bone hypertrophy around the distal end of the femoral implant. The frequency of distal cortical bone hypertrophy that we found was high compared to other studies with medium-term follow-up [8-10].

We attribute these phenomena–radiolucencies in the proximal femur and cortical hypertrophy around the tip of the femoral implant–to a non-physiological loading pattern, which was previously described by Decking et al. [7]. In their study, these authors observed a change in the strain pattern after implantation of the Optan femoral stem, with a major principal strain reduction of 43% in the medial part of the

proximal femur and 69% in the lateral part. We attribute this to insufficient proximal bone in-growth due to the stiffness of the Optan femoral implant and the insufficient roughness of the proximally porous-coated part. Furthermore, we consider that the cortical bone hypertrophy is the result of an increase in load transfer around the tip of the femoral implant. We hypothesize that insufficient proximal bone in-growth leads to more load transfer at the distal end of the femoral implant, subsequently leading to distal cortical bone hypertrophy and/or the formation of a pedestal. Furthermore, the mechanical mismatch between the Optan femoral implant and the femoral bone leads to stress shielding and subsequent bone resorption in the proximal femur. These implant properties offer poor conditions for osseointegration. We believe that these properties caused the high frequency of aseptic loosening at medium-term follow-up that was observed in the present study.

The frequency of periprosthetic fractures in our study was within the range reported for other (cementless) femoral implants, ranging from 2.3% to 3.5% at an average of 6.9 and 3 years of follow-up, respectively [11, 12]. We found that varus or valgus malpositioning or undersizing of the femoral implant did not affect the frequency of periprosthetic fractures ($p = 0.2$ and 0.7). Furthermore, we did not observe periprosthetic fractures without an adequate trauma. We therefore believe that the prevalence of periprosthetic femoral fractures is not related to the geometry or to the degree of osseointegration of the femoral implant. We hypothesize that the frequency of periprosthetic fractures is related to the low BMD and frailty of the patients. This is supported by the fact that we observed fewer periprosthetic fractures in patients with a metal-on-metal articulation, which was used in young and active patients only.

In summary, the survival of the Optan anatomically adapted femoral implant at 5-year follow-up was disappointing in terms of the high frequency of aseptic loosening. We observed a high number of cases with evidence of insufficient proximal bone in-growth and distal cortical bone hypertrophy. We attribute this to the high stiffness of the implant and to the inadequate surface roughness of the porous-coated proximal part.

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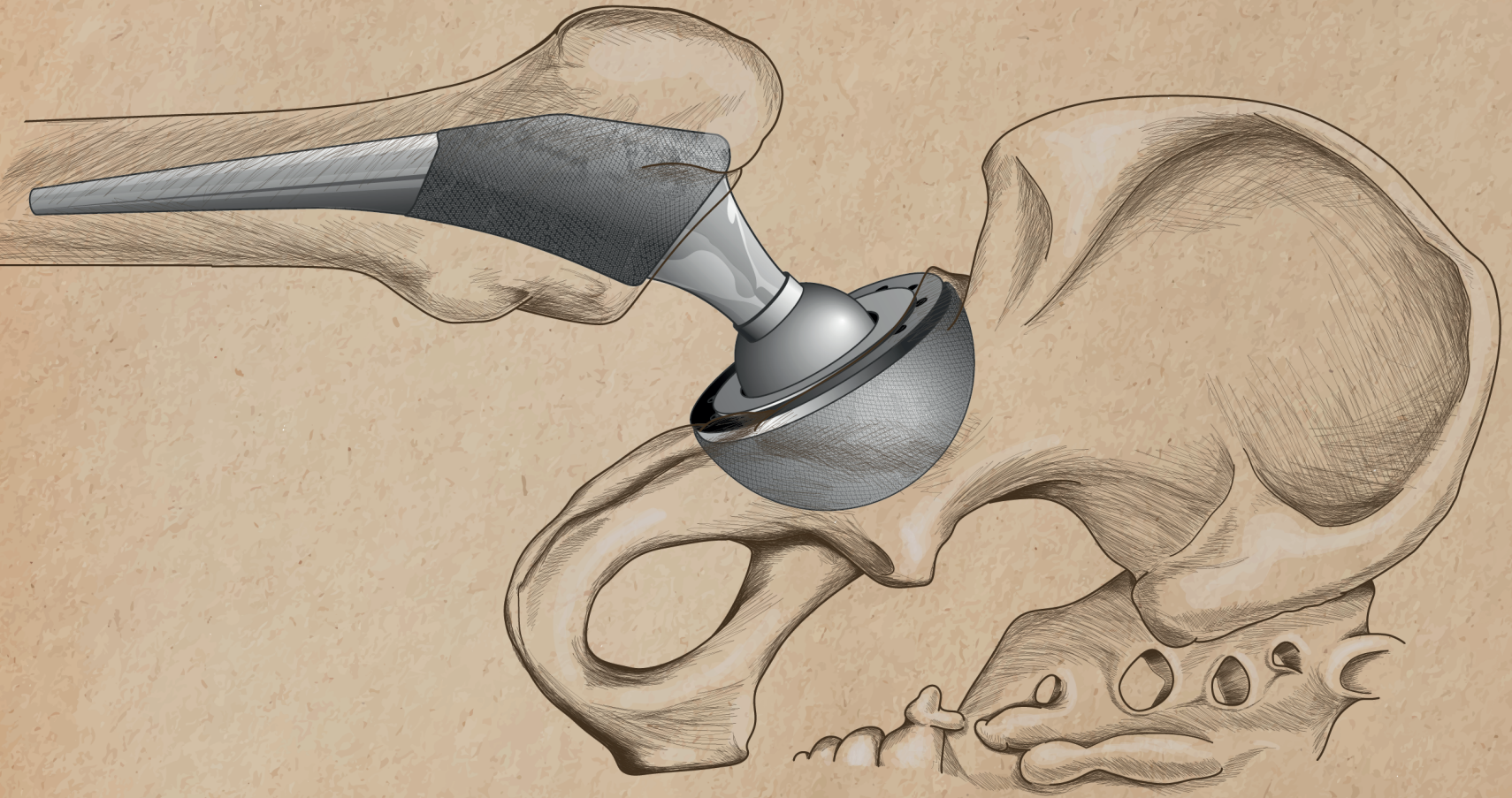

Chapter 3

Excellent survival of two anatomically adapted hydroxyapatite coated cementless Total Hip Arthroplasties.

A mean follow-up of 11.3 years.

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Submitted

ABSTRACT

Introduction

There are many different types of cementless anatomically adapted Total Hip Arthroplasties (THAs) on the market. The Anatomic Benoist Girard (ABG) I and II are such types of cementless THAs. In this retrospective single-centre study we evaluated the overall survival with revision for any reason and aseptic loosening as endpoint at more than 11-year follow-up.

Patients and Methods

Between 2000 and 2004, 244 cementless THAs were performed in 230 patients in a primary care hospital. At a mean of 11.3-year follow-up (range 9.8 – 12.8 years) clinical examination, plain radiography and Patient Reported Outcome Measures (PROMs) were obtained and analyzed. The PROMs consisted of the Oxford Hip Score (OHS) and the Western Ontario and McMaster University Index (WOMAC).

Results

At a mean of 11.3-year follow-up 32 patients (13.1%) had died of unrelated causes. Of the remaining cohort all 198 patients (212 THAs) had been reached for evaluation. There were no patients considered as lost to follow-up. At a mean of 11.3 years 11 patients (11 THAs) had had a revision of either the femoral implant or acetabular component resulting in an overall survival of 95.5%. There was no statistically significant difference (p=0.564) in survival between the ABG I and II THAs. Radiographic there were no changes between the ABG I and II at last follow-up. The ABG II performed statistically significant better in PROMs.

Conclusions

We concluded that both anatomically adapted hydroxyapatite coated cementless THAs show excellent survival at more than 11-year follow-up.

INTRODUCTION

Different types of cementless femoral implants with variable shapes are on the market. Based on shape and geometry the femoral implants can be divided in six groups according the classification of Khanuja et al. (2011) [1]. They are all thought to lead to sufficient bone-ingrowth onto or into the total hip arthroplasties (THA) and thereby creating a physiological stress distribution to the host bone. According to Wolffs law, the implantation of a THA, with or without cement fixation, will induce remodelling of the host bone in response to the changing stress transmission [2]. Optimally the stress distribution of the cementless femoral implant and acetabular component (AC) must be in the same range as the physiological femoral and acetabular stress distribution [3, 4]. The use of an anatomically adapted THA might reduce stress shielding, theoretically resulting in less failure and osteolysis of the THA. Examples of an anatomically adapted femoral implant are the Anatomic Benoist Girard (ABG) I and II. The main difference between the ABG-I and II femoral implants is the reduction of the overall length by 8% and the reduction of 10% of the proximal and distal diameter of the ABG-II. The ABG-I and II have widely been used for many years and are analyzed in several studies with variable years of follow-up [5-9], however a comparative study between these two cementless femoral implants has never been published. This retrospective single-centre study was designed to evaluate the survival and clinical follow-up of these THAs. The primary aim of this study was to evaluate the overall survival with revision for any reason and aseptic loosening as endpoint. The secondary aim was the clinical and radiological evaluation of both femoral implants and the AC.

PATIENTS AND METHODS

Patients

This retrospective single-centre study comprises of 244 primary cementless THAs implanted between May 2000 and December 2004 in 230 patients. Patient characteristics are summarized in **Table 1**. Initial diagnosis for THA was primary osteoarthritis in 237 patients (97.1%), secondary osteoarthritis in 1 patient (0.4%), congenital hip dysplasia in 2 patients (0.8%) and a fracture of the proximal femur in 4 patients (1.6%). Approaches used during operation were a lateral approach (n= 167, 68.4%), posterior approach (n= 70, 28.7%) or an anterolateral approach (n= 7, 2.9%). Clinical and radiographic follow-up was at 6 weeks, 1 year and 2 years after initial surgery without obtaining Patient Reported Outcome Measurements (PROMs).

	Total	*ABG-I*	*ABG-II*	*p-value*
Age, mean at operation (range)	62.3 (36.4 – 83.1)	63.0 (36.4 – 83.1)	60.3 (37.6 – 72.6)	0.002
THA, n (%)	244	178 (73)	66 (27)	
Left, n (%)	116 (47.5)	81 (45.5)	35 (53.0)	0.300
Mean follow-up, yr (range)	11.3 (9.8 – 12.8)	11.4 (9.8 – 12.8)	11.0 (9.9 – 12.6)	0.016
Male, n (%)	117 (48.0)	80 (44.9)	37 (56.1)	0.125

Table 1 Details of the patient characteristics.

Implants

The cementless femoral implants of the ABG-I and II (Stryker, Herouville Saint Clair, France) are made out of titanium alloy (Titanium Molybdenum Zirconium Ferrum, TMZF) and are both anatomically shaped (**Figure 1**). The implants are designed for proximal fixation. The anatomical shape with 7° anteversion in the metaphyseal area and 5° anteversion in the femoral neck is important to obtain proximal anatomic press-fit and proximal rotational stability [7, 8, 10]. Proximal fixation is achieved by the hydroxyapatite coating on the proximal third of the femoral implant and by the proximal anatomic press-fit which lead to a close contact and fixation in the cancellous metaphyseal bone. The main difference between the ABG-I and II femoral implants is the reduction of the overall length by 8% and the reduction of 10% of the proximal and distal diameter of the ABG-II (**Figure 1**) [5, 11]. There is no difference in the operation technique between both femoral implants. Bearings used were cobalt/chromium (CrCo) in 190 patients (77.9%) and oxide ceramic (Al_2O_3) femoral heads in 54 patients (22.1%) both articulating with highly cross-linked nitrogen-irradiated polyethylene.

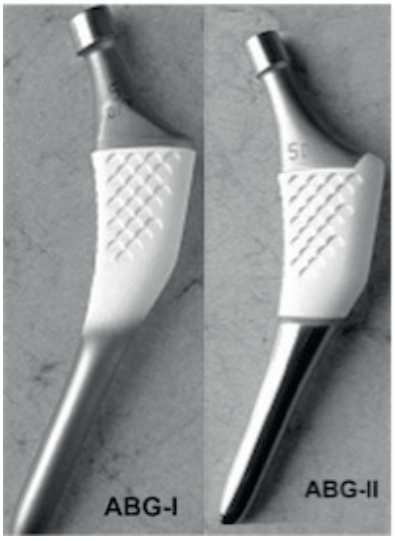

Figure 1 Differences between the Anatomic Benoist Girard I (left) and II (right).

Evaluation

Clinical and radiological evaluation was at a mean follow-up of 11.3 years. Patients received an invitation for follow-up and two different PROMs; the Western Ontario and McMaster University Index (WOMAC) [12, 13] and the Oxford Hip Score (OHS) [14-16]. The WOMAC can be scored from 0 – 100 (best score = 100, worst score = 0) and the OHS can be scored from 12 – 60 (best score = 12, worst score = 60). An overall questionnaire was used in which patients could indicate if they had had revision surgery of their THA, if they experienced pain of the THA using the Visual Analogue Scale [17] and whether they were able to walk unaided. If patients were unable to attend the follow-up appointment the information of the different PROMs returned by the patients was used. These patients were classified as patients participated with a partial follow-up. Patients, without a reaction to the invitation for the follow-up appointment and who did not return the PROMs, were consulted by phone to make inquiries on possible revision surgery of their THA. These patients were also classified as patients with a partial follow-up. When patients could not be reached or if the patients were deceased during the follow-up, their general practitioner (GP) was contacted and questioned on possible revision surgery of the THA. In case of no patient related information from the GP patients were considered as patients lost to follow-up.

Adverse Events

Adverse events (AE) during follow-up were classified as patient related (e.g., psychological problems), wound related (e.g. wound leakage, post-operative bleeding), prosthesis related (e.g. dislocation, fracture and loosening) and surgery related (e.g. infection). If an AE led to death or revision surgery of the THA it was classified as a serious AE.

Radiological evaluation

Antero-posterior and lateral X-rays were taken of the operated side(s). Radiographs were examined for periprosthetic osteolysis and radiolucency. Radiolucencies were defined as a radiolucent line between the implant and bone of 1mm or more and were described according the Gruen zones [18] for the femoral implant and the zones of DeLee and Charnley [19] for the AC. Varus- or valgus malpositioning of the femoral implant was also assessed as well as cortical bone hypertrophy or resorption. We also assessed whether the femoral implant was undersized. Total polyethylene (PE)-wear at follow-up and the wear angle of the AC insert was measured using Roman software [20]. All radiographs were examined by 3 different observers (two orthopaedic surgeons and one radiologist).

Statistical analysis

Statistical evaluation and analysis was performed using SPSS 21.0 software (IBM SPSS, NY, USA). Kaplan-Meier survival analysis was used for revision for any reason and aseptic loosening as endpoint. The 95% confidence intervals (95% CI) were calculated. Log-rank (Mantel-Cox) test was used to determine the statistical differences between different survivorship outcomes in the different groups. A generalized linear mixed model (GLMM) approach was used to estimate the effect of type of femoral implant adjusted to age on the different PROMs. With a GLMM statistical analyses the outcomes could be adjusted for specific co-variables [21]. We considered p-values of ≤ 0.05 to be statistical for all statistical analysis.

RESULTS

After a mean of 11.3-year follow-up 32 patients (32 THAs, 13.1%) had deceased of unrelated causes. All the 198 patients (212 THAs, 86.9%) of the remaining cohort were reached and additional information about possible revision surgery was obtained, resulting in no patients considered as lost to follow-up (**Figure 2**).

Survival analysis

Eleven patients (11 THA, 4.5%) had undergone revision surgery of the femoral implant and/or AC at a mean of 11.3-year follow-up. The mean time to revision surgery was 57.6 months (range 1.0 – 135.6) or 4.8 years after initial surgery. The reasons for revision surgery were a periprosthetic fracture in six patients (2.5%), aseptic loosening in three patients (1.2%), infection (0.4%) and recurrent dislocations (0.4%). This results in an overall survival for any reason of 95.5% (CI 95%, 92.6 – 98.0) and for aseptic loosening

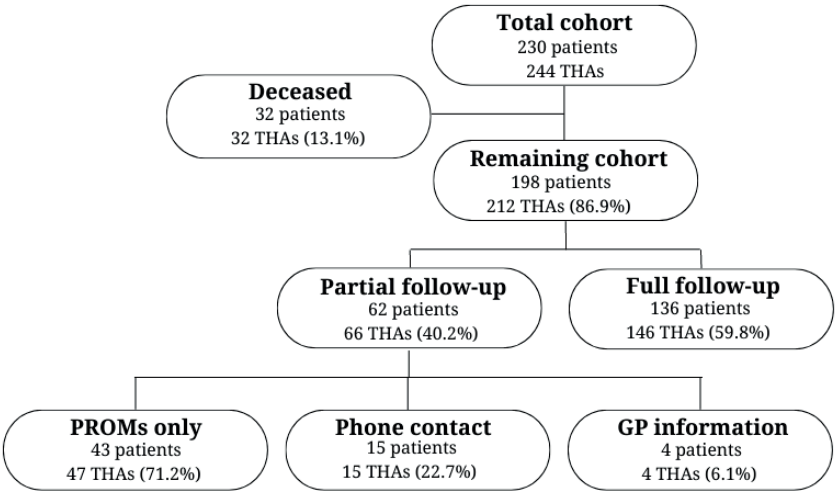

Figure 2 Flow-chart of patients in this study.

of 98.8% (CI 95%, 97.1 – 100). In four patients both the femoral implant and the AC were revised, in five patients the femoral implant was solely revised and in two patients the AC was solely revised. The initial diagnosis of the patients, which had revision surgery, was primary osteoarthritis (n=10) and a fracture (n=1). There was no relation between the approach used during surgery and revisions.

The ABG-II femoral implant had a (p = 0.564) higher survival rate at 11.3-year follow-up compared to the ABG-I femoral implant (**Table 2**). Indication for both revisions of the ABG-II femoral implant was a periprosthetic fracture. Survival for aseptic loosening of the ABG-II implant is 100% compared with 98.3% for the ABG-I implant (p = 0.313). In total six ABG-II AC were revised resulting in a survival of 97.5% (CI 95%, 95.5 – 99.2).

	N	*Revisions*	*Survival (CI 95%)*
ABG-I	178	9	94.9% (91.6 – 97.8)
ABG-II	66	2	97.0% (92.4 – 100)
Overall	244	11	95.5% (92.6 – 98.0)

Table 2 Number of revisions for the ABG-I and ABG-II femoral implant p = 0.564.

Radiographic results

The radiographic results at 11.3-year follow-up are summarized in Table 3. Radiolucent lines of >1mm were located at the greater trochanter of the femoral implant at Gruen zone 1 (2 THAs, 1.4%). There was no statistically significant difference in PE-wear and wear angle (**Table 3**).

	Overall n=146	*ABG-I n=105*	*ABG-II n=41*	*p-value*
Varus malpositioning (%)	2 (1.4)	1 (1.0)	1 (2.4)	0.573
Undersized implant (%)	2 (1.4)	1 (1.0)	1 (2.4)	0.573
Radiolucent line (%)	2 (1.4)	2 (1.9)	0	0.158
Total PE-wear (mm, range)	0.92 (0.0 – 2.7)	0.90 (0.0 – 2.2)	0.96 (0.0 – 2.7)	0.607
Wear-angle (degrees, range)	30.7 (0.0 – 84.9)	30.3 (0.0 – 84.9)	31.9 (0.0 – 81.5)	0.670

Table 3 Radiographic results at a mean of 11.3 years follow-up. There was no statistically significant difference between the ABG-I and ABG-II femoral implant.

Clinical results

PROMs were returned by 172 patients (186 THAs), which is a response rate of 92.5%. Fifteen patients were consulted by phone, to assess if revision surgery occurred, without obtaining the PROMs (**Figure 2**). With GLMM statistical analysis the ABG-II femoral implant performed statistically significant better in the PROMs, except for the WOMAC pain score (**Table 4**).

	Overall	*ABG-I*	*ABG-II*	*p-value*
WOMAC Total Score (SD)	74.6 (21.3)	72.1 (21.4)	80.9 (19.9)	<0.001
WOMAC Functional (SD)	74.3 (26.3)	70.2 (27.0)	82.7 (24.1)	0.047
WOMAC Pain (SD)	81.1 (12.2)	78.2 (23.6)	86.9 (21.4)	0.079
WOMAC Stiffness (SD)	71.2 (25.1)	68.8 (26.4)	75.2 (23.1)	0.030
Oxford Hip Score (SD)	30.3 (12.2)	33.7 (25.4)	21.5 (22.3)	0.013

Table 4 Results of the PROMs at a mean of 11.3 years follow-up. Because of a significant difference in age at operation between the two groups a GLMM approach was used to adjust for age.

Adverse Events

During follow-up an AE occurred in 33 patients (33 THAs, 13.5%), two patient related (0.8%), twelve wound related (4.8%), sixteen prosthesis related (6.4%) and three surgery related (1.2%). There was no difference in the AE between the ABG-I and II femoral implants.

DISCUSSION

In this retrospective single centre study, we investigated and compared the survival at a mean of 11.3-year follow-up of two cementless anatomically adapted THAs. The mid- and long-term survival of the ABG-I femoral implant, published in other studies, showed excellent survival rates up to 99.2% at 5-year, 98% at 9-year and 98.6% at 15-year follow-up [8, 22, 23]. Compared to these studies the overall survival of the ABG-I femoral implant is slightly lower in this present study. The design and anatomical geometry of the ABG-I femoral implant is based on the principle of proximal fit and fill. In a radiosterometric analysis by

Nysted et al. the ABG-I femoral implant was compared with a different type of cementless anatomically adapted femoral implant [10]. Nysted et al. observed in-growth mainly proximally and a small amount of movement of the cementless ABG-I femoral implant [10]. They observed a better fit and fill in a Dorr type B (regular) or a Dorr type C (stovepipe) shape of femur at 5-year follow-up [24, 25]. Failure of proximal in-growth with a tight distal fit and a loose proximal fit were seen in patients with a Dorr type A femur (champagne-flute). Questions rose if the ABG-I femoral implant might cause problems for patients with a non-conformity femur [10]. The adjustments of the ABG-I cementless THA into the ABG-II cementless THA was mainly because of high failure rates of the ABG-I AC with excessive PE wear. Adjustments of the femoral implant were made resulting in the ABG-II. Reduction of the total length and a polished distal end of the femoral implant had to prevent distal bone in-growth and better proximal fit and fill in Dorr type A shaped femurs. The survival of the ABG-II femoral implant in this study was excellent and is consistent compared to other studies [5, 7, 9]. We observed no patients with aseptic loosening of the ABG-II femoral implant, which is also consistent with other studies [5, 9]. The absence of patients with aseptic loosening of the ABG-II femoral implant in this study might suggests a reliable fixation of the proximal end of the ABG-II femoral implant.

Radiological radiolucent lines in Gruen zone 1 were seen in two patients with an ABG-I femoral implant, compared to the complete absence of these lines in patients with an ABG-II femoral implant. These radiolucent lines are caused by the stress-shielding phenomenon, which is common to all cementless femoral implants and in the ABG-I femoral implant they are mainly located in Gruen zone 1[22]. The reduction of the total length and the altered distal design of the ABG-II femoral implant are thought to minimize the stress-shielding, resulting in a decreased number of radiolucent lines [7]. No radiolucent lines were observed round the ABG-II AC. The mean PE wear of the ABG-II AC found in this study was acceptable (<1mm) and is consistent compared to other studies [7, 9].

Patients with the ABG-II femoral implant performed better than patients with the ABG-I femoral implant on the PROMs, also when adjusted for age at operation and follow-up time there was a statistical difference in the outcomes of the PROMs.

This study had some limitations. There was a significant difference in the follow-up time and age at operation between the two patients' groups. Retrospectively there is adjusted for age at operation and time of follow-up with a GLMM [21]. A relatively small number of patients (136 patients with 146 THAs, 68.9%) attended the follow-up appointment with clinical and radiographic examination, however the response rate of the PROMs was 92.5% of the contacted patients, with no patients considerd as lost to follow-up. The most frequent reason not to attend the follow-up appointment were financial restrictions. As this study had no financial support, a number of patients had to pay the costs of radiographic examination themselves.

In conclusion, this study showed an excellent survival rate for both anatomically adapted cementless femoral implants and cementless AC. A reduction of the total length and the polished distal end might be the reason for a better proximal bone ingrowth and a better overall survival, although there was no statistically significant difference between both anatomically adapted femoral implants. Patients with the ABG-II femoral implant performed significant better on PROMs than patients with the ABG-I femoral implant, also when retrospectively adjusted for age at operation and follow-up time.

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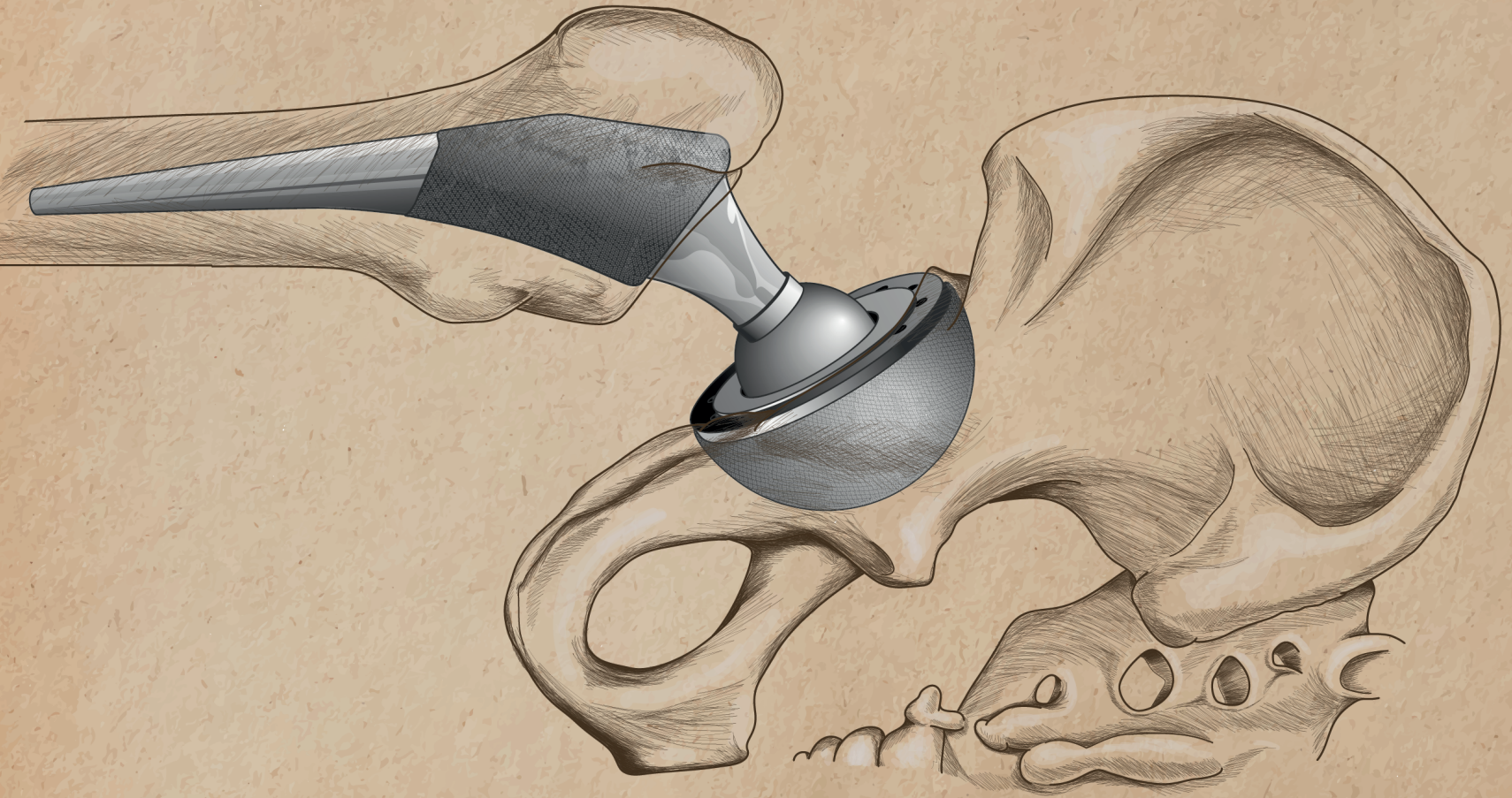

Chapter 4

Results of Cemented anatomically adapted Total Hip Arthroplasty.

A follow-up longer than 10 years.

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Journal of Arthroplasty. 2016 Jan;31(1):194-8. doi: 10.1016/j.arth.2015.08.023. Epub 2015 Aug 29. PMID: 26404845.

ABSTRACT

This retrospective single-centre study evaluated the >10-year follow-up (FU) and survival of 2 anatomically adapted cemented total hip arthroplasties (THAs) in a series of 308 patients (323 THAs) with a mean age of 76.2 years at operation. At a mean of 11- year of FU, patient-reported outcome measures (PROMs), clinical examination and plain radiography were analyzed. In 6 THAs, the femoral implant and/or acetabular component was revised. Reasons for revision were aseptic loosening and infection. At >10-year of FU, there was an overall survival for both THAs of 98.1%. Radiographic radiolucent lines were seen in 15 THAs affecting Gruen zone 4 and DeLee and Charnley zone II. We conclude that both anatomically adapted cemented THAs have an excellent survival at 11-year of FU.

INTRODUCTION

Cemented total hip arthroplasty (THA) in older patients (>65 years of age) results in an effective fixation of the implant to the host bone and shows better implant survival compared with cementless fixation in this age group [1]. Over the last years, the use of cement fixation in Scandinavia and the Netherlands remained steady at approximately 30% of all THAs [2, 3]. Different types of femoral implants with varying anatomical shapes and geometries are thought to lead to better fixation and better overall survival rates [4], especially in cementless femoral implants. In cemented femoral implants the anatomical geometry would be of lesser importance. Both straight tapered implants as well as anatomically shaped cemented implants show excellent long-term survival [5, 6]. Nevertheless, studies have shown the importance of anatomically shaped and adapted cemented femoral implants, resulting in a better overall survival of the cemented THA [7]. This retrospective single-center study is designed to evaluate the survival and clinical benefits of 2 different anatomically shaped cemented THA (Anatomic Benoist Girard, ABG I and II). The primary aim was to evaluate the overall survival with revision for any reason as endpoint. The secondary outcome was the clinical and radiological evaluation of the femoral implant and acetabular component (AC) and the evaluation of the patient-reported outcome measurements (PROMS).

PATIENTS AND METHODS

Before the start of the study, institutional review board approval was obtained and registered online (www.trialregister.nl).

Patients

This study comprises 308 patients, 323 THAs in total. Patient characteristics are summarized in **Table 1**. All patients who were included for cemented THA between May 2000 and December 2004 received a cemented ABG I or II femoral implant and ABG-II cemented AC (Stryker, Hérouville Saint Clair, France). In all patients, the ABG-I or II femoral implants were combined with the cemented ABG-II standard AC. A lateral approach (n= 236, 73.1%), a posterior approach (n=75, 23.2%) and an anterolateral approach (n=12, 3.7%) were used by 6 orthopaedic surgeons or residents under direct supervision. Primary osteoarthritis was the most frequent index diagnosis for THA (97.2%) (**Table 2**).

	n=308
Mean age at operation (range)	76.2 (55.6 – 93.0)
THA, n	323
Left, n (%)	133 (41.2)
Male, n (THA, %)	63 (67, 20.5)

Table 1 Patient characteristics of the total cohort.

	Total (%)	*ABG-I (%)*	*ABG-II (%)*
Primary osteoarthritis	314 (97.2)	224 (97)	90 (97.8)
Rheumatoid arthritis	1 (0.3)	1 (0.4)	0
Congenital hip dysplasia	1 (0.3)	1 (0.4)	0
Femoral fracture	6 (1.9)	5 (2.2)	1 (1.1)
Broken dynamic hip screw	1 (0.3)	0	1 (1.1)

Table 2 Patients primary index diagnosis for indication of THA of the total cohort (n=323 THA), differentiated between ABG-I and II femoral implants.

Implants

The ABG cemented femoral implant is a short anatomically shaped chrome cobalt femoral implant with primarily proximal fixation. In comparison to other anatomically adapted femoral implants, the ABG THA has a higher "shoulder" that facilitates proximal contact to the cancellous metaphyseal bone [8, 9]. The ABG-I femoral implant has been widely used since 1989 in Western European countries. Since 1997, there was an adjustment of the femoral implant geometry because of high failure rates of the cementless version [9], which led to the introduction of the ABG-II femoral implant for both the cementless as cemented versions. The main differences between the ABG-I and II femoral implants concern the overall length which has been reduced by 8% and the proximal and distal diameters which have been reduced by 10% [10]. The articulations used were cobalt/chromium (Co/Cr) on high cross-linked nitrogen-irradiated polyethylene (PE) in 322 cases (99.7%) and aluminium oxide ceramic (Al_2O_3) on high cross-linked nitrogen-irradiated PE in only 1 case (0.3%).

Evaluation

Patients received a letter containing an appointment date for follow-up (FU) and 2 different PROMs; the Dutch-translated and -validated version of the Western Ontario and McMaster University Index (WOMAC) [11, 12] and the Oxford Hip Score [13-15]. The WOMAC can be scored from 0 – 100 (best score = 100, worst score = 0) and the Oxford Hip Score can be scored from 12 – 60 (best score = 12, worst score = 60). An overall questionnaire was used in which patients were asked whether they had had any revision surgery of their THA, whether they experienced pain of the THA using the visual analogue scale [16] (no pain = 0, worst pain = 100), and whether they were able to walk unaided. If patients were not able to attend the FU session, we used the information of the different PROMs. Patients who did not respond to the invitation for the FU appointment and did not return the PROMs were contacted by telephone and asked if they had revision surgery of their THA. Patients who died during the >10-year FU were reported, and the medical records were analyzed to determine if revision surgery had been performed in our medical center. The general practitioner of the deceased patients and patients who could not be reached by repeated phone contacts was contacted, and inquiries were made on possible revision surgery in other medical centers. If the general practitioner had no patient-related information, patients were considered as lost to FU. Different survival analyses were carried out for the 2 different types of femoral implants, ABG-I and II, in combination with the cemented ABG-II AC.

Adverse Events

If an adverse event occurred during FU, it was classified as patient related (e.g. psychological problems), wound related (e.g. wound leakage, postoperative bleeding), surgery related (e.g. infection), or prosthesis related (e.g. dislocation, fracture, and loosening).

Physical Examination

Examination consisted of gait assessment, leg length discrepancy, lateral thigh pain on palpation, and range of motion.

Radiological evaluation

Anteroposterior and lateral radiographs were taken of the operated side(s). Radiographs were examined for periprosthetic osteolysis and radiolucency. A radiolucent line of >1 mm was considered relevant and described according the Gruen zones [17] for the femoral implant and the zones of Delee and Charnley [18] for the AC. Varus or valgus malpositioning of the femoral implant was assessed as well as cortical bone hypertrophy or resorption and whether the femoral stem was undersized. Polyethylene wear and linear head penetration of the insert were measured using Roman software [19]. All radiographs were examined performed by 3 observers (2 orthopaedic surgeons and 1 radiologist).

Statistical analysis

Statistical evaluation and analysis were performed using SPSS 21.0 software (IBM SPSS, Armonk, NY). Survivorship analysis using Kaplan-Meier was carried out with revision for any reason and revision for aseptic loosening as the endpoint. The 95% confidence intervals (95% CIs) were calculated and reported. Log-rank (Mantel-Cox) test was used to compare the statistical differences of the survival outcomes between both the ABG-I and II femoral implants. We considered p-values of ≤0.05 to be significant for all statistical analysis.

RESULTS

At a mean of 11.0-year FU, 146 patients (156 THAs, 48.3%) had died of unrelated causes. Seven patients (7 THAs, 2.2%) did not respond, and additional information could not be obtained. These patients were considered as patients lost to FU. The remaining cohort consisted of 155 patients (160 THAs, 49.5%) with a mean age of 85.3 years (range 66.8 – 101.1) at FU. Patient distribution is summarized in **Figure 1**.

Survivorship Analysis

At FU, six patients (6 THAs, 1.9%) had undergone revision surgery of the femoral implant and/or AC after a mean of 18 months (range, 1.0 – 40.4) after initial surgery. The main reason for revision surgery was aseptic loosening (0.6%) and infection (1.2%), resulting in a survival for any reason and aseptic loosening of, respectively, 98.1% (95% CI, 96.6 – 99.4) and 99.4% (95% CI, 98.5 – 100). In three patients both

the femoral implant and AC were revised, in two patients only the AC was revised; and in one patient the femoral implant was revised. Of the six patients who had undergone revision surgery, five patients were initially treated for primary osteoarthritis and one patient for a femoral fracture. Kaplan-Meier survival analysis with revision for any reason and aseptic loosening of either one or both of the cemented femoral implants are shown in **Figure 2 and 3**.

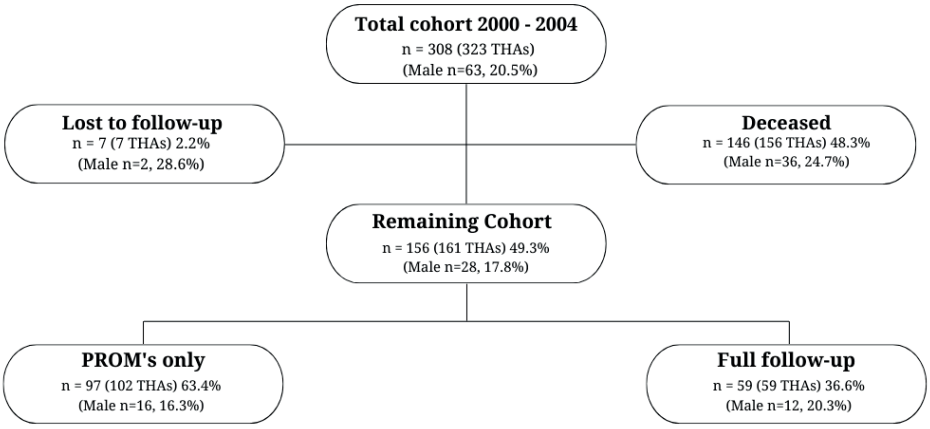

Figure 1 Patient distribution of the total cohort.

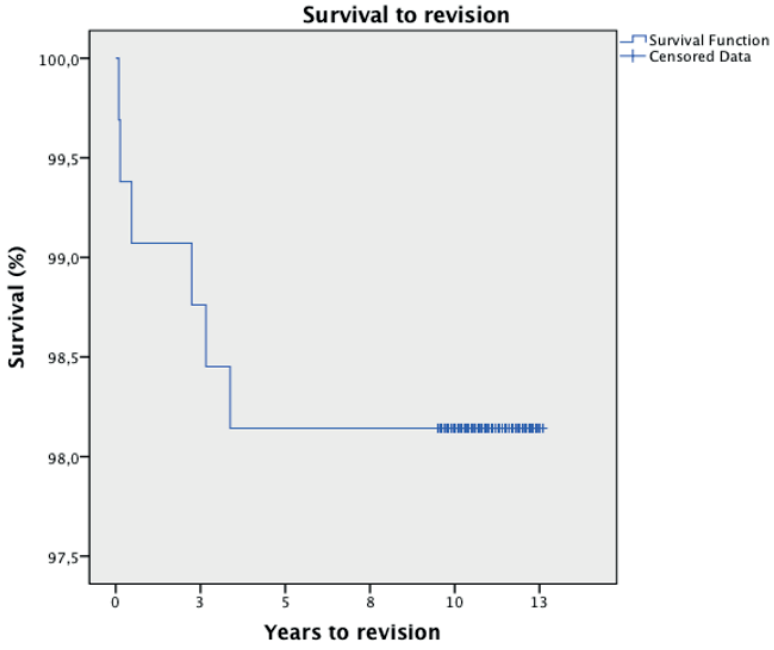

Figure 2 Kaplan-Meier survival curve of survival to revision for any reason, with a survival of 98.1% (96.6 – 99.4) after >10-year FU.

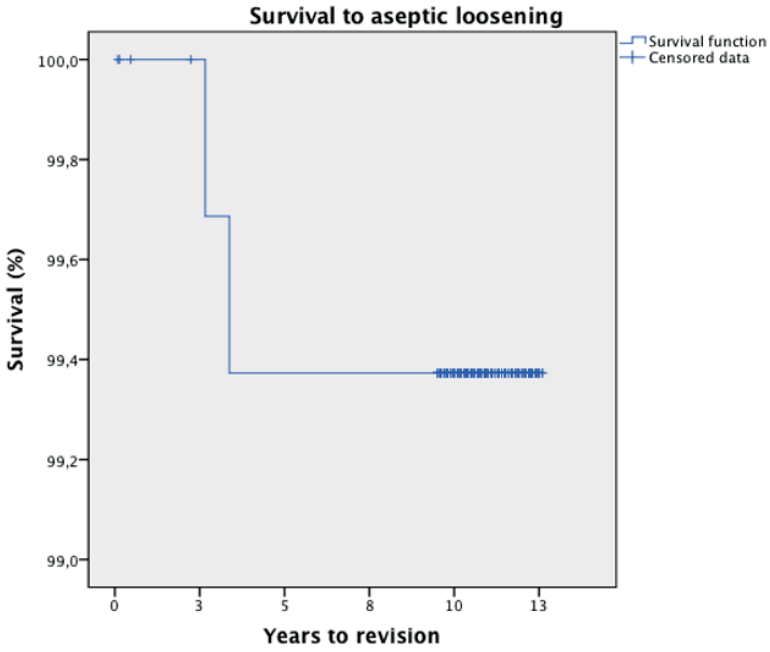

Figure 3 Kaplan-Meier survival curve of the survival to revision for aseptic loosening, with a survival of 99.4% (98.5 – 100) after >10-year FU.

There was no statistically significant difference in the survival rates of the ABG-I and II femoral implant (p=0.873, **Table 3**). In total, five AC were revised, resulting in a survival rate of 98.5% (95% CI, 96.9 – 99.7) for the cemented ABG-II AC. A worst-case scenario, in which all patients lost to FU were considered to have revision surgery of either the femoral implant or AC, would indicate a survival of 96.0% (95% CI, 93.8 – 97.8).

	N	*Revisions*	*Survival (95% CI)*
ABG-I Cemented	231	3	98.7% (97.4 – 100)
ABG-II Cemented	92	1	98.9% (96.7 – 100)
Overall	323	4	98.8% (97.5 – 99.7)

Table 3 Survival outcomes of the two types of femoral implants used in this cohort using Kaplan-Meier survival analysis.

In 48 patients (49 THAs, 15.2%) a postoperative complication occurred; these complications are summarized in **Table 4**. Two patients with a surgery-related adverse event had revision surgery of the femoral implant and AC because of a high-grade infection.

	ABG-I n= 231 (%)	*ABG-II n=92 (%)*	*Total n=323 (%)*
Patient related	1 (0.4)	0 (0)	1 (0.3)
Wound related	15 (6.5)	3 (3.2)	18 (5.6)
Surgery related	11 (4.8)	2 (2.2)	13 (4.0)
Prosthesis related	16 (6.9)	1 (1.1)	17 (5.3)
Total	43 (18.6)	6 (6.5)	49 (15.2)

Table 4 Adverse events during FU, differentiated between ABG-I and II femoral implant.

Radiographic results

Radiolucent lines of >1 mm was seen in 15 patients (15 THA, 25.4%) on the anteroposterior radiograph (**Table 5**). These radiolucent lines were mostly primarily located around the AC in DeLee and Charnley zones I, II and III (11 THAs, 18.6%) and at the distal end of the femoral implant in Gruen zone 4 (4 THAs, 6.8%). In two patients with severe radiolucent lines around the AC and without clinical complaints, a FU appointment after 0.5 and 1 year was made to evaluate these radiological findings. The mean PE wear and linear head penetration were, respectively, 0.56 mm (range, 0.0 – 2.3) and 1.6 mm (range, 0.0 – 6.1). There was no statistically significant difference in PE wear (p=0.814) between the ABG-I and II femoral implants (0.55 mm [range, 0.0 – 2.1] and 0.58 mm [range, 0.0 – 2.3], respectively). Nor was there a statistically significant difference in linear head penetration (p=0.914) between the ABG-I and II femoral implants (1.59 mm [range, 0.0 – 2.3] and 1.63 mm [range, 0.4 – 4.6], respectively).

	n (%)
Loosening	1 (1.7)
Radiolucent line	15 (25.4)
PE-wear >1mm	7 (11.9)

Table 5 Results of the radiological findings at >10-year FU.

Clinical results

Mean passive anteflexion in the hip joint was 104.6 degrees (80 – 130 degrees) at >10- year FU. Walking distance was unlimited in 50.8% of the patients, and pain was reported in 51.4% of the patients, with a visual analogue scale of 54.2 (0 – 100).

Patients who had revision surgery during the FU period were not clinically assessed. Results of 156 patients (161 THAs, 49.5%) were obtained (**Figure 2**). Patient-reported outcome measures were returned by 105 patients (107 THAs, 33.1%, **Table 6**). A further 51 patients were contacted by phone, assessing occurrence of revision surgery, without obtaining the PROMs.

	Mean (SD)
WOMAC Total Score	57.4 (25.8)
WOMAC Functional	57.9 (28.1)
WOMAC Pain	67.0 (27.4)
WOMAC Stiffness	54.1 (27.0)
Oxford Hip Score	32.0 (13.5)

Table 6 Results of the PROMs at >10-year FU.

DISCUSSION

The survival of both the anatomically adapted ABG-I and II THAs are investigated in other studies [8, 20, 21]. However, these studies focused solely on the cementless ABG-I or II THAs. We could not find studies in which the survival of the cemented version of the ABG-I and II THA is investigated. In our study we analyzed the >10 years survival of the cemented ABG-I and ABG-II THAs.

As a result of the high mean age of 85.3 years at FU, our study suffers from a substantial number of deceased patients: 146 patients (156 THAs, 48.3%). By contacting the general practitioners of the deceased patients, we received information about possible revision surgeries in the past or revision surgery in other medical centers. We believe that this makes the survival outcome reliable. Ninety-eight patients (103 THAs, 31.9%) were not able to attend the FU session because of age-related and financial reasons. By using PROMs and an overall questionnaire, clinical information of all these patients was obtained and the number of patients lost to FU is minimized (n=7, 2.2%). We believe that this results in valid survival rate. Even in a worst-case scenario, assuming that all patients considered as lost to FU had had a revision, the survival is 96.0% at >10-year FU. The reason not attending the FU session was mainly financially related. As this study had no financial support, a number of patients had to pay the costs of radiographic examination themselves and refused this.

The overall survival for the anatomically adapted cemented ABG-I and II in our study was good compared with that in other studies with different types of anatomically shaped cemented THAs [22, 23]. The survival for aseptic loosening in our study was also excellent. Both the survival for any reason and for aseptic loosening have fulfilled the benchmark, devised by Aamodt et al. [24], with a survival of >90% after >10-year FU. A notable result in the survival analysis is that 2 revisions took place in the first 2.5 years after initial surgery, both for revision for aseptic loosening, that is, revision at 29 and 41 months. Generally, aseptic loosening occurs in the majority after 5 years/60 months of FU because of a slowly progressive osteolysis. Therefore, the number of revisions for aseptic loosening is expected to increase with the years of FU [25]. Retrospectively, this contrasting finding is possibly explained by a steep angle (61.5 degrees) of the AC in 1 patient (revision at 29 months) and by an intertrochanteric osteotomy in the past in the other patient (revision at 41 months).

These good survival rates for the ABG-I and II cemented femoral implants might be due to the anatomical shape of the femoral implant with a higher "shoulder". Compared to the femoral implants with a straight design, anatomically shaped femoral implants lead to a better centralization and to an even thickness of the cement mantle, mainly in Gruen zones 8 and 9 [7]. Retrospectively, the survival rates of various types of cemented THA are analyzed with data from major hip registers like the Swedish Hip Arthroplasty Register, Danish Hip Arthroplasty Register, Norwegian Arthroplasty Register, and the Finnish Arthroplasty Register [3, 22]. The Swedish Hip Arthroplasty Register showed a 10-year survival rate of 94.6% of the cemented THAs for both anatomically adapted and straight implants [22]. Mäkelä et al. [23] analyzed and compared the databases of the Danish Hip Arthroplasty Register, Norwegian Arthroplasty Register and, Finnish Arthroplasty Register and reported a survival rate of 93.1%, 93.4% and 92.0%, respectively, after 10-year FU. Both the ABG-I and II cemented femoral implants outperform the other types of cemented THAs; however, the advanced age of our patients has to be taken into consideration. Hailer et al. [22] found that the survival rates of the cemented THAs in general outperform the cementless THAs. The cemented Charnley straight stem prostheses has been the best documented THA and has published clinical results of >20 years, with a clinical survival of >90% after 10-year FU [24]. Furthermore, compared to the Charnley prostheses, the overall survival of the ABG-I and II cemented femoral implants and ABG-II AC is good. In this study, we observed no statistically significant differences between the ABG-I and II femoral implants.

The adjustments of the ABG-I into the ABG-II in 1997 were mainly due to the unacceptable high failure rates of both the femoral implants and AC [9]. These complications of the femoral implant were observed in the cementless titanium version of the ABG-I THA. However, the cemented ABG-I was also replaced for the ABG-II THA. The AC of the cemented ABG-I, with high revision rates, excessive PE-wear and signs of AC osteolysis [26], have never been used in our institution. Overall, AC are revised more often compared to the femoral implants mainly because of PE wear and loosening. The survival of the cemented AC is superior to the cementless AC. Polyethylene wear is seen more frequently in cementless ACs [22]. In our study radiolucent lines around the AC components were seen in 10 THAs, and PE wear was seen in 7 THAs.

In summary, there is an acceptable overall survival, more than 95% after >10-year FU, for the cemented ABG-I and II femoral implants and ABG-II AC when revision and aseptic loosening are considered as endpoint. There were no statically significant differences in the 2 types of femoral implants. The anatomical shape of the ABG-I and II femoral implants might contribute to the good survival rates found in this study.

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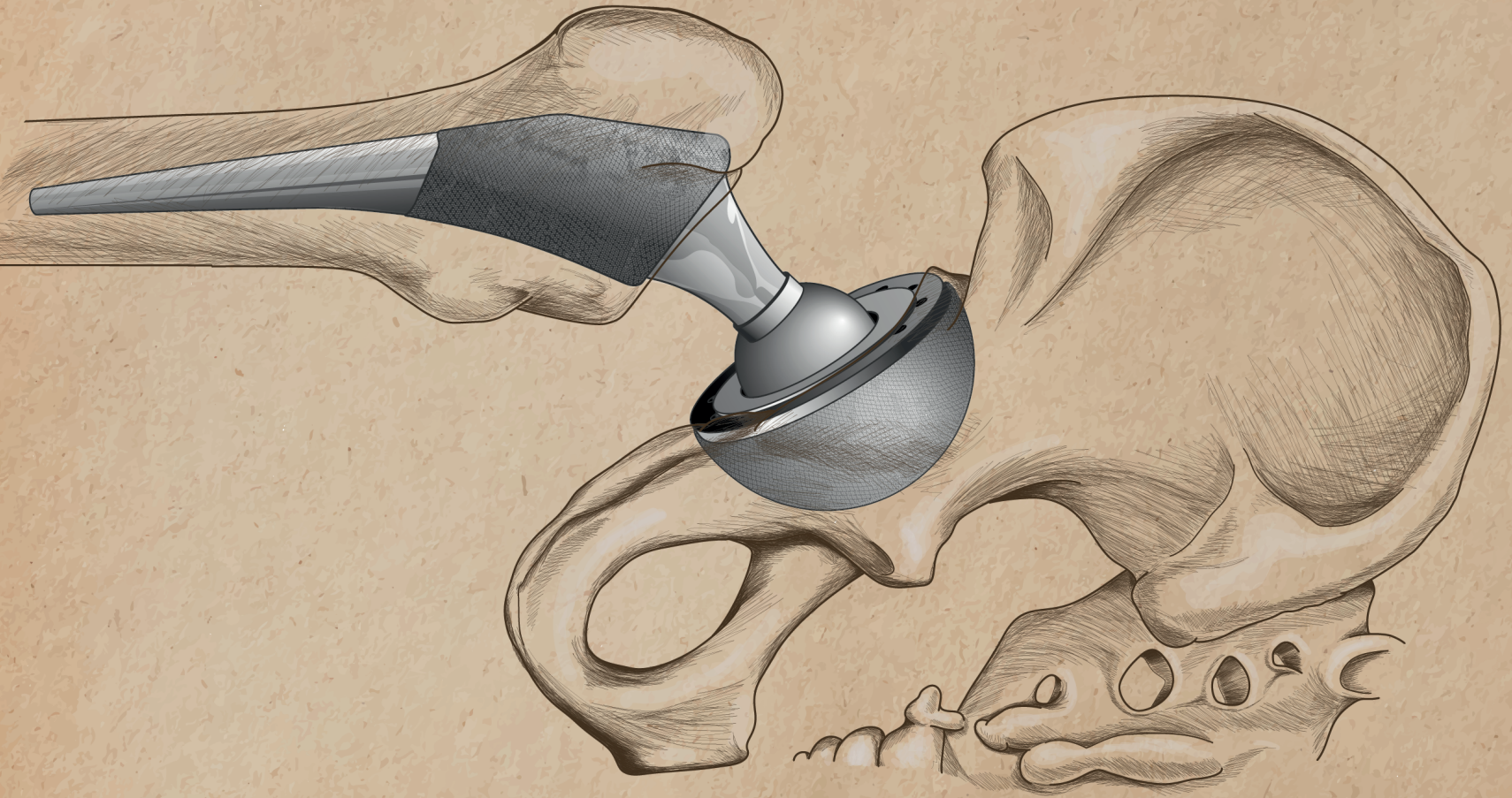

Chapter 5

Survival rates of anatomically shaped and tapered slip cemented femoral implants.

An analysis of 76,281 femoral implants of the Dutch arthroplasty register (LROI)

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HIP International. 2022 December doi: 10.1177/11207000221145150 PMID:36536533 Epub ahead of print

link to article

ABSTRACT

Introduction

In cemented total hip arthroplasty (THA) various shapes and geometries of femoral implants are in use. Collarless, polished, and tapered (CPT) implants, and anatomically shaped (AS) implants are most commonly used. Due to their different design features, this might lead to different survival outcomes. In this register-based study, the overall implant survival and short-term complications of CPT and AS cemented implants were evaluated.

Methods

Data of the Dutch Arthroplasty Register (LROI) were used. Cemented femoral implants, which could be classified as CPT or AS were included in this study. Implants were excluded when no classification could be made or if implanted <100 times. Survival analyses were performed using Kaplan-Meier survival analysis and multivariable Cox-proportional hazard analysis.

Results

76,281 cemented THAs were included. At a mean of 5.1-year follow-up (SD 3.1, range 0 - 12 years), the overall survival of the AS implants was higher compared with the CPT implants, with a survival, of 99.2% and 99.0% respectively (log-rank; $p<0.001$). Multivariable regression analysis revealed a higher rate for revision because of loosening of the AS implants (HR 2; CI, 1.4 – 3.1). AS implants had a lower rate for periprosthetic fractures compared with the CPT implants (HR 0.13; CI, 0.07 – 0.23).

Conclusion

Both designs show excellent overall survival rates at short-term follow-up. There is a higher overall survival of AS implants when compared with CPT implants. Revision for implant loosening, however, was statistically significantly higher in AS implants when compared with the CPT implants.

INTRODUCTION

There are various shapes and geometries of cemented femoral implants in total hip arthroplasty (THA), all with different philosophies [1, 2]. Depending on shape, geometry and function the implants can be divided into four groups [1]. Tapered slip implants, also referred to as collarless, polished and tapered (CPT), and the anatomically shaped (AS) implants, also referred to as composite beam or I-beam (**Figure 1**) are the most commonly used cemented implants [1]. Both cemented CPT implants and AS implants show excellent long-term survival outcomes [3, 4]. In AS implants the fixation is between the implant and cement, and also between the cement and the bone. The fixation between implant and cement can be obtained by a roughed surface and shape/geometry of the implant [5]. In the CPT implant, however, there is no direct fixation between the implant and the cement mantle [5]. A regulated and controlled subsidence in the cement mantle is the mechanism of femoral-locking. This locking-mechanism is mainly due to the axial load and thereby compression of the cement mantle (**Figure 1**). These different fixation mechanisms result in different bone reactions in the host bone [6]. A CPT implant can induce reaction forces in the interface of the implant and cement mantle compared with reaction forces between the cement mantle and the host bone in AS implants (**Figure 1**) [1, 7]. These differences in reaction forces, with compression forces on the cement mantle and host bone in the CPT implants and shear forces in the cement mantle around AS implants, might lead to different survival outcomes mainly because cement can withstand compression forces better than shear forces. The purpose of this national register-based study is to assess the survival and short-term complications of the AS implants compared with the CPT implants in cemented THAs. We hypothesise that the CPT implants would outperform the AS implants in survival for loosening.

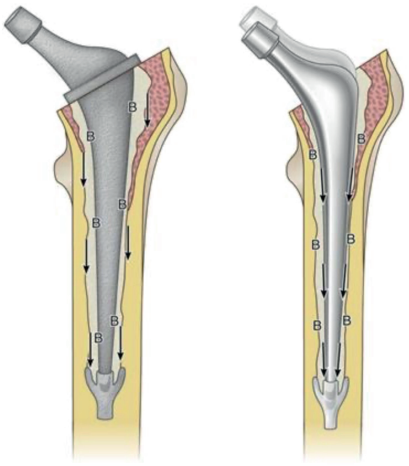

Figure 1. AS femoral implant left and CPT right. Shear forces are transmitted directly to the cement (B) and bone interface in the AS femoral implants. In the CPT femoral implants, the shear forces are transmitted to the stem-cement interface.

PATIENTS AND METHODS

Data sources

Data were collected from the Dutch Arthroplasty Register (LROI). The Netherlands Orthopaedic Association (NOV) founded the LROI in 2007. The LROI register contains the data of the primary and revision THAs performed in the Netherlands including information on procedure, patient and prosthesis characteristics. The completeness has been verified up to >99% for the primary THAs and 97% for the hip revision surgery [8, 9]. Revision surgery is defined in the LROI register as any intervention in which prosthetic components were removed, exchanged or added. To verify if patients are deceased, the patient's data in the LROI is matched with the national insurance database on healthcare [9]. In 2014 body mass index (BMI), Charnley classification and smoking habits were added to the patient's characteristics [10].

Data selection

For this study we selected all cemented primary THAs implanted between January 2007 and December 2018. Data on revision surgery, including time to and reason for revision of the femoral implants, were collected. All femoral implants, registered in the LROI were divided into CPT or AS using the classification described by Huiskes et al. [11]. Three researchers, two orthopaedic surgeons and an orthopaedic registrar (IH, EvH, LH), independently classified the implants. In case there was a difference in the classification, it was discussed until consensus was reached. Inclusion criteria were a cemented CPT or AS implant and above 50 or under 100 years of age at initial surgery. Exclusion criteria were implants unable to be classified as CPT or AS, implants used less than 100 times, cementless femoral implants, fracture as initial diagnosis, or incomplete data on patient characteristics (e.g. sex, age, type of surgical approach) in the LROI register. The four most used cemented implants of each group (CPT or AS) were included. THAs with a metal-on-metal (MoM) articulation were excluded from this study, because of the discussion of adverse reactions to metal debris in MoM articulations. The primary comparison of this study was CPT versus AS femoral implants. The implants were also analyzed separately. Cases of revision procedures without a femoral implant revision and periprosthetic fractures treated with osteosynthesis (without implant revision) or non-surgically were not included in the study.

Statistics

Statistical evaluation and analysis were performed using SPSS software for Windows version 26.0 (IBM, SPSS, Armonk, NY). Kaplan-Meier survival analysis was performed to examine the survival probability of the patients over time with revision of the implant, death of the patient or the end of the study follow-up (31 December 2018) as endpoint. To analyse the differences between the overall survival outcomes of the different implants a log-rank (Mantel-Cox) test was used. A multivariable Cox-proportional hazard analysis was performed to examine the effect of implant design (CPT or AS) on revision of the femoral implant. Specific demographic variables like age, sex, ASA (American Society of Anaesthesiologists) classification, initial diagnosis, BMI, smoking habit, surgical approach, Charnley classification and type of bearing were included as covariates. The Hazard ratios (HRs) and the 95% confidence intervals (CIs) were calculated and reported. The reasons for revision surgery were compared between the CPT and AS and a

HR was calculated. A log-minus-log (LML) test was used to evaluate the assumption of the proportional hazards. We considered p-values ≤0.05 to be statistically significant for all statistical analyses.

Ethics

For the current study no ethical approval is required since all the data in the LROI are collected in the context to improving quality of care.

RESULTS

Between January 2007 and December 2018, 91,369 cemented femoral implants were registered in the LROI register that could be classified as CPT or AS. Consensus regarding classification was reached for all implants. 4,010 implants were excluded because of insufficient data about sex, age, type of approach, diagnosis, ASA classification, or the number of implants were less than 100. 1,546 implants were excluded because of the age of the patient at initial surgery of <50 years. 4,453 implants were excluded because of a fracture as initial diagnosis. The 4 most used cemented implants of each group were included, the rest (*n*=5,079, 5,6%) were not included in the analyses. The remaining 76,281 implants were included. More AS implants (*n*=60,655, 79.5%) than CPT implants (*n*=15,626, 20.5%) were included. The baseline characteristics of the CPT implants and AS implants are summarized in **Table 1**. A hybrid fixation technique, a cemented femoral implant and cementless acetabular component, was performed in 11,510 (15.1%) cases. The 2 most used bearing types were the metal on cross-linked-polyethylene (XLPE) and ceramic on XLPE in respectively 32,067 (42%) and 27,091 (35.5%) cases. The number and distribution of the implants, by manufacturer, are summarized in **Table 2**.

Revisions

At a mean follow-up of 5.1 years (range 0 – 12 years), 9,872 (12.9%) patients were deceased. There were 161 (1%) femoral implant revisions in the CPT implants compared with 455 (0.8%) implant revisions in the AS implants, with an overall survival rate of 99.0% (CI, 98.9 – 99.1) and 99.2% (CI, 99.1 – 99.3) for CPT and AS respectively. Results of the Kaplan-Meier survival analyses are summarized in **Figure 2**. There was a statically significant difference in the overall survival outcomes between the CPT and AS implants (log-rank; p= <0.001). The LML test showed that the different lines of the covariates were parallel, and the proportional hazards assumption was well met. Multivariable Cox regression analysis revealed a lower revision rate (HR 0.7; CI, 0.5 – 0.9) of the AS implants compared with the CPT implants when adjusted for known confounders (sex, age, ASA classification, initial diagnosis, surgical approach and previous surgery on the affected hip). The hazard rates were consistent after adjusting also for smoking habit, Charnley classification and BMI as confounders, the confounders were added to the LROI database in 2014. In general, male patients had a statistically significantly lower hazard rate for overall revision surgery of the femoral implant (HR 0.5; CI, 0.4 – 0.6). Patients with hip dysplasia as initial diagnosis had a lower hazard rate for overall revision of the femoral implant (HR 0.5; CI, 0.3 – 0.7). The overall survival outcomes of the different types of implants separately, at a mean follow up time of 5.1 years, are summarized in **Table 3**.

	CPT n=15,626	*AS n=60,655*	*p-value*
Mean age at operation (SD)	74 (8.4)	75 (7.3)	<0.001[1]
Mean follow-up time (SD)	5.1 (3.1)	5.1 (3.1)	0.9[1]
Female n.	11,136 (71)	44,998 (74)	<0.001*
Deceased at FU n.	1,829 (12)	8,043 (13)	<0.001*
BMI n.			
Morbid obesity >40	139 (0.5)	382 (0.6)	<0.001*
Obesity 30-40	2,021 (13)	7,045 (11)	
Being overweight 25-30	3,701 (24)	13,498 (22)	
Normal weight 18.5-25	2,940 (19)	10,970 (19)	
Underweight <18.5	107 (0.5)	321 (0.4)	
Not registered	6,718 (43)	28,439 (47)	
Charnley Classification n.			
A	3,581 (23)	12,879 (21)	<0.001*
B1	2,361 (15)	8,624 (14)	
B2	1,878 (12)	7,200 (12)	
C	206 (1)	1,084 (2)	
Not registered	7,600 (49)	30,868 (51)	
ASA Classification, n.			
ASA 1	1,590 (10)	8,349 (14)	<0.001*
ASA 2	10,308 (66)	40,027 (66)	
ASA 3 & 4	3,728 (24)	12,279 (20)	
Diagnosis, n.			
Osteoarthritis	13,879 (89)	55,456 (91)	<0.001*
Dysplasia	235 (2)	449 (1)	
Osteonecrosis	502 (3)	1,739 (3)	
Late post traumatic	555 (4)	1,838 (3)	
Other	455 (2)	1,173 (2)	
Approach, n.			
Anterior	248 (2)	5,152 (8)	<0.001*
Anterolateral	331 (2)	3,712 (8)	
Direct lateral	2,402 (16)	10,902 (18)	
Posterolateral	12,636 (81)	40,539 (65)	
Trochanter osteotomy	3	9	
Other	6	341(0.5)	

Table 1. Baseline patient characteristics and indicators after THA in the period 2007 – 2018.
Values are count (%) unless otherwise specified. * is *p*-value calculated with a Pearson-Chi square test, [1] is *p*-value calculated with a Student's t-test.

CPT	*n.*	*AS*	*n.*
Exeter (Stryker)	13,570 (87)	Lubinus SPII (Link)	26,793 (44)
Taperloc (ZimmerBiomet)	779 (5)	Müller (OHST)	14,590 (24)
Twinsys stem (Mathys)	702 (4)	Stanmore (ZimmerBiomet)	9,722 (16)
C-stem AMT (Johnson&Johnson)	575 (4)	Spectron EF (Smith&Nephew)	9,550 (16)

Table 2. Classification and distribution of the femoral implants. Values are count (%).

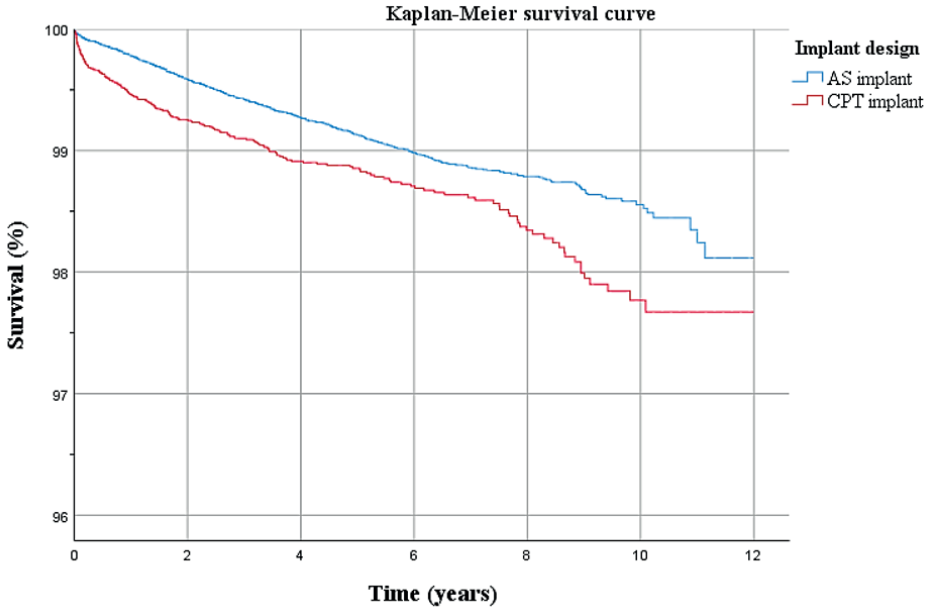

Figure 2. Kaplan-Meier survival curves of the AS (n=60,655) and CPT (n=15,626) implants in the Netherlands 2007 – 2018. There was a statistically significant higher survival of AS implants *p*= <0.001 (Log-rank, Mantel-Cox).

Femoral implant	*Survival (CI)*	*Mean follow-up time in years (SD)*
C-stem AMT (Johnson&Johnson)	99.8% (98.8 – 99.9)	1.4 (0.9)
Twinsys stem (Mathys)	99.4% (98.7 – 99.9)	4.0 (2.5)
Taperloc (ZimmerBiomet)	99.0% (98.3 – 99.5)	3.4 (2.5)
Exeter (Stryker)	98.9% (98.6 – 99.0)	5.3 (3.1)
Lubinus SPII (Link)	99.3% (99.2 – 99.4)	5.0 (3.1)
Muller (OHST)	99.5% (99.4 – 99.6)	4.5 (3.1)
Spectron EF (Smith&Nephew)	98.9% (98.7 – 99.1)	5.9 (3.0)
Stanmore (ZimmerBiomet)	99.2% (99.0 – 99.3)	5.6 (3.1)

Table 3. Survival outcomes of all different brands of femoral implants.

Reason for revision

Loosening of the implant, periprosthetic fracture, and dislocation were the most reported reasons for revision of the implants. There was statistically significantly more loosening of AS implants (HR 2; CI, 1.4 – 3) compared with CPT implants. The survival for loosening of the femoral implant was 99.6% and 99.8% for the AS and CPT implants respectively. A statistically significantly lower rate of periprosthetic fractures was observed in AS implants (HR 0.1; CI, 0.07 – 0.2) compared to CPT implants. The mean time to revision of the femoral implant because of a periprosthetic fracture, in the group of revised femoral implants, was 4 (range 0 – 11; SD 3.3) and 3.6 years (range 0 – 10; SD 3.2) for AS and CPT implants respectively. If these periprosthetic fractures were not included in the survival analysis the survival of the CPT (99.2%) and AS (99.3%) was not statistically significant different (log-rank $p = 0.6$). The survival for infection was 99.7% for both CPT and AS implants. The survival for dislocation was 99.9% and 99.8% for AS and CPT implants respectively. In the revisions due to dislocation, a posterolateral approach was used at initial surgery in 69% and 90% of the revisions for AS and CPT implants respectively. Other reasons for revision, between CPT and AS implants, are summarized in **Table 4**.

	AS n=60,655	*CPT n=15,626*	*Hazard Ratio (95 CI)*
Infection, n.	148	50	0.9 (0.6 – 1.2)
Fracture, n.	17	41	0.1 (0.07 – 0.2)
Dislocation, n.	35	32	0.4 (0.2 – 0.6)
Loosening femoral implant, n.	221	30	2 (1.4 – 3)
Other reasons, n.	38	15	0.7 (0.4 – 1.4)

Table 4. Reasons for revision surgery of the femoral implants. One patient may have more than one reason for revision, as such the total proportion is over 100%. HR were adjusted for implant design, type of surgical approach, ASA classification, smoking and gender.

DISCUSSION

In this national register-based study, with 76,281 primary cemented THAs, we assessed the short-term (mean 5.1 years) survival rates of two types of cemented femoral implants; CPT and AS implants. The main result of this study is a statistically significant difference in the overall survival in favor of AS implants also when adjusted for known confounders (HR 0.7; CI, 0.6 – 0.8). The CPT implants outperformed the AS implants on survival because of revision for (aseptic) loosening of the implant.

Loosening of cemented femoral implants have multi-factorial causes [12, 13]. The most commonly proposed theory for (aseptic) loosening is the development of excess wear particles which induces an inflammatory state. This might result in osteolysis and eventually in (aseptic) loosening of the implant [14]. Cement viscosity and modern cementation techniques, as pressurizing the cement and use of pulse lavage, have an influence on (aseptic) loosening. These factors, however, are not assessed in this study.

Other factors influencing the survival rates of (aseptic) loosening like the type of bearing, fixation, and implant design have been assessed in this study.

In a retrieval study of Howell et al. the surface finish was found to be one of the main factors in the mechanism of implant longevity and function; and thereby the survival of the implant [15]. In contrast to the AS implants, the CPT implants are designed to subside over time and give compression to the cement mantle. AS implants are designed to be fixed to the cement, resulting in shear forces in the cement-bone interface [6]. In the study of Howell et al. and the radiostereometric analysis (RSA) study of Alfaro-Adrian et al. it was claimed that CPT implants showed higher survival rates [6, 15]. In the present study, we found a statistically significant difference in the overall survival in favor for the AS implants. Nevertheless, this difference was only for the overall survival and not solely for the loosening. Loosening of the CPT implants was also less commonly observed in other recent register-based studies [2, 16]. Hoskins et al. reported lower revision rates of the CPT implants in a national register-based study of 96,315 THAs at 14-year follow-up [16]. The reason for revision because of aseptic loosening in the CPT implants was 20% of all revisions reported. In matt finish implants, like the AS implants, this percentage of revision because of aseptic loosening was 75% of the revisions reported [16]. Hoskins et al. concluded that CPT implants outperform the AS implants, mainly because of these (aseptic) loosening's, and the AS implants becoming an issue over time with regards to long-term survival [16]. Kazi et al. found, in a national register-based study of 292,987 THAs, an increased incidence of revision of AS implants compared with the CPT implants in a similar register-based study design [2]. The results found in the study of Kazi et al. are in contrast to the ones presented in this study, as we found higher overall revision rates for the CPT implants compared with the AS implants [2]. This difference might be explained by differences in the patient characteristics and distribution of the different types of implants. The higher overall revision rate for the CPT implants is mainly because of the periprosthetic fractures in the CPT implants. Revisions because of periprosthetic fractures in the CPT implants is a factor that influenced the significance of the overall survival between the AS and CPT implants (Log-rank p=0.6). Other different studies assessing the revision rates of the CPT implants reported a higher rate of periprosthetic fractures in CPT implants when compared to AS implants [5, 17-20]. The subsidence mechanism of the CPT implants induces hoop stresses to the cement mantle into the host bone which can act as a wedge, fracturing the femur during a fall [5, 21]. Also, in the national register-based study of Kristensen et al., with 20,532 primary cemented bipolar hemiarthroplasties, more periprosthetic fractures were observed in CPT implants [18].

Strengths and limitations

The strength of this national register-based study is the high number of implants included in this study (n=76,281). Also, the high completeness number of the LROI register, with a percentage of completeness of more than >95%, is a strength of this study [8].

There are also some limitations of the study that should be discussed. The biggest limitation of this study is the short-term follow-up of 5.1 years. This short-term follow-up could affect the results of the number of

(aseptic) loosening and periprosthetic fractures in the CPT and AS implants. Aseptic loosening is a process developing over time and is a late complication [13]. BMI, Charnley classification and smoking habits were not documented in the LROI register till 2014. These known confounders could not be adjusted for patients before 2014, although residual confounding will always be present in a register study. The differences in the femoral implants, all with different characteristics and features, can also be addressed as a limitation. Some data was not collected in the register, like perioperative fractures treated with osteosynthesis without implant revision, or periprosthetic fractures (Vancouver A and B) treated conservatively. Because of the lack of registration of this specific data in the LROI register, only conclusions can be drawn on revisions with exchange of implants, which are registered in the LROI register with a high number of completeness [8]. In literature it is known that a large part of the fractures mainly around the AS implants, are treated without exchange of the implant [22]. The AS implant is fixated onto the cement mantle, as described in the introduction, and the implant is not loose or not recognized as a loose implant, so implant revision for periprosthetic fractures is lower [23].

CONCLUSION

There is an excellent survival for both the CPT and AS implants at short-term follow-up (5.1 years). Nevertheless, there is a lower revision rate for the AS implants for all cause revisions, also when adjusted for known confounders at short-term follow-up. A lower revision rate for (aseptic) loosening was observed in the CPT implants; however, with a higher rate of periprosthetic fractures in these types of implants. Future research with long-term follow-up results is necessary to clarify the differences in long-term survival between the CPT and AS implants.

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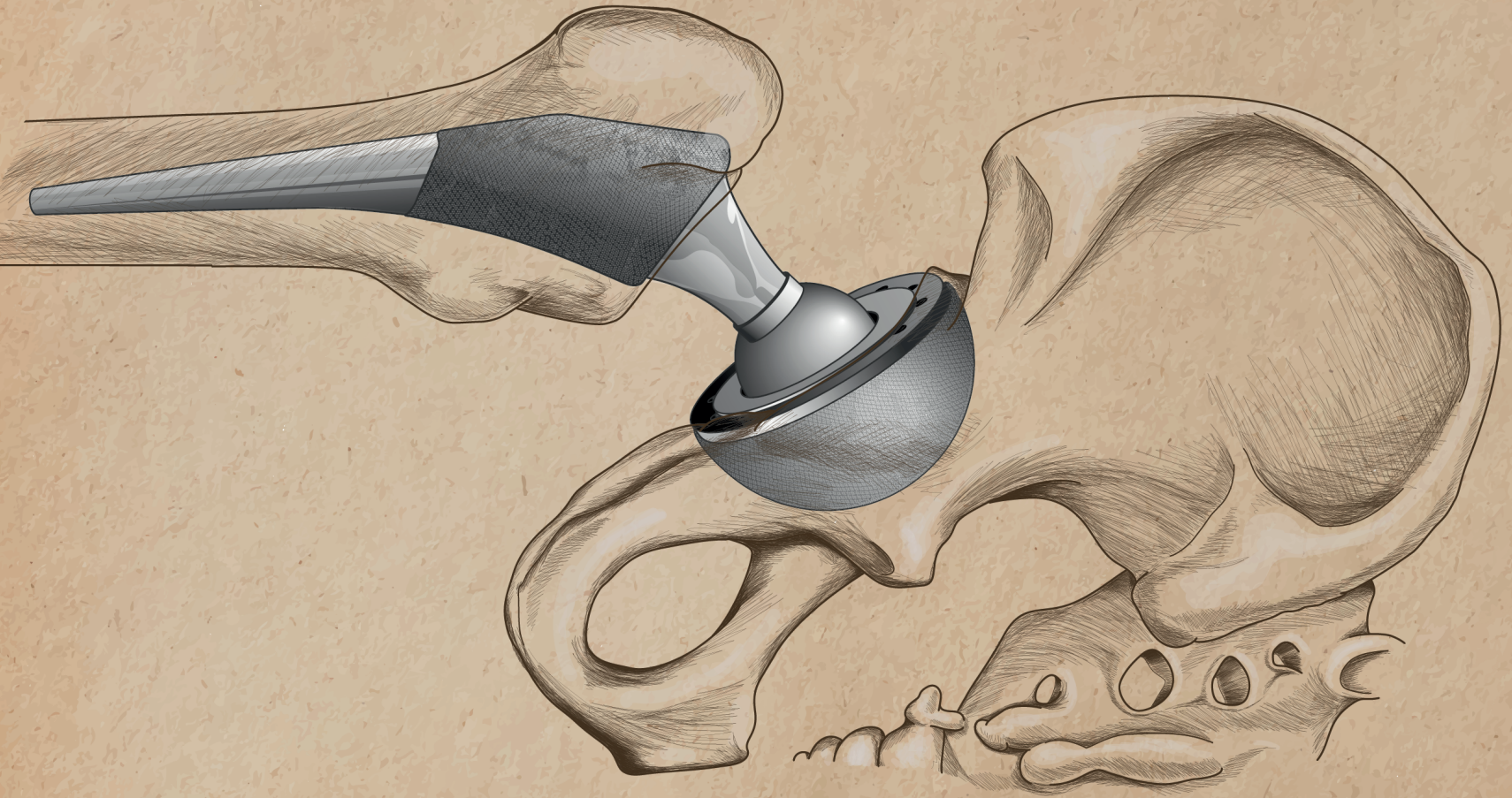

Chapter 6

Disappointing long-term outcome of total hip arthroplasties with Carbon-Fiber-Reinforced Poly-Ether-Ether-Ketone (CFR-PEEK) as acetabular insert liner.

A prospective study with a mean follow-up of 14.3 years.

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Hip International. 2021 Nov; 31(6):735-742. doi: 10.1177/1120700020918157. PMID: 32340489.

link to article

ABSTRACT

Introduction

Insert liner wear of the acetabular component is one of the predictive values for survival of Total Hip Arthroplasties (THAs). This prospective single-centre study was designed to evaluate the follow-up of carbon-fiber-reinforced poly-ether-ether-ketone (CFR-PEEK) insert liner used as bearing in cementless THAs.

Methods

Twenty-nine healthy patients with an indication for cementless THA were selected for a CFR-PEEK insert liner and followed over time. All patients received a cementless THA with a CFR-PEEK insert liner used as bearing. At different follow-up moments patients were routinely examined and were analyzed using the Oxford Hip Score (OHS), the modified Merle d'Aubigne-Postel (MAP) score, and radiologically. At the follow-up moments the plain radiographics were assessed for loosening, cyst formations and wear of the CFR-PEEK liners.

Results

At a mean of 14.3-year follow-up four revisions of the acetabular component were performed, resulting in a survival rate of 86.5% (CI 95%, 72.4–96.6). A statistically significant difference in OHS and MAP scores between pre- and postoperative follow-up moments was observed. The acetabular components of the remaining patients showed no radiological abnormalities at 14.3-year follow-up. The overall CFR-PEEK wear was low, with a mean of 0.81 (0.2–1.4) mm wear at 14.3-year follow-up.

Conclusion

In this series we found an aseptic loosening with unclear reasons in four well-positioned acetabular components, hence we do not recommend routine use of CFR-PEEK insert liners as bearing in cementless THAs. All the remaining THAs and acetabular components were ***in situ*** without abnormalities at 14.3-year follow-up.

INTRODUCTION

Liner wear of the acetabular component is thought to be one of the predictive factors in the overall survival of total hip arthroplasties (THAs) [1, 2]. Ultra-high molecular weight polyethylene (UHMWPE) and cross-linked UHMWPE are currently the most used insert liners in THA. UHMWPE, however, is vulnerable to long-term wear and release of polyethylene (PE) particles. These PE particles activate macrophages, releasing cytokines and inducing a higher osteoclastic activity, which results in bone absorption, osteolysis and eventually in aseptic loosening of the cup and femoral implant [1]. This may lead to revision surgery of the acetabular component and/or femoral implant. However, marked liner wear is not always associated with osteolysis [2]. Recognition of the biological response initiated by the wear of UHMWPE has led to a renewed interest in discovering new bearing materials, with less response. One of the materials has been carbon-fiber-reinforced poly-ether-ether-ketone (CFR-PEEK). CFR-PEEK is considered to have a low wear rate. It is composed of a tough polymer matrix (PEEK) with reinforced carbon fibres (CF). Clinical use of this material in orthopaedic surgery as bearing for arthroplasties has been low since the 1990s as CFR-PEEK *in vivo* survival rates have not been clarified [3-5]. However, laboratory *ex vivo* studies are promising and show excellent wear resistance of CFR-PEEK [6]. Because of these studies, even in the era of cross-linked polyethylene, it was felt that CFR-PEEK might be an alternative as liner in THAs; however long-term *in vivo* survival analyses have never been published. The primary aim of this prospective study was to identify the potential benefit and the overall long-term survival rates of CFR-PEEK liners used in primary cementless THAs, and to evaluate the radiological and clinical results over time.

PATIENTS AND METHODS

Study Design

A prospective longitudinal study design was used to evaluate the CFR-PEEK liner used as bearing in THAs. The local ethical committee approved the study protocol (IRB no. 14-N-03).

Patients

Twenty-nine patients with indication for primary THA were enrolled, without randomisation or a comparison group, and were followed prospectively. Informed consent for the study was obtained prior to all operations. All patients were informed about the study and they all received a cementless THA with a CFR-PEEK acetabular insert liner. The inclusion criteria were primary osteoarthritis, secondary osteoarthritis due to congenital hip dysplasia, good physical condition (ASA 1 or 2) and under the age of 70 years at the time of operation. Exclusion criteria were previous surgery of the affected hip. The patients had elective primary total hip surgery between July 2002 and July 2003. All patients were clinically and radiologically evaluated prior to the study entry in order to obtain baseline information. The clinical results were assessed with the Oxford Hip Score (OHS) the modified Merle d'Aubigne-Postel (MAP) score [7-10]. Preoperative radiographic evaluation involved assessing bone quality, loss of joint space and cyst

and/or osteophyte formation on standard plain radiographs. Primary aims for surgery were pain relief and improvement of function of the affected hip joint. Initial diagnosis for THA was primary osteoarthritis in 27 patients (93.1%) and secondary osteoarthritis due to congenital hip dysplasia in two patients (6.9%). Patient characteristics and operative data are summarised in **Table 1**.

	N=29
Mean age at operation (range)	55.43 years (40.1–66.4)
Mean follow-up time (range)	14.3 years (13.4–15.4)
Left, n. (%)	13 (44.8)
Male, n. (%)	15 (51.7)
Mean BMI at operation (range)	27.2 (20.5–38.5)
Comorbidities, n. (%)	
Cardiovascular	3 (10.3)
Respiratory disease	1 (3.4)
Preoperative Charnley Classification, n. (%)	
A	22 (75.9)
B	7 (24.1)
Type of anaesthesia, n. (%)	
General	2 (6.9)
Spinal	26 (89.7)
Epidural	1 (3.4)
ASA, n. (%)	
1	24 (82.8)
2+	5 (17.2)
Mean operation time in mins. (range)	71.6 (50–120)
Mean blood loss in cc. (range)	659.3 (200–2100)
Mean time of hospitalisation in days (range)	6.3 (5–9)
Mean acetabular component size (range)	54 (50–58)
Femoral bone quality during surgery, n. (%)	
Normal	26 (89.7)
Mild osteoporosis	1 (3.4)
Mild sclerosis	1 (3.4)
Severe sclerosis	1 (3.4)
Acetabular bone quality during surgery, n. (%)	
Normal	23 (79.3)
Mild osteoporosis	2 (6.9)
Mild sclerosis	4 (13.8)

Table 1. Patient characteristics and operative data, including bone quality observed by the consultant orthopaedic surgeons during surgery.

Implants

The cementless Anatomic Benoist Girard (ABG)-II THA (Stryker, Herouville Saint Clair, France) was used in all patients. This cementless ABG-II THA is an anatomically-shaped femoral implant with a hydroxyapatite-(HA) coating on the proximal third of the femoral implant designed for proximal fixation [11, 12]. The ABG-II acetabular component is fully coated with HA to obtain fixation into the cancellous bone. Spikes were used for fixations of the acetabular component in 20 patients (68.9%). The femoral implant and the acetabular component are both made of titanium alloy. The ABG-II THA was introduced and developed in 1997 as an improved cementless anatomically THA of the ABG-I [13]. In all patients, the CFR-PEEK insert liner with PEEK locking ring was placed in the acetabular component and articulated with an aluminium oxide ceramic (Al_2O_3) 28-mm head.

CFR-PEEK liner

CFR-PEEK is composed of a tough polymer matrix (PEEK) with reinforced carbon fibres (CF) [3-5]. PEEK is synthesised from hydroquinone and 4.4-difluorbenzophenon to form a high-performance thermoplastic [3]. Carbon fibre is added to the PEEK to obtain more tensile strength and better wear properties [14]. CFR-PEEK has been used since the late 1990s for spinal and orthopaedic implants, but not as insert liner in THAs [4].

Surgical Procedure

Three experienced orthopaedic surgeons, each of whom performs more than 100 THAs per year, performed all operations for this study. During surgery a straight lateral approach (n=20, 69.0%), a posterolateral approach (n=7, 24.1%) and an anterolateral approach (n=2, 6.9%) were used. All patients received identical antibiotic prophylaxis (cefazolin two grams) prior to surgery. Operative details are summarised in **Table 1**. All orthopaedic surgeons aimed for a cup inclination position of 45° and 20° anteversion position and a femoral implant anteversion of 10 - 15 degrees, taking into account the local anatomical landmarks of the specific patient. All patients with the exception of one were allowed full weight-bearing the day after surgery. That one patient required bone grafting of an acetabular defect using bone obtained by the reaming process. Subcutaneous low molecular-weight heparin was administered daily to all patients until six weeks after surgery.

Evaluation

Clinical and radiological follow-up were obtained before surgery and at 6-12 weeks, 1 year, 2 years, 5 years, 11.9 years and 14.3 years after initial surgery. At the follow-up sessions the Oxford Hip Score (OHS), the modified Merle d'Aubige-Postel (MAP) score and an x-ray were obtained. Hip joint mobility was also examined and inquiries about pain experience of patients' THA were made. At the 6-12 weeks follow-up the OHS was not obtained. Both the OHS and MAP scores are patient-reported outcome measures (PROMs) specific for THA; the OHS can be scored 12–60 (best score = 12, worst score = 60) and the modified MAP score 3–18 (best score = 18, worst score = 3). Radiological evaluation consisted of an anteroposterior and a lateral radiograph of the affected site. The Gruen zones of the femoral implant and

the DeLee and Charnley zones of the acetabular component were examined for radiolucent lines (more than 1mm), bone reabsorption, cancellous densification, cortical thickening, inclination angle and cyst formation, and were compared with previously taken radiographs [15, 16]. Insert liner wear was measured and annual insert liner wear calculated using Roman software [17]. Roman software is designed for accurate wear measures on 2D radiography. Two different observers examined all the radiographs.

Statistical analysis

Statistical evaluation and analysis were performed using SPSS 21.0 software (IBM, SPSS, Armonk, NY, USA). A survival analysis was carried out using Kaplan-Meier with revision for aseptic loosening as endpoint. A general linear mixed model (GLMM) analysis was used for repeated measurements during the follow-up [18]. This analysis can deal with missing values over time (i.e. death or revision). The 95% confidence intervals (95% CIs) were calculated and reported. We considered p-values ≤ 0.05 to be significant for all statistical analyses.

RESULTS

At last follow-up (range 13.4–15.4 years) two patients (6.9%) had died of unrelated causes. These patients died 8.92 and 9.25 years after initial surgery with asymptomatic hips. All but one of the remaining patients of the cohort completed every follow-up session. This patient was unable to attend the last follow-up due to financial reasons. Through telephone consultation this patient confirmed that the THA was asymptomatic at 13.7 years after initial surgery. The OHS of this patient was returned by mail. As information was obtained from all patients, there were no patients considered lost to follow-up. **Table 2** summarises the number of patients at each follow-up moment. Two patients had a direct postoperative complication: a wound leakage and a general medical problem. Both postoperative complications were managed conservatively and had no influence on the overall rehabilitation.

	6-12 weeks	*1 year*	*2 years*	*5 years*	*11.9 years*	*14.3 years*
Number of hips (%)	29 (100)	29 (100)	29 (100)	28 (96.5)	25 (86.2)	25 (86.2)
Deceased (%)	0 (0)	0 (0)	0 (0)	0 (0)	2 (6.9)	2 (6.9)
Rx (%)	29 (100)	29 (100)	29 (100)	28 (96.5)	24 (82.8)	24 (82.8)
PROMs (%)	29 (100)	29 (100)	29 (100)	28 (96.5)	25 (86.2)	25 (86.2)

Table 2. Number of patients at each follow-up session.

Survivorship Analysis

During follow-up four patients had undergone revision surgery for aseptic loosening of the acetabular component. Revision surgery took place at 5.25, 6.75, 13.4 and 15.4 years after initial surgery. Primary osteoarthritis was the initial diagnosis for these patients and the acetabular component had additional

spike fixation in two cases. These patients complained of hip pain, and a bone scintigraphy showed increased uptake of the acetabular component. During revision surgery the acetabular components were loose with a blackish mild reactive joint fluid. Also, black colouring of the capsule was found in all cases, and in two cases, a revision at 6.75 years and 15.4 years, a quite extensive pseudotumour formation was seen (**Figure 1**). No signs of infection was seen on the acetabular bone or the surrounding soft tissue. Multiple cultures showed no growth of micro-organisms in any of the patients. The retrieved acetabular components were analyzed, and the synovial fluid and acetabular interface showed increased reactive fibrosis with a mild nonspecific inflammatory reaction, mainly macrophage activity with some hemosiderin pigmentation. No giant-cell activity was observed. Also, signs of metallosis were seen with blackish CFR-PEEK particles (**Figure 2**). No signs of excessive wear of the CFR-PEEK insert or of impingement on the retrieved acetabular components were seen (**Figure 3**). Kaplan-Meier survival analysis with revision for aseptic loosening as endpoint showed a survival of the CFR-PEEK insert liner of 86.5% (95% CI, 72.4-96.6) after a mean of 14.3-year follow-up. All cementless femoral implants were *in situ* and stable at last follow-up, resulting in a survival rate of 100%.

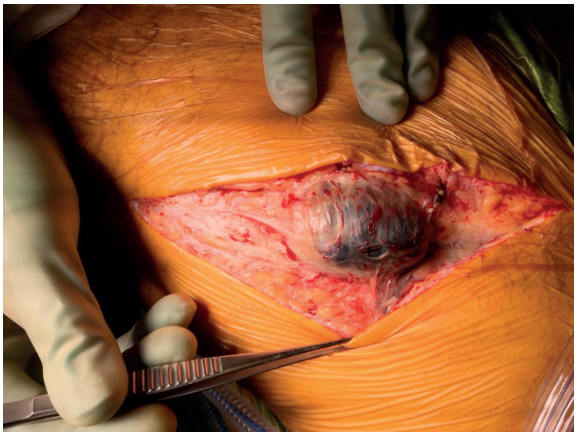

Figure 1. Black-coloured pseudotumour during revision surgery, there were no signs of bacterial growth.

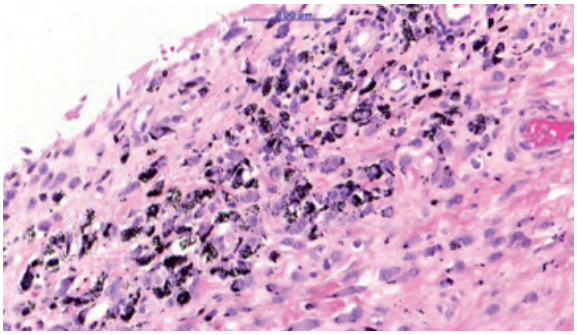

Figure 2. Histopathological examination, HE stain magnification 20x, where CFR-PEEK particles could be found in macrophages. No giant-cell incorporation could be found.

Figure 3. A retrieved AC that showed no signs of excessive wear. The damage of the locking ring occurred by revision surgery.

Clinical results

The MAP score and OHS were routinely obtained at every follow-up session (**Figures 4 and 5**). Both scores showed a statistically significant improvement up to 2 years after initial surgery (GLMM, $p<0.001$). After 2-year follow-up there was a slight decrease in MAP scores, although they remained unchanged with 14.27, 14.96 and 15.2 ($p<0.001$) at respectively 5-year, 11.9-year and 14.3-year follow-up. The OHS also showed a slight reduction after 2-year follow-up, although progressively over time 21.06, 23.74 and 23.09 at respectively 5-year, 11.9-year and 14.3-year follow-up. Still, there was no statistically significant difference ($p=0.214$ and $p=0.690$) at 11.9-year and 14.3-year follow-up. Mean hip joint mobility in flexion showed improvement after surgery from 93.5° preoperatively to 118.6° at final follow-up. Twenty-eight patients (96.5%) complained about pain preoperatively. At 6-12 weeks, 1 year and 2 years follow-up 3 patients (10.3%) complained of pain, at 5-year follow-up 5 patients (17.9%) did, and at 11.9-year follow-up and at final follow-up eight patients (32%) complained of slight pain in their operated hip.

Radiological results

Radiological data were obtained at every follow-up moment. Direct postoperative radiographs showed well-positioned acetabular components with a mean inclination angle and anteversion angle of respectively 40.2° and 19.6°. At the final follow-up there was a statistically significant increase in wear and annual wear of the CFR-PEEK insert (**Table 3**). The overall annual wear at 14.3-year follow-up was 0.056mm/year. The mean wear rate of the four revised acetabular cups was 0.7mm (0.2 – 1.5) with a wear angle of 66.1 degrees (36 – 88.2 degrees). Radiological changes of the acetabular component during follow-up are summarised in **Table 4**. In two patients with a revision of the acetabular component because of aseptic loosening a radiolucent line in the DeLee and Charnley zone I and a small cyst formation were observed 2 years prior to revision surgery with no other symptoms (**Figure 6**). Radiological

Figure 4. Mean and range of the modified Merle d'Aubige-Postel (MAP) score over time. There was a statistically significant difference (GLMM, p<0.05) between all outcomes over time.

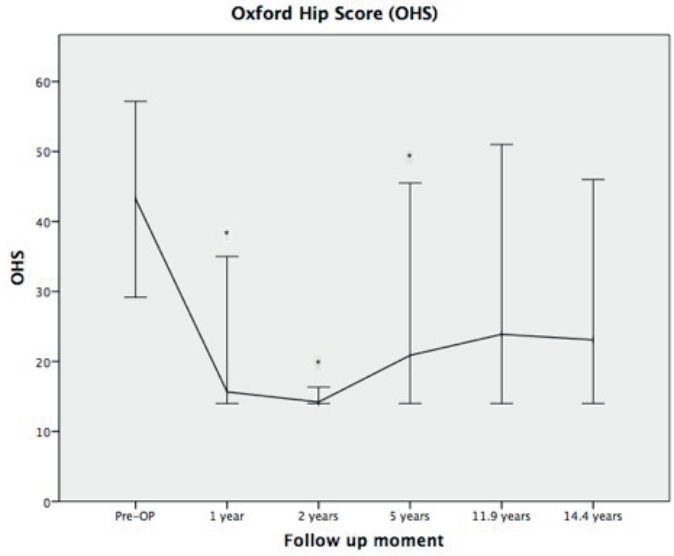

Figure 5. Mean and range of the Oxford Hip Score (OHS) over time. There was a statistically significant difference (GLMM, p<0.05) between the outcomes marked with an asterisk.

changes of the femoral implant are summarised in **Table 5**. All remaining femoral implants and acetabular components were stable at final follow-up. Multiple radiological changes could be found in the same patient (**Tables 4 and 5**).

	1 year	*2 years*	*5 years*	*11.9 years*	*14.3 years*
Wear in mm. (range)	0.38 (0–1)	0.5 (0–1.2)*	0.58 (0.1–1.2)*	0.7 (0.2–1.4)*	0.81 (0.2–1.4)*
Annual wear in mm. (range)	0.38 (0–1)	0.11 (0–0.6)	0.02 (0–0.17)	0.02 (0–0.1)*	0.07 (0–0.7)*
Inclination angle (range)	44.93 (15–70)	46.70 (28–70)	45.96 (25–70)	47.92 (37–70)	47.32 (38–68)

Table 3. CFR-PEEK insert liner wear over time and annual wear in mm. The asterisk indicates that there was a statistically significant difference (GLMM, p<0.05).

	1 year	*2 years*	*5 years*	*11.9 years*	*14.3 years*
Radiolucent line (%)	0 (0)	2 (6.9)	0 (0)	0 (0)	1 (4.5)
Bone reabsorption (%)	6 (20.7)	1 (3.4)	2 (7.1)	0 (0)	0 (0)
Cyst formation (%)	0 (0)	2 (6.9)	2 (7.1)	2 (8)	2 (8)
Brooker I (%)	2 (6.9)	2 (6.9)	2 (7.1)	2 (8)	2 (8)

Table 4. Radiographic results of the acetabular component over time, most affecting DeLee and Charnley zones II and III.

	1 year	*2 years*	*5 years*	*11.9 years*	*14.3 years*
Radiolucent line (%)	2 (6.9)	4 (13.8)	4 (14.3)	5 (20)	4 (18.2)
Bone reabsorption (%)	8 (27.6)	1 (3.4)	2 (7.1)	2 (8)	3 (13.6)
Cancellous densification (%)	3 (10.4)	4 (13.8)	5 (17.8)	7 (28)	7 (31.8)
Cortical thickening (%)	1 (3.4)	3 (10.4)	5 (17.8)	5 (20)	9 (40.1)

Table 5. Radiographic results of the femoral implant over time, most affecting Gruen zones 1 and 7.

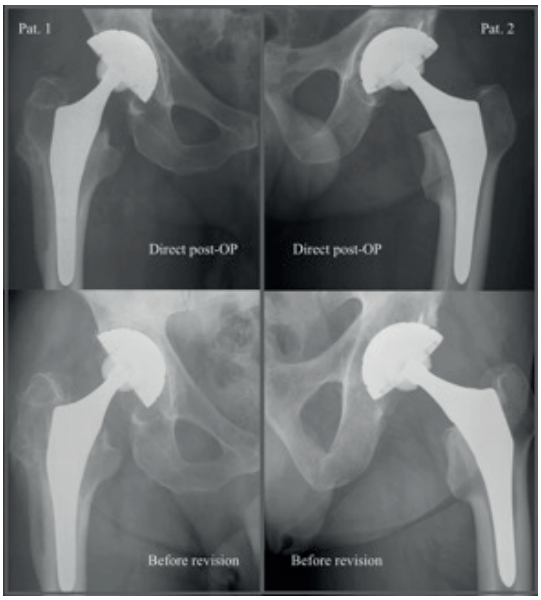

Figure 6. Radiological changes of 2 retrieved acetabular components, direct postoperative X-ray compared with the last X-ray before revision surgery.

DISCUSSION

This is the first manuscript of CFR-PEEK being used *in vivo* as bearing in THAs with a long-term follow-up of 29 patients over a period with a mean time of 14.3 years. The most important finding of this study is that there were four revisions of the acetabular component because of aseptic loosening, although low CFR-PEEK wear was measured. In retrospect, there were no radiological abnormalities that could have predicted these aseptic loosenings. Only a small radiolucent line (1–3 mm) was observed on the acetabular side, but no complaints of pain or reduction in outcome of the PROMs were reported at the last attended follow-up. At the revision surgery there were multiple black-coloured pseudotumours with no signs of excessive liner wear (Figure A and C). There were no signs of infection or bacterial growth. All the retrieved acetabular components showed mild inflammatory reaction on the outer side of the acetabular shell, and no signs of infection, excessive wear, retroacetabular wear or impingement were observed. The blackish colour of the joint fluid we observed at revision surgery is investigated in a study by Paulus et al. [19]. They analyzed the joint fluid of total knee revisions with a CFR-PEEK and UHMWPE component and found a different scatter behaviour of CFR-PEEK in human joint fluid compared with UHMWPE. No giant-cell incorporation of CFR-PEEK, which is very common in UHMWPE, was observed either. They concluded that because of the different scatter behaviour a different type of cytokine expression of CFR-PEEK arises which needs further specific investigation. The four revisions due to aseptic loosening in this study would suggest a possible adverse tissue reaction that could result in osteolysis and eventually in revision because of aseptic loosening of the acetabular component. *In vitro* studies focusing on the reliability, cytotoxicity and safety of CFR-PEEK report promising outcomes. Katzer and Devine [3] showed in an *in vitro* study that there is no evidence of mutagenic or cytotoxic activity of CFR-PEEK particles in the human body. Besides, CFR-PEEK has a good biocompatibility and there are no *in vitro* indications of cytotoxic effects [20].

Tissue necrosis cytotoxic effects are absent *in vitro* [6]. The wear particles of CFR-PEEK are in the phagocytosable size range (0.1–10 μm), yet the literature is inconsistent and focuses on the inflammatory cytokine release produced in reaction of the presence of CFR-PEEK [21]. Increased inflammatory reaction of CFR-PEEK particles is seen when injected in mice, although such a reaction is comparable with that of UHMWPE wear particles, as presented by Utzschneider et al. [22]. They concluded that CFR-PEEK represents a safe alternative as insert liner material because of its superior mechanical and stable chemical behaviour.

In the light of these studies, it is remarkable that we found quite extensive pseudo-tumour formation in two revision cases in our series; however mechanically assisted crevice corrosion of the taper of the femoral component cannot be ruled out in this study. Nevertheless, at revision surgery no signs of corrosion of the taper of the femoral component were found.

With the four revisions the overall survival rate for the CFR-PEEK insert liner was 86.5% after a mean of 14.3-year follow-up. The same cementless acetabular component (ABG-II) with UHMWPE in combination with a cementless anatomically adapted femoral implant showed excellent long-term survival rates of up to 98.3% after 11.0 years [12]. Compared with these results, the survival rate of the acetabular component combined with CFR-PEEK insert is disappointing. However, the wear rates of the CFR-PEEK inserts (0.056 mm/year) were lower than those of the UHMWPE (0.093 mm/year) [12]. A cementless flexible horseshoe-shaped acetabular component made of CFR-PEEK with a CFR-PEEK insert liner as bearing showed a survival rate of 96% in a prospective 3-year follow-up study (n=25 patients) by Field et al. [23], yet radiologically three acetabular components were not stable at the 3-year follow-up. Revision of the acetabular component because of aseptic loosening was necessary, resulting in a survival rate of 88% at 4-year follow-up. There is a difference between our study and that of Field et al. [23]: they used an open backside MITCH PCR acetabular component of CFR-PEEK combined with cemented or cementless femoral implants. In our study a standard closed cementless titanium acetabular component was used, combined with standard cementless hydroxyapatite femoral implants. This combination has a proven excellent long-term survival rate combined with conventional UHMWPE [12].

The wear of the CFR-PEEK insert liner was measured at every follow-up session. A peak in annual wear (0.38mm/year) was found in the first year. After the first year of follow-up the annual wear dropped and remained steady. The high mean wear rates in the first year after initial surgery (0.38mm/year) could be explained by the approximated tolerance band of the CFR-PEEK combined with a 28-mm aluminium oxide ceramic head of 0.1 - 0.35 mm and an approximated radial tolerance band of 0.05 - 0.175 mm (Stryker, Herouville Saint Clair, France). However, in ***ex vivo*** studies CFR-PEEK showed high creep resistance [4]. Friction studies on CFR-PEEK show low wear rates [24-28], yet friction rates of CFR-PEEK are significantly higher than those of UHMWPE bearings [29]. Differences in wear rates were observed between CFR-PEEK and cross-linked UHMWPE [25], with wear rates of CFR-PEEK in the same range as metal-on-metal articulations without the cytotoxic effects [25]. Wear rates of CFR-PEEK are dependent on the circumstances in which the material is used. Wang et al. [27] concluded that CFR-PEEK can be optimally used in a ball-socket joint (i.e. the hip joint) but not in a high-stress non-conforming contact situation (i.e. the knee joint).

This study has limitations. The major limitation of this prospective study is the absence of a comparison group with conventional PE used as acetabular insert liner. The study design was a prospective control study and not as a randomized control trial study. Also, the small sample size, three different surgeons and three different surgical approaches of this study is a major limitation; however, this study is the first of CFR-PEEK used ***in situ*** in THA. One patient was unable to attend the last follow-up due to financial reasons. We obtained information by telephone consultation, including PROMs, and this patient had no complaints of the THA, but radiological results were not obtained. All patients were contacted and no patients were considered lost to follow-up. The use of Roman software to measure the CFR-PEEK is a limitation of this study. Roman software is the most accurate method for measuring liner wear on plain

radiographies, yet it is vulnerable to measurement failures. Another limitation of this study might be that only a cementless THA was used in all patients. Conclusions can be drawn only on the combination of CFR-PEEK and cementless femoral implants.

In conclusion, we found a survival rate of 86.5% for the CFR-PEEK acetabular insert liner used as bearing in cementless THA after a mean of 14.3-year follow-up. The reason for aseptic loosening of these well-positioned acetabular components is unclear. Aside from the unexplained loosening of acetabular components, we observed low CFR-PEEK wear and satisfactory PROMs outcomes. Considering the acetabular component revisions for unexplained loosening, we do not recommend the use of CFR-PEEK insert liner as a bearing in cementless total hip arthroplasty. Despite the successful performance in ***ex vivo*** studies there was no successful performance of CFR-PEEK in this ***in vivo*** study. We recommend further investigation of inflammatory reactions to CFR-PEEK particles in the human body.

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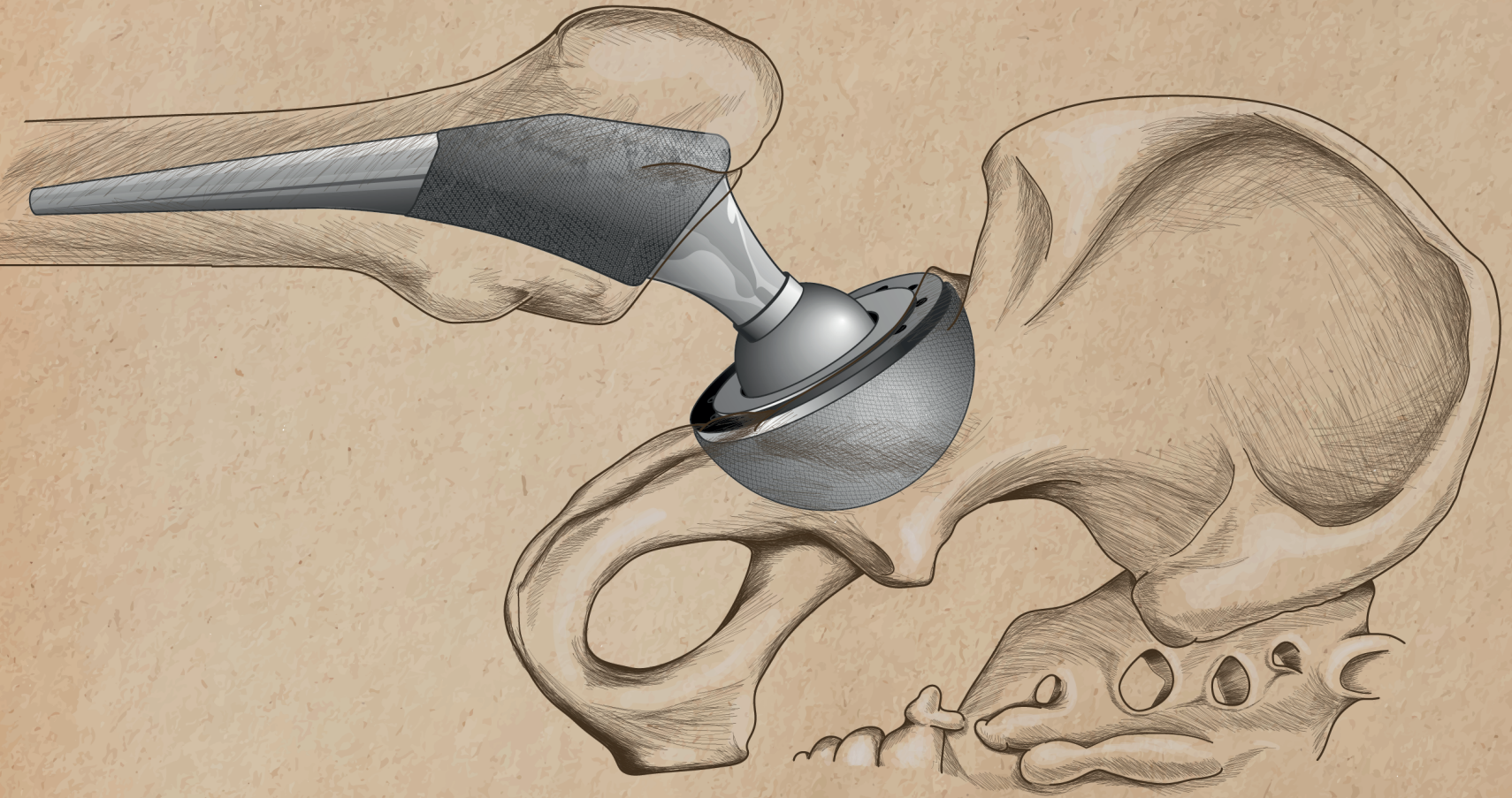

Chapter 7

General Discussion, what have we learned?

GENERAL DISCUSSION, WHAT HAVE WE LEARNED?

This thesis focused on increasingly important aspects of innovations in design, geometry and materials in total hip arthroplasty (THA) surgery. In this final chapter, the main findings and limitations of the previous chapters are discussed, and general conclusions and recommendations as well as directions for future research are provided.

In the field of orthopaedic surgery, but also in health-care in general, there is a constant rapid development and search for innovations and improvements. In THA surgery these developments are mainly focused on optimizing clinical, radiological, and functional outcomes. In recent years there were lots of innovations in the THA surgery, however not all innovations have led to an improvement of patientcare [1].

Implant long-term survival is multifactorial and multidimensional, and can be divided into three aetiological subgroups; patient, surgeon, and implant related [2]. In the patient related group, the age of the patient, initial diagnosis, body mass index and level of activity are factors that might influence the functional and clinical outcomes of the THA. The experience of the orthopaedic surgeon, his/her preferences and expertise, surgical approach and protocol used, and other surgical factors are important for clinical, functional and radiological outcomes of the THA. Factors that are mainly determined by the orthopaedic surgeon are the surgical technique and patient selection. The final subgroup concerning the implant characteristics is depending on type of fixation (cemented/cementless), bearing surfaces, modularity of the implant, head size, type of materials used, and implant design. The emphasis of this thesis is on this final subgroup. However, is should be kept in mind that implant survival is multifactorial and multidimensional.

Long-term clinical outcomes can only be obtained after more than ten-year follow-up and with Radiostereometric Analysis (RSA) studies of the specific implants [3]. Therefore, orthopaedic surgeons have to learn from, sometimes devastating, clinical failures. In an attempt to reduce complications and revision rates, long-term follow-up criteria were formulated to classify the quality of THAs. The National Institute for Health and Clinical Excellence (NICE) in the United Kingdom reported the 10-year follow-up after different types of THAs. According to the NICE guidelines a THA can only be indicated for patients with end-stage osteo-arthritis (OA) of the hip joint if the implant has a revision rate (or projected rate) of 5% or less at 10-year follow-up [4]. Despite the fact that the NICE guidelines contain only peer-reviewed registry studies and lack actual registry reports, the NICE criteria were hegemonic for a long time in the field of THA surgery. In order to overcome the 10-year bench of the NICE guidelines the Orthopaedic Data Evaluation Panel (ODEP) started in 2002 to comply the methodological criteria and data before the 10-year bench of the implants. The ODEP agency is part of the National Health Service (NHS) and seeks to assess follow-up data for different primary THAs [5, 6]. In the ODEP rating, implants are rated in time of follow-up and their survival rates. Nevertheless, there is still the question; are the innovations in THA

surgery always just as effective as we think in advance, and what have we learned from the different types of implant designs, fixation methods and materials used in the past?

ANATOMICALLY FEMORAL IMPLANT DESIGN IN CEMENTLESS FIXATION

Research question:

- **What are the survival outcomes of anatomically shaped cementless femoral implants, with a proximal hydroxyapatite coating, in THA?**

In cementless femoral implants the primary fixation is achieved by a press-fit technique in which the femoral implant is press-fitted in the prepared femoral canal. Press-fit fixation will lead to secondary biological fixation (osseointegration) as explained in **Chapter 1**. Femoral implant design is of utmost importance for fixation of THA and survival rates. The design of the femoral implant dictates the contact sites to the cortical bone which determines the amount of biological fixation. This thesis focuses on the medium- and long-term clinical, radiological and functional outcomes of anatomically shaped cementless femoral implants. These femoral implants are curved in the anterior-posterior plane and have an anteversion of the neck similar to that of the average native proximal femur. It is postulated that anatomically adapted femoral implants might have less failures, osteolysis, and lower numbers of aseptic loosening. In **Chapter 2 and 3** different types of anatomically shaped cementless femoral implants are investigated. The implants all differ in design, materials used and geometry. The Optan anatomically shaped femoral implant, described in **Chapter 2**, showed a poor survival of 94% after only 5-year of follow-up. The main reason for revision surgery was aseptic loosening (3.2%), which is a long-term complication and should not be expected at a 5-year follow-up period. We concluded that the early aseptic loosening of the Optan femoral implants could be caused by a non-physiological loading pattern which might be caused by the implant design. The Anatomic Benoist Girard (ABG) I and II cementless femoral implant, described in **Chapter 3**, showed an excellent survival at a mean of 11.3-year of follow-up. The reason for revision surgery was mainly a periprosthetic fracture. After 11.3-year follow-up survival for aseptic loosening was 100% for the ABG-II femoral implants and 98.3% for the ABG-I femoral implants which is an excellent result. The ABG-II femoral implant had a reduction of the total length and a bulkier proximal part compared with the ABG-I. These features facilitate the proximal press-fit and reduce distal ingrowth. In distal in-growing cementless femoral implants stress shielding might occur. When femoral implants have primarily distal fixation the weightbearing stress is transmitted less in the proximal femur, and bone resorption might occur in the proximal femur. Stress shielding in distally fixated femoral implants is mainly seen in the first 5 years after implantation and can result in periprosthetic fractures or loosening at longer follow-up time. A pedestal formation, as sign of distal fixation and/or proximal loosening, was seen in the Optan femoral implants and was not observed in the ABG-I and II femoral implants. As shown in the results of **Chapter 2 and 3,** a different type of geometry can influence the survival of the THA.

The first generations of the anatomically adapted cementless femoral implants performed poorly mainly because of the undesired distal ingrowth [7, 8]. Main complaints were a high prevalence of mid-thigh pain and loosening of the femoral implants. Modifications to the proximal and lateral metaphyseal portions were made. Widened proximal portion for a sufficient fit and fill of the proximal femur led to a better primary press-fit fixation and in extend to an optimal secondary biological fixation. The results in **Chapter 3** illustrate that these small modifications can lead to a higher survival of the femoral implants. For example, a mismatch of the femoral implant and the femoral bone, as seen in **Chapter 2**, can result in an unstable primary press-fit fixation and lower medium- and long-term survival rates [9]. In this manner the expected osseointegration (secondary biological fixation after the primary mechanical fixation) is not optimal [9]. A solid proximal fit and close contact of the femoral implant to the cortical bone is of utmost importance for the fixation in the anatomically shaped cementless femoral implants. However, not only design and geometry of femoral implants are responsible for the fixation, as explained earlier it remains a multifactorial issue. Stiffness, biocompatibility, surface roughness and the modulus of elasticity are important features to obtain fixation of the cementless femoral implants. Titanium, to which bone reacts and create a fixation between the implant and bone, can lead to pure osseointegration [10, 11]. Titanium can withstand large mechanical stress and with an excellent biocompatibility a pure osseointegration between the interface of the implant and bone can be realized. All femoral implants discussed in **Chapter 2 and 3** are made out of a titanium alloy.

What have we learned from the cementless anatomical femoral implants?

We can conclude that small changes in the implant geometry and in the surface can influence fixation and survival of the cementless anatomically adapted femoral implants on the long-term follow-up. Optimal proximal ingrowth of femoral implants seems to be paramount in the anatomically adapted femoral implants as described in this thesis. Insufficient proximal ingrowth can lead to higher revisions rates due to stress shielding and aseptic loosening, as described in **Chapter 2**.

FEMORAL IMPLANT DESIGN IN CEMENTED FIXATION

Research questions:

- **What are the survival outcomes of anatomically shaped femoral implants when cemented in THA?**

- **Is there a difference in survival outcome and reason for revision between cemented anatomically shaped and cemented collarless, polished, tapered femoral implants in THA?**

A cemented femoral fixation in THA is the golden standard in hip replacement surgery [12]. Despite this, the number of implanted cemented femoral implants is slowly declining in the last years while the cementless fixation is performed more frequently in the Netherlands. Still, approximately 25% of all the THAs performed in the Netherlands is a cemented fixation [13]. Age, medical history, bone quality, type/geometry of the femoral implant, and preference of the orthopaedic surgeon are all factors to choose for a cemented or cementless fixation[14, 15]. There are different mechanisms of fixation in cemented femoral implants, the forced closed and shaped closed fixation. In the shaped closed femoral implants, there is fixation between the implant and the cement, and between the cement and the bone. The fixation between implant and cement can be obtained by a roughed surface and the geometry of the implant. In the forced closed femoral implants, there is no direct fixation between the implant and the cement mantle. A regulated and controlled subsidence in the cement mantle is the mechanism of femoral locking. This locking-mechanism is mainly due to axial load resulting in compression of the cement mantle. These different fixation mechanisms result in different bone reactions in the host bone. A shaped closed femoral implant can induce reaction forces in the interface between the implant and cement and between the cement and the bone based on the fixation between the cement and the implant and between the cement and the bone. In forced closed implants there is no fixation between the cement and the implant. Reaction forces are mainly based on the fixation between the cement mantle and host bone. The differences between compression forces in the cement mantle and host bone in the forced closed implants and shear forces in the cement mantle around shaped closed implants might lead to different survival outcomes. Cement can withstand compression forces better than shear forces. In **Chapter 4 and 5** the results of cemented femoral implants with a forced closed and shaped closed fixation were described. Anatomically shaped femoral implants, with a shaped closed fixation, showed an excellent long-term follow-up of 98.1% at more than 10 years (**Chapter 4**). Revisions were mainly performed because of infection and aseptic loosening of the cemented femoral implants. Collarless, tapered slip cemented femoral implants, with a forced closed fixation, showed also an excellent medium-term survival of 99.0% after 5.1-year follow-up (**Chapter 5**). Revisions were mainly because of early periprosthetic fractures and (aseptic) loosening of the cemented femoral implants. The shaped closed femoral implants had higher overall survival rates, however they had statistically significant higher rates of revisions because of (aseptic) loosening when compared to the forced closed femoral implants. In

recent studies (aseptic) loosening was seen more frequently in the shaped closed when compared to the forced closed femoral implants [16, 17]. Loosening in cemented femoral implants, is a multifactorial event with different causes like design, cementing technique, surface roughness, type of bearing and stiffness of the implant. In an RSA study and a retrieval study (aseptic) loosening was observed more frequently in the shaped closed cemented femoral implants [18, 19]. This is in line with our findings. The reason for a higher number of (aseptic) loosening's of the shaped closed cemented femoral implants is thought to be the mechanism of fixation. In the shaped closed femoral implants, it is essential that a cement mantle with an even thickness is established to create a solid fixation between the stem-cement interface and also between the interface of the cement and cortical bone [20]. This type of fixation, with an even cement mantle, is described as a paramount factor for the survival outcomes of the ABG-I and II femoral implants, as explained in **Chapter 4**. In contrast to the shaped closed femoral implants, the forced closed femoral implants, with a taper, seems to be the best and reliable mechanism to transmit the axial and torsional forces between the implant and the cement mantle to the bone. Forced closed femoral implants with the ability to subside, needs to be polished, and cannot have a collar, which can prevent subsiding. Forces generated during this subsidence do not damaging the fixation in the bone-cement interface, which is observed in the shaped closed femoral implants, with transmission of forces to the cement bone interface. Hoop stresses arise around the forced closed femoral implants during the subsidence process, and produce a residual hoop strain in the cement mantle, which lead to an even more compression type fixation. Hoop stresses and residual hoop strain, however, can lead to a higher chance of periprosthetic fractures when axial loading on the femoral implant becomes too high. In this thesis we observed more periprosthetic fractures in the forced closed femoral implants compared to the shaped closed femoral implants, which is confirmed by literature [21, 22].

What have we learned from the different designs in cemented femoral implants?

We can conclude that both the forced closed and shaped closed cemented femoral implants are capable producing successful medium- and long-term implant survival rates, despite the different types of force transmission. However, an even and solid cement mantle thickness seems to be an important factor in the fixation of the shaped closed femoral implants and seems to be of lesser concern in the forced closed femoral implants.

CFR-PEEK USED AS INSERT BEARING IN THA

Research question:

- **Is CFR-PEEK a safe and effective material to use as insert liner in cementless THA in patients with end stage OA?**

The bearing of the THA is the key component of the THA, like the engine in a car. Without a sufficient and reliable bearing the survival rates and clinical outcomes of the THA will decline tremendously. In 5% of the THAs failure of the articulating surfaces or articulating materials will occur over time, resulting in osteolysis and eventually revision surgery [12, 23]. Cross-linked polyethylene (XLPE) seems to have very low wear rates which makes wear of a XLPE bearing probably an historically problem. Long-term follow-up studies will provide the answer on this question [24]. Nevertheless, even in the era of these (potentially) reliable XLPE in combined with a ceramic or metal head, the search for innovations remained. In **Chapter 6** we described the results of a prospective study with patients with a cementless THA in which a carbon-fiber-reinforced poly-ether-ether-ketone (CFR-PEEK) bearing was used. High revision rates were found, up to 86.5% at 14.3-year follow-up, and during revision surgery pseudotumor formation was found in a couple of cases. CFR-PEEK used as insert bearing in THA is not recommended because of these high revision rates despite the promising *ex-vivo* studies published prior the start of this prospective cohort study [25, 26]. CFR-PEEK is not used on a large scale as bearing in THA, however it is used in a couple of cases as bearing in total knee arthroplasty (TKA) [26]. In the TKA CFR-PEEK showed good results with low wear rates and successful biomechanical results [27, 28]. However, Wang et al. concluded, in an *ex-vivo* study, that CFR-PEEK could also be optimally used in a ball-socket joint (i.e. the hip joint) but not in a high-stress non-conforming contact situation (i.e. the knee joint) [29]. Despite these results in this *ex-vivo* study, we found a high number of revisions of the acetabular components in **Chapter 6**. The reason for this high percentage of revisions is unclear, however the pseudotumor formations found at revision surgery suggest a biological response which could induce osteolysis and loosening. Despite the successful performance in *ex-vivo* situations there was no successful performance of CFR-PEEK in this *in-vivo* study. CFR-PEEK was not the only material with an expected low wear rate, which might be an alternative for XLPE. Metal-on-metal (MoM) bearings, for example, showed low wear rates, even lower than metal on PE, and were reintroduced in the late 1990s and early 2000s [30]. Adverse local tissue reactions of the MoM bearing and revisions were seen after a medium follow-up time [31]. MoM bearings were used in a large scale and because of these adverse local tissue reactions more revisions were performed. With a 'retrospectoscope' the use of CFR-PEEK and MoM as bearing in THAs did not live up their promises and should never have been used in THAs. These two types of bearings can be addressed as clinical failures as explained earlier.

What have we learned from CFR-PEEK used as bearing in THA?

We can conclude that CFR-PEEK in THA seems to be no safe and effective alternative when used as insert bearing. Promising ***ex-vivo*** results don't necessarily result in good ***in-vivo*** results. Long-term follow-up is paramount to find the optimum biomaterial used as bearing in THA.

WHAT DO WE STILL HAVE TO LEARN? SUGGESTIONS FOR FUTURE RESEARCH

The search for perfection and innovations in orthopaedics, as mentioned earlier, is an ongoing process. These innovations, with specific implants, (bio)materials, surgical approaches and rehabilitation protocols, will lead to a more personalized patient care in hip surgery, hopefully leading to reliable patients' satisfaction and implant survival results. The last decade the revision rates for THA in the Netherlands decreased with 25% [32]. Perfection of the THA, with low revision rates and high patients' satisfaction, could possibly be feasible in the (near) future. Nevertheless, there are some topics concerning the implant survival and implant reliability which are still unclear and future research might bring some answers.

3-D printed implants and robotics in THA

In recent years patient specific instruments (PSI), customized implants, 3-D printed implants and robotics in THA have become the main domain for innovations in orthopaedics. Especially the 3-D printed implants and robotics in THA have seen an increase of interest in the last years [1]. Currently the conventional THAs and conventional implants are most commonly used in the primary THAs. 3-D applications in orthopaedics are still limited mainly because of the costs and processing time. Also, the current evidence in literature is insufficient, especially for the 3-D printed femoral implants [1, 33, 34]. However, 3-D printed implants are an extremely promising technology and might become the standard type of care in the future for revision surgery. Regarding the 3-D printed implants we still have to learn if these femoral implants can be printed in the shape of the specific native femoral canal to obtain optimal press fit fixation and in extend optimal bone-in growth in cementless femoral implants. We also have to learn if these 3-D printed implants are cost-effective for standard procedures or only in specific patients with abnormal anatomy. Future research focusing on the survival of 3-D printed femoral implants might answer this question.

Robotics in THA (autonomous or active-constrained) has been attempted in the past decades. The last years robotics in THA have become more developed and more reliable. Studies showed a great precision of the position of the implants, mainly the acetabular components, when performed with robotics [35]. However, there are different types of robotics on the market all with other features and mechanisms of navigation. All these types of different robotics need to collect data to prove the added value of robotics in THA. Another issue in the use of robotics in THA is cost-effectiveness, which is not yet clear and needs further research. We still have to learn if robotics in THA will lead to higher survival rates at long-term

follow-up. Long-term follow-up results, both survival and patient reported outcome measures, can provide answers on this topic.

Type of bearing and biomaterials in THA

The bearing in THA is the key component. XLPE is widely the most used type of insert in THA. Metal on XLPE (MoXLPE), Ceramic on XLPE (CoXLPE) and Ceramic on Ceramic (CoC) bearings could be expected to provide similar clinical results up to 10 – 15 years [36]. In the most ideal bearing of a THA the components should be biocompatible, friction-resistant, corrosion resistant and with proper mechanical strength. [37]. All bearings in THA, even the now thought most ideal bearing surfaces, have their advantages and disadvantages, as seen in **Chapter 6**. We still have to learn if the bearing surfaces and biomaterials, which are currently used, guarantee the promising results in long-term follow-up. To confirm the long-term reliability of these bearings long-term follow-up clinical studies are necessary.

Approaches used in THA

Direct anterior approach (DAA) has become a frequently used approach in THA, although the long-term follow-up is not yet clear. Orthopeadic surgeons use it as standard approach for primary THA more and more, up to 50% of the orthopaedic surgeons in the US [38]. The surgical approach is a surgeon related factor that can influence the implant survival. DAA has a steep learning curve compared with the conventional (posterolateral) approach [39]. What we still have to learn from the different approaches used, but especially from the DAA, is the long-term survival rates of the implants with these specific approaches. Future research might provide the answer on this topic. The observation of increased popularity of the DAA raises the question why new developments are used even without sounds of proof of their advantages. This question needs to be discussed by orthopaedic surgeons.

The combination of 3-D implants, robotics, reliable biomaterials, specific approach and personalized rehabilitation might facilitate the transition to an individualized THA in the (near) future [1].

FINAL REMARKS

Hip replacement surgery is the most successful orthopaedic elective surgical procedure [40]. The group of patients requiring a THA is getting younger and more active and therefor more demanding. Implant design, fixation and materials used in THAs are important features to achieve the best clinical outcome and survival. Materials with less wear and implants with even better fixation properties could reduce the risk of (aseptic) loosening and increase overall survival rates, leading to lower revision rates. Although, sometimes expectations turn out to be different as described in this thesis.

We have learned from this thesis that implant survival is a multifactorial issue and can be influenced by small changes in the geometry and design in both the cemented and cementless implants. Sufficient proximal fixation is paramount in anatomically shaped cementless femoral implants. In cemented THA both the forced and shaped (anatomically) closed femoral implants are capable of producing a successful survival at long-term follow-up. CFR-PEEK used as bearing in THA is not advised because of loosening and high revision rates. Nevertheless, orthopaedic surgeons need to keep in mind that implant survival is a multifactorial issue and it is not only just the geometry, fixation and materials of the implant. The indication, correct surgical technique, tissue handling and positioning of the implants are the most important factors influencing the survival of a THA.

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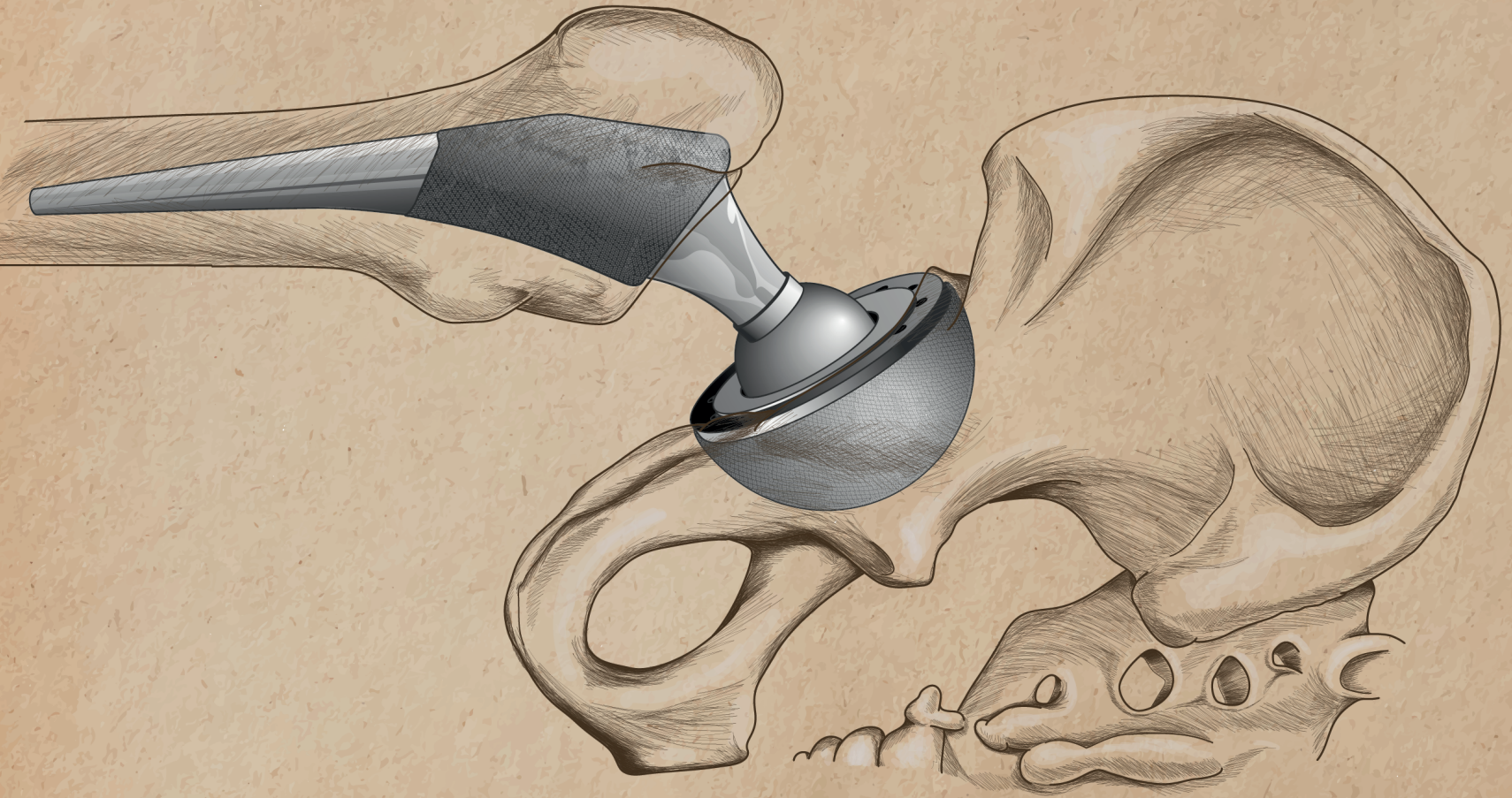


Chapter 8

Impact paragraph

IMPACT PARAGRAPH

Innovations and the search for perfection always start with ideas, followed by *ex-vivo* and *in-vivo* research, as long as this is applicable. These results need to be implemented into daily practice, so eventually the long-term follow-up results can be obtained. In the journey from idea(s) to implementation and finally to (long-term) follow-up different successes and failures can occur. Other researchers can learn from these success or failures, it is important to share these positive and negative outcomes. Sometimes results and expectations turn out to be different than expected, as seen in the present thesis. This **Chapter 8**, the impact paragraph, attempts to discuss the impact of the results of the present thesis on patients, society and (future) research.

Main findings in this thesis

The aim of this thesis was to analyze the different aspects of geometry, fixation and materials in total hip arthroplasty (THA). Therefore, different types of cemented and cementless femoral implants have been analyzed with medium and long-term follow-up, and CFR-PEEK, used as insert bearing, was investigated. The main findings in this study showed that sufficient proximal fixation is paramount in anatomically shaped femoral implants. This thesis underlines the differences of the survival between two different hip implant designs: the shaped closed and the forced closed cemented femoral implants. Based on these findings, CFR-PEEK is not recommended to be used as insert liner in THAs.

Impact group

The results in this thesis can have impact on all patients receiving a THA in the past or in the future. Orthopaedic surgeons and residents in orthopaedic surgery can use the results of this thesis to improve their understanding of different aspects of femoral implants in THA and (bio)materials. The results of this thesis also has a potential impact on future research focusing on innovations in THAs.

Impact on patients and society

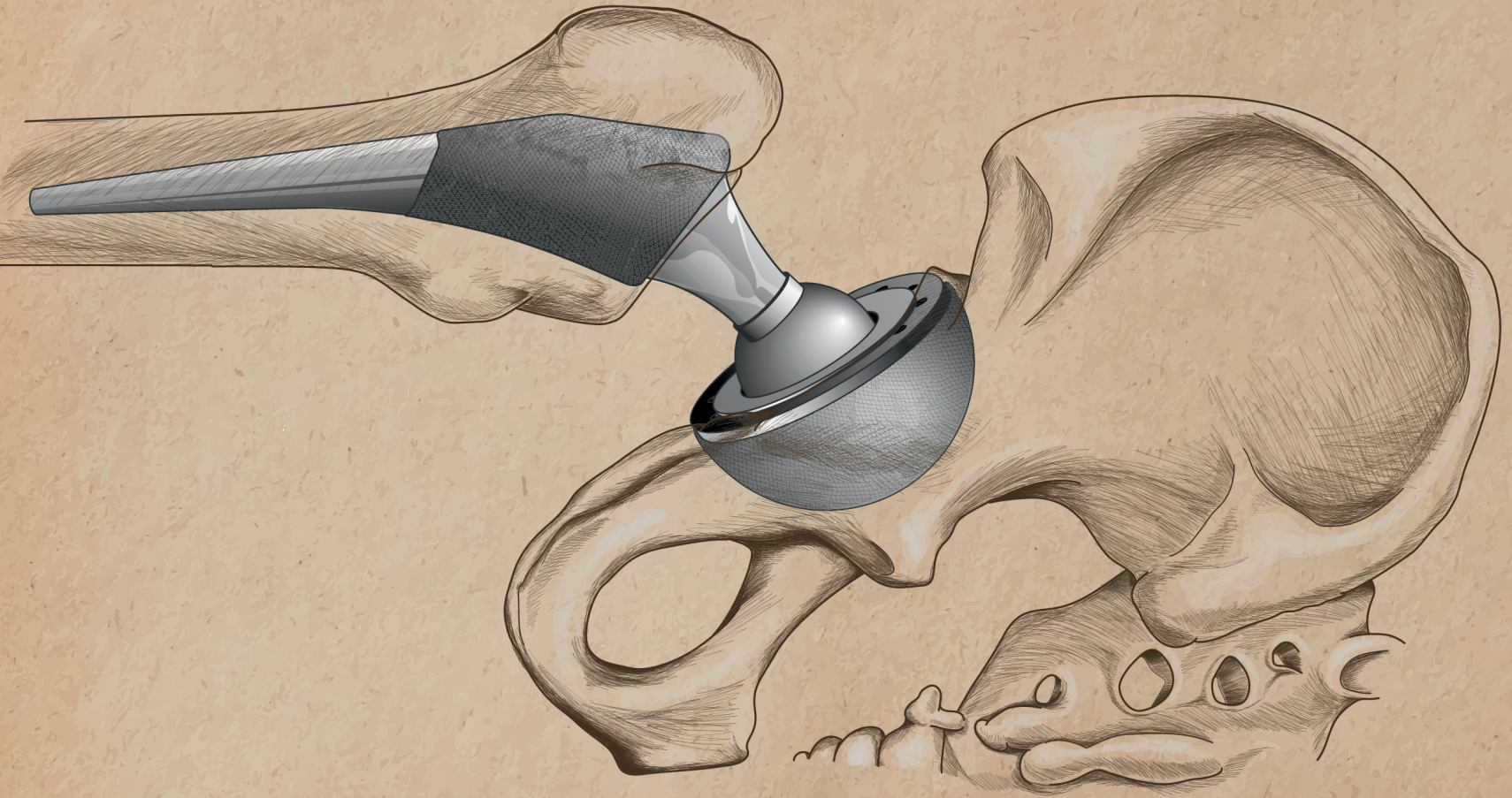
The last decades different improvements were made in THA surgery, not only in the field of implant design, fixation and materials, but also in surgical approach, patients' pathways and patients' rehabilitation programs. The era of five days of hospitalization after THA surgery is history in al lot of countries. Same day admission for THAs is as safe and effective as inpatients pathways in selected populations, with a potential reduction of costs. Despite the (expected) improvements we can still learn and we will keep learning from the past, mainly due to long-term follow-up results. Innovations and changes in the geometry and in the type of (new) biomaterials in THA all intended to achieve a better survival and satisfaction for patients over time. Reliable survival rates and patients reported outcomes have direct impact on the results, with lower revision rates and higher patients' satisfaction rates. Revision surgery is associated with longer operation times, longer length of stay, more complications, higher morbidity and higher costs. Thus, lower revision rates and higher survival outcomes, analyzed in this thesis, have a direct impact on the patient although also on the society and on the government expenditure.

Innovations in health care, and also in orthopaedic care, should not only solely focus on patient related outcomes but also on the financial outcomes to maintain a sustainable healthcare system now and in the future. The costs in general health care are raising every year. In the Netherlands the government spends more than 33% (105.9 billion euro's) of their yearly budget to health care and these costs are expected to rise the next years, mainly because of the rising health care consumption.

However, revisions of THAs will continue to exists in the future, periprosthetic fractures and loosening of components will continue to occur as indications. In the Netherlands we observe a stagnation in the revisions performed nationally, although the number of primary THAs is rising every year. To prevent revision surgery the index diagnosis and treatment must be accurate. In this manner orthopaedic surgeons and residents not only need to focus on the surgical and clinical aspects of osteoarthritis (OA), discussed in this thesis, but also on the preventive topics. Sometimes it is better not to operate the patient, to protect the patient from unnecessary pain and discomfort and early revision surgery of the THA. Aging, the increasing incidence of obesity and a sedentary lifestyle of the world's population will lead to a higher incidence of OA worldwide, but predominantly in the developed countries. Prevention of obesity and promotion to an active lifestyle is an underexposed topic in hip joint surgery and in the training as an orthopaedic surgeon. The role of the orthopaedic surgeon and the resident's orthopaedic surgery is important for these lifestyle changes. Prevention is of higher importance than a surgical solution for hip joint OA and will reduce costs in primary and revision THAs.

Impact on research and healthcare professionals

Sometimes innovations cannot life up its promises and patients need to undergo revision surgery caused by failures of the specific implant characteristics as seen in this thesis. As mentioned previously, survival of a THA is a multifactorial issue. In this thesis implant related innovations are described. The last decades research and scientific publications on specific domains of THAs have increased rapidly. Some of these research projects and scientific publications are money driven and the incentive is not only solely focused on patient's outcomes. A critical and thoughtful appraisal on these results is important. Implementation of new (bio)materials and new designs of THAs should be based on evidence-based literature and well conducted research, which is not always the case. As healthcare professional we have to keep in mind that the interpretation of the results made in scientific publications is important. Translation of ***ex-vivo*** results to ***in-vivo*** use and research must be with caution. Although, before innovations are investigated and implemented there must be the question if these innovations are necessary. For example, with the current cross-linked polyethylene, with very low wear rates, it seems to make wear of the bearing a historically problem. Has the optimum of geometry and biomaterials not already been reached? Long-term follow-up results will provide the answer, this underlines the importance of retrospective and register-based research. We can and need to learn from the past to improve in the future.



Chapter 9

Summary

SUMMARY

Osteoarthritis of the hip joint, coxarthrosis, is a very common degenerative joint disease. The treatment can start non-surgical and in end-stage OA with surgery of the effected hip joint. With a surgical intervention the effected hip joint can be replaced with an artificial joint, a total hip arthroplasty (THA). A THA consists of different components; the femoral implant, the acetabular implant and the bearing/articulation of the THA. There are two different manners of fixation, with and without bone cement. Many different types of THAs are in use all with different geometries, designs and philosophies of fixation and long-term follow-up. Biomaterials used in THAs are important for the long-term survival of the THAs.

In this thesis the (retrospective) results of different types of femoral implants and materials of the articulation in THAs are presented.

In **Chapter 1**, the general introduction, the prevalence of OA of the hip joint and the associated patient characteristics are described. In addition, the general history and the origin of the THA as we know it today is discussed. In this chapter a distinction is made between cementless and cemented THA and the differences in types of femoral implants. The cemented femoral implants can be divided into 4 different types with different ways and philosophies of fixation (**Figure 4**, **Chapter 1**). The cementless femoral implants can be divided into 6 groups, with the anatomical type being most addressed in this thesis (**Figure 5**, **Chapter 1**). Different (bio)materials that can be used as bearing in THA are also described. At the end of this chapter the research questions and thesis outline are formulated and described.

Chapter 2 includes the results of 432 patients (432 THAs) who received a cementless anatomically adapted Optan femoral implant. The cementless anatomically adapted femoral implants has an anteversion equivalent to the native proximal femur in the implant itself. It contains a porous coating on the proximal 1/3 of the implant. The revision and survival of these anatomical femoral implants are described in this chapter. Patient reported outcome measures (WOMAC) and radiological outcomes of these anatomical femoral implants are presented in this chapter. Five years after the primary operation, 39 patients had died and 26 femoral implants were revised, resulting in an overall survival of 94%. The reason for revision was aseptic loosening in 14 cases (3%) and in 12 cases (3%) a periprosthetic fracture was the reason for revision. Radiologically, signs of loosening were seen in multiple implants, especially on the proximal side of the femoral implant. In conclusion, the cementless Optan anatomically adapted femoral implants showed poor overall survival 5 years after initial implantation.

The overall survival of different types of cementless anatomical femoral implants are described in **Chapter 3**. This chapter describes the results of a retrospective study with a mean follow-up of 11-year. Two different types of cementless anatomical femoral implants, the Anatomic Benoist Girard (ABG) type I and II, are evaluated separately and compared with each other. The ABG-I and II have an anteversion of 7 degrees in the metaphyseal portion of the implant and 5 degrees of anteversion in the neck of the

femoral implant. There is a press-fit fixation mainly in the proximal 1/3 of the implant. The difference between the ABG-I and II is the reduction in the length and reduction in proximal and distal diameter. In total, the results of 230 patients (244 THAs) are presented. The primary outcome measure is overall survival and survival based on aseptic loosening. The secondary outcomes are the radiological findings and the patient-reported outcome measures (OHS and WOMAC). 11.3 years after primary operation, 32 patients (13.1%) had died. A total of 11 revision were performed with an overall survival of 95.5%. The ABG-I femoral implant showed a lower overall survival compared to the ABG-II femoral implants; however no statistically significant difference was found. Radiologically, there was no difference between the ABG-I and II femoral implants. Patients with an ABG-II femoral implant had a statistically significantly better score on the WOMAC and OHS. In conclusion, both anatomical femoral implants showed good survival outcomes after 11.3-year follow-up.

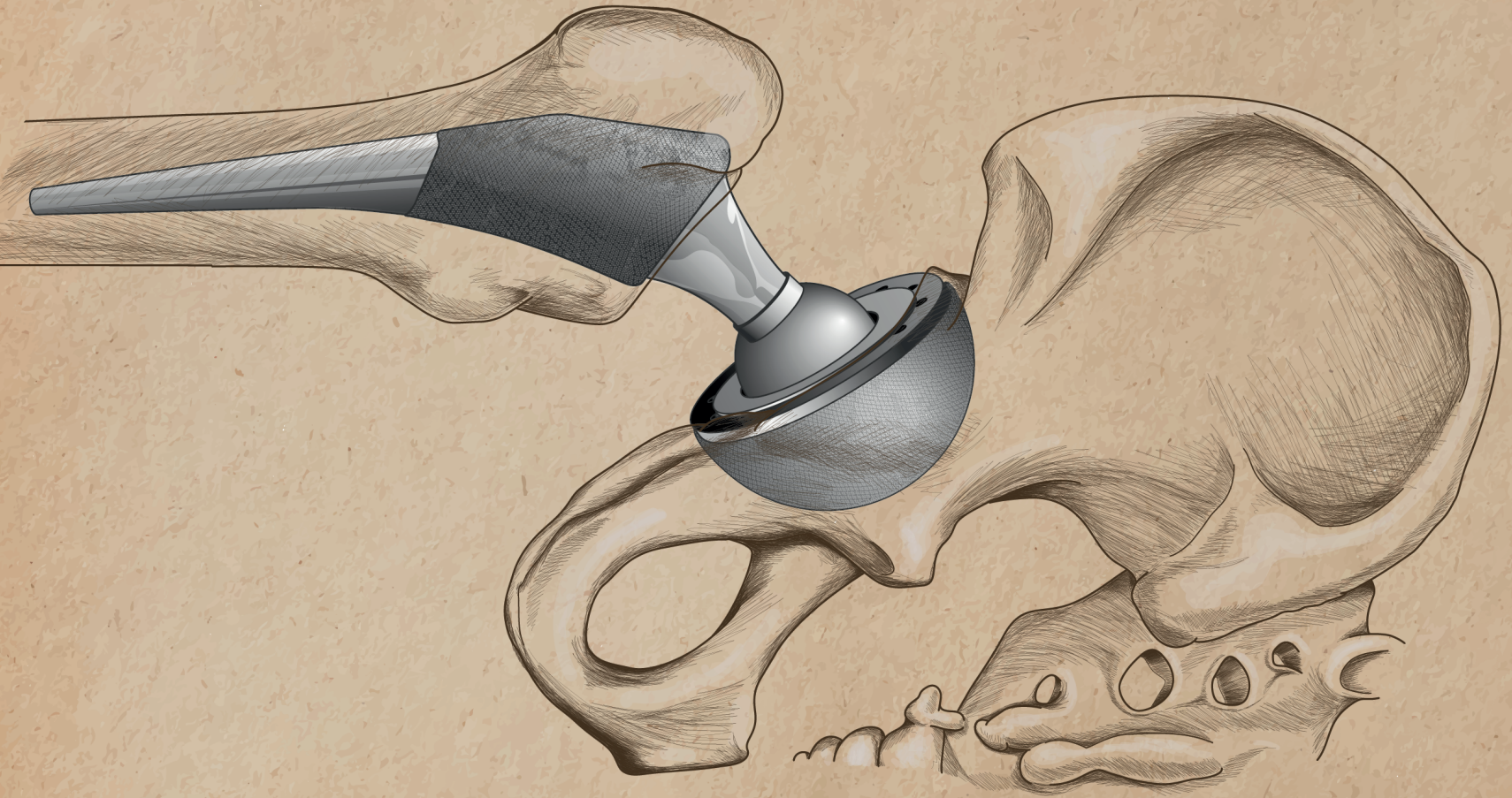
The anatomical cemented femoral implants are discussed in **Chapter 4**. In this chapter, as in chapter 3, the results of the ABG-I and II femoral implants are presented, the cemented versions. A total of 308 patients (323 THAs) were analyzed. 11 years after implantation of the femoral implants, 146 patients (48.3%, 156 THAs) had died. A total of 4 revision of the femoral implants were performed. Resulting in an overall survival of 98.8%. The revision percentage of the ABG-I and II femoral implants showed no statistically significant differences. In conclusion, both cemented anatomical femoral implants showed good survival after more than 11-year follow-up.

The results of a national registry study are presented in **Chapter 5**. In this chapter the revision rates of 76,281 femoral implants are analyzed. A subdivision is made between anatomically shaped femoral implants and 'collarless, polished and tapered' (CPT) femoral implants. These CPT implants have the ability to subside into the cement and fixation of this femoral implant is between the cement and the bone. In this chapter data is used from the national register of orthopaedic implants (LROI). A total of 60,655 anatomical femoral implants and 15,626 CPT implants were included. 5.1 years after implantation, there was a statistically significantly higher overall survival for the anatomically shaped femoral implants compared to the CPT implants with 99.2% and 99.0% respectively. When considering aseptic loosening as a reason for revision, the CPT implants showed a better survival compared to the anatomically shaped implants. CPT implants, on the other hand, showed a statistically significantly higher risk of peri-prosthetic fractures postoperatively. In conclusion, both the CPT and anatomically shaped cemented femoral implants showed good survival rates, but the overall survival of the anatomically shaped femoral implants is higher compared to the CPT implants. However, the risk for aseptic loosening with the anatomically shaped femoral implant is higher and the risk of a peri-prosthetic fracture with the CPT implant is higher.

Chapter 6 presents the results of carbon-fiber-reinforced poly-ether-ether-ketone (CFR-PEEK) used as bearing in THAs. CFR-PEEK is a hard polymer (PEEK) reinforced with carbon fibers. This combination was thought to have low wear rates of the bearing in THAs. In this study, 29 patients were prospectively fol-

lowed and the patient-reported outcome measures, radiological data and overall survival of the prosthesis were examined. 14.3 years after initial implantation of the CFR-PEEK bearings 2 patients had died. In total 4 revisions of the acetabular component due to loosening occurred. At the revision operation, black pseudotumor was seen without microbiological growth. However, increased macrophage activity was seen. The survival of the CFR-PEEK bearings in THAs was 86.5%. Radiologically, the CFR-PEEK bearings showed low wear rates. In conclusion, CFR-PEEK used as bearing in THAs showed poor survival despite good radiological characteristics. CFR-PEEK used as bearing in THAs is not recommended.

Chapter 7 contains a general discussion and what we have learned. In addition, the research questions formulated in chapter 1 are answered and discussed. Future research and topics we still need to learn are discussed.



Chapter 10

Nederlandse samenvatting

NEDERLANDSE SAMENVATTING

Slijtage van de heup, coxartrose, is een veel voorkomende aandoening waarbij de behandeling kan bestaan uit een conservatieve en een operatieve behandeling. Bij een operatieve behandeling kan er een totale heupprothese (THP) geplaatst worden. Deze THP kan op verschillende manieren gefixeerd worden, met of zonder botcement. Een THP bestaat uit verschillende componenten; namelijk uit een femoraal (steel) component, een acetabulair (kom) component en een gewricht component. Er zijn veel verschillende THPs op de markt vaak met verschillende geometrieën en filosofieën over fixatie. Daarnaast wordt er in THPs gebruik gemaakt van verschillende biomaterialen welke een zo hoog mogelijke duurzaamheid moeten hebben om een THP te krijgen die een lange tijd mee zal gaan.

In dit proefschrift worden de resultaten van verschillende vormen van steel componenten en de biomaterialen van de gewrichtscomponenten van THPs belicht.

In **hoofdstuk 1** wordt middels een algemene introductie de prevalentie van coxartrose en de daarbij passende patiënten kenmerken beschreven. Daarnaast wordt de algemene geschiedenis en de ontstaanswijze van de THP, zoals wij deze nu kennen, besproken. Er wordt in dit hoofdstuk een onderscheidt gemaakt tussen ongecementeerde en gecementeerde THPs en de daarbij passende vormen van stelen. De ongecementeerde stelen kunnen worden onderverdeeld in 6 verschillende types waarbij het anatomische type in dit proefschrift het meest belicht wordt. De gecementeerde stelen kunnen worden onderverdeeld in 4 verschillende types met verschillende vormen van fixatie. Naast de geometrie van de stelen worden ook de verschillende type materialen beschreven die gebruikt kunnen worden als gewricht van de THP. Aan het einde van dit hoofdstuk zijn de vraagstellingen van dit proefschrift geformuleerd en wordt de opbouw van dit proefschrift beschreven.

Hoofdstuk 2 omvat de resultaten van 432 patiënten (432 THPs) die een ongecementeerde anatomische Optan steel hebben gekregen. De ongecementeerde anatomische Optan steel heeft een anteversie gelijk aan de native proximale femur in het implantaat zelf. Daarnaast bevat het een poreuze coating aan het proximale 1/3 deel van de steel. De revisie en implantaat overleving van deze anatomische stelen worden beschreven in dit hoofdstuk. Daarnaast worden de patiënt specifieke uitkomst maten (WOMAC) en radiologische uitkomsten van deze anatomische stelen in dit hoofdstuk gepresenteerd. 5 jaar na het plaatsen van de ongecementeerde anatomische stelen waren 39 patiënten overleden en waren 26 stelen gereviseerd wat resulteert in een algemene overleving van 94%. Als reden van revisie was er sprake van een aseptische loslating in 14 gevallen (3%) en was in 12 gevallen (3%) een periprothetische fractuur de reden van revisie. Radiologisch werden er tekenen van loslating gezien bij meerdere implantaten met name aan de proximale zijde van de steel. Concluderend laat de ongecementeerde Optan een slechte algemene overleving zien 5 jaar na implantatie.

De algemene overleving van andere typen ongecementeerde anatomische stelen worden beschreven in **hoofdstuk 3**. In dit hoofdstuk worden de resultaten beschreven van een retrospectief onderzoek met een gemiddelde vervolging van 11 jaar. Twee verschillende type ongecementeerde anatomische stelen, de Anatomic Benoist Girard (ABG) type I en II, worden afzonderlijk geëvalueerd en vergeleken met elkaar. De ABG-I en II hebben een anteversie van 7 graden in het metaphysaire gedeelte van het implantaat en 5 graden anteversie in de nek van de steel. Er is een press-fit fixatie met name in de proximale 1/3 van de steel. Het verschil tussen de ABG-I en II is de reductie in lengte en reductie van de proximale en distale diameter. In totaal worden de resultaten gepresenteerd van 230 patiënten (244 THPs). De primaire uitkomstmaat is de algemene implantaat overleving en de implantaat overleving op basis van aseptische loslating van de steel. De secundaire uitkomstmaat zijn de radiologische bevindingen en de patiënten specifieke uitkomstmaten (OHS en WOMAC). 11.3 jaar na implantatie van deze stelen waren 32 patiënten (13.1%) overleden. In totaal waren er 11 revisies verricht waarbij een algemene implantaat overleving werd gevonden van 95.5%. De ABG-I steel liet een lagere algemene implantaat overleving zien in vergelijking met de ABG-II steel, echter was hierbij geen statistisch significant verschil aanwezig. Radiologisch was er geen verschil tussen de ABG-I en II stelen. De patiënten met een ABG-II steel hadden een statistisch significant betere score op de WOMAC en OHS-score. Concluderende laten beide anatomische stelen een goede implantaat overleving zien bij een langdurige vervolging na 11.3 jaar.

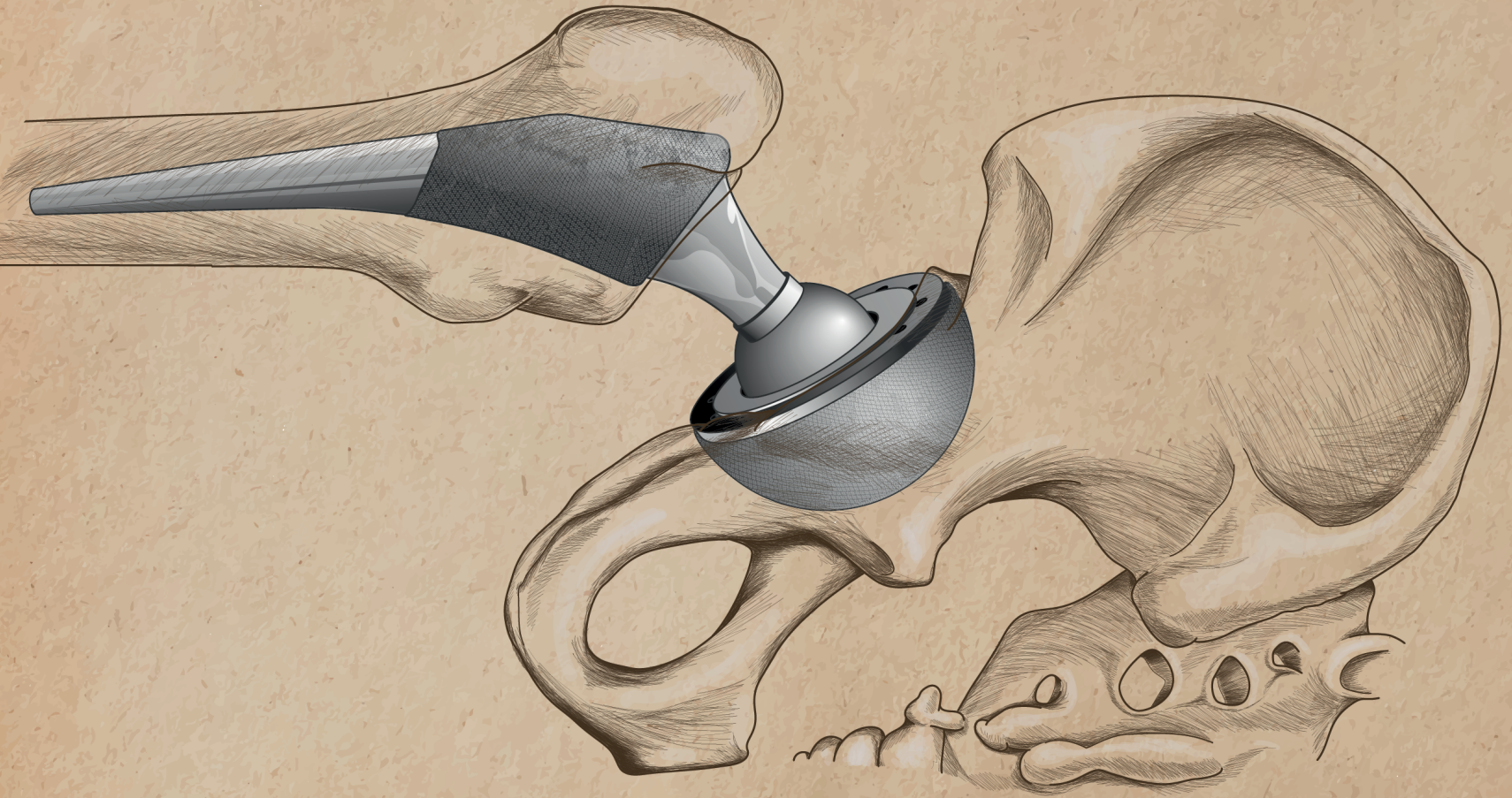
De anatomische gecementeerde stelen worden besproken vanaf **hoofdstuk 4**. In dit hoofdstuk worden net zoals in hoofdstuk 3 de resultaten van de ABG-I en II stelen gepresenteerd echter dan de gecementeerde versies. In totaal worden 308 patiënten (323 THPs) met deze typen stelen geanalyseerd. 11 jaar na implantatie van de stelen waren 146 patiënten (48.3%, 156 THPs) overleden. In totaal werden er 4 revisies verricht van de steel resulterende in een algemene implantaat overleving van 98.8%. Het revisie percentage van de ABG-I en II stelen liet geen statistisch significant verschil zien. Bij 25.4% van de patiënten werd een radiolucente lijn gezien rondom de prothese. Concluderende lieten beide gecementeerde anatomische stelen een goede implantaat overleving zien na meer dan 11 jaar na implantatie.

De resultaten van een landelijke register studie worden gepresenteerd in **hoofdstuk 5**. In dit hoofdstuk worden de revisie cijfers geanalyseerd van 76,281 stelen. Er wordt een onderverdeling gemaakt tussen anatomisch gevormde stelen en 'collarless, polished and tapered' (CPT) stelen. Deze CPT-stelen hebben de mogelijkheid om in het cement te zakken en fixatie van deze steel zit niet tussen het implantaat en het cement maar tussen het cement en het bot. In dit hoofdstuk wordt gebruik gemaakt van de data welke beschikbaar is gekomen vanuit het register van de landelijke register orthopedische implantaten (LROI). In totaal werden er 60,655 anatomische stelen en 15,626 CPT stelen geïncludeerd. 5.1 jaar na implantatie was er een statistisch significant betere algemene implantaat overleving voor de anatomisch gevormde stelen vergeleken met de CPT-stelen respectievelijk 99,2% en 99,0%. Als er gekeken wordt naar aseptische loslating als reden voor revisie dan lieten de CPT-stelen een betere implantaat overleving zien vergeleken met de anatomische stelen. CPT-stelen daarentegen lieten weer een statistisch significant hoger risico zien op peri-prothetische fracturen postoperatief. Concluderende laten zowel

CPT als anatomische stelen een goede implantaat overleving zien maar is de algemene implantaat overleving van de anatomische stelen hoger in vergelijking met de CPT-stelen. Echter is de kans op een aseptische loslating bij de anatomische stelen hoger en is de kans op een peri-prothetische fractuur bij de CPT-stelen hoger.

Hoofdstuk 6 geeft de resultaten van carbon-fiber-reinforced poly-ether-ether-ketone (CFR-PEEK) gebruikt als materiaal voor de lager in THPs. CFR-PEEK is een hard polymeer (PEEK) verstevigd met carbon vezels. Met deze combinatie was er de gedachte dat er een lage slijtage zou zijn van de geïmplanteerde lager van de THP. In deze studie zijn 29 patiënten prospectief gevolgd en is er gekeken naar de patiënt specifieke uitkomst maten, radiologische data en algemene overleving van de prothese. 14.3 jaar na implantatie van de CFR-PEEK waren 2 patiënten overleden. In totaal vonden er 4 revisies plaats van het acetabulair component vanwege loslating. Bij de revisie operatie werden zwarte pseudotumoren gezien welke microbiologisch geen groei lieten zien. Wel werd er een verhoogde macrofaag activiteit gezien. De implantaat overleving van de CFR-PEEK lagers in THPs was 86.5%. Radiologisch liet CFR-PEEK een lage slijtage zien. Concluderende laat CFR-PEEK gebruikt als lager in THPs een slechte implantaat overleving zien ondanks de goede radiologische kenmerken. Er wordt geadviseerd om CFR-PEEK niet te gebruiken als lager in THPs.

Hoofdstuk 7 bevat een algemene discussie over wat we geleerd hebben en daarnaast worden de onderzoeksvragen zoals geformuleerd in hoofdstuk 1 beantwoord en besproken.



Chapter 11

Dankwoord

DANKWOORD

Het combineren van gezin, werk, opleiding, bestuursfuncties, promotieonderzoek en sociale activiteiten is passen en meten wat ik absoluut niet alleen heb kunnen doen. Graag wil ik een aantal mensen bedanken voor de hulp die ik, op welke manier dan ook, gekregen heb. De realisatie van dit proefschrift was er niet geweest zonder jullie.

Prof. dr. I.C. Heyligers, beste Ide. Jij gaf mij tijdens onze eerste ontmoeting als coassistent in jouw oude kantoor, met vitrinekast vol met protheses en overal boeken, direct het vertrouwen om mijn opgezette plan om orthopaedisch chirurg te worden waar te maken. Jouw scherpe visie en kijk op onderzoek heeft mij veel geleerd en mijn proefschrift gemaakt tot wat het nu is. Het proefschrift waarop jij gepromoveerd bent, ''bone-reactions to bone-implants'', heeft natuurlijk veel te maken met het onderwerp van dit proefschrift. Daarnaast mag ik mij erg gelukkig prijzen dat ik je als opleider heb mogen meemaken. Jouw woorden zijn vaak scherper dan het mes en het 'verbaal' opereren heb ik zeker aan jou te danken. Ook vind ik het bijzonder dat ik mijn proefschrift mag verdedigen met jou als promotor en Emil van Haaren als co-promotor die jij in 2011 hebt begeleid in zijn promotie traject. Dit laat zien hoe jij inspireert.

Dr. E.H. van Haaren, beste Emil. Vanaf het moment dat ik begonnen ben in het Orbis Medisch Centrum voor mijn onderzoeken ben jij altijd actief betrokken geweest. Jouw snelle en goede commentaren op mijn stukken hebben ervoor gezorgd dat er een momentum in het onderzoekstraject bleef bestaan. Het feit dat je nu plaatsvervangend opleider bent in het Zuyderland Medisch Centrum is een grote aanwinst. Met veel bewondering kijk ik naar jouw chirurgische vaardigheden en hoop dat ik daar, al is het maar een klein beetje, op mag gaan lijken. Een voorbeeld om te volgen. In de toekomst hoop ik nog andere (wetenschappelijke) projecten met jou op te mogen pakken.

Dr. M.G.M. Schotanus, beste Martijn, beste Tinus. Jij bent niet alleen de copromotor, maar zeker de motor, achter dit proefschrift. Als jij mij in 2014 niet had teruggebeld naar aanleiding van een sollicitatie in het Orbis Medisch Centrum, had ik dit proefschrift waarschijnlijk nooit geschreven. De manier waarop jij weet te prikkelen om wetenschappelijk onderzoek te doen is uniek en een groot aanwinst voor de orthopaedie. Jij bent een duizendpoot en weet altijd de juiste snaar te raken. Je hebt mij ook geleerd dat het soms helemaal niet belangrijk is om met het werk bezig te zijn, zo zijn menig ideeën voor onderzoek ontstaan onder het genot van een 'klein' kaboutertje (of nog één) bij de Foroxity tegenover het ziekenhuis. Maar naast co-promotor kan ik wel zeggen dat je de afgelopen jaren ook een echte vriend bent geworden waarvoor ik heel dankbaar ben. Hopelijk mag ik in de toekomst met je samen blijven werken.

De leden van de beoordelingscommissie **prof. dr. R.A. de Bie, prof. dr. B.W. Schreurs, dr. R.H.M. ten Broeke** en **dr. W.L.W. van Hemert**, dank voor het kritisch lezen en beoordelen van het proefschrift en de tijdsinvestering. Daarnaast dank voor de bereidheid om zitting te nemen in de beoordelingscommissie.

Er moeten altijd mensen achter je staan en niet alleen figuurlijk maar tijdens zo'n promotie traject ook letterlijk. Ik ben trots dat **Jeroen van Esch** en **Jurian Aarts** mij bij willen staan als paranimf. **Jeroen** wat fijn om een vriend te hebben zoals jij. We hoeven elkaar niet veel te spreken maar weten altijd precies wat we aan elkaar hebben. Je liet me vertellen zonder enig idee te hebben waar het nu eigenlijk om ging, dank daarvoor! **Jurian** altijd een kritische noot om anderen nog beter de motiveren en stimuleren, het is niet voor niets dat jij het huisartsen vak in bent gegaan, iets wat perfect bij je past. Aan onze avonden met een biertje en gewoon praten hecht ik veel waarde. Laten we dit er vooral in houden.

Alle manuscripten in dit proefschrift zijn geschreven in 'team verband'. Graag wil ik mijn co-auteurs bedanken. Beste **Jelle Halma, Steven van Gaalen, Arthur de Gast**, **Bert Boonen, Anneke Spekenbrink-Spooren, Nanne Kort** en **Aart Verburg** dank voor jullie aanvullingen op de manuscripten, zonder jullie hulp was het niet gelukt.

Een speciaal woord van dank aan **Aart**, de inbreng die jij gegeven hebt voor de hoofdstukken van dit proefschrift zijn groot. De kijk op onderzoek zoals jij die hebt is uniek. Niets op het vlak van wetenschappelijk onderzoek is jou te gek. Ik ben blij dat ik samen met je heb mogen werken op wetenschappelijk niveau aan het begin van mijn eigen carrière en het einde van jouw carrière.

Beste **Edwin, Emil, Inez, Elmar, Bert, Thijs, Wieske, Nick, Wouter, Roel, Matthijs, Steven, Pieter, Ralf, Steffie** en **Patrick** dank voor al jullie opleidingsmomenten in het Zuyderland Medisch Centrum. De opleiding is van hoge kwaliteit en de opleidingsmogelijkheden zijn zeer divers een heerlijke plek om te (blijven) werken.

Beste **Heleen, Peter, René, Mark, Pieter, Paul, Jan, Joris, Adhiambo, Tim, Maarten, Loek** en **Erwin** dank voor de opleidingsmomenten die ik heb gehad en nog ga krijgen in het Maastricht Universitair Medisch Centrum. Niet voor niets ben ik bij jullie teruggekomen voor het laatste deel van mijn opleiding.

Beste (oud)bestuursleden van de VOCA **Dino, Loek, Kim, Louren, Dirk, Koen Dulaert, Thomas, Anna, Martijn, Koen Steentjes, Jonneke, Sander, Joris, Ralph** en **Casper** wat is het toch mooi om in een bestuur te zitten met mensen die net dat beetje extra willen en kunnen doen. De vergaderingen die we hebben zijn altijd goed en gezellig en onze uitstapjes zijn legendarisch. Hard werken maar ook hard genieten. Jammer dat mijn bestuur jaren er weer op zitten, ik had dit voor geen goud willen missen! Nu is het aan de volgende generatie. Leve de VOCA!

Dank aan alle **(oud) assistenten orthopedie** van ROGO-zuid voor jullie collegialiteit en betrokkenheid. Speciale dank aan **Jetse Jelsma, Baris Koc** en **Vincent Groen.** Ook dank aan **Yoeri Bemelmans** onze gemeenschappelijke achtergrond als fysiotherapeut geeft ons toch wel een speciale connectie er is altijd wel iets te lachen.

Beste **Eva Jacobs** ik wil je hier toch graag persoonlijk noemen omdat er gedurende onze opleiding een goede vriendschap is ontstaan. Dank voor je kritische en goede punten op mijn proefschrift. Ik hoop dat we in de toekomst nog regelmatig met onze gezinnen blijven afspreken. Wie weet worden we nog wel eens collega's!

Myrthe Boymans dank voor het maken van de illustraties en omslag van dit proefschrift. Knap hoe je na één gesprek al mijn wensen wist te vangen.

Dank aan alle **poliassistenten** van het Zuyderland Medisch Centrum, het oproepen van de patiënten voor de onderzoeken heeft destijds veel werk gekost maar uiteindelijk hebben we bijna iedereen benaderd, dit komt mede door jullie oplettendheid!

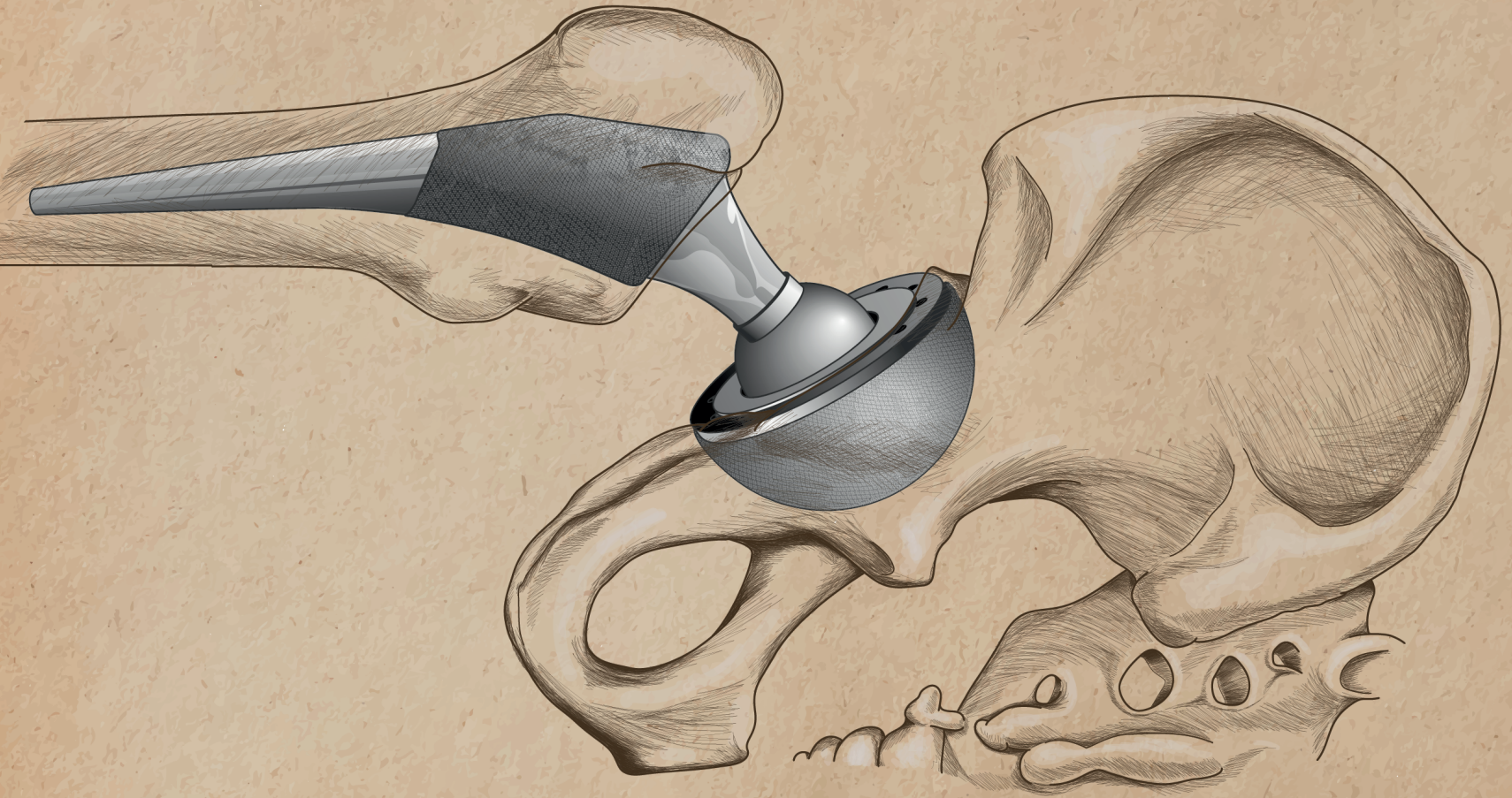
Om werk, bestuursfuncties, opleiding en een promotieonderzoek te kunnen combineren is er eigenlijk maar een ding belangrijk; een stabiele thuishaven. Dit had ik nooit kunnen bereiken met de onderstaande en meest belangrijke mensen in mijn leven.

Lieve schoonouders **Henk** en **Karin** wat fijn dat jullie ons zo veel hebben kunnen ondersteunen de afgelopen jaren bij onze drukke banen en nevenactiviteiten. Hiervoor ben ik jullie heel erg dankbaar, dit proefschrift was er zeker niet geweest zonder jullie steun bij ons thuis.

Lieve papa en mama, lieve **Jan** en **Marian** wat ben ik toch blij dat we samen in hetzelfde dorp wonen. Gewoon binnenlopen is zo belangrijk voor ons allemaal. Zonder jullie steun en opvang voor de kinderen had ik dit niet kunnen bereiken, hiervoor ben ik jullie heel erg dankbaar. Mama dank dat je altijd klaar staat om te ondersteunen en wat mooi om te zien wat dit met ons als gezin doet. 'It takes a village to raise a child' slaat hier zeker op. Papa wat fijn dat ik soms gewoon mijn hart kan luchten en je gewoon luistert zonder direct te oordelen.

Lieve **Nele, Louve** en **Ine**, wat zijn jullie toch prachtig! Er is niets beters dan met jullie te knuffelen en lachen. 'Erf de ogen van je kind en kijk er door' besef ik me maar al te goed als ik naar jullie kijk (ondanks dat jullie dit niet doorhebben). Ik hou zielsveel van jullie!

Last but not least mijn vrouw, lieve **Julie**, mijn steun en toeverlaat, rots in de branding en thuishaven. Het is erg fijn dat je een luisterend oor kunt zijn, hier kan ik nog veel van leren. We hebben alle twee een verantwoordelijke baan en zijn hier ook druk mee bezig, knap hoe jij dit zo kunt combineren en jezelf nooit op de eerste plek zet. Het is af en nu verder kijken naar de toekomst. Ik hou van je!



Chapter 12

Curriculum vitae

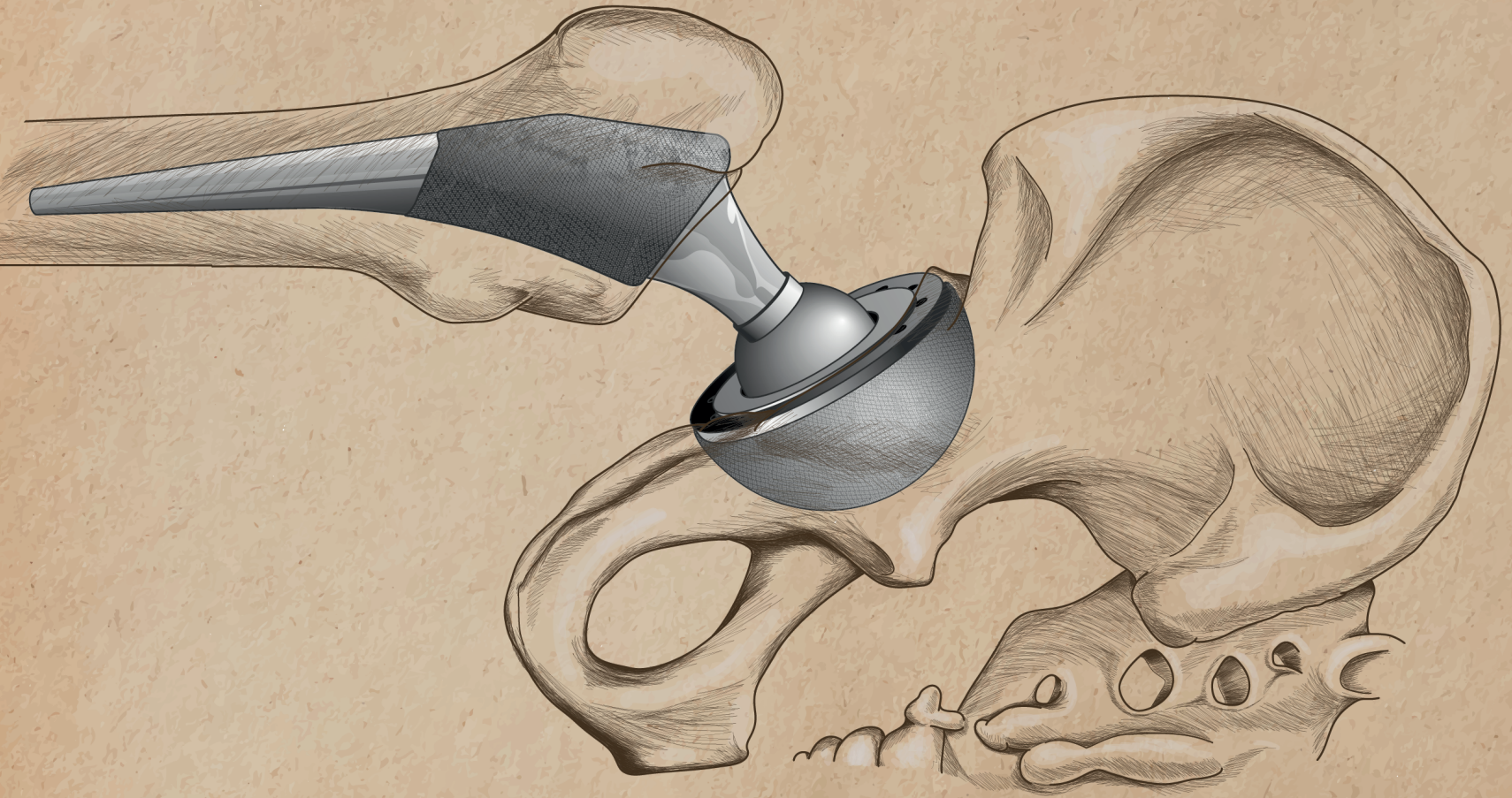
CURRICULUM VITAE

Luc Heijnens was born in Veghel, the Netherlands, on October 24th, 1988. He is the youngest to Jan and Marian and brother to Sanne, Ilse and Meike. He graduated from higher general secondary school (Trevianum scholengroep Sittard) in 2006 with specialization Nature & Health. After graduating he started with the study to become physical therapist at the Fontys Hogeschool in Eindhoven. In 2010 he graduated and worked as physical therapist at Fit & Fysio in Linne, simultaneously he started medical school at the Maastricht University. In July 2016, he completed his medical degree and started working as a resident (non-training) at the Department of Orthopaedic Surgery, Zuyderland Medical Centre in Heerlen-Sittard-Geleen (supervision: prof. dr. I.C. Heyligers and dr. E.J.P. Jansen). His specialist orthopaedic training started in July 2017 at the Department of General Surgery, Zuyderland Medical Centre in Heerlen-Sittard-Geleen (supervisor: dr. M.N. Sosef).

Before the start of his residency in orthopaedic surgery he was already interested in scientific research in orthopaedic surgery. He started his scientific career in 2013 at the Clinical Orthopaedic Research Centre – midden Nederland Zeist/Utrecht (supervision: dr. A. de Gast). In 2014 he continued his scientific career, at the Zuyderland Medical Centre, with the ambition to obtain his PhD degree (supervisor: prof. dr. I.C. Heyligers, dr. E.H. van Haaren and dr. M.G.M. Schotanus), leading to this thesis.

In 2019 he continued his residency at the Zuyderland Medical Centre in Heerlen-Sittard-Geleen (supervisor: dr. E.J.P. Jansen), and in 2020 he started at the Maastricht University Medical Center (supervisor: dr. H. Staal). In the autumn of 2021, he returned to the Zuyderland Medical Centre in Heerlen-Sittard-Geleen. In April 2023 he returned to the Maastricht University Medical Center for his last 6 months of training.

He married to Julie Fincken in 2015 and together with their three daughters Nele (2016), Louve (2018) and Ine (2022) they are living in Bingelrade, the Netherlands.



Chapter 13

List of publications/presentations

LIST OF PUBLICATIONS/PRESENTATIONS

Publications

Poor intermediate term survival of the uncemented Optan anatomically adapted femoral component. A retrospective study of 432 patients with a mean follow-up of 5 years.
Luc J.M. Heijnens, Jelle J. Halma, Steven M. van Gaalen, Arthur de Gast
Acta Orthop. 2014 Aug

Results of cemented anatomically adapted Total Hip Arthroplasty. A follow-up longer than 10 years.
Luc J.M. Heijnens, Martijn G.M. Schotanus, Nanne P. Kort, Aart D. Verburg, Emil H. van Haaren
J Arthroplasty. 2016 Jan

Disappointing long-term outcome of THA with Carbon-Fiber-Reinforced Poly-Ether-Ether-Ketone (CFR-PEEK) as acetabular insert liner. A prospective study with a mean follow-up of 14.3 years.
Luc J.M. Heijnens, Martijn G.M. Schotanus, Aart D. Verburg, Emil H. van Haaren
Hip Int. 2021 Nov

Excellent survival of two anatomically adapted hydroxyapatite coated cementless total hip arthroplasties. A mean follow-up of 11.3 years.
Luc J.M. Heijnens, Martijn G.M. Schotanus, Emil H. van Haaren
Submitted

Higher overall survival rates of anatomically shaped femoral implants compared with tapered slip femoral implants in cemented total hip arthroplasty: an analysis of 87,359 femoral implants.
Luc J.M. Heijnens, Ide C. Heyligers, Bert Boonen, Anneke Spekenbrink-Spooren, Emil H. van Haaren, Martijn G.M. Schotanus
Hip Int. 2022 Oct

Traumatische anterieure natieve heupluxatie, casus beschrijving.
Luc J.M. Heijnens, Roel P.M. Hendrickx, Yoeri F.L. Bemelmans
Tijdschrift Wetenschap in Beweging Oktober 2022

Oral/poster Presentations

Excellent survival of two different anatomically adapted hydroxyapatite coated cementless THAs. A follow-up of more than 11 years.
Oral presentation European Orthopaedic Research Society (EORS) 2019 Maastricht
Luc J.M. Heijnens, Martijn G.M. Schotanus, Emil H. van Haaren

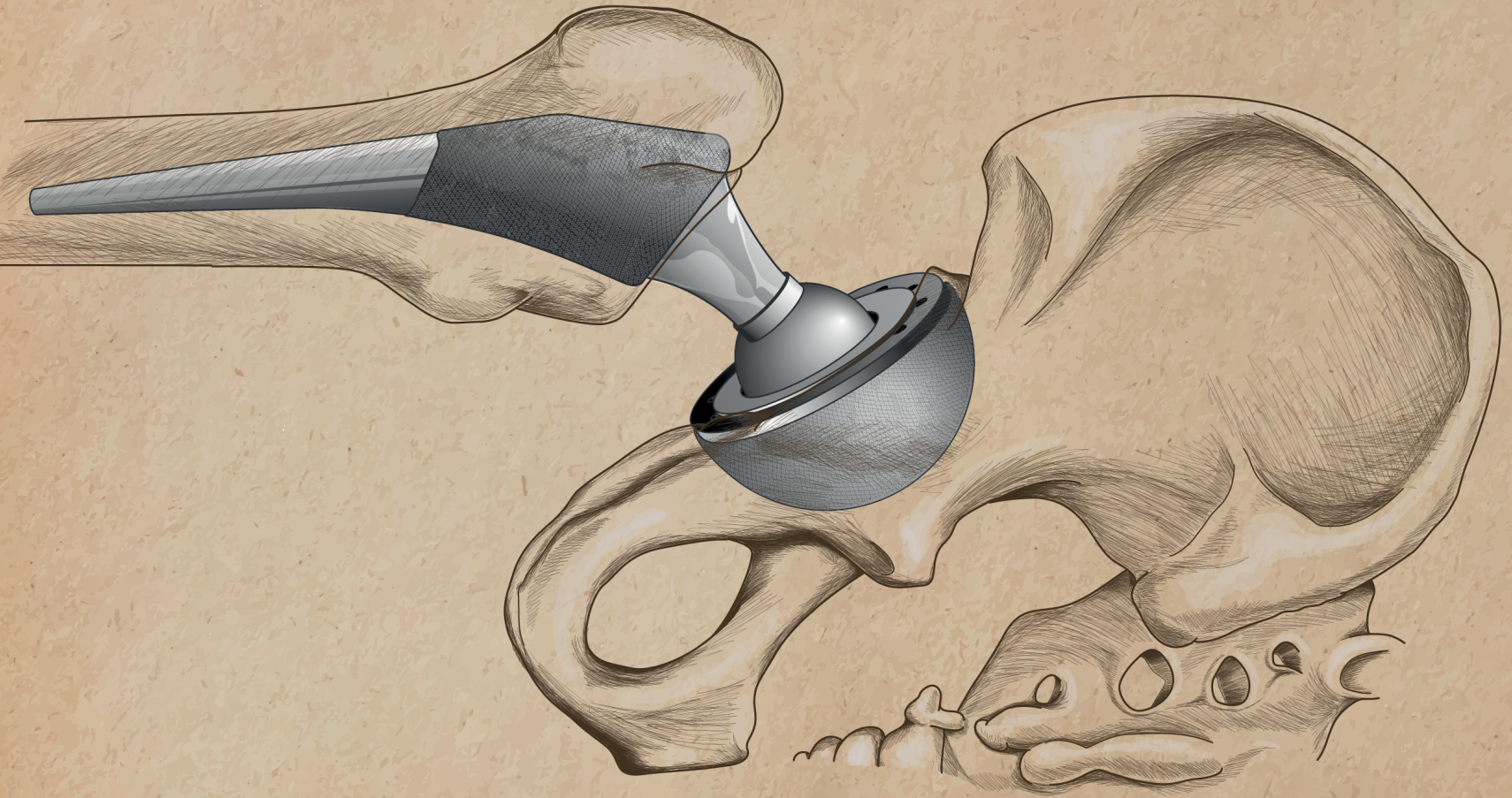
Disappointing long-term outcome of Total Hip Arthroplasties with Carbon-Fiber-Reinforced Poly-Ether-Ether-Ketone (CFR-PEEK) as insert liner. A prospective study of 14.3 years.
Poster presentation European Orthopaedic Research Society (EORS) 2019 Maastricht
Luc J.M. Heijnens, Martijn G.M. Schotanus, Emil H. van Haaren

Books

Probleem georiënteerd denken in de orthopedie.
Author chapter 16 'Een kind met een mankend looppatroon en beenlengte verschil'
Luc J.M. Heijnens, Vincent A. Groen, Heleen Staal.
In progress

Other

Luc J.M. Heijnens is reviewer for the Journal of Arthroplasty.



Chapter 14

List of abbreviations

LIST OF ABBREVIATIONS

THA:	total hip arthroplasty
OA:	osteoarthritis
TJR:	total joint replacement
PE:	polyethylene
UHMWPE:	ultra-high molecular weight polyethylene
XLPE:	highly cross-linked polyethylene
HA:	hydroxyapatite
CFR-PEEK:	carbon-fiber-reinforced poly-ether-ether-ketone
WOMAC:	western Ontario and McMaster universities index score
OHS:	Oxford hip score
ABG:	Anatomic Benoist Gerard
PROMs:	patient reported outcome measures
AC:	acetabular component
CI95%:	95% confidence intervals
FU:	follow-up
LROI:	Dutch arthroplasty register
CPT:	collarless polished and tapered
AS:	anatomically shaped
HR:	hazard ratio
MAP:	Merle d'Aubige-Postel score
NICE:	National institute for health and clinical excellence
ODEP:	Orthopaedic data evaluation panel
NHS:	National health service
RSA:	Radiostereometric analysis