Diplomarbeit

Survival analysis of 998 Corail® stems implanted at the Department of Orthopaedic Surgery, Medical University of Graz, from 2005 to 2012

eingereicht von

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zur Erlangung des akademischen Grades

Doktor(in) der gesamten Heilkunde

(Dr. med. univ.)

an der

Medizinischen Universität Graz

ausgeführt an der

Universitätsklinik für Orthopädie und orthopädische Chirurgie

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Graz, 4. November 2016

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Graz, am 4. November 2016 *Maier Michael eh*

1 Danksagungen

Ich danke OA Dr. Werner Maurer-Ertl und DDr. Jörg Friesenbichler sehr herzlich für die Unterstützung und Betreuung bei der Erstellung meiner Diplomarbeit. Beide sind während dieser Zeit gute Freunde von mir geworden. Bedanken möchte ich mich für die stets kompetente, zuverlässige und schnelle Unterstützung bei der Erstellung der vorliegenden Arbeit. Ebenso möchte ich mich bei Herrn Univ. Prof. Dr. Andreas Leithner für die Ermöglichung dieser Arbeit an der Universitätsklinik für Orthopädie und orthopädische Chirurgie Graz bedanken.

Ein weiterer Dank gilt meinen Freund/Innen und Studienkollegen/Innen. Bernadette möchte ich speziell erwähnen, mit ihr habe ich viel Zeit beim Lernen verbracht und sie ist mir jederzeit mit Rat und Tat zur Seite gestanden.

Mein größter Dank gilt jedoch meinen Eltern, die mich in jeder erdenklichen Weise gefördert und unterstützt haben.

2 Abstract

Background: The first implantation of the Corail® hip system was performed in 1986 by the French "ATRO-Groupe". Till 2012, more than 1.000.000 Corail® implants have been sold worldwide since introduction. Meanwhile, this hydroxyapatite (HA) coated stem is established worldwide by excellent long-term results.

The aim of this retrospective study was the clinical evaluation and site analysis for the HA coated Corail® stem, which was in use since 2005 at the Department of Orthopaedic Surgery, Medical University of Graz.

Patients and methods: From January 2005 to December 2012, 891 patients, 408 men and 483 women, were identified and included in this study. Within this collective, 998 Corail® stems were implanted. The average age of patients at the time of surgery was 63 years (range, 18-91 years). The mean postoperative radiological follow-up of all patients together was 45 months (range, 3-128 months). Three months postoperatively, 807 patients were available for clinical and radiological follow-up, whereas the number of participants was decreasing during the time of follow-up (e.g. 724 patients after 6 months and 668 patients after one year). The assessment of the radiographs included leg length differences, sign of stress shielding, lysis, heterotopic ossification according to the classification of Brooker, bone resorption rated in Gruen zones and the implant position. An implant survival for aseptic loosening as well as any reason for revision as endpoint was done using the Kaplan-Meier method.

Results: In 75% of the cases a standard Corail® stem was implanted, followed by the Corail® high offset stem (21%) and the coxa vara stem (4%). The Corail® stem was combined with a Pinnacle® cup in 93%. The most common bearing used was ceramic-on-ceramic (n=873, 88%) with the head size 36 mm (75%). Heterotopic ossification was observed in 52 patients (5.2%) and clinically irrelevant radiographic loosening lines in 166 patients.

Five out of 912 Corail® stems implanted, had to be revised due to aseptic loosening (= revision rate: 0.5%). According to the method of Kaplan-Meier, the survival of the implant was 99% at 5 years and 97.6% after 10 years. Eleven other stem revisions had to be made due to periprosthetic fractures (=1.1%).

Conclusion: The results of our study showed excellent clinical results and minimal risk for aseptic loosening of the Corail® stem compared with international registry data. The number of early periprosthetic fractures was stated to be part of a kind of learning curve

and was eliminated by adapting the implantation technique. In different register data such as Australia, New Zealand, Denmark and England, an implant survival for the Corail® stem was reported from 97% to 99% after a follow-up up to15 years.

3 Kurzfassung

Hintergrund: Die erste Implantation des Corail® Hüftprothesenschaftes wurde 1986 von der französischen „ARTRO-Groupe“ durchgeführt. Mit dem Jahr 2012 waren über 1.000.000 Implantate seit der Markteinführung implantiert. Mittlerweile hat sich dieses mit Hydroxyapatit (HA) beschichtete Schaftsystem durch hervorragende Langzeitergebnisse weltweit etabliert.

Ziel dieser retrospektiven Studie war die klinische Auswertung und Standzeitanalyse für den HA beschichteten Corail® Schaft, der seit 2005 an der Universitätsklinik für Orthopädie und orthopädische Chirurgie Graz in Verwendung ist.

Patienten und Methoden: Für den Zeitraum von Jänner 2005 bis Dezember 2012 konnten 891 Patienten, 408 Männer und 483 Frauen, identifiziert und in die Studie eingeschlossen werden. Insgesamt wurden innerhalb dieses Kollektivs 998 Corail® Hüftendoprothesen implantiert. Das durchschnittliche Alter der Patienten zum Zeitpunkt der Operation betrug 63 Jahre (18 bis 91 Jahre). Das postoperative radiologische Follow-up liegt im Durschnitt bei 45 Monaten (3 bis 128 Monate). 3 Monate postoperativ wurden 807 Patienten klinisch und radiologisch nachuntersucht, während die Anzahl der Patienten über die Zeit des follow-ups abnahm (z.B. 724 Patienten nach 6 Monaten und 668 Patienten nach einem Jahr. Neben der Analyse von Revisionzahlen und Revisionsgründen wurden anhand der Röntgenbilder Beinlängendifferenzen, Zeichen für Stress Shielding, Lysezeichen, heterotope Ossifikationen nach Brooker und Resorptionssäume sowie die Implantatposition beurteilt. Des Weiteren wurde die Implantatüberlebensrate für aseptische Lockerungen sowie für jeglichen Revisionsgrund mittels der Kaplan-Meier-Überlebenskurve berechnet.

Ergebnisse: In 75% der Fälle wurde ein Corail® Standard Schaft implantiert, gefolgt von der High Offset Variante (21%) und der Vara Version (4%). In 93% der Fälle wurde der Corail® Schaft mit einer Pinnacle® Pfanne kombiniert. Die häufigste verwendete Gleitpaarung war Keramik-Keramik (873 = 88%) mit der Kopfgröße 36 mm (75%). Heterotope Ossifikationen wurden in 52 Patienten (5,2%) und klinisch meist nicht relevante Resorptionssäume in 166 Patienten gefunden.

Von 912 Corail® Schäften wurden 5 Schäfte auf Grund einer aseptischen Lockerung revidiert (= Revisionsrate: 0,5%). Nach einer Kaplan-Meier-Überlebenskurve beträgt die Implantatüberlebensrate nach 5 Jahren 99% und nach 10 Jahren 97,6%. Elf weitere

Schaftrevisionen mussten auf Grund von periprothetischen Frakturen durchgeführt werden (=1,1%).

Schlussfolgerung: In unterschiedlichen Registerdaten wie zum Beispiel aus Australien, Neuseeland, Dänemark und England wird ein Implantatüberleben für den Corail® Schaft von 97% bis 99% nach bis zu 15 Jahren Follow-up berichtet. Die Ergebnisse unserer Studie zeigen mit internationalen Registerdaten absolut vergleichbare, sehr gute klinische Ergebnisse und nur ein minimales Risiko für aseptische Lockerung für den Corail® Schaft. Die Zahl der frühen periprothetischen Frakturen konnte durch Adaptierung der Implantationstechnik eliminiert werden.

Inhaltsverzeichnis

4 Glossar und Abkürzungen

ANFH	Avascular necrosis of the femoral head
AVN	Avascular necrosis
CoC	Ceramic-on-Ceramic
HA	Hydroxyapatite
IQR	Interquartile range
JSN	Joint space narrowing
Lig.	Ligamentum
M.	Musculus
MoM	Metal-on-Metal
NSA	Neck-shaft angle
NJR	National Joint Registry
OA	Osteoarthritis
PE	Polyethylene
PMMA	Polymethylmethacrylate
THR	Total hip replacement
UHMWPE	Ultra-high molecular weight polyethylene
WHO	World Health Organization

5 Abbildungsverzeichnis

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7 General Part

7.1 Introduction

A total hip replacement (THR) has been referred to the most successful orthopaedic procedure and has increased the quality of life for all affected patients.(4-6) More than 100 years ago, the first total joint replacement was performed by Themistocles Gluck in Berlin in1890, implanting a device made by carved ivory.(7) The first prosthetic THR was developed by Wiles in 1938, inserting a pre-formed acetabulum and femoral head made of stainless steel .The acetabulum was prevented from rotating by a couple of screws, and the femoral head was secured by a bolt passing through the neck of the femur.(8) Time went by and it took until the 1950s so that the hip replacement procedure had become reliable and simple enough to be practiced by normal surgeons. Two major contributions of the development of progress in THR were made around that time, first, Austin Moore, who introduced the long stem prosthesis in the 1950s, and then, in 1963, Sir John Charnley introducing a new design using highly cross-linked polyethylene on a metal femoral head and stem fixation with the use of bone cement.(9, 10) This type of implant is still in use today.

Nowadays, the development of hip prostheses reaches a high level of maturity. There are hip implants of different types and materials like ceramic, metal alloys and polymers for clinical use applied. Today it is estimated that around one million patients undergo surgery for THR every year around the world.(11) Kurtz et al. predicted that primary hip arthroplasty procedures in the United States will grow by 174% between 2010 and 2030.(12) From 2003 to 2015, 708.311 primary hip operations were documented in the National Joint Registry (NJR) for England, Wales, Northern Ireland and the Isle of Man. The majority of the primary hip procedures were carried out in women (males 40.3%, females 59.7%). The median age at primary operation was 69 years (IQR 61- 76). In 2011, 22 932 patients were treated with a THR in Austria.(13)

The most common reason for implanting a THR is primary osteoarthritis (93%), which is associated with aging. Further reasons for undergoing a THR may be fracture or trauma, whereby THR gives back mobility and reduces pain for the patient. There are several reasons for primary revision (reoperation) of the prosthesis.

In the NJR of England 2015 (the date for the most recent data available), the main reason for revision was aseptic loosening (52,0%), followed by pain (23,4%), lysis (15,8%) and dislocation/subluxation (15,0%). In case of cemented THR the most common articulation was metal-on-polyethylene, whereas in case of cementless procedures ceramic-on-ceramic was favored.(14)

7.2 Hip disease

Although the joints of the human being are able to bear large stresses, joint degeneration in elderly people, the osteoarthritis (OA), might be observed afterwards. OA has often been found in approximately 50% of adults over the age of 65 years.(15) However, different changes in the hip, innate or acquired in the course of life, might cause the implantation of an artificial joint replacement. Most of the people, who are undergoing THR, are women.(16) Individuals with hip disease will often suffer from pain, stiffness of the hip and immobility with its social consequences. Recurrent inflammatory joint conditions, rheumatological disease, can also be another important category of patients needing a THR. These are often younger patients with either ankylosing spondylitis or rheumatoid arthritis. Patients who had an early pediatric hip disease with deformation of the articulating portion of the pelvis or the femur (e.g. dysplastic hips, epiphysiolysis, and Perthes' disease) and patients with fracture of the femoral neck, are also possible candidates for THR. A hip replacement is only considered if medication, conservative treatment or physical activity/therapy does not have a satisfactory effect.

7.2.1 Primary osteoarthritis of the hip

Primary osteoarthritis of the hip is defined as an advanced degeneration and ultimately loss of joint cartilage, especially in heavily loaded joints, with a painful functional reduction. OA has characteristic structural alterations of the joint, including focal degradation of articular cartilage and remodeling of subchondral bone with the formation of osteophytes at the joint margins, as well as an illness defined by a person's symptoms, including pain, fatigue, mood alterations and sleep disturbance.(17, 18)

A primary and a secondary osteoarthritis can be distinguished.

- Primary osteoarthritis (25%): The cause of the disease is unknown. Mechanical and biological factors might play a major role in aging of the cartilage, bone and connective tissue.
- Secondary osteoarthritis (75%): Development out of an incomplete healed hip disease. Main causes are hip dysplasia (30%), epiphyseolysis capitis femoris (20%) and rheumatic and bacterial osteoarthritis (10%)

Pathogenesis: It is triggered by an increased mechanical stress, which is associated with a loss of matrix molecules and degeneration of cartilage cells. Reinforcing factors are overweight and high-performance sport. From chondrocytes and synovial cells liberated proteases enhance the process.

Radiological classification of OA by Kellgren and Lawrence (19):

Grade 0: no radiographic features of OA are present

Grade 1: doubtful joint space narrowing (JSN) and possible osteophytic lipping

Grade 2: definite osteophytes and possible JSN on anteroposterior weight-bearing radiograph

Grade 3: multiple osteophytes, definite JSN, sclerosis, possible bony deformity

Grade 4: large osteophytes, marked JSN, severe sclerosis and definite bony deformity (20, 21)

7.2.2 Avascular necrosis of the femoral head

Avascular necrosis (AVN) is defined as cellular death of bone components due to interruption of the blood supply; the bone structures then collapse, resulting in bone destruction, pain, and loss of joint function. The avascular necrosis of the femoral head (ANFH) can either be traumatic or non-traumatic. AVN usually involves the epiphysis of long bones, such as the femoral and humeral heads and the femoral condyles, but small bones can also be affected. In clinical practice, AVN is most commonly encountered in the hip.(22) The non-traumatic avascular necrosis of the femoral head is a frequently progressive disease that occurs in young adults. The most common reasons for an ANFH are:

- chronic corticosteroid therapy
- alcoholism
- smoking
- systemic lupus erythematosus
- hyperlipidemias
- human immunodeficiency virus
- haemoglobinopathies
- chronic renal failure
- diabetes

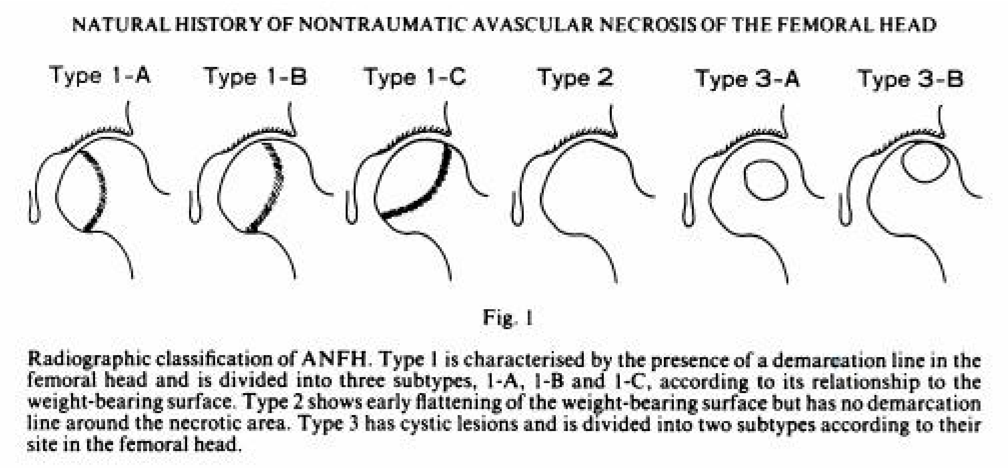


Figure 1: Figure 1: Nontraumatic avascular necrosis of femoral head from Ohzono et al. J Bone Joint Surg Br. 1991(3)

The annual incidence of avascular necrosis is about 5 per 10 000 population.(23) Males population is four times more frequently affected than the female population. The main age of this disease, which affects both joint in 30-70%, is between 25 and 55 years with a peak at 35 years.(24)

7.2.3 Hip dysplasia

The hip dysplasia is a very common congenital skeletal disease which occurs in around 3% of the infants. The prevalence in the USA is estimated to be 1.5–15 per 1000 births.(25) The acetabulum is not correctly formed and the femoral head is not completely covered. In most cases, there is also a steep thigh neck angle (coxa valga). As a consequence of this faulty molding partial (subluxation) or complete dislocation of the femoral head might occur. Due to the faulty molding, there is an overload in the joint, which often results in OA. Hip dysplasia tends to occur five to eight times more often in the female population than in the male population. It may occur in one or both joints simultaneously. Early diagnosis, using the Ortolani and Barlow tests, is important in the treatment of hip dysplasia to prevent hip dislocation and to permit the best possible hip joint development.(26, 27)

7.2.4 Articular fractures

Articular fractures (femoral neck or head fracture or acetabular fracture) often lead to osteoarthritis, because there is also an injury of the cartilage. The cartilage injury entails a deformation, so that sliding of the two articulating surfaces without friction is not possible any more, resulting in a joint degeneration.

7.3 Anatomical structure of the human hip joint

The hip joint (articulatio coxae) is a special ball and socket joint, an enarthrodial joint that allows movements in three dimensions of space. It is built by the acetabulum and the femoral head. Nearly two-thirds of the femoral head (caput femoris) is encompassed by the acetabulum which is increased through a bony (limbus acetabuli) and a fibrocartilaginous rim (labrum acetabular). The femoral head rubs on the crescent-shaped articular surface (facies lunate). The joint is surrounded by a strong joint capsule, which is amplified by three strong ligaments (Lig. iliofemoral, Lig. pubofemoral, Lig. ischiofemoral).(2)

7.3.1 Bony structures

The hip joint consists of the pelvic bone and the tigh bone.

7.3.1.1 Pelvic bones

The pelvis consists of the two hip bones (ossa coxae) and the os sacrum. These three bones are forming the so-called pelvic ring and are responsible for the load transmission from the upper to the lower body.(28) The hip bone is composed of three parts, the pubic bone (os pubis), the iliac bone (os ilium) and the ischium (os ischium).(28)

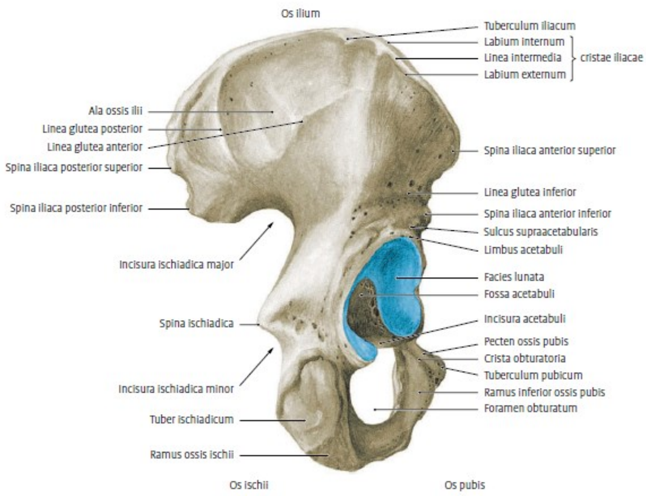


Figure 2: Figure 2: Os coxae, outer side from Anderhuber et al. Waldeyer - Anatomie des Menschen(2)

7.3.1.2 Thigh bone

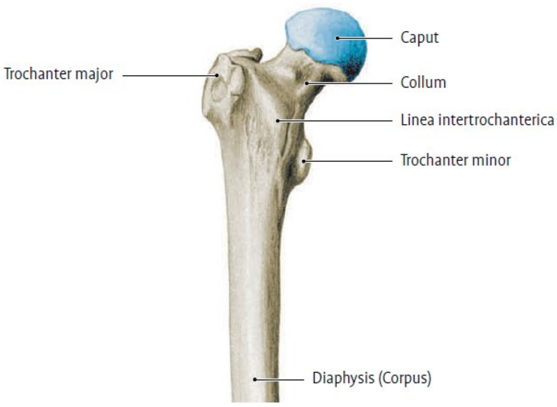


Figure 3: Femur from Anderhuber et al. Waldeyer - Anatomie des Menschen(2)

The femur is the longest bone of the human skeleton and essentially determines the height. It is subdivided into the femoral head (caput femoris), the femoral neck (collum femoris), the femoral shaft (corpus femoris) as well as the femoral condyles (condyli femoris).(27) Because of these anatomical features some clinically relevant angles can be determined on the femur and the hip joint which are also of relevance in the arthroplasty.

7.3.2 Joint capsule and ligaments of the hip

The joint capsule is fixed to the acetabular cup outside the labrum on the one hand, and on the other hand, on the femoral head. The ventral part includes the complete femoral neck while the dorsal part only encloses two-thirds. The fossa trochanterica and the two trochanters remain extracapsular.

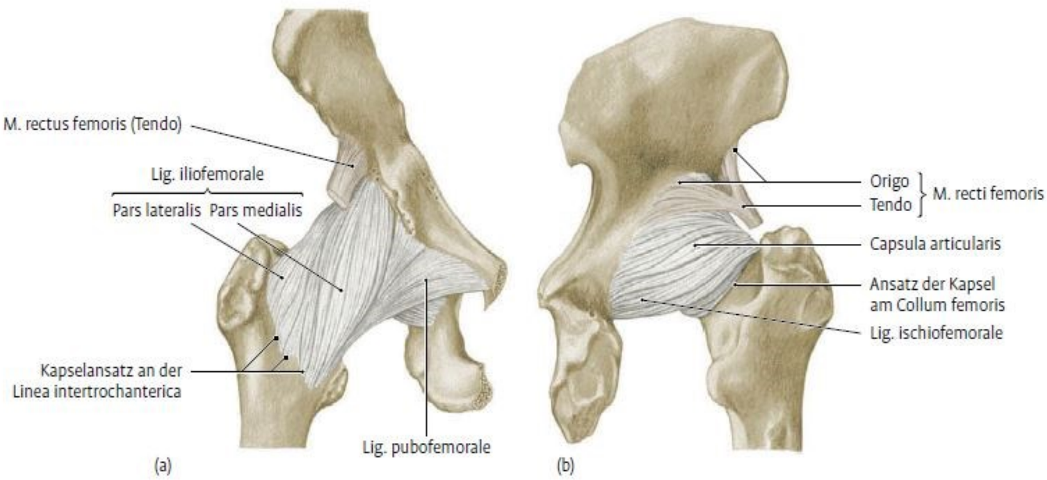


Figure 4: Ligaments and capsule of the hip from anterior (a) and dorsal (b) from Anderhuber et al. Waldeyer – Anatomie des Menschen(2)

Five ligaments are distinct, four of them are intracapsular and one remains extracapsular. Among them, there is the strongest ligament of the human body, the Lig. iliofemorale. It inhibits the hyperextension of the hip joint and prevents tilting the pelvis.
The Lig. ischiofemorale lies dorsally and amplifies the capsule. Due to its location, it inhibits the internal rotation, extension and abduction.
The Lig pubofemoral reinforces the joint capsule, caudally. It is the weakest out of the three ligaments above (29) It inhibits the extension, abduction and external rotation.
The zona orbicularis also constitutes a thickening of the capsule. Filler (2005, p.5) describes them as circular fibers having a sling or collar around the femoral neck. The one intraarticular ligament is the Lig. capitis femoris. It acts as a leading structure for blood vessels and has no mechanical function (2, 27)

7.4 Muscles

7.4.1 Flexors

The iliopsoas muscle consists of two parts, the M. psoas major and the M. iliacus. They are responsible for the diffraction of the hip joint, external rotation and adduction and raising of the torso in back position. The M. psoas minor occurs in only 30% of all people and supports the M. psoas major. Further flexors muscles of the hip joint are the M. sartorius, M. tensor fasciae latae and the M. rectus femoris.(2)

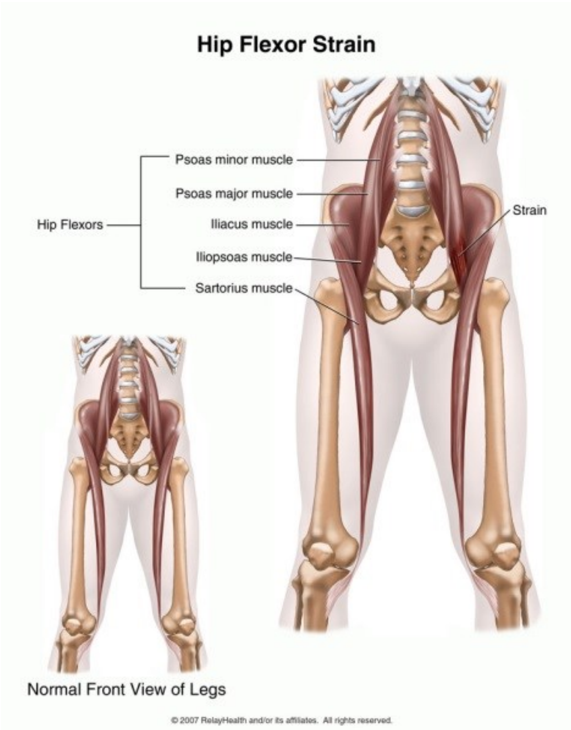


Figure 5: Flexors of the Hip from http://lillypt.com/the-quick-trick-to-getting-rid-of-back-pain/ accessed 2016/10/16

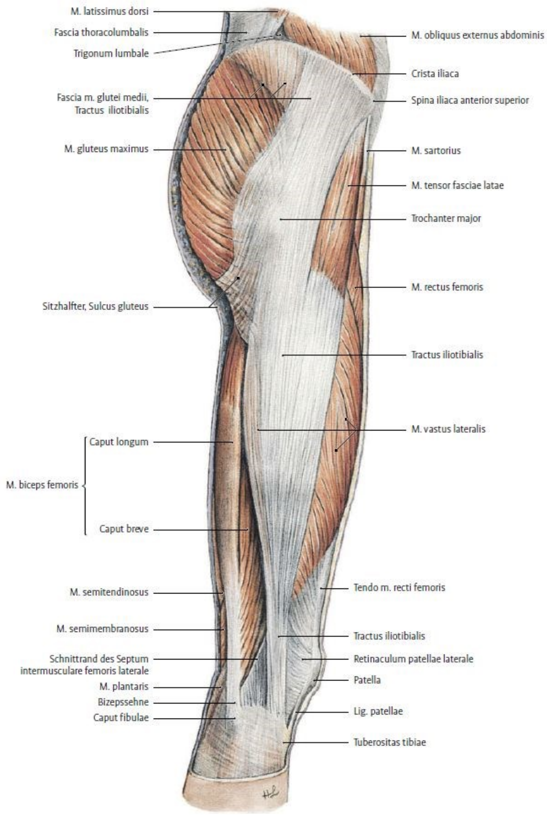


Figure 6: External hip and thigh muscles from lateral view from Anderhuber et al. Waldeyer - Anatomie des Menschen(2)

7.4.2 **Extensors**

The M. gluteus maximus is the strongest extensor in the hip. It also causes an external rotation; the upper fibers are responsible for abduction and the lower fibers for adduction. The M. semitendinosus, the M. biceps femoris and the M. semimembranosus also act as extensors on the hip joint.(2)

7.4.3 **Adductors**

The adductors are located on the inside of the hip joint: M. pectineus, M. adductor longus, M. adductor brevis, M. adductor magnus and M. gracilis are leading the thigh towards the body.(2)

7.4.4 **External rotators**

External rotation is done by the M. obturator internus and M. obturator externus, two twin muscles (M. gemellus superior and M. gemellus inferior and the square thigh muscle (M. quadratus femoris)). All muscles cause eversion, as well as, the M. piriformis.(2)

7.4.5 **Internal rotators**

The middle gluteal muscle (M. gluteus medius), the little gluteal muscle (M. gluteus minimus) and the M. tensor fascia lata cause an internal rotation and adduction in the human thigh.(2)

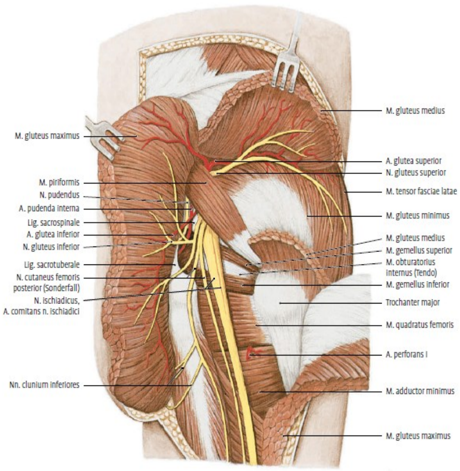


Figure 7: Regio glutealis from Anderhuber et al. Waldeyer - Anatomie des Menschen(2)

7.5 Angles and axes in the hip

For an endoprosthetic treatment of the hip and an assessment of the joint some clinical parameters are important. These are:

7.5.1 Collum-corpus-angle (CC-angle)

This is angle between the axis of femoral neck and the axis of the femoral diaphysis. It is also called collo-diaphyseal angle or collum corpus angle. In the newborn it is 150° and between 126° and 128° in the adult.(29)

7.5.2 Caput collum-diaphyseal angle (CCD-angle)

This angle, also known as neck-shaft angle (NSA), is formed by the axis of the femoral shaft and a line drawn along the axis of the femoral neck passing through the center of the head of the femur. Between different studies, the NSA is ranging between 125° and 133°.(30, 31) An abnormally small angle is known as coxa vara and an abnormally large angle as coxa valga.

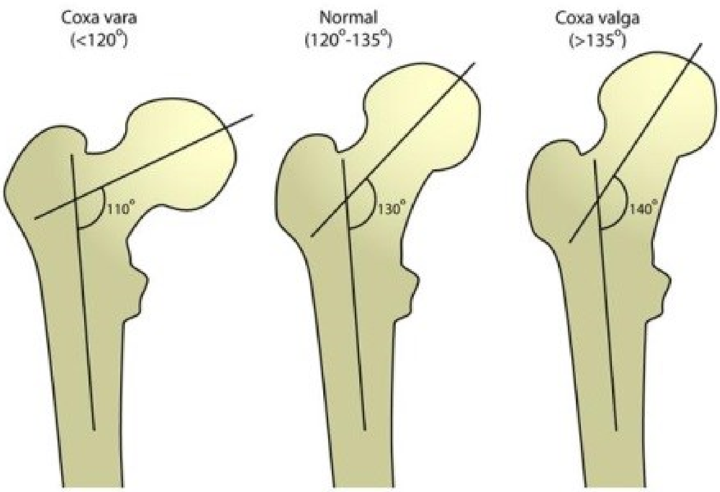


Figure 8: CCD-angle from https://radiopaedia.org/articles/coxa-valga accessed 2016/10/16

7.5.3 Centre-edge angle (CE angle)

The CE-angle is an angle between a vertical line through the center of the femoral head and a line from the center of the femoral head to the most lateral part of the acetabulum. Very small values indicate a subluxation or dislocation, while a very large one indicates a coxa profunda.(31)

7.5.4 Antetorsion angle

Femoral antetorsion is the angle between the central axis of the neck and the transcondylar axis. It was first described by Julius Wolff in 1868.(32, 33)

It is well known that the angle of anteversion of the femoral neck is greater in young children than in older children and decreases during the first years of life. An investigation of 630 cases of dried specimen showed an average torsion of the femur of 8.021 degrees with a variation from +38 to -20 degrees.(32) Abnormal femoral antetorsion is associated with slipped capital femoral epiphysis, developmental dysplasia of the hip, and early-onset hip osteoarthritis.(34-36)

7.5.5 Inclination (IN) und Anteversion (AV)

The inclination is the angle between the implanted cup axis measured against to the longitudinal body axis, usually 45-50 °.The anteversion of the hip is defined through the angle between the socket entry level, a tangent to the front and rear hip socket rand at CT-sectional plane and the sagittal body axis, parallel to an anterior-posterior directed line exactly in the middle between the two pelvic bones.(37)

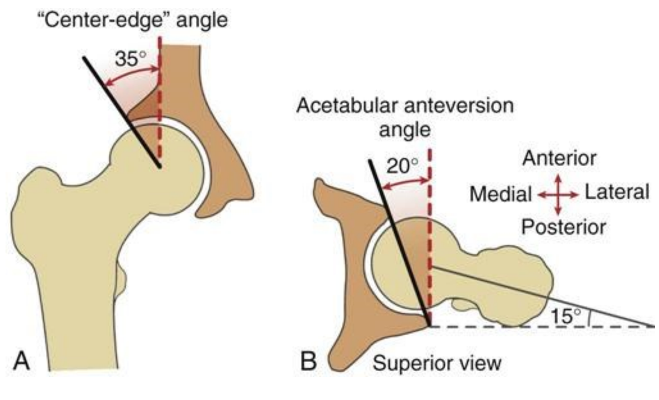


Figure 9: Angles of the hip from http://clinicalgate.com/hip-3/ accessed 2016/10/16

7.6 Ranges of motion of the hip joint

The determination of the range of motion in healthy as well as in an operated patient is known to be of great importance. It is possible to make statements regarding joint function, ligaments and muscle status.

Movements in the hip joint can be determined by three main axes: the transverse axis for extension/flexion, the sagittal axis for abduction/adduction and the vertical axis for external/internal rotation.(2)

The range of motion is shown in Figure 8:

Extension: 0°~10°	Flexion: 120°~140°
Adduction: 15°~20°	Abduction: 30°~45°
External rotation: 40°~50°	Internal rotation: 30~45°

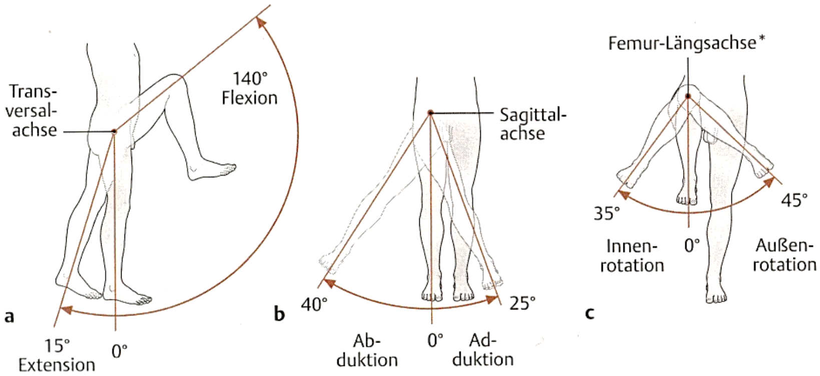


Figure 10: Range of motion hip from Aumüller et al. Duale Reihe Anatomie (27)

The neutral-null-method has been established for the measurement of joint movement. The possible degrees of freedom of each joint are measured by an upright standing or lying human. The output position is always referred to as the middle of the three values and two opposite movement directions around the same axis to the left and right. If the physiological starting position cannot be achieved, the angle of the maximum possible basic position is used instead of the centrally standing zero degrees.

7.7 Materials in hip joint replacements

An orthopaedic implant has to accomplish certain criteria. It has to fulfill mechanical standards, but also chemical and biological properties of an implant are important. Implants survival is often limited, by fracture of the carrier material, septic or aseptic loosening or wear of the sliding contact surface. There are special requirements for used materials:

- not to trigger allergies and/or immunological processes
- not to cause foreign body reactions
- not be toxic for different tissues
- not to have an adverse influence on the cell growth
- not to have carcinogenic or mutagenic effects (38)

Furthermore, certain functionality must be added, which is the natural joint justice and at least everyday movements. The surgeon demands like easy implantability and good anchoring ability are also crucial features, which influence the frequency and practice as well as the survival of a device on the market. Fixation techniques for femoral stems are cemented or cementless. Possible bearing combinations could be:

- Ultra-high molecular weight polyethylene (UHMWPE)
- Ceramics (alumina, zirconia)
- Metals (steel)

Last but not least, the costs for production should be manageable.(24)

7.7.1 Metals

The three main groups of biomedical alloys used for the articulating surface, stem and taper are cobalt-chromium alloys, titanium alloys and stainless steel.(39) The most common used stainless steel was 316L. It was an early metal of choice in joint replacements. Its use is limited by its relatively low resistance to breakage corrosion, even if the material is economical itself.(40) The "submarine steel", Cobalt-Chromium-Molybdenum (CoCrMo) alloy, is widely used today in THR. The English orthopaedic, Smith-Petersen, adapted this material for his "Smith-Peterson-Cup".(41) CoCrMo is valued for its corrosion resistance along with its high strength and fatigue and wear resistance.(42) On the other hand, in case of MoM bearings, the metal debris and ions that originate from CoCrMo might cause adverse biological reactions.(43, 44) Since the issues associated with MoM articulations were discovered, their use has significantly decreased. In Sweden for instance, the use of MoM bearings decreased to 0.4% in 2013.(45)
Because of the introduction of titanium alloys, steel implants got replaced by time due to the advantages of better biocompatibility and lower infection rates.(38)

7.7.2 Polymers

Ultra-high molecular weight polyethylene (UHMWPE) has been the most common used material for joint replacements. It was first introduced in the 1960`s.(46) It has an excellent bio-compatibility, sufficient mechanical properties and above-the-average tribological properties.(46-48) Although the conventional UHMWPE was performing well for decades, it created a sufficient volume of wear debris in a critical sub-micron size, which triggers macrophage activity, resulting in aseptic loosening of the implant. This was thought to be the main cause of late aseptic loosening.(49, 50)

This wear debris was also blamed to be responsible for resorption of bone and/or periprosthetic osteolysis.(6) Since the 1990s, UHMWPE has undergone structural developments introducing the more wear-resistant highly cross-linked UHMWPE (HXLPE).(51) This results in a lower resistance to crack propagation and a low fracture toughness.(24) From 2005 to 2013, the use of HXLPE increased from 1% to 70% in Sweden.(45)

7.7.3 Ceramics

Alumina (Al2O3) and zirconia (ZrO2) ceramics have been used in orthopaedics for more than 30 years. Advantages with these ceramics include low wear rates, resistance against scratch, chemical stability and biocompatibility.(51) Ceramic components are often recommended for younger patients or patients with metal sensitivity because among all bearings they have the lowest wear rate.(51) Early stage ceramics showed fractures and catastrophic failures, however, improvements in composition and structure led to enhanced mechanical properties.(51) CoC bearings showed lower rates of osteolysis than CoP bearings, but might be more fragile and sometimes this bearings produce squeaking sounds.(5)

7.7.4 Coatings

The advantages of using coatings in THR are to enhance bone ingrowth and to minimalize friction, wear debris or corrosion. Coatings provide a beneficial effect while the bulk of the component has a different function, like elasticity. Coatings must fulfill two essential requirements: biomechanical environments and sufficient protection of substrate from corrosion and no delamination in biochemical environments.(52) Coated articulating components have been used in joint replacements for many years. Today there are several commercially available coatings or coated components, for example deposited coatings such as TiN, TiAlN, AlTiN, TiNbN, CrN, ZrN and physical vapour deposition (PVD) or plasma-enhanced chemical vapour deposition (PECVD) Coated surfaces are generally recommended for patients who are known to be at risk for metal sensitivity. Today, hydroxyapatite coatings are the most common used coatings related to joint replacement. The main advantages are its biocompatibility and its osteoinductive properties. Early stability was shown to be better than press-fit and as good as cemented.(53) It has equally good osteointegrating results in young and elderly people.(53, 54)

7.8 Fixation and anchoring techniques

The anchoring of cup and stem of an artificial THR can be, roughly divided, either with bone cement or without bone cement. The cemented anchorage with polymethylmethacrylate (PMMA) introduced by Charnley was the standard in hip surgery for decades, but nowadays it comes into the background. Considering the incidence of aseptic loosening of the implant over a period of 5 to 10 years, cementless prostheses have a significantly lower revision rates than cemented, while the overall survival is comparable.(14) Considering the tendency of implant loosening in relation to wear-induced osteolysis, it is 3.76 times lower for cementless prostheses according to Wechter et al.(55) For the cemented implantation, a smooth polished shaft should be used, while for cementless implants an osteoinductive surface is of importance.(56)

7.8.1 Fixation with bone cement

With the first use in 1960, the fixation with bone cement has a relatively long tradition. The prosthesis design is a decisive factor for the operation results. The prosthesis neck is limiting the penetration depth into the femoral shaft in cemented stem prosthesis. In addition, the prosthesis neck with his connection to the bone cement leads to an improved power transfer to the femoral shaft. Bone cement (polymethylmethacrylate, PMMA) is biocompatible, which means it does not come into direct contact with the bone. There will be no growth of bone into the PMMA. PMMA has some unfavorable properties: During the curing process, the polymerization produces heat which can lead to denaturation of protein and can cause cell necrosis. There can be also monomers with a locally toxic effect. These effects can be compensated with appropriate surgical techniques. Another important and much-discussed factor is the surface texture of the material. Rough surfaces connect better with the bone cement as smooth ones. In case of loosening of the prosthesis, wear particles can be produced because of the rough surface, which is why highly polished shafts are also in use. While aging, PMMA can get brittle leading to fractures of the cement. Special sensitivity is against lateral impact and shear forces. Bone cement clogs the medullary cavity, interferes with the blood flow and prevents the repair processes. Bone cement is getting hard within a few minutes. For homogeneity of the cement, it gets mixed without bubbles in a vacuum and it is also implanted under vacuum with the prosthesis in order to avoid damage to the cancellous bone or even squeezing into the bloodstream, leading to cement embolism. The reaction of the human tissue and bone to PMMA remains unpredictable and is often crucial for the stability of the prosthesis.(24, 57, 58)

7.8.2 Fixation without bone cement

For a fixation without bone cement, direct contact between implant and bone is needed. It is generally accepted that fixation surfaces need to be circumferential and in continuous. These qualities enhance metaphyseal osseointegration and proximal stress transfer and decrease bone loss from stress-shielding. Prostheses with a long stem tend to transfer the force punctual to the femur. Proximal atrophy of bone and trouble removing the stem were observed. Therefore, the ends are partly manufactured without roughness. Direct bearing the bone is a requirement for the use of materials with osteointegrating surface to be sufficiently stable and to achieve adequate load. The smooth surface at the lower end of the stem should prevent the punctual transformation of forces to the femur. To achieve a high stability from the outset, the prosthesis must be fitted as closely as possible in the bone bed. By adequately load the ingrowth of bone trabeculae in the roughness of the prosthesis is induced.(24, 57, 58) A recent systematic review demonstrated no difference in postoperative mortality, revision rates or rates of complications between cemented and cementless stems. Cementless stems offer shorter operating times and diminished blood loss.(59)

7.9 Surgical approach

Different surgical approaches are used for THR.

7.9.1 Anterior approach

With the anterior approach, also known as Smith-Peterson, the hip joint is reached between the gap of the M. tensor fasciae latae and the M. Sartorius. The preparation of the femur is done in hyperextension and external rotation.

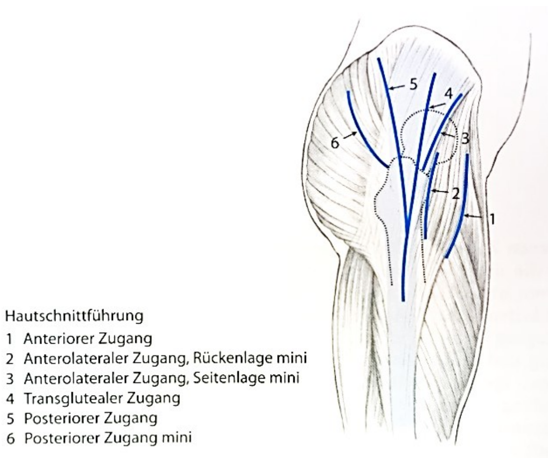


Figure 11: Surgical approaches from Pfeil et al. Hüftchirurgie(1)

The main indications are open reduction by dislocation of the hip of the infant, ventral impingement or THR. The Patient is positioned in the supine or lateral position. The M. Sartorius, M. rectus femoris and M. iliopsoas on one side and M. tensor fasciae latae on the other side are mobilized and held back by retractors.(1, 20, 60-62)

7.9.2 Anterolateral approach

With the anterolateral approach, popularized by Watson-Jones and modified by Charnley, Harris and Müller, the hip joint is reached between the gap of the M. gluteus medius and the M. tensor fasciae latae. Decisive is the approach of the hip capsule anterior of the M. gluteus medius with retraction of the same muscle dorsal lateral without splitting it. It's the most common used surgical approach in Europe for THR, but is also suited for femoral neck osteotomy, synovectomy or femoral neck reconfiguration. The Patient is positioned in the supine or lateral position. Special caution has to be taken for the N. glutaeus superior.(1, 20, 61, 63, 64)

7.9.3 Transgluteal approach

The hip joint is exposed through a muscle splitting approach. A longitudinal section is made through the Fascia lata. The M. gluteus medius and the M. vastus lateralis are split at their anterior third. This approach is most common used for THR. T offers a good view over the acetabulum and the femoral neck.(1, 20)

7.9.4 Posteriorlateral approach

Approach to the hip joint in the space between the anterior border of the M. gluteus maximus and the posterior border of the Fascia lata and in the depth the M. gluteus medius. Main indications are primary or revision arthroplasty. The distal expandability is especially favorable for revision surgery. It is the most common used surgical approach in the USA. (1, 20, 61)

7.9.5 Medial approach

With the thigh slightly flexed and abducted curved longitudinal incision approximately five cm distal at the groin. Temporary, a partial detachment of the long abductor at the area of its tendinous insertion has to be done. Afterwards, the hip joint can be opened. The femoral head can be medial and distal dislocated. For the implantation of the prostheses femoral neck osteotomy and head neck resection is done.(1, 20, 65)

7.10 Implants

7.10.1 Corail® Stem

The first implantation of Corail® stem was carried out by the French "ARTRO-Groupe" in 1986. By 2012, more than 1,000,000 stems have been sold since its launch. Meanwhile, the hydroxyapatite (HA) coated stem has been established worldwide by excellent long-term results with a survival rate of 98% following 10 years and 97% after 15 years.(66)

The Corail® Stem offered five different primary stems and two cemented stem. In 2015, the Corail® line extension was launched with short neck stems with 125° and 135° neck angles with or without collars and a High Offset Stem with collar.

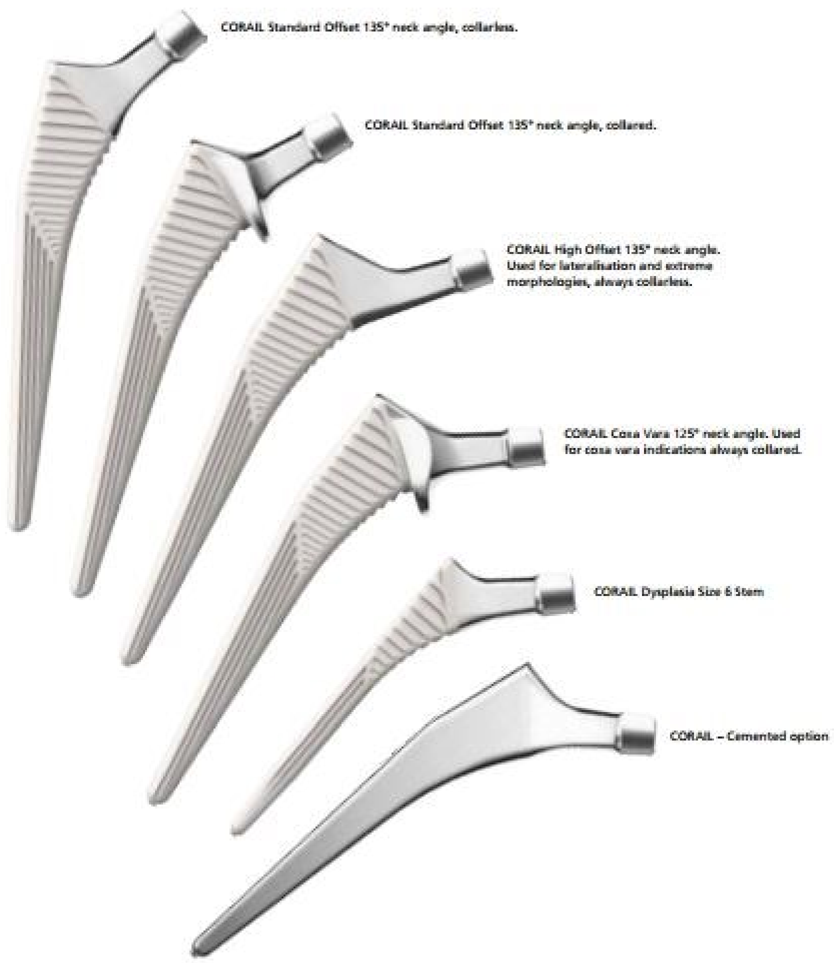


Figure 12: Corail® stems from http://www.corailpinnacle.net/sites/default/files/2016-04/corail-product-rationale-and-surgical-technique.pdf accessed 2016/10/24

The Corail® stem is a double-tapered titanium stem which is fully coated with 150 µm HA applied by an atmospheric plasma spray.(67, 68) It is a foursquare, straight implant and for three-dimensional stabilization the proximal part is flared in the coronal und sagittal plane. It is made of forged titanium alloy (TiAl6V4). The stem is entirely coated with HA to prevent release of metal ions and to provide better osseous integration. It has also horizontal and vertical grooves to enhance primary stability.(68) It is available in a range of sizes (6 to 20) and neck offsets (Standard, 'Lateralised Coxa Vara', and 'High Offset') and can be used with or without a collar. The primary mechanical fixation is offered by press-fit fixation, the secondary fixation is created through the osseous integration by the HA.

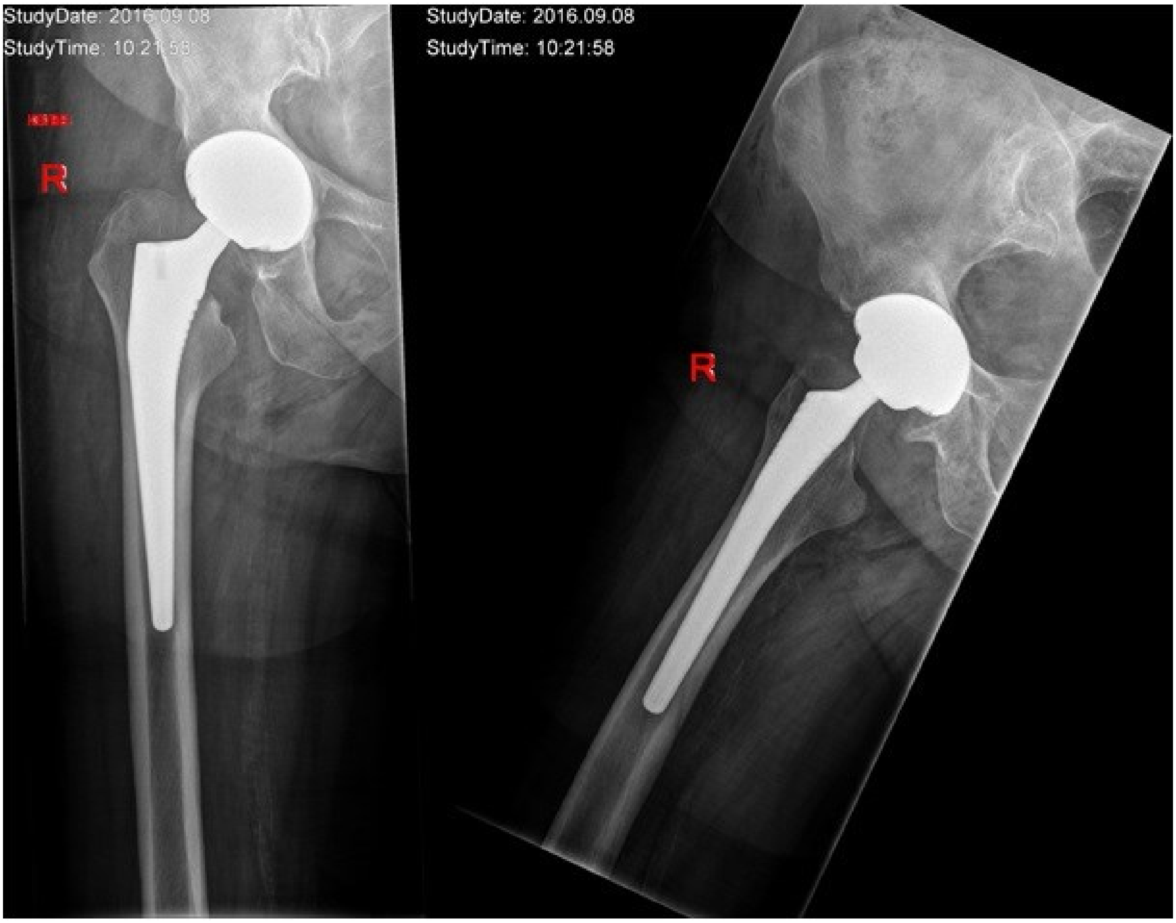
8 Special Parts

8.1 Study Aims

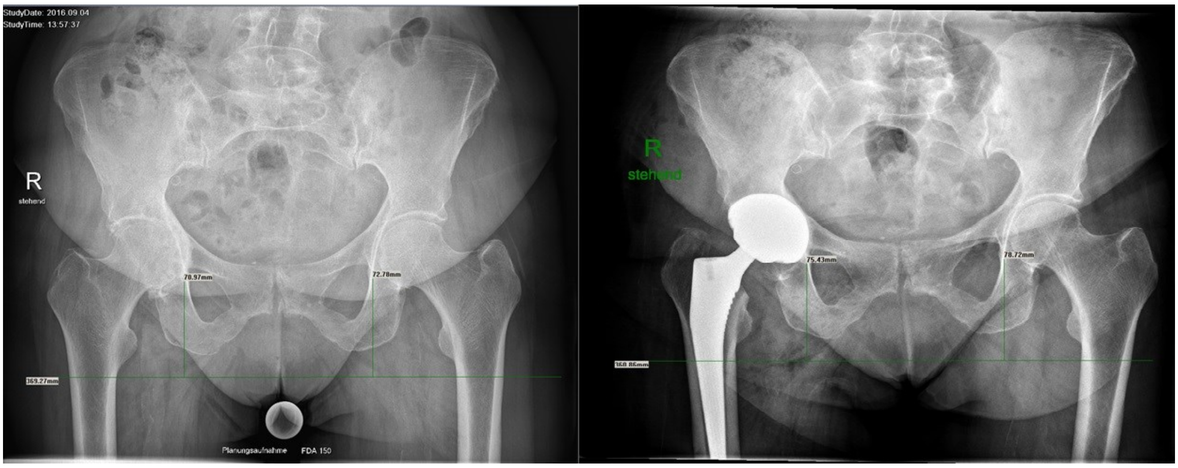
In 2005, the Corail® stem was first introduced at the Department of Orthopaedic Surgery in Graz and nowadays it is the implant of first choice. In this retrospective study, 891 patients, 408 men and 483 women, who had a primary THR performed with the Corail® stem, were included. In total 998 operations were performed. The primary aim of this study was a survival analysis of the Corail® stem. Furthermore, the clinical and radiological performance of the Corail® stem was determined. Therefore, radiographs of all patients were assessed for leg length discrepancy, sign of stress shielding, lysis, heterotopic ossification according to classification system of Brooker, resorption in Gruen zones and implant position. This was based on analysis of the data of a well-documented patient cohort.

8.2 Materials and Methods

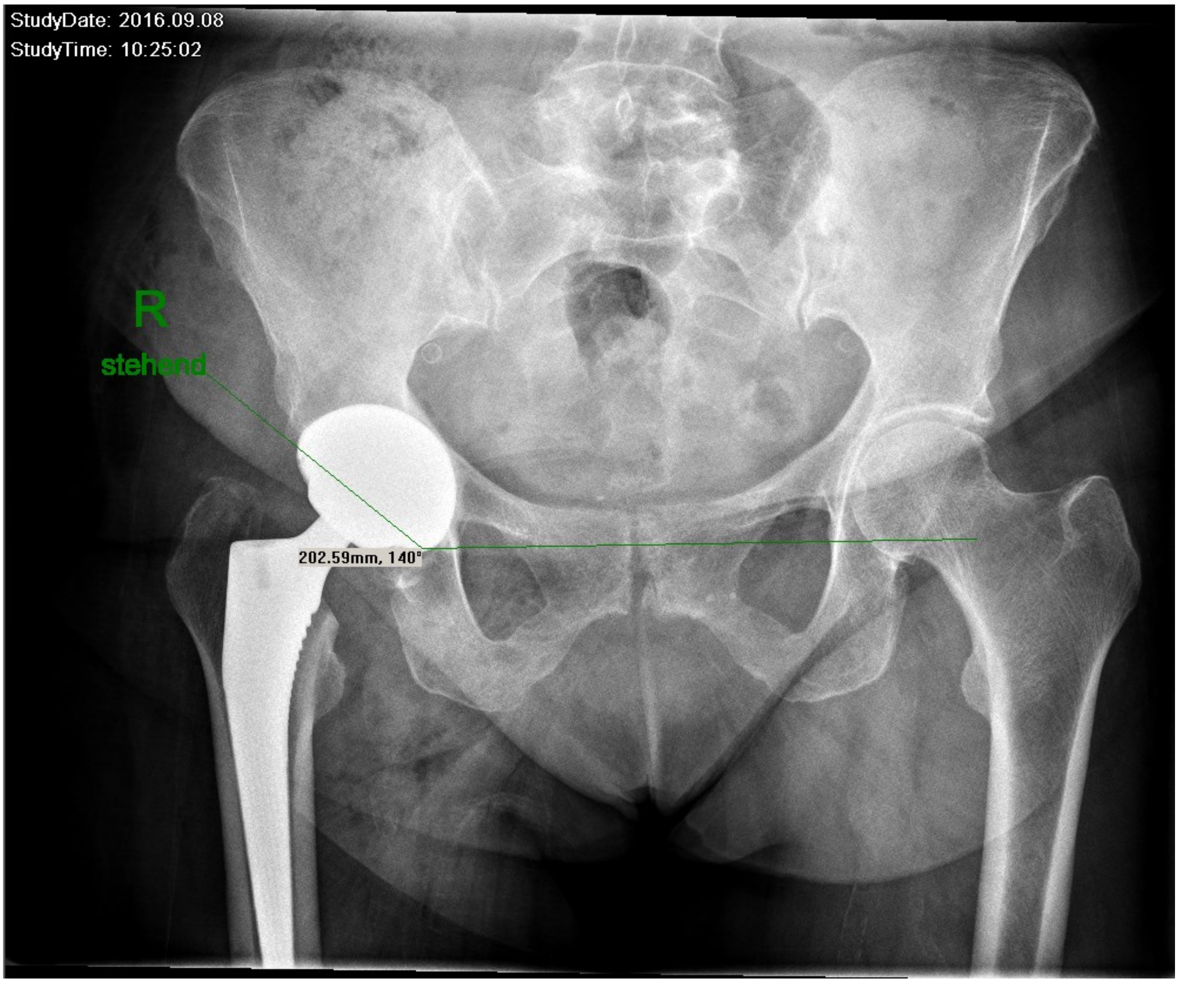
From January 2005 to December 2012, 1782 patients were treated with primary THR at the Department of Orthopaedic Surgery, Medical University of Graz. Eight-hundred-ninety-one patients, 408 men and 483 women, were treated with a Corail® stem and included in this study. For these patients, a new external data base for study-related information was created. Apart from name, gender, age and operation side, the operations of the corresponding patient reports were searched and information regarding surgical indications, anchorage, surgeon and implant size of cup and stem were taken into the database. Height, body weight and BMI, as well as the ASA score were collected from the preoperative anesthesia suitability protocols and entered into the data. Based on the BMI, the patients were divided into groups corresponding to the obesity classification. This was done according to the WHO criteria from 2004 in the categories underweight, normal weight, overweight and obesity. In this study, patients aged 18-91 years with a primary or secondary osteoarthritis (avascular necrosis, tumour, hip dysplasia, femoral neck fractures) were included. Exclusion criteria were preliminary operation on the hip or age younger than 18 years.



Assessment of the radiographs included leg length discrepancy, cup inclination, sign of stress shielding, lysis signs, heterotopic ossification according to Brooker,(69) resorption rate in Gruen zones and the implant position (axis deviation of about 5° varus or valgus)



The leg length discrepancy was measured by the difference of vertical lines from the acetabular teardrop figure to a horizontal line pre- and postoperatively.



The cup inclination was measured by a line between the acetabular teardrop figures and the inclination of the cup.

8.3 Results

Patients with bilateral hip prostheses were assumed to be two independent patients. Overall, 46 female and 61 male patients had bilateral implantations.

At the beginning, 891 patients, 408 men and 483 women, treated for osteoarthritis of the hip were included in the study. Clinical and radiological examinations were planned 3 months, 6 months, 1 year, 3 years and 5 years, postoperatively.

Overall, 807 patients were available for examination after 3 months (one patients died, four stems had to be revised and 64 patients were lost to follow-up), 738 patients after 6 months (two patients died and 68 were lost to follow-up) and 667 patients one year following index surgery (five patients died, 45 were lost to follow-up). Three years postoperatively, 532 patients were investigated (17 patients died, 2 stems had to be revised, 123 were lost to follow-up), and 264 patients following 5 years (33 of the cohort died, 5 stems had to be revised and 121 were lost to follow-up. Additionally, 135 patients had a follow-up higher than three but shorter than five years following index surgery). In total, 998 Corail® stems were implanted. Sixty-seven patients died between 2005 and 2016.

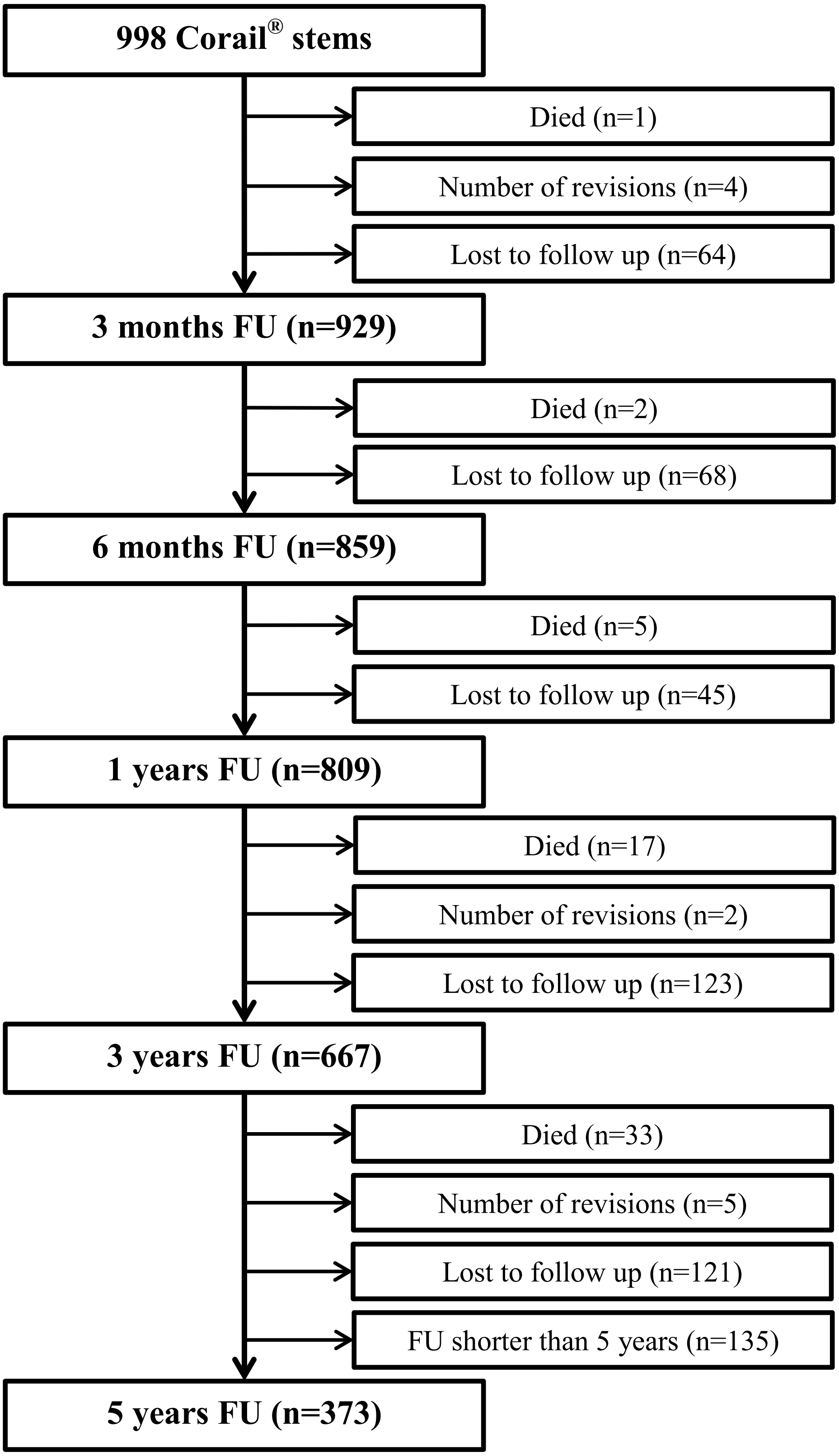


Figure 13: Development of the Corail@ stems during five years follow-up period

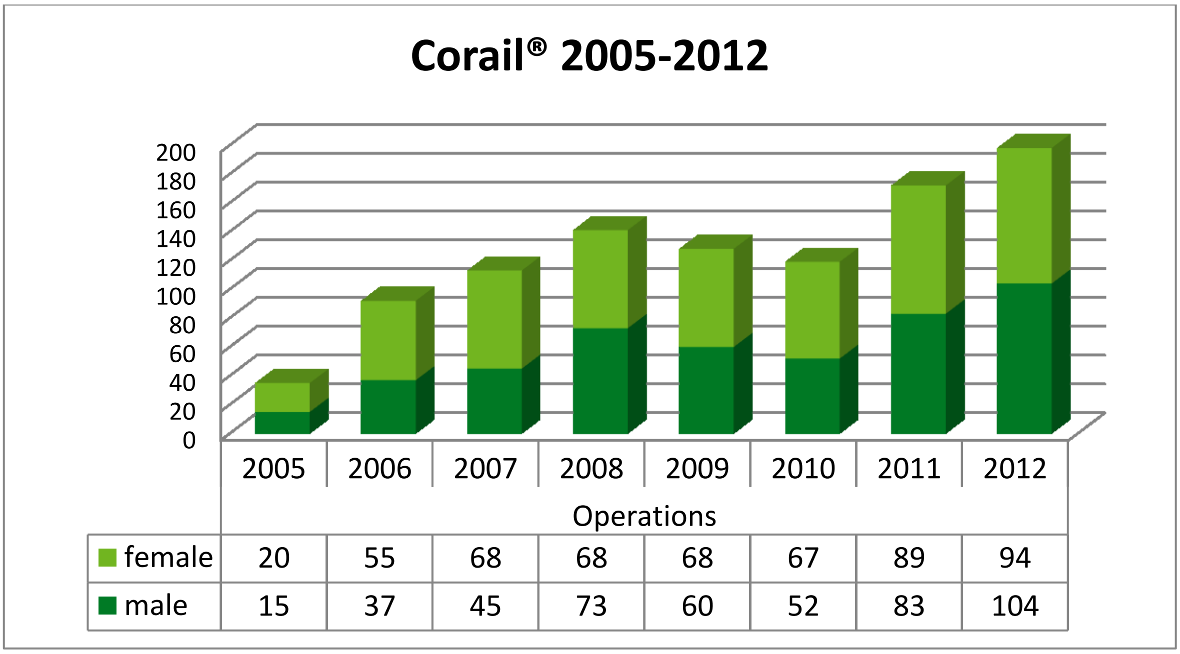


Figure 14: Annual implantations

In the year 2005 when the new implant was introduced at the department, 35 Corail® stems were implanted. Afterwards, the number of patients treated increased every year and till 2012, 198 Corail® stems were implanted, annually.

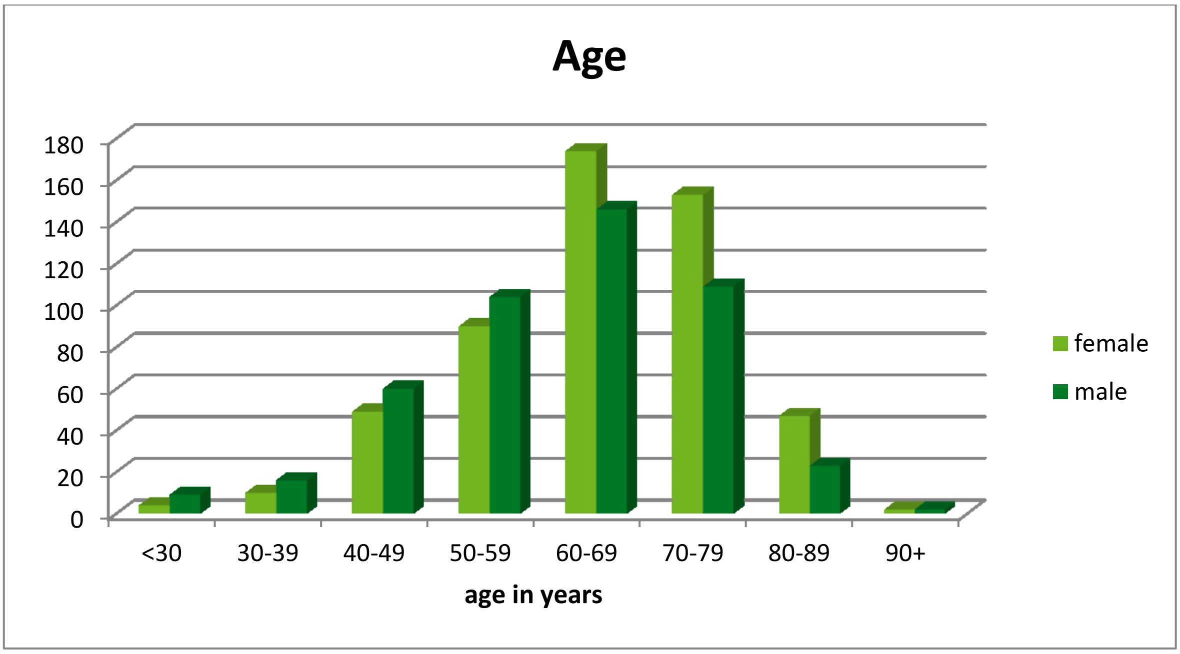
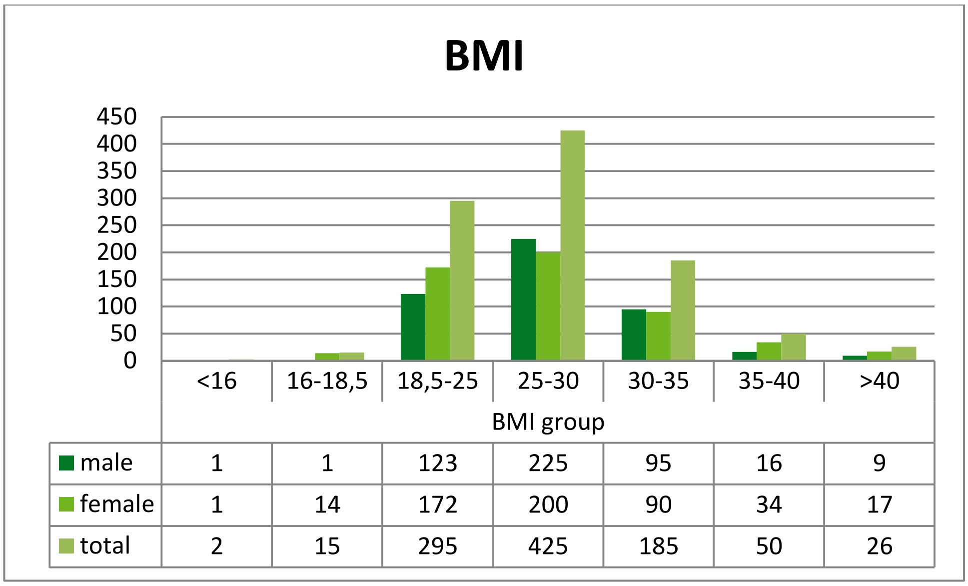


Figure 15: Age of patients

The mean age of the patients at time of operation was 63, with a range from 18 to 91 years. The mean age for female patients was 64, with a range from 18 to 91 years. The mean age for male patients was 61 with a range from 20 to 90 years.



	<16	16-18,5	18,5-25	25-30	30-35	35-40	>40
male	1	1	123	225	95	16	9
female	1	14	172	200	90	34	17
total	2	15	295	425	185	50	26

Figure 16: BMI of Patients

The mean weight of the female patients at the preoperative examination was 72 kilograms (range, 36 to 150 kilograms) and 85 kilograms for males (range, 49 to150 kilograms). The average BMI was 27,4 (standard deviation=5,55) for females with a range from 15,1 to 53,2. For males the mean BMI was 27,8 (standard deviation = 4,53) with a range from 16,0 to 56,8.

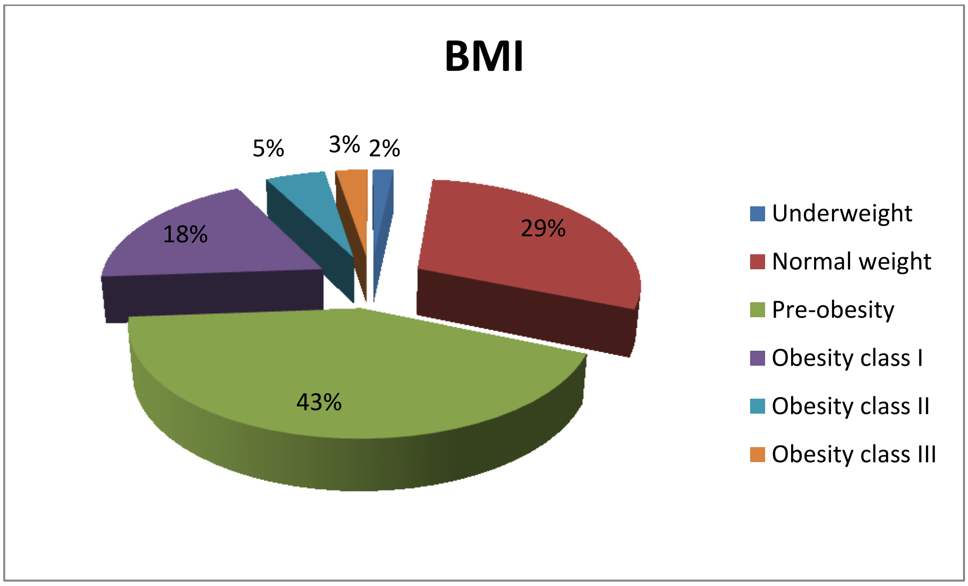


Figure 17: Distribution of the study cohort according to body mass index (BMI) classification. BMI classifications assigned according to the World Health Organization (WHO): Underweight, BMI < 18.50; Healthy weight, BMI = 18.50–24.99; Pre-obese, BMI = 25.00–29.99

According to the World Health Organization (WHO) classification, 29% (n=295) of our patients had a normal weight, 43% (n=425) had a pre-obesity status and 28% (n=261) had an obesity class I –III.

The patients' height showed also a broad distribution: the mean height was 162,5 cm for female patients (range, from 140 to 190 cm) and the mean height was 174,8 cm for males (range, from 153 to 198 cm).

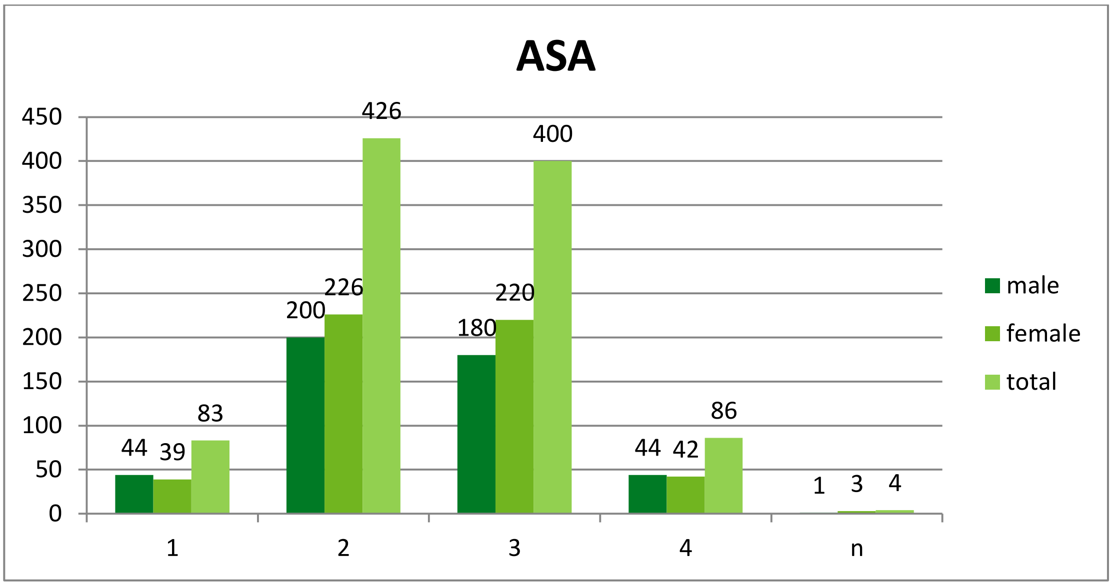


Figure 18: ASA Score of patients

The analysis of the anaesthesia score showed an ASA score from 1 in 8% (n=83) of all patients who were operated, which indicated a completely healthy patient. Forty-two percent (n=426) of the patients had an ASA score of 2, which indicates a mild systemic disease, followed by 40% (n=400) of the patients had an ASA score of 3, which indicates a severe systemic disease which is not incapacitating. The ASA score of 4 was found in 8% (n=86) of the patients, which indicates an incapacitating disease, which was a constant threat to life. In 4 cases no ASA score was documented.

Table 1: Diagnosis for implantation

Indication	Male	Female	Total
Primary osteoarthritis	346	402	748
Avascular necrosis	88	61	149
Hip dysplasia	13	39	52
Posttraumatic osteoarthritis	8	8	16
Protrusion osteoarthritis	5	10	15
Tumour	2	5	7
Girdlestone	4	1	5
ECF	2	1	3
Metal debris after ASR hip	1	1	2
Septic coxitis		1	1

The indications for total hip replacement were primary osteoarthritis in 748 cases (75%, male 346, female 402), avascular necrosis in 149 cases (14,9%, male 88, female 61), hip dysplasia in 52 cases (5,2%, 13 male, 39 female), posttraumatic osteoarthritis in 16 (1,6%, male 8, female 8), protrusion osteoarthritis in 15 (1,5%, male 5, female 10), implantation following resection of primary bone tumour in 5 seven cases (0,5%, 2 male, 3 female), implantation for stabilization of local bone metastases in 2 (0,2%, 2 female), girdlestone after infection in five cases (0,5%, 4 male, 1 female), ECF in three cases (0,3%, 2 male, 1 female), metal debris following ASR metal-on-metal THR in two cases (0,2%,1 male,1 female) and septic coxitis in one case (0,1%, 1 female).

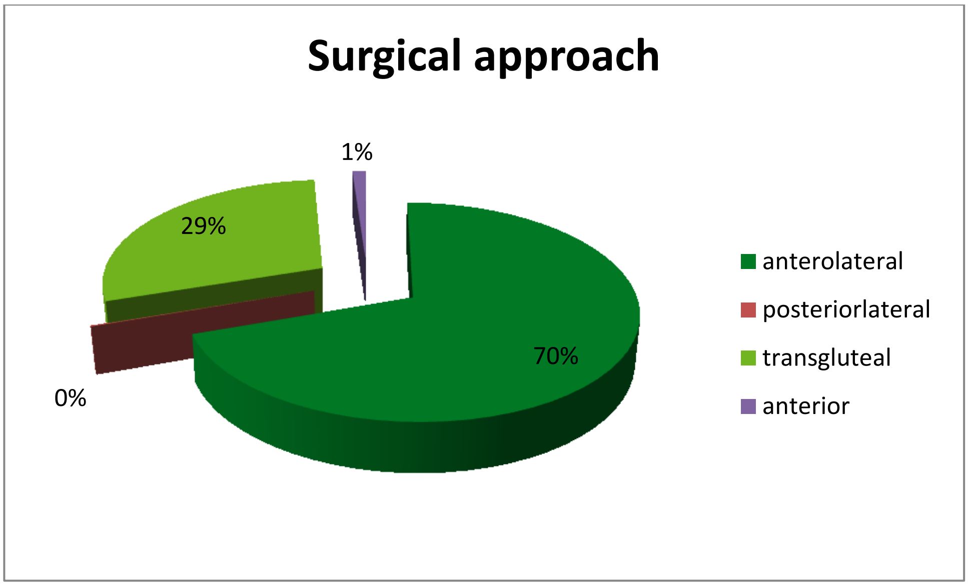


Figure 19: Surgical approach

The surgical approach of choice was an anterolateral approach in 696 operations (69,7%, 319 male, 377 female) followed by a transgluteal approach in 290 operations (29,1%, 144 male, 146 female). In 11 operations (1,1%, 5 male, 6 female) an anterior approach was used and a posteriorlateral approach in one operation (0,1%, 1 male).

Five different Corail® stems have been used in this study:

Table 2: Used Corail® stems

	Female	Male	Total
Corail® Standard	372	317	689
Corail® High Offset	86	120	206
Corail® Standard with collar	20	7	27
Corail® Coxa Vara with collar	24	18	42
Corail® Standard cemented	27	7	34

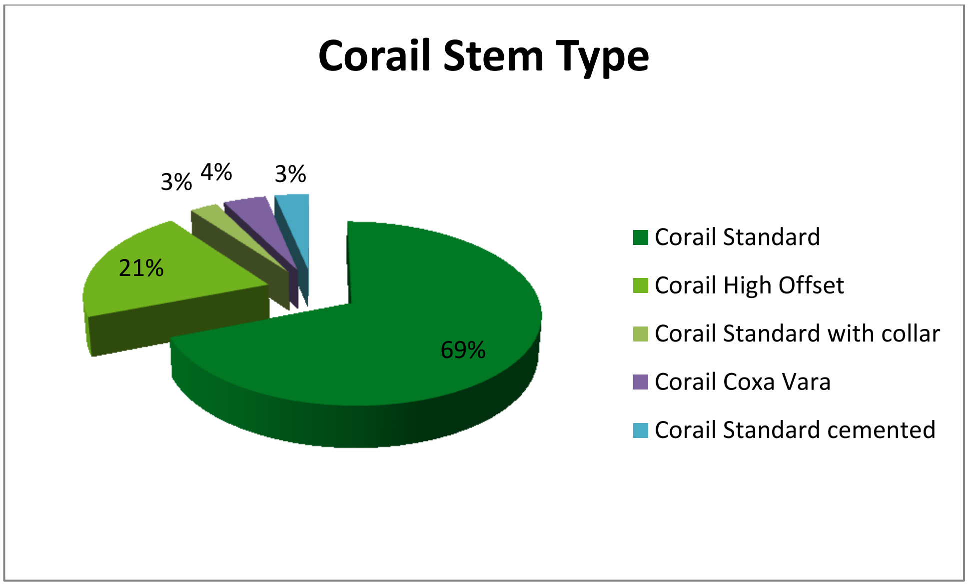


Figure 20: Used Corail® stem types

The Corail® Standard stem was used in 689 cases (69,0%, 273 female, 317 male), in 206 cases (20,6%, 86 female, 120 male) the Corail® High Offset stem was implanted. In 27 cases (2,7%, 20 female, 7 male) the Corail® Standard with collar was used and in 42 cases (4,2%, 24 female 18 male) the Corail® Coxa Vara with collar. The cemented Corail® Standard stem was used in 34 cases (3,4%, 27 female, 7 male).

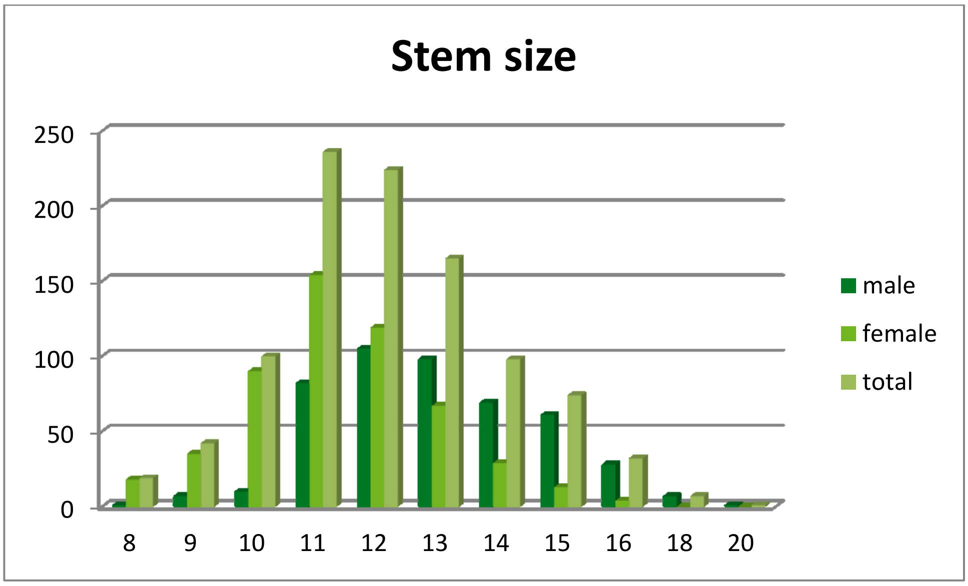


Figure 21: Corail® stem size

The most often used Corail® stem sizes for female patients were size 10 (17,1%, n=90), size 11 (29,1%, n=154) and size 12 (22,5%, n=119). For male patients, the most used Corail® stem sizes were size 11 (17,5%, n=82), 12 (22,4%, n=105) and size 13 (20,9%, n=98).

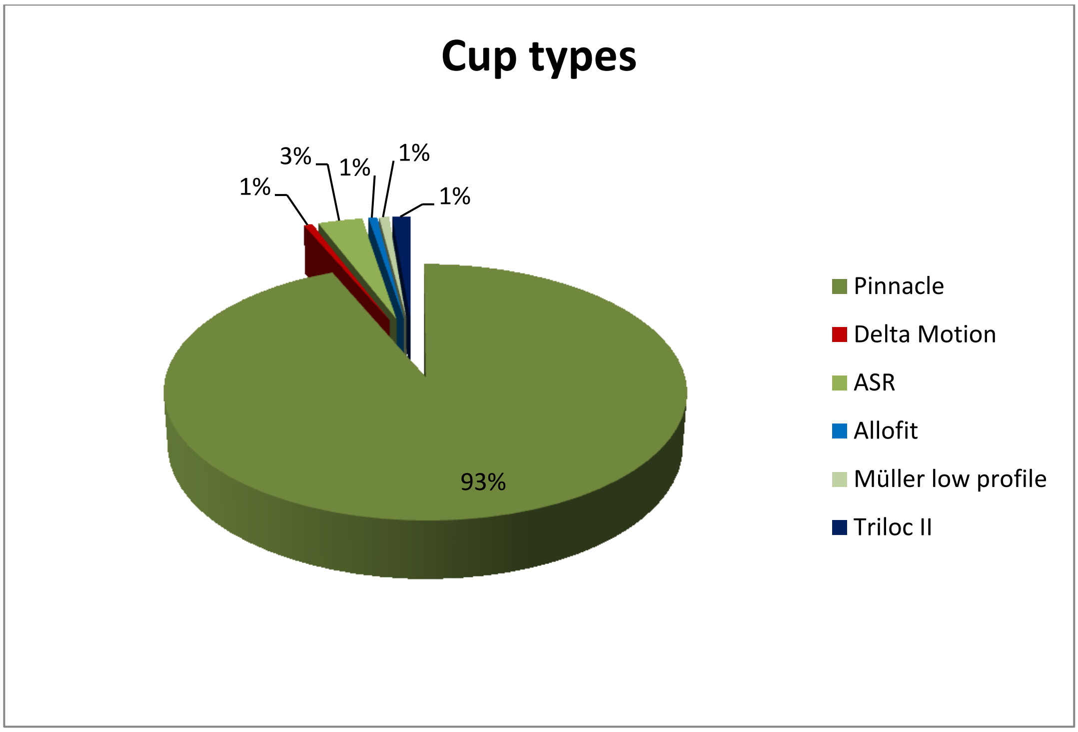


Figure 22: Cup types

The Corail® stem was combined with a Pinnacle Cup in 93,6% of all cases (n=934, 487 female, 447 male), followed by a Pinnacle Delta motion cup in 0,6% (n=6, 5 female, 1 male), in 3,2% (n=32, 18 female, 14 male) with an ASR cup, in 0,6% (n=6, 3 female, 3 male) with a Allofit cup, in 0,7% (n=7, 6 female, 1 male) with a cemented Müller low profile cup and in 1,3% (n=13, 10 female, 3 male) with a Triloc II cup.

Table 3: Pinnacle Cups and cups sizes

	Female	Male	Total
Pinnacle 100	416	408	824
Pinnacle Multihole	4	4	8
Pinnacle Sector	64	35	99
Bantam	2	0	2

	44	48	50	52	54	56	58	60	62	64	66	68
Male	0	1	16	56	125	108	73	35	23	7	1	2
Female	2	62	81	159	105	49	21	6	1	0	0	0
Total	2	63	97	215	230	157	94	41	24	7	1	2

The Corail® stem was combined in most of the cases with a Pinnacle cup. Four different types of this cups were used: the Pinnacle 100 in 88,3% (416 female, 408 male), the Pinnacle multihole in 0,9% (4 female, 4 male), the Pinnacle Sector in 10,6% (female 64, male 35) and the Bantam cup in 0,2% (2 female, 0 male).

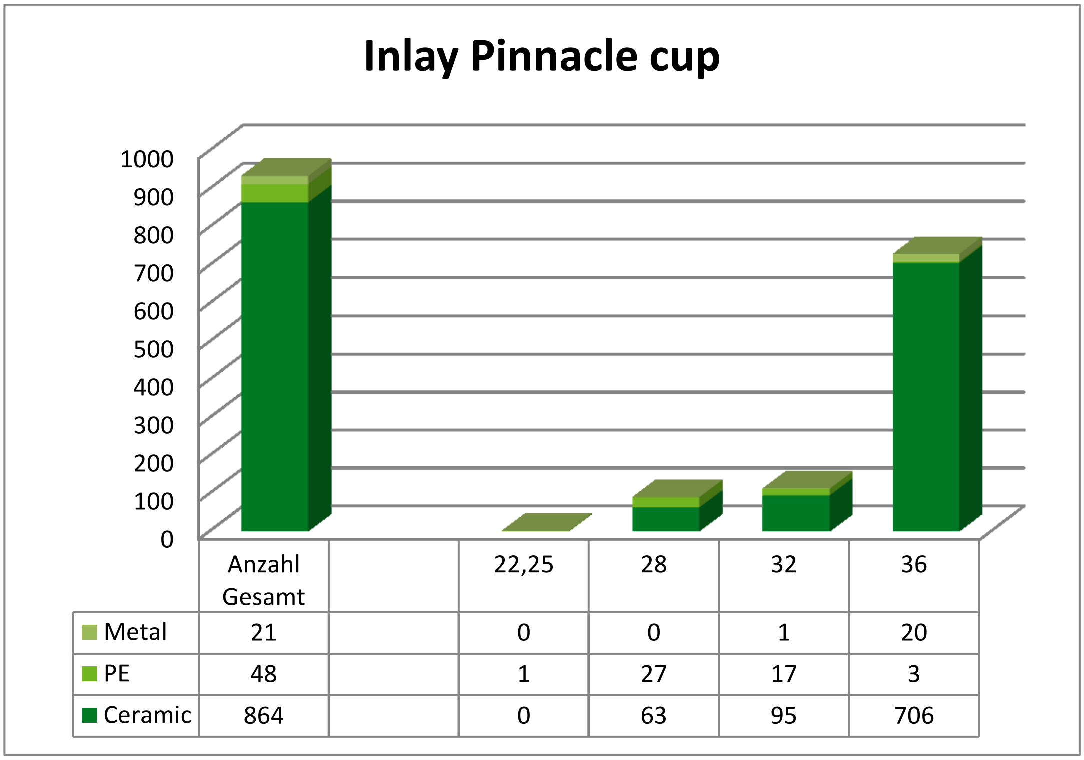


Figure 23: Inlay combined with Pinnacle Cup

The Pinnacle Cup was combined in 92,6% with a ceramic inlay, in 5,1% with a polyethylene (PE) inlay and in 2,3% with a metal inlay.

Table 4: Bearings

Bearing	N	%
Ceramic-on-Ceramic	873	87,6%
PE-on-Ceramic	60	6,0%
XL-Head	32	3,2%
Metal-on-Ceramic	21	2,1%
PE-on-Metal	11	1,0%

The most common used bearing was Ceramic-on-Ceramic in 87,6% (n=873) followed by Ceramic-on-PE in 6% (n=60) and ASR XL-Head in 3,2% (n=32).

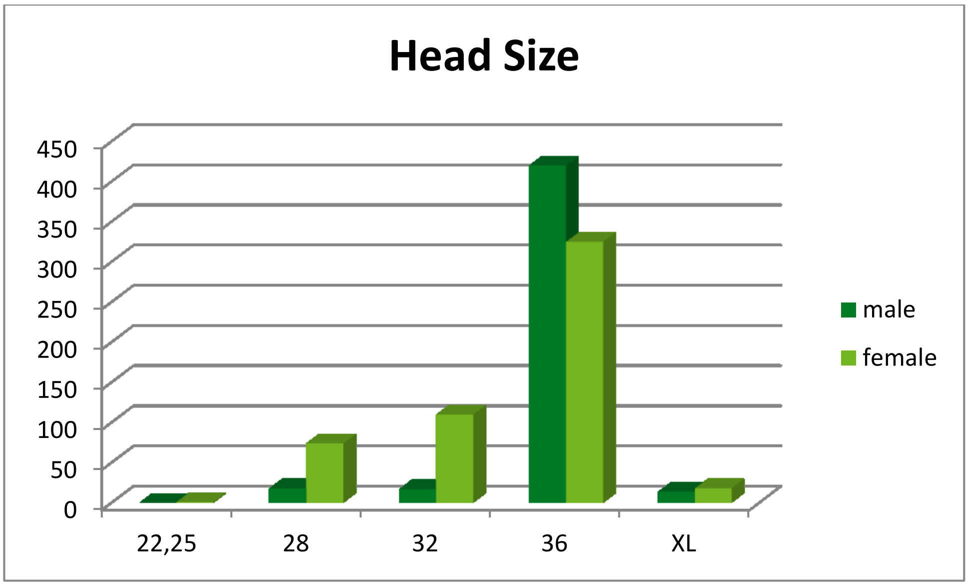


Figure 24: Head Size

The most frequent used head size was 36 mm in 74,7% (n=765, 325 female, 420 male), whereas, 12,7% of the patients (n=127, female 110, male 17) were treated with a 32 mm head. A head size of 28 mm was used in 9,2% (n=92, 74 female, 18 male). The ASR XL Head device was used in 3,2% of the patients (n=32, 18 female, 14 male) and 1 female patients had 2,25 mm metal head.

Table 5: Intraoperative complications

Intraoperative complications	**3,9 %**
Femoral fissure	22
Greater trochanteric fracture	13
Acetabulum fissure	1
Vascular injury	1
Inlay fracture	1

The most frequent intraoperative complications were femoral fissure in 22 cases (2,2%, 14 female, 8 male) followed by fracture of the greater trochanter in 13 cases (1,3%, 9 female, 4 male). Fissure of the acetabulum, vessel injury and inlay fracture also occurred in one cases, each.

Table 6: Revisions

Revisions 41	4,1%
Periprothetic fracture	11
Aseptic loosening	5
Metal debris	5
Haematoma	4
Leg length discrepancy	3
Dislocation	3
Cup loosening	2
Early infection	2
Impingement und subluxation	2
Infection	1
Acetabulum fracture	1
Cup malposition	1
Squeaking	1

8.4 Radiographic evaluation

Table 7: Cup inclination

Cup inclination	postoperative	Latest X-ray
<30°	20	20
30-50°	670	774
>50°	109	152
No date available	199	52

The mean postoperative cup inclination was 43,20° ± 7,09° and the mean cup inclination at the latest available X-ray was 43,41° ± 7,41°. Sixty-seven percent (n=670) were in the "safe zone" proposed by Lewinnek (70), 2% (n=20) were under and 10,9% (n=109) over the "safe zone". In 19,9% (n=199) of all cases, no postoperative data was available. At the latest follow up with a mean of 45,3 months (range, 0 to128 months), 77,4% (n=774) of the patients were in the safe zone, while 17,2% (n=172) were above or under.

Table 8: Leg length discrepancy

Leg length discrepancy	Mean ± SD mm	Min mm	Max mm
preoperative	-0,22 ± 6,60	-49	25
postoperative	-0,64 ± 6,28	-27	25

The mean preoperative leg length discrepancy was -0,22 mm with a standard deviation of ± 6,60 mm. The range was from -49 mm to +25 mm. The mean leg length discrepancy changed postoperative to -0,64 mm with a standard deviation of ± 6,28 mm. The minimum leg length discrepancy was -27 mm and the maximum was +25 mm.

Table 9: Stem alignment

Stem alignment	Postoperative	Latest x-ray
Neutral	806	882
Varus	32	65
Valgus	5	6
No data	155	45

On the postoperative x-rays, 80,6% (n=806) of the stems were implanted in neutral position. Three percent (n=32) were found to be in varus and 0,5% (n=5) in valgus position. In 15,5% (n=155) no statement about the stem position could be made. On the latest x-rays, with a medium follow up of 45,3 months (range 0 to 128 months) 88,2% (n=882) of the stems were in neutral position, whereas 6,5% (n=65) were in varus and 0,6% (n=6) in valgus position. In 4,5% (n=45) no statement about the stem position could be made.

Table 10: Stress shielding

Stress shielding	Latest x-ray
yes	5
no	993

Stress shielding associated with the prostheses could be found in 5 cases at a mean radiological follow up of 45,3 months (range, 3 to 128).

Table 11: Osteolysis

Osteolysis	Latest x-ray
yes	4
no	994

Osteolyses were found in four cases following a mean radiological follow up of 45,3 months (range, 3 to 128). One patient had the osteolyses in gruen zone 3, one patient in gruen zone 3 and 10, one patient in gruen zone 3 and 5 and one patient in gruen zone 2.

Table 12: Heterotopic ossification

Heterotopic ossification by Brooker	Latest x-ray
Grade 0	942
Grade 1	39
Grade 2	10
Grade 3	6
Grade 4	1

At a mean radiological follow up of 45,3 months (range, 3 to 128), no heterotopic ossifications were found in 94,2% (n=942). In 3,9% (n=39), a heterotopic ossification Grade 1, in 1% (n=10) a heterotopic ossification Grade 2, in 0,6% (n=6) a heterotopic ossification Grade 3 and in one case a heterotopic ossification Grade 4 were found.(69)

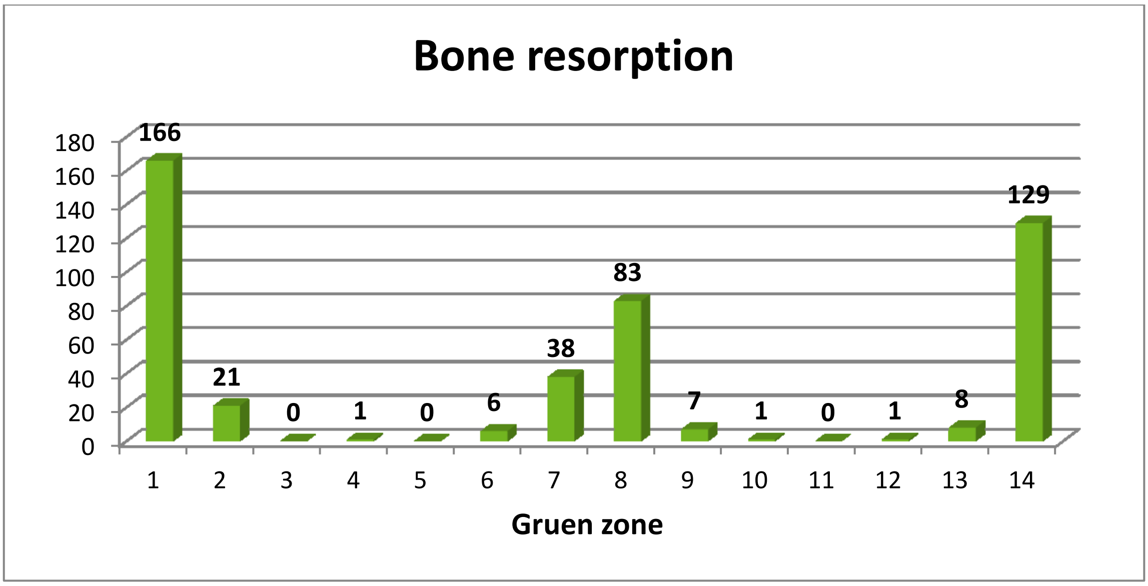
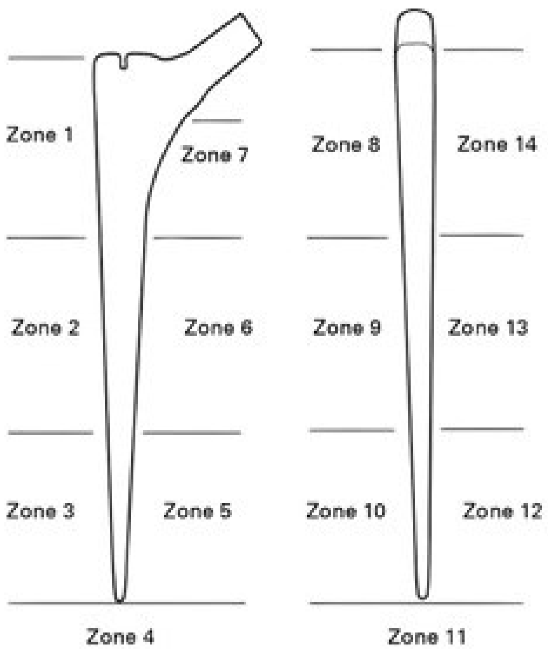


Figure 25: Bone resorption in Gruen zones



The most common location for bone resorption was in Gruen zone 1 in 16,6% (n=166) of all cases and in Gruen zone 14 with 12,9% (n=129). These results were followed by Gruen zone 8 with 8,3% (n=83) and Gruen zone 7 with 3,8% (n=38). In Gruen zone 2 2,1% (n=21) and in Gruen zone 13 0,8% (n=8) of the bone resorptions occurred.

Figure 26: Distribution of bone resorption according to the zones of Gruen and Johnston from http://www.bjj.boneandjoint.org.uk/content/94-B/7/889/F2 accessed 2016/10/16

8.5 Statistic

8.5.1 Implant survival

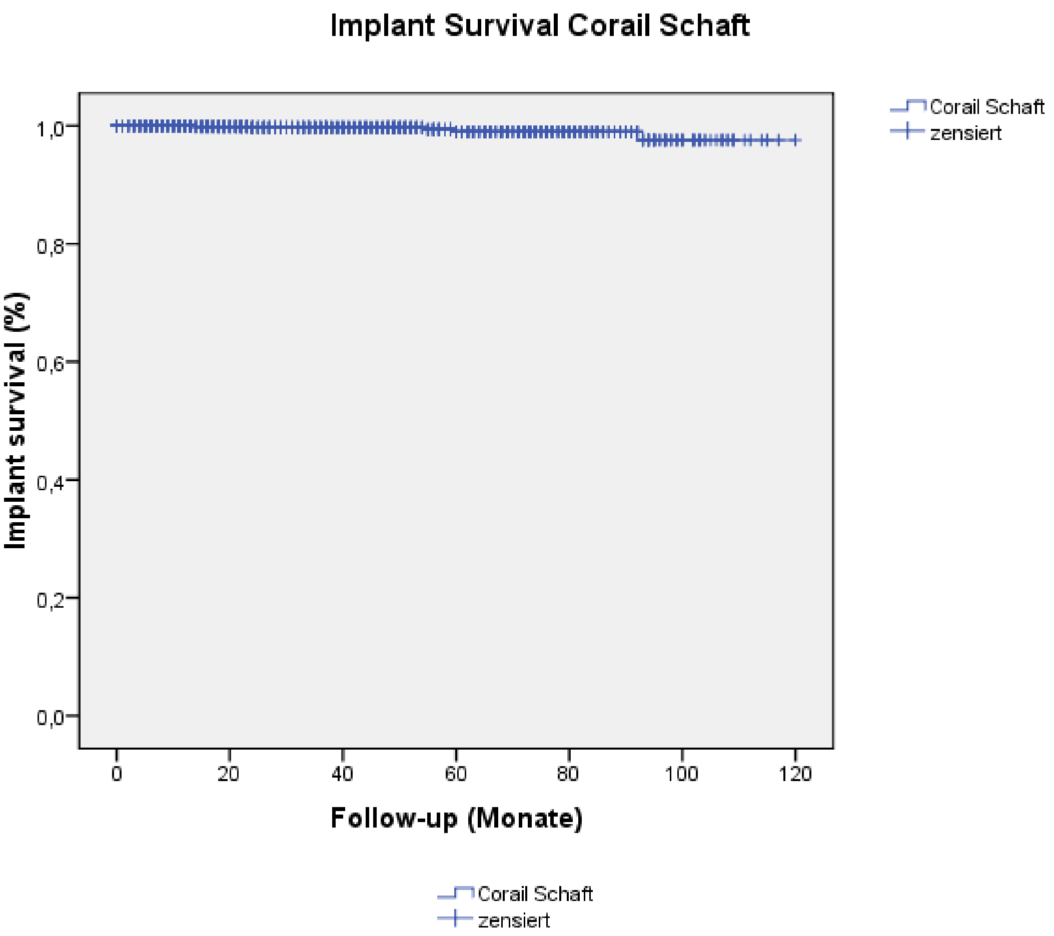


Figure 27: Implant survival for aseptic loosening

The Kaplan-Meier curve showed an implant survival of 99% after 5 years and 97,6% after 10 years with aseptic loosening as endpoint.

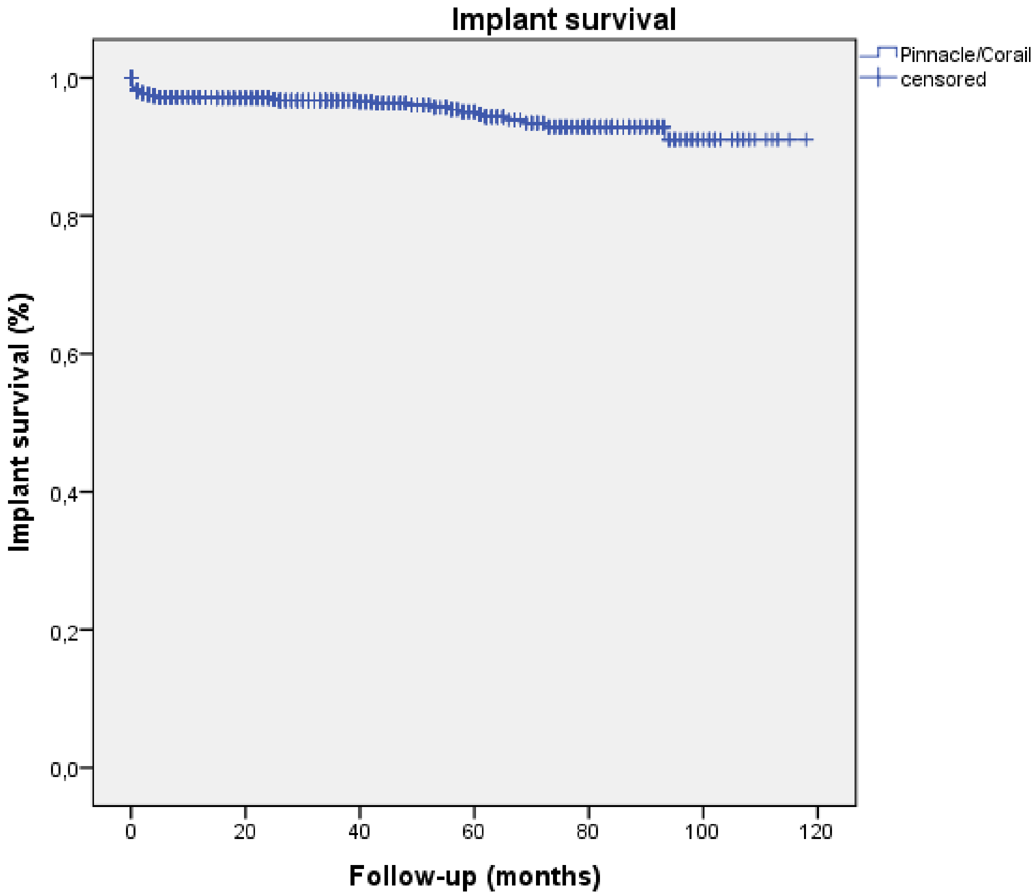


Figure 28: Implant survival for any reason for revision

The Kaplan-Meier curve for revision for any reason as endpoint showed an implant survival of 95% after 5 years and 91% after 10 years.

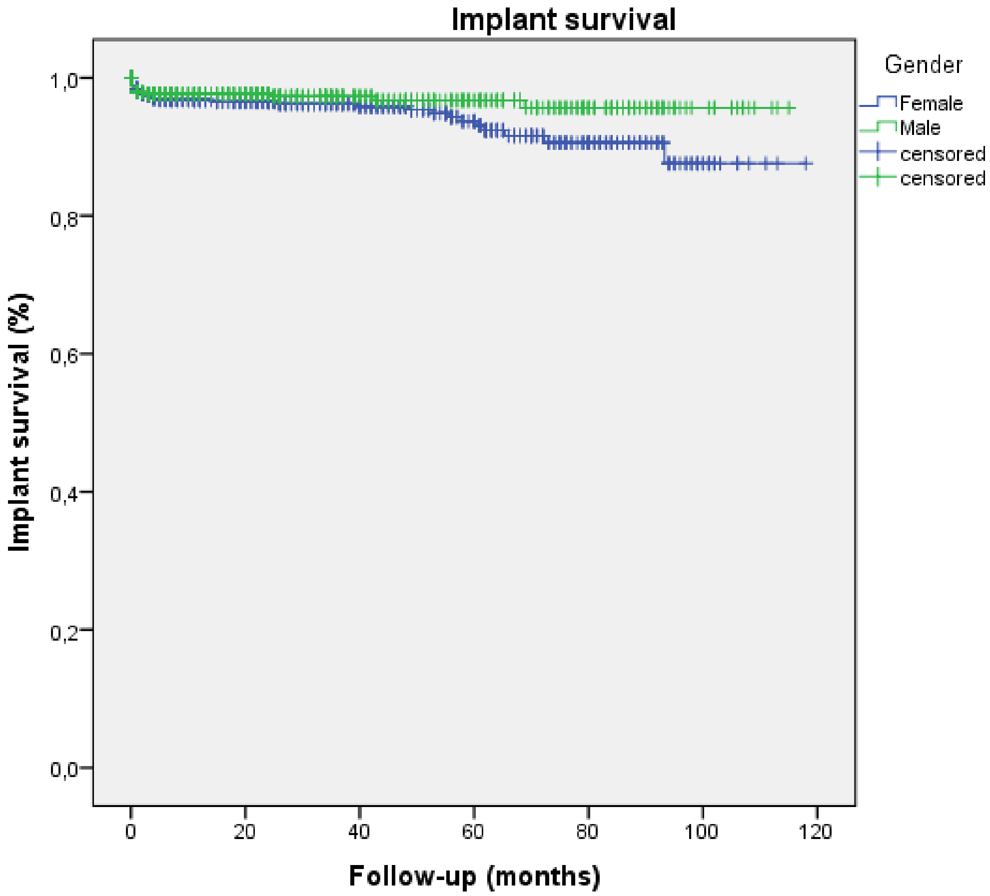


Figure 29: Implant survival for any reason divided by sex

The Kaplan-Meier curve of implant survivorship divided by sex showed an implant survival for women of 94% after 5 years and 88% after 10 years, for men 97% after 5 years and 96% after 10 years. The endpoint for both groups was revision for any reason. Differences for implant survival were statistically not significant (log rank, p=0.090)

Total comparison

	Chi-Quadrat	degrees of freedom	Sig.
Log Rank (Mantel-Cox)	2,881	1	,090

Test for equality of survival distributions for the different levels of sex.

A Mantel-Cox test showed no significant difference between the sexes.

8.5.2 Correlation divided by sex

8.5.2.1 BMI and heterotopic ossification

Female

Correlation to Pearson	,014
Significance (2-sided)	,755
N	527

No correlation between BMI and heterotopic ossification in female patients group could be found.

Male

Correlation to Pearson	,012
Significance (2-sided)	,790
N	468

No correlation between BMI and heterotopic ossification in male patients group could be found.

8.5.2.2 BMI and stress shielding

Female

Correlation to Pearson	,007
Significance (2-sided)	,865
N	527

No correlation between BMI and stress shielding in female patients group could be found.

Male

Correlation to Pearson	,059
Significance (2-sided)	,205
N	468

No correlation between BMI and stress shielding in male patients group could be found.

8.5.2.3 BMI and osteolysis

Female

Correlation to Pearson	-,008
Significance (2-sided)	,848
N	527

No correlation between BMI and osteolysis in female patients group could be found.

Male

Correlation to Pearson	-,029
Significance (2-sided)	,532
N	468

No correlation between BMI and osteolysis in male patients group could be found.

8.5.2.4 BMI and bone resorption

Female

Correlation to Pearson	-,036
Significance (2-sided)	,410
N	526

No correlation between BMI and bone resorption in female patients group could be found.

Male

Correlation to Pearson	,036
Significance (2-sided)	,436
N	468

No correlation between BMI and bone resorption in male patients group could be found

8.5.2.5 Heterotopic ossification and stress shielding

Female

Correlation to Pearson	-,024
Significance (2-sided)	,576
N	529

No correlation between heterotopic ossification and stress shielding in female patients group could be found.

Male

Correlation to Pearson	,180
Significance (2-sided)	,000
N	468

No correlation between heterotopic ossification and stress shielding in male patients group could be found.

8.5.2.6 Heterotopic ossification and osteolysis

Female

Correlation to Pearson	-,024
Significance (2-sided)	,576
N	529

No correlation between heterotopic ossification and osteolysis in female patients group could be found.

Male

Correlation to Pearson	-,018
Significance (2-sided)	,703
N	468

No correlation between heterotopic ossification and osteolysis in male patients group could be found.

8.5.2.7 Heterotopic ossification and bone resorption

Female

Correlation to Pearson	,032
Significance (2-sided)	,465
N	528

No correlation between heterotopic ossification and bone resorption in female patients group could be found.

Male

Correlation to Pearson	-,031
Significance (2-sided)	,506
N	468

No correlation between heterotopic ossification and bone resorption in male patients group could be found.

8.5.2.8 Osteolysis and bone resorption

Female

Correlation to Pearson	-,050
Significance (2-sided)	,253
N	528

No correlation between osteolysis and bone resorption in female patients group could be found.

Male

Correlation to Pearson	-,037
Significance (2-sided)	,428
N	468

No correlation between osteolysis and bone resorption in male patients group could be found.

9 Discussion

Nowadays, THR is the most important and successful orthopaedic surgery and has increased the quality of life for people since more than 100 years. The prosthesis and the use of bone cement for fixation described by Sir John Charnley, which is still in use today, was one of the major contributions in the history of THR.

The introduction of cementless THR in the 1970´s was an attempt to improve implant survival in younger patients.(71) Nowadays, there are several types of cementless fixation techniques, bearing material und designs available. Further, to decrease the risk of dislocation, different femoral head sizes have been introduced. Additionally, a range of 'hard' bearings (ceramic-on-ceramic (CoC), metal-on-metal (MoM), and ceramic-on-metal (CoM)), have become available to reduce wear and prolong survival.

The advantages of CoC bearings are a low rate of volumetric wear, optimal surface material properties (high chemical stability, excellent lubrication (hydrophilic surface) and maximum biocompatibility), excellent clinical results and high resistance to mechanical damage (i.e. scratch resistance). CoC bearings allow the use of larger femoral heads, which does not result in larger rates of wear. One of the most often disadvantages of CoC bearings mentioned is the possibility of fracture, squeaking and fewer choices for the head and liner.(51)

There is still a big controversy concerning the use of cementless implant designs, supposed to be superior or whether cemented prostheses still provide a better outcome. In 2005, only 22% of THRs in England and Wales were cementless. However, till 2009, their popularity surpassed cemented THR, and in 2015, 39,0% of all devices implanted were cementless, whereas 26,1% were cemented.(14)

In Norway, the use of cemented THR is decreasing since 2003.(16) In Sweden, cemented prosthesis are still the most common used method with 67,5%, but the use of cementless or hybrid fixation is also still increasing.(45)

The main reasons for revision after THR were aseptic loosening of the acetabular or femoral component, dislocation, femoral fracture, infection or chronic pain.(5, 14, 16, 51, 55, 72)

Jameson et al.(71) found in a retrospective study a significantly higher risk of revision in patients receiving metal-on-metal and ceramic-on-ceramic bearings compared with metal-on-polyethylene bearing. Smaller femoral stems (sizes 8 to 10) had also a higher risk of revision. Also a BMI ≥ 30 kg/m2 significantly increased the risk of revision. The risk of revision did not depend on age, gender, head size and offset, shell, liner and stem type, or surgeon characteristics. There was also a trend towards ASA grade influencing the risk of revision.

Even with the risk of higher revision rate, there has been a significant increase in the use of CoC bearings worldwide. On reason was that in laboratory experiments the wear rates and osteolytic potential of CoC bearings have been shown to be lower than those of CoP bearings. Adverse events of CoC bearings may be squeaking or that they are considered to be more fragile than the PE. (5) In the UK, the usage of CoC bearing was decreasing while CoP bearing still gains popularity.(14)

Bozic et al.(4) reported a higher risk of periprosthetic joint infection for patient with MoM bearings compared to patients who were treated with a CoC bearing. Hard-on-hard bearings are also associated with lower wear rates in the laboratory setting and may be less vulnerable to wear-related failures, such as bearing surface wear, osteolysis, and mechanical loosening.

For long term survival, an implant has to be well fixed to the bone with the absence of advents that could compromise the fixation like stress shielding or osteolysis. To achieve a stable bony ingrowth, a cementless femoral component needs a particular design and surface.(73) Hallan et al.(66) has shown that well-performing stem designs were all titanium alloys with rough or coated surfaces. Some were straight and others anatomical, fit and fill or flat-tapered. Some had an HA-coating on a blasted surface, some were porous-coated and some had HA on porous coating. For cementless stems it seems that more than one design allows good performance. As for the surface, there is considerable clinical and experimental evidence suggesting that HA coating enhance initial fixation and ultimate osseous integration. Comparative studies have indicated advantages of HA-coated implants over non-coated implants of similar design.(73)

Hailer et al.(72) questioned if the presence of HA coating had a beneficial effect on revision because of aseptic loosening. This author group could not find a statistically significant effect on the risk of stem revision for aseptic loosening and revision due to infection between the group of THAs with HA-coated stems and that with non-HA-coated stems.

Another reason for revision can be dislocation because of femoral head size. By analyzing the Finish Arthroplasty Register, Kostensalo et al.(74) found a higher dislocation rate for the femoral head size of 28 mm compared to the sizes of 32 mm or 36 mm. This was also reported in other studies.

The aim of the current study was the implant survival of the Corail® stem for aseptic loosening as well as for revision for any reason. We think that evaluating the performance of an implant used at your department as well as comparing these results with national and international registers are of great importance for quality assessment.

From 2005 to 2012, 891 patients, 408 men and 483 women, were treated with a primary THR at our department. Forty-six female and 61 male had bilateral implantations. In total, 998 Corail® stems were implanted. The mean age of the patients at the time of operation was 63 with a range from 18 to 91 years. The mean BMI was 28,9 with a SD of ±5,10.

Fifty-one percent (n=509) had an ASA score of ≤2, 40,1% (n=400) of the patients had an ASA score of 3 and 8,6% (n=86) of the patients had an ASA score of 4.

The main indications for primary THR were primary osteoarthritis in 75% (n=748), avascular necrosis in 14,9% (n=149) and hip dysplasia in 5,2% (n=52). The Corail® Standard stem was used in 68,9%, followed by the Corail® High Offset stem in 20,6% and the Corail® Standard with collar. The most used Corail® stem sizes were size 11 in 23,6%, size 12 in 22,4%, and size 13 in 16,5%. The most common used bearing was CoC in 87,6% (n=873) operations followed by PoC in 6% (n=60) and ASR XL-Head MoM in 3,2% (n=32). The mean cup inclination was 43,20° ± 7,09°.

Stress shielding associated with the stem could be found in 5 patients, and periprosthetic osteolysis was found in 4 patients at a mean radiological follow up of 45,3 months (range, 3-128), respectively.

In 3,9% of all patients (n=39), a heterotopic ossification Type Brooker Grade 1 was found, in 1,0% (n=10) a heterotopic ossification Grade 2, in 0,6% (n=6) a heterotopic ossification Grade 3 and in one case a heterotopic ossification Grade 4. The Kaplan-Meier curve of implant survivorship showed an implant survival of 99% and 97,6% after 5 years and 10 years, respectively, with aseptic loosening as the endpoint. Implant survival for any reason for revision as endpoint was 95% after 5 years and 91% after 10 years. Furthermore, a competing risk model survival analysis will be performed obtaining probabilities of death broken down by specific causes.(75)

These results are similar to the known registry reports from Australia, with a 7 year survival rate of 99% and a 94.6% survival rate at 10 years. In the UK, there was a revision rate of the cementless Corail® of 2,89% after 5 years and 7,94% after 10 years. In Norway the survivorship was more than 95% after 5 years. The Corail® implant survival was 98.3% at 5 years in Sweden and 97% in New Zealand, respectively.

The most frequent indications for revision were aseptic loosening, dislocation/subluxation, adverse soft tissue reaction to particulate debris, infection, periprosthetic fracture and pain.(14) Co-factors for adverse events were BMI and ASA classification. A high BMI increased the risk of re-operation. The BMI correlated with the ASA classification for complications like dislocation and infection.(45)

Dislocation is a major complication and an increasing problem. It usually occurs within a month after operation and its frequency is reported to be 2,0-3,0%.(76) Further, aseptic loosening is the most frequent cause of early component failure in THA.(14, 16, 45)

Havelin et al.(77) suggested that the design of the stem plays a major role for aseptic loosening. By analyzing the Norwegian Arthroplasty Register he showed that some inferior prosthesis designs were responsible for the high revision rate. Krismer et al.(78) published a relationship between early migration and survivorship. There are several theories about the causes of aseptic loosening osteolysis resulting in loosening of the implant. The dominant theory was the particle disease theory. The effect of this theory was the development of cementless implants, but the outcome was no better than with the early cemented systems which indicated that the reasons for aseptic loosening are most probably multifactorial. It was proposed that immunological mechanisms, implant design, surgeon skills and patient related factors were responsible for aseptic component failure.(79)

9.1 Conclusion

The Corail® stem provides a good performance at our department as well as the national registers. Due to the low rate of aseptic loosening in this study, we consider the Corail® stem as a stable implant and confirm our decision to use this prosthesis for implantation at our department.

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