Diplomarbeit

Squeaking ceramic-on-ceramic total hip arthroplasties: 3D analysis of CT scans

eingereicht von

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Graz, 22.03.2018

Eidesstattliche Erklärung

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Graz, am 22.03.2018 *Boris Schiller eh*

Danksagungen

Ich danke Werner und Jörg, ohne euch wäre es mir nicht möglich gewesen diese Arbeit zu erstellen. Lukas, danke für deine Hilfe bei der statistischen Auswertung. Danke auch an Prof. Leithner, der die Durchführung der Studie ermöglicht hat. Es war eine großartige Erfahrung auf so hohem Niveau wissenschaftlich arbeiten zu dürfen. Ich habe vieles gelernt, dass mich ein Leben lang begleiten wird.

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Abstract

Inroduction: Although the success rate of total hip arthroplasty is high, the occurrence of audible sounds during movement of the hip joint, commonly referred to as squeaking, remains to be an ongoing concern with ceramic-on-ceramic bearings. Different studies have proposed and investigated implant positioning as one important factor, but there have been varying results.

The primary aim of this study was to investigate if implant positioning is linked to noise generation. The combined anteversion, calculated by adding the acetabular anteversion to the femoral anteversion, was of particular interest.

The secondary aim was to establish a database for future research on noisy hip prostheses, which includes various information like demographic data, scores, a specific questionnaire, exact descriptions if and how different types of noise could be provoked, types and sizes of the prosthesis components, clinical assessment of the radiographs, measurements of implant position in 2D and 3D and Einzel-Bild-Röntgen-Analyse – Femoral-Component-Analysis (EBRA-FCA). If participants still had a non-operated hip joint on the contralateral side, it was also measured, to collect data about the natural configuration of these joints.

Materials and Methods: A case group of 20 patients was compared to a control group of 21 patients.

MediCAD hip 3D® (Hectec) was used to measure implant position from CT scans. The investigated prostheses consisted of a Corail® (DePuy Synthes) stem and Pinnacle® (DePuy Synthes) cup with ceramic-on-ceramic bearings, that were implanted at the Department of Orthopaedics and Trauma -Medical University of Graz from 2005 to 2012.

Results: The statistical analysis did not show a significant correlation between the two groups regarding implant position, demographic data or radiological assessment.

A significant difference was found when comparing the natural hip joints. The case group had higher combined (p = .029) and acetabular (p = .046) anteversion angles, but the available data was limited (case group n=11, control group n=6).

Conclusions: This suggests that for patients with exceptional anatomical properties, a standardized anatomical reconstruction with prosthesis implantation might result in suboptimal biomechanics, which subsequently leads to a higher incidence of noise.

Kurzfassung

Hintergrund: Obwohl die Erfolgsrate des totalen Hüftgelenkersatzes hoch ist, bleibt das Auftreten von hörbaren Geräuschen, häufig als Quietschen bezeichnet, eine Komplikation bei Keramik-Keramik Gleitpaarungen. Andere Studien haben die Implantatposition als einen wichtigen Faktor vermutet und untersucht, mit variierenden Ergebnissen.

Hauptziel dieser Studie war es zu untersuchen, ob die Implantatposition mit Geräuschentwicklung in Verbindung steht. Die kombinierte Anteversion, berechnet durch Addition der acetabulären und femoralen Anteversion, war von besonderem Interesse. Nebenziele waren die Begründung einer Datenbank für zukünftige Forschung über Geräuschentwicklung von Hüftprothesen, welche Informationen wie demographische Daten, Scores, einen spezifischen Fragebogen, genaue Beschreibungen ob und wie verschiedene Geräuscharten provoziert werden konnten, Arten und Größen der Prothesenkomponenten, klinische Beurteilungen des Bildmaterials, Messungen der Implantatposition in 2D und 3D und Einzel-Bild-Röntgen-Analyse – Femoral-Component-Analysis (EBRA-FCA). Wenn die StudienteilnehmerInnen auf der kontralateralen Seite noch ein nicht-operiertes Hüftgelenk hatten, wurden diese ebenfalls vermessen, um Daten über die natürliche Ausrichtung dieser Gelenke zu sammeln.

PatientInnen und Methoden: Eine Fallgruppe von 20 PatientInnen wurde mit einer Kontrollgruppe von 21 PatientInnen verglichen. MediCAD hip 3D® (Hectec) wurde verwendet um die Implantatposition in CT-Bildern zu vermessen.

Die untersuchten Prothesen bestanden aus einem Corail® (DePuy Synthes) Schaft und einer Pinnacle® (DePuy Synthes) Pfanne mit Keramik-Keramik Gleitpaarung, welche an der Abteilung für Orthopädie und Traumatologie des LKH-Univ. Klinikum Graz von 2005 bis 2012 implantiert wurden.

Ergebnisse: Die statistische Analyse ergab keine signifikante Korrelation bezüglich der Implantatposition, der demographischen Daten oder radiologischen Beurteilung. Ein signifikanter Unterschied wurde bei den natürlichen Hüftgelenken gefunden. Die Fallgruppe hatte eine höhere kombinierte (p = .029) und acetabuläre (p = .046) Anteversion, allerdings waren die verfügbaren Daten begrenzt (Fallgruppe n=11, Kontrollgruppe n=6).

Schlussfolgerung: Dies lässt die Vermutung zu, dass bei PatientInnen mit außergewöhnlichen anatomischen Eigenschaften eine standardisierte anatomische Rekonstruktion durch Prothesenimplantation ein suboptimales biomechanisches Ergebnis hervorbringen könnte, welches zu einer höheren Inzidenz von Geräuschentwicklung führt.

Index

Glossar und Abkürzungen

2D	Two-dimensional
3D	Three-dimensional
art.	Articulatio
CCD	Centrum – collum – diaphyseal
CoC	Ceramic on ceramic
CRF	Case report form
CT	Computed tomography
EBRA-FCA	Einzel-Bild-Röntgen-Analyse – Femoral-Component-Analysis
HHS	Harris Hip Score
HMWP	High Molecular Weight Polyethylene
HO	Heterotopic ossification
lat.	Latin
lig.	Ligamentum
M.	Musculus
mm	Millimeter
Mm.	Musculi
MoP	Metal on polyethylene
N.	Nervus
Nn.	Nervi
PIBR	Peri-implant bone resorption
PMMA	Polymethylmethacrylate
ROM	Range of movement
THA	Total hip arthroplasty
THR	Total hip replacement
USA	United States of America
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index

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1. Introduction

1.1. Objective of the study

Total hip arthroplasty is one of the most common orthopedic procedures today. Although the success rate is high, some complications remain to be ongoing concerns. With ceramic-on-ceramic (CoC) being the only bearing combination that combines long-term survival of 10 to 20 years without adverse reaction to wear debris (1), it is becoming the predominant type of total hip arthroplasty (THA).

One concern regarding ceramic bearings is the occurrence of audible sounds during movement of the hip joint, commonly referred to as squeaking. This phenomenon is thought to be multifactorial and is yet to be completely understood.

Different studies have proposed and investigated implant positioning as one important factor, but there have been varying results.

The primary aim was the identification and interpretation of different factors, which lead to noise generation in THAs, with a focus on implant positioning. The combined anteversion, calculated by adding the acetabular anteversion to the femoral anteversion, was of particular interest for this study. True femoral anteversion is measured by putting the position of the femoral neck in relation to the femoral condyles, for this a computed tomography (CT) scan of the hip and the knee is needed. A case group of patients with a noisy THA was compared to a control group. A clinical examination as well as a radiological examination were performed. X-ray images and low dose rotation CT scans, which were converted into digital two-dimensional (2D) and three-dimensional (3D) models, were obtained.

The secondary aim was to establish a database for future research about noisy THAs which includes various information like demographic data, scores, a specific questionnaire, exact descriptions if and how different types of noise could be provoked, types and sizes of the prosthesis components, clinical assessment of the radiographs, measurements of implant position in 2D and 3D and Einzel-Bild-Röntgen-Analyse – Femoral-Component-Analysis (EBRA-FCA). If participants still had a non-operated hip joint on the contralateral side it was also measured, to collect data about the natural configuration of these joints.

1.2. Basic knowledge

1.2.1. Anatomy of the hip joint

The hip joint, or acetabulo-femoral joint (lat.: art. coxae) is an enarthrodial joint, a special type of ball and socket joint, because the socket encloses more than half of the ball head (2). Formed by the pelvic acetabulum and the head of the femur, it is the bony connection of the lower limb to the axial skeleton of pelvis and torso. The joint surfaces are covered with hyaline cartilage and lubricated with synovial fluid.

Bony structures

The acetabulum is composed three parts, the pubic bone (lat.: os pubis), the iliac bone (lat.: os ilium) and the ischium (lat.: os ischium). The Y-shaped growth plate between them is fused definitely at an age between 14 to 16 years (3). The acetabular labrum (lat.: labrum acetabuli), a fibrocartilaginous collar attached to the bony rim of the acetabulum (lat.: limbus acetabuli) further deepens the cavity.

The femur is the longest bone in the human body, it consists of the femoral head (lat.: caput femoris), the femoral neck (lat.: collum femoris), the femoral shaft (lat.: corpus femoris) and the femoral condyles (lat.: condyli femoris) (2).

Joint capsule and ligaments

Proximally the capsule is fixed right outside the acetabular labrum on the socket, distally the ventral part encloses the whole femoral neck, the dorsal part about two thirds of it.

There is one intraarticular ligament, the ligament of the femoral head (lat.: lig. capitis femoris), which has no mechanical function. It is a leading structure for blood vessels that supply the femoral head.

A stable connection between the femoral neck and the three parts of the pelvic bone (lat.: os coxae) is provided by three ligaments, the iliofemoral ligament (lat.: lig. iliofemorale), which is the strongest ligament of the human body, the pubofemoral ligament (lat.: lig. pubofemorale) and the ischiofemoral ligament (lat.: lig. ischiofemorale) (2). They also form a thick, strong part of the capsule, the zona orbicularis, which is a collar at the smallest diameter of the neck.

Muscles

Since tilting over to the back in the hip is prevented by the iliofemoral ligament, the flexors are not nearly as massive as the extensor muscles, which prevent tilting forwards.

The two main flexors are the M. iliopsoas and the M. rectus femoris, which are supported in their function by the M. tensor fasciae latae, the ventral parts of the Mm. gluteus medius and gluteus minimus, as well as by the M. sartorius.

The M. gluteus maximus, the strongest muscle in the human body and necessary for the ability to stand and walk upright, it is the main extensor and external rotator of the hip joint. The aforementioned Mm. gluteus medius and glutes minimus, function primarily as abductors and are necessary for stabilizing the pelvis during the walking gait.

The pelvitrochanteric muscles (M. piriformis, Mm. gemellus superior and inferior, Mm. obturatorius internus and externus, M. quadratus femoris) are known to be external rotators.

The adductors (M. pectineus, M. gracilis, Mm. adductor magnus, longus and brevis) are the antagonists of the abductors. They stabilize the leg during walking and running (2).

Nerves

The lower limbs are innervated by the lumbosacral plexus, a network of nerve fibers formed by the anterior rami of Th 12 – S4. It can be further divided into the lumbar plexus, the sacral plexus and the coccygeal plexus. These give rise to the N. iliohypogastricus, N. ilioinguinalis, N. genitofemoralis, N. cutaneus femoris lateralis, N. femoralis, N. obturatorius, Nn. glutei superior et inferior, N. ischiadicus, N. cutaneus femoris posterior, N. pudendus and the Nn. anococcygei.

1.2.2. History of hip prostheses

1891, Germany, Themistocles Gluck (1853 – 1942), first implantation of an artificial femoral head made of ivory, attached with nickel-plated screws, plaster and glue.

1938, Great Britain, Philip Wiles (1899 – 1967), first total hip arthroplasty with acetabular and femoral components made of stainless steel.

1953, USA, Edward J. Haboush (1904 – 1973), first use of bone cement (polymethylmethacrylate - PMMA)

1962, Great Britain, Sir John Charnley (1911 – 1982), regarded as the "father of modern THA", first use of High Molecular Weight Polyethylene (HMWP) for the socket in combination with a metal femoral head, thus establishing the Low Friction Arthroplasty Concept. The idea to reduce friction came to him when he encountered a patient with a prosthesis that was constantly squeaking (4).

1971, France, Pierre Boutin (1924 – 1989), first use of ceramic-on-ceramic bearings in hip replacements.

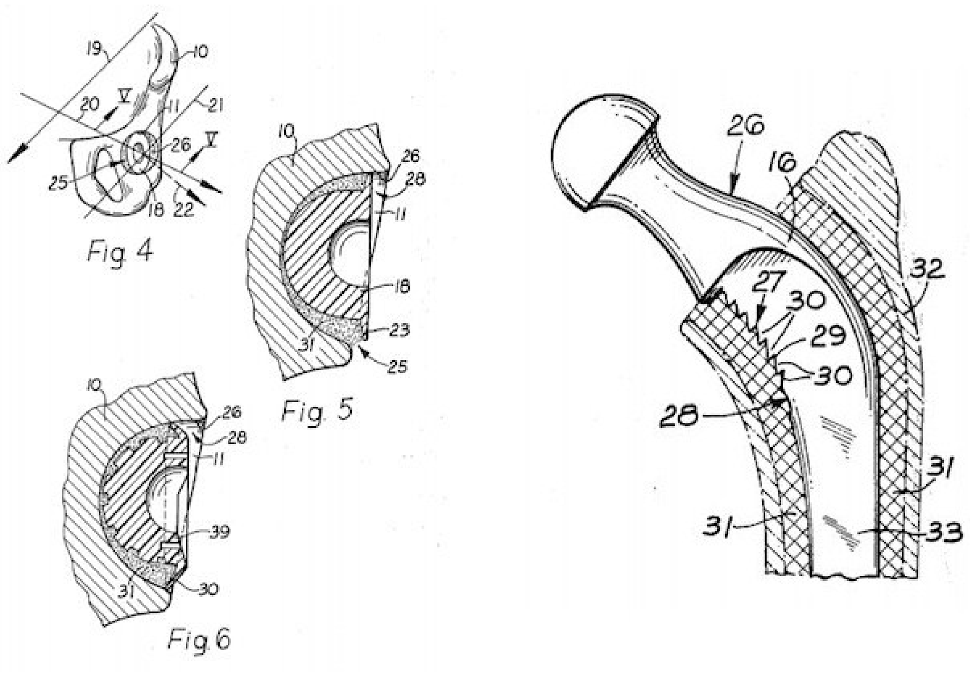

Fig. 1: Acetabular and femoral prosthesis developed by Sir John Charnley from http://www.ipwatchdog.com/2014/04/21/the-evolution-of-hip-replacements/id=49209/ accessed 2017/09/24

1.2.3. Assessment of hip prosthesis radiographs

Heterotopic ossification

Heterotopic ossification (HO) is the abnormal formation of mature lamellar bone in soft tissues. Although typically asymptomatic and as such most commonly identified as an incidental radiological finding, it can present with a reduced range of movement (ROM) and may lead to a poor outcome following replacement. Pain is uncommon, but can occur (5).

The Brooker system (6) is the most commonly used for classification of HO. It defines four grades (Fig. 3). For this the appearance of ossification on anteroposterior X-ray images of the hip is evaluated.

Pohl et al. (7) have shown that Brooker grades III and IV have far less favorable outcomes than the lower grades regarding the postoperative ROM.

Surgical excision of the heterotopic bone can improve the ROM significantly but cannot be expected to predictably alleviate pain (8).

Fig. 2: Heterotopic ossification of the hip after total hip arthroplasty from https://commons.wikimedia.org/wiki/File:Heterotopic_Ossification_Hip1.JPG accessed 2017/09/26

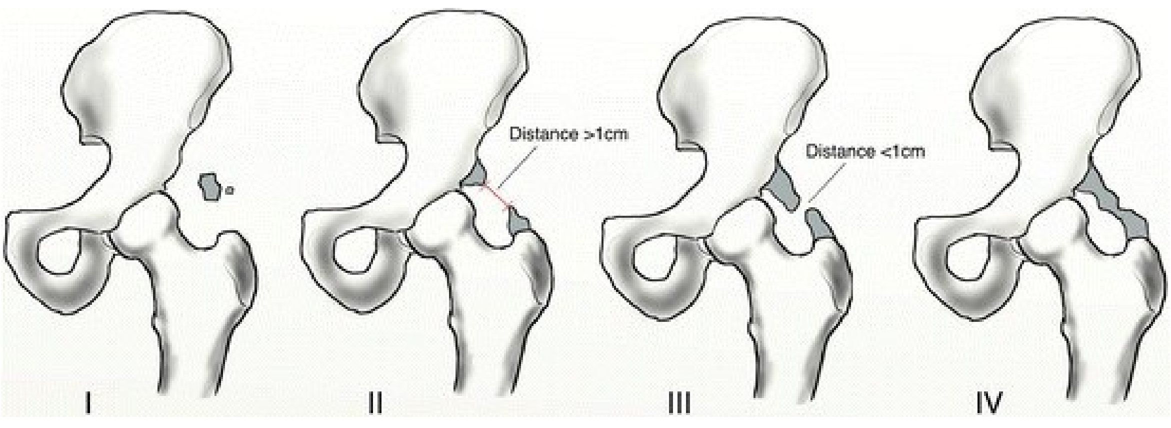

Fig. 3: Brooker classification system; class I: islands of bone within soft tissues; class II: bony spurs leaving >1 cm between opposing surfaces; class III: bony spurs with <1 cm between opposing surfaces; class IV: radiographic ankyloses from https://www.researchgate.net/figure/278679886_fig1_Figure-1-81-The-four-types-of-the-Brooker-classification-system-class-I-islands-of accessed 2017/09/26

Bone loss after total hip arthroplasty

The continuous cycle of bone formation and bone resorption requires a balanced function of osteoblasts and osteoclasts to maintain proper bone structure. Several mechanisms can disturb this balance after implantation of an endoprosthesis.

Due to the ageing process some bone loss occurs naturally, causes can be changes in hormone levels, less physical activity, nutrition, medication or a combination of various factors. Especially women after menopause have a higher risk for **osteoporosis** because of lower estrogen levels (9). It has been shown that this does not necessarily result in low mechanical stability (10, 11).

Another mechanism is **stress shielding**, or adaptive bone remodeling. This happens when the load is transmitted through the metal stem to the distal femur, effectively bypassing the proximal femur (12). This changes the mechanical stimulus which affects bone remodeling. It is not yet clear if this affects long-term mechanical stability (11, 13, 14).

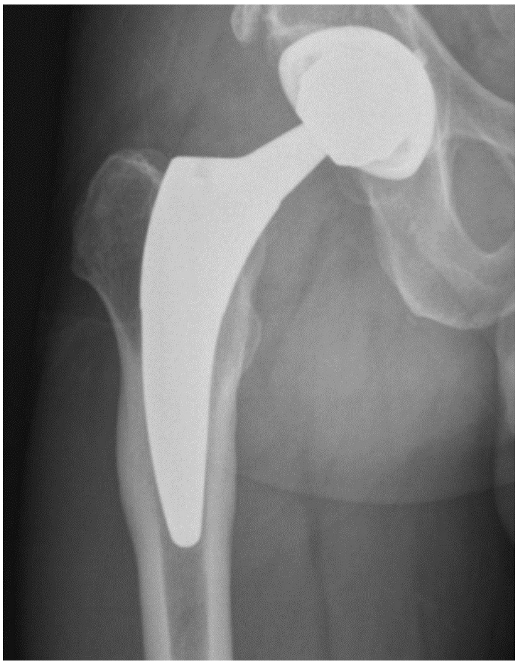

Fig. 4: Distal cortical hypertrophy and proximal stress shielding from Gustke K. J Bone Joint Surg Br 2012;94-B, Supple A:47–51.

Also known as aseptic loosening, **periprosthetic osteolysis** is one of the most significant long-term complications of THA (15, 16). There are several factors that are supposed to contribute to this condition.

It has been shown that subsidence of the femoral component has a strong predictive value for future prosthetic loosening and the complications that it entails (17, 18). Why this

migration occurs has not yet been fully understood, but improvements in surgical technique and better prostheses and materials apparently have a positive effect (18).
A widely accepted theory is that particulate debris from worn prosthetic materials is responsible for periprosthetic osteolysis (11), although it has been strongly opposed that it is the primary and single cause for it (19, 20).
The periprosthetic membrane, a layer of soft tissue between the bone and prosthesis, forms in both aseptic and septic loosening. Surrounding this membrane bone defects appear, resulting from cellular activity and enzymatic processes (21-23), and/or from synovial fluid pressure that may rise significantly when loading the prosthesis (20, 24).

The **radiographic manifestations** of osteolysis can be seen as radiolucent lines around the prostheses. These findings are common – even when the prostheses are stable - and most often incidental, although they can be an indicator for loose prosthetic components. However, the absence of radiolucent lines does not exclude migration of the components (25).

Fig. 5: Radiolucent lines around the proximal femoral stem

1.2.4. Ceramic-on-ceramic bearings

Alumina/zirconia composite ceramics have been in use since the 1970s. They have some advantages compared to metal-on-metal or polyethylene bearings like low rates of wear, high chemical stability, excellent lubrication, maximum biocompatibility, excellent clinical results and high resistance to mechanical damage (26). The main concern regarding this material is, apart from squeaking, the risk of fracture. Developments in manufacturing and implant design have contributed to the safety of modern ceramic bearings (26, 27).

1.2.5. Edge loading

In the production process the bearing surface of ceramic liners is ground and polished, which results in a hard edge a few millimeters from the face of the implant. (Fig. 1) When the femoral head moves over this hard edge the forces increase and lead to damage on both bearing surfaces. This process is known as edge loading. The resulting roughened area on the head is referred to as stripe wear. The measurement of the location of stripe wear allows for analysis of the mechanism of edge loading, with the most common type being subluxation of the head over the posterior hard edge during deep flexion (28).

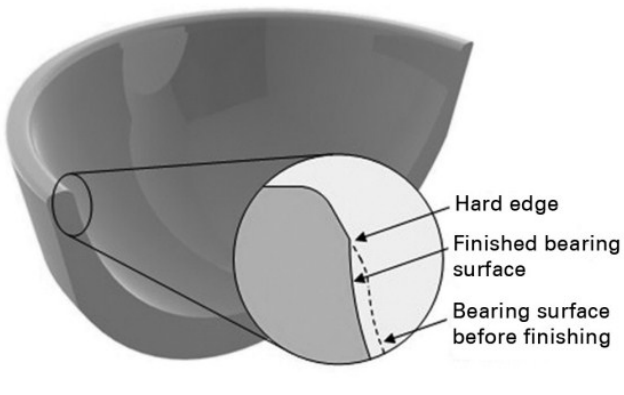

Fig. 6: Cross-section of a ceramic acetabular component showing the hard edge at the intersection of the finished and untreated surface. From Jeffers et al. J Bone Joint Surg Br 2012;94-B:735–45.

Another mechanism is impingement of the femoral neck and the cup of the prosthesis (29), which leads to severe edge loading and is a result of poor positioning of the acetabular component.

1.2.6. Noise generation

To generate audible noise, vibrations have to be transmitted from the bearing surfaces to the metal components of the prosthesis, which then amplify these. If this happens at a frequency that is in the audible range of humans, a noise can be heard. This happens only when the friction in the joint reaches a high enough level to transmit the necessary energy. Hothan et al. (30) found in their in vitro testing, that it is mainly the stem which is responsible for the audible noise from THAs and that the design of the stem plays a significant role. Bishop et al. (31) used a hip simulator and showed that dry conditions can increase the friction for ceramic bearings up to a ratio of 10.1, compared to sufficiently lubricated surfaces. If, due to the strong forces during edge loading, a breakdown of the lubrication film occurs, this can also contribute to noise generation. In another hip simulator study performed by Taylor et al. (32) squeaking was only encountered after a wear stripe formed on the bearing surfaces and when the load application was in line with this area, implying a run out phase until the effects of edge loading lead to noise. Other studies in a clinical setting also support this, by observing a run out phase until the onset of squeaking (33-41). Third bodies, like ceramic debris from damaged surfaces, loosening and fractures of the prosthetic components were also suggested as contributing factors by other authors (1, 42-44).

2. Material and methods

2.1. Participants

From November 2016 until December 2017, thirty-five patients with squeaking hips were examined. They received a written invitation by mail and were also contacted by phone to confirm the appointments at our clinic. All were selected from an existing database (45). The medical history of all the patients in the database was looked through for any reports on noise in the past, to identify the case group. The control group consisted of patients who were randomly chosen from the same database and reported no noise whatsoever from their artificial hip joints. If patients from the case group had a silent hip on the contralateral side which met inclusion criteria, they were included as well. In our study population of thirty-five patients, fifty-eight hip joints met the inclusion criteria. Of these total fifty-eight hip joints twenty were assigned to the case group, twenty-one hip joints were assigned to the control group. In seventeen cases, eleven in the case group and six in the control group, natural hip joints were examined as well.

The inclusion criteria were a minimal age of eighteen years and implantation of a total hip replacement (THR) consisting of a Corail® (DePuy Synthes) stem and Pinnacle® (DePuy Synthes) cup with ceramic-on-ceramic bearings at our clinic from 2005 to 2012. The exclusion criteria were an acute infection of the prosthesis at the time of the study and, because of the radiation involved, pregnancy.

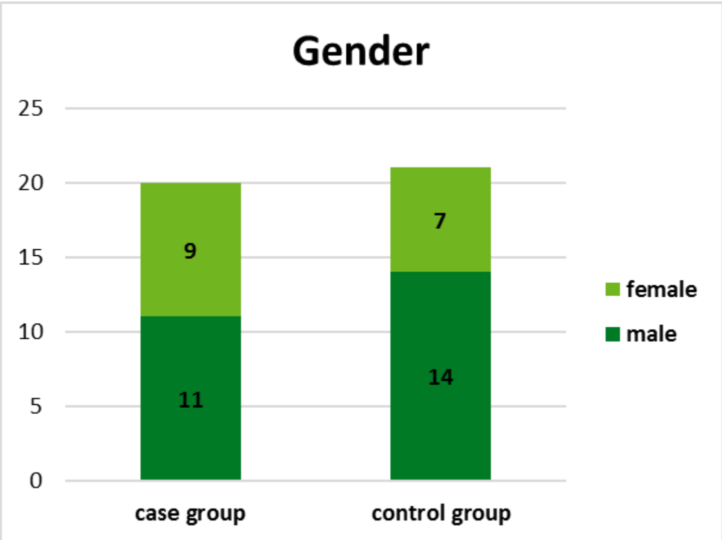

Fig. 7: Examined hip joints, sorted by case group (20 in total) and control group (21 in total), divided by gender.

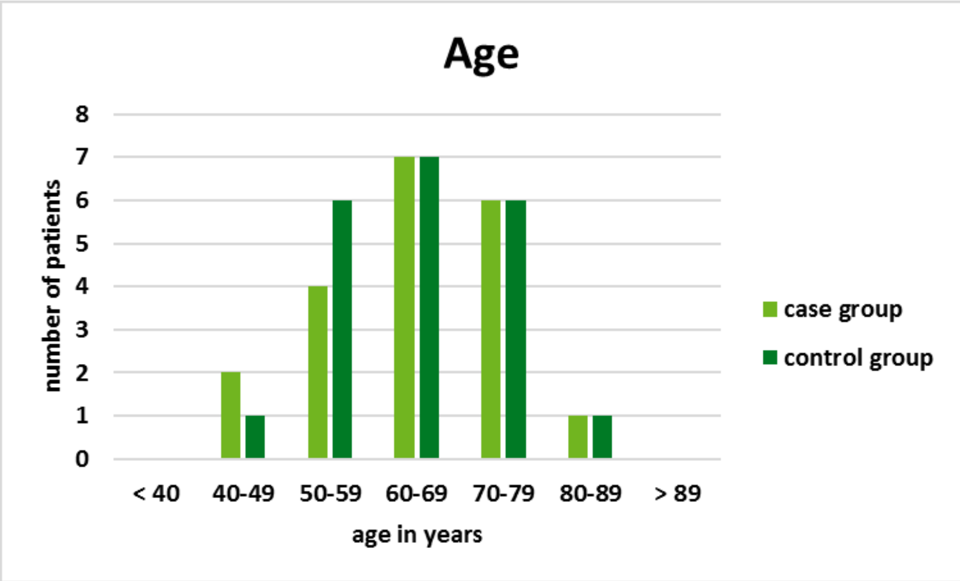

Fig. 8: Age groups within the study population

2.2. Collection of clinical data and image material

Age, gender, body weight and body height were noted in the Case Report Form (Table 1 and 2).

Table 1: Demographic data of the case group

Number of patients in case group		Details of case group	
Patients in database*	873	Male : female	11 : 9
Patients with noisy hip (incidence)	27 (3,09 %)	Mean age (range) [yrs]	63,75 (45-80)
Patients available for study (THAs included in study)	20 (20)	Mean BMI (range)	27,26 (21,6-35,5)

*Database of patients with primary CoC-THR (DePuy Pinnacle-Corail) between 2005-2012, performed at the Department of Orthopedics and Traumatology, LKH Graz, Austria

Table 2: Demographic data of the control group

Number of patients in control group		Details of control group	
Patients available for study (THAs included in study)	18 (21)	Male : female	14 : 7
		Mean age (range) [yrs]	64,05 (45-83)
		Mean BMI (range)	29,02 (19,8-39,5)

The WOMAC and Harris Hip Scores were obtained for all patients. A patient questionnaire on noise - which was created for this study - was filled out by the case group. This questionnaire included questions about the type of noise the patients have heard, the time of onset of the noise and if it was related to a specific event, if a certain movement produces the noise, how often the noise occurs, if it is associated with pain and if it has a negative impact on the quality of life. All additional relevant information about their perception of the noise from their THRs was written down as well.

In a functional examination the participants were asked to perform a certain set of movements/actions (squatting and rising, turning inwards and outwards with fixed foot, walking across the room, climbing stairs, low intensity cycling on home trainer for 1 minute and also other movements/actions if necessary) in an attempt to provoke noise generation. If noise provocation was possible, the exact movement, body position and type of noise were noted and an audio recording was obtained for future research.

A low-dose rotation CT-scan of the pelvis and knees was performed, as well as X-ray imaging from the anterior-posterior and lateral view.

A consulting physician of the department of Orthopaedics and Trauma reviewed the radiographic images for signs of loosening or damage and performed a clinical examination of every patient participating in the study.

2.3. Description of THR

Using the database (45) mentioned above the following data was retrieved: In the case group one patient had a femoral head with 32 mm in diameter, all other nineteen patients 36 mm. There were three Corail High Offset 135°® stems, one collared Corail Standard® stem and sixteen collarless Corail Standard® stems, ranging from size 11 to 16. None of the stems were cemented. For the cup shell two Pinnacle Sector® and eighteen Pinnacle 100® models were used. The cup shell size varied from 48 mm to 58 mm.

In the control group all patients had a femoral head with 36 mm in diameter. There were three Corail High Offset 135°® stems, one collared Corail Standard® stem and seventeen collarless Corail Standard® stems, ranging from size 11 to 16. None of the stems were cemented. Only Pinnacle 100® cup shells were used. The cup shell size varied from 52 mm to 62 mm.

2.4. Measurements of radiographic images

2.4.1. 2D measurements of X-ray images

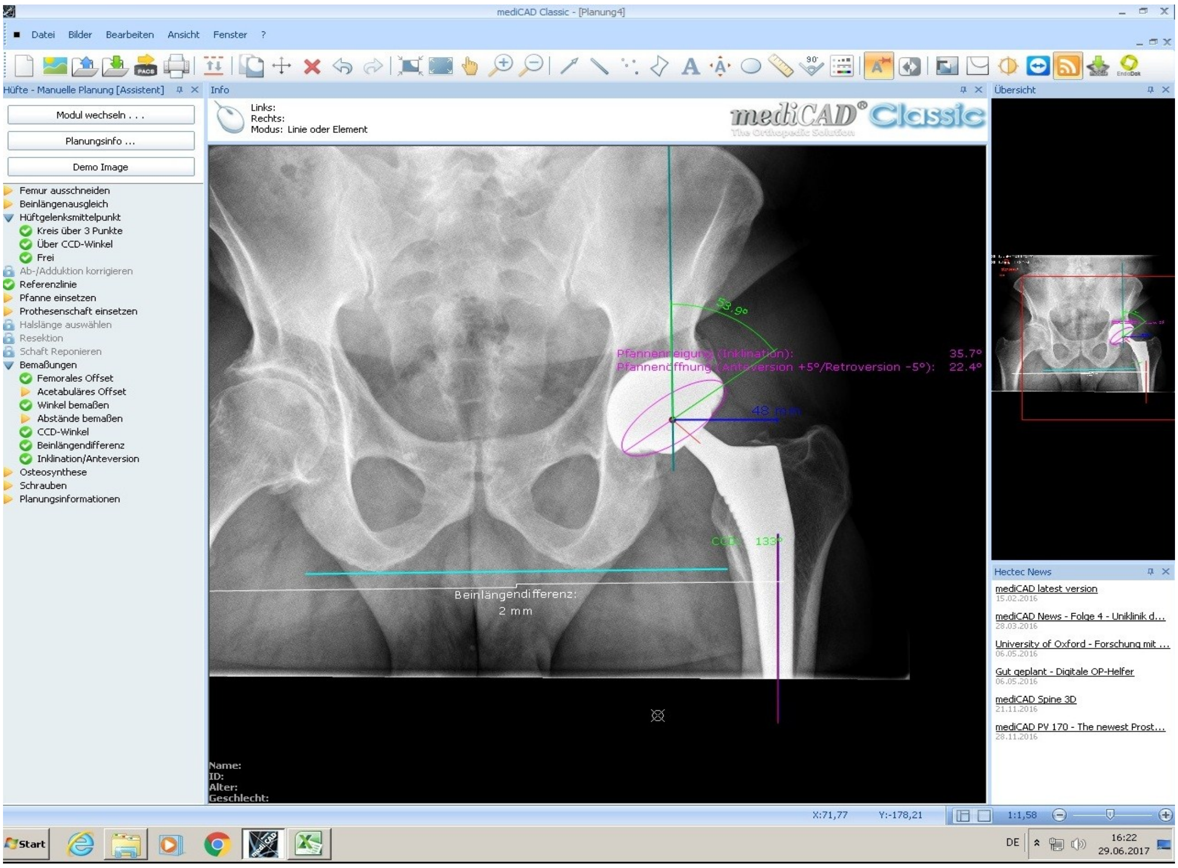

Fig. 9: Measurement with Hectec mediCAD Classic®

The 2D measurements were attained by using the Hectec mediCAD Classic® software. For this the anteroposterior image of the pelvis was uploaded into the program. If the femoral shaft was not sufficiently visible on that image, a second image of the anteroposterior view of the hip was used. The following parameters were assessed: acetabular inclination and anteversion, femoral offset and stem alignment by measuring the CCD angle, the leg length discrepancy and the arc of cover.

2.4.2. 3D measurements of CT scan images

The 3D measurements were attained by using the Hectec mediCAD hip 3D® software. For this the CT scan images were uploaded into the program, which then converted these into digital three-dimensional models. The following parameters were assessed: acetabular inclination, anteversion and offset, femoral anteversion and offset, stem alignment by measuring the CCD angle, the leg length discrepancy and the arc of cover. By adding the acetabular to the femoral anteversion, the combined anteversion was calculated. If there was a healthy natural hip on the contralateral side, the same measurements were performed.

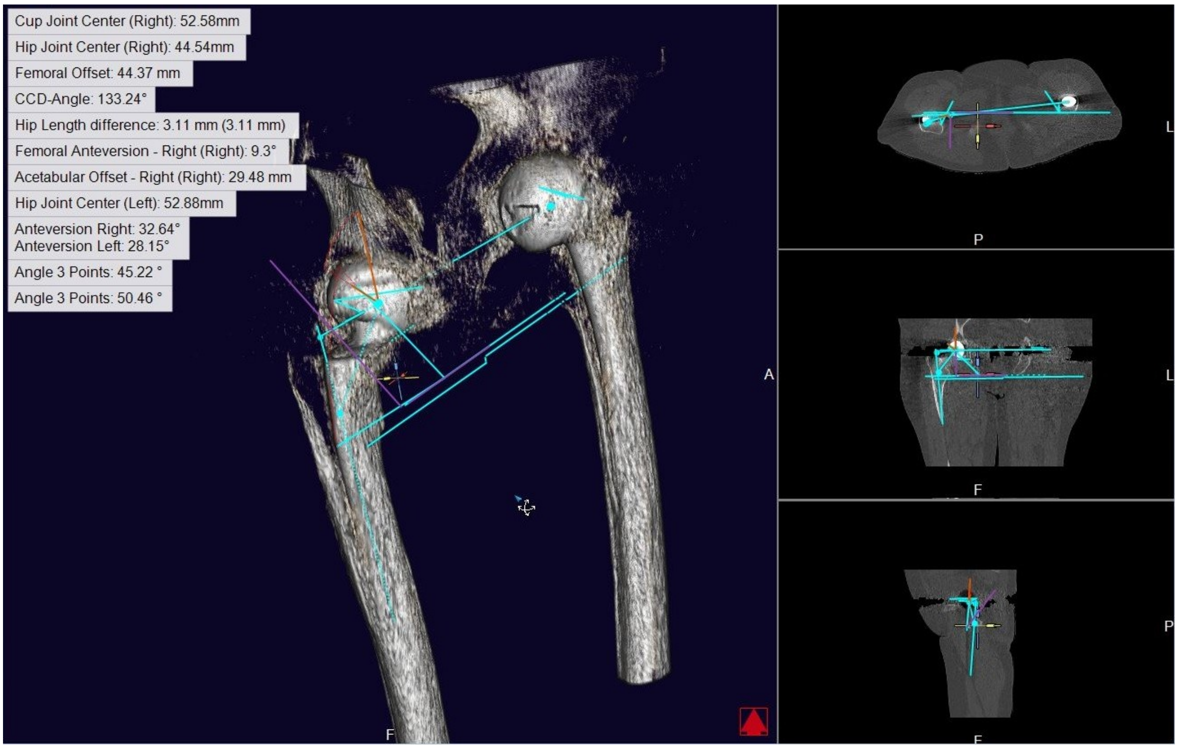

Fig. 10: Measurement with Hectec mediCAD hip 3D®

2.4.3. EBRA-FCA

The Einzel-Bild-Röntgen-Analyse – Femoral-Component-Analysis (EBRA-FCA) is a non-invasive, computer-based method for measuring the migration of implanted femoral shafts by comparing digital serial radiographs of the hip or pelvis (the tip of the femoral shaft must be visible). It was developed by a group from the University of Innsbruck, Austria (46).

It is a reliable method to detect loosening of the prostheses (25).

The medical records of all patients were searched for anteroposterior X-ray images of their hip joints, which were taken during routine controls in the past. At least three images of every hip were attained.

Fig. 11: EBRA-FCA

2.4.4. Statistical analysis

Statistical analysis was done with SPSS Statistics, Version 20 (IBM, Armonk, NY). The Chi-squared test was used to show relationships between categorical parameters and the t-test for comparison of continuous normally distributed values. A p-value of < 0.05 was considered to be statistically significant.

3. Results

3.1. Implant position

When comparing implant position from 3D measurements between the case group and the control group, the analysis of the combined anteversion yielded no significant difference (t-test; $p = .718$). Neither did the analysis of the arc of cover (t-test; $p = .450$) nor any other implant position factor (Table 3).

Table 3: T-test analysis of implant positon between case group and control group

Parameter	Case group mean value (n = 20)	Control group mean value (n = 21)	*P*
Combined anteversion	43,9° ± 13,6°	45,4° ± 13,0°	.718
Arc of cover	23,6mm ± 3,7mm	24,5mm ± 3,6mm	.450
Esposito-Walter formula	17,2° ± 12,5°	10,2° ± 11,5°	.066

To minimize wear in ceramic bearings and therefore reduce squeaking, Esposito et al. (47) suggested the following formula regarding the orientation of the acetabular component:

inclination + (7/5)*anteversion – 75° = 0°

According to their study, the further the result is from 0°, the greater the chance of high wear. The analysis of our data did not show a significant difference in the deviation from 0° between the two groups when this formula was applied (t-test; $p = .066$).

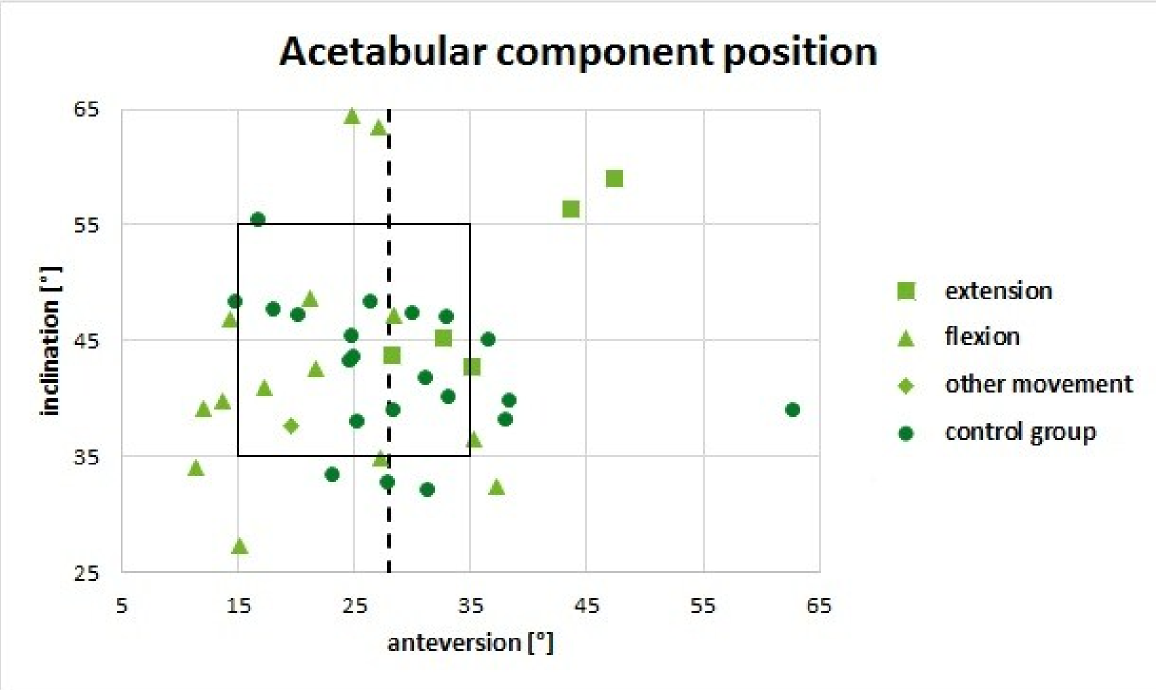

Fig. 12: Acetabular component position. The case group is divided according to the movement that provokes noise. The square marks the region of 15° to 35° anteversion and 35° to 55° inclination. The dashed line marks the minimal acetabular anteversion for the extension subgroup, suggesting anterosuperior edge loading is more likely to occur with higher acetabular anteversion angles.

If the acceptable range of the acetabular component is defined as anteversion between 15° and 35° and the inclination between 35° and 55°, then seven of twenty (35,0%) of the noisy hips met these criteria, whereas this was true for twelve of twenty-one (57,1%) hips in the control group (Fig. 12).
The subgroup of joints that squeaked in flexion (n=14) showed a lower mean acetabular anteversion 21,9° ± 8,4°, than those that squeaked in extension (n=5) 37,4° ± 7,9°. The latter had an acetabular anteversion angle of at least 28,2° (Fig. 12).

3.2. Demographic data

Neither height (t-test; p = .319), weight (t-test; p = .145), BMI (t-test; p = .191), age (t-test; p = .191) or gender (chi-squared; p = .889) showed significant difference.

3.3. Harris Hip Score and WOMAC Score

The mean Harris Hip Score for the case group was 93,7 points (range: 63-100 points), for the control group 93,4 points (range: 64-100 points) and showed no significant difference (t-test; p = .928) (Fig. 6). The mean WOMAC Score for the case group was 19,6 points (range: 0-110 points), for the control group 26,6 points (range: 0-157 points) and did not differ significantly either (t-test; p = .646) (Fig. 7).

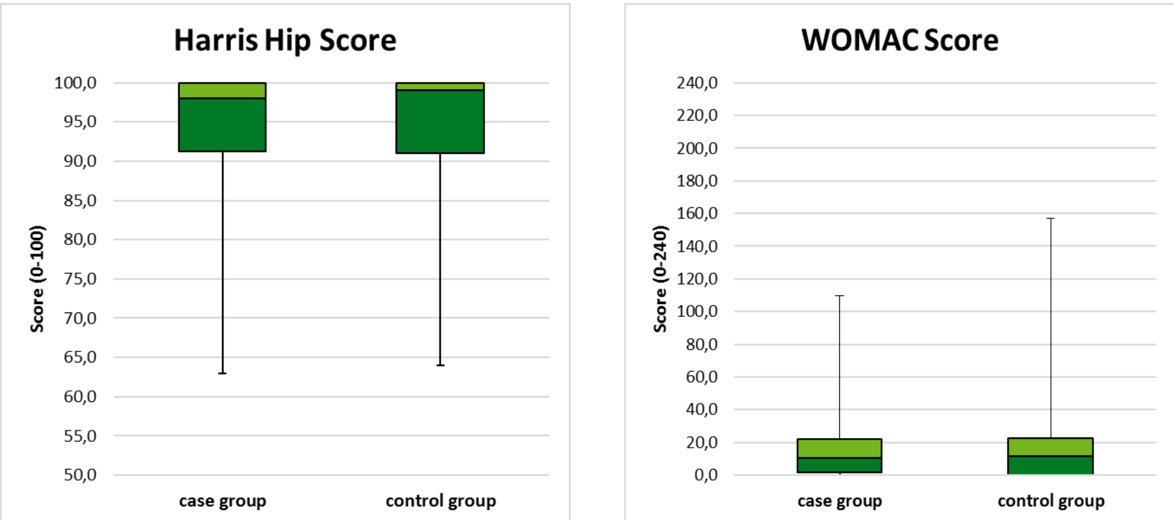

Fig. 13 a/b: Comparison of the Harris Hip Score and the WOMAC Score between case group and control group. Boxplots showing median, lower/upper quartile and whiskers for minimum/maximum values for each group.

3.4. Patient questionnaire

Every type of noise was taken into account seperately, for example if squeaking and grinding occured in one patient, this resulted in two cases of noise. Every movement that provoked a noise was taken into account seperately as well, for example if squeaking could be provoked by flexion and rotation in one hip, this also resulted in two cases.

The participants reported twenty-four cases of different noises in total, which can be divided into fourteen cases of squeaking, defined as a long, high-pitched sound, seven cases of grinding, defined as a long, low-pitched sound, and three cases of clicking, defined as a short, concise sound. No other type of sound was reported.

In twelve cases the noises could be heard less than daily by the patients, in ten cases the sound occurred every day at least once and in two cases it could be provoked almost every time by a certain movement. According to the patients, the movements that provoked noise in everyday life were flexion in the hip in seventeen cases, extension in five cases and one case for rotation in the hip with the foot fixed. One patient could occasionally hear squeaking and grinding when standing and rocking back and forth, resulting in two cases of “other movement”. None complained of audible sounds when performing repetitive movements like bicycling or hiking (Table 3).

When asked for the onset of the noise, the time lay between 2 weeks and 7 years, with a mean postoperative time until onset of 31,5 months for the whole case group.

Table 4: Noise as described by the patients in the patient questionnaire

Occurence of noise [cases*]		Type of noise [cases*]		Movement that provokes noise [cases**]	
Permanent	2	Squeaking	14	Flexion	17
Often (daily)	10	Grinding	7	Extension	5
Seldom (less than daily)	12	Clicking	3	Rotation	1
		Other noise	0	Repetitive movement	0
				Other movement	2

*Every type of noise was taken into account seperately, for example if squeaking and grinding occured in one patient, this resulted in two cases of noise.

**Every movement that provoked a noise was taken into account seperately, for example if squeaking could be provoked by flexion and rotation in one hip, this resulted in two cases

In one case pain was reported in deep flexion, that also produced grinding, on a level of 3 in a scale ranging from 0 (= no pain) to 10 (= extreme pain), but the patient didn’t feel like the pain and the noise were connected. Neither of the other members of the case group complained of any pain when their noise occurred.

The participants were also asked to rate the negative impact the noise had on their quality of life on a scale from 0 (= no neg. impact) to 5 (= severe neg. impact). In twelve cases the negative impact was rated with level 0, seven cases of level 1, four cases of level 2 and one case of level 3 negative impact with no reports of levels 4 or 5 (Fig. 14).
Although this was not a specific question, six patients (30%) reported to hear noise from their THR mostly in the morning, while still feeling a bit stiff after getting out of bed.

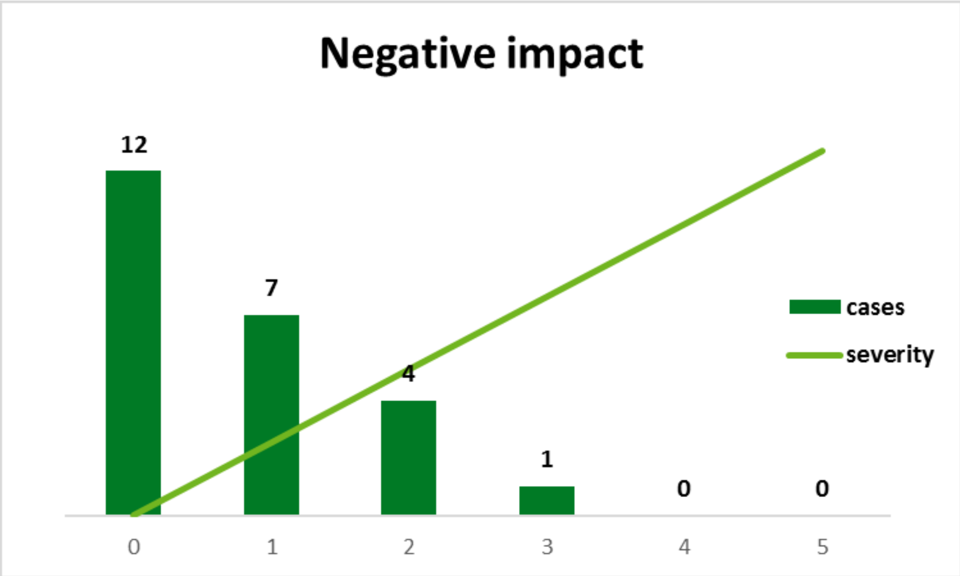

Fig. 14: Negative impact of noise on the quality of life. Bars showing the number of cases for each level, the line visualizing increasing severity on a scale from 0 to 5.

3.5. Functional examination

It was possible to provoke noise during examination at our clinic in eight cases (Table 4).
Case 1: There was a clicking sound when the hip joint of the patient was in extension, especially after the last step was taken at the end of the stairs and the first full step on even ground was made. It could not be reproduced every time the motion was performed.
Case 2: A barely audible grinding sound could be heard when the hip was at about 100° flexion, while the patient was doing squats and also when he sat down and started rocking back and forth on the chair, with the hip again at about 100° flexion. With neither movement the grinding occurred constantly but only sporadic.
Case 3: Quite loud squeaking when walking on even ground, at about every third step and according to the patient even more often after longer walks. The same squeak could be

heard at almost every step when walking upstairs. This happened as the hip joint was in full extension at about 5°. The patient also complained about pain during inward as well as outward rotation of the joint. Because of the severity of the noise and the pain a revision surgery was scheduled at the request of the patient.

Case 4: A rather quiet squeak, described by the patient quite fittingly "like the chirp of a little bird", when he stood still with both feet and rotated his upper body. It could be heard only infrequently.

Case 5: When the patient squatted with his hip joint at about 90° and leaned forward a constant clicking could be heard.

Case 6: While assessing the patient's ROM for the HHS a grinding sound could be heard when the hip was passively flexed to about 120°. It was not possible to provoke the sound more than once. The patient also reported never hearing the sound more often than once a day.

Case 7: Inconstant squeaking could be provoked while the patient was walking, at about every third step when he intentionally went into full extension in the hip joint. Because of a stiff knee on the contralateral side the patient is limping.

Case 8: A rather loud clicking sound while in extension during the gait, almost constantly audible during the examination of the patient. A squeaking sound could also inconstantly be heard when the patient was rotating with the foot fixed on the floor.

Case	Noise	Movement	Position	Reproducibility
1	clicking	walking upstairs	0° extension	inconstant
2	grinding	squatting	100° flexion	inconstant
	grinding	rocking back and forth while sitting	100° flexion	inconstant
3	squeaking	walking on even surface, at about every third step	5° extension	constant
	squeaking	walking upstairs, when two steps are taken at once	5° extension	constant
4	squeaking	rotation with fixed foot	10° outw. rot.	inconstant
5	clicking	squatting	90° flexion	constant
6	grinding	passive deep flexion while assessing ROM for HHS	120° flexion	inconstant
7	squeaking	walking on even surface, at about every third step when leg was intentionally fully extended in the hip joint	0° extension	incostant
8	squeaking	rotation with fixed foot	10° inw. rot.	inconstant
	clicking	constantly while walking, also inconstantly when rising from squatting position	0 ° extension	constant

Table 5: Details of cases where noise could be provoked in a functional examination

3.6. Radiographic evaluation of peri-implant bone structure

All X-ray images that were taken during the study were evaluated for signs of heterotopic ossification (HO) – using the Brooker system - and bone loss after THA.

There were four cases of HO in the case group, of these two were Brooker grade I and two Brooker grade II. In the control group one case of Brooker grade I and two cases of Brooker grade II were found, a total of three cases of HO. The occurrence of HO did not show a statistical significance in the Chi-squared test (p = .171).

Bone loss was described using three categories; osteolysis zones, peri-implant bone resorption (PIBR) and stress shielding. The acetabular zones of DeLee-Charnley and the femoral zones of Gruen were used to describe the localization of the findings (Fig. 15 a/b).

Thirteen cases of PIBR were found in the case group. With one exception the PIBR was limited to the proximal area of the femoral shaft. One case showed more extensive bone loss around the prosthesis, in femoral zones 1, 2, 6, 7, 8, 9, 13, 14. This was the same case that showed constant squeaking in extension when walking and climbing stairs (see chapter 3.3 – case 3). In the control group eight cases with PIBR were found, all limited to the proximal area of the femoral shaft. The occurrence of PIBR did not show a statistical significance in the Chi-squared test (p = 3.436).

In neither group signs of osteolysis or stress shielding could be found.

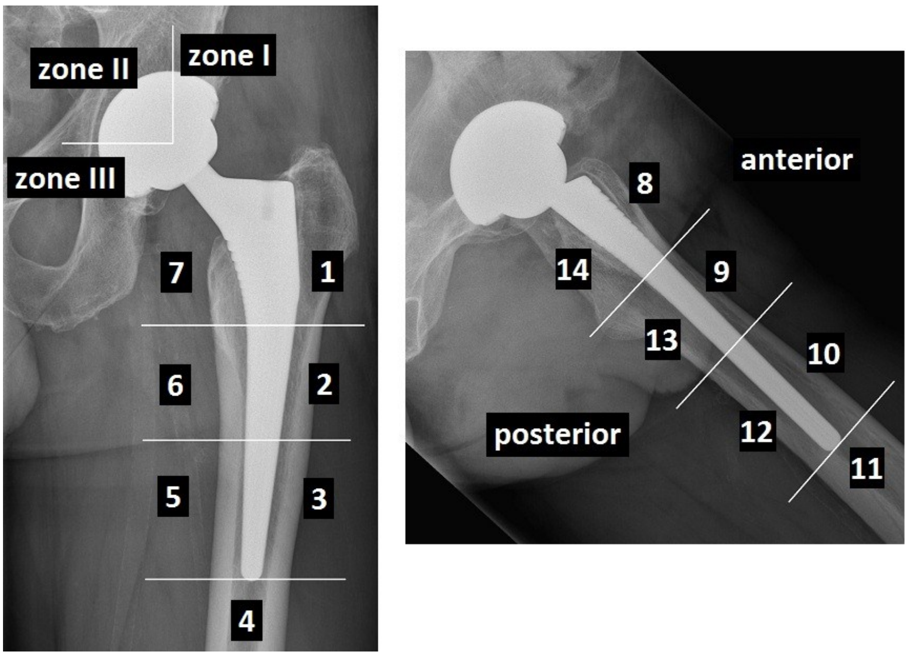

Fig. 15 a/b: Acetabular DeLee-Charnley zones I-III and femoral Gruen zones 1-7 on an anteroposterior hip radiograph and Gruen zones 8-14 on an axial hip radiograph

3.7. EBRA-FCA

No prosthesis in the study showed significant subsidence (> 2mm) in the EBRA-FCA analysis.

3.8. Comparison of the natural anatomy

Although not the primary aim of this study, the 3D measurements of the natural hip joints were also analyzed. We compared the anatomical configuration of the case group (n = 11) to that of the control group (n = 6). Assuming that the hip joints on both sides were similar, this gave us information about the configuration prior to the implantation of a prosthesis.

A significant difference was found when comparing the combined anteversion (t-test; p = .029) as well as just the acetabular anteversion (t-test; p = .046). Both mean values were higher in the case group than in the control group. The mean value for femoral anteversion was also higher in the case group, but this was not statistically significant (t-test; p = .068) (Table 6) (Fig. 16).

Table 6: T-test analysis of natural hip anatomy between case group and control group

Parameter	Case group mean value (n = 11)	Control group mean value (n = 6)	*P*
Combined anteversion	46,5° ± 3,3°	33,6° ± 3,8°	.029
Acetabular anteversion	21,1° ± 1,3°	16,0° ± 2,1°	.046
Femoral anteversion	25,3° ± 2,6°	17,5° ± 2,5°	.068

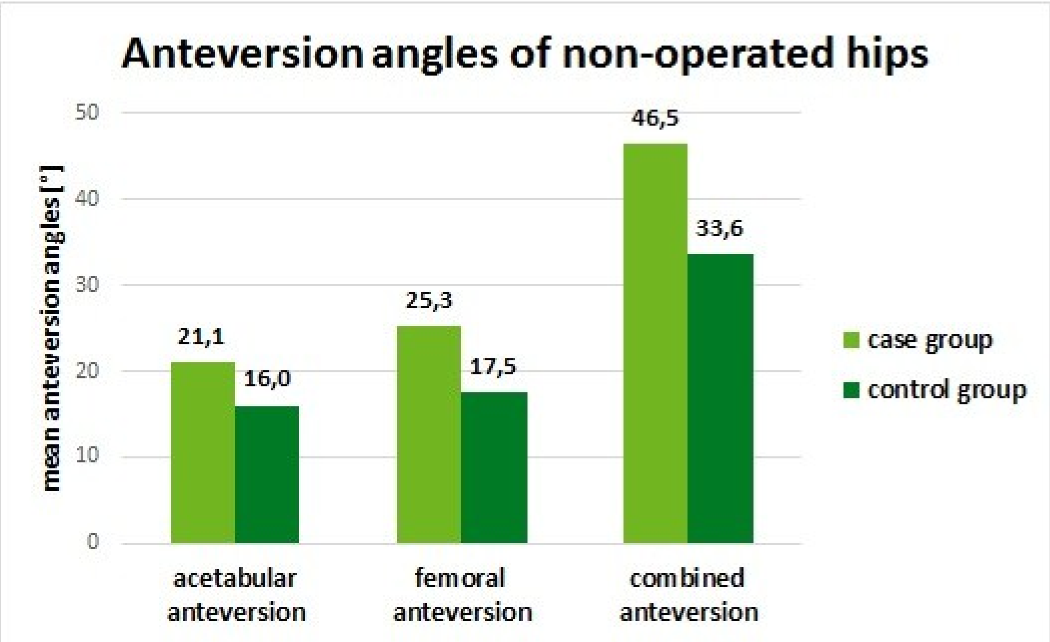

Fig. 16: Comparison of mean anteversion angles of non-operated hips between the case group and the control group.

4. Discussion

The main hypothesis of this study, that squeaking hip prostheses differ in their position from non-squeaking prostheses regarding the combined anteversion, was not supported by our data. The combined anteversion did not differ significantly between the noisy hips and the controls, so while this may contribute to squeaking in some cases, it does not appear to be a highly decisive factor. In the case reports by Sariali et al. (29), an excessive combined anteversion generated a posterior neck-rim impingement, clearly visible on their CT scans. No CT scan in our study showed these obvious signs of impingement. In two of three cases they found that the acetabular liner was not fully seated, something we did not observe in any of our cases. Also, none of our patients in the case group heard noise from their implant immediately after the operation, which differs from their patients. In a way it could be said that we did not have any "extreme" cases. Actually, the anteversion angles of our study population are all within a range that has been observed by another study done by Sendtner et al. (48) in Munich, Germany, which would suggest that our data is comparable to other clinics.

In 2012 Esposito et al. (47) analyzed 54 CoC bearings that were retrieved at revision operations, measured their wear and divided them into two groups for anterosuperior and posterior edge loading, according to the position of stripe wear. They found that the bearings that showed signs of anterosuperior edge loading were all high-wear, squeaking hips with an acetabular anteversion of > 22°. We also assessed the anteversion of the acetabular components for the case group, analyzing the cases that produced noise in extension - suggesting anterosuperior edge loading – and in flexion – suggesting posterior edge loading – separately. Our data confirms the finding that anterosuperior edge loading is more likely to occur with higher acetabular anteversion angles. We found a minimal acetabular anteversion of 28,2° for the extension group, as well as higher mean anteversion compared to the flexion group. This shows that a separate assessment of the different types of edge loading and the factors that contribute to them, may be crucial to understand and successfully reduce the incidence of squeaking. They (47) also proposed a more complex acetabular safe zone than the recommended square (49, 50), that could be determined mathematically. We applied their suggested formula for positioning of the acetabular component, to see if we could find a significant difference between our noisy hips and the controls, which we could not. Walter et al. (49) found that 35% of the acetabular components of their case group was inside the range of 15° to 35° anteversion and 35° to

55° inclination, opposed to 94% in the control group. In our study we also had 35% of the case group inside this range, but only 57% of the control group. Although our numbers don't point as decidedly towards the position of the acetabular components as a cause for noise, it still suggests that placing them in the ideal range more often would reduce the incidents of squeaking. It also shows how often the safe zone is missed.

Migaud et al. (51) argued that cup and stem fixation failures of CoC THA lead to earlier revisions than metal on polyethylene (MoP) THA, because of their relation to ceramic-related complications like breakage, squeaking and incorrect liner insertion. We do not disagree with this, but it can't be said that conversely, cup and stem fixation failures have to be present for squeaking to develop. We found only one case of somewhat extensive peri-implant bone resorption in the case group and no cases of osteolysis, stress shielding or stem subsidence at all. Neither radiographic evaluation for peri-implant bone loss and stress shielding, nor EBRA-FCA showed reliable signs for the identification of noisy hips. This is supported by data of Molloy et al. (33), who found that all 74 squeaking hips in their cohort showed evidence of stable bony ingrowth in the radiographs.

The difference in the anatomy of the non-operated natural joints, with higher anteversion angles for the case group, suggests that for patients with exceptional anatomical properties, a standardized anatomical reconstruction with prosthesis implantation might result in suboptimal biomechanics, which subsequently leads to a higher incidence of noise. This has to be further investigated when sufficient data from noisy hips, including pre-operative radiographic image material, is available. Other complications, like higher risk of aseptic loosening, higher wear rates and changes of gait function, that are results of inaccurate restoration of anatomical properties after THA, are well described in other studies (52-54).

We did not observe a correlation of squeaking and demographic data as described in other studies, who found noise to be more likely for younger, heavier and taller patients (33, 40, 55) or higher BMI (56).

As for patient satisfaction, no significant difference in the Harris Hip Score or WOMAC Score could be found, which is in line with other authors (33), although noise from the hip prosthesis is definitely worry- and bothersome to some patients, as the evaluation of the negative impact on quality of life from our patient questionnaire clearly shows. In addition, the number of unrecorded cases of noisy THAs among patients might be quite high, since incidence varies drastically between different studies and there is no standardized way to assess noise from hip prostheses. A meta-analysis from 2014 of Owen et al. (57) found a mean incidence of 4,2% for a total of 43 studies including 16.828 CoC THAs. In our study population the incidence of squeaking was 3,1% (27 of 873 hip joints), but we did not actively ask for noise, so we only became aware of this when patients reported it. Sexton et al. (40) asked their patients at follow up for noise and also reported an incidence of 3,1% (74 of 2406 hip joints). In contrast, Owen et al. (39) had an incidence of noise of 24,6% (17 of 69 hip joints), Molloy et al. (33) also 24,6% (74 of 301 hip joints) and Wyatt et al. (36) reported 37,3% (26 of 69 hip joints).

A strength of this study is the availability of CT images that enabled a precise measurement of implant position, especially femoral anteversion, adding more data to an insufficiently investigated element of noise generation in artificial hip joints. The comparison between a case group and a control group as well as a comparison of natural joints cover a broader range of aspects than many other available studies. If CT images are available, femoral anteversion - and subsequently combined anteversion - should be measured, as this is an important factor of implant position.

One limitation of this study is the low number of available participants for the case group, which makes reliable statistical analysis difficult. Another limitation is, that only in eight patients noise could be provoked during the examination. For the rest of the study population their own personal reports had to be relied upon, without the possibility of verification. Furthermore, no pre-operative CT scans of the hips were available, so comparison of implant position to the natural configuration of the joint was only possible with patients who still had a natural hip joint on the contralateral side, under the assumption that it mirrored the examined joint before surgery.

Cases of squeaking hips certainly deserve more attention in everyday clinical practice, publications like the "Practical Guide for Handling Noises in Hard-on-Hard Bearings" from Walter et al. (58) provide valuable information for physicians.

In conclusion, squeaking continues to be a complex, multifactorial problem in need of further investigation. Combined anteversion does not seem to be a highly decisive factor, although only a limited amount of data is available as of now. It appears highly recommendable to assess different mechanisms of noise generation separately. For patients with exceptional anatomical properties, a more accurate reconstruction of those properties with prosthesis implantation may be necessary to reduce complications, although this needs to be proven by more reliable statistical analysis as more data becomes available.

By providing a database for a wide range of potential factors regarding noisy hips, the foundation for further systematic research of this phenomenon has been established at our clinic.

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Appendices

- Participant invitation
- Informed consent form
- Study protocol
- Case report form

Einladung zur Teilnahme an der Nachuntersuchung

"Quietschende Hüft-Totalendoprothesen mit Keramik-auf-Keramik Gleitpaarung: 3D-Analyse von Computertomographiebildern"

durchgeführt an der

Universitätsklinik für Orthopädie und Orthopädische Chirurgie

LKH Univ.-Klinikum Graz

Auenbruggerplatz 5

8036 Graz Austria

Sehr geehrte/r…….

Sie haben an unserer Klinik ein künstliches Hüftgelenk mit einer Keramik auf Keramik Gleitpaarung erhalten. Wir hoffen, dass es Ihnen damit nach wie vor gut geht und Sie mit dem Ergebnis zufrieden sind.

Warum erhalten Sie diese Einladung

Im Zuge der Nachuntersuchung aller Patienten, die zwischen 2005 und 2012 eine Hüftprothese mit Keramikgleitpaarung an unserer Klinik erhalten haben, identifizierten wir einige sogenannte „quietschende" Hüften. Dieses hörbare Quietschen kann gelegentlich bei Keramikgleitpaarungen auftreten und stellt an sich keine Gefahr dar. Die genauen Gründe für das Auftreten dieses Geräusches sind noch nicht restlos geklärt. Wir möchten Sie daher bitten, für eine weitere Untersuchung an unsere Klinik zu kommen.

Was ist das Ziel der Studie

Ziel unserer Studie ist es mehr Klarheit darüber zu gewinnen, warum Hüftgelenksprothesen mit einer Keramikgleitpaarung gelegentlich hörbare Geräusche erzeugen.

Wie wird diese Studie durchgeführt

Patienten mit quietschenden Prothesen werden mit einer Kontrollgruppe mit unauffälligen Prothesen verglichen.
Im Zuge einer ambulanten Kontrolle werden Fragebögen mit Ihnen durchgegangen, es erfolgt eine klinische Untersuchung und es werden Röntgenbilder sowie Computertomographieschichtbilder erstellt. Das Bildmaterial wird in weiterer Folge mit einem völlig neuen Computerprogramm digital dreidimensional rekonstruiert, vermessen und die Bewegung in einem dreidimensionalen Modell simuliert und ausgewertet.

Wie ist der Ablauf bei Teilnahme

Die Teilnahme an der Studie erfolgt freiwillig und kann jederzeit ohne Angabe von Gründen beendet werden.

Alle Befragungen und Untersuchungen erfolgen bei einem einzelnen Besuch an der Universitätsklinik für Orthopädie und orthopädische Chirurgie des Univ.-Klinikum LKH Graz.

Sie werden gebeten einen Fragebogen auszufüllen und einige Angaben bezüglich Ihrer Hüftgelenksprothese zu machen, welche wir schriftlich festhalten werden.

Die Beweglichkeit Ihres künstlichen Hüftgelenkes wird vermessen und Bewegungen die zur Geräuschentwicklung führen werden genau dokumentiert.

Röntgenaufnahmen und eine Computertomographie-Schichtbildgebung (sogenanntes CT) Ihres Hüftgelenkes werden erstellt.

Wann ist eine Teilnahme nicht möglich?

Falls Sie zurzeit schwanger sind, können Sie nicht an der Studie teilnehmen.

Ihr Termin wäre am XXXXX um XXXXX in der orthopädischen Hüftambulanz.

Falls Sie diesen Termin nicht einhalten können, bitten wir um telefonische Terminverschiebung unter 0316/385-12877 (Frau Primus Stefanie).

Falls Sie noch Fragen zur Studie haben sollten stehen wir selbstverständlich jederzeit zu Ihrer Verfügung.

Ansprechpartner:

OA Dr. Werner Maurer-Ertl
Leiter Sektion Hüfte
Universitätsklinik für Orthopädie und Orthopädische Chirurgie
LKH Univ.-Klinikum Graz
Auenbruggerplatz 5
8036 Graz Austria

cand. med. Boris Schiller

Wissenschaftlicher Mitarbeiter im Zuge der Diplomarbeit

oder

Frau Stefanie Primus
LKH Univ.-Klinikum Graz
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8036 Graz Austria

Patienteninformation

"Quietschende Hüft-Totalendoprothesen mit Keramik-auf-Keramik Gleitpaarung: 3D-Analyse von Computertomographiebildern "

Univ.-Ass. Dr.med.univ. Werner Maurer-Ertl, Dr.med.univ. Dr.scient.med. Jörg Friesenbichler, c.m. Boris Schiller, Univ.-Prof. Dr.med.univ. Andreas Leithner

Universitätsklinik für Orthopädie und Traumatologie, LKH Graz
Auenbruggerplatz 5, 8036 Graz

Sehr geehrte Studienteilnehmerin, sehr geehrter Studienteilnehmer!

Wir laden Sie ein an der oben genannten Fall-Kontroll-Studie teilzunehmen. Die Aufklärung darüber erfolgt in einem ausführlichen ärztlichen Gespräch.

Die Teilnahme an einer Studie ist freiwillig und kann jederzeit ohne Angabe von Gründen durch Sie beendet werden.

Bitte unterschreiben Sie die Einwilligungserklärung nur

- **wenn Sie Art und Ablauf der klinischen Prüfung vollständig verstanden haben,**
- **wenn Sie bereit sind, der Teilnahme zuzustimmen und**
- **wenn Sie sich über Ihre Rechte als Teilnehmer an dieser klinischen Prüfung im Klaren sind.**

In Fall-Kontroll-Studien werden die Daten von einer Gruppe von Personen mit einer Komplikation oder Erkrankung und einer Gruppe von Personen ohne diese Komplikation oder Erkrankung verglichen und auf das Vorhandensein von Risiko- oder schützenden Faktoren überprüft. Diese Studien sind notwendig um neue medizinische Forschungsergebnisse über die Ursachen von Komplikationen und Erkrankungen zu gewinnen.
Bitte lesen Sie den folgenden Text als Ergänzung zum Informationsgespräch mit Ihrem Arzt sorgfältig durch und zögern Sie nicht Fragen zu stellen.

Diese Studie, die Patienteninformation und Einwilligungserklärung wurden von der Ethikkommission der Medizinischen Universität Graz geprüft.

Wer organisiert diese Studie:
Diese Studie wird von der Universitätsklinik für Orthopädie der Medizinischen Universität Graz unter der Leitung von Univ. Prof. Dr. A. Leithner und Dr. W. Maurer-Ertl organisiert und durchgeführt.

Was ist das Ziel dieser Studie?
Ziel unserer Studie ist es, mehr Klarheit darüber zu gewinnen, warum im Alltag Hüftgelenksprothesen hörbare Geräusche von sich geben. Dies wird umgangssprachlich auch als "Quietschen" bezeichnet.

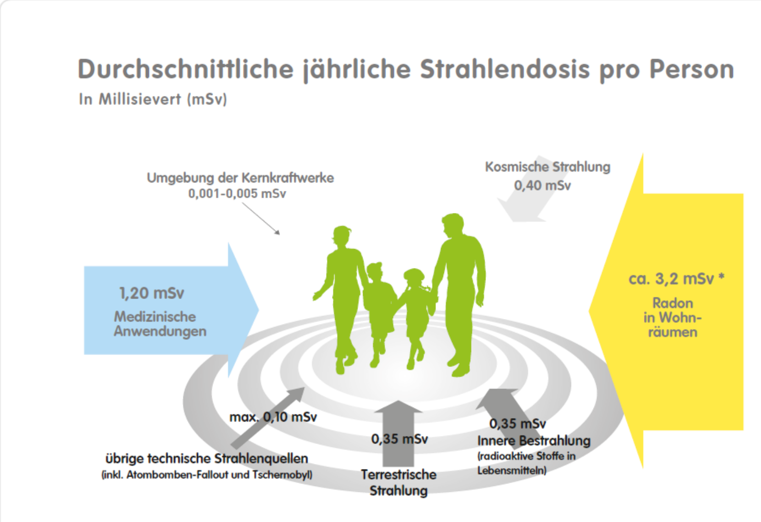
Warum wird diese Studie durchgeführt?
Es konnte noch nicht endgültig geklärt werden, wodurch dieses Phänomen entsteht und welche medizinischen Konsequenzen sich daraus ergeben.
Wir möchten durch die in der Studie gewonnenen Erkenntnisse dazu beitragen, dass in Zukunft die Auswirkungen des Quietschens besser verstanden und die Entstehung von vornherein besser vermieden werden kann.

Wie ist der Ablauf der Studie?
Alle Befragungen und Untersuchungen erfolgen bei einem einzelnen Besuch an der Abteilung für Orthopädie und Traumatologie des Univ.-Klinikum LKH Graz.
Sie werden gebeten den WOMAC-Fragebogen (Western Ontario and McMaster Universities Arthritis Index) auszufüllen und einige Angaben bezüglich Ihrer Hüftgelenksprothese zu machen, welche wir im Harris-Hip-Score und in einem Probandenfragebogen festhalten werden.
Die Beweglichkeit Ihres künstlichen Hüftgelenkes wird vermessen und Bewegungen die zur Geräuschentwicklung führen werden genau dokumentiert.
Die radiologische Untersuchung umfasst das Anfertigen von einer Low Dose Rotations-Computertomographie des Beckens, sowie von drei Röntgenbildern (Beckenübersichtsröntgen stehend, Aufnahmen von anterior-posterior und axial), falls keine aktuellen Röntgenbilder aus vorhergehenden Routinekontrollen vorhanden sind.
Das Bildmaterial wird in weiterer Folge dazu verwendet mit dem Computerprogramm Hectec mediCAD 3D digitale dreidimensionale Modelle der Hüftgelenke zu erstellen und zu vermessen und mit der herkömmlichen 2D-Vermessung zu vergleichen.

Wann ist eine Teilnahme nicht möglich?
Falls Sie zurzeit schwanger sind oder Ihr Hüftgelenk momentan entzündet ist, können Sie nicht teilnehmen.

Gibt es Risiken?
Durch die radiologischen Untersuchungen zur Erstellung der Röntgen- u.
CT-Bilder setzen Sie sich einer gewissen Dosis an ionisierender Strahlung aus.
Durch die Verwendung modernster Geräte wird diese so gering wie möglich gehalten und entspricht in etwa der Strahlendosis, der sich jeder Einwohner Österreichs durch natürliche Strahlungsquellen in unserer Umgebung innerhalb eines Jahres aussetzt.

Die zu erwartenden Strahlungsmengen betragen für die Röntgenaufnahmen etwa 1,0 mSv und für die Low Dose Rotationscomputertomographie etwa 2,0 mSv. Da die notwendige Strahlendosis von verschiedenen Faktoren, wie zum Beispiel dem Körperbau abhängt, können diese Werte nicht ganz exakt im Vorhinein angegeben werden. Die Untersuchungen werden in Ihrem elektronischen Röntgenpass vermerkt und können unter www.patienten-portal.kages.at jederzeit eingesehen werden.



Unmittelbare Umgebung eines Kernkraftwerks	0,001-0,005 mSv pro Jahr
Röntgen eines Zahns	0,005 mSv
Interkontinentalflug retour	0,03 mSv
Nahrung (radioaktive Stoffe in Lebensmitteln)	0,35 mSv pro Jahr
Mammographie	ca. 0,5 mSv
Kosmische Strahlung im Engadin	1 mSv pro Jahr
Röntgen Darmtrakt	4 mSv
Natürliche Strahlenexposition Schweiz im Durchschnitt	4,2 mSv pro Jahr
Gesamte Strahlenexposition Schweiz im Durchschnitt	5,6 mSv pro Jahr
Zwanzig Zigaretten täglich	ca. 8,8 mSv pro Jahr
Computertomographie des Rumpfs	ca. 10 mSv
Natürliche Strahlenexposition im Schwarzwald	20 mSv pro Jahr
Natürliche Strahlenexposition in Kerala (Indien)	80 mSv pro Jahr
Natürliche Strahlenexposition in Ramsar (Iran)	bis zu 200 mSv pro Jahr
Tödliche Einmaldosis	5000 mSv

Werden ihre Daten vertraulich behandelt?

Selbstverständlich werden ihre Daten streng vertraulich behandelt. Gewonnene Daten aus dieser Untersuchung sind zwar für wissenschaftliche Veröffentlichungen vorgesehen, Sie werden aber dabei niemals mit Ihrem Namen oder Geburtsdatum angeführt, sodass Ihre Anonymität stets garantiert ist. Auch die Datenauswertung erfolgt lediglich unter Verwendung Ihrer Initialen und Ihrer Studienteilnehmernummer.
Sofern gesetzlich nicht etwas anderes vorgesehen ist, haben nur die Prüfer/innen und deren Mitarbeiter/innen Zugang zu den vertraulichen Daten, in denen Sie namentlich genannt werden („personenbezogene" Daten). Weiters können Beauftragte von in- und ausländischen Gesundheitsbehörden, der zuständigen Ethikkommission, sowie – wenn zutreffend – des Auftraggebers der klinischen Prüfung Einsicht in diese Daten nehmen, um die Richtigkeit der Aufzeichnungen zu überprüfen. Diese Personen unterliegen einer gesetzlichen Verschwiegenheitspflicht.

Die Einwilligung zur Verwendung Ihrer Daten kann jederzeit von Ihnen widerrufen werden.

Die Weitergabe der Daten im In- und Ausland erfolgt ausschließlich zu statistischen Zwecken in verschlüsselter (nur „indirekt personenbezogener") oder anonymisierter Form, das heißt, Sie werden nicht namentlich genannt. Auch in etwaigen Veröffentlichungen der Daten dieser klinischen Prüfung werden Sie nicht namentlich genannt.
Die Prüfer/innen und Ihre Mitarbeiter/innen unterliegen im Umgang mit den Daten den Bestimmungen des österreichischen Datenschutzgesetzes 2000 in der jeweils geltenden Fassung.
Wenn Sie Ihre Einwilligung zurückziehen und damit Ihre Teilnahme vorzeitig beenden, werden keine neuen Daten mehr über Sie erhoben. Aufgrund gesetzlicher Dokumentationspflichten (Arzneimittel- bzw. Medizinproduktegesetz) kann jedoch weiterhin für einen gesetzlich festgelegten Zeitraum eine Einsichtnahme in Ihre personenbezogenen Daten zu Prüfzwecken durch autorisierte, zur Verschwiegenheit verpflichtete Personen erfolgen.

Wird die Teilnahme vergütet?
Da wir keinerlei finanzielle Unterstützung von Firmen oder Organisationen bei unserer Studie bekommen, ist es uns leider nicht möglich Ihnen eine Vergütung für die Teilnahme anzubieten.

Für weitere Fragen
Ansprechpartner:

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Frau Stefanie Primus
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Auenbruggerplatz 5
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0316 385 DW 1287

Vielen Dank

Wir möchten Ihnen danken, dass Sie sich die Zeit nehmen an dieser Studie teilzunehmen.

Name des Studienteilnehmers: ……………………………………………………………

Geburtsdatum: …………………………………………..

Mit nachstehend geleisteter Unterschrift bestätige ich oben angeführte Erklärungen zusätzlich zum ärztlichen Aufklärungsgespräch über die geplante Studie gelesen und verstanden zu haben.

Ich willige hiermit zur Teilnahme an der Studie

"Quietschende Hüft-Totalendoprothesen mit Keramik-auf-Keramik Gleitpaarung: 3D-Analyse von Computertomographiebildern"

ein.

Eine Kopie dieser Patienteninformation und Einwilligungserklärung habe ich erhalten. Das Original verbleibt beim Prüfarzt.

Graz am ……………………………..

…………………………… ……………………………………………………………………..

Unterschrift Studienteilnehmer

……………………………………………………………………..

Unterschrift verantwortlicher Arzt

PROTOCOL

Squeaking ceramic-on-ceramic total hip arthroplasties: 3D analysis of CT scans

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1. Introduction

Total hip arthroplasty is one of the most common orthopedic procedures today. Although the success rate is high, some complications remain to be ongoing concerns.
One of these is the occurrence of high pitched audible sounds during movement of the hip joint, commonly referred to as „squeaking“. This phenomenon is thought to be multifactorial and is yet to be completely understood.
Different studies have proposed and investigated implant positioning as one important factor, but there have been varying results, which make further research necessary.

2. Objective

Our aim is the identification and interpretation of different factors, which lead to noise generation in THAs, with a focus on implant positioning. We intend to do this by a clinical examination of patients with noisy THRs and a matched control group, as well as a radiological examination, using low dose rotation CT scans, which will be converted into digital 3D models. We will also compare the contralateral, physiological hip joint to the THAs, to be able to find and interpret differences of the configuration between the natural and artificial joints. The results could help to lower the number of future revision surgeries, by providing data that leads to a better understanding and avoiding of squeaking.

3. Study Design

Single center-, retrospective, case-control study performed at the Department of Orthopaedics and Orthopedic Surgery.
EBM Level 3, Centre for Evidence-Based Medicine, Oxford, UK www.cebm.net

4. Material and Methods

4.1. Participants

14 patients identified with squeaking hip and an equal sized control group within 997 THA out of follow up data base of primary THA performed at our clinic from 2005 to 2012. The data base was created as part of a previous study [1] at our clinic.
Case group and control group will be matched for:

- Gender
- Age
- Height
- Weight
- Primary diagnosis
- Date of surgery
- Femoral head size / acetabular component size

4.1.1. Sample Size

14 patients itendified with squeaking hip within 997 THA form the case group.
As a control group we include an equal number of patients with silent hip after THA.

4.1.2. Recruitment

The patients will be informed and invited to join the clinical follow up by mail or additionally by phone if necessary.

4.1.3. Inclusion criteria

- Minimal age: 18 years
- Implantation of THR Pinnacle Corail with COC at our clinic from 2005 to 2012

4.1.4. Exclusion criteria

- Acute infection of prosthesis
- Pregnancy

4.2. Implants

4.2.1. DePuy Pinnacle / Corail

For further information, see appendix - product information sheets 12.3

4.3. Clinical examination

4.3.1. Demographic data

- Gender
- Age
- Height and weight → BMI

4.3.2. Scores

4.3.2.1. Harris Hip Score

See „http://www.orthopaedicscore.com/scorepages/harris_hip_score.html“ for more information.

4.3.2.2. WOMAC Score

See „http://www.orthopaedicscore.com/scorepages/knee_injury_osteopaedic_outcome_score_womac.html“ for more information.

4.3.3. Implant data (for details see CRF 12.2)

- Side
- Cup shell
- Liner
- Femoral head
- Femoral stem
- Operating surgeon
- Primary diagnosis
- Surgical method

4.3.4. Specific queries (for details see CRF 12.2)

- Does your THR make noises?
- How is the noise described?
- When did the noise first occur?
- Did a specific event lead to first occurrence of the noise?
- Which movement/action leads to noise?
- How often does the noise occur?
- Is the noise associated with pain?
- Does the noise have a negative impact on the quality of life?

4.3.5. Functional examination (for details see CRF 12.2)

The participants will be asked to perform a certain set of movements/actions in an attempt to provoke noise generation. These are:

- Squat and rise
- Turn with fixed foot (on side of noisy THR)
- Walk across the room
- Climb stairs
- Cycle on home trainer for 1 minute (low intensity)
- Other movement/action (only if necessary to provoke noise)

4.4. Radiological examination

4.4.1. Low dose rotation CT

CT scans for the 3D modelling with the software in use. The radiation exposition for the participants is about 2.0 mSv per examination.

4.4.2. X-Ray images

Will be obtained from previously attended regular control examinations. Whole pelvis and hip in anterior-posterior and axial view.

SSK

Strahlenschutzkommission

Geschäftsstelle der
Strahlenschutzkommission
Postfach 12 06 29
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Orientierungshilfe
für bildgebende Untersuchungen

– Tabellen –
Klinische Fragestellungen und empfohlene Untersuchungsverfahren

Empfehlung der Strahlenschutzkommission

Tabelle 1: Typische effektive Dosen durch medizinische Strahlenexposition

Diagnoseverfahren	Typische effektive Dosis (mSv)	Anzahl von Untersuchungen des Thorax in 2 Ebenen, die zu einer vergleichbaren Exposition führt	Ungefährer Zeitraum der natürlichen Strahlenexposition, der zu einer vergleichbaren Exposition führt[1]
Röntgenuntersuchungen:[2]			
Extremitäten und Gelenke (außer Hüfte)	0,01	0,1	1,5 Tage
Thorax (einzelne p.a.-Aufnahme)	0,04	0,4	7 Tage
Thorax in 2 Ebenen	0,1	1	15 Tage
Schädel	0,07	0,7	12 Tage
Brustwirbelsäule	0,7	7	4 Monate
Lendenwirbelsäule	1,3	13	7 Monate
Hüfte	0,3	3	7 Wochen
Becken	0,7	7	4 Monate
Abdomen	1,0	10	6 Monate
Mammographie bds. 2 Ebenen	0,5	5	3 Monate
Ausscheidungsurografie	2,5	25	14 Monate
Barium-Bolus	1,5	15	9 Monate
Bariumbrei	3	30	17 Monate
Bariumeinlauf	7	70	3,3 Jahre
CT - Kopf	2,3	23	1,1 Jahr
CT - Thorax	8	80	3,8 Jahre
CT - Abdomen oder Becken	10	100	4,8 Jahre
CT - Ganzkörper[3]	14	140	6,7 Jahre
Nuklearmedizinische Untersuchungen:			
Nierenfunktionsszintigraphie (100 MBq Tc-99m-MAG3)	0,7	7	4 Monate
Schilddrüsenszintigraphie (75 MBq Tc-99m)	1,0	10	5,7 Monate
Lungenperfusionsszintigraphie (100 MBq Tc-99m-Micropartikel)	1,1	11	6,3 Monate
Skelettszintigraphie (500 MBq Tc-99m-Phosphonat)	2,9	29	1,4 Jahre
Hirnszintigraphie (550 MBq Tc-99m-HMPAO o.ä.)	5,1	51	2,4 Jahre
Myocardperfusionsszintigraphie (600 MBq Tc-99m-MIBI)[5]	5,4	54	2,6 Jahre
Positronen-Emissions-Tomographie (200 MBq F-18-FDG)	3,8	38	1,8 Jahre

[1] Durchschnittliche natürliche Strahlenexposition in Deutschland: 2,1 mSv pro Jahr [BMU: Umweltradioaktivität und Strahlenbelastung im Jahr 2005, Unterrichtung durch die Bundesregierung (Parlamentsbericht), 2007] (äußere Exposition, natürliche Strahlenquellen, Ingestion und Radonexposition in Häusern).

[2] In Anlehnung an die Europäische Kommission: Leitlinien für die Überweisung zur Durchführung von bildgebenden Verfahren, Strahlenschutz 118 (2001), S. 20.

[3] Im Normalfall als diagnostische Maßnahme nicht gerechtfertigt.

[4] Zur Berechnung der effektiven Dosen wurden die vom Bundesamt für Strahlenschutz 2003 veröffentlichten Referenzaktivitäten verwendet.

[5] Unter Ruhebedingung; 4,7 mSv unter Belastung.

4.5. Hectec mediCAD Hip 3D software

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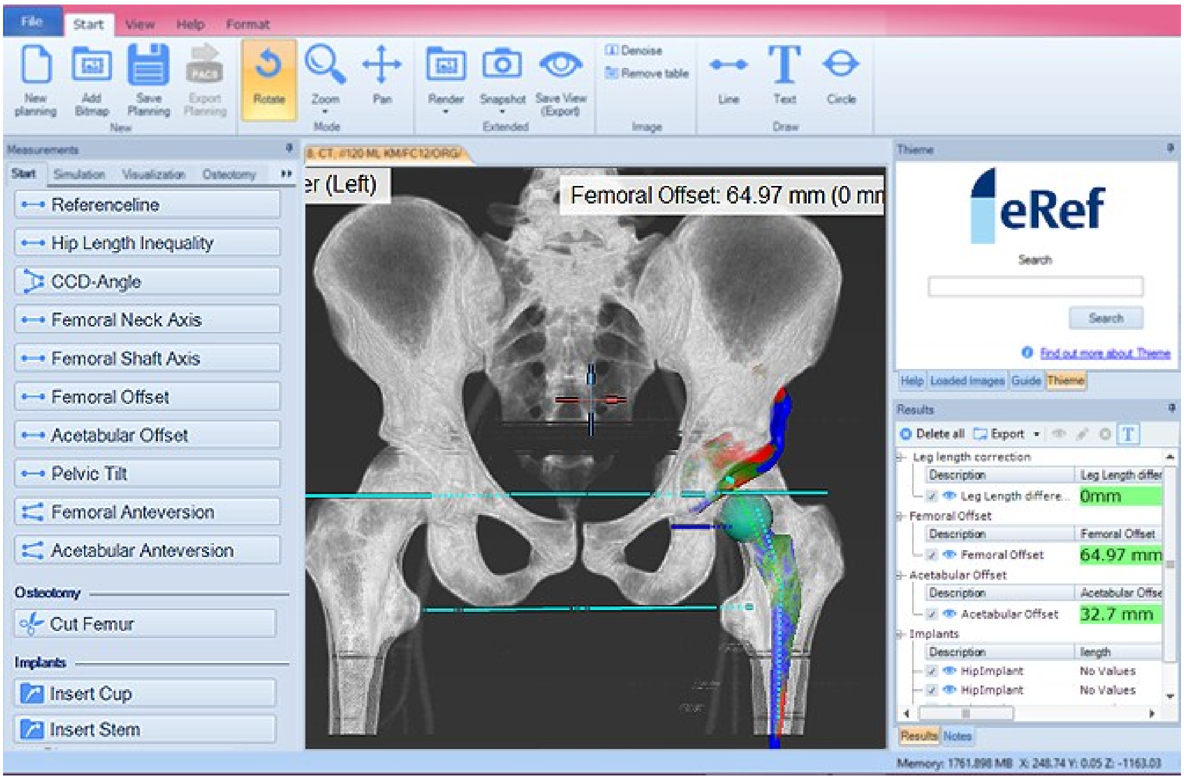

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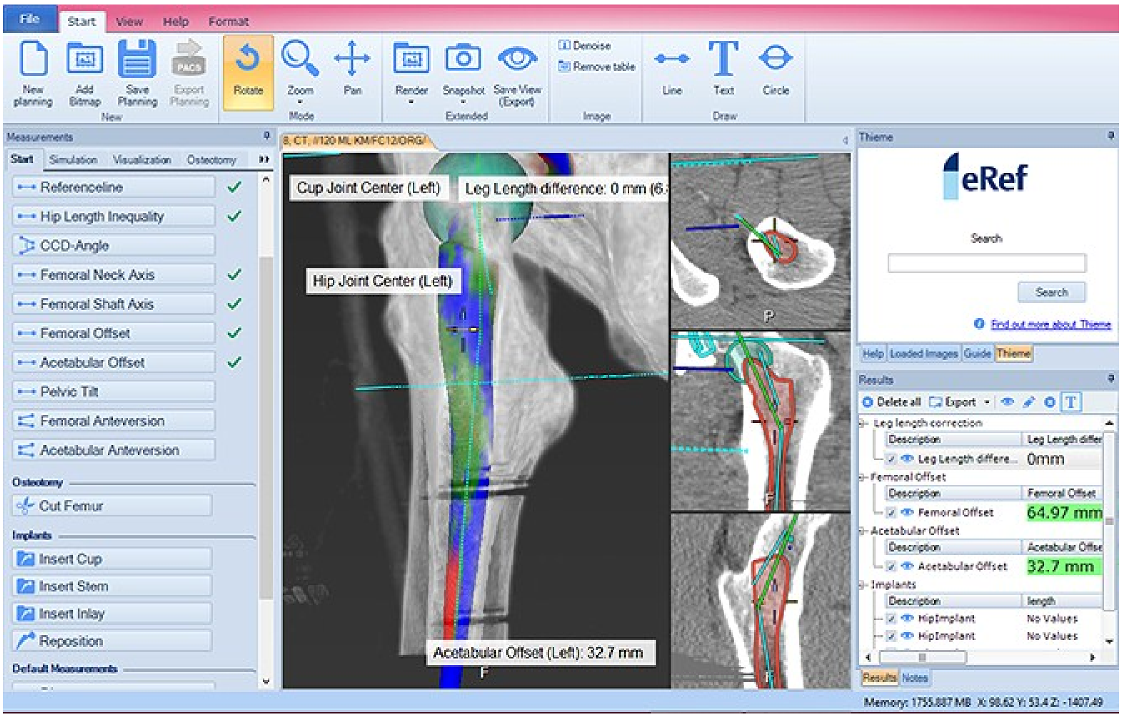

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5. Measurements

Measurements of 2D and 3D images will be compared to each other.
If the necessary x-ray images can be obtained, EBRA (Einzel-Bild-Röntgen-Analyse) will be performed to measure prosthesis migration.

Primary outcomes

- Acetabular inclination
- Acetabular anteversion
- Femoral anteversion
- Combined anteversion
- Femoral offset
- Femoral stem alignment varus-neutral-valgus
- CCD Angle
- Leg length discrepancy
- Arc of cover
- Active head-liner contact area in E20-0-F90
- Neck-cup impingement
-

Secondary outcomes

- Bony ingrowth of prosthesis
- Loosening of prosthesis
- Fractures of prosthesis
- Stress shielding
- Osteolysis zones
- Heterotopic ossification (Brooker classification)
- Peri-implant bone resorption (De Lee and Charnley zones / Gruen zones)
- Prosthesis migration (EBRA)

6. Timetables

Timetable of study

June 2016 – August 2016	August 2016 – September 2016	September 2016 –December 2017	January 2018 – February 2018	May 2018
Preparation and literature search	Identification and recruitment of participants	Examinations – data acquisition	Data analysis and interpretation	Publication of findings

Timetable of examinations and data acquisition

	Before visit	During visit	After visit
Informing of participants	x		
Signing of informed consent		x	
CRF		x	
Harris Hip Score		x	
WOMAC Score		x	
low dose rotational CT scan		x	
X-Ray imaging		x	
Hectec mediCAD 3D			x
Hectec mediCAD 2D			x

7. Statistics

An exploratory data analysis will be performed to possibly formulate hypotheses about factors that contribute to noise generation in THRs. For parametric quantitative data we will calculate the Pearson correlation and work with an independent samples t-test. The Spearman correlation and the Mann Whitney U-test will be used for non-parametric quantitative data. To show relationships between the categorical variables a chi-squared test will be applied.

8. Risk-benefit assessment

Risk of harm to long-term health of the participants, particularly cancer induction due to exposition to radiation during the radiological examination, will be kept minimal by using state-of-the-art examination methods that keep ionizing radiation as low as reasonably possible.
The participants will not benefit immediately from our possible findings, since these are aimed at improving future implantations of THAs.
The possible reduction of complications for this frequent and globally carried out operation justifies the risk that the participants are subjected to.

9. Confidentiality

According to the Datenschutzgesetz 2000.
All personal data of the participants will be pseudonymized to ensure protection of privacy. Information linking responses and findings to individual participants will be collected separate from other documents in a data base on a PC in the Department of Orthopaedics and Orthopedic Surgery, accessible only by authorized personnel to ensure confidentiality.

10. Declaration of interests

All authors declare: no support from any organization for the submitted work; no financial relationships with any organizations that might have an interest in the submitted work; no other relationships or activities that could appear to have influenced the submitted work.

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12. Appendices

12.1. Informed consent material

12.2. Case Report Form

12.3. Product information sheets of implants

CASE REPORT FORM

Squeaking ceramic-on-ceramic total hip arthroplasties: 3D analysis of CT scans

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Initials: __________ (E.g.: **Mu**ster **Ma**x = MUMA)

Participant Number.: __________

Group assignment: □ Case group □ Control Group

Side of THA: □ left □ right

Date of study inclusion: ____ / ____ / ________ (DD MM YYYY)

Age: __________

Gender: □ female □ male

Body weight [kg]: __________

Body height [m]: __________

Body-Mass-Index BMI: __________ (Body weight / Body height^2)

Inclusion criteria

- Minimal age: 18 years □ yes □ no
- Implantation of THR Pinnacle Corail with COC at our clinic from 2005 to 2012 □ yes □ no

Exclusion criteria

- Acute infection of THR □ yes □ no
- Pregnancy □ yes □ no

Informed consent signed □ yes □ no

CT Scan pelvis-knee performed □ yes □ no

X-Ray whole pelvis, hip AP and axial view performed □ yes □ no

Harris-Hip-Score

Pain

- ☐ None (44)
- ☐ Slight (40)
- ☐ Mild (30)
- ☐ Moderate (20)
- ☐ Marked (10)
- ☐ Totally Disabled (0)

Function

Limp

- ☐ None (11)
- ☐ Slight (8)
- ☐ Moderate (5)
- ☐ Severe (0)
- ☐ Unable to walk (0)

Support

- ☐ None (11)
- ☐ Stick long walks (7)
- ☐ Stick full time (5)
- ☐ Crutch (3)
- ☐ 2 Sticks (2)
- ☐ 2 Crutches (0)
- ☐ Unable to walk (0)

Distance walked

- ☐ Unlimited (11)
- ☐ 600 metres (8)
- ☐ 200-300 metres (5)
- ☐ Indoors only (2)
- ☐ Bed and chair (0)

Activities

Stairs

- ☐ Normally (4)
- ☐ Normally with banister (2)
- ☐ Any method (1)
- ☐ Not able (0)

Socks/Tie shoes

- ☐ With ease (4)
- ☐ With difficulty (2)
- ☐ Unable (0)

Sitting

- ☐ Any chair, one hour (5)
- ☐ High chair, half hour (3)
- ☐ Unable to sit half hour [any chair] (0)

Public Transport

- ☐ Able to enter (1)
- ☐ Unable to enter (0)

Absence of deformity

Requires absence of all four below:

- ☐ Yes (fixed adduction <10°, fixed internal rotation [in extension] <10°, leg length discrepancy <3.2cm and fixed flexion >30°)
- ☐ If less than all of above

Range of motion

Flexion __________

Abduction __________

Adduction __________

External rotation __________

Internal rotation __________

Total degrees __________

ROM score

- ☐ 210°-300° (5)
- ☐ 160°-209° (4)
- ☐ 100-159° (3)
- ☐ 60°-99° (2)
- ☐ 30-59° (1)
- ☐ 0°-29° (0)

Cumulative score

Pain (max 44) __________

Function (max 33) __________

Activities (max 14) __________

Absence of deformity (max 4) __________

Range of motion (max 5) __________

Total HHS (max 100) ______

WOMAC SCORE

(Western Ontario and McMaster Universities Osteoarthritis Index)

Dieser Score besteht aus 24 Fragen (5 Schmerz, 2 Steifigkeit und 17 körperliche Funktion). Insgesamt sind somit 240 Punkte möglich, 0 Punkte gilt als bestes, 240 Punkte als schlechtestes Ergebnis.

Schmerzfragen:
Die folgenden Fragen beziehen sich auf die Stärke der Schmerzen, die Sie in ihre Hüfte haben. Bitte geben Sie für jede Frage die Stärke der Schmerzen an, die Sie in den letzten 2 Tagen verspürt haben (Bitte kreuzen Sie das zutreffende Kästchen an).

1. Wie starke Schmerzen haben Sie beim Gehen auf ebenem Boden

0	1	2	3	4	5	6	7	8	9	10

keine Schmerzen extreme Schmerzen

2. Wie starke Schmerzen haben Sie beim Treppen hinauf oder hinuntersteigen

0	1	2	3	4	5	6	7	8	9	10

keine Schmerzen extreme Schmerzen

3. Wie starke Schmerzen haben Sie nachts im Bett

0	1	2	3	4	5	6	7	8	9	10

keine Schmerzen extreme Schmerzen

4. Wie starke Schmerzen haben Sie beim Sitzen oder Liegen

0	1	2	3	4	5	6	7	8	9	10

keine Schmerzen extreme Schmerzen

5. Wie starke Schmerzen haben Sie beim Aufrecht stehen

0	1	2	3	4	5	6	7	8	9	10

keine Schmerzen extreme Schmerzen

Fragen zur Steifigkeit:
Die folgenden Fragen beziehen sich auf die Steifigkeit (nicht die Schmerzen) ihrer Hüfte. Steifigkeit ist ein Gefühl von Einschränkung oder Langsamkeit in der Beweglichkeit, wenn Sie ihre Gelenke bewegen. Bitte geben Sie für jede Frage die Stärke der Steifigkeit an, die Sie in den letzten 2 Tagen verspürt haben (Bitte kreuzen Sie die zutreffenden Kästchen an).

6. Wie stark ist die Steifigkeit gerade nach dem Erwachen am Morgen?

0	1	2	3	4	5	6	7	8	9	10

keine Steifigkeit extreme Steifigkeit

7. Wie stark ist die Steifigkeit nach Sitzen, Liegen oder Ausruhen im späteren Verlauf des Tages?

0	1	2	3	4	5	6	7	8	9	10

keine Steifigkeit extreme Steifigkeit

Fragen zur körperlichen Tätigkeit:
Die folgenden Fragen beziehen sich auf Ihre körperliche Tätigkeit. Damit ist Ihre Fähigkeit gemeint, sich im Alltag zu bewegen und sich um sich selbst zu kümmern. Bitte geben Sie für jede der folgenden Aktivitäten den Schwierigkeitsgrad an, den Sie in den letzten 2 Tagen wegen Beschwerden an ihrer Hüfte gespürt haben (Bitte kreuzen Sie die zutreffenden Kästchen an).

8. Wie groß sind ihre Schwierigkeiten beim Treppen hinuntersteigen?

0	1	2	3	4	5	6	7	8	9	10

keine Schwierigkeiten extreme Schwierigkeiten

9. Wie groß sind ihre Schwierigkeiten beim Treppe hinaufsteigen?

0	1	2	3	4	5	6	7	8	9	10

keine Schwierigkeiten extreme Schwierigkeiten

10. Wie groß sind ihre Schwierigkeiten beim Aufstehen vom Sitzen?

0	1	2	3	4	5	6	7	8	9	10

keine Schwierigkeiten extreme Schwierigkeiten

11. Wie groß sind ihre Schwierigkeiten beim Stehen?

0	1	2	3	4	5	6	7	8	9	10

keine Schwierigkeiten extreme Schwierigkeiten

12. Wie groß sind ihre Schwierigkeiten beim sich zum Boden Bücken?

0	1	2	3	4	5	6	7	8	9	10

keine Schwierigkeiten extreme Schwierigkeiten

13. Wie groß sind ihre Schwierigkeiten beim Gehen auf ebenem Boden?

0	1	2	3	4	5	6	7	8	9	10

keine Schwierigkeiten extreme Schwierigkeiten

14. Wie groß sind ihre Schwierigkeiten beim Ein und Aussteigen in ein Auto?

0	1	2	3	4	5	6	7	8	9	10

keine Schwierigkeiten extreme Schwierigkeiten

15. Wie groß sind ihre Schwierigkeiten beim Einkaufen gehen?

0	1	2	3	4	5	6	7	8	9	10

keine Schwierigkeiten extreme Schwierigkeiten

16. Wie groß sind ihre Schwierigkeiten beim Socken/Strümpfe anziehen?

0	1	2	3	4	5	6	7	8	9	10

keine Schwierigkeiten extreme Schwierigkeiten

17. Wie groß sind ihre Schwierigkeiten beim Aufstehen aus dem Bett?

0	1	2	3	4	5	6	7	8	9	10

keine Schwierigkeiten extreme Schwierigkeiten

18. Wie groß sind ihre Schwierigkeiten beim Socken/Strümpfe ausziehen?

0	1	2	3	4	5	6	7	8	9	10

keine Schwierigkeiten extreme Schwierigkeiten

19. Wie groß sind ihre Schwierigkeiten beim Liegen im Bett?

0	1	2	3	4	5	6	7	8	9	10

keine Schwierigkeiten extreme Schwierigkeiten

20. Wie groß sind ihre Schwierigkeiten beim ins Bad/aus dem Bad steigen?

0	1	2	3	4	5	6	7	8	9	10

keine Schwierigkeiten extreme Schwierigkeiten

21. Wie groß sind ihre Schwierigkeiten beim Sitzen?

0	1	2	3	4	5	6	7	8	9	10

keine Schwierigkeiten extreme Schwierigkeiten

22. Wie groß sind ihre Schwierigkeiten beim sich auf die Toilette Setzen/Aufstehen von der Toilette?

0	1	2	3	4	5	6	7	8	9	10

keine Schwierigkeiten extreme Schwierigkeiten

23. Wie groß sind ihre Schwierigkeiten bei anstrengenden Hausarbeiten?

0	1	2	3	4	5	6	7	8	9	10

keine Schwierigkeiten extreme Schwierigkeiten

24. Wie groß sind ihre Schwierigkeiten bei leichten Hausarbeiten?

0	1	2	3	4	5	6	7	8	9	10

keine Schwierigkeiten extreme Schwierigkeiten

Total WOMAC score (max 240) ______

Participant questionnaire

1. Does your THR make noises?

□ **yes** → **assign to case group, continue with questionnaire**

Side of noisy THR □ left □ right

□ **no** → **assign to control group**

2. How is the noise described?
(Fill out questionnaire for every type of noise separately)

□ long, high-pitched sound - "squeaking"

□ long, low-pitched sound - "grinding"

□ short, concise sound – "clicking"

□ other noise, describe:

____

3. When did the noise first occur? Date/period of time as precise as possible:

____

4. Did a specific event lead to first occurrence of the squeaking/grinding/clicking/other noise?

□ no

□ yes, describe event:

____

____

5. Which movement/action leads to squeaking/grinding/clicking/other noise?

□ hip extension (e.g. walking, climbing stairs)

□ hip flexion (e.g. rising from a chair, squatting, bending over)

□ rotation (e.g. turning with fixed foot)

□ repetitive movement (e.g. when hiking)

□ other movement/action, describe:

____

6. How often does the squeaking/grinding/clicking/other noise occur?

□ permanently (every time when movement/action is performed)

□ often (daily)

□ seldom (less than daily)

7. Is the squeaking/grinding/clicking/other noise associated with pain?

NO PAIN	0	1	2	3	4	5	6	7	8	9	10	**MAX. PAIN**

8. Does the squeaking/grinding/clicking/other noise have a negative impact on the quality of life?

NO IMPACT GREAT	0	1	2	3	4	5	**IMPACT**

Functional examination

Let the participant perform the following movements/actions and describe findings on the next page. Record on video if possible.

1. Let participant squat and rise

Type of noise: □ no noise
□ squeaking □ grinding □ clicking □ other noise

Noise occurs in: □ flexion _______ [°] □ extension _______ [°]
Reproducibility: □ constant □ inconstant

2. Let participant turn with fixed foot (on side of noisy THR)

Type of noise: □ no noise
□ squeaking □ grinding □ clicking □ other noise

Noise occurs in: □ outward rotation _______ [°] □ inward rotation _______ [°]
Reproducibility: □ constant □ inconstant

3. Let participant walk across the room

Type of noise: □ no noise
□ squeaking □ grinding □ clicking □ other noise

Noise occurs in: □ flexion _______ [°] □ extension _______ [°]
Reproducibility: □ constant □ inconstant

4. Let participant climb stairs

Type of noise: □ no noise
□ squeaking □ grinding □ clicking □ other noise

Noise occurs in: □ flexion _______ [°] □ extension _______ [°]
Reproducibility: □ constant □ inconstant

5. Let participant cycle on home trainer for 1 minute (low intensity)

Type of noise: □ no noise
□ squeaking □ grinding □ clicking □ other noise

Noise occurs in: □ flexion _______ [°] □ extension _______ [°]
Reproducibility: □ constant □ inconstant

6. Other movement/action (only if necessary to provoke noise, describe on next page)

Type of noise: □ no noise
□ squeaking □ grinding □ clicking □ other noise

Noise occurs in: □ flexion _______ [°] □ extension _______ [°]
Reproducibility: □ constant □ inconstant

Functional examination

Describe **thoroughly:**

- If and how noise could be provoked
- The type of noise (record if possible)
- The position of the joint in which the noise occurs (flexion/extension/abduction/etc.)
- How constantly the noise could be provoked (with every move/occasionally, was a pattern recognizable?)
- Make a drawing if it seems useful

____

____

____

____

____

____

____

____

____

____

____

____

____

____

____

____

Description of THR

Side □ left □ right

Date of OP ___ / ___ / ______

Cup shell □ Pinnacle 100 □ Pinnacle Sector □ Pinnacle Multihole

Size □ 48 / □ 50 / □ 52 / □ 54 / □ 56 / □ 58 / □ 60 / □ 62

Inlay □ Ceramic

Femoral head □ Ceramic Size □ 28 / □ 32 / □ 36

Femoral stem □ Corail Standard □ Corail Standard w. Collar
□ Corail High Offset 135° □ Corail Vara 125°

Size: □ 9 / □ 10 / □ 11 / □ 12 / □ 13 / □ 14 / □ 15 / □ 16

Cemented: □ yes □ no

Primary diagnosis ____

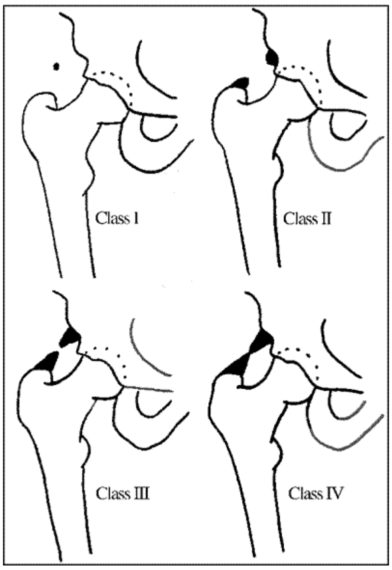
Surgeon ____

Surgical approach ____

Heterotopic ossification □ no □ yes, describe:
Brooker □ I / □ II / □ III / □ IV

____

____



Osteolysis zones □ no □ yes, describe:

Acetabular zones (De Lee and Charnley) □ 1 / □ 2 / □ 3
Femoral zones (Gruen) AP □ 1 / □ 2 / □ 3 / □ 4 / □ 5 / □ 6 / □ 7
AX □ 8 / □ 9 / □ 10 / □ 11 / □ 12 / □ 13 / □ 14

____

____

Peri-implant bone resorption □ no □ yes, describe:

Acetabular zones (De Lee and Charnley) □ 1 / □ 2 / □ 3
Femoral zones (Gruen) AP □ 1 / □ 2 / □ 3 / □ 4 / □ 5 / □ 6 / □ 7
AX □ 8 / □ 9 / □ 10 / □ 11 / □ 12 / □ 13 / □ 14

____

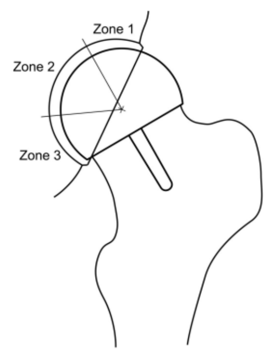
____

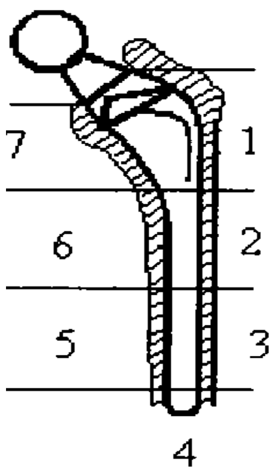
Stress shielding □ no □ yes, describe:

Acetabular zones (De Lee and Charnley) □ 1 / □ 2 / □ 3
Femoral zones (Gruen) AP □ 1 / □ 2 / □ 3 / □ 4 / □ 5 / □ 6 / □ 7
AX □ 8 / □ 9 / □ 10 / □ 11 / □ 12 / □ 13 / □ 14

____

____





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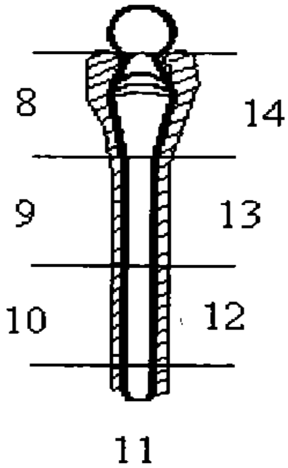


Measurements with Hectec mediCAD 3D

Side □ left □ right

Acetabular inclination [°] __________

Acetabular anteversion [°] __________

Acetabular offset [mm] __________

Femoral anteversion [°] __________

Femoral offset [mm] __________

Femoral stem alignment □ varus (< 130°) / □ neutral (135°) / □ valgus (> 140°)

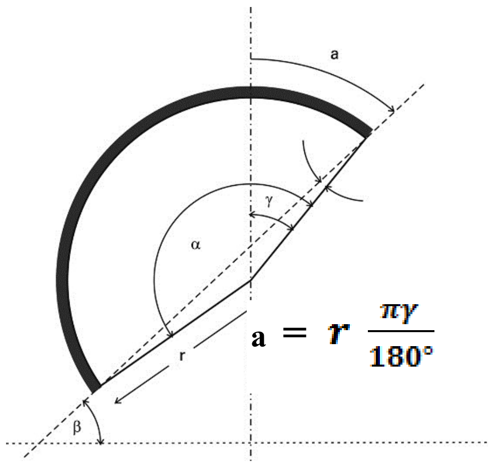
Hip length discrepancy [mm] __________

Combined anteversion [°] __________ (acet. antev. + fem. antev.)

Arc of cover [mm] __________

r [mm]__________ (cup shell / 2)

γ [°] __________



$$a = r\,\frac{\pi\gamma}{180°}$$

Measurements with Hectec mediCAD 2D

Side □ left □ right

Acetabular inclination [°] ___________

Acetabular anteversion [°] ___________

Femoral offset [mm] ___________

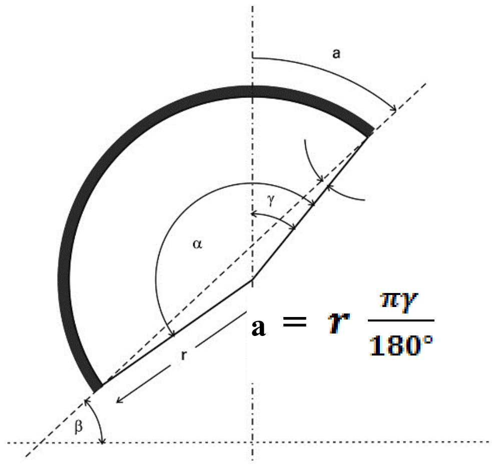
Femoral stem alignment □ varus (< 130°) / □ neutral (135°) / □ valgus (> 140°)

Leg length discrepancy [mm] ___________

Arc of cover [mm] ___________

r [mm]___________ **(cup shell / 2)**

γ [°] ___________



EBRA

months post op	flag	med. distances 1-4				lat. distances 5-8				angle	subsidence

Timetable of examinations and data acquisition

	Before visit	During visit	After visit
Informing of participants	x		
Signing of informed consent		x	
CRF		x	
Harris Hip Score		x	
WOMAC Score		x	
low dose rotational CT scan		x	
X-Ray imaging		x	
Hectec mediCAD 3D			x
Hectec mediCAD 2D			x