

AUS DER FAKULTÄT FÜR MEDIZIN
DER UNIVERSITÄT REGENSBURG
PROF. DR. MED. BENJAMIN CRAIOVAN
ORTHOPÄDIE

**GAIT RESTORATION IN PAPROSKY TYPE 3 PATIENTS
WITH CUSTOM MADE HIP ARTHROPLASTY**

Inaugural – Dissertation
zur Erlangung des Doktorgrades
der Medizin

der
Fakultät für Medizin
der Universität Regensburg

vorgelegt von
Lena Christina Witzmann

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1 Abstract (deutsch)

Hintergrund: Das zunehmende Bevölkerungsalter sowie das Bedürfnis von Patienten, auch im höheren Lebensalter noch schmerzfrei mobil zu sein, stellt neue Ansprüche an die Hüft-Endoprothetik. Während die degenerative Coxarthrose in über 90% der Fälle primär komplikationslos mit einem Standardimplantat versorgt werden kann, stellt uns die Revisions-Endoprothetik vor neue Herausforderungen – maßgeblich bedingt durch teils großflächige ossäre Defekte. Maßgefertigte 3D-gedruckte Beckenteilersätze gehören zu den innovativsten Möglichkeiten, die bei Patienten mit Paprosky-Index > IIIA angewandt werden.

Patienten und Methodik: In dieser Arbeit wurden acht Patienten mit einem Paprosky-Index > IIIA, die im Universitätskrankenhaus Bad Abbach zwischen 2013 und 2017 mit einem maßgefertigten Beckenteilersatz versorgt wurden, umfassend untersucht. Hierzu wurden die Patienten im Ganglabor bewertet, hinsichtlich Lebensqualität, Schmerz und Alltagsstrukturierung befragt, klinisch untersucht, sowie postoperativ mittels einer CT basierten ROM-Analyse vermessen. Ziel war es, das gewonnene Bewegungsausmaß und geistige wie körperliche Verfassung von Patienten nach der Versorgung mit High-End 3D-Implantaten zu beurteilen.

Ergebnisse: Bei allen acht Patienten konnte postoperativ eine statistisch signifikante Verbesserung des klinischen Bewegungsausmaßes festgestellt werden (ROM^{improvement}: min=90°, max=180°. Median=100°. Mittelwert=119° (SD=33,38), p<0,00). Das Implantat-Überleben zum Zeitpunkt der finalen Untersuchung betrug 100%. Die Ganganalyse ergab eine etwas verlangsamte mittlere Schrittgeschwindigkeit von 0,9m/s auf einer Spurbreite von 0,14m mit durchschnittlich 104 Schritten pro Minute. Die durchschnittliche Schrittlänge für Einzel- und Doppelschritte ergab keinen signifikanten Unterschied zwischen operiertem und nicht-operiertem Bein ($p^{\text{single_step_length}}=0,686$; $p^{\text{double_step_length}}=0,293$), genauso wie das Verhältnis von ein und beidseitigen Standphasen (median^{double_support_OP}=52,5%, median^{double_support_notOP}=47,5%, p=0,345). Ebenso waren die Bewegungsausmaße in allen drei Hüftebenen (sagittal, transversal, koronar) vergleichbar gut mit der nicht behandlungsbedürftigen Seite.

Eine deutliche postoperative Verbesserung wurde auch mittels der hüftbezogenen Fragebögen HOOS und HHS sowie der physikalischen Komponente des EuroQol-Fragebogens registriert. Die Auswertung der EuroQol-Fragen zum psychischen Gesundheitszustands zeigte hingegen keine signifikante Verbesserung, wobei die Patienten jedoch angaben, sich nach der Operation vitaler zu fühlen, ihre Gesundheit insgesamt als verbessert zu empfinden ($p=0,095$), weniger Schmerz zu empfinden ($p=0,03$), und mehr am sozialen Leben teilhaben zu können ($p=0,2$).

Fazit: Die erhobenen multimodalen Ergebnisse können den positiven Einfluss auf Mobilität und Aktivität durch eine maßgefertigtes Beckenteilimplantat bei terminaler Hüftdegeneration (>Paprosky 3A) bestätigen. Unser kleines Patientenkollektiv fand sich postoperativ in einer selbstständigeren und mobileren Lebenssituation, mit einem alters- und komorbiditäts-entsprechendem Gangbild. Die weitere Entwicklung, vor allem hinsichtlich der Langzeitergebnisse, bleibt abzuwarten.

Die anfänglich im Mittelpunkt gestandene, durch ärztliches Personal selbstständig durchgeführte, virtuelle postoperative ROM-Vermessung von Implantaten mittels einer CT-gestützten Softwareanalyse erwies sich zum durchgeführten Zeitpunkt als wenig kliniktauglich. Die investierte Zeit, die insbesondere im klinischen Alltag nicht gegeben ist, scheint die Aussagekraft der Ergebnisse nicht zu rechtfertigen. Die softwaregestützte Rekonstruktion zur Positionsüberprüfung, die im Zuge einer anderen Studie durchgeführt wurde, bewährte sich hingegen als eine wertvolle Untersuchung.

2 Abstract (english)

Background of this study: The demand for revision hip arthroplasty is rising – even expected to substantially grow - and orthopedic surgeons are more frequently confronted with complex patients suffering from severe bone deficiency (>Paprosky 3A). Customized implants belong to the latest introduced possibilities in modern end-stage revision arthroplasty. Our aim was to investigate the process of planning, implanting and to measure ROM and gait restoration in patients who were subserved with these implants.

Patients and methods: In this work, eight patients with Paprosky type >IIIA, who were subserved with a custom-made hip/ partial pelvic replacement between 2013 and

2017 at Bad Abbach University Hospital, were included. The recruited collective was asked to fill out hip- and QOL-related questionnaires pre- and postoperatively. Every patient was clinically examined and assessed in our gait laboratory at a final follow up after approximately one year. Additionally, we assessed virtual ROM analysis using CT-based software.

Results: All patients showed significant improvement regarding their clinical range of motion (ROM^{improvement}: min=90°, max=180°. median=100°. mean=119° (SD=33,38), p<0,00). Implant survival rate at the time of our final follow up (max. 3 years) was 100%. In our gait laboratory, a reduced pace of 0,9m/s on a trackwidth of 0,14m with approximately 104 steps per minute was detected. There was no significant difference between the operated and the non-operated leg concerning single and double step length (p^{single_step_length}=0,686; p^{double_step_length}=0,293) as well as double support stance phases (median^{double_support_OP}=52,5%, median^{double_support_notOP}=47,5%, p=0,345). Moreover, possible range of motion in all three planes (sagittal, transversal, coronary) was comparable with the healthy side.

Further there was significant improvement registered in questionnaires regarding physical functioning. EuroQol mental component summary however postulated no positive impact in our patients mental wellbeing postoperatively. Nevertheless, participants stated to feel more vital, socially involved (p=0,2), less anguished (p=0,03) and altogether in a better state of health (p=0,095) after surgery.

Conclusion: These multimodal results show a positive impact particularly in mobility and physical activity after implanting a custom-made hip replacement in cases of severe osseous deficiency. Our small collective was able to live a more independent and active lifestyle. Their postoperative gait pattern was solid in accordance with age and comorbidities. Regardless, CM implants should not be used as a fashion but as a necessity - when standard implants cannot provide enough stability or adequate load transmission. Long term results, especially long-term implant survival rates, are still awaited.

At the given time, it seemed not suitable to use a CT-based software for virtual ROM-analysis under clinical conditions. It turned out to be time-consuming with only a modest gain of information when executed by clinical staff. Despite that, reconstruction

analysis performed by experts for evaluating the positioning of an implant showed valuable results.

3 Introduction

Custom made hip arthroplasty belongs to the latest introduced possibilities of THA. Detailed planning and careful preparation of three-dimensionally reconstructed partial pelvic replacements should help treating patients in end-stage cases of revision arthroplasty.

In this clinical work, we evaluated 8 patients undergoing revision surgery with the aim to assess planning, implementing and evaluating custom made implants in terms of gait patterns, range of motion and quality of life impacts before and after surgery.

3.1 Anatomy of the hip

To fully comprehend the issues of revision total hip arthroplasty and partial pelvic replacement, it is important to review the basic anatomy first. Only by understanding the function and role our natural hips have, we can consider what we should demand of modern replacement hips.

What differs men and apes from other mammals is their erect stand – and one of the reasons, why they can walk upright, is to be found in the hip. Our hip joint not only enables our lower extremities to rotate and move, also, it is fixed by a strong muscular and ligamentous apparatus, making it effortless to stand straight.

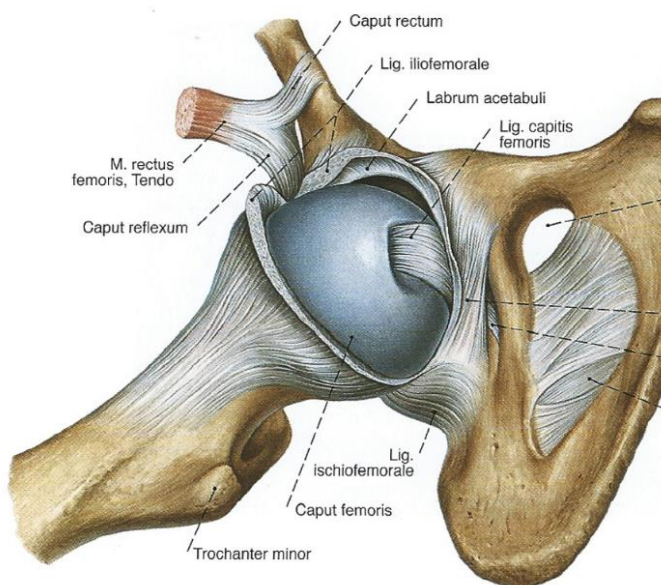


Image 1: Articulatio coxae, after opening the capsula and partly exarticulating the femoral head from laterodistal (right, 70°); From: Sobotta Atlas der Anatomie des Menschen© Auflage 21, 2004, Elsevier GmbH, Urban & Fischer, Munich

Femoral bone and acetabulum compose the Art. coxae as they form an enarthrodial joint. One could compare this type of joint to a nut in a shell, meaning that most part of the caput femoris is surrounded by the cavernous acetabulum. Its cartilaginous fascia lunata coats around three-fourths of the socket, further it is encircled by the fibrocartilaginous labrum acetabuli. The femoral head, with a diameter of ~2,5 cm, is almost spherical, and located on the medial collum femoris. It is tightly secured in place by the Zona orbicularis, a ligamental structure surrounding it.

There are three ligaments inserting the Articular Capsula: Ligg. Iliofemorale, Pubofemorale and Ischiofemorale. The Lig. Iliofemorale is the strongest ligament of the body, showing a tensile strength of more than 350kg, blocking strong extension and adduction. Pubo- and ischiofemoral (mainly internal rotation) ligament fixate the joint towards the other directions. With its deep socket and the tight ligamentous and muscular support, it takes great energetic impact to dislocate the femoral head. If so, more than half of traumatic dislocations occur between the Ligg. Ischio- and iliofemorale to dorsocranial.

Further, some of the most important muscles should be mentioned here. The inner M. iliopsoas is the strongest flexor of the hip joint. On the outer, the M. gluteus max., strongest muscle of the human body, not only gives our posterior its shape but is essential for standing upright, walking stairs and running, as it is a powerful extensor. Deficiency of the M. gluteus maximus is rare, comparing it to the other two gluteal muscles: M. gluteus medius and minimus. They are our prime abductors, ensuring a fluent gait by maintaining both hips at the same level during stance phase. If the innervating N. gluteus superior is injured after surgery or insufficient use of the muscle, the deficiency of the smaller gluteal muscles can show as the Trendelenburg sign (see Image 2). The M. tensor fasciae latae supports their function as abductors but more importantly tightens the Tractus iliotibialis, a tension band to prevent femoral lateral deflection. M. tensor fasciae latae and M. glutes maximus are described as the doorway to the hip joint.¹

External rotation of the hip is performed by the pelvitrochanteric muscles: Mm. piriformis, gemelli sup. and inf., obturatorius and quadratus femoris. The last major muscular group of the hip are the adductors, including M. pectineus, M. gracilis, Mm.

adductor longus, brevis and magnus). Ischiocrural musculature functions as the hips extensor. ²

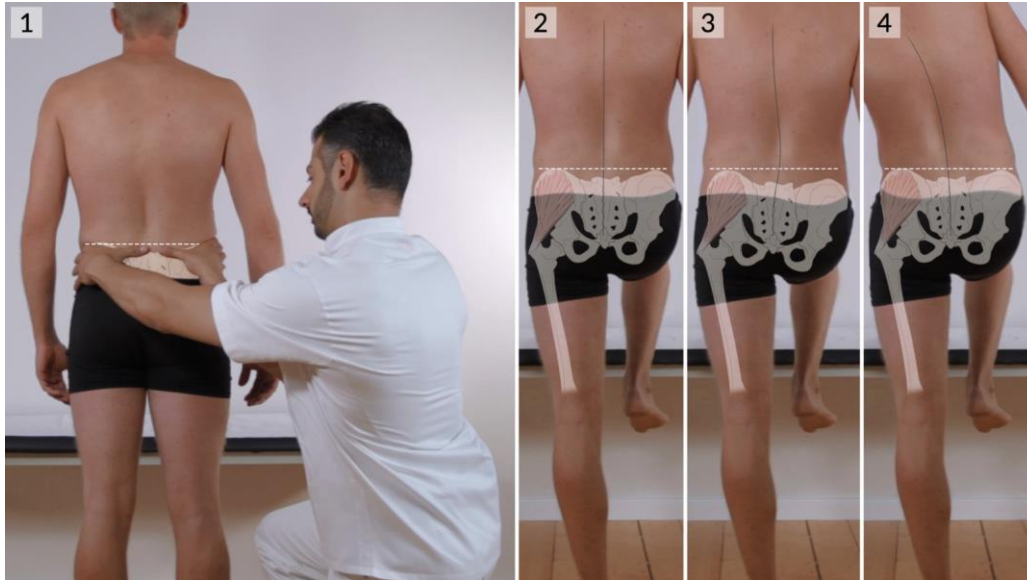


Image 2: clinical exam of the hip: 1) evaluation of pelvic obliquity 2) properly working gluteal muscles 3) the unsupported side of the pelvis drops: Trendelenburg sign, can result in 4) Duchenne-limp, by shifting the weight to the instable side to balance out instability; From: Amboss Miamed Neurologie; Link: <https://amboss.miamed.de/library#xid=o500Og&anker=Z626a3b52cabfd6eca7353cedf533d48c> (Date 27.06.2017)

3.2 Coxarthrosis and treatment options

Coxarthrosis is a common degenerative joint disease. It can be divided into primary and secondary coxarthrosis. Primary osteoarthritis of the hip is mostly a problem due to wear and tear, explaining, why our older-growing population is being more and more concerned.³ It is a result of disbalance between degradation and growing of cartilage. Cartilage matrix is losing its ability to regenerate with age; morphological correlates are subchondral sclerosis, reactive synovitis and formation of cysts. Primary coxarthrosis is not linked with obesity or hard physical work.⁴

Diseases such as congenital hip dysplasia, Morbus Perthes, epiphysiolysis capitis femoris and rheumatism trouble the normal development of the hip and can therefore lead to secondary arthrosis.³

Typically, hip arthrosis first causes pain on initial movement, then stress-induced and later even at rest. Severe coxarthrosis is defined by strong pain and limitation in daily life.

At the age of 65-74, 2% of our population suffer from moderate to severe coxarthrosis.⁵ Its prevalence increases with age. In Iceland, for example, more than a third of >85-year-olds suffer from severe coxarthrosis.⁶

3.3 Conservative treatment

Conservative methods can ease the symptoms but cannot heal hip arthrosis. They include:

- I. A change of lifestyle: avoiding physical and postural stress, weight loss, healthy eating, joint-friendly activities such as swimming and biking
- II. Medical treatment: Paracetamol, Metamizol, NSARs, Opioids, intra-articular glucocorticoid injections, hyalurone
- III. Physical therapy: muscular and coordinative improvements through exercise, also using hydrotherapy, electrotherapy, ultrasound-therapy, magnetotherapy⁷

As the disease progresses, surgery becomes a relevant option for many patients. Only patients who are refractory to all conservative treatments are advised to undergo THA surgery.⁷ In more than 70%, severe coxarthrosis is the main indication for total hip arthroplasty.³

3.4 Historical development of THA

Treating patients with aching joints has been a medical issue for centuries. Curing them by using techniques like TCM or simple bone resection didn't seem to bring much success. It was only in the late 19th century, when the first one to ever transplant a prosthesis, the German Themistocles Gluck, successfully performed two kneejoint and one ankle surgery. Those artificial joints were made of ivory at that time. Furthermore, Gluck tried securing his prosthesis with a mixture of Colophonium with pumice or gypsum, which is comparable to modern cement used in hip replacements nowadays.^{8,9}

After Gluck set an example, doctors like Erich Lexer tried implanting homologue joints of human donors, showing no good long-term results. In 1939, Smith Peterson published his invention of the Vitallium-Cup, a metal cup (CoCrMo legation) to be put on the femoral head, serving as a slide bearing between the two parts of the joint.¹⁰

English surgeon George Mc Kee was the first to use metal-on-metal prosthesis in 1953. He used a cemented hemiarthroplasty stem and a cobalt-chrome socket, a quite durable combination with a long survival rate. Nevertheless, metal particles seemed to cause local unwanted effects and metallosis, so surgeons were looking to find a low friction alternative. In the early 1960s, Sir John Charnley, the so-called founder of modern total hip arthroplasty, invented a prosthesis that was very similar to the implants we use today. His arthroplasty included three different components: a polyethylene cup, a femoral stem out of metal and acrylic bone cement. By using a smaller femoral head, Sir Charnley was able to reduce friction in his designs.

Metal-on-polyethylene is still the most widely used combination in THA. It is a cost-effective and safe solution in arthroplasty surgery. Polyethylene debris though is considered to lead to periprosthetic loosening by enhancing a local migration of cytokines and osteolytic cells.

Ceramic implants (ceramic-on-ceramic) were the latest to be introduced in the late seventies. Ceramic convinces with a good wear resistance, as the substance is inert and very hard, causing only low friction. On its downside, ceramic implants are expensive and need high expertise in surgery – a fracture of the ceramic implant could be fatal.

Modern metal-on-metal implants on the other hand show a longer durability and are used in younger patients due to their wear characteristics. Long term side effects of cobalt and chromium ions circulating in the blood stream are still feared, as they could be cancerogenic. Results of long-time studies are awaited.¹¹

As mentioned, Sir Charnley was the first using cement (PMMA) for fixation. But soon the substance grew unpopular as it was associated with high loosening rates ('cement disease').¹² In 1975, Mittelmeier presented a new edged shaft design, revolutionizing uncemented fixation. Shafts were then given special surface structures to enable good stability. Soon, also the acetabular component evolved: press-fit and screw cups were

invented. To date, various designs have been introduced, aiming to facilitate biological fixation.

Creating a stable implant without using PMMA requires macro- and microlocking. Macrolocking describes the process of fixation during surgery itself- using screws, fins, grooves or press-fit. Microlocking stands for the bone ingrowth to the pores of the implant. It determines the ultimate long-time success of an uncemented implant. ¹³

In the 90s, it was common to use hybrid solutions- a press-fit cup with a cemented shaft for example. Today, the indication is patient-customized. Patients who are expected to have at least one revision surgery (e.g. young age) in the future are usually provided with uncemented implants, as it makes revision procedures easier. In short term, however, cemented implants show a better outcome, as the implant can be loaded instantly. ¹⁴

To sum up, it can be said that every prosthesis needs to comply with certain biomechanical requests and should be chosen after these criteria. Technical requirements in general are:

- Mechanical stability
- Fine load transmission and a safe load rate
- Well-fitting design of the stem
- Adequate range of motion

Biological criteria to be considered are:

- Allergy
- Type of bone and its remodeling ability
- Capsule-ligamental condition ¹⁵

3.5 Surgical hip replacement today

Total hip arthroplasty is one of the most performed orthopedic procedures worldwide. In 2014, there were 236.464 endoprosthetic hip surgeries documented in the German Endoprosthetics Register. 67,9% (n=160.559) of those were elective primary implantations, whereas 20,8% (n=49.159) procedures were performed after femoral trauma and 11,3% (n=26.746) as revision surgeries. ¹⁶

Primary hip replacements have become a routine procedure. More than 90% of the patients experience total pain relief and improvement of function.¹⁷ Revision surgery on the other hand turns out to be more complicated, with bad long-term results and oft-cited restricted quality of life.

3.6 Revision surgery

3.6.1 Indication

Revision surgery has become a big issue in the last couple of years. Reasons are amongst others that more primary THA surgeries are performed in younger and still active patients. The world's population is growing older, and the lifespan of a primary implant is only around 12-18 years, resulting in (multiple) revision surgeries for our patients.

The need for revision surgery is projected to substantially grow – as shown in a paper by Kurtz et al, expecting the number of revision surgeries in the United States to be doubled by 2026. As the outcome is not yet satisfying, new, individual methods for partial pelvic replacements are being introduced.

Why primary implants fail after some time? Most common causes are prosthesis dislocation/instability (22%), mechanical loosening (19%) and infection (14%). Placing the implant correctly in surgery has high impact on the durability. If not in correct position, abrasion (especially in polyethylene implants) is stronger. Set-free microparticles cause corrosion between bone and implant, leading to osteolysis and furthermore mechanical loosening.¹⁸

Septic loosening due to infection is a relevant cause too. Periprosthetic infection is one of the most frightened risks in orthopedic surgery. The risk of having a periprosthetic infection is around 1-3% with primary implants, in revision surgery even 5%. Mostly, they are caused by bacteria producing a micro-film, such as staphylococcus aureus, enterococcus, streptococcus, etc.¹⁹

Diagnosing a loose implant contains a clinical exam, medical pain history and an X-ray picture. Patients usually suffer pain when walking or putting weight on the concerned leg. When examined, they feel pain when rotating, extending, forging or shaking the leg. Furthermore, articular effusion, swollen joints or a shortened leg can be indicative

of prosthetic loosening. Plus, when septic, the concerned area can feel hot and look reddened.

The X-ray exam can give closure. A >2mm radiological translucency and a changed position of the implant (compared to earlier pictures) correlates to implant loosening.

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3.6.2 Defect Classification

Especially in revised total hip replacement, the surgeon can be confronted with massive bone deficiency. Bone deficiencies can be classified by different kinds of scales, often after Paprosky. Paprosky differs between acetabular and femoral bone loss.

Acetabular bone loss is classified as following:

In Paprosky Type 1, there is only a cavitory damage, but the implant does not migrate, and the rim stays intact. Type 2 describes, when the hemispheric bracing does not work, but the columns remain supportive. Stage 2A-C differ between superior (2A), superolateral (2B) and medial (2C) migration <2cm of the implant. In case of migration more than 2cm, due to a huge superolateral defect (3A), and maybe pelvic discontinuity (3B), Paprosky Type 3 sets in.

3.6.3 Defect adjusted strategy

Primarily, revision implants should provide durability and stability. One of the main issues in surgery is the reconstruction of the anatomical hip center, respecting acetabular, femoral and global offset. Careful planning of the right stem and socket position (in anteversion) can prevent prosthetic or osseous impingement and abrasion. Further, reconstruction of bone stock and permanent secondary integration in the bone is relevant.

Criteria for selecting the right, defect adjusted implant include:

- stage and composition of defect
- anchoring technique (cement/ no cement)
- mix and match with potentially remaining opponent
- design of the implant
- reason of previous implant failure

- patient related factors such as: weight, age, level of activity, allergies, life expectancy

Craiovan et al. reviewed different types of devices applied in revision surgery. Below, I want to discuss these strategies using Paprosky's classification in detail.

Paprosky Type 1

In Paprosky Type 1, standard press-fit sockets are used, because the acetabular circumference is still obtained and therefore equatorial transmission with hemispheric standard cups can be ensured.

Paprosky Type 2A

In case of Paprosky 2A, implantation can either be done with primary press-fit or threaded cups, where the osseous deficiency is padded with spongiosa-plasty or using uncemented oval (e.g. cranial) and hemispheric cups. Further, acetabular roof cages augment osseous structures towards cranial load.

Paprosky Type 2B

Acetabular roof structures are supported with standard cups plus well-integrated rim plastics or also revision cups with big integrated or separate augments (out of trabecular metal). Further, acetabular roof cups with a caudal hook to ensure distal fixation in the acetabular notch can relieve the rim and prevent horizontal dumping as well as cranialization of the center of rotation.

Paprosky Type 2C

As acetabular rims are even more deficient in Paprosky Type 2C, anti-protrusio cages with cranial loops such as the Burch-Schneider-Ring are preferred. Screws following the direction of the load vector from the cranial acetabular roof to the sacrum provide tight und force fit between pelvis and implant. Distal, a hook in the acetabular notch or a caudal ischial lug ensure higher stability.

Paprosky Type 3A

Severe osseous deficiency concerning the superior, ventral and dorsal acetabular margin leads to a total lack of load capacity. At this stage, support shells with long

ischial tabs show good results (bridging over >7cm defects). Also, custom made implants should be considered.

Paprosky Type 3B

Paproskys classification of bone defects ends with stage 3B. In this case, massive bone destruction leads to pelvic discontinuity. A stable fixation is needed. Custom-made implants can help by providing high stability in all areas needing much support.

Further, Kim Young-Hu designed an algorithm that can easily be used to determine the right defect adjusted strategy (see image 4).

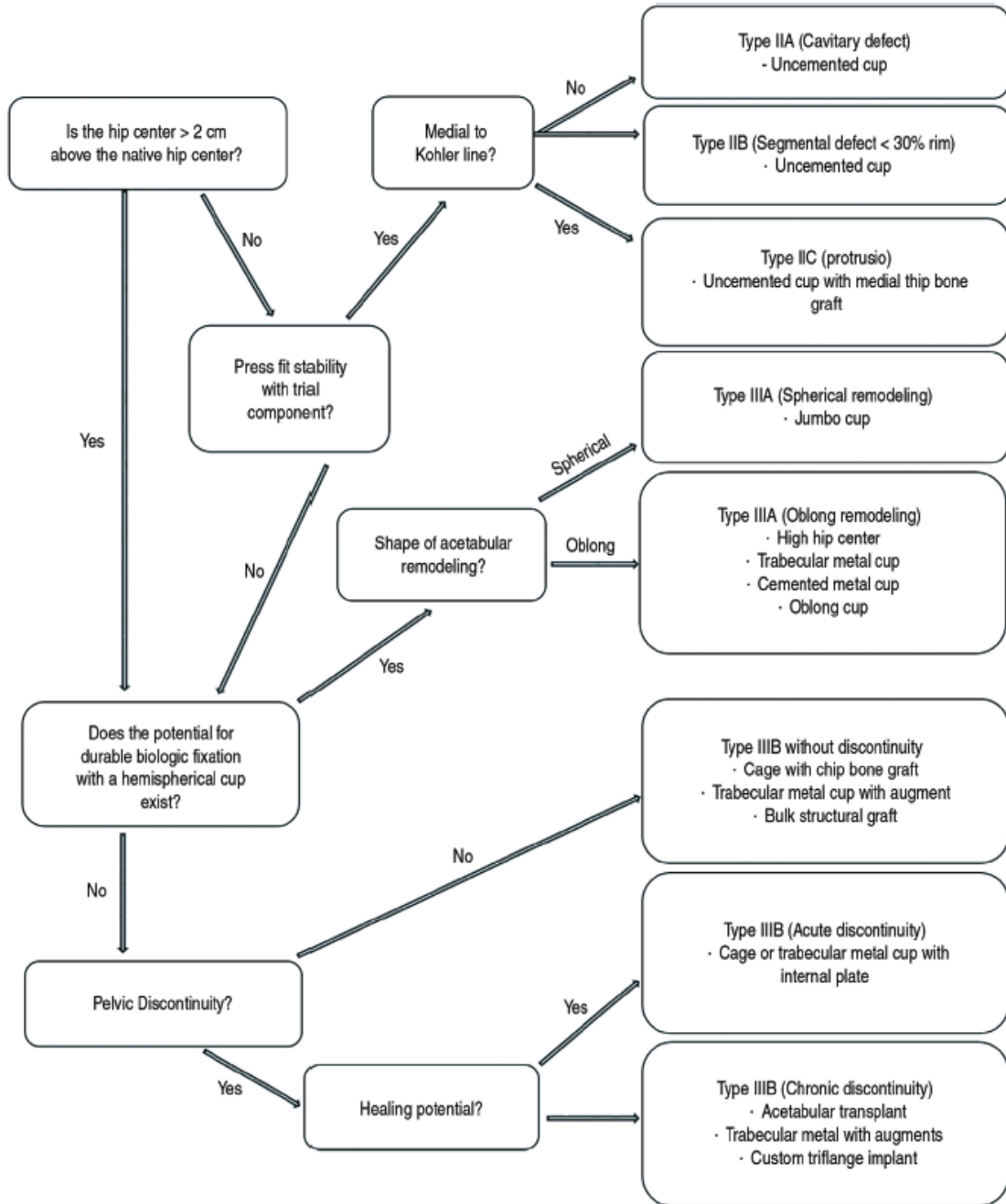


Image 3: Treatment algorithm for management of acetabular defect. Kim, Young-Ho (2017): Acetabular Cup Revision. In: Hip & Pelvis 29 (3), S. 155–158. DOI: 10.5371/hp.2017.29.3.155.

3.6.4 Girdlestone-hip

Usually, revision surgery is performed as a one stage exchange, meaning, that the old prosthesis is removed and immediately after the new arthroplasty is implanted. In some cases though, patients with severe bone deficiencies combined with periprosthetic infection are left with a Girdlestone situation. A Girdlestone-situation is described as a two-stage-exchange, where the old implant is taken out and source control is realized through surgical debridement. The patient must wait weeks to months for the new implant. In this special situation, risk of revision surgery is higher for dislocation, trochanteric pseudo-arthritis, reinfection, and postop surgical drain. In the clinical work of Charlton W.T.H. et al, it still shows better results to perform surgery than to leave the patient with no joint (97,7% were infection-free at time of final examination). Still, more than a third was restricted in walking in a long-time basis because of humping. There is not yet proof that custom-made implants could improve humping and pain. ²⁰

3.7 Implant positioning

Lewineck described a safe zone for anteversion and inclination, namely $AV=15^{\circ}\pm 10^{\circ}$ and $INCL=40^{\circ}\pm 10^{\circ}$. Being in this zone is supposed to reduce the risk of dislocation. It is controversial but still surgeons aim to stay within. ²¹ However, these results cannot always be reached by intraoperative estimation. Today, different procedures to optimize the implants position and therefore impingement-free mobility have been introduced using biomathematical algorithms. They show better success than intraoperative ROM estimation by eye, but don't consider soft tissue impingement. Further, preoperative 3D CT planning can be used to detect osseous or prosthetic contact. Unfortunately, they don't factor in soft tissue either. What can be shown in image 3 is comparable to the software evaluation we used. (see Materials and Methods) ^{22,23}

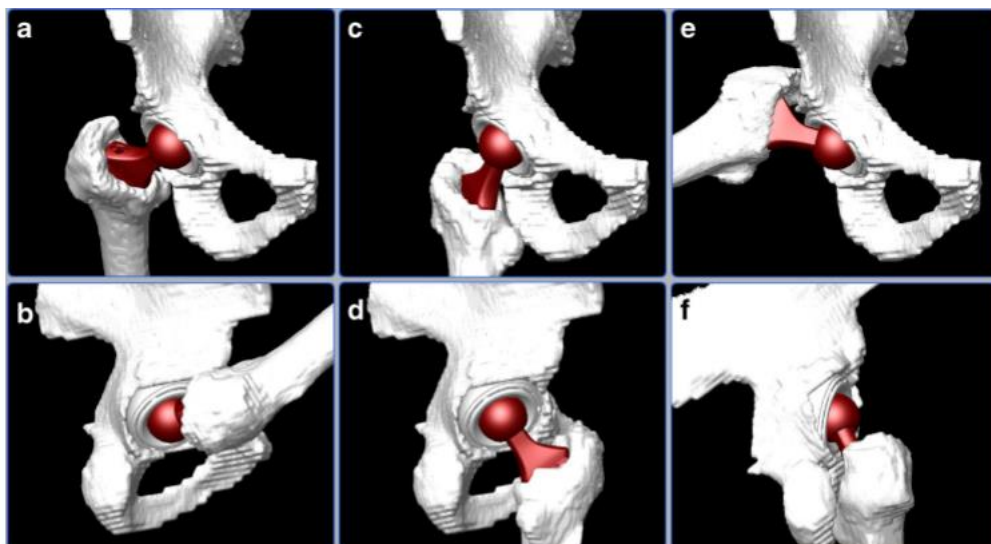


Image 4: 3D CT Planning, Impingement is determined by virtually moving the leg until two objects collide, shown in all six degrees of movement. From: Weber, M et al. (2016): Current standard rules of combined anteversion prevent prosthetic impingement but ignore osseous contact in total hip arthroplasty. In: Int Orthop, S. 1–10. DOI: 10.1007/s00264-016-3171-x.

3.8 ROM – range of motion

The original, osseous hip joint enables a great range of motion. To be precise, a well-functioning hip can perform flexion up to 125° and extension around 10-40° using the neutral-zero-method. It can rotate externally to around 45° and internally to 40°. Possible ab- and adduction measure around 45° and 30°. In total, this makes an overall range of motion of ~300°, when efficient. How vital this is, was shown by a paper published in 2007 by K. Davis. He outlined the important value of range of motion in postop outcome after total hip arthroplasty – a high range of motion (115° of flexion, 25° of abduction, 20° of external rotation, and less than 20° of flexion contracture) correlates with a good function and a high Harris Hip Score, whereas low ROM-measures (less than 90° of flexion, 15° or less of abduction, 10° or less of external rotation, or 20° or more of flexion contracture) correlate with poor outcomes of HHS.

3.9 Impingement

The major source of reduced ROM after surgery is impingement. Impingement can be caused by bony, prosthetic or soft tissue components. A recent study from Woerner M. et al show that in most cases soft tissue is the limiting component for all movements

but internal rotation. High BMI is considered the most significant cause of soft tissue impingement.²²

3.10 Object of this study

The focus of this work is evaluating gait restoration and potential mobility in patients who were suffering from end-stage hip dysfunction and got subserved with custom-made partial pelvic replacements. Using CM implants is high-end arthroplasty, that has only been performed for a couple years and in specialized centers only. Therefore, it is essential to discuss the benefits of considerate planning and crafting of prosthesis.

Further, the handling of reconstruction software for range of motion analysis is reviewed.

4 Material and Methods

4.1 Background of this study

We included 8 patients (6 female, 2 male), aged between 38-85 years, designated for revision total hip replacement using custom made partial pelvic replacements between December 2013 and July 2017. Orthopedic University Hospital Regensburg Asklepios Klinik Bad Abbach. All procedures were performed by two senior surgeons, Benjamin Craiovan and Tobias Renkawitz.

The investigation was approved by the local medical ethics committee on February 22nd, 2017 (No.: 17-415-101).

AQ Implants, a company seated in Ahrensburg, Germany, planned and manufactured all implants.

In this non-interventional clinical study, different methods were used to precisely evaluate postoperative success.

We compared the original planning of the implant with a postop scan, analyzing the precision of the implants position. Working with a second 3D measuring software by the company Materialise, CT Scans could be used to measure the impingement-free range of motion.

In routine follow up examinations, we determined the clinical possible range of motion. Also, patients filled in questionnaires concerning quality of life (SF36, EuroQol) and function of the hip as well as experience of pain (Harris Hip Score, HOOS). To gain more information about load sharing and maybe non-axial stress, we used our orthopedic gait laboratory.

Demographic parameters raised contained date of birth, sex, weight and height, taken from ORBIS.

The patients were informed about the purpose and meaning of this study. They know about the anonymization of their data and the publication of this work. They gave their written consent.

4.2 Patients

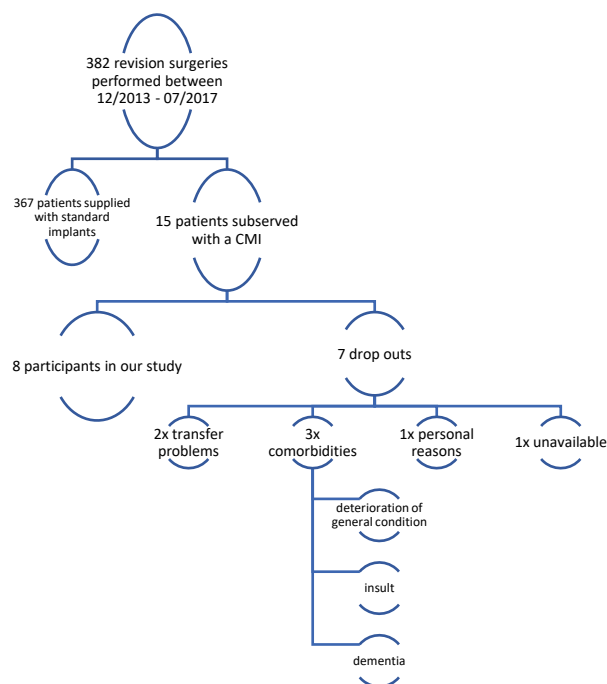


Figure 1: inclusion criteria (data source: „annual reports of orthopedic university hospital Bad Abbach 2013-2017“)

In this case series, all 15 patients that were subserved with individual implants in Bad Abbach until July 2017 were tried to be recruited. Criteria for using a custom-made implant was severe acetabular damage, classified by Paprosky as Type 3A or 3B. Patients were suffering from severe limitation in their daily lives.

Seven of those fifteen patients dropped out due age-related morbidities (n=3), living too far away (n=2), unavailability (n=1) or other personal issues(n=1).

Of the eight remaining recruits, it was revision surgery for 5 of them – the need for revision was primarily aseptic loosening or recurrent dislocation. The more unusual event of using 3D implants as primary THA was observed in 3 patients: one suffered from a gunshot wound and the two others from congenital hip dislocation (CHD).

4.3 Planning surgery

As soon as a patient seemed to be a good fit for three-dimensional reconstruction, he was confronted with the possibility of such. He had to be informed that creating an individual implant could take more time and planning and cost than ready-made implants. After his confirmation, CT data was sent to AQ. AQ is a German company specializing on custom-made and revisio-implants for severe cases of bone destruction.

They used a special CT section scanning a larger part than usual (from the upper ankle joint to the pelvis), trying to capture the patient's individual biomechanics. With the help of this scan, biomechanical 3D planning was performed including orthograde alignment of spine and pelvis as well as ROM adjustment.

In three steps, reconstruction took place. First, the cup's position was defined and aligned. In the second step, femoral head and taper orientation were positioned. Adjusting the right acetabular position meant in this study a planned inclination of 45° in all patients and anteversion individually varying from 10-20°. Also, possible extension of the leg and stem position were determined.

Using an iterative technique, the range of motion was optimized in step three. The patient's postoperative mobility was simulated with a graphical depiction using indicative color codes.

After achieving fine results with the ROM-analysis, the future prosthesis was designed. Orientated by the femur's contours, the stem was reconstructed on CT-base.

Then, it took a careful evaluation of the surgeon, deciding, if a standard prosthesis could do or an individual implant was needed. In the latter happening case, a custom-made partial pelvic prosthesis was indicated. Therefore, the base of the cup was

constructed and then extended with different fixation mechanisms. AQ designs a lot of their implants with a modular iliac peg. The iliac peg can be inserted from inside, once the implant is in place, making the process of implantation easier. It provides high stability. Other fixation options are individual tabs and refilling cavities with metal or spongiosa grafts.

The process from giving the assignment to craft an implant until completing surgery lasted from 13 to 436 days. Extended processes were mainly dependent from the patient and his ability to have surgery, but also minimal changes in the developing implant.

4.4 Surgical procedure

During surgery, a correspondent of AQ implants was present, in case of questions or issues with the implant. A detailed description of the implant was pinned on a wall in the operating theatre to follow and consider all steps.

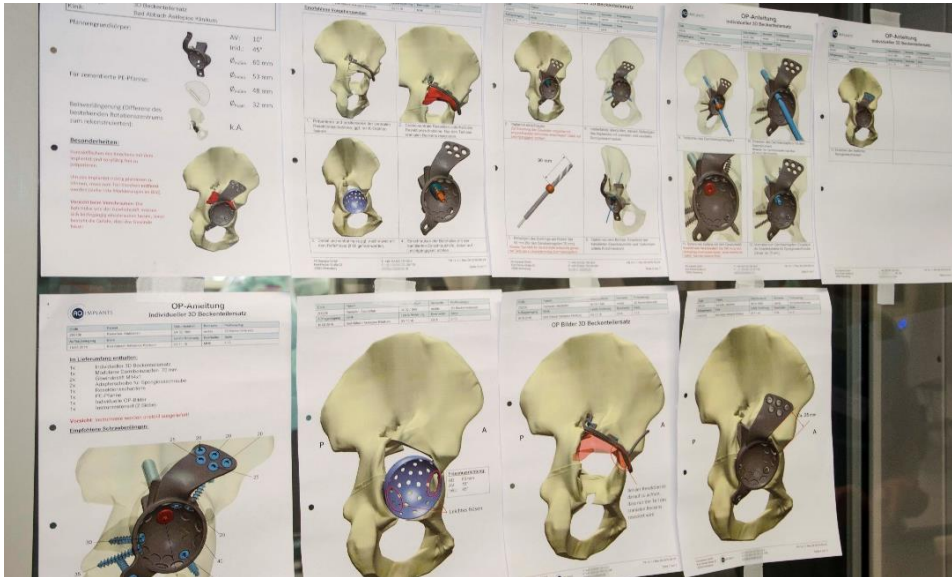


Image 5: instruction displayed in the operating theatre (photographs with kind permission of Prof. Craiovan)

A 3D-printed model of the pelvis was available for the surgeon to go through the procedure beforehand and to re-evaluate during surgery. X-ray examinations were used to check the implants position during surgery.

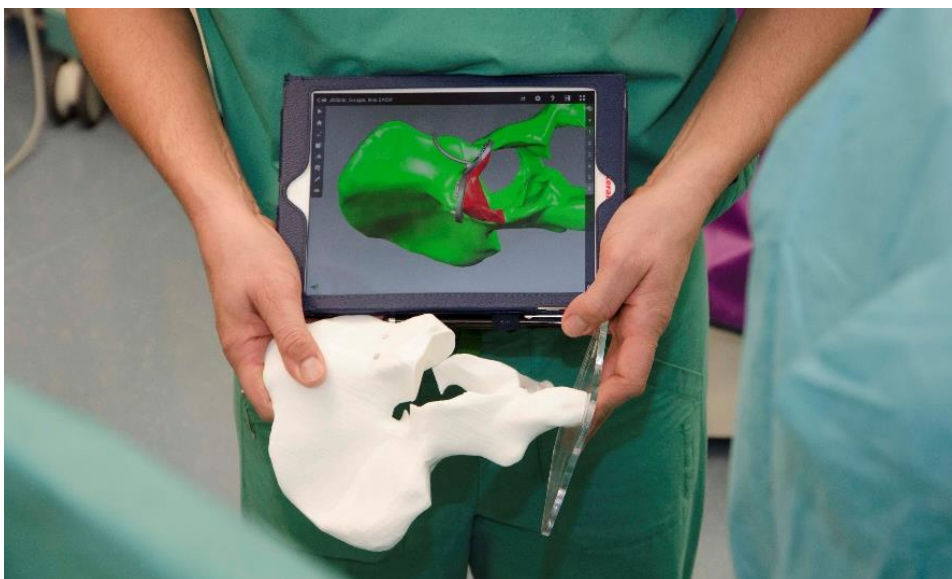


Image 6: printed model of the damaged pelvis (photographs with kind permission of Prof. Craiovan)

In the following, an example of the surgical procedure is roughly outlined:

- Operation under general anesthesia in lateral position
- Dorsal skin approach with incision of skin and gluteal fascia



Image 7: during surgery from a dorsal approach (photographs with kind permission of Prof. Craiovan)

- Detachment and excision of adhesions, if existent
- Exposure of the major trochanteric bone and inserting external rotating muscles
- Resection of the dorsal hip capsular after retracting the surrounding structures
- Evaluation of the in-situ implant: dislocation of the cup, stable/instable femoral component?
- Removal of the cup in toto
- Analyzing the extent of the acetabular defect: osseous deficiencies, hypertrophic structures, anatomical characteristics
- Usage of allogenic and autologous osseous chips for refilling osteolytic areas
- Milling and trimming of the remaining acetabulum according to AQ's planning
- Display of the proximal iliac bone to ensure nice a contact face for the iliac peg
- Fitting of the implant using the iliac tab as a guiding structure



Image 8: fitting of part of the implant (photographs with kind permission of Prof. Craiovan)

- Gradually putting in of the first drill; probing regarding the implants intraosseous position

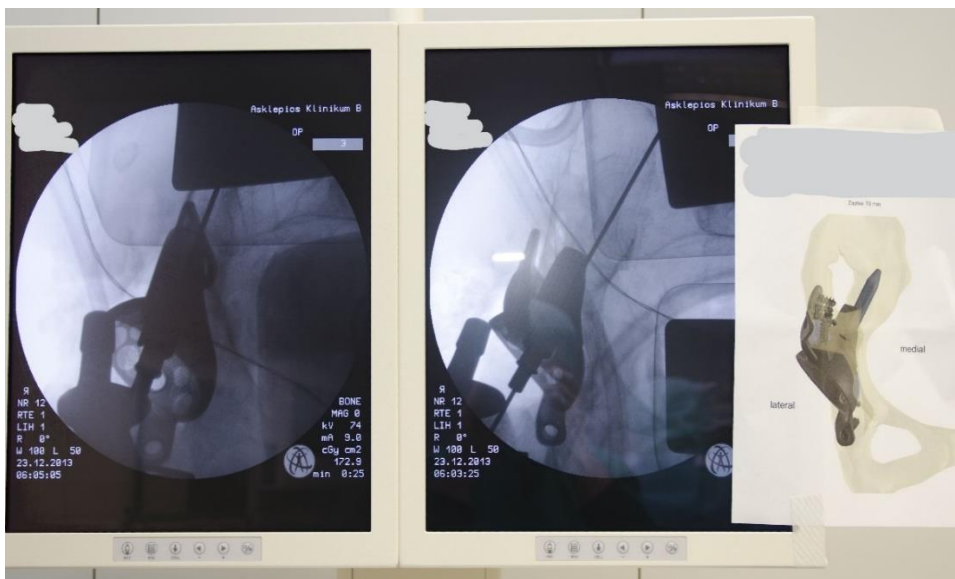
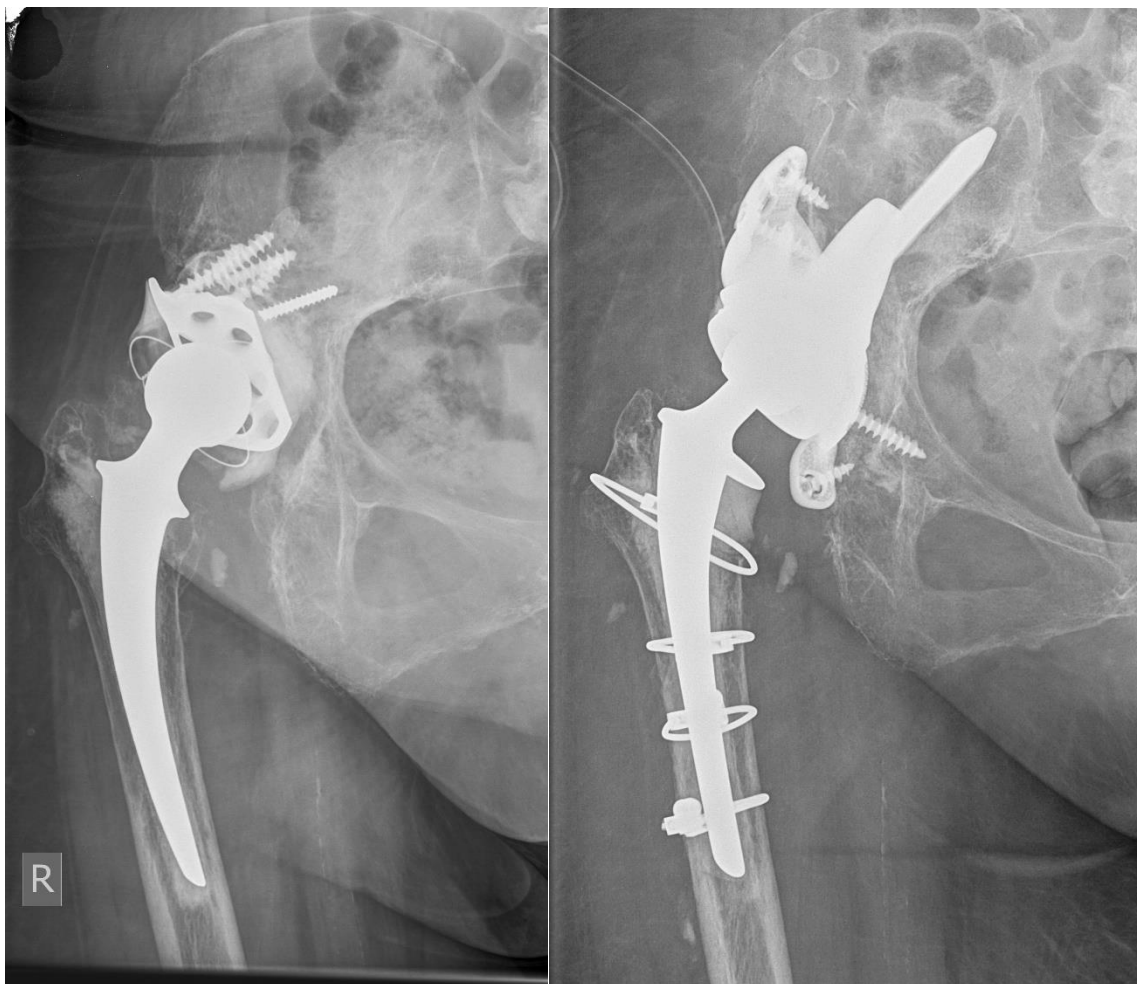


Image 9: intraoperative X-ray examination (photographs with kind permission of Prof. Craiovan)

- Placement of cranial screws, refilling osseous deficiencies with spongiosa
- Measurements of anteversion and inclination
- Decision-making for size of cup and femoral head prosthesis
- Exact placement of the cup with cementation, assembling of the head
- X-ray examination

- Reviewing of ROM and impingement
- intraarticularly inserting of a Redon's suction drainage
- Gradual wound closure (capsule, fascia, subcutaneous tissue and skin)
- Sterile bandage

Postsurgical proceeding included systematic total weight-bearing for 2 weeks, partial weight-bearing for another 4 weeks with individual increase after x-ray follow up examinations. Standard procedure further involved antibiotic prophylaxis (e.g. Cefazolin 3x2g) until wound conditions were without pathological findings.



*Image 10: left: preop X-ray of the right hip (loosened BSR cup); right: postop X-ray (CM implant with iliac tab)
(source: university hospital Bad Abbach data files)*

4.5 Clinical follow-up

After implanting a custom-made prosthesis, regular follow ups are indicated. Final examination took place from 9 months – 3 years after surgery. For this work, only final follow ups were considered.

Imaging needed was a postop CT and a recent x-ray of the hip. If not existing, images were made at Orthopaedic University Hospital Regensburg Asklepios Klinik Bad Abbach during the patients visit.

CT and x-ray were analyzed regarding the implants position and possible prosthesis loosening.

Further, patients were examined regarding level of the pelvis (oblique or even), existing Trendelenburg signs, inguinal pressure pain or trochanteric pain on percussion, thomas test, gait patterns, medication and clinical range of motion. Results were recorded on an examination sheet that is regularly used in Bad Abbach. Follow up examinations were performed by Dr. Craiovan and attendings.

4.6 Questionnaires

All patients were asked to fill out four questionnaires, two of those hip-bound and two associated to their quality of life right before and approximately one year after surgery. Partly missing data of four patients of the preop situation was supplemented with information from the patients recalling their earlier condition. One patient could not be asked about his preop condition because of a language barrier.

4.6.1 Euroqol 5D-3L ²⁴

As an instrument to measure pre- and postoperative quality of life EQ 5D was used. The EQ-5D includes a visual analog scale (VAS) which states the patient's self-perceived health on that day. The scale goes gradually from 0-100, with 100 being the best imaginable status of health. It provides a simple and direct valuation of the patient's current health state.

Further, EQ-5D-3L contains single choice questions with three severities covering five different dimensions of health: mobility, self-care, usual activities, pain and anxiety/depression. This descriptive system can be used to convert health states into

a weighted index by applying scores from preference weights determined from national population samples. One can either use the time trade-off (TTO) valuation technique or the visual analog scale (VAS) valuation technique. On both scales, death has a value of 0 and complete health a value of 1. As TTO is more commonly used in economic studies, it was more appropriate to use a VAS value set for this study.

4.6.2 SF-36 ^{25,26}

SF-36 score captures subjective health-related quality of life. Respondents were asked 36 questions about their everyday-lives and must choose the most applicable answers. Answers reach from yes/no up to 6 choosing options.

The questions can be pooled into 8 different dimensions, where every group enlightens certain outcome characteristics. Every answer holds a certain point value that is coded and added to the final sum of one dimension. Mean values are available for different population groups, differing in nationality, age or certain morbidities.

Eight subgroups are:

1) Physical functioning

How strong is the patient limited in his daily routine regarding physical aspects? Questions refer to physical condition only. Patients are asked about challenging activities such as running and simple physical labour such as bathing or walking stairs. Three available options for answering are: Yes, limited a lot/ Yes, limited a little/ No, not limited at all.

2) Physical role functioning

Is limited physical ability affecting other aspects in the patient's life? 4 polar questions review the person's individual evaluation: did he accomplish less than he wanted and could not do work as long or as effortless as he liked.

3) Bodily pain

Pain dimension consists of severity (1=no pain at all, 6= very strong pain) and restriction in daily life through pain (1=not at all, 5=very).

4) General health perceptions

General health perceptions include assessing health – now, in the near future or in comparison to others as well as actual state of health (1= excellent, 5= bad)

5) Vitality

How often does the patient feel certain emotions: full of energy, tired, exhausted, happy...?

6) Social role functioning

Patients are asked about how physical wellbeing or emotional distress interfere with social contacts (1= not at all, 5= very).

7) Emotional role functioning

Three yes-or-no questions deal with emotional strains influencing the patient's everyday life in a negative way, asking about perseverance and quality of work regarding mental issues.

8) Mental health

This last dimension captures the general mental health status. Five questions state how often the patient is nervous, down, sad, exhausted or calm and serene.

Z-value

Statistical distribution depends on the scale of abscissa. As Gaussian distribution applies, the scale for the x-axis can be empirically calculated standard deviation, leading to one characteristic appearance.

This recourse is calculated as follows:

$$z - value = \frac{\text{mean value of recruited collective} - \text{mean value of normal population}}{\text{standard deviation of normal population}}$$

This calculation transforms raw values in standard norms.

Every z-value is therefore defined by how far out the related SF-36 raw value is from the mean value of the population. They are calculated for all eight dimensions.

Z-values turn positive, when the patients score higher in SF36 than the normal sample, and vice versa, they are negative when the scale value is lower.

Norm group for SF 36 was a non-gender-specific population of Germans aged between 14-80 years (N=2773-2911).

4.6.3 Harris Hip Score (HHS) ²⁷

Harris hip score is one of the hip-related scores that were used. It is a standardized questionnaire assessing the hips function. It was developed by Harris in 1969 and modified by Haddad later. The score includes subjective and objective criteria, it is reproducible and globally used. Especially in clinical setting the score is popular for its short length, taking only 5-10 min to complete.

Four domains with differing weights determine the outcome of the score:

- 1) Pain (severity, need for medication) – max. 44 points
- 2) Function (gait, daily living) – max. 47 points
- 3) Absence of deformity (hip flexion, adduction, internal rotation, and extremity length discrepancy) – max. 4 points
- 4) Range of motion (sum of arc of six motions) – max. 5 points

All subgroups are summarized to a maximum of 100 points, minding that “pain” and “function” alone reach 91 points already.

A score of 90-100 points is considered as excellent, whereas 80-89 points are a good, 70-79 points a fair and everything <70 points a poor result.

4.6.4 Hip Osteoarthritis Outcome Score (HOOS) ²⁷

40 questions with each 5 answering options, divided into 5 subscales, form the HOOS. They are aiming on

- 1) Pain (how often/ in certain activities such as climbing stairs or walking)
- 2) other symptoms (stiffness, clicking or crunching of the joint)
- 3) function in daily living (standing, walking on different surfaces, putting on socks or shoes...)
- 4) function in sport and recreation (running, turning)
- 5) hip-related QOL (how restricted is the patient in terms of life quality?)

The score is calculated in percentage and therefore shows a maximum of 100% and a minimum of 0%.

For evaluating this score, a free online software program called <http://www.orthopaedicscores.com> was used.

4.7 3D reconstruction

4.7.1 Materialize

Materialize, a 3D-print-company headquartered in Löwen, Belgium, provided us with two of their Software installations: 3-matic Medical 11.0 and Mimics inPrint 1.0. Their Software was used to virtually reconstruct the patients hips based on their CT-scan after implantation.

Therefore, CT data was imported as a DICOM file into Mimics inPrint. The software views the three sectional planes (axial, coronary, transversal) and leaves one window for creating the three-dimensional image. As the density of bone and soft tissue differ on a quite large scale, a threshold tool can be used to segment the CT and mark the osseous structures only. With different tools, the program creates so called regions of interest, enabling one to separate femur from acetabulum, and when working with an implant, two more regions of interest: sheath and cup.

After putting the finishing touches on the different, then solid parts by smoothing, the four parts can be copied into 3-matic Medical. 3-matic Medical is only working three-dimensionally. It offers tools such as manual smoothing and masking. By turning the femoral head into a spherical centre of rotation and selecting femur and sheath as moving along entities, the software makes it possible to analyze the impingement-free range of motion in extension/flexion (Y), abduction/adduction (X), external/internal rotation (Z).

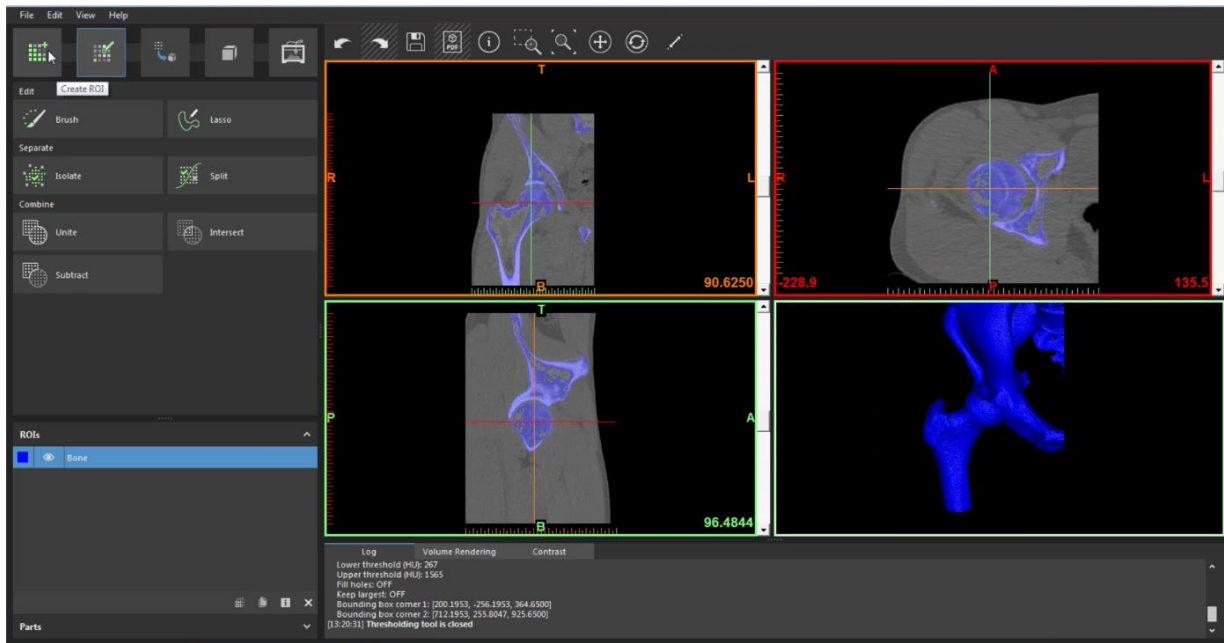


Image 11: Setup of Mimics in-Print (screenshot)

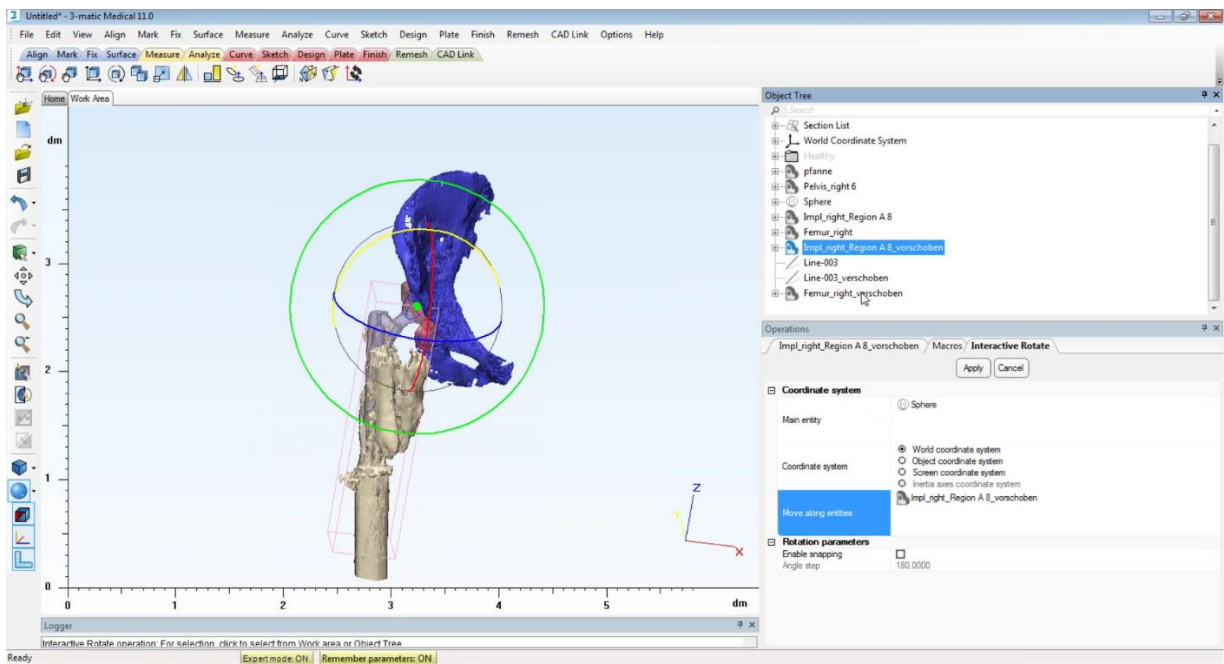


Image 12: Setup of 3-matic Medical (screenshot)

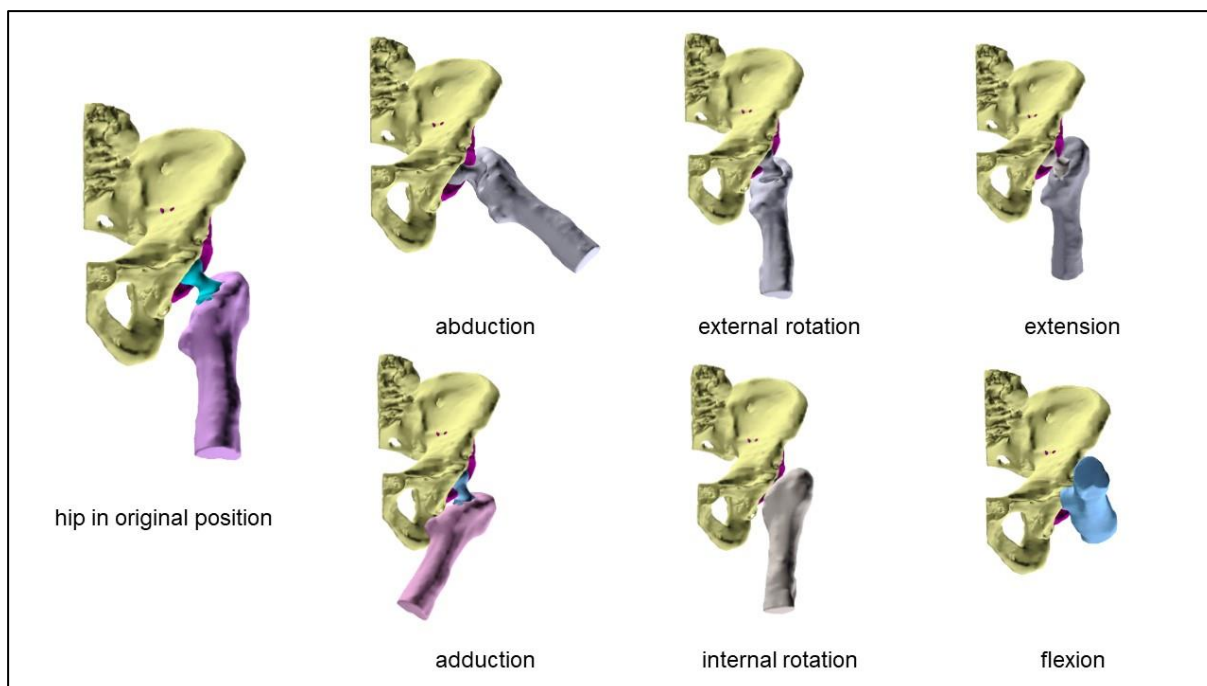


Image 13 final version of a male patient's virtual hip reconstruction using MimicsinPrint and 3-matic Medical. Abduction/Adduction: 48°/28°, External/Internal Rotation: 2,4°/0,9°, Extension/Flexion: 41°/87°. Total ROM = 207,3°

Employees of the company trained our team by virtual instructions and one day of schooling in Munich. They supported us regarding all issues coming up with the software.

The most important precondition for using Materializes Software is a high-quality CT. Data with a small pixel size makes it difficult to achieve a satisfactory result. Especially with the images that were used for this work, scattering of the prosthesis made it difficult to edit and work. Some results could not be utilized.

4.8 Gait laboratory

The gait laboratory in University hospital Bad Abbach is a modern equipped laboratory with a 10m long walking distance. Though gait disorders can be detected by visual observing, quantitative measurements should be made using technology. Patients received reflecting markers on certain palpable landmarks on their lower extremity. They were asked to walk up and down, while six Basler-cameras were recording. One set of static pictures and many more dynamic frames were recorded. Moreover, two central force plates registered ground reaction forces, plus 16 channels registered surficial electromyography.

Next step was a three-dimensional digital reconstruction of the patient's gait. For this study, we used a software called Simi Motion, whereby force, moment and ankle of the joints can be calculated. Therefore, the reflecting markers in the video were registered by the software as highlighting dots. With manual support, the dots were assigned to their defaulted bony landmarks (amongst others: greater trochanter, ASIS, calcaneus, metatarsal bones, lateral and medial epicondyles, tibia) in the program in every camera perspective. Automatic acquisition applied the fixed points to every frame. The frames were then checked manually, as especially swinging arms can cover markers and mislead the program. When the 3D model was completely reconstructed, the report was compiled.

A gait report contains range of motion angles in ankle, knee and hip joint as well as pelvic tilt, obliquity and rotation. Also, speed, step-length, track width, stance and swing phase and kinematics in sagittal, frontal and transverse planes are measured.

Usually, patients were recorded walking four to five times. Once analyzed, the best try was taken as a representative. Criteria for the best try were:

- Velocity: the patient should walk at mediate pace. Naturally, pace differs depending on the patient's level of fitness and physical condition. Best tries should neither be their fastest nor their slowest walk.
- Balance: an equally balanced gait shows stability and secureness. On that score, single-step-length of right and left leg were compared. Little to no difference shows an even use of both legs. A high percentage of double support during stance phase indicates instability too, so tries were picked in favor to a higher single support ratio.
- Kinematics: kinematic graphs should show a smooth motion sequence. Unnatural spikes can be rated as hardware faults.

Of the eight recruits we had, only 6 analyzes were evaluable. One patient was still using crutches, which made analyzing difficult, and the other was recovering from a fall and indisposed.

Every gait laboratory has its own group of norm population it is referring to. In case of this work, norm was defined by a group of healthy mid-twenties ($n=11$, mean age=25,7 years, mean BMI=22,22(+/-3,05); mean velocity=1,34m/s). We referred to the norm

group in our kinematic graphs, but for other measures, we compared operated to non-operated leg.

4.9 Data analysis

All data collected from ORBIS and gait laboratory was documented in one central excel map (Microsoft Excel 2007, Microsoft Corporation, Redmond, USA). Statistical evaluation was made using IBM SPSS Statistics 24 (International Business Machines Corporation (IBM), Armonk, USA) for Windows.

Variables are presented as mean +/- standard deviation (SD) in the case of normal distribution, and median plus range if data had a skewed distribution. Categorical variables were presented with absolute and relative frequency, using bar diagrams as visual support. Statistical significance was set at $p < 0.5$.

5 Results

5.1 Demographics

In table 1, the recruited collective's characteristics are summarized.

Table 1: depiction of the recruits

CASE NUMBER	AGE	BMI	SEX	OP. SIDE	ASA	PRIMARY DIAGNOSIS
1	76	28	F	Right	3	OA
2	61	24	F	Left	3	CHD
3	60	28	F	Left	2	rA
4	86	24	F	Right	3	OA
5	80	31	F	Right	3	OA
6	76	25	M	Left	2	OA
7	38	25	M	Right	2	Gunshot wound
8	71	40	F	Right	2	CHD
STATISTICS						
MEAN	68,4	28,1				
MEDIAN	73,5	26,5				
SD	15	5,4				
RANGE	47	16				
MIN	38	24				
MAX	85	40				

The recruited collective consisted of 75% women (n=6) and 25% men (n=2). They were aged between 38 and 85 years, with a mean age of 68,4 years and a median of 73,5 years.

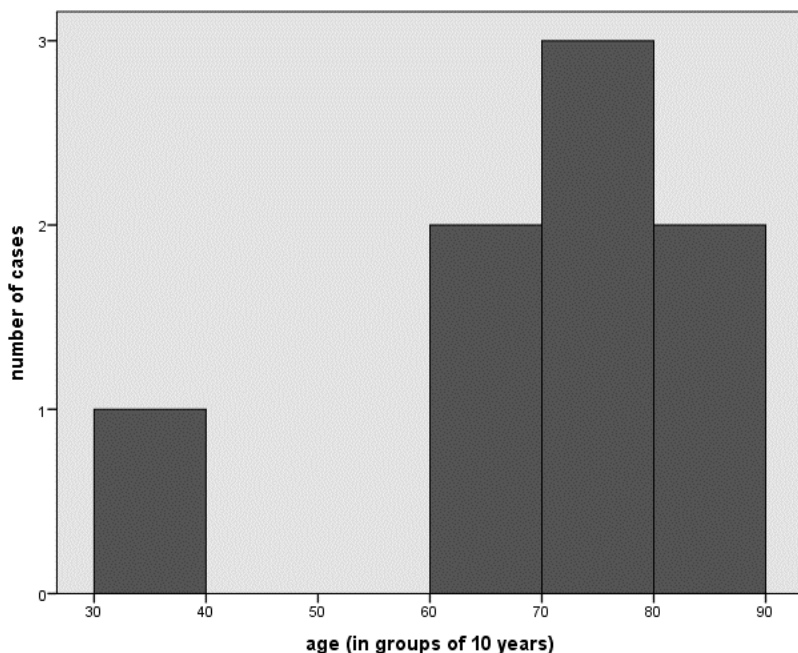


Image 14: age pattern

The patients' heights were measured between 153cm to 181cm (162,63cm +/-10,7). Their mean weight was 78,75kg (min: 58kg, max:103kg) and their BMI averaged to 28,13 (min:24, max:40).

62,5% (n=5) of the patients were operated on their right leg, 37,5 % (n=3) on their left.

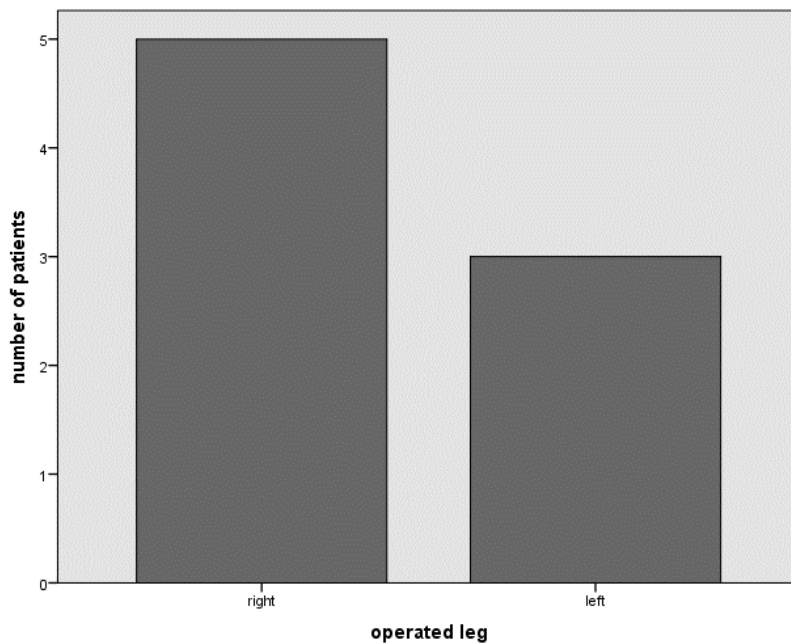


Image 15: distribution of operating on right and left leg

Half of the collective (n=4) reached an ASA score of 2, the other half (n=4) reached a score of 3.

5.2 Preoperative situation

5.2.1 Primary diagnosis

In 50%(n=4), the primary diagnosis was osteoarthritis. Congenital hip dysplasia was primarily diagnosed by 25%(n=2) of the patients. 12,5% (n=1) suffered from rheumatoid arthritis and another 12,5% (n=1) from a gunshot injury.

5.2.2 Reason for revision

Half of all patients (n=4) underwent revision surgery due to aseptic loosening. Two patients (25%) were treated because of severe hip dysplasia, one patient (12,5%) with recurrent dislocation and one (12,5%) with massive bone destruction due to an injury.

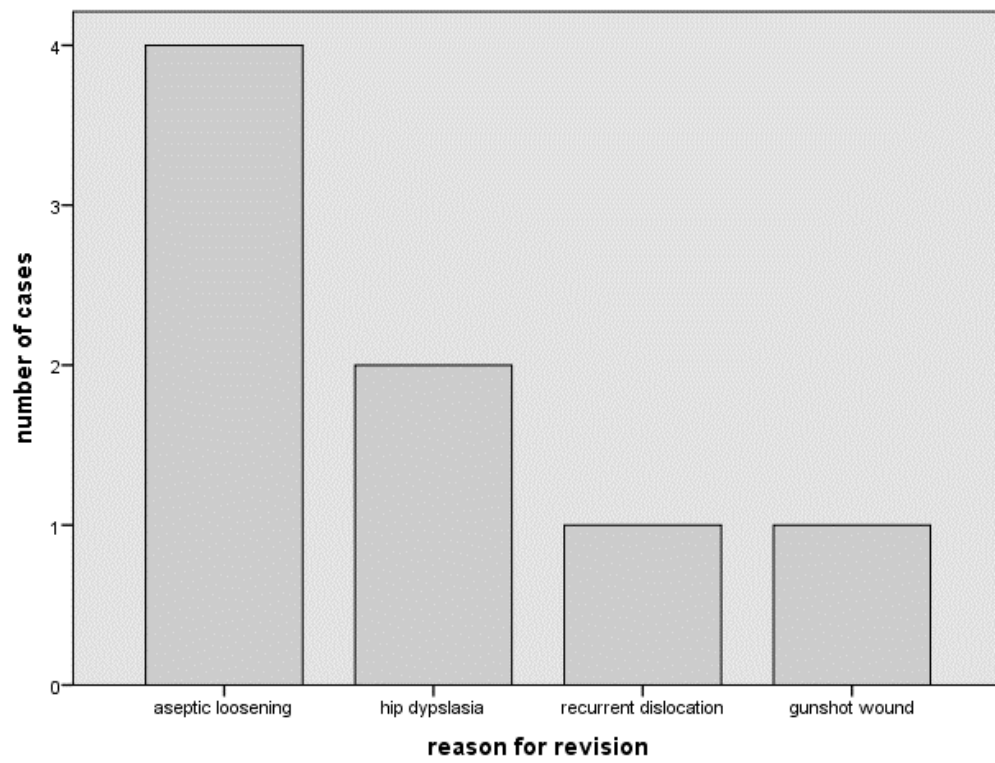


Image 16: indication for revision surgery

5.2.3 Previous implant

Previous implant was in two cases (25%) a Bruch-Schneider-Ring, in two more (25%) a cemented cup and in another one (12,5%) a screw cup. It was primary arthroplasty for three patients, of which one (12,5%) did not have hip surgery before. This patient was a victim of a gun shooting. The two others (25%) suffered from congenital hip dislocation and had corrective osteotomy before but no previous implant.

5.3 Implant planning

Table 2: preoperative implant planning measures

CASE NUMBER	STEM REVISION	CUP SIZE IN MM	LEG EXTENSION IN MM	INC IN °	AV IN °	ASSIGNMENT – SURGERY IN DAYS
1	no	58	50	45	10	13
2	no	58	39	45	10	99
3	no	60	9	45	10	81
4	no	56	3	45	20	85
5	no	58	22	45	20	73
6	yes	n.g.	49	45	15	436
7	yes	60	n.g.	45	10	144
8	yes	58	n.g.	45	10	148
STATISTICS:						
MEAN		58	28,67	45	13,1	135
MEDIAN		58	30,5	45	10	92
SD		2	20,3	0	4,6	129
RANGE		4	47	0	10	423
MIN		56	3	45	10	13
MAX		60	50	45	20	436

Of all eight patients, 37,5% (n=3) underwent both cup and stem revision, whereas in 62,5% (n=5) only the acetabular component was replaced.

The size of the cup ranged from 56 – 60 mm, with a mean and median value of 58mm. Planned inclination of the cup was 45° in all patients, intended anteversion between 10° and 20°, with a median of 10° and a mean value of 13,1°.

Leg extension was projected between min. 3mm and max. 50mm (mean: 28,67mm +/- SD = 20,3mm). Median value was 30,5mm.

Time of giving assignment until surgery was 135 days in average, with a minimum of 13 and a maximum of 436 days, and a median time of 92 days.

5.4 Intraoperative characteristics

5.4.1 Time aspects

In average, surgery took 232,6 min (SD= 54,8min). The shortest period for incision-suture-time was 167 min, the longest 317 min.

After the procedure, patients stayed from 9 – 22 days in Bad Abbach hospital, with a mean stay of 13,6 days and a median and modal time of 11 days.

5.4.2 Perioperative blood loss

Hemoglobin concentration was measured before and after surgery. Mean preop HB concentration was 13,88 g/dL (SD= 1,75g/dL), postop it dropped to an average of 10,12 g/dL (SD= 1,6g/dL), with a mean loss of 3,76 g/dL. The highest difference in HB concentration after surgery was 6,2 g/dL, the lowest 1,6 g/dL.

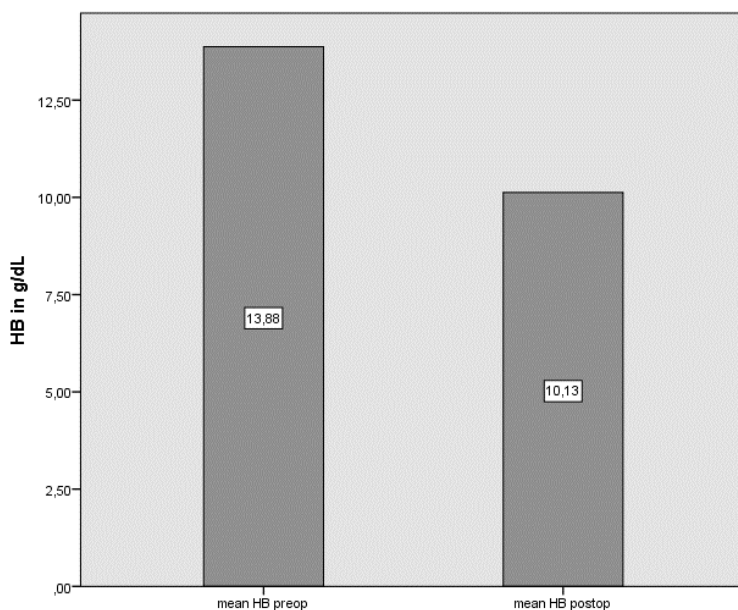


Image 17: Hemoglobin concentration pre- and postop

5.5 Scores

5.5.1 EuroQol

EuroQol-5D VAS results summed up to a mean of 0,35 (+-0,24) and a median of 0,24 preoperatively. After surgery, mean had a value of 0,75 (+-0,27) and median a value of 0,78. The positive changes in EuroQol can be stated as statistically significant ($p=0,018$).

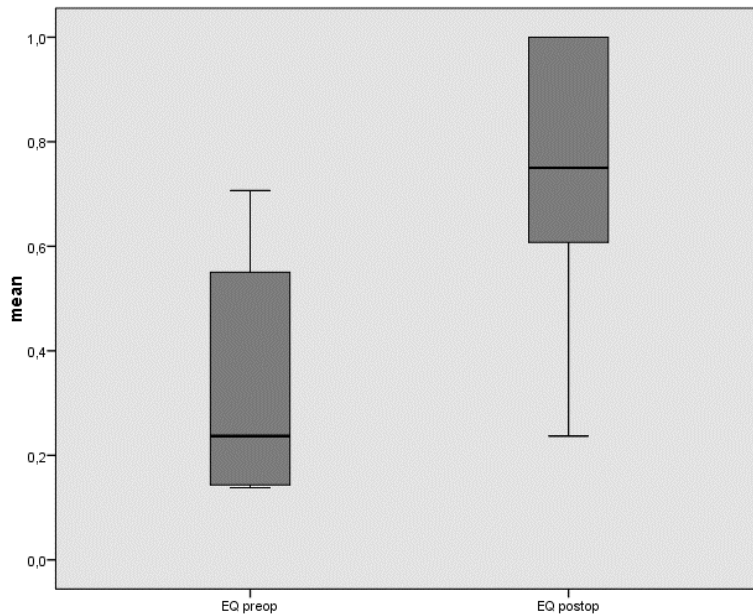


Image 18: EQ results pre- and postop

On the visual analog scala regarding the actual health state, results improved from a preop median of 60,5% to a postop median score of 72,5%.

5.5.2 SF36

5.5.2.1 Physical and Mental Component Summary

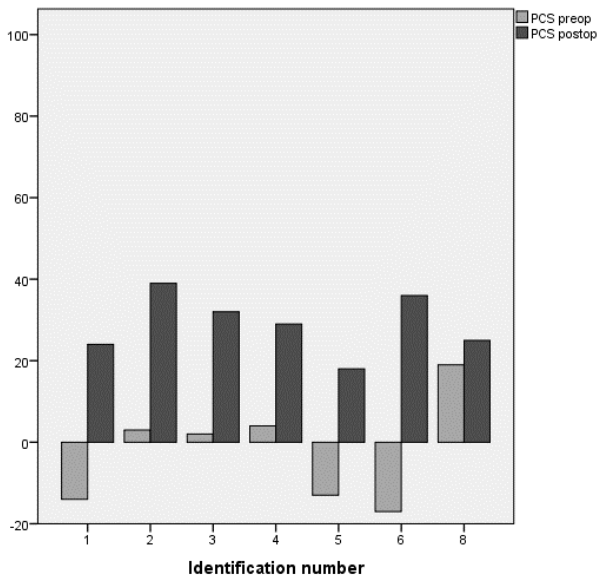


Image 19: Physical Component Summary pre-/postop for each individual

In every patient, improvement in the sum of physical components was registered with a mean norm value of $PCS_{preop} = -2,3 (+-13)$ preoperatively and $PCS_{postop} = 29 (+-7,3)$ postoperatively, proven significantly ($p = 0,001$).

Regarding the sum of mental components, no such improvement was found. In mean, patients had a sum of $MCS_{preop} = 37,7 (+-37)$ points before and $MCS_{postop} = 39,9 (+-32,8)$ points after surgery. The difference was not significant ($p = 0,8$).

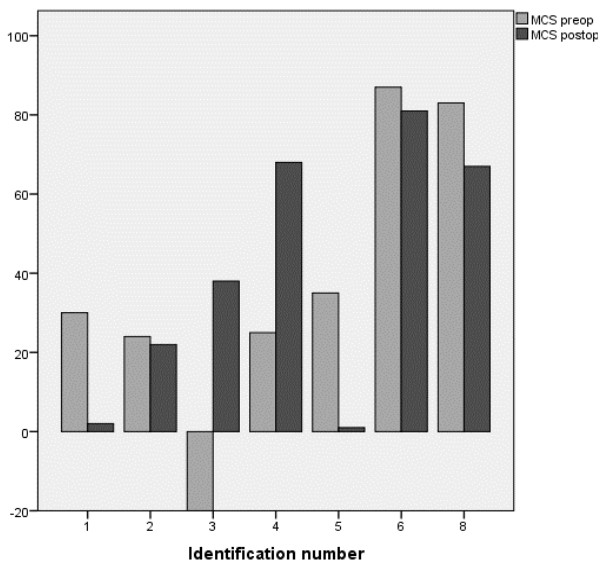


Image 20: Mental Component Summary pre-/postop for each individual

5.5.2.2 Detailed characteristics

With a significance of $p=0,095$, patients considered their health as improved after surgery. They felt less pain ($\text{mean}_{\text{pain_preop}} = 5,7 (+-26,3)$, $\text{mean}_{\text{pain_postop}} = 36,6 (+-20,6)$, $p=0,03$), more vital ($\text{mean}_{\text{vitality_preop}} = 23,3 (+-21,9)$, $\text{mean}_{\text{vitality_postop}} = 41,2 (+-26)$, $p=0,1$) and more socially involved ($\text{mean}_{\text{socialfunctioning_preop}} = 9,8 (+-42)$, $\text{mean}_{\text{socialfunctioning_postop}} = 25,4 (+-38,1)$, $p=0,2$).

5.5.3 HHS

Preoperatively completed Harris Hip Score showed a result of 34 points in mean (SD=17p), with a median value of 27p and a range from 23-73p. After surgery, mean value was 69 points (SD=18p), median was 71 points and the range reached from 39 to 92 points. The improvement was statistically significant ($p=0,028$).

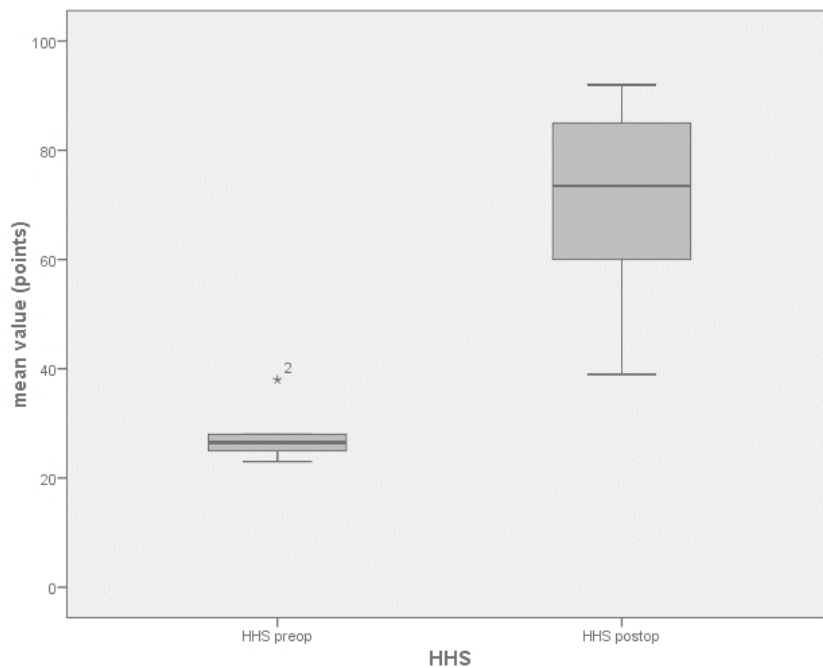


Image 21: HHS mean results (pre- versus postop)

5.5.4 HOOS

Following results were evaluated before surgery. Mean for the dimension 'symptoms' was 30% (SD=22%) on a range from 7,5 - 65%. 'Pain' had a mean of 35% (SD=22%)

ranging from 0-60%. 'Activities in daily life' achieved an average of 26% (SD=44,12) on a range of 6-50%.

'Sports' as a dimension achieved poorest results with a mean of 17% (SD=17%; min:0%, max:44%). 'Quality of life' averaged to 22% (SD=17%), ranging from 0-50%,

In total, preop HOOS scored mean 27% (SD=17%) with a minimum outcome of 9,4% and a maximum score of 47,4%.

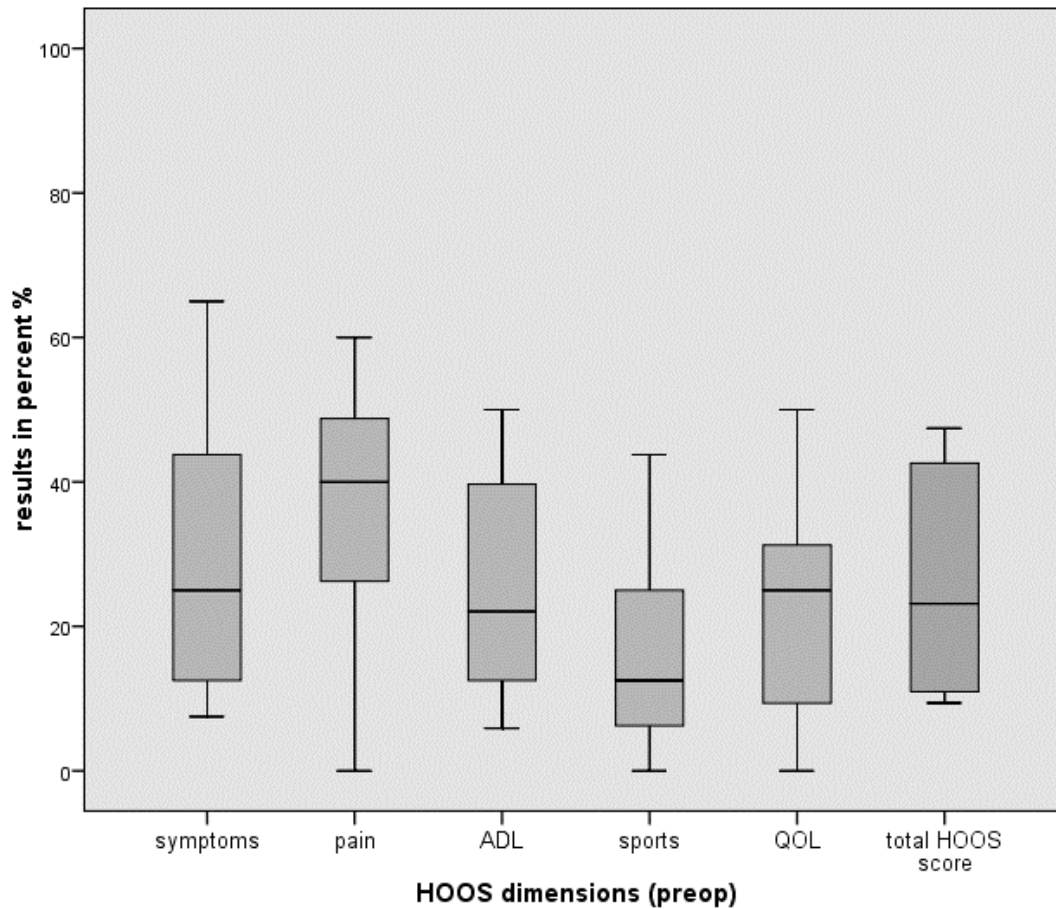


Image 22: preoperative HOOS results (5 dimensions + total score)

After surgery, mean total HOOS was 74% (SD=22%), ranging from 34-96%. The five subgroups differed as follows.

'Symptoms' achieved mean 79% (SD=21,2%) with a minimum of 50% and a maximum of 100%. 'Pain' showed a mean result of 82,5% (SD=16%) ranging from 57,5-100%. 'ADL' values averaged to 75% (SD=30%) on a range from 22-97%. Mean 'sports'-result was 47% (SD=32,5%) on a range from 0-81%. 'Quality of Life'-mean was 65%

(SD=22%; min: 34%, max:96%). The outcome of HOOS improved significantly in all dimensions (p=0,018).

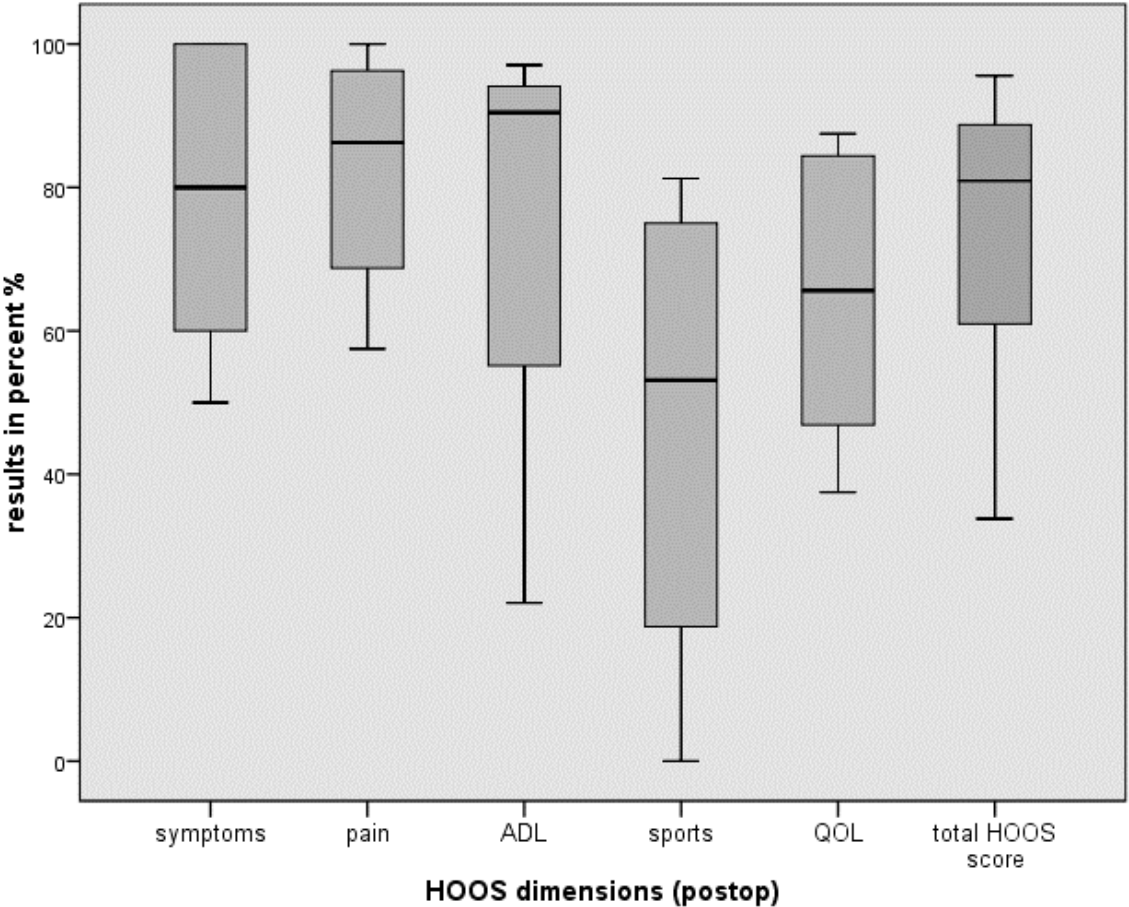


Image 23: postoperative HOOS results (5 dimensions + total score)

5.6 Virtual range of motion

Two dimensions of virtual reconstruction (ab-/adduction and extension/flexion) in 5 patients postoperatively were measured.

The sum of ab- and adduction had a mean value of 91° (SD=15,7°) and a median of 98° on a range of 75°-111°.

In terms of extension and flexion, mean score was 146° (SD=65,4°), with a median of 157,1° and a range of 108°-173°.

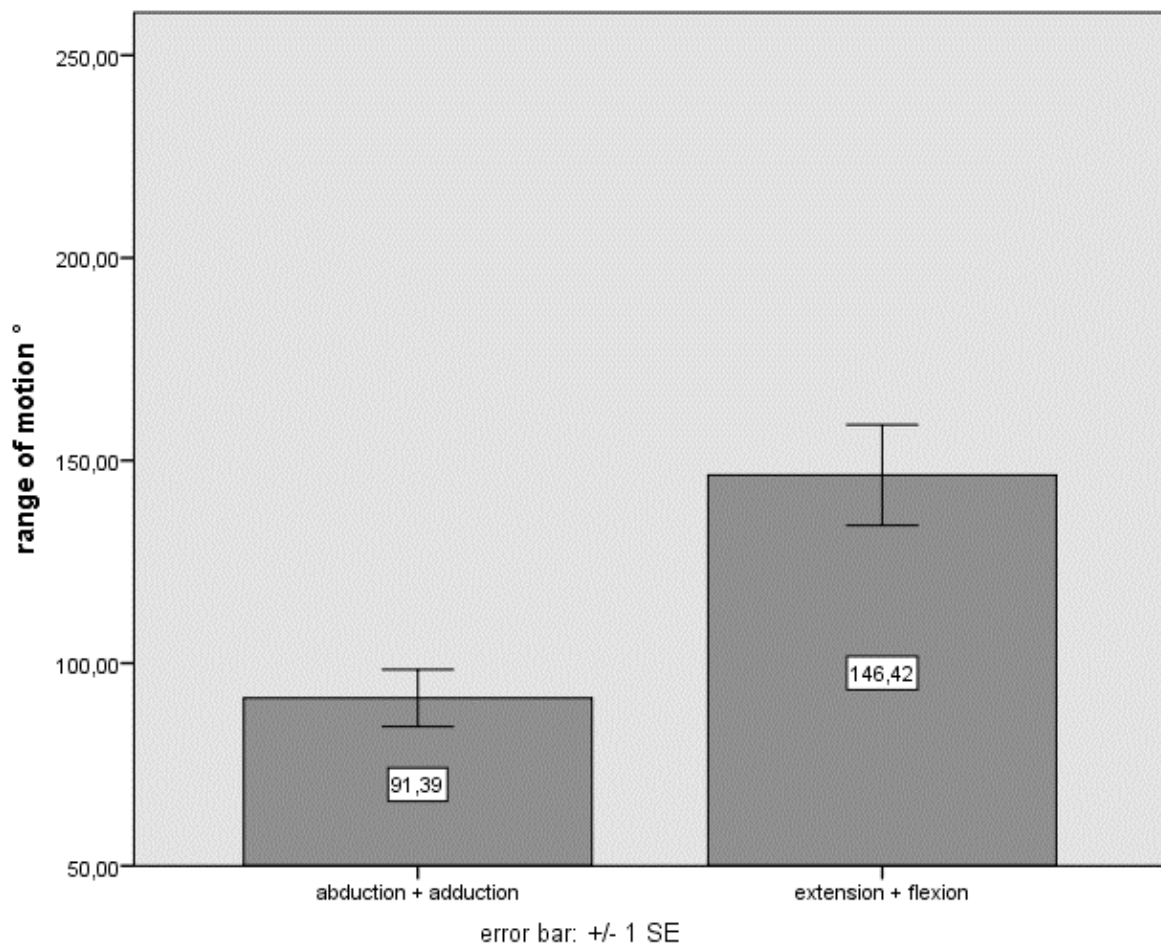


Image 24: mean virtual ROM measures (postop)

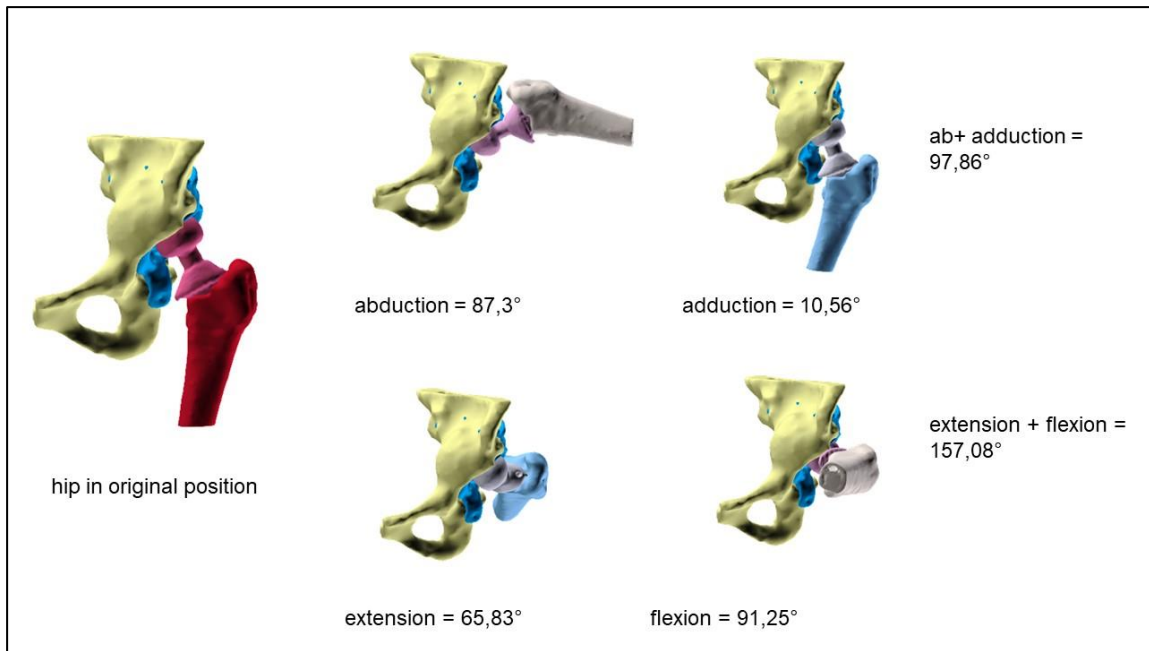


Image 25: female patient's left hip showing her fine results of virtual ROM reconstruction

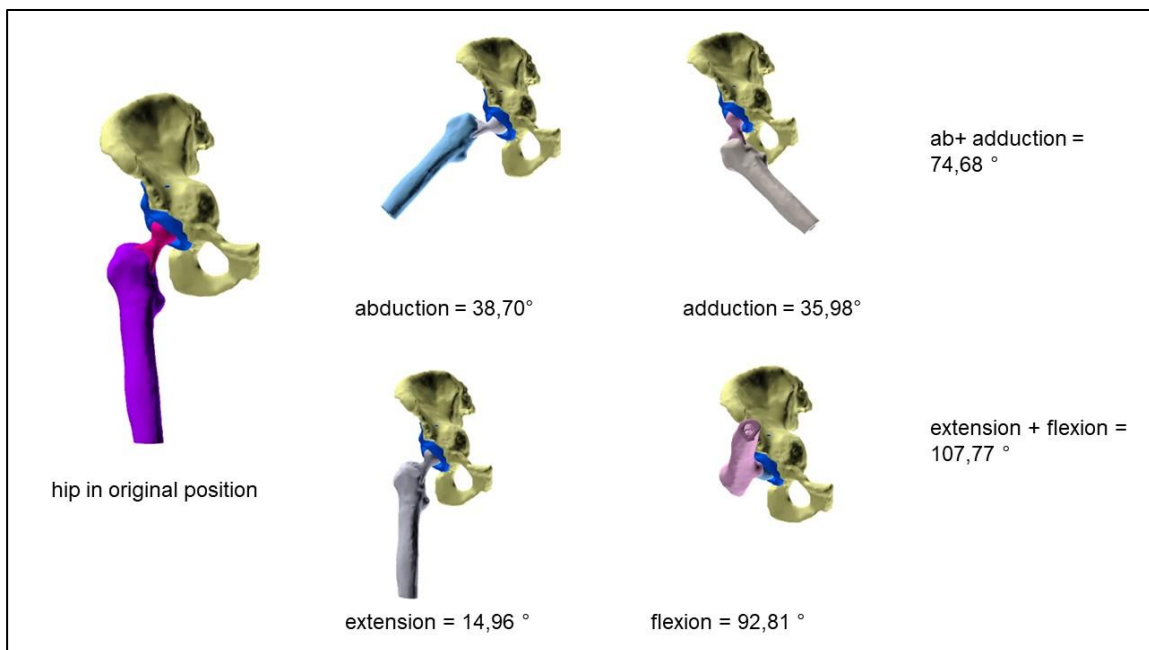


Image 26: female patient's right hip showing her relatively poor results of virtual ROM reconstruction

5.7 Virtual versus clinical ROM

Postop virtual reconstruction showed a wider motion range than clinical ROM scores. In average, patients reached 25° more (SD=15,2°) in abduction + adduction (min:4,7°, max:40,7°) and 42° more (SD=24,1°) in extension + flexion (min:7,77°, max:66,52°)

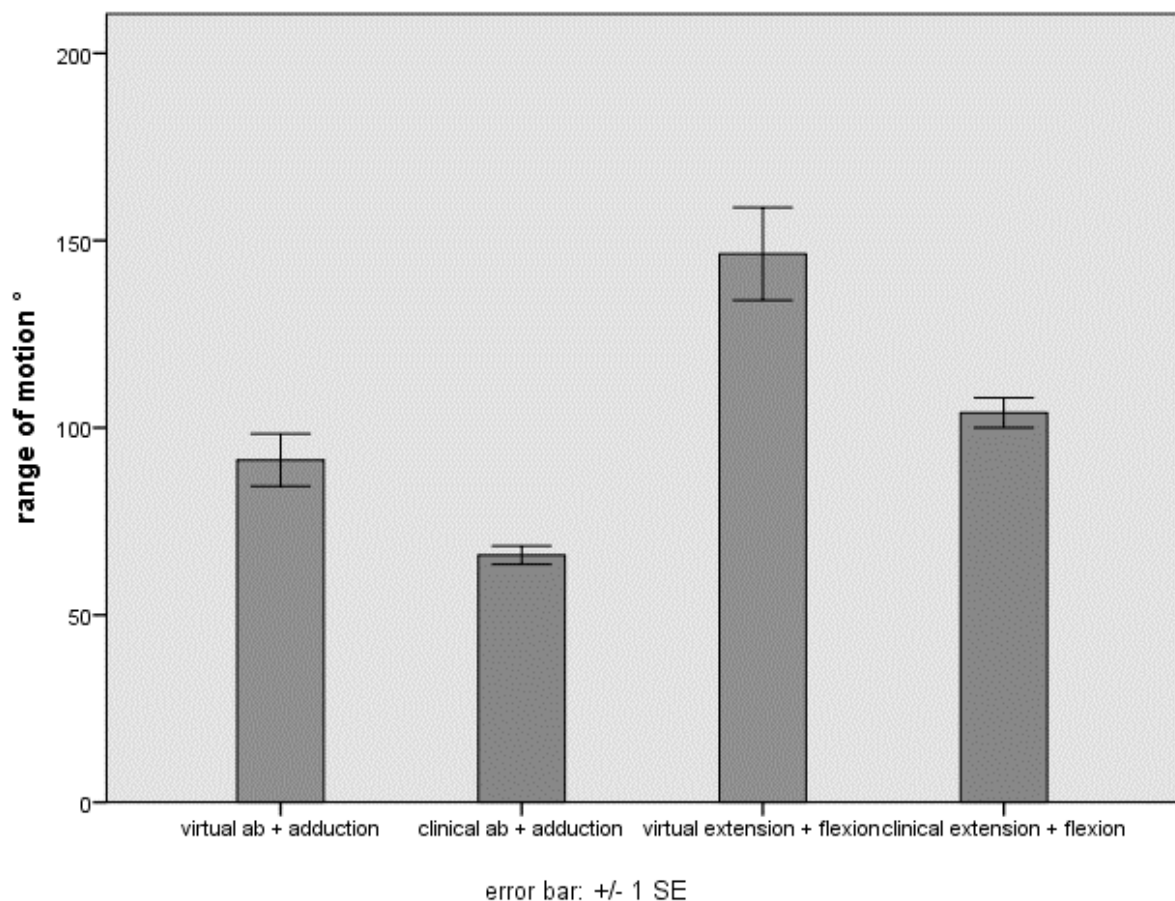


Image 27: mean results for virtual and clinical ab-/adduction & extension/flexion

5.8 Clinical Range of Motion

5.8.1 Before and after surgery

Clinical ROM examination was performed in all patients pre- and postoperatively. Mean value for abduction and adduction were 17,5°, for external and internal rotation also 17,5° and for extension plus flexion 72°. Total clinical ROM measured 101,25° in mean (SD= 27°) before surgery. Median was 90°, the smallest motion range 70° and the widest 150°.

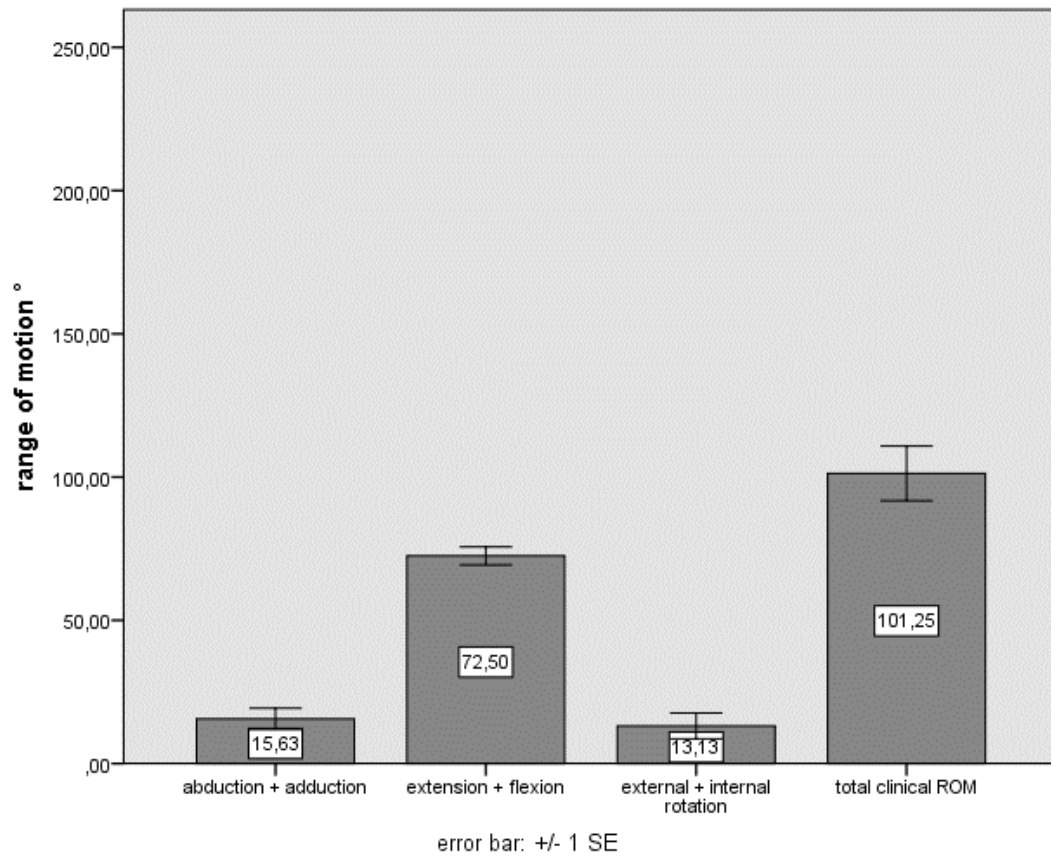


Image 28: mean clinical ROM measurements (preop)

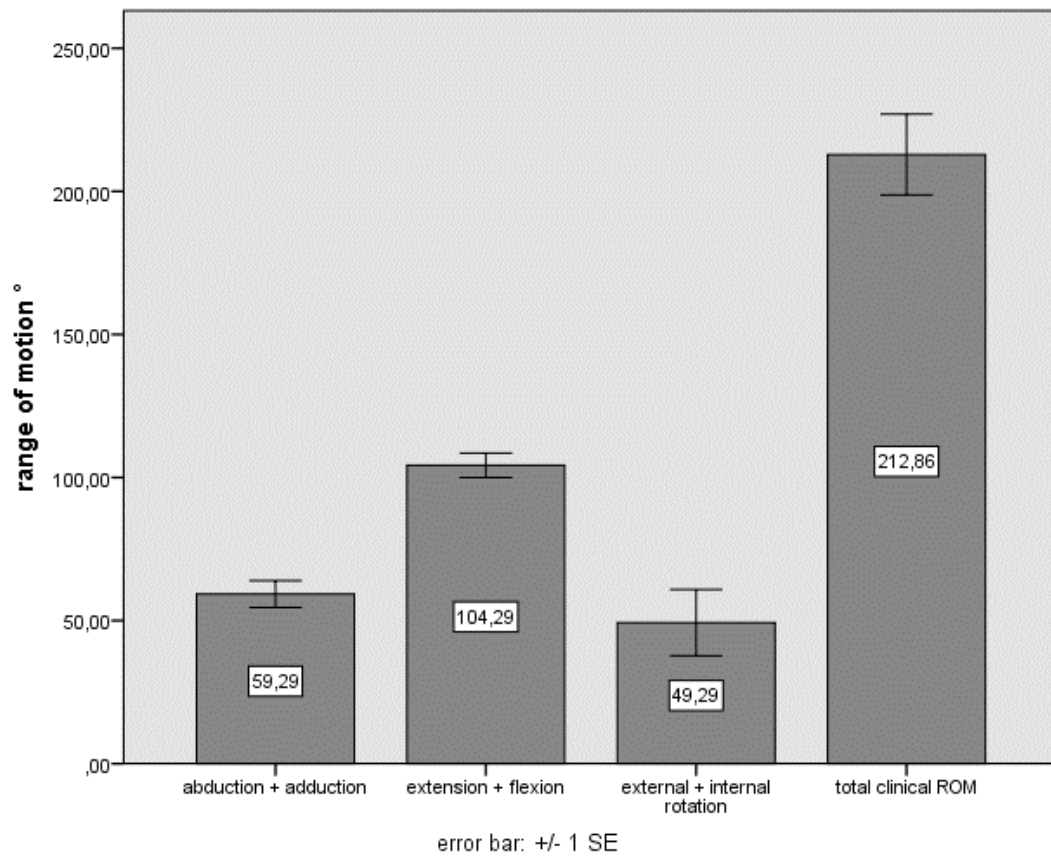


Image 29: mean clinical ROM measurements (postop)

Postoperative range of motion outcomes were examined during the last follow up. One patient was prevented due to a domestic fall. Results for ab- and adduction differed between 40° and 70°, with a mean value of 59° (SD= 12,4°) and a median of 60°. Extension plus flexion summed up to mean 104° (SD= 11,3°) and median 100° (min:90°, max:120°). External plus internal rotation added to a mean value of 49° (SD= 37,3°)

5.8.2 Improvement

In every patient, improvement in terms of motion range was registered. The minimal total improvement was 90°, the maximal total improvement 180°. In mean, the difference of ROM measures was 119° (SD= 33,38), median was 100°. The result was statistically significant (T=9,34; df=6; p<0,000).

Ab- and adduction enhanced around 46° (SD=10,3°, max: 60°, min:35°), extension and flexion around 32° (SD=15°; max:60°, min:20°) and rotation around 39° (SD=29,2°; max:90°, min:0°). All improvements were statistically proven as significant using a paired T-test (Ab/Ad: T=11,934, df=6, p<0,000; Ex/Flex: T=5,811, df=6, p<0,001; Ex./Int. rotation: T=3,558, df=6, p<0,012).

5.9 Implant survival

Implant survival rates at the time of our final follow up equaled 100%.

5.10 Gait laboratory

In gait lab, the collective was not evenly distributed, as one patient who needed manual support differed widely from the rest. Therefore, median ranges were considered for all tests in our gait laboratory results.

5.10.1 Gait parameters

Patients walked at a median speed of 0,9m/s on a width of 0,14m around 104 steps per minute.

Table 3: gait characteristic

STATISTICS	VELOCITY (M/S)	TRACK WIDTH (M)	CADENCE (STEPS/MIN)
MEAN	0,9	0,14	102,5
MEDIAN	0,9	0,14	104
SD	,42	0,04	14,7
RANGE	1,19	0,11	43
MIN	0,15	0,09	78
MAX	1,34	0,2	121

Step length was registered for single and double steps. For both items, Wilcoxon tests were made. The difference between operated and non-operated leg with a median of 0,005m for single step length and 0,02m for double step length was not statistically significant (single step length: $p=0,686$; double step length: $p=0,293$).

Table 4: single and double step length measured in meters

STATISTICS	SINGLE STEP LENGTH OP.	SINGLE STEP LENGTH NOT-OP.	SINGLE STEP LENGTH DIFF.	DOUBLE STEP LENGTH OP.	DOUBLE STEP LENGTH NOT-OP.	DOUBLE STEP LENGTH DIFF.
MEAN	0,51	0,52	0,015	1,0	1,04	0,04
MEDIAN	0,59	0,53	0,005	1,06	1,13	0,02
SD	0,24	0,187	0,09	0,41	0,41	0,07
RANGE	0,65	1	0,26	1,13	1,1	0,17
MIN	0,04	0	-,12	0,23	,24	-,03
MAX	0,69	1	0,14	1,36	1,34	,14

5.10.2 Gait cycle

Gait cycle on the operated leg showed a slight shift to a longer swing phase in proportion (median stance phase^{OP}: 63,5%, median swing phase^{OP}: 36,5%) in comparison to the healthy leg (median stance phase^{notOP}: 69,5%, median swing phase^{notOP}: 30,5%) with statistical significance (p= 0,027).

Table 5: gait cycle: stance and swing phase in percent %

STATISTICS	STANCE PHASE OP.	STANCE PHASE NOT-OP.	STANCE PHASE DIFF.	SWING PHASE OP.	SWING PHASE NOT-OP.	SWING PHASE DIFF.
MEAN	67,5	70,8	3,3	32,5	29,2	-3,3
MEDIAN	63,5	69,5	2,5	36,5	30,5	-2,5
SD	9,35	8,95	2,25	9,35	8,95	2,25
RANGE	25	26	6	25	26	6
MIN	61	62	1	14	12	-7
MAX	86	88	7	39	38	-1

With a value of p=0,345, the ratio of double and single support did not statistically differ on both legs (median^{OP}: double support=52,5%, single support=47,5%; median^{notOP}: double support=47,5%, single support=52,5%).

Table 6: distribution of double and single support during stance phase in percent %

STATISTICS	DOUBLE SUP. OP.	DOUBLE SUP. NOT-OP.	DOUBLE SUP. DIFF.	SINGLE SUP. OP.	SINGLE SUP. NOT-OP.	SINGLE SUP. DIFF.
MEAN	54,7	52,5	-2,2	45,3	47,5	2,2
MEDIAN	52,5	47,5	-2,5	47,5	52,5	2,5
SD	17,9	15,5	5,6	17,9	15,5	5,6
RANGE	52	43	15	52	43	15
MIN	35	40	-10	13	17	-5
MAX	87	83	5	65	60	10

5.10.3 Gait dynamics of the hip

On the main dynamic axis (=sagittal), median values for extension and flexion were: Ex/Flex^{OP}=34,5°; Ex/Flex^{notOP}=41,5°. For coronal movement, Ab/Ad^{OP} was 13° and Ab/Ad^{notOP} was 10,5°. The median arc of transverse motion was Rotation^{OP}=19° and Rotation^{notOP}=17,5°.

The differences in all three planes between operated and non-operated leg were not statistically significant ($p(\text{Ex/Flex}) = 0,528$; $p(\text{Ab/Ad}) = 2,14$; $p(\text{Rot}) = 1,0$).

Table 7: dynamic ROM of the hip in three planes in °

STATISTICS	EX / FLEX OP.	EX / FLEX NOT-OP.	AB / ADD OP.	AB / ADD NOT-OP.	ROTATION OP.	ROTATION NOT-OP.
MEAN	35	38	13	12	18,5	18,3
MEDIAN	34,5	41,5	13	10,5	19	17,5
SD	7,95	12,6	4,6	2,9	5,2	6,4
RANGE	23	29	13	8	14	19
MIN	25	22	8	9	13	11
MAX	48	51	21	17	27	30

The following graphs depict the arc of motion in relation to the phase of the gait cycle. The light grey area describes the mean value of our healthy norm-population (n=11, mean age=25,7years) +- standard deviation. Red and blue line stand for mean values for operated and non-operated side. Image 33 shows individual results of all six patients for both sides.

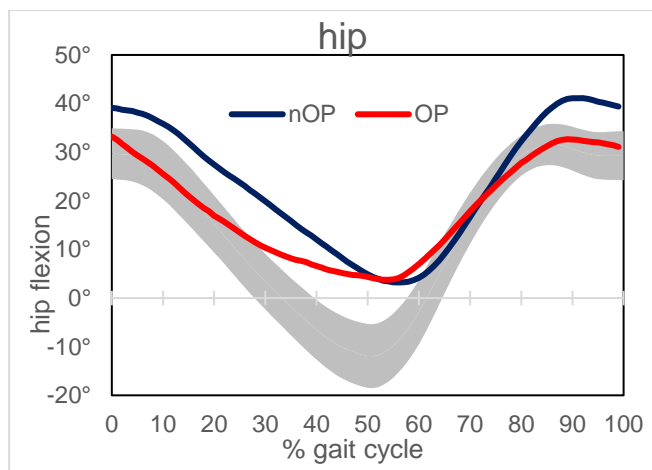


Image 30: inverse kinematics of the hip in sagittal plane

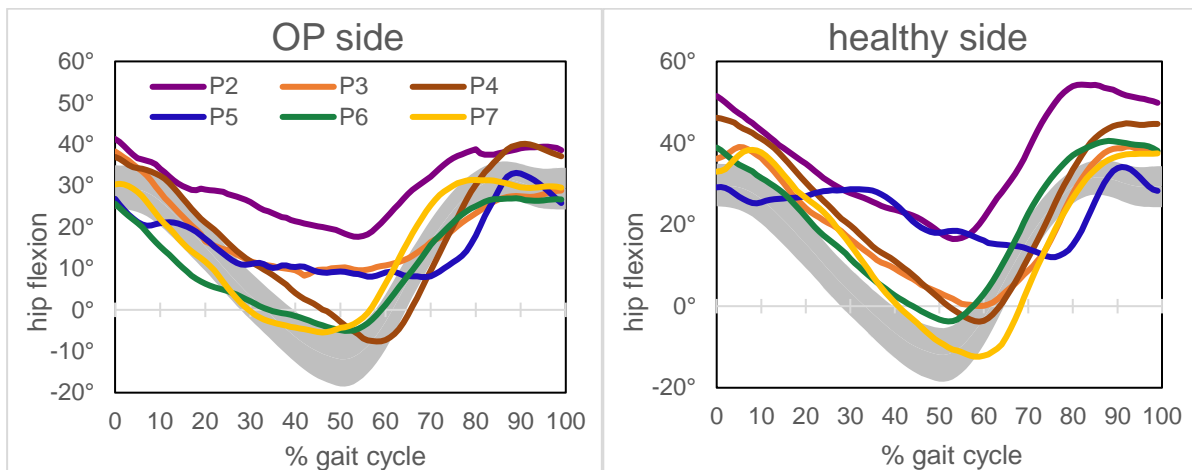


Image 31: individual kinematic results for hip flexion for Patient 2-7 on their operated leg versus on their healthy leg (color code applies to both depictions)

It can be observed that three patients (P4,6,7) were able to extend both hips when walking, approaching normal values. One patient (P2) needed support when walking, therefore this patient's results should not be taken as representative.

5.10.4 Gait dynamics of the pelvis

Also, measures for pelvic tilt, drop and rotation were made. Differences between the two sides were not proven significant ($p(\text{tilt})=,655$; $p(\text{drop})=,564$; $p(\text{rotation})=,236$). The median value for pelvic tilt on the operated side was $7,5^\circ$, on the other side 8° ; pelvic drop median was $7,5^\circ$ on the operated side and 7° on the contrary. The arc of rotation had a median of $16,5^\circ$ (OP) versus $12,5^\circ$ (not OP).

Table 8: Pelvic motion ranges in $^\circ$

STATISTICS	PELVIC TILT OP.	PELVIC TILT NOT-OP.	PELVIC DROP OP.	PELVIC DROP NOT-OP.	PELVIC ROT. OP.	PELVIC ROT. NOT-OP.
MEAN	9	9	6	6	19	18
MEDIAN	7,5	8	7,5	7	16,5	12,5
SD	4,6	4	2,9	2,5	11,4	12,8
RANGE	12	11	7	5	31	33
MIN	6	6	2	3	8	7
MAX	18	17	9	8	39	40

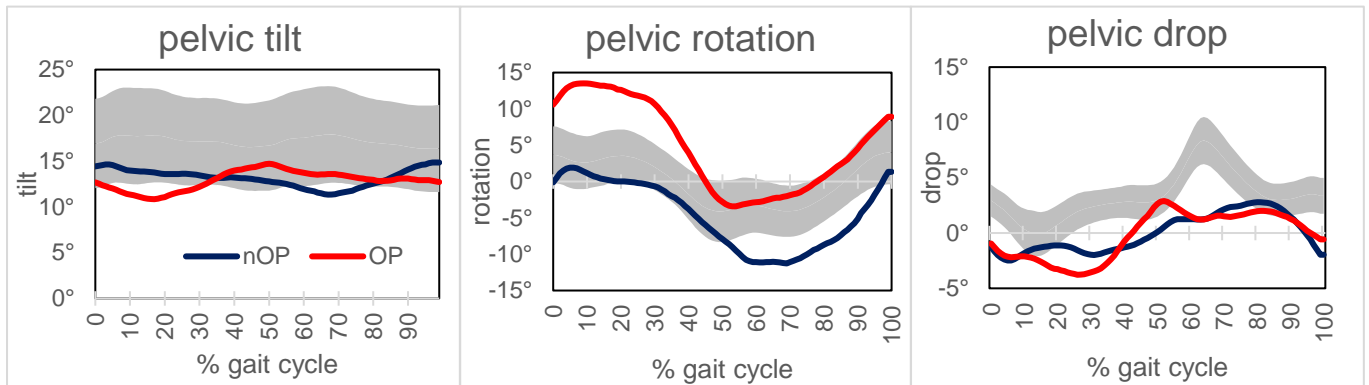


Image 32: inverse kinematics of pelvic tilt, rotation and drop in sagittal plane

For better replicability, also here individual results are shown for pelvic rotation and drop.

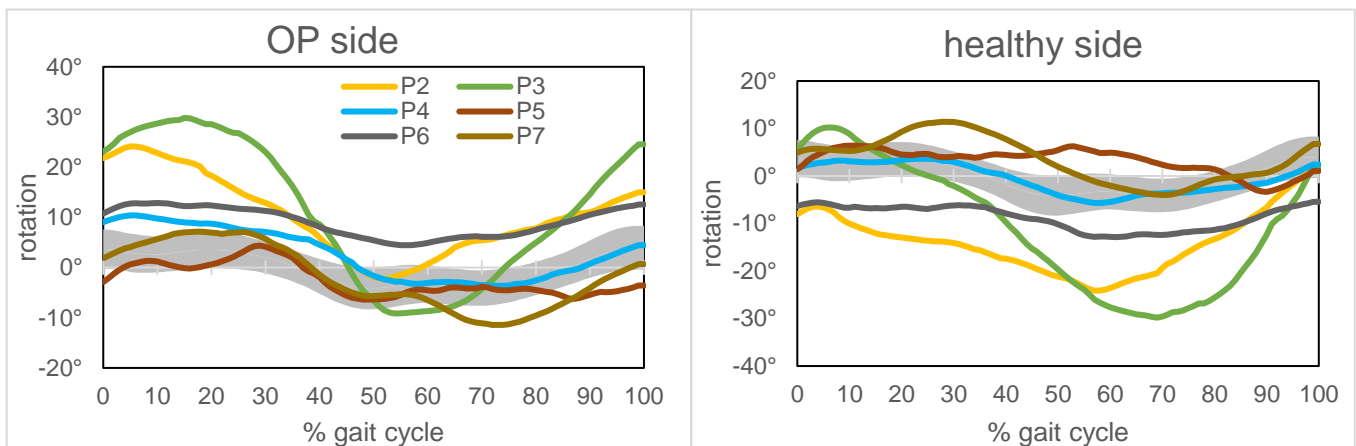


Image 33: kinematic results for pelvic rotation for Patient 2-7 on operated and healthy leg

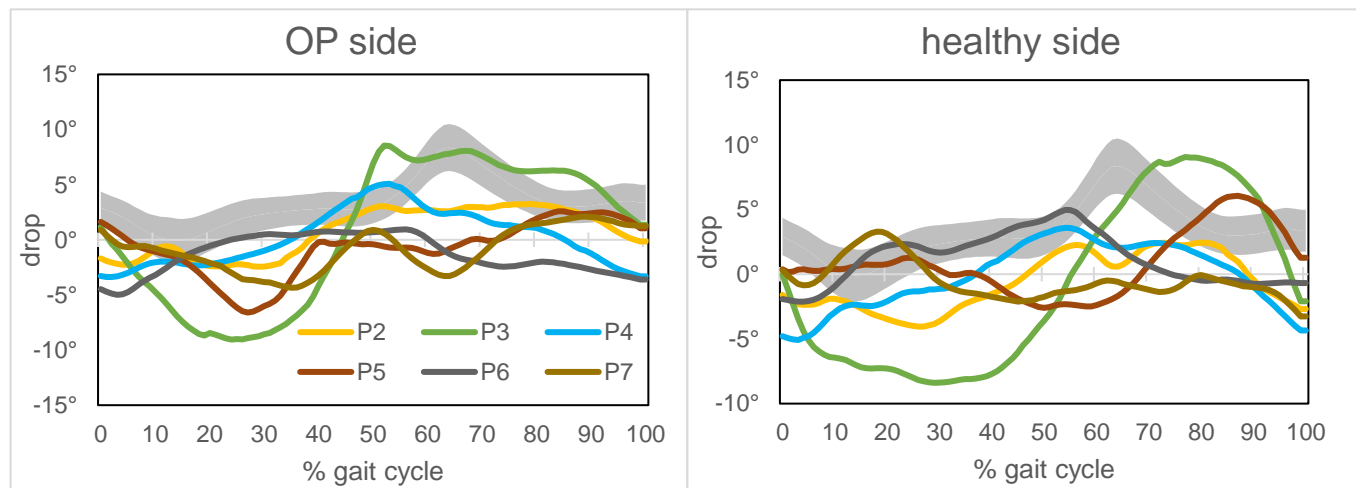


Image 34: kinematic results for pelvic drop for Patient 2-7 on operated and healthy leg

5.10.5 Gait dynamics of knee and ankle

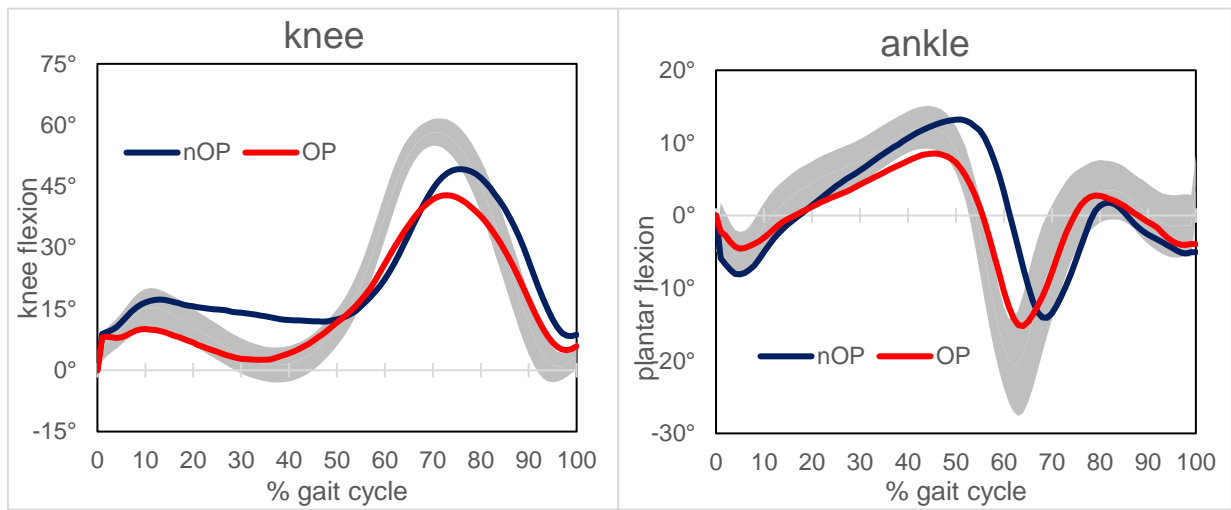


Image 35: inverse kinematics of knee and ankle in sagittal plane

Knee and ankle motion showed satisfying results comparable to the norm values.

6 Discussion

The aim of this study was to investigate the process of planning and evaluating CM implants. Our results were in line with a metanalysis published by Chiarlone F. et al assessing 627 patients with severe acetabular bone loss, presenting good clinical and radiological outcomes at mid-term follow ups.²⁸

Three-dimensional reconstruction used for custom made implants makes certain things possible, that were not imaginable some time ago. Every CM prosthesis can be precisely adjusted to given anatomical conditions. By calculating load vectors beforehand, physiological transmission is possible and primary stabilization is obtained.¹⁵

6.1 Questionnaires

Comparing pre- and postoperative scores, substantial physical improvement was measured by HHS and HOOS in our collective after THA. Naturally, absolute score values were lower than those in primary THA, but results were in line with previous reports of Weber et al. in 2017 on revision arthroplasty with large defects.²⁹

It was noticeable that EuroQol Questionnaires showed a significant overall improvement with an increase on the VAS for actual state of health of 12%, whereas SF36 MCS results stayed roughly the same. However, in subgroups, it did postulate improvement in the state of health, pain and social involvement.

6.2 Implant survival

Larger-scaled studies revealed data concerning custom-made implant survival rates. Fröschen et al recently published work including 68 patients that showed a survival rate of 75% after an average follow-up time of 43 months and compared survival rates of several studies (see Image 36). Failure rates, mostly due to aseptic loosening, ranged between 6-25%.³⁰ At the time of our final follow up (max. 3 years postoperatively), we registered an implant survival of 100% in all eight patients. This can be interpreted as a highly satisfying result in patients with severe acetabular bone deficiency – considering it is a relatively new and still evolving technique. Future

development and long-time survival will be reassessed at the time of our ten year follow up.

Despite, there are other relevant options in revision arthroplasty showing good midterm results. De Meo F. et al reviewed trabecular titanium implants in revision arthroplasty in 2018. So-called TT cups remain a more cost-efficient solution with a stable outcome, especially in patients with a Paprosky Type < IIIB. ³¹

Table 3 Complication rate, clinical results and details of current studies for trabecular titanium (TT) cups and custom-made acetabular implants

	No. of hips	Implant type	Follow-up (months)	Acetabular defect (Paprosky or AAOS)	Complications: revision rate [#] /explantations	Dislocation rate	HHS	Implantation survival
De Meo et al. [18]	58	TT cup	48	IIB: 25; IIC: 15; IIIA: 15; IIIB: 9	10.3%/5.2%	5%	83	94% (4 year KM) ^a
Hipfl et al. [21]	34	TM shell/TT cage	47	IIC: 3; IIIA: 7; IIIB: 25	11%/ –	6%	71	89% (5 year KM) ^b
Steno et al. [19]	80	TT cage/TT augment	38	I: 9; IIA: 11; IIB: 27; IIC: 6; IIIA: 15; IIIB: 13	6.2%/ –	1%	– ^c	– ^c
Gallart et al. [20]	67	TT cup/modular TT augment	30	I: 19; IIA: 19; IIB: 9; IIC: 16; IIIA: 12; IIIB: 4	11.9%/7%	5%	– ^c	90% (5 year KM) ^b
Myncke et al. [27]	25	CMAC	25	III ^d : 25	36%/0%	5%	68	– ^c
Taunton et al. [14]	57	CMAC	65	AAOS IV ^e : 57	35%/9%	21%	75	– ^c
Christie et al. [8]	76	CMAC	53	AAOS III ^f : 39; AAOS IV ^e : 39	22%/0%	16%	82	– ^c
DeBoer et al. [26]	18	CMAC	123	AAOS IV ^e : 28	30%/0%	30%	80	– ^c
Friedrich et al. [5]	18	CMAC	30	IIIB: 18	28%/11%	17%	69	89% (2.5 year KM) ^b
Jones et al. [28]	91	CMAC	25	IIA: 2; IIB: 4; IIIA: 43; IIIB: 47	23%/13%	– ^c	– ^c	87% (2.5 year KM) ^b
Wind et al. [17]	19	CMAC	31	IIIA: 3; IIIB: 16	32%/11%	26%	63	– ^c

[#]For any reason; ^aendpoint explantation; ^bendpoint revision for any cause; ^cnot evaluated; ^dno differentiation between IIIA and IIIB; ^ePaprosky III not evaluated; custom-made acetabular component (CMAC); Kaplan–Meier (KM)

Image 36: comparison of average complication/implant survival rates: From: Fröschen, F. et al (2020): Mid-term results after revision total hip arthroplasty with custom-made acetabular implants in patients with Paprosky III acetabular bone loss. In: Arch Orthop Trauma Surg. DOI:10.1007/s00402-019-03318-0

6.3 Gait parameters

Gait analysis was used to evaluate general postoperative mobility in our patients.

Jaquelin Perry postulates, that an average adult walks 82 meters per min on an even surface choosing his/her own pace. Our patients with a mean of 54 meters per min were clearly slower. In 2004, Götze et al. already described a decrease in hip mobility after primary hip arthroplasty concerning extension, stability, and pace.³² Further, studies showed that older patients (60- 87 years) walk 11% slower. Also, significant decline in general walking ability is proven for >70-year-olds.³³

Generic normal distribution of gait cycling phases is ~60% for stance and ~40% for swing. Duration of floor contact is dependent of the patient's velocity, however. As speed slows, the change in stance and swing phase becomes increasingly greater. A proportionally longer swing phase as it is described in our results can be explained with a slightly reduced loading of the operated leg.

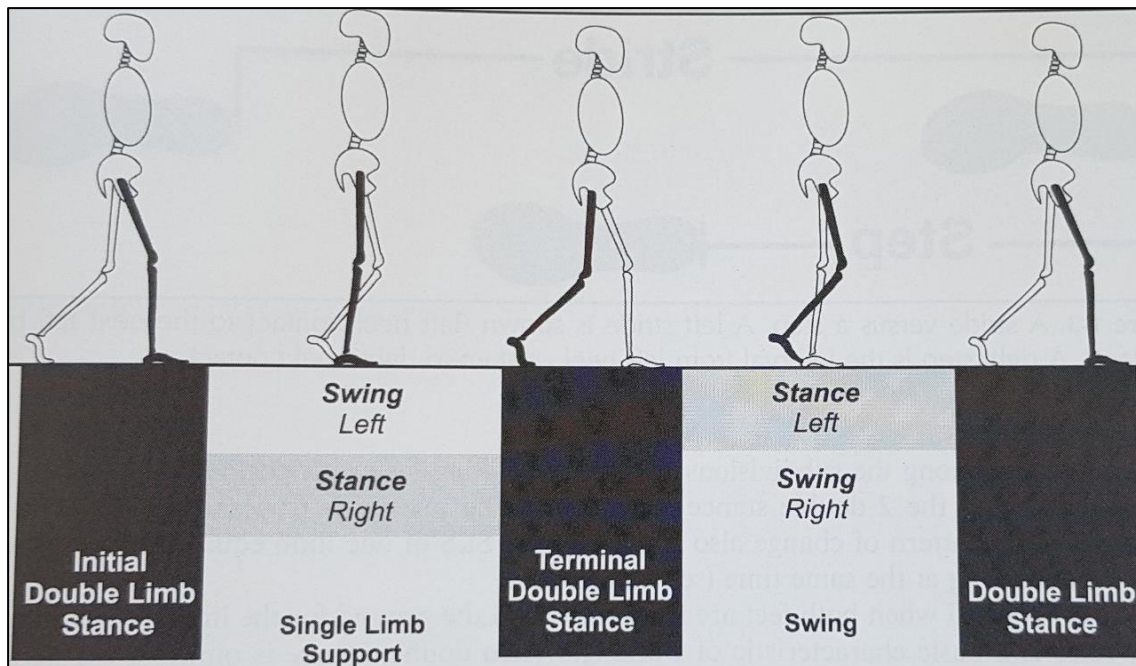


Image 37: Stance and Swing Phase. From: Jaquelin Perry: Ganganalyse: Norm und Pathologie des Gehens, Auflage 1, 2003. Urban & Fisher

A proportionally long double limb stance can be connected to insecurity in the patient's walk. Generic timing is 40% single limb support and 20% double stance (10% for initial double stance and 10% for terminal double stance). Our patients had a median distribution of 52,5% for double support and 47,5% for single limb support on their operated leg. The healthy side had a result of 47,5% for double support and 52,5% for single support. Patients were more likely to walk cautiously regarding not only their operated but both of their hips. After THA this can be connected to e.g. a reduced proprioception in the replaced joint, as Murray et al. suspected in 1974³⁴. In 2000, Perron et al. described gait insecurities due to deficient extension caused by preoperative joint contractures.³⁵

The ROM-results for hip dynamics are not comparable to clinical or virtual ROM as they only describe the motion-range a person reaches when walking. In our case, the difference between the two sides was not significant, but:

The main moving axis of the hip during walking is the sagittal plane. The sum of ab- and adduction is normally 40 – 48°. The operated hip reached results of around 35°, only slightly reduced comparing it to the other side (41,5°).

In the coronal plane, arcs of motion occurring are relatively small. Values described are a maximum of 10° of adduction and 5° of abduction. With a median of 13° on their operated leg patients were closer to the norm values than with their healthy leg (Ab/Ad=10,5°).

6.4 Socioeconomic aspects

Considering socioeconomic aspects, revision arthroplasty is often mentioned as an economic burden. As a recent study by Weber et al from 2018 showed, revision surgery results in a higher financial expense of 76% compared with primary joint replacements, mostly due to cost-intensive implants and longer hospital duration plus more frequent occurrence of perioperative complications. In this study, all kind of revision implants were considered.³⁶ The cost of production in CM implants is the highest - regarding manufacturing as well as doctor's and engineer's and patient's time involvement.³⁷ We consort with Pozowski et al. (2009), postulating that CM prostheses should only be discussed when it cannot be guaranteed for a standard implant to provide full primary stability, equalization of leg length discrepancy, correct load transmission and at least approaching physiological joint function.¹⁵ If it really improves the patient's life, enabling a reasonable range of motion, longer endurance and more stability, the trade-off seems beneficial. Also, the question if CM implants might be more cost-efficient in the long-term, remains.³⁸

6.5 Virtual and clinical range of motion

Analogue to Woerner. et al.²², who compared virtual and clinical impingement in primary implants in 2017, we tried to assess postoperative ROM reconstruction as a tool of analyzation. As suspected, virtual ROM results described a wider range of

motion than clinical results, as impingement is usually soft tissue related and for virtual measures, only osseous contact counted. Prospectively, it could be interesting to analyse virtual ROM before surgery and to take these results into consideration for further surgery planning – possibly reducing postoperative osseous impingement.

Nevertheless, the viability of this method was restricted as some patients' images could not be used. A major problem with the virtual reconstruction was low quality in CT imaging. By default, in the process of saving CT images for longer periods of time in our university hospital department, data size is reduced, making images more pixelated. In combination with scattering of the prosthesis, some images could not be exploited or showed unrealistic results after exploitation. Especially evaluation for external and internal rotation was impractical. Despite re-measuring, results were around 0°, which was either user-related or connected to software issues with the transverse plane. Due to these circumstances, all results for rotation had to be left out. Results were viable for ab-/adduction and flexion/extension.

In our case, postoperative virtual range of motion analyzation could not be considered a helpful method in a clinical setting. It was time-consuming and only provided a modest gain of information. In a more standardized setting, with a software expert, improved quality of CT imaging and a higher number of patients, this tool could still be valuable.

Additionally, virtual measuring can be an effective method in evaluating the implants position. A further investigation to this work showed the accuracy of positioning in custom made hip arthroplasty. A 3D CAD model of the pelvis was generated by AQ using a semi-automatic bone segmentation algorithm in order to improve the accuracy of the reconstructed bone geometry. This procedure facilitated the evaluation of the acetabular bone defect. Anteversion, inclination and restoration of center were compared and showed fine accuracy of positioning according to preoperative planning.

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6.6 Limitations

This study was limited by numbers - primarily due to the applied inclusion criteria, since patients with Paprosky type III defects are rare even in a university medical centre with over 100 revision arthroplasties per year. All other patients were subserved with less

invasive standard implants according to Kims treatment algorithm 2017.⁴⁰ Secondly, seven of fifteen possible recruits dropped out of the study due to their comorbidities or personal issues.

With a group size this small, results are valuable but cannot provide a fundamental basis for further investigations.

7 Conclusion

Today, custom made hip / partial pelvic replacements are a relevant option in extended prosthetic care. Regardless, CM implants should not be used as a fashion but as a necessity. They can be precisely adjusted to anatomical conditions and should be considered when patients suffer from massive bone deficiency (>Paprosky type IIIA) and standard implants cannot provide a safe solution. Using treatment algorithms helps choosing the right implant. Since revision arthroplasty is often mentioned as an economic burden, expenses should be observed regarding possible long-term cost efficiency.

Individual implants showed a fine gait restoration in accordance with age and comorbidities. No implant loosening or failures were registered in our collective this far. Also, substantial postoperative physical improvement was measured by HHS and HOOS. Further studies are required to reveal the generalizability of these results.

In our case, virtual ROM reevaluation only provided a modest gain of information. It could be a useful tool in the future to reduce postoperative impingement.

Taking larger-scaled studies in consideration but also concluding from personal experience, by meeting and spending time with every patient throughout this work, custom made acetabular implants remain a good choice when osseous defects cannot be handled with standard implants. Critical reevaluation in ten years follow ups will be initiated.

8 Attachments

8.1 Abbreviations

CM = custom made

CHD = congenital hip dysplasia

HHS = Harris hip score

HOOS = Hip osteoarthritis outcome score

MCS = mental component summary

OA = osteoarthritis

PCS = physical component summary

PMMA = polymethylmethacrylate

QOL = quality of life

rA = rheumatoid arthritis

ROM = range of motion

SD = standard deviation

THA = total hip arthroplasty

VAS = visual analogue scale

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