# GAIT AND MOTION ANALYSIS OF HIP ARTHROPLASTY Validity, reliability and long-term results

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"It is obvious that any improvement – either in surgical and/or in physiotherapeutic procedures or in braces and prostheses – must rest upon an accurate knowledge of the functional characteristics of the normal locomotor system."

Berkeley group founded in 1945, headed by Verne T. Inman (1905-1980)

Till min livskamrat Maria och mina 3 underbara barn Hannes, Ellinor och David och 3 fantastiska barnbarn Hedda, Signe och Alvar och mina strävsamma föräldrar Erna och Anton



### **ABSTRACT**

Walking is one of the most important fundamental activities of daily living in humans. The hip joint is one of the most important joints in power transmission between the lower extremities and the pelvis. Within orthopaedics, osteoarthritis (OA) in the hip joint is increasing in an ageing population. OA is a chronic joint disease that causes more or less pronounced pain, functional impairment and impaired quality of life. The World Health Organisation (WHO) reports that 10% of all men and 18% of all women over 60 years of age have symptomatic osteoarthritis and osteoarthritis has an effect on the mobility of 80% of those with OA. Total hip arthroplasty (THA) is a common treatment for patients diagnosed with hip osteoarthritis when non-surgical treatments have failed. In Sweden, approximately 17,000 THAs are performed every year and the majority of them are due to primary osteoarthritis. According to the Swedish Hip Arthroplasty Register (SHAR), most patients (89%) report that they are satisfied with the results one year after hip surgery. The remaining 11% report that they are less satisfied or dissatisfied with the performed surgery. The reported problems mainly involve pain, difficulties with activities of daily living, anxiety and/ or depression and lack of mobility. Recordings of walking ability before and after THA are one way of assessing the effect of the operation. Furthermore, objective measurements of any remaining limitation in walking ability and its potential impact on the clinical outcome can be a valuable diagnostic tool and perhaps also a starting point for the further improvement of the intervention procedure.

Optical tracking systems (OTS) based on cameras and force plates mounted in the floor have been used since the 1960s. Since then, these methods have been further developed to enable high-resolution recordings of body movements during walking. The technique can be briefly described as the attachment of reflective markers with double-adhesive tape to the skin of the patient/subject on well-defined anatomical bone structures. Marker positions are recorded when the patient/subject walks at a self-selected pace through a calibrated measurement volume. Synchronised with the camera system, the load is recorded by the force plates integrated in the floor. Kinematics and kinetics are calculated in three anatomical planes and the collected data are presented using graphs and animations.

In Study I, hip joint movements were measured with two different dynamic motion analysis systems, optical tracking systems and roentgen stereophotogrammetric analysis (RSA) of 16 patients undergoing THA. The RSA method

measures motion with high precision and the method is based on the installation of markers made of tantalum ( $\emptyset = 1$  mm) in the skeleton at the thigh and pelvis. Synchronized exposure with two angled X-ray tubes enables the calculation of three-dimensional movements between skeletal structures.

The results in this study show that dynamic hip movements induced soft-tissue movements that cause differences compared with skeletal movements. A model based on skin markers produced a better correlation to roentgen stereophotogrammetric measurements of skeletal movements than a cluster marker model (plates with four markers) relating to flexion and abduction movements.

Study II examined whether the reproducibility of measured values differs depending on whether the hip joint is unaffected by disease or has developed from hip osteoarthritis (OA) or THA. Gait analysis was performed by three different groups: healthy controls, hip OA patients and THA patients. Each group was composed of 10 men and 10 women. The study also examined whether it was possible to distinguish the different groups from one another using data from the OTS.

Patients with hip OA had poor repeatability between different investigators and analytical events compared with THA patients and healthy controls. The study further revealed that there was still a difference in gait pattern after one to two years after THA surgery compared with controls.

In Study III, gait was investigated in 22 patients operated on bilaterally with two different types of stem at the same time of surgery. At surgery, the first operated hip joint was randomised to either a short or a conventional stem. The type of stem not used in the first surgery was chosen for the opposite hip joint. The same acetabular cup was used on both sides. Gait analysis was performed one and two years after THA surgery and the data were compared with those of a control group consisting of 66 subjects. There were no differences in speed, step length and frequency, or regarding kinematics or kinetics between short and conventional stems. Although both hip joints were operated on during one-stage bilateral THA, there was still a difference between gait patterns two years after surgery compared with controls.

Study IV is based on a clinical long-term follow-up of 62 patients (66 hips) undergoing surgery with a Madreporic Lord hip prosthesis between 1979 and 1986. The average follow-up period was 26 years (23-29 years). At the latest investigation, the Harris Hip Score (HHS), EQ-5D and patient satisfaction and pain registration on a visual analogue scale were recorded. In the

follow-up, the HHS was recorded with an average of 81 (SD 14) and a pain score of 41 (SD 5), despite the fact that more than half the patients had undergone a revision of the acetabular cup on at least one occasion.

In Study V, gait analysis was recorded simultaneously using two different motion analysis systems, one based on an optical tracking system with measurements of reflective skin markers and one based on accelerometers. A total of 49 patients with hip prostheses participated in the study. Movements in the sagittal plane of the pelvis, hip and knee joint were compared between the methods.

The accelerometer system measured movements of the pelvis and knee joint that did not differ from the optical system. However, when measuring the hip joint flexion extension, a significantly smaller motion was recorded compared with the optical motion analysis system.

This dissertation shows that the deviation from skeletal movements measured using the optical tracking system is smallest when measuring hip flexion extension in patients with hip prostheses. Furthermore, the optical tracking system is able to distinguish patients with hip arthritis, prosthetic patients and a healthy control group with regard to hip movements while walking. The optical tracking system shows that the walking ability of patients with hip prostheses is still affected two years after surgery, although they state that they have no problems when walking. A long-term follow-up of patients undergoing surgery with an uncemented hip prosthesis still revealed good function, despite the fact that the joint had been replaced in almost 50% of cases. The type of accelerometer-based motion analysis system that was examined had good validity when measuring pelvis and knee movements in the sagittal plane, but it indicated significantly lower measurements of hip joint flexion and extension.

**Keywords:** Gait analysis, Hip arthroplasty, Kinematics, Radiostereometric analysis, Hip osteoarthritis

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## SAMMANFATTNING PÅ SVENSKA

Artros är en kronisk ledsjukdom som ofta orsakar mer eller mindre uttalade smärtor, funktionspåverkan och försämrad livskvalitet. Världshälsoorganisationen (WHO) rapporterar att 10 % av alla män och 18 % av alla kvinnor över 60 år har symptomatisk artros. 80 % av de med artros har en påverkan av sin rörelseförmåga. Total höfledsartroplastik (THA) är en vanlig behandling för patienter som diagnostiserats med höftartros när icke-kirurgisk behandling, som exempelvis artrosskola och/eller medicinering har misslyckats. I Sverige utförs cirka 17 000 THA per år och huvuddelen av dessa beror på primär artros. Enligt det svenska höftartroplastregistret (SHAR) rapporterar de flesta patienterna (89 %) att de ett år efter höftoperationen är nöjda med resultatet. De resterande 11 % rapporterar att de är missnöjda eller mindre nöjda med operationen. De problem som rapporteras är i huvudsak: smärta, ångest, depression och bristande rörelseförmåga. Objektiv registrering med hjälp av ett gånganalyssystem före THA kan vara av ett stort värde för att mäta effekten av höftledsoperationen, samt att efter genomförd operationen kunna registrera eventuell kvarstående begränsning av gångförmågan och dess potentiella inverkan på det kliniska resultatet.

Optiska rörelseanalyssystem baserat på kameror fästa på väggen eller på stativ och kraftplattor monterade i golvet började användas på 1960-talet och har sedan dess vidareutvecklats för att med hög upplösning kunna registrera kroppsrörelser vid gång. Tekniken kan i kort beskrivas med att reflekterande markörer fästs med dubbel-häftande tejp på huden på väldefinierade anatomiska benstrukturer på en patient eller försöksperson. Markörernas position registreras med hjälp av kameror då patient/försöksperson går i en självvald hastighet genom en kalibrerad mätvolym. Synkroniserat med kamerasystemet, registreras belastningen med hjälp av i golvet infällda kraftplattor. Kinematiken och kinetiken beräknas i tre anatomiska plan och insamlade data presenteras med hjälp av grafer och animeringar.

Det övergripande syftet med denna avhandling är att undersöka gång- och rörelseförmåga hos patienter opererade med höftprotes med focus på validitet, reliabilitet samt långtidsuppföljning.

I Studie I jämfördes höftledsrörelser mätta med två olika dynamiska rörelseanalyssystem, optiskt rörelseanalyssystem och röntgenstereofotogrametrisk analys på 16 patienter opererade med THA. Den röntgenstereofotgrametriska metoden RSA mäter rörelse med hög precision och metoden bygger på att man i samband med operation installerar markörer gjorda av grundämnet tantalum (Ø = 1 mm) i lårben och bäcken. Synkroniserad exponering med två vinklade röntgenrör, möjliggör beräkning av tredimensionella rörelser mellan skelettstrukturer.

Resultaten i studien visar att dynamiska höftrörelser framkallade mjukdelsrörelser som medför skillnader jämfört med skelettrörelser. En modell baserat på hudmarkörer gav en bättre korrelation till radiostereometrisk mätning av skelettrörelser än en klustermarkörmodell (plattor med 4 markörer) beträffande flexion- och abduktionsrörelser.

I Studie II studerades om mätvärdenas reproducerbarhet skiljer sig åt beroende på om höftleden är opåverkad av sjukdom, har utvecklat artros eller är opererad med höftprotes. Gånganalys utfördes av tre olika grupper: friska kontroller, patienter med höftartros och patienter opererade med en total höftledsartroplastik. Varje grupp utgjordes av 10 män och 10 kvinnor. I studien undersöktes även om det gick att särskilja de olika grupperna från varandra med hjälp av data ifrån det optiska rörelseanalys systemet.

Patienter med höftartros hade sämre repeterbarheten mellan olika undersökare och analystillfällen jämfört med patienter opererade med THA och friska kontroller. Studien visade vidare att det fanns en fortsatt skillnad i gångmönstret 1-2 år efter total höftledsartroplastik jämfört med kontroller.

I Studie III, undersöktes gången på 22 patienter som opererats bilateralt med 2 olika typer av protes-stammar utförda vid samma operationstillfälle. Vid operation randomiserades (lottades) den först opererade höften till antingen kortstammad eller konventionell stam. Den typ av stam som inte användes vid första operationen valdes till den motsatta höftleden. Samma typ av ledskål användes på bäckenets båda sidor. Gånganalys utfördes 1 och 2 år efter operation och data jämfördes mot en kontrollgrupp bestående av 66 försökspersoner.

Det förelåg inte några skillnader beträffande hastighet, steglängd och steg frekvens, och inte heller beträffande kinematik eller kinetik mellan kort och konventionell stam. Trots att båda höftlederna opererades vid samma operationstillfälle fanns det fortsatt en skillnad av gångmönstret 2 år efter operation jämfört med kontroller.

Studie IV baseras på en klinisk långtiduppföljning av 62 patienter (66 höfter), som opererats med Madreporic Lord höftartroplastik mellan 1979-1986. Medeluppföljningstiden uppgick till 26 år (23-29 år). Vid det senaste undersökningstillfället registrerades Harris Hip score (HHS), EQ-5D samt grad av patientnöjdhet och smärta på en visuell analog-skala.

Vid efterundersökningen noterades ett Harris Hip Score med medelvärde

på 81 (SD 14) och smärtscore på 41 (SD 5) trots att fler än hälften hade genomgått byte av ledskålen vid minst 1 tillfälle.

I Studie V, studerades höftledsrörelser vid gång mätta med 2 olika rörelseanalyssystem, ett baserat på optisk mätning av reflekterande hudmarkörer samt ett baserat på accelerometrar. Sammanlagt 49 patienter som opererats med höftprotes deltog i studien. Rörelser i sagittalplanet av bäcken, höftoch knäled, jämfördes mellan metoderna.

Accelerometersystemet uppmätte rörelser av bäcken och knäled som inte skiljde sig från det optiska systemet. Vid mätning av höftledens flexion-extension registrerades dock ett signifikant mindre rörelseutslag jämfört med optiskt rörelseanalys system.

Sammanfattningsvis visar avhandlingen att avvikelsen från uppmätta skelettrörelser för optiska systemet är lägst vid mätning av höftflexion-extension på patienter som opererats med höftprotes. Vidare kan det optiska rörelseanalyssystemet särskilja patienter med höftartros, protesopererad patient och en frisk kontrollgrupp med avseende på höftens rörelser vid gång. Det optiska rörelseanalyssystem visar att patienter opererade med höftprotes har en fortsatt påverkad gångförmåga 2 år efter operation trots att de uppger att de inte har några problem när de går. Långtidsuppföljning av patienter opererade med en ocementerad höftprotes visade fortsatt god funktion trots att ledskålen bytts ut i närmare 50 % av fallen. Den typ av accelerometer baserat rörelseanalyssystem som undersöktes hade god validitet vid mätning av bäcken och knäledsrörelser i sagittalplanet men angav signifikant lägre mätning av höftledsflexion och extension.



## **LIST OF PAPERS**

This thesis is based on the following studies, referred to in the text by their Roman numerals.

- I. Validation of gait analysis with dynamic radiostereometric analysis (RSA) in patients operated with total hip arthroplasty.
   Zügner R, Tranberg R, Lisovskaja V, Kärrholm J
   J Orthop Res. 2016 Sep 3. doi: 10.1002/jor.23415.
- II. Different inter-observer reliability of instrumented gait analysis between patients with unilateral hip osteoarthritis, unilateral hip prosthesis and healthy controls.

Zügner R, Tranberg R, Lisovskaja V, Kärrholm J. In manuscript

III. One stage bilateral total hip arthroplasty operation in 22 patients with use of short and standard stem length on either side gait analysis in 22 patients one and two years after bilateral THA.

Zügner R, Tranberg R, Puretic G, Kärrholm J. Hip international. 2017 Ref.: Ms. No. HIPINT-D-17-00162R1 DOI: 10.5301/hipint.5000596

IV. Stable fixation but unpredictable none remodelling around the lord stem: minimum 23-year follow-up of 66 total hip arthroplasties.

Zügner R, Tranberg R, Herberts P, Romanus B, Kärrholm J. J Arthroplasty. 2013 Apr;28(4):644-9. doi: 10.1016/j.arth.2012.07.041. Epub 2012 Nov 8.

V. Validation of inertial measurement units with optical tracking system in patients operated with total hip arthroplasty.

Zügner R, Tranberg R, Timperley J, Hodgins D, Mohaddes M, Kärrholm J.

In manuscript

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# **ABBREVIATIONS**

AP	Anterior pelvis view
ASIS	Anterior superior iliac spine
CI	Confidence interval
COP	Centre of pressure
3/6DOF	Three/six degrees of freedom
GRF	Ground reaction forces
HHS	Harris Hip Score
HJC	Hip joint centre
IMU	Inertial measurement units
LFA	Low friction arthroplasty
OA	Osteoarthritis/osteoarthrosis
OTS	Optical tracking system
PSIS	Posterior superior iliac spine
RLL	Radiolucent lines
ROM	Range of motion
STA	Soft-tissue artefacts

# **DEFINITIONS IN SHORT**

Bartlett's test	The Bartlett test is used to test whether k samples are from populations with equal variances.
Calibrated volume	.The volume (height, width and depth) in which measurements can take place
Centre of mass (COM)	A point at which the entire mass of a seg- ment could be concentrated, while still hav- ing the same mechanical effect
Cluster	A plastic shell equipped with three or more reflective markers that are used to track a body segment
Force plate	A device that measures force, commonly in three dimensions, i.e. vertical and horizontal (forward and side)
Intraclass correlation (ICC)	Quantitative measurements made on units that are organised into groups. It describes how strongly units in the same group resemble one another.
Inverse dynamics	A process by which intersegmental forces and moments are calculated by applying Newton's equations of motion. This process includes measured data, i.e. kinematics and ground reaction forces, as well as the estimated inertial properties of involved segments.
Mann-Whitney U test	Non-parametric rank sum test for differences between two independent variables, mainly used when data are not normally distributed

Retro-reflective marker/s......A polystyrene hemisphere, covered with a retro-reflective material

Reference object .....L-shaped metal profile used together with a calibration wand during calibration. Defines the global co-ordinate system with its three axes

The value of rho varies between 0 and 1. A rho with a value of 1 indicates an absolute dependence between the two variables that are being studied.

Spearman's rank correlation.. Non-parametric rank test for correlations between two variables, making no assumption regarding the distribution of data

Wilcoxon's signed-rank test ... Non-parametric rank sum test for differences between two dependent variables making no assumption regarding the distribution of data. The test can be used for differences between two different follow-ups in the same group of subjects.

## 1. INTRODUCTION

The prevalence of hip osteoarthritis (OA) is increasing, in an ever older population. OA is a chronic joint disease that causes more or less pronounced pain, functional impairment and impaired quality of life (Figure 1). The incidence of this disease is increasing probably because of several factors of which increasing age in the population is the most important. The World Health Organization (WHO) reports that 10% of all men and 18% of all women over 60 years have symptomatic osteoarthritis. 80% of those with osteoarthritis have an influence on their mobility.<sup>[2]</sup>



Figure 1 | Hip osteoarthritis, right hip.

Total hip arthroplasty (THA) is based on complete removal of the articulating surfaces including a fairly constant amount of the adjacent bone tissue on the acetabular side and a more variable amount of bone on the femoral side. This treatment is chosen for patients with end-stage osteoarthritis of the hip (Figure 2). The pain relieving effect of this procedure is extremely well documented, whereas its effect on the walking pattern is more sparsely documented. After the introduction of the so-called "Low Friction Arthroplasty" (LFA) based on cemented fixation and a small femoral head

to provide a minimum amount of friction there has been a rapid development of implants.[3] This development has sometimes been associated with success, sometimes with catastrophic failures and a number of new designs with a performance equal or close to the original cemented Charnley design. [4, 5]

Today total hip arthroplasty (THA) has become a routine treatment for patients diagnosed with hip osteoarthritis when non-surgical treatment, such as physiotherapy and/or medication has failed. In Sweden, approximately 17.000 THA is performed every year, and the majority of these are due to primary osteoarthritis. According to the Swedish hip arthroplasty register (SHAR), most patients (89%) report that they are satisfied with the results one year after hip surgery. The remaining 11% report that they are dissatisfied or less satisfied with the operation. The problems reported are mainly pain, problems with activities of daily living, anxiety/depression and a lack of movement ability.[6] Recordings of walking ability before and after THA is one way to assess the effect of the operation. Furthermore, objective measurements of any remaining limitation of the walking ability and its potential impact on the clinical outcome can be a valuable diagnostic tool and maybe also an outset for further improvement of the procedure.



Figure 2 | Total hip arthroplasty, left hip.



Figure 3 | Ogus-Camera (Qualisys AB, Gothenburg, Sweden).

Optical tracking systems (OTS) based on cameras mounted on the wall or tripod and force plates mounted into the floor have been used in the 1960s. Since then these methods have been further developed to enable high-resolution recordings of body movements. [7-9] The technique includes attachment of reflective markers with double-adhesive tape on the skin on well-defined anatomical land marks on the patient/subject. Markers' position is recorded when the patient/subject is walking at a self-chosen or predefined pace through a calibrated measurement volume. Synchronized with the camera system (Figure 3), the force is recorded by the force plates integrated to the floor. Kinematics and kinetics are calculated in three anatomical planes, and collected data is presented using graphs and animations.

In this dissertation the validity of an optical tracking system was studied by comparison with simultaneously performed recordings of skeletal markers

with use of radiostereometric analysis. The clinical resolution of OTS when used to study patients with different conditions of the hip joint (osteoarthritis, THR, normal) and patients with different designs of hip prostheses were evaluated. A long-term follow up of an early design of uncemented THR was performed. Thereafter we used the OTS to validate a new convenient system to record hip motions with use of inertial measurement units (IMU).

### 1.1 The evaluation of gait

### 1.1.1 History

The interest in the movements involved in walking has been more or less in focus for more than two thousand years. Aristotle (384-322 BCE) noticed that the head of a man is moving up and down during gait when the locomotion is observed from a side view. During the period from 1500s up to 1900s there were several scientists who made important contribution to different physiological parts in gait analysis. The first studies of walking were probably mathematical descriptions of three dimensional angles, documented in the 1533 by Girolamo Cardan (1501-1576) and later on and in more detail by Leonhard Euler (1707-1783). The first who described the position of an object in space related to an orthogonal co-ordinate system was Rene Descartes (1596-1650). The mathematical algorithms of Isaac Newton (1642-1727) was probably first applied to humans by Hermann Boerhaave (1668-1738).[1]

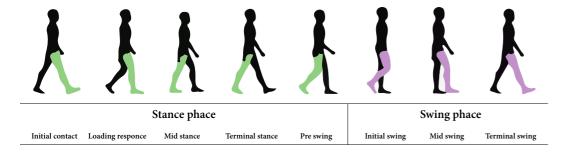
In 1836 the brothers Willhelm and Eduard Weber published "Mechanik der Gehewerkzeuge" in which they concluded that step length and cadence differed according to walking speed. This was investigated by use of telescope, stop-watch and measuring tape. Furthermore, force and pressure measurements were introduced by Jules Etienne Marey (1830-1904) in 1870s. Wallace Fenn constructed a one component force plate and introduced this device to studies of gait in 1930. The first description of a gait cycle was made by Gaston Carlet (1849-1892) in 1872 and the first three-dimensional gait analysis was performed by Willhelm Braun (1831-1892) and Otto Fischer (1861-1917) and reported in "der Gang des Menschen" in 1895. At this time 1895 Freiderich Trendelenberg reported pelvic drop at swing phase and pelvic oblique at stance phase due to weak abductor muscles.<sup>[1]</sup>

In 1945 the first founded biomechanical laboratory was set up in the United States by Verne Inman (1905-1980) and Howard Eberhard (1906-1993). Later, Jürg Baumann (1926-2000), Gordon Rose in Europe and David Sutherland (1923-2006), Jacquelin Perry and Jim Gage in United States presented further important contributions to the development of instrumented gait analysis focused on cerebral palsy in children. [1, 10]

#### 1.1.2 Observational gait analysis

In clinical practice, the physiotherapist plays an important role in the early rehabilitation process and in observing and registering patient mobility and the function of the locomotor system. He/she may record normal activities of daily living (ADL), such as the ability to get out of bed and get up from a chair, estimated walking distance, use of walking devices and the ability to climb stairs. Furthermore, during investigations of different patient cohorts, the physiotherapist has an opportunity to use other clinical research methods such as the six-minute walk test [11], timed up and go [12, 13], physical cost index [14] or other measurements of functional ability.

Visual or observational gait analysis according to the principles of Rancho Los Amigos was used to distinguish pathological gait from normal gait in a structured way, as instrumented analyses were not available. The Rancho Los Amigos scoring system comprised 169 major and minor gait deviations. Regular courses in this technique were given during the 1980s and 1990s and they were well attended by many physiotherapists. The Rancho Los Amigos scoring system was applied both before and after different interventions. The gait cycle was divided into three main parts; weight acceptance, single limb support and swing limb advancement. The first part included initial contact and loading response, the second included mid-stance and terminal stance and the third part included pre-swing, initial swing, mid-swing and terminal swing. The stance phase, 60% of the gait cycle, is defined as the time during which the limb is in contact with the ground and supporting the weight of the body. The swing phase, 40% of the gait cycle, is defined as the time period in which the limb is off the ground and swings forward (Figure 4). Normal gait is briefly defined as movement actions synchronised all the way from the trunk, including the head and arms, the pelvis and, above all, the major joints of the lower extremities. Gait is mainly reflected by two important sequences; stability during stance and stride length.<sup>[15]</sup>



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Figure 4 | Right stance phase and swing phase during a gait cycle.

#### 'The six determinants of gait" [16, 17]

- 1. Hip flexion
- Pelvic rotation
- Pelvic obliquity
- Knee flexion at initial contact
- Plantar- and toe flexion of the foot
- Hip adduction

According to Lin et al. the three major determinants of the displacement of the centre of mass in the sagittal plane are hip flexion (Figure 5), knee flexion and plantar and toe flexion during normal gait. Hip adduction and pelvic obliquity are the main determinants of displacement in the mediolateral direction.

In order to lengthen the step, the pelvis is rotated anteriorly at initial contact and posteriorly at pre-swing pelvis obliquity, together with dorsiflexion and plantar flexion on both these occasions. The calf goes from an external to an internal rotation during this period, which affects foot pronation at initial contact which, upon load, changes into supination and takes the femur into an external rotation.

The swing phase is initiated at pre-swing by knee flexion in order to shorten the leg before toe-off and initial swing [18] Patients with gait pathologies solve their problems in the swing phase by hip hiking, different trunk and pelvic movements, circumduction or combinations of the above.

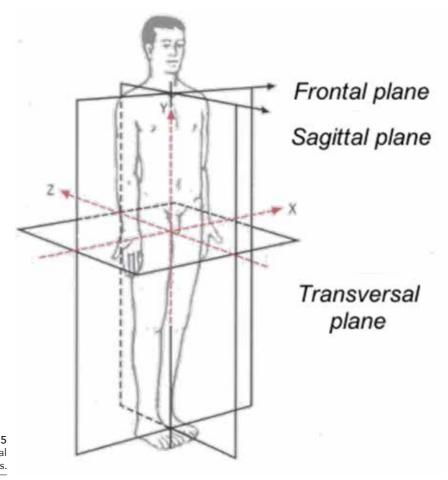


Figure 5 Anatomical planes.

### Normal walking

In 1992 Jaquelin Perry stated that

"Normal walking depends on the satisfactory functioning of the locomotor system at all levels. Overall control comes from the motor cortex and other higher centres of the brain. Coordination and pattern generation are provided by the extrapyramidal system, especially the cerebellum. The tension generated by individual muscles from instant to instant is modulated by spinal reflexes, which receive sensory input from muscle spindles, Golgi tendon organs, and other proprioceptive receptors. The muscles themselves need to be able respond to the level of neural activation, by developing appropriate levels of tension. Between them, all the various levels of motor control need to be able to produce muscular contraction, which is of appropriate magnitude, and begins and ends at appropriate times. The joints must be able to move through an appropriate range of motion, without pain and without abnormal joint angulations. The bones must be free from deformity, and capable of transmitting the necessary forces. A failure to meet all of these requirements, at any level from the brain to the bones, is likely to lead to an ab-

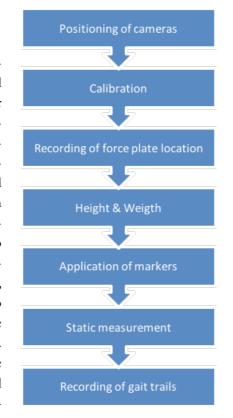


Figure 6 | Preparatory steps at clinical

normal gait. The exact nature of the gait disorder depends on the particular deficit in the brain, spinal cord, peripheral nerves, muscles, joints or bones. Severe abnormalities may lead to an inability to walk. Less severe abnormalities may produce an abnormal gait, and gait analysis may contribute to patient management by identifying in detail the deficits which are present, and thereby to suggest the best course of treatment for that patient". [10, 19]

### 1.1.3 Clinical gait analysis

### The gait laboratory

Before the patient/subject enters the gait laboratory, a number of checks (Figure 6) have to be made using a computer, software, reflective markers and clusters. In a gait laboratory, the patient/subject is surrounded by a number of high-speed video cameras (Figure 3) in order to capture the 3D positions of reflective markers attached to the patient/subject.

The reflective markers used in gait analysis are manufactured in different sizes and are covered with retro-reflective material (Figure 7). Synchronised force plates integrated in the floor measure the load on the patient/subject.

To optimise the settings of the video cameras in the laboratory and make it possible to capture all the markers at different angles, it is necessary to calculate the volume of interest in order to make all the markers visible (Figure 8).



Figure 7 Reflective markers and cluster used in gait analysis



Figure 8 Gait laboratory with 16 high speed motion analysis cameras and four force plates

The cameras are calibrated using an L-shaped frame (Figure 9), used as a reference object, with four fixed mounted markers placed on the floor. The L-frame defines the origin of the global co-ordinate system, as well as the axis (x y z) orientation. A T-shaped metal stick, called a wand, with two markers mounted at a fixed distance of 750 mm, is moved over the L-frame and around in the volume of interest. The position of the force plates is located using reflective markers in the calibrated volume.

The patient/subject is then prepared with appropriate clothing. His/her height and weight are measured. Markers are then attached to the skin with double-adhesive tape on anatomical landmarks, clusters and sensors (IMUs in Study V) with an elastic strap around the lateral part of the thigh and shank. The patient/subject is given information about the procedure and then has time to familiarise him/her self with the gait



Figure 9 | Calibration kit. (Qualisys AB, Gothenburg, Sweden).

investigation. A clinically referred patient also frequently undergoes some additional investigations of muscle strength, range of motion (ROM), spasticity and foot pressure analysis. Digital filming and photographs may also be used. These additional investigations will not be discussed in this thesis.

#### Marker models

For several decades but rarely today, motion was only captured in the sagit-

tal plane and thus included only two dimensions. The marker models were simpler and less precise and the markers, at that time, were larger. There were fewer cameras with poorer resolution, which made gait analysis less accurate and also time consuming during post-processing. The field of gait analysis today works with smaller markers, more segments and cameras with much higher resolutions in order to capture smaller movements. Furthermore, post-processing time and software development have resulted in a continuous reduction in the time taken by the analyses.

Today, several marker models are used in the field of gait analysis, based on either three degrees of freedom (3DOF) or six degrees of freedom (6DOF) principles. The 3DOF segment model, normally based on skin markers (Figure 10), is assumed to be connected and rotated according to an intermediate hinge. The 6DOF model is based on rigid clusters together with calibration markers. It also rotates according to an intermediate rotation axis but also with a certain translation. A conventional gait model has some variations (Figure 11), such as the Helen Hayes, Cleveland Clinic or Cast (calibrated anatomical systems technique) models. [20] A conventional gait model refers to a certain marker set and algorithms used to estimate the position and anatomical



Figure 10 | Skin marker model used in Study I-V

orientation of the segments representing joint angles and moments. The main differences between models are the placement of markers and the algorithms used to estimate the position and orientation of the segments.

The model used in this thesis is based on a modified Helen Hayes model using the anatomical locations of the anterior superior iliac spine (ASIS) and the posterior superior iliac spine (PSIS) in order to make regression equations to locate the hip joint centres (Coda pelvis). This model is based on skin markers attached to the proximal border of the sacrum, the anterior/superior of the iliac spine, in order to calculate the hip joint centre, lateral knee joint line, proximal border of the patella, tibial tubercle, tuber calcanei at the heel, lateral malleolus and finally between the second and third metatarsals. To calculate the thigh segment, the hip joint centre, the knee joint centre and the supra patellar marker are used. For the length of the shank, the lateral marker of the knee and lateral malleolus is used. [23, 24]

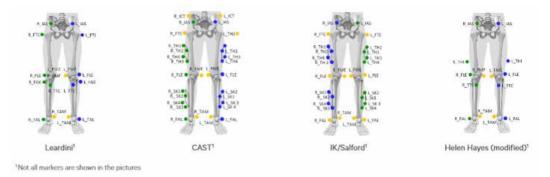


Figure 11 | Example of marker models yellow markers is used as static markers (Qualisys AB, Gothenburg, Sweden)

The cluster-marker model comprises four clusters (plastic shells) containing four reflective markers on each cluster. These "clusters" are attached laterally to the thigh and shank on both sides with an elastic strap. On the foot, skin markers are applied to the proximal joint of the big toe and the fifth toe respectively. For the cluster model, additional calibration markers are attached bilaterally to the greater trochanter of the femur, the medial and lateral central part of the femoral condyle, the medial malleolus, the insertion of the Achilles tendon and finally between the second and third metatarsals. The purpose of these markers is to define the end points of each body segment.

#### Temporal spatial gait parameters

During an instrumental gait analysis, a number of basic parameters are calculated as stride duration, stance and swing time, single- and double support time, stride and step length, base of support width, foot progression, cadence and velocity (Figure 12). These parameters together with kinematics (e.g. joint angles, translation of segment) and kinetics (e.g. moments) is normally presented in a gait report (Figure 13).

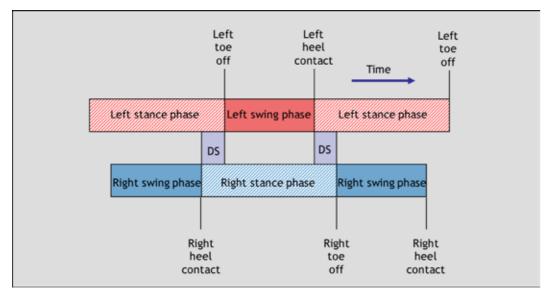


Figure 12 | Left and right stance phase (60%) with corresponding right and left swing phase (40%) including right and left heel contact and toe off. DS=double support (both feet's on the ground surface).

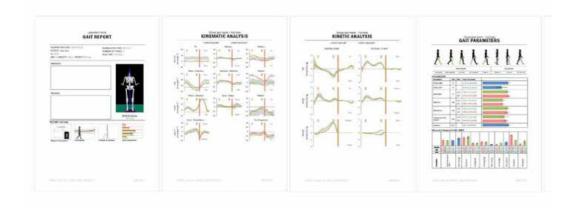


Figure 13 | Gait report (Qualisys AB, Gothenburg, Sweden).

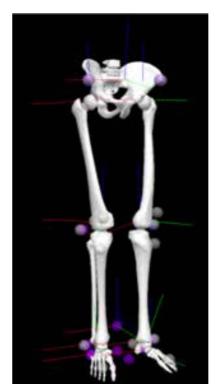


Figure 14 | Segment model.

#### **Kinematic**

According to gait analysis, kinematics is the measurement of movement and describes the motion of segments or/and systems of segments. The joint angle or inter-segmental angle is the angle between two segments measured in degrees and is not dependent on body orientation. On the other hand, the segment angle according to the right-hand sequence is an absolute measurement which changes according to body orientation.

In gait analysis, these segments would be pelvis, thigh, calf and foot segments in the lower body (Figure 14). The foot could be divided into more than one segment, such as in the Oxford foot model.<sup>[25]</sup> The upper part of the body, trunk with the arms and head, can be divided into several segments, but segments in the upper part of the body and the foot model have not been used in this thesis and will not be further addressed here.

In gait analysis, kinematic angular rotation is captured in three planes; sagittal (x) flexion/extension;

frontal (y) abduction/adduction and longitudinal or transverse (z) internal/ external rotation corresponding to three degrees of freedom (3-DOF). There

is also a certain sliding component, translation, which occurs during all rotations (6-DOF). Kinematic joint calculations assume that the segments are rigid and are defined by markers in gait analysis. Calculations of angles, between planes, are based on the Euler principles, with the proximal segment fixed and the distal segment as a moving part. The order of calculations is x, y, z. [26]

Figure 15 | Ground reaction forces obtain ned from force plates

#### **Kinetics**

Angles recorded during motion and ground reaction forces recorded by the force platform are used to calculate joint moments. In addition, the velocity and changes in velocity are computed. Gait velocity is measured in metres per second, m/s, and acceleration by m/s<sup>2</sup>. The position is given in Cartesian co-ordinates, first in the horizontal and then in the vertical position. External forces that affect the body (Figure 15), such as the

position of the centre of gravity and ground reaction forces (GRF) or the centre of pressure (COP), can be calculated, based on data obtained from the force plates (Figure 16). The centre of gravity of a body is one point at which all the weight is concentrated in one moment. The ground reaction force is presented as a line which represents its direction and magnitude. Using geometry, the position, velocity and acceleration of any parts of the segments can be determined. In this calculation, it is assumed that the segments are rigid, which creates an opportunity for the use of studies in which the segments are affected by external forces, rigid-body dynamics. The dynamics are described by Newton's three laws of motion and from Lagrangian mechanics, which results in a description of the position, the motion and the acceleration of the segments, as a function of time. [23, 24]



Figure 16 Amti-force plate © Advanced Mechanical Technology, Inc (With permission from Qualisys AB, Gothenburg, Sweden)

### Invasive methods for recording skeletal movements

Accurate recordings of skeletal motions are mandatory when it comes to evaluating soft-tissue artefacts. For this purpose, intercortical pins have been used. A procedure of this kind implies a certain risk of infection and results in some pain, which raises ethical considerations. In addition, the pins themselves might alter the skin and soft-tissue motions during activity. [27]

### Fluoroscopy

Fluoroscopy makes it possible to obtain digital medical imaging during motion. This technique is able to capture internal bone structures and joints during movement. This method has been used to validate the accuracy of

optical tracking systems (OTS) based on reflective skin-markers. Soft-tissue artefacts have been primarily studied during different active motions or treadmill gaits. Fluoroscopy usually exposes the patient to higher radiation doses than conventional radiography because of the longer exposure which is necessary for these types of study. The performed activity is limited to the field of view between the X-ray source and the recording screen which corresponds to a comparatively limited volume. [28-30]

#### Roentgen stereophotogrammetric analysis

Roentgen stereophotogrammetric analysis (RSA) is an invasive tantalum marker-based method, which has often been used to measure the migration and wear of prosthetic components, mainly for research purposes. This method can also be used to measure joint motions, either by repeated static examinations or by using dynamic techniques based on film exchangers or high-speed digital screens. RSA can be regarded as the "gold standard" in the investigation of joint motions because of its high accuracy, high resolution and detailed documentation. [31-43] There are only a few studies that have used the RSA method to validate OTS measurements, perhaps because the activity performed is limited to the field of view for the two X-ray tubes used when recording RSA images.

### Soft-tissue artefact validity and reliability

Instrumental gait analyses based on recording the position of optical markers fixed to the skin introduce more or less pronounced soft-tissue artefacts (STA). This occurs even if markers are routinely placed on locations with a short distance between the skeleton and the skin. Markers may be individually attached to the skin or alternatively rigidly connected to one another in clusters with the aim of facilitating data capture in the recordings. Soft-tissue artefacts may have many causes such as skin deformation, skin sliding, muscle contraction and gravity.

Recently, Cereatti et al. estimated the magnitude of soft-tissue artefacts based on data from several studies, of which two reported level walking with median values of 8 mm and maximum values of 25 mm. No consensus has been reached on the true value of maximum errors in the available methods. These studies would require comparisons with invasive methods. At present, the available studies are difficult to compare due to variations in subjects' BMI and the type of movement performed. [35, 44-56]

In 2010, Peters et al. [57] performed a systematic review comprising 20 studies with the aim of quantifying soft-tissue artefacts using OTS. In 13 of these studies, invasive methods, including intra-cortical bone pins or X-rays, were used. The authors concluded that there are several important factors such

as the location of markers, activity performed, segment used and individual characteristics that can influence the results. Exceptionally high soft-tissue artefacts, up to 40 mm, have been reported at the thigh and the authors called for improved methods to increase the resolution.

Recently, soft-tissue artefacts were studied during dynamic motions with quantification of the error of the estimated position of the hip joint centre (HJC). Measurements were made simultaneously using skin markers and dual fluoroscopy. The mean and standard deviation (SD) of the variation in HJC position was 16.6 (8.4) mm with skin markers and 11.7 (11.0) mm using dual fluoroscopy using the femoral head centre as a reference. [29]

Another bi-plane fluoroscopic system was used in 19 subjects when walking on a treadmill. Model-based RSA was used to identify the position of the prosthesis and each of the bone segments with an accuracy of 0.18 degrees root-mean-square difference (RMSD). Simultaneous recordings using 40 reflective markers attached to the thigh and shank were made. The individual marker displacements varied between 4.4 and 24.9 mm on the thigh and between 2.5 and 15.3 mm on the shank. For both locations, the highest values were recorded in the proximal direction. [28]

In 2005, Stagni et al. studied STA during different activities using fluoroscopy and OTS in two female subjects who had undergone total knee replacement. The implants and the bone were tracked on the fluoroscopy images and a grid with reflective markers was attached to the thigh and shank to be tracked by the OTS. They recorded an SD of 31 mm and 21 mm for the thigh and shank respectively. They also concluded that the magnitude of the error was subject and performance specific.[30]

In one study, OTS recordings were compared with dynamic radiostereometry during active knee motions in nine subjects (10 knees). In this study, flexion/extension showed good agreement and produced reliable data on an individual and group basis with a difference of between two and five degrees (4-10%) during the flexion/extension movement of the knee. Movements in the frontal and horizontal planes (abd-/adduction and internal /external rotation) showed less agreement. The authors assumed that the most probable reason was soft-tissue artefacts and small motions in these planes, resulting in large relative errors.[34]

### Reliability of gait analysis using optical tracking systems

In a meta-analysis of the reliability of optical tracking system (OTS) studies, McGinley et al. [49] concluded that most errors in gait analysis are probably acceptable but generally not small enough to be ignored in clinical studies. Studies revealed varying results relating to measurements within assessors.

Higher reliability was reported in the sagittal plane (correlation coefficient > 0.8), less in the coronal plane (>0.7) and least in the transverse plane (<0.7). The authors felt that errors of two degrees would be acceptable, two to five degrees reasonable, while more than five degrees would mislead the interpretation. They presumed that new techniques, less dependent on accurate marker placement, had the potential to improve the resolution of the OTS. Inaccuracies in marker placement, the ability of the system to track markers and soft-tissue artefacts are also regarded as important sources of error. The studies included in the meta-analysis were all based on repetitions of the measurements for each application. None of them included a comparison between skin-marker-based measurements and simultaneous recordings of true skeletal motions.

#### 1.1.4 Osteoarthritis

Osteoarthritis (OA) is a chronic disease which gradually destroys the joint over time. This disease affects 235 million people worldwide, involves all the components of the joint and is often associated with increasing stiffness, reduced mobility and pain. The clinical course varies between patients and depending on the joint(s) involved. Typical radiographic findings are a reduction in joint space due to cartilage destruction and secondary changes in the bone adjacent to the joint such as sclerosis, cysts and the formation of osteophytes. [58] The underlying reason for primary osteoarthritis is not known. Several factors or combinations of factors, such as age, genetics, overweight, joint mechanics, changes in the synovial fluid and inflammation, have been discussed. Secondary osteoarthritis can develop for various reasons such as trauma, inflammatory arthritis, avascular necrosis, growth disorder or metabolic disease.<sup>[59]</sup>

### 1.1.5 Hip arthrosis

The symptoms of hip osteoarthritis commonly appear according to a certain pattern, but there are numerous variations. In the early phase, the first steps taken after inactivity or in the morning could be painful or pain may only appear after strenuous activities. Pain at rest and especially during the night often appears later and the walking distance is gradually restricted. Pain is often located in the groin, radiating down to the knee joint, but the location of pain may vary and may be localised in the buttock or the trochanteric region. Low back pain is often added, but knee pain is rarely the most significant complaint. [60]

Hip joint extension and internal rotation are often first affected and reduced. Due to restricted hip extension, lumbar lordosis may be increased during walking. Limping is common, as well as a feeling of stiffness. At visual inspection, leg-length discrepancy, together with the atrophy of thigh and

calf muscles, can be observed. When examining range of motion, extension and internal rotation are almost always reduced, even if this finding may also occur in any disease of the hip joint.

#### Hip arthroplasty

When performing a total hip arthroplasty the femoral head and parts of the femoral neck are normally removed and replaced with a metal stem fixed with or without bone cement into the femoral canal. On the concave pelvic side of the joint, a cup with an outer shell of metal and an inner surface of polyethylene or more rarely ceramic or metal is used for uncemented fixation. Most commonly, whole-polyethylene cups are used for cemented fixation.

Several ways of evaluating the outcome of a total hip arthroplasty have been used during the last few decades. Commonly, recordings of revisions or re-operations and examinations of radiographic images to evaluate bone reactions such as the development of radiolucent lines and osteolysis have been used to account for different types of complication. Clinical evaluation has traditionally been based on the collection of functional scores such as Harris Hip score (HHS)(Appendix 1) and EQ-5D (Appendix 2), including different parameters, such as the use of walking aids, walking distance, stair climbing, sitting ability, tying shoelaces, the presence of pain and the clinical examination of the hip range of motion. Each item is given a certain score which is added up to produce a total index score. [61-65]

Patient-reported outcome measurements (PROMs), including the EQ-5D questionnaire, have been used in the SHAR both pre- and postoperatively since 2002. PROMs include measurements of disease symptoms, functional ability and health-related quality of life. [6] There have been some studies comparing outcomes after THA with gait analysis performed with OTS.[66]

In 2006, Lindeman et al. investigated the correlation between the Western Ontario and McMaster University questionnaire (WOMAC) and gait analysis in order to determine objective gait parameters preoperatively and three months postoperatively in 17 patients with a median age of 70 years. Temporal gait parameters together with health parameters improved postoperatively, p < 0.047. The correlation between gait parameters and the WOMAC was poor (r = -0.27) and bad to good according to changes in gait parameters (r  $= 0.01 \text{ to } -0.72).^{[46]}$ 

Recently Foucher (2016) investigated the possibility to identify postoperative benchmarks for values of minimal important improvements of self-selected walking speed, hip flexion-extension range with peak values and hip moments

measured during gait analysis. A number of 145 patients were analysed preoperative and 1 year postoperative with HHS and gait analysis. The minimal important improvements, as the 75th percentile mark on a plot of the cumulative percent of subjects with HHS >/= 80 versus the postoperative value was used together with calculated 95 % confidence intervals. In order to test the association of age, gender, BMI and benchmarks of HHS logistics regression was used. Minimal clinical important improvements in the comparison for speed 0.32 (0.30, 0.35) m/s, hip flexion-extension 13.3 degrees (12.1-14.8) and for adduction moment 0.87 (0.57, 1.17) % of Body Weight x Height was observed. The results showed that lower BMI predicted hip flexion-extension and adduction moment postoperative (ORs 0.85-0.88, p  $\leq$ /= 0.015). Furthermore, lower preoperative HHS predicted speed, hip flexion-extension and adduction moments in minimal clinical important improvements (ORs 0.95-0.97, p </= 0.012). The author concluded that validation, of clinically-relevant gait benchmarks can improve THA outcomes.<sup>[67]</sup>

Instrumental gait analysis has been used for many years to evaluate the gait performance after total hip arthroplasty, mainly for research purposes. There are several factors which might make the interpretation of the results difficult, such as weight, height, BMI, gender and age. Other factors could include velocity, implant selection, surgical approach, implant fixation and follow-up period. The influence of these factors has been only partially mapped out, which might be one reason for the restricted use of this method in clinical practice. Another and perhaps even more important reason is that, in the majority of its applications, this technique has been somewhat laborious and time consuming.

In 2012, Ewen et al. performed a review of seven studies of patients after THA surgery. There was a great variation in study design. Gait velocity was reported to be significantly lower in three studies, while six reported shorter stride length, four with significant stride length values compared with healthy controls. All seven studies reported reduced hip range of motion (flexion/ extension). Sagittal peak moments tended to have a large variation across the seven studies and significantly less abduction moment was reported in the frontal plane in one study, while it was reduced in two studies in THA patients compared with controls. The most important variables in the evaluation of THA patients compared with a healthy control group were gait velocity, stride length, range of hip flexion/extension and peak hip abduction moments.<sup>[9]</sup>

Recently, Bennett et al. (2016) presented the results of 139 unilateral THAs, performed using a posterior approach by a single surgeon, who used the same type of implant in all patients. The studies were performed 10 years postoperatively and the patients were stratified in five different age groups

from 54 to > 80 years. Reduced gait speed and stride length were found in all groups but only reached significance in the group aged > 80 years. Compared with healthy subjects, reduced peak hip extension moments but not flexion and abduction moments were observed. Hip power generation at late stance was significantly reduced in all groups compared with normal. The authors concluded that good hip abduction moments were reached but not extension and rotation moments, which they thought should be the focus during preand postoperative rehabilitation.

### 2. AIMS

The evaluation of total hip arthroplasty focused initially on the risk of revision or re-operation.<sup>[68]</sup> Walking ability and the presence of gait abnormalities such as limping were mainly evaluated using questionnaires filled in by the examiner, together with a clinical examination. [61, 65] During the last one to two decades, information about patient mobility, walking endurance and other types of physical activity has mainly been collected using questionnaires filled in by the patients themselves [6, 46, 69]. Studies focusing on objective recordings of motions and walking pattern have been comparatively few in number. [9] Such studies are, however, of interest in order more precisely to evaluate the result of the surgical procedure and to study any association between patient dissatisfaction and failure to regain normal walking ability. To perform studies of this kind, the methods used to record motions need to be sufficiently accurate and reproducible. To further explore this field, the following studies were initiated.

## 2.1 Specific aims of studies

### Study I

To evaluate the accuracy of two different marker models in a three-dimensional gait analysis system using dynamic radiostereometric analysis during simultaneous recordings of active hip motions.

### Study II

To study the gait pattern using OTS in three groups; healthy controls, subjects with unilateral hip OA and subjects undergoing unilateral THA. The primary aim of the study was to determine whether there is a systematic difference in the repeatability of measurements within subjects with or without hip disease, or with a replaced hip joint in terms of hip kinematic and kinetic data obtained from the OTS measurements. The secondary aim was to delineate differences in hip motion during walking between these groups.

### Study III

To evaluate differences in hip flexion-extension, hip abduction-adduction and hip abduction moment in patients undergoing one-stage bilateral THA with the same type of uncemented acetabular cup during gait. The secondary aim was to evaluate the extent to which gait parameters in patients undergoing one-stage bilateral THA returned to normal one and two years after THA.

### Study IV

To report the clinical and radiological results of the Madreporic Lord THR in 66 hips with at least the original stem left in place out of 107 THRs primarily included, with a minimum follow-up time of 23 years.

### Study V

To study the accuracy of an IMU system using a gait analysis system as a reference, during simultaneous recordings of pelvic, hip and knee joint motions in patients undergoing a total hip replacement.

## 3. PATIENTS AND METHODS

Table 1 | Summary of patient and subjects/controls participating in the five studies I-V.

Study	I	II	Ш	IV	V
Patients	16	40	22	62	50
Subjects/controls		20	66		
Males/females Controls (Males/females)	10/6	30/30	8/14 29/37	20/42	25/25

### 3.1 Patients and subjects

### Study I

16 subjects, 10 males and 6 females, volunteered for this prospective comparative therapeutic (level 2) study (Table 2). The median (range) age and BMI was 58 (44-69) and 27 (23-34) respectively. All subjects had undergone total hip arthroplasty (THA) surgery 5-13 years prior to study start. Nine subjects had been operated with cemented (cup, stem) THA, three with surface replacement and two with hybrid THA. All subjects participated in different prospective studies with the aim to measure implant migration and wear. At the previous THA operation 6 to 9 tantalum markers (Ø=0.8 or 1.0 mm) had been inserted into the pelvis and the proximal femur. We used a median number of 5 (3-9) markers in the pelvic and 6 (3-9) markers in the femoral segments. Two subjects (1 male, 1 female) had difficulties to perform the requested movements and stay within the field of radiation and had to be excluded.

Table 2 | Number of inserted implant in men, women and design of prosthesis.

Prosthesis	Men	Women
Trilogy/Spectron	2	
Durom	1	2
Spectron/Reflexion		2
CLS/Trilogy	8	1

### Study II

This cross-sectional test-retest study included 3 groups with 20 subjects (10 males and 10 females) in each (Figure 17). The first group constituted healthy controls, the second group subjects with unilateral hip OA and the

third group subjects operated with unilateral THA. The control group was recruited locally from laboratory staff and their relatives and friends. None of the healthy subjects had any problems related to the musculoskeletal system.

Subjects with hip OA were recruited from the waiting list for hip surgery at the Department of Orthopaedics at our University hospital. Presence of hip OA was verified on radiographs. 6 hips were classified as Stage 2 according to Ahlbäck, 10 hips as Stage 3 and 4 hips as Stage 4 [70]. On the contralateral side, all subjects were without symptoms. 12 had no signs of OA and 8 had a minor reduction of the joint space (Stage 1).

All 20 subjects with unilateral THA had undergone surgery 1-2 years prior to the study. 13 of these subjects had their surgery on their right side. Femoral head

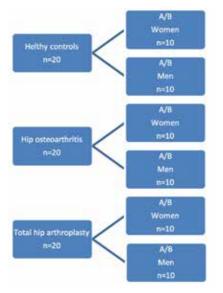


Figure 17 | Flow shart of included subjects.

sizes of 32 mm (18 hips), 36 mm (1 hip) and 28 mm (1 hip) had been used. A lateral incision was used in 13 hips, and an anterior incision in 3 hips. For the remaining 4 hips, a posterior incision was used. All subjects were without symptoms on the contra lateral side, even though radiographs revealed that 7 subjects had minor reduction of the joint space (Stage 1).<sup>[70]</sup>

### Study III

Patients with primary hip osteoarthritis, idiopathic femoral head necrosis or mild dysplasia involving both hips on our waiting list for bilateral THA between 35-70 years of age were asked to participate (Figure 18). To become included the anatomy of both hips should be compatible with use of a short femoral stem corresponding to the Fitmore design (Biomet-Zimmer, Warsaw, USA). 44 patients met the inclusion criteria and accepted to participate in this randomised therapeutic level 1 study. Three patients had to be excluded early in the study. One of these patients developed blisters on the contralateral side during operation of the first one and two patients developed infection. Further one patient developed acute pancreatitis during the postoperative period and later on severe heterotopic bone formation. Three patients did not attend or withdraw consent for gait analysis at the 1-year follow-up. Fifteen patients had not passed the 2-years follow up at the time period for this study or did not want to undergo gait analysis at this occasion. The remaining 22 patients, (8 males/14 females, mean age 60, range 45-75 years BMI 28 range 19.6-39.4) accepted to participate in gait analysis studies both at one and two years after the operation.

66 individuals, 37 females and 29 males, mean age of 53 years (range 38-84) with a BMI of 25 (range 16-35.8) served as a control group.

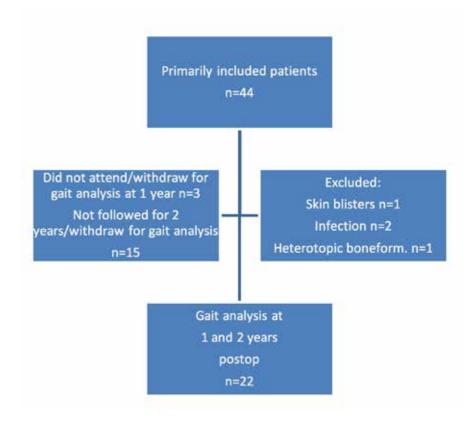


Figure 18 | Flow shart of included and excluded patients and patients patients who has conducted a gait analysis at 1 and 2 year follow-up.

#### Study IV

Between September 1979 and November 1986, 98 patients, 58 females and 40 males (107 hips), with a median age of 48 years (25-67), were recruited to this prospective study. At the index operation, 59 had unilateral and 28 bilateral disease. 11 patients had reported multiple joint problems according to the Charnley classification. The majority of the hips were operated on due to secondary osteoarthritis (OA), (sequelae childhood diseases = 33; idiopathic femoral head necrosis = 13; sequelae femoral neck fracture = 8; ankylosing spondylitis = 5; other = 14). Thirty-four hips had primary OA. Two stem lengths were used, 150 mm (69 hips) and 180 mm (38 hips), and four different stem thicknesses, 11 (5 hips), 13 (64 hips), 15 (29 hips) and 18 mm (9 hips). Information about any re-operations and revisions was obtained from medical records and cross-checked with the Swedish Hip

Arthroplasty Register (SHAR).

At the last follow up, 71 patients (78 hips) of the original 98 patients, with at least one of the prosthetic components in situ, were still available (Figure 19). Five patients (5 hips) had both components exchanged or extracted. Two patients (2 hips) had moved abroad and could not be contacted. Two patients (3 hips) could not, or did not want to, participate due to high age or generalised disease. Finally, one patient only underwent radiographic examination but did not show up for the clinical examination. Seventeen patients had deceased.

62 patients (66 hips), with a mean age of 72 (54-88) years, attended the clinical examination 26 years and 1 month (23 years 6 months to 29 years 3 months) after the initial operation.

#### Additional information

At the last follow up 16 patients (18 hips), 9 women and 7 men, with both components in situ accepted to perform a gait analysis assessment minimum 23 years postoperatively compared with 48 healthy subjects.

### Study V

A cohort of 25 patients operated with THA during 2011-2013 at the Sahlgrenska University Hospital and with no reported mobility problems in the EQ-5D form was identified and accepted to participate. Further 25 operated during the same period in the same hospital, who had reported mobility problems one year postoperatively also accepted to participate. They were selected from a group of 54 patients with mobility problems based on their acceptance to participate in our study. One patient was excluded due to technical problems, which resulted in 25 males and 24 females analysed. Nineteen had been operated on the left and 30 on the right side and sixteen of the patients had also been operated on the contralateral side earlier. At the latest operation the patients had a mean age of 71 years (51-80) and a body mass index (BMI) of 28.7 (20-44). The median time between the last surgery with total hip arthroplasty and the gait investigation was 36 (22-56) months.



Figure 19 | Madreporic Lord total hip arthroplasty, left side

### 3.2 Methods

#### 3.2.1 Dynamic radiostereometry and synchronisation with the OTS

#### Study I

An RSA system (modified Adora Laboratory, Nordisk Røntgen Teknik a/s, Denmark) with two simultaneously exposing roentgen tubes angled at 40 degrees to one another was used, with a film focus distance of 1.5 m. This system was supplied with two high-speed digital screens (Canon CXDI 50RF detectors), designed for both static and dynamic RSA, with an imaging space of 35 x 43 cm (2,208 x 2,688 pixels, equal to 3,943 pixels/1 square cm). At the dynamic examinations, the exposure rate of the RSA system was set at four exposures/s, exposed at 140 kV and 5 mAs. All the RSA radiographs were analysed using UmRSA Analysis software, version 6.0 (UmRSA Biomedical, Umeå, Sweden).

The accuracy and precision of the calculations in radiostereometric analysis are dependent on the configuration or spread of markers. The condition number (CN) describes the distribution of the tantalum markers in a segment. A low CN indicates well-scattered tantalum markers in the segment of interest. The mean error (ME) of rigid body fitting describes the stability of the markers. In the majority of previous RSA studies of implant migration, the maximum value of the condition number and the maximum of the mean error of rigid body fitting have usually been set at 125-130 and 0.35 mm respectively. In this study, we occasionally accepted a slightly higher condition number. This was done for solitary exposures preceded and followed by examinations with lower values for this parameter and a high degree of marker stability, as reflected in a low mean error of rigid body fitting. So, in this study, the median CN and ME for the pelvic segment were 46 (range 22-154) and 0.1 mm (0.02-0.36) respectively. The corresponding values for the femoral segment were 46 (range 19-156) and 0.07 mm (range 0.01-0.36). The mean total effective radiation dose was 19.3 (SD 9) mSv.[36]

Before the dynamic examination took place, a static examination was performed, with the subject standing in an upright position in the calibrated volume aligned to the axes of the global co-ordinate system. This static examination was used as a zero position for each of the two systems.

At the dynamic examinations, the patients performed three separate motions. The first series of sequential radiographs were exposed when the patient flexed his/her hip in the sagittal plane. In the second series, the patient performed abduction in the frontal plane. Finally, the subjects were instructed to perform a rotation of the hip, from maximum external to maximum internal rotation in the coronal plane. The main load was on the hip of interest

and the subjects were instructed to perform a squat (flexion), a lateral flexion of the trunk over the hip (abduction) and a twist (rotation). All motions were to be performed at a relatively slow pace. Before exposure of the sequential series, all the subjects had the opportunity to perform a number of trials for each motion under the guidance of one of the authors (Figure 20a-d).

The examination of each of the three studied hip motions (flexion, abduction, external-internal rotation) lasted for 1.25-5.5 seconds. The subjects therefore had a window of 5.5 seconds to perform their motion. Some subjects started immediately and others when one to two seconds had elapsed. All the patients had reached their endpoint after 3.75 seconds, excluding cases with too few observations for inclusion (<3). When hip flexion, for example, was studied, there were also small rotations around the longitudinal and sagittal axes.

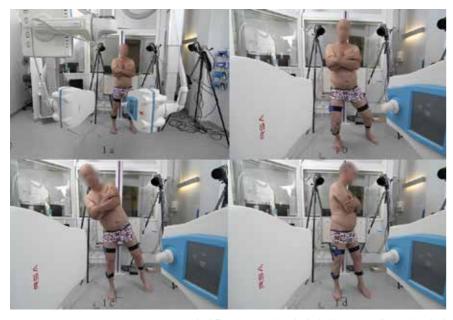


Figure 20 | 1a static position, 1b a loaded flexion, 1c a loaded abduction and 1d a loaded rotation.

We focused on the main rotation of the three studied hip motions. As a result, these concomitant rotations around these axes were not accounted for.

A 12-camera motion capture system was used to determine the positions of skin and cluster markers (Oqus 4, Qualisys AB, Göteborg, Sweden). The exposure rate of the motion analysis system was set at 240/s, i.e. a ratio of 60 to 1 between the two systems. The motion analysis system was hardware triggered to start at same time as the RSA system. The design of the RSA system made it possible to achieve a trigger impulse at the time of the start of

exposures. A cable from the RSA system was connected directly to the trigger input on the master camera of the OTS. Prior to the recording, the OTS was set in external trigger mode awaiting the trigger signal from the operator of the RSA system.

The local co-ordinate system for the two methods was aligned by positioning the reflective markers on the calibration cage (UmRSA<sup>TM</sup> Biomedical, Umeå, Sweden) in the RSA system, thereby allowing a comparison of motion data between the two systems.

#### 3.2.2 Optical Tracking System (OTS)

#### Studies I-III and V, additional information Study IV

For data acquisition with the OTS system, in Studies I-III and V, a 12-camera motion capture system (Oqus 4, Qualisys AB, Göteborg, Sweden) was used to determine the positions of reflective markers. In order to record the hip kinematics and kinetics with the OTS, a total of 15 spherical markers (Ø 12 mm) were attached to the skin of the lower extremities and the pelvis, with double-adhesive tape, according to a skin marker model presented in detail by Weidow et al. [71] Skin markers were attached to the proximal border of the sacrum, the anterior/superior of the iliac spine, the lateral knee joint line, the proximal border of the patella, the tibial tubercle, the tuber calcanei at the heel, the lateral malleolus and finally between the second and third metatarsals. A modified Coda pelvis was used in the marker model. This segment was based on the bilateral markers on the anterior superior iliac spine, together with one marker at the mid-point on the proximal border of the sacrum. Hip joint centres were defined in relation to the pelvis segment, according to the recommendations of Bell et al. for the right and left hip joint centres. [21, 22] In the OTS, the proximal segment was fixed and the distal segment was moving. The OTS calculations were based on Euler angles. The exposure rate of the OTS was 240 Hz. The recorded marker data were filtered using a Butterworth 4th order filter, with a cut-off frequency of 6 Hz. Before the dynamic examination took place, a static examination was performed with the subject standing in an upright position in the calibrated volume aligned with the global co-ordinate system. During the examination, the subjects wore underwear and they were then asked to walk five to 10 times at a self-selected speed through the calibrated volume to familiarise themselves with the situation. One trial was randomly selected for further evaluation in all studies.

Two force plates were used (Kistler 9182C, Kistler Group, Winterthur, Switzerland), synchronised with the OTS in order to record ground reaction forces (Studies II and III) and additional in Study IV.

The cluster-marker model (Study I) comprised four clusters (plastic shells) with four reflective markers in each cluster. They were attached laterally with an elastic strap on the thigh and shank on both sides. On the foot, skin markers were applied to the proximal joint of the big toe and the fifth toe respectively. For this model, additional calibration markers were attached bilaterally to the greater trochanter of the femur, the medial and lateral central part of the femoral condyle, the medial malleolus, the insertion of the Achilles tendon and finally between the second and third metatarsals. The purpose of these markers was to define the end points of each body segment.

Gait analysis in Study IV (additional information, not accounted for in the paper) was performed using an eight-camera motion capture system (ProReflex<sup>TM</sup> MCU240, Qualisys AB, Sweden) to record the hip kinematics and kinetics. Fifteen spherical markers (Ø 19 mm) were attached to the skin of the lower extremities and the pelvis. The same skin-marker model as above was used. The exposure rate of the OTS was 240 Hz. Marker data were filtered using a Butterworth 4th order filter with a cut-off frequency of 6 Hz.

#### Study II

The gait pattern was studied using the OTS in three groups with 20 subjects in each group, 10 males and 10 females. Each group constituted healthy controls, subjects with unilateral hip OA or subjects who had undergone unilateral THA. Each of the subjects was examined by two observers. Both examiners applied all the markers before each of the examinations and recorded the data. The order in which the two examiners studied the subjects was randomised. Both examinations were performed during the same session within a two-hour period. A total of 120 examinations were performed.

### Study III

Patients with primary hip osteoarthritis, idiopathic femoral head necrosis or mild dysplasia involving both hips on the department's waiting list for surgery and between 35-70 years of age were asked to participate. To be included, the anatomy of both hips needed to be compatible with the use of a short femoral stem corresponding to the Fitmore design (Biomet-Zimmer, Warsaw, USA). Gait analysis was performed with an optical tracking system (OTS) one and two years after the operation. Variables chosen for further calculation were hip joint maximum extension, flexion and range, maximum adduction, abduction and range and finally maximum hip moment in adduction, abduction and range in the frontal plane.



Figure 21 | Right side view IMU's together with reflective skin markers.

#### Study V

For the inertial motion units (IMU) (GaitSmartTM, Hertfordshire, United Kingdom), joint angle was calculated by computing the angle required to rotate one sensor onto the second sensor using an axis of rotation that is not constrained to a specific plane. The device measures sagittal plane and frontal plane motions, which will match those of the subject, provided that it is correctly positioned in relation to anatomical axes. After calibration, the IMU system measures angles in relation to an axis perpendicular to the floor (global system). Proprietary software (Poseidon Version 9.1.4) transformed the raw data from the gyroscopes and accelerometers into angular positions along the sensor axes, primarily aligned laterally with the pelvis, thigh and calf to measure rotations in the sagittal plane (flexion-extension) according to the manufacturer's instructions. The sampling rate was 102.4 Hz. Rotation in the transverse plane is not measured by the IMU and it was therefore excluded from our evaluation. The hip joint angle was determined by the pelvis and thigh sensors and, for the knee joint, the angle subtended by thigh and calf sensors. The IMU model for the pelvis uses two sensors which detect movements at the sacroiliac joints (Figure 21). The joint angle is the angle required to rotate the lower limb into alignment with the upper

about the hinge axis in a right-handed rule. In the IMU system, the angle measured corresponds to the combined angle in the sagittal and frontal planes, whereas the OTS is based on calculations of Eulerian angles and therefore more strictly measures flexion-extension as sagittal plane motions. Recordings were performed simultaneously for the systems, following two consecutive steps in the order of right and left.<sup>[72]</sup>

### Randomisation, surgical procedure and clinical follow-up Studies III and IV

In Study III, all the subjects were randomised, prior to their operation, to one of the two THA stems, according to the hip with the most pronounced pain. If a patient regarded both hips as equally painful, the one with the most advanced degenerative changes on radiographs was randomised to either of the two stems (CLS-Spotorno® or Fitmore®, Zimmer, Warsaw, USA).

A Trilogy® cup (Zimmer, Warsaw, USA) was used on both sides. A lateral incision with the patient placed on his/her side was used bilaterally. Four experienced surgeons performed the operations. Postoperatively, all the subjects were mobilised the day after the operation with as much weight-bearing as was tolerated.

All the patients were followed according to a standardised clinical protocol. For the purpose of this study, a pain VAS and the Harris Hip Score (HHS) at one and two years were included. All the patients filled in a questionnaire in which they gave their opinion of the hip they thought was their best one (left, right or no difference).

In Study IV, all the patients completed the EQ-5D form and reported their pain and satisfaction on a VAS scale [6]. One physiotherapist carried out all the clinical examinations. The Harris Hip Score (HHS) was evaluated preoperatively, at the 10-year follow-up and at the last examination. A database originally constructed for this study was used to collect clinical information. It was, however, incomplete for some of the participating patients. However, for reasons not known to us, the total scores could only be calculated preoperatively for 18 of the hips (six unrevised, 12 with cup revision), at 10 years for 57 hips (20 unrevised, 37 with cup revision) and at 26 years for 66 hips in the patients who attended the last follow-up (24 unrevised, 42 revised).

### Evaluation of radiographs and bone mineral density

#### Studies III and IV

Radiographs were examined using Mdesk software (RSA Biomedical, Umeå, Sweden). Stem offset and cup offset were measured on the postoperative radiographs corresponding to the length of a line perpendicular to the centre of the femur and the centre of the femoral head and the centre of the symphysis respectively. The length of the remaining part of the femoral neck on postoperative radiographs from the most prominent part of the lesser trochanter was measured. At the follow-up examination at two years, the presence of any heterotopic bone formation and tip sclerosis (yes/no) was recorded [73]. The percentage of radiolucent lines occupying the stem bone interface and the location of these lines related to the Gruen regions (1-7 and 8-14) were recorded on the AP and lateral views [74]. In two patients, we used the one-year follow-up radiographs for both sides, due to missing radiographs. Correction for magnification was performed using the known diameter of the femoral head ( $\emptyset$ =32 mm) or a steel ball ( $\emptyset$  =30) placed at the same height as the hip joint.

In Study IV, 63 patients (67 hips) underwent a radiographic examination

including a frontal (AP), lateral and pelvic view. The extension of radiolucent lines (RLL) was recorded in each Gruen region and classified into four groups (0=0%; 1=1-50%; 2=51-99%; 3=100%). Bone remodelling was classified in four classes (1=obvious cancellation of the cortex; 2=probable cortical thinning; 3=no obvious change from normal; 4=cortical hypertrophy). Osteolysis of the proximal femoral bone was classified in three classes (0=none; 1=up to one cm; 2=more than one cm). All 67 sets of radiographs were analysed by two of the authors. The bone mineral density (BMD) was studied in 55 of the hips using a Lunar DPX-IQ densitometer (Lunar Corporation, Madison, WI). [75, 76]

#### 3.2.3 Statistics

#### Study I

Dynamic data from the RSA system were interpolated using a linear approach at every 2.5 degrees. The high-speed data collection of the OTS could be read directly without any interpolation. Mean values, standard deviations (SD) and standard errors of the mean (SEM) and the difference between the methods were calculated for the skin and cluster models and for the RSA data. Because of difficulties visualising sufficient numbers of bone markers during motion, the number of observations at each examination varied between three and 12 at each time point. Data from the hip flexion movement were available in nine subjects, abduction movement in 13 subjects and rotation movement in 14 subjects.

Due to small sample size and problems covering the same range of motion in all subjects, only three observations were selected from each individual examination for statistical calculations. Of the three observations, the first and the last in each series and a further one observation in between, corresponding to the one closest to the middle, based on the elapsed time period of active motion, were used for statistical analysis. Comparisons between RSA and the marker models were made using repeated measurement ANOVA to evaluate any systematic over- or underestimation of the registered rotations. Furthermore, the intraclass correlation coefficients (ICC) using single measurements were calculated on the three occasions (first, middle and end) to study agreement between the obtained data. A two-way single-measurement model (model 3) to determine consistency in agreement was used. An ICC equal to 0.7 or higher was regarded as acceptable. [77]

#### Study II

Two analyses were performed; the first one aimed to compare the data scatter of measurements between the three groups, while the second aimed to

detect systematic differences in kinematics and kinetics between the groups. In the first analysis, we examined the difference in measurements that the two examiners registered for each patient. The variances for this difference were calculated for each group and their equality was assessed using Bartlett's test.

In the second analysis, we evaluated the systematic differences in group joint kinematics and kinetics using ANOVA, including data from all three groups and linear regression for pairwise comparisons between groups. In the first linear regression model, only the membership was included as a dependent variable, while, in the second, BMI and age were added to the covariates to compensate for any differences in BMI and age between the three groups. In these analyses, the average values of the two examiners were used.

Bland-Altman plots for joint kinematics of hip extension-flexion, adduction-abduction and joint moments of adduction-abduction were constructed after averaging the two examiners' findings. The affected side was investigated in the OA and THA subjects, while only the right side was examined in the healthy subjects.

### Study III

In this study, all the variables were not normally distributed and non-parametric statistical tests were used (Wilcoxon's signed rank test and the Mann-Whitney U test).

### Study IV

The influence of age, gender, weight, diagnosis (primary/secondary OA; sequelae of childhood disease/other), stem length, stem width proximally (regions 1 and 7) and distally (regions 3-5) and bone mineral density at the last follow-up was studied using linear regression analysis.

Cup and stem failure were defined as the exchange or extraction of the implant for any reason and regardless of whether this procedure was performed as a first- or second-time revision. Cup and stem survival were calculated according to Kaplan-Meier [78]. Non-parametric tests were used to compare groups (Mann-Whitney U test) and changes over time (Wilcoxon's signed rank test).

In addition gait analysis was performed in 16 patients (18 hips) minimum 23 years postoperative with the Madreporic Lord stem and acetabular component still in situ. Non-parametric tests (Mann-Whitney U test) were used to compare the Lord groups with 48 healthy controls.

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#### Study V

An exploration of the data set with the Shapiro-Wilks test revealed that the variables of hip and knee extension-flexion were normally distributed, whereas the recorded pelvic motions were not. The reliability of the IMU- system with use of the OTS as reference standard was evaluated with calculation of the intraclass correlation coefficient and Bland-Altman plots. Wilcoxon rank test was used to compare the calculated median values with use of the two methods.

The significance level was set at p < 0.05 in all five studies (Study I-V). SPSS 18-22 was used for statistical calculations in all studies. In Study II, the R statistics program was also used.

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## 4. RESULTS

### Study I

The mean differences between the OTS and RSA system in hip flexion, abduction and rotation varied up to 9.5 degrees for the skin-marker models and up to 11.3 degrees for the cluster-marker models respectively (Figure 22-24). Both models tended to underestimate the amount of flexion and abduction, but a significant systematic difference between the marker and RSA evaluations could only be established for recordings of hip abduction using cluster markers (p=0.04). The intra-class correlation coefficient (ICC) (*Table 3*) was 0.7 or higher during flexion for both models and during abduction using skin markers, but it decreased to 0.5-0.6 when abduction motion was studied with cluster markers. During active hip rotation, the two marker models tended to deviate from the RSA recordings in different ways with poor correlations at the end of the motion (ICC  $\leq$  0.4).

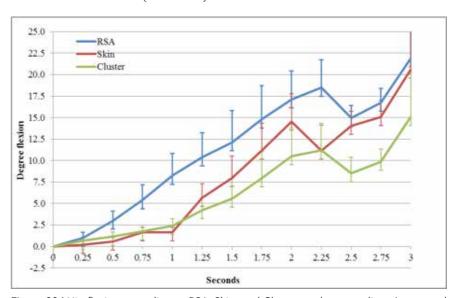


Figure 22  $\mid$  Hip flexion according to RSA, Skin- and Cluster marker recordings (mean and standard error of mean, SEM).

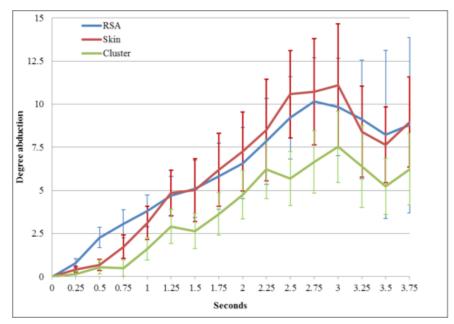


Figure 23 | Hip abduction according to RSA, Skin- and Cluster marker recordings (mean and standard error of mean, SEM).

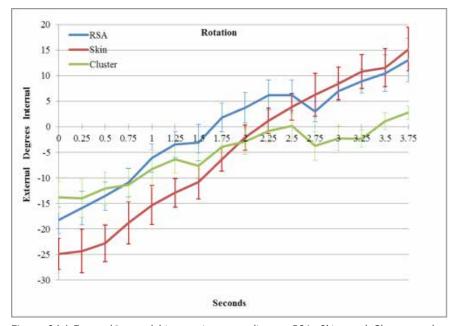


Figure 24 | External/internal hip rotation according to RSA, Skin- and Cluster marker recordings (mean and standard error of mean, SEM)

Table 3 | Intraclass correlation (ICC) between RSA-Skin marker model and RSA-Cluster marker model at 3 time-points start, middle and end. P-values refer to testing using repeated measure ANOVA.

	RSA vs Skin model (p=0.3)	RSA vs Cluster model (p=0.6)
Flexion n=9	ICC	ICC
Start	0.8	0.8
Middle	0.7	0.8
End	0.9	0.9
	RSA vs Skin model (p=0.8)	RSA vs Cluster model (p=0.04)
Abduction n=13	ICC	ICC
Start	0.8	0.5
Middle	0.8	0.6
End	0.7	0.6
	RSA vs Skin model (p=0.9)	RSA vs Cluster model (p=0.1)
Rotation n=14	ICC	ICC
Start	0.7	0.7
Middle	0.3	0.3
End	0.4	0.2

#### Study II

The variability of the extension-flexion recordings was smallest in healthy controls (SD<7.7°), increased in patients with THA (SD<11.1°) and was most pronounced in the OA patients (SD<12.2°). The degree of hip extension-flexion turned out to be the variable that was able most effectively to distinguish the controls from the two patient groups and the patient groups from one another. One to two years after total hip arthroplasty, the gait pattern had improved, but it still differed from normal (Table 4).

### Study III

No or only minimum differences were observed, between or within the two different stem designs during gait, on the two follow-up occasions (Table 5). Comparisons between each of the two stem designs and controls at two years revealed reduced stride length (p=0.009), cadence, hip extension (p<0.001) and hip extension-flexion range (p=0.021) for both designs. Furthermore, the range of hip adduction-abduction (p=0.046) and hip abduction moment for both designs in the frontal plane was also reduced bilaterally (p<0.001).

Table 4 | Standard deviations for each of the parameters presented in Table 2a. P-values refer to comparison of variances (Bartlett's test).

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			Standard	Standard deviations			H vs OA	H vs THA	OA vs THA
	Healthy, examiner 1	Healthy, examiner 2	OA, examiner 1	OA, examiner 2	THA, examiner 1	THA, examiner 2	p-value	p-value	p-value
s/m pəədS	0.14	0.2	0.2	0.2	0.2	0.2	0.142	0.660	0.058
Hip extension degrees	6.0	7.6	11.3	12.2	10.6	11.1	0.664	0.984	0.678
Hip flexion degrees	5.0	7.7	7.9	8.5	8.3	8.8	0.557	0.638	0.907
Hip ext-flex range degrees	4.4	4.8	6.7	6.7	5.5	5.9	0.005	0.521	0.027
Hip abduction degrees	3.1	3.8	4.5	3.9	3.2	3.0	0.807	0.298	0.200
Hip abduction degrees	2.8	4.2	3.9	3.9	3.2	3.0	0.844	0.872	0.720
Hip add-abd range <i>degrees</i>	4.2	4.2	2.7	3.1	2.9	3.4	0.339	0.097	0.010
Hip add moment <i>Nm/kg</i>	0.1	0.1	0.1	0.1	0.1	0.1	0.152	0.143	0.974
Hip abd moment <i>Nm/kg</i>	0.1	0.1	0.4	0.3	0.1	0.2	0.138	0.391	0.021
Hip add-abd moment range Nm/kg	0.2	0.2	0.3	0.3	0.1	0.2	0.555	0.352	0.121

**Table 5**  $\mid$  Gait parameters in the patient group and controls at 1 and 2 years follow up.

		Short stem	tem			Con	Conventional stem	stem		රි	Controls	Short vs. conventional stem	t vs. nal stem	Comparison with controls at 2 years	Comparison with
	One year	¥	Two years		One	One year	Two	Two years				1 year	2 years	Short stem	Conv. Stem
Mean	an 95% C.I.	.l. Mean	95% C.I.	p-value*	Mean	95% C.I.	Mean	95% C.I.	p-value*	Mean	95% C.I.	p-value#	p-value#	p-value#	p-value#
Speed (m/s) 1.1	1.1-1.2	1.1	1.1-1.2	0.4	1.1	1.1-1.2	1.1	1.1-1.2	0.4	1.2	1.2-1.3	1.0	1.0	80.0	0.08
Stride (m)	1.2-1.3	3 1.2	1.2-1.3	0.4	1.2	1.2-1.3	1.2	1.2-1.3	0.4	1.3	1.3-1.4	1.0	1.0	0.009	0.009
Cadence (Steps/min) 79.2	2 73.8- 84.6	80.6	74.7- 86.4	0.3	79.2	73.8- 84.6	9.08	74.7- 86.4	0.3	105.7	102.0- 109.4	1.0	1.0	<0.001	<0.001
Stance (%) 62.3	3 61.5-	61.8	60.9-	0.3	62.8	61.6-	61.5	60.8- 62.2	0.036	61.1	60.6-61.5	0.5	0.7	0.3	0.1
Hip extension degree -4.4	t -6.6-(- 2.1)	-6.1	-8.8-(- 3.3)	0.2	-3.6	-5.5-(- 1.6)	-6.1	-9.1-(- 3.2)	0.2	-12.8	-14.3-(- 11.4)	9.0	0.8	<0.001	<0.001
Hip flexion degree 32.2	2 29.2- 35.3	31.3	28.0- 34.6	0.8	32.4	29.7- 35.1	31.4	28.2- 34.6	0.7	28.1	26.4-29.7	6.0	0.8	90.0	0.037
Hip ext-flex range 36.6 degree	34.3- 38.9	37.4	34.8-	0.8	35.9	33.6- 38.3	37.5	35.0- 39.9	0.1	40.9	39.6-42.2	0.7	0.8	0.020	0.021
Hip adduction degree -2.6	-4.5-(-	-3.0	-4.5-(- 1.6)	9.0	-3.1	-4.6-(- 1.7)	-3.6	-5.0-(- 2.1)	8:0	-4.0	-4.8-(-3.2)	0.5	0.9	0.5	0.4
Hip abduction degree 5.9	4.3-7.5	5 5.7	4.4-7.0	0.5	5.4	4.5-6.4	5.1	3.7-6.5	6.0	6.5	5.6-7.3	0.4	0.4	0.4	0.1
Hip add-abd range 8.4 degree	7.3-9.6	5 8.7	7.7-9.8	0.8	8.6	7.3-9.8	8.6	7.4-9.9	6:0	10.4	9.6-11.3	6.0	0.8	0.03	0.046
Hip adduction moment 0.9 Nm/kg	0.8-0.9	9.0	0.8-0.9	0.4	8.0	0.8-0.9	8.0	0.8-0.9	6:0	0.3	0.2-0.4	0.7	0.8	<0.001	<0.001
Hip abduction moment Nm/kg	-0.3-(-	0.2	0.3-0.2	0.3	-0.2	-0.2-(- 1.9)	-0.2	-0.3-(- 0.2)	0.4	-0.8	-0.8-(0.7)	0.5	9.0	<0.001	<0.001
Hip add-abd moment range Nm/kg	1.0-1.2	1.1	1.0-1.1	0.9	1.0	1.0-1.1	1.	1.0-1.1	0.7	1.1	1.0 - 1.1	9.0	0.9	0.9	0.8

### Study IV

At the last follow-up, five stems and 54 cups had been revised, corresponding to stem and cup survival rates of  $92 \pm 3\%$  and  $45 \pm 5\%$  at 26 years. In all, 66 hips with a remaining Lord stem were available for clinical follow-up 26 years (24-29) after the index operation. The mean total Harris Hip Score and pain scores were 81 (SD 14) and 41 (SD 5) (Table 6). None of the stems was loose, whereas the majority of the cups showed insufficient fixation. Osteolysis was observed in Gruen regions 1 and 7 in almost half the cases. Bone resorption was mainly seen in regions 1, 6 and 7.

Table 6  $\mid$  Specific sub-scores and total Harris Hip Score preoperatively; 10 years and 26 years after THR. Median, (range).

	Preoperatively	10 years	26 years	Difference preop 10 years	Difference 10 - 26 years
Pain Unrevised Cup revised	0 (0-20) 0 (0-30)	44 (20-44) 42 (20-44)	44 (30-44) 40 (30-44)	34 (10-44) 40 (10-44)	0 (-14-20) 0 (-14-24)
Limp Unrevised Cup revised	0 (0-8) 0 (0-8)	9.5 (0-11) 11 (5-11)	11 (0-11) 8 (0-11)	8 (0-11) 8 (0-11)	0 (-11-5) 0 (-6-6)
Walking aids Unrevised Cup revised	2.5 (0-11) 2 (0-11)	11 (3-11) 11 (0-11)	9 (0-11) 7 (0-11)	7 (-2-11) 8 (0-11)	0 (-11-4) -1 (-11-8)
Walking length Unrevised Cup revised	5 (2-8) 2 (2-11)	9.5 (5-11) 11 (5-11)	6.5 (0-11) 5 (0-11)	4.5 (0-9) 6 (-3-9)	0 (-9-6) -3 (-11-6)
Total score* Unrevised	44.5 (10-56) <sup>*</sup>	90.5 (66-100) #	87.5 (46-100) <sup>1</sup>	49 (22-81)	-3.5 (-36-18)
Cup revised	33 (10-81)*	95 (52-100)#	81 (52-100) <sup>1</sup>	61 (19-82)	-12 (-40-48)

<sup>\*6</sup> unrevised and 12 cup revised hips with complete data enabling total score calculation

We performed gait analysis, additional information, after a minimum follow up of 23 years postoperative in 16 patients (18 hips) with Madreporic Lord stem and acetabular component in situ and compared these data with 48 healthy controls (*Table 7*). The healthy controls were younger with a mean age of 57 years compared to 71 years in the Lord group (p<0.001) but with a BMI which was comparable between the groups (p=0.9). The basic gait parameters speed, stride, and cadence was affected (p=0.001), and hip extension and

flexion was less (p=<0.001) and (p=0.01) respectively. In frontal plane hip adduction and range of hip adduction-abduction was also reduced (p<0.009) together with the moments (p<0.001) compared to healthy controls.

Table 7 | Descriptive data, temporal spatial gait parameters, hip kinematics in the sagittal and frontal plane and hip kinetics in the frontal plane. Mean and 95% confidence interval of mean (CI) for 16 patients (18 hips with Lord Madreporic stem) and 48 healthy controls are presented. Nonparametric test (Mann Whitney U) were used.

	Mad	Madreporic Lord		althy, controls	Mann Whitney U test
	Mean	95% CI	Mean	95% CI	p-value
Age	71	67.2 to 74.8	57	54.2 to 59.9	<0.001
Weight kg	70.7	64.2 to 77.1	75.3	71.4 to 79.3	0.09
Length m	1.66	1.61 to 1.70	1.71	1.69 to 1.74	0.008
BMI	25.7	23.9 to 27.5	25.6	24.5 to 26.7	0.9
Speed m/s	1.0	0.9 to 1.1	1.2	1.1 to 1.2	0.001
Stride m	1.1	1.0 to 1.2	1.3	1.3 to 1.4	<0.001
Cadence Step/min	73.6	66.3 to 81.0	104	99.7 to 108	<0.001
Stance %	61.8	60.2 to 63.4	61.3	60.7 to 61.9	0.60
Hip extension degrees	-3.7	-7.1 to -0.3	-13.9	-15.5 to 12.3	<0.001
Hip flexion degrees	31.1	27.3 to 34.9	26.9	25.1 to 28.8	0.01
Hip ext-flex range degrees	34.8	30.4 to 39.2	40.8	39.2 to 42.4	0.058
Hip adduction degrees	-1.0	-2.8 to 0.7	-3.5	-4.3 to -2.6	0.009
Hip abduction degrees	6.1	4.7 to 7.6	6.5	5.5 to 7.5	0.62
Hip add-abd range degrees	7.2	6.0 to 8.3	10.0	9.0 to 10.4	0.002
Hip add moment Nm/kg	0.60	0.51 to 0.70	0.30	0.23 to 0.37	<0.001
Hip abd moment Nm/kg	-0.18	-0.21 to -0.16	-0.78	-0.85 to -0.69	<0.001
Hip add-abd moment range <i>Nm/kg</i>	0.79	0.69 to 0.88	1.1	1.01 to 1.12	<0.001

<sup>#20</sup> unrevised and 37 cup revised hips with complete data enabling total score calculation

<sup>&</sup>lt;sup>1</sup>24 unrevised and 42 cup revised hips with complete data enabling total score calculation

### Study V

The comparison between the two gait analysis methods revealed no significant difference for the mean pelvic tilt range (4.9 vs. 5.4 degrees) or the mean knee flexion range (54.4 vs. 55.1 degrees) on either side (p>0.7) (Table 8). The IMU system did, however, record slightly less hip flexion on right and left sides 36.8 and 37.7 degrees for the OTS compared with 34.0 and 34.4 degrees for the IMU, p<0.001).

Table 8 | Gait parameters for optical tracking system (OTS) and inertial measurement units (IMU).

		OTS			IMU		Wilcoxon	Intraclass correlation
	Mean	95% C.I.	Median	Mean	95% C.I.	Median	p-value#	ICC (CI) ¤
Pelvic range degree	5.4	4.5-6.3	4.5	4.9*	4.4-5.3	4.6	0.95	0.08 (-0.20- 0.35)
Hip ext/flex range right degree	36.8	35.2- 38.5	36.2	34.0	32.2- 35.9	33.4	<0.001	0.75 (0.34-0.89)
Hip ext/flex range left degree	37.7	36.0- 39.4	38.3	34.4	32.7- 36.2	34.4	<0.001	0.73 (0.22-0.89)
Knee ext/flex range right degree	55.1	53.5- 56.7	55.0	54.9	53.1- 56.6	53.9	0.75	0.83 (0.72-0.90)
Knee ext/ flex range left degree	54.4	52.8- 55.9	54.2	54.4	52.8- 56.0	54.9	0.69	0.86 (0.77-0.92)

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<sup>\*</sup>Mean of right and left side

<sup>\*</sup> P-values refer to Wilcoxon sign ranks test between OTS and IMU

<sup>&</sup>lt;sup>n</sup> Intraclass correlation coefficient (ICC) and 95% confidence interval (CI)

### 5. DISCUSSION

#### Validity and reliability

Optical tracking systems are based on the presumption that the kinematic data that are recorded mirror the true skeletal motions occurring during an examination reasonably well. Studies that explore the true influence of soft-tissue artefacts are, however, rare [53, 57]. Ideally, studies of this kind should be available for different marker qualities, recording systems and marker placements used with the OTS systems now in use. One way to quantify soft-tissue artefacts is to use the RSA as a validation method for the non-invasive OTS method. RSA is an invasive, marker-based method that can be used to measure joint motions. Even if RSA can be regarded as the "gold standard" for studying skeletal motions [31-43], this method has its limitations. Only a few laboratories in the world are able to conduct dynamic studies and the number and types of joint motion that can be recorded are limited, due to radiation issues and limitations related to the field of view and the radiographic set-up.

In Study I, the patients performed three separate dynamic motions with the main load on the hip of interest. The first series of sequential radiographs were exposed when the patients flexed their hip and performed a squat in the sagittal plane. This motion has similarities to parts of stair climbing, for example. In the second series, the patients performed abduction in the frontal plane, which has similarities to limping. Finally, the subjects were instructed to perform a rotation of the hip corresponding to making a twist or turning. This motion was made from maximum external to maximum internal rotation in the coronal plane. All the motions had to be performed at a relatively slow pace due to technical limitations related to the performance of the roentgen generators and the image quality obtained. The motions that were studied are therefore selections of motions that may actually occur, but they nonetheless represent common ranges of motion during daily activities.

The choice of marker positions most probably influences the magnitude of soft-tissue artefacts, but this question has not been studied in detail. Intuitively, it should be the case that, the less soft tissue, the fewer the artefacts. It might be that the inferior results observed with the cluster-marker model could be attributed at least in part to this factor, because the cluster markers were placed on locations with more underlying soft tissue compared with the skin markers. If the soft tissues happen to displace in the same direction as the motion direction of interest, they might magnify or reduce the recorded values. If they displace in a direction perpendicular to this motion, the error might be smaller. In reality, the displacement can be expected to be more or less multidirectional and perhaps also unpredictable, which calls for experimental studies to delineate this problem more precisely.

In Study I, the cameras were much closer to the performed motion than during regular gait examinations in the gait laboratory, which will affect the resolution of each marker position in some way. The subjects performed motions or sequences which may correspond to parts of a gait cycle but without any forward propulsion, which might diverge from the situation occurring during normal gait. The dynamic pace/velocity was also slower than during normal gait, due to the comparatively slow digital screens exposing four images a second. Furthermore, there was limited visibility in front of the 40-degree angled roentgen cameras and the digital screens, which made it difficult for some patients to stay in the field of radiation, thereby limiting the number of approved examinations. The implication of these circumstances in terms of the observed results is unknown, but it might be that the differences have been underestimated due to lower speed of motion compared with normal gait and the well-controlled patterns of motion during the standardised examinations.

Compared with the only dynamic RSA study of the hip performed by Digas et al. that has previously been published, the number of drop-outs was, however, about the same. These authors used dynamic radiostereometric examination at two exposures/s. In contrast to our examination technique, active abduction was studied with weight-bearing on the opposite leg to evaluate femoral head translations and cup displacements.<sup>[37]</sup> So far, our study is therefore the only one that has evaluated the resolution of hip motions with OTA using skeletal motions recorded with RSA as a reference standard.

The RSA technique is an invasive method, as the accurate determination of skeletal motions with high resolution requires the use of implanted markers or implants. In Study I, patients who had undergone THA and were already equipped with bone markers were used. This opens the door to speculation about whether these hips have a normal motion pattern. During the insertion of a THA, bone and remaining cartilage are removed and the surgery itself interferes to a varying degree with the soft tissues. This means, as demonstrated in Studies II and III, that the hip motions are not normal and that the reproducibility of the hip motions might be slightly inferior compared with the situation in the normal hip. Since the recording with RSA and OTS took place simultaneously, it seems improbable that the choice of patients with THA influenced the differences observed between the two methods to any significant degree. Nonetheless, further studies of other types of activity and also patient populations with normal joints or hip disease might be desirable.

During the examination of flexion, both marker models underestimated

the amount of skeletal motion during the first five degrees. Thereafter, the difference tended to remain fairly constant and was about five degrees for the skin model and seven degrees for the cluster model, with reasonable or good agreement between the methods (ICC values between 0.7-0.9). The reason for this underestimation of flexion is probably the contraction of the thigh muscles during hip flexion. As previously mentioned, the skin markers are placed on skeletal landmarks covered with a comparatively thin layer of soft tissue, which might explain why this model was superior to the cluster model. The cluster markers are fixed with strapping around the leg. This tighter fixation to the skin and slight compression of the soft tissues should theoretically reduce soft-tissue artefacts, but seemingly not well enough. It might be that the strapping even has the opposite effect by displacing the soft tissues in a way that obscures the true skeletal motions.<sup>[30]</sup>

Movement into loaded abduction of up to 15 degrees by swaying the body laterally appeared to be easier to detect for both marker protocols. Again, soft-tissue motions, especially in front of the abdomen, might have caused artefacts, especially as the true amount of abduction in many of the patients was comparatively small. The mean BMI in our patients was 27.6 (SD 3.9), corresponding to "overweight" according to the WHO. This average does, however, correspond fairly well to the average of all patients undergoing a THA in Sweden (Swedish Hip Arthroplasty Register Annual Report 2013 www.shpr.se). The subjects in this study underwent surgery over a period of several years, with different surgical approaches and different types of THA, which could have influenced their ability to perform an abduction of the hip. It does not, however, seem reasonable to think that this source of variation had any influence on our comparisons. [27, 30, 57]

During hip rotation, both marker models showed a pronounced mean divergence. The overall differences corresponding to the presence of any systematic error or "off-set" did not, however, reach significance, probably because of poor statistical power and comparatively high individual variability. Based on the available observations, the cluster-marker model showed five degrees of underestimation and the skin-marker model almost five degrees of overestimation at the starting position. The skin-marker model recorded neutral rotation of the hip about 0.5 seconds later than the RSA recordings and, in the case of the cluster-marker model, the delay exceeded 1.5 seconds. With proceeding internal rotation, the cluster model in particular failed to react. The reason for this is not known, but factors such as decreasing marker visibility and the inherent restriction of the cluster markers, tightly strapped to the leg, might have had some effect. The total range of rotation extended over more than 40 degrees for some of the patients. With the hip in extreme external or internal rotation, this might occur during some types of sport, but this is rarely studied with an OTS.

In an OTS, the positions of the hip joint centres are calculated, based on the position of the two skin markers attached on SIAS and the sacrum marker. If these calculations are skewed, due to incorrect marker positioning, this could lead to a different alignment of the segment co-ordinate systems, even if the same mathematical principle is used. In this study, we define the pelvis segment and hip joints by using a modified CODA pelvis. The location of the hip joint centres is calculated in relation to skin markers located at the pelvis segment. Individual variations in soft-tissue mass and body constitution will probably mean that errors related to the OTS technique will vary between patients, but, according to our study, there are nonetheless systematic errors mainly related to recordings of hip abduction and probably also hip flexion (p=0.06) using cluster markers. [21, 22, 57, 79]

One of the strengths of this study is the use of a radiostereometric system, which is probably the most accurate validation tool when subjects perform different dynamic bone movements. Fine-tuning the examination technique and using supporting frames and handles to guide the patient, as far as possible, to stay within the field of radiation might be one way to improve the examination technique.

In Study II, the reproducibility of the measurements varied between patient groups, indicating that the observed errors are at least partly associated with the studied condition. The data scatter might therefore be more pronounced in patients with different types of gait abnormality than in patients without any disease or condition which influences the walking pattern. The data scatter might also vary between patients with different types of disease, because the ability of an individual patient to reproduce his/her pattern of gait from one examination to another might vary, depending on the type of disease. As a result, data relating to reproducibility in "normals" cannot always be directly transferred to studies of patient groups with various diseases. Our observations instead indicate that the reproducibility of OTS should preferably be tested for each individual patient group and especially in groups where the pattern of motion is known to display pronounced deviations from normal.

Hip osteoarthritis (OA) results in reduced joint mobility, stiffness and gait dysfunction, due to the destruction of the joint, pain and the development of contractures. After a total hip arthroplasty, the aim is for joint function to become normal and for most of the pain to disappear more or less completely. Previous studies of the walking pattern after THA have, however, shown that gait does not return to normal, [9, 80, 81] as was also observed by us in Studies II and III. Even if the reason for this is not known, it is possible to speculate that any remaining contracture or dysfunction of the muscles surrounding the hip joint due to atrophy could be of importance. The establishment of an abnormal walking pattern during the progression of the hip disease may become habitual with time and this could be another explanation.

Ornetti et al. (2010) made a systematic review of OTS studies of subjects with hip and knee osteoarthritis (OA). Eleven hip studies comprising 343 hip OA patients were found and one study reported test-retest reliability data. This study reported a variation of 10% for gait speed and stride and 20% for hip angles in the sagittal plane. This study made assessments at an interval of one month. The authors found two studies of hip OA patients comparing the Lequesne index and the WOMAC with gait analysis. There was good correlation between the Lequesne index and both gait speed and hip flexion. A weak correlation was also found between the WOMAC, gait speed and stride length. Seven studies have found that hip OA patients have reduced gait speed and stride length, with a mean reduction of 13% and 8% respectively. Reduced hip extension was found in all the studies, whereas reduced hip flexion was only observed in some of them. [82-84] Two studies comprising 42 patients reported that speed and stride length were able to distinguish OA patients from normal individuals, with an effect size of 0.40-1.41. They concluded that there still is lack of validated and reliable kinematic data that can be used to distinguish between normal subjects and subjects with OA.[66]

A bilateral hip osteoarthritis gait analysis study was performed in 12 subjects compared with 12 healthy subjects. Temporal-spatial gait parameters were all affected, with lower gait speed, step length and cadence. The pelvis was tilted forward, with less peak extension and a smaller abduction angle, together with less peak abduction moment in the hip joint, which instead results in high cadence and power generation in the ankle joints. [85]

In 2014, Constantinou et al. conducted a systematic review and meta-analysis of spatial and temporal gait parameters in hip OA subjects including 30 articles. They found that the self-selected speed was 26% slower than that of healthy controls, with shorter stride length and greater asymmetry and also shorter stance time in the affected limb.

We were able to confirm that patients with hip OA had a slower walking speed and reduced hip extension. We also observed reduced abduction, range of hip extension-flexion, range of adduction-abduction, reduced adduction moment and range of adduction-abduction moment. After adjusting for covariates such as age and BMI, speed and adduction moment differences decreased or became insignificant. The remaining decrease in the flexion-extension range is compatible with a remaining decrease in stride length, but it

could also be a functional adaptation to persistent abductor weakness.

Significantly reduced peak hip abduction moment in THA patients compared with controls was observed by Beaulieu et al. [80] Foucher et al. and Nantel et al. also observed reduced abduction moments, but this reduction did not reach significance. [86, 87] In the review presented by Ewen et al., including the three above-mentioned articles, a reduced peak hip abduction moment with an overall effect size of 0.539 (CI = -0.575/-0.064;  $I^2=41.2\%$ ) was noted in the THR group, with a negative effect, indicating a reduced peak hip abduction moment.[9]

Short femoral stems have the potential to offer better hip function and improved gait by facilitating the insertion. Many patients with hip osteoarthritis suffer from bilateral disease and it might be that the status of the opposite hip has an influence in those cases. In Study II, patients with unilateral THA had no symptoms from the opposite side, but radiographs revealed radiographic signs of osteoarthritis in seven of them. According to our observations, it does, however, seem that operating on both hips in patients with bilateral OA results in about the same deviation from normal gait as observed in cases only operated on one side.

Several studies of short stems with varying designs have shown similar clinical outcomes when compared with stems of standard length after various follow-up periods [88-91]. We performed one-stage bilateral operations and found no or only minimal differences in gait parameters between the two sides undergoing short stem and conventional hip arthroplasty. Compared with healthy controls, both sides showed reduced hip extension, reduced range of flexion-extension and reduced abduction moment.

In Study III, each patient was his or her own control, which should minimise the influence of any confounding factors. One potential limitation is, however, the fact that there might have been unknown differences in muscle strength between the groups of hips with different implants. The extent to which this influenced the results is unclear, but the presence of these differences should be less likely due to the randomisation process in which the most painful hip or the one with the most pronounced degenerative changes was randomised to one of two stems.

It appears that the OTS is able to differentiate gait between healthy controls and patients that have undergone THA surgery in general and in patients that have developed OA. There are, however, several intrinsic and extrinsic factors that may influence the outcome of THA surgery, which makes the reason for the gait disturbance difficult to determine. The influence of the contralateral side is one confounding factor which also influences the gait pattern in some way. In Study II, a comparison between groups of THA and

OA patients was performed with healthy subjects. The contralateral side was examined in order to ascertain that a diseased hip on the opposite side also had an influence on the studied gait parameters. In Study III, both hips underwent surgery at the same time and were randomised to different THA designs. This means that, in our study, each patient was his/her own control, which should minimise the influence of any confounding factors. In spite of this, the 22 patients who were examined exhibited the same movement pattern as patients after unilateral THA surgery.

The gait analysis of THA patients may raise questions about the extent to which gait can deviate from normal and have any influence on patient satisfaction, performance and the risk of late implant failure. Further studies including PROM data and CT-based determinations of implant positioning and offset, in addition to gait analyses preferably preoperatively and about one year after the operation with further long-term follow-up, are necessary to answer these questions.

In Study V, we observed a 26-year survival rate of the stem using all the reasons for revision as the end-point of 95% and a corresponding survival rate of 65% for the cup. These observations concur fairly well with or may even be somewhat superior to previous and contemporary observations in the literature. Overall good long-term results have been reported for fully coated uncemented stems even in younger patients (Eskelinen et al. 2005). According to a similar study also from the Finnish Arthroplasty Register, the 15-year survival of the Lord Madreporic stem in patients younger than 55 years was only surpassed by the Bi-Metric and reached 90%, based on any stem revision as the outcome. [92] Later on, excellent long-term survival based on mechanical failure as the outcome has been reported for other uncemented stem designs. [93, 94] Grant and Nordsletten (2004) followed 59 patients (70 hips) undergoing surgery with a Lord stem in a prospective study. After 17.5 years, they observed 98% survival of the stem and 65% for the cup, based on any kind of mechanical failure or radiographic signs of loosening as the endpoint. Similar observations were made by Inoue et al., who reported a stem survival of 96.9% after 16 years. [95]

Our study was initiated in 1979 to address the loosening problem that was starting to become evident with cemented fixation in young patients at this time. In 1987, however, the Madreporic Lord THR was abandoned because of concerns about possible negative effects of stress shielding over time. Later on, the poor fixation of smooth threaded cups was reported and high revision rates were observed [96, 97]. The uncemented Lord cup did not address the loosening problem, whereas, at least in our study with only a few dedicated

surgeons involved, the stem reached survival comparable to that reported for cemented stems with a polished surface. [98] These authors performed a systematic review of cemented femoral stems with a minimum follow-up of 20 years. They observed better survival as regards aseptic loosening for polished stems reaching 93.5 to 98% at 20 years compared with stems with a rougher surface finish.

Even if there was a clear tendency towards increased bone loss proximally, the radiographic evaluation indicated wide individual variability. Female gender and the length of the stem were able to predict the amount of loss of bone mineral density to some extent, but the degree of explanation in the regression analysis (r<sup>2</sup>-value) was poor.

Merle and Streit et al. [99] used DXA to measure bone remodelling between 12 and 17 years around the uncemented CLS® stem and noted a minor decrease in most regions during this period. Despite the fact that the CLS® stem with its tapered design might transfer more load proximally, the recorded BMD in regions 1 and 7 was fairly similar to ours. In the proximal region, factors other than stress shielding will influence the rate of bone resorption and particle-induced synovitis in particular and will increase joint fluid pressure. Distally, in regions 3-5, the Madreporic Lord stems did, however, appear to have lost more bone than the CLS® stems in the study mentioned above, with an average difference of about 0.2 g/cm<sup>2</sup>. Several confounders and not least the absence of preoperative data in both studies obscure this comparison.

There are concerns that progressive stress shielding around uncemented stems will result in loosening in the long term [100-103]. In the present study, only one stem loosened and this loosening occurred at an early stage. To our knowledge, there is no case of stem loosening that can only be related to severe stress shielding. The loss of bone mineral around uncemented stems does, however, have clinical implications, because the results of any revision due to infection or other reasons might be jeopardised by extensive proximal bone loss. As the proximal bone becomes thinner and even disappears, the stem is unsupported by bone, with an increased risk of implant fracture [95]. We had two such fractures. In one case, the stem broke 5 cm distal to the shoulder, probably because this part of the stem had lost its bone support. In the second case, there was a neck fracture, probably initiated by taper corrosion [104, 105]. A similar case has previously been reported [106]. These fractures occurred 17 and 20 years after the primary operation. Since several stems had lost their proximal bone support, in our follow-up, further fractures could be anticipated during the third decade after the operation. To date, no further implant fractures have been observed.

We also performed gait analysis, unpublished data, a minimum of 23 years postoperatively in 16 patients (18 hips) with Madreporic Lord stems and acetabular components in situ compared with 48 healthy controls. The results indicated that most of the basic gait parameters, such as speed, stride, cadence and hip kinematics in the sagittal and frontal plane, were significant (p<0.009). Even with a comparable BMI (p=0.9), the healthy control group was significantly younger (p=<0.001), which could influence the outcome. In a longer perspective, this comparison indicates that some of the hip kinematic and kinetic variables, together with basic gait parameters, remain over time.

To summarise, our Madreporic Lord stems showed excellent fixation in a 26-year perspective. The main problem with this stem is proximal bone loss caused partly by stress shielding and partly by particle-induced inflammatory osteolysis. This problem raises concerns about further future revisions due to implant fracture. The extent to which this problem can be reduced in modern designs using improved metallurgy and better articulation materials remains to be seen.

Patient dissatisfaction with the movement pattern after THA could have several reasons. Expectations could be too high due to insufficient information or unexpected complications might have occurred. After the hip has been replaced, symptoms due to general osteoarthritis in the spine or other loaded joints, for example, might become more evident. Further studies of remaining mobility problems such as this must therefore not only include the hip. Nonetheless, the hip joint and its function are of primary interest if patients are dissatisfied with the outcome of the operation.

Gait analysis based on optical systems is a comparatively time-consuming examination requiring resources in terms of advanced equipment, data analysis and interpretation. The use of simpler devices that can be used to scan important gait parameters in a larger cohort of patients is therefore of interest in order to find patients who are dissatisfied due to poor hip function. However, the question of whether recordings of only range of hip flexion-extension could be used to select patients with complaints relating to inferior hip function for further analysis after THA remains to be studied.

Unlike the OTS system, the IMU-based systems all use their own algorithms. IMU and OTS comparison studies therefore refer to specific systems. McCarthy et al. used the same system as in the present study to compare the OTS with the IMU system to measure knee flexion range. The conclusion was that there was no statistical difference between the two

systems, which supports the findings of this study.

In 2014, Leardini et al. performed a reliability and validity study of an IMU system (RiabloTM; Trento, Italy) using the OTS [107]. The accuracy was tested in 17 healthy subjects with five different rehabilitation exercises which were repeated twice, including re-mounting the IMUs. The OTS was used simultaneously to record thorax and knee flexion angles in the sagittal plane with attached reflective markers. Thoracic motions were measured in relation to the laboratory co-ordinate system and the thigh and shank relative to one another. Synchronisation between the systems was made visually. The reliability of positioning the IMU sensors was acceptable for rehabilitation programmes due to the shape of the IMU, including an alarm when the malalignment was greater than 15° during calibration. Furthermore, the results from the validation using the OTS showed a mean difference of 5° in knee flexion and 3° in thorax flexion between systems. This discrepancy is higher than the difference between OTS and IMU systems that was observed for knee motion in the present study, which did not reach statistical significance.

Bolink et al. compared a single IMU sensor with OTS recordings of pelvic movements during gait in 17 healthy subjects [108]. The error of the IMU system was estimated at 2.7°, which is higher than in this study, although the correlation between the two methods was high (rho= 0.92), which is also in contrast to our observations.

The IMUs and the OTS system use a global co-ordinate system, but the correlation between the data for recorded pelvic movements was nonetheless poor. It should, however, be noted that the measured values for pelvic tilt were small. Soft-tissue motion around the pelvis generates about the same magnitude of errors as when recording hip and knee flexion. The relative influence of the error when related to the magnitude of the recorded value will therefore be larger than for measurements of hip and knee motions. Another source of error could be that the definition of the pelvic position is based on skin markers initially attached overlying skeletal landmarks. The proximity of the landmark and the IMU sensors may be lost by the time the investigation starts. This will cause inaccuracy in measurements of the rotation of the pelvis in the sagittal plane due to different starting positions according to the global co-ordinate system. Positioning the IMU sensors on the pelvis (left and right) will not take account of the amount of pelvic tilt compared with the OTS in a standing still position. Another difference is that the OTS uses one pelvic segment and the IMU system uses two separate sensors (left and right) during calculations, assuming that the left and right pelvis move independently. The mean value of the two

sensors (left and right) was used in the comparison of the two systems. This might allow the range of motion to slide relative to one another in the sagittal plane. Furthermore, the OTS calculates hip motions relative to the pelvis co-ordinate system and knee motions relative to the co-ordinate system of the thighs. The IMU system calculates the sagittal angles between the segments relative to the global co-ordinate system defined by an axis of rotation that is not constrained to lie in either the sagittal or frontal planes. It is also important to be aware that there is a certain amount of movement in the other planes which can generate cross-talk, which, at least to some extent, could obscure the results. Despite these potential sources of error, the two systems showed a comparatively high degree of agreement when measuring range of hip and knee motions in the sagittal plane.

## 6. CONCLUSIONS

## Study I

During active hip motions, soft-tissue displacements occasionally induced considerable differences when compared with skeletal motions. The best correlation between RSA recordings and the skin- and cluster-marker model was found for studies of hip flexion and abduction with the skin-marker model. Studies of hip abduction using cluster markers were associated with a constant underestimation of the motion. Recordings of skeletal motions using skin or cluster markers during hip rotation were associated with high mean errors amounting to about 10 degrees in certain positions.

## Study II

Patients with hip osteoarthritis showed the poorest repeatability between gait recordings collected by different examiners, as compared to patients undergoing a THA and healthy controls. The walking pattern after THA still differed from that of healthy controls one to two years after the operation.

## Study III

We found no difference in gait parameters between the short and the conventional stem after one-stage bilateral total hip arthroplasty. Although both hip joints were operated on at the same time, motions and moments did not normalise after bilateral one-stage operations.

## Study IV

The study population displayed comparatively good function after 26 years, despite the fact that more than half the population had undergone revision of the cup once or twice. The documented poor fixation of the original Madreporic Lord cup continued to cause revisions in both the second and third decade after insertion. The Lord stem showed a high survival rate and the clinical results were acceptable after revision of the cup.

## Study V

We found that inertial measurement units are able to produce reliable data in range of motion in the pelvis and knee flexion-extension range. Slightly less hip flexion was recorded with the inertial measurement units.

## 7. FUTURE PERSPECTIVES

The gait analysis method has areas which need to be improved from the patient and community perspectives. A camera technique with higher resolution would make it possible to use smaller reflective markers which might reduce soft-tissue artefacts. There is therefore a need for further studies of modified markers, in addition to studies of alternative placement. The development of mathematical models to define the true position of the joint for different types of body constitution could improve the resolution of optical tracking systems.

The further development of the examination technique during dynamic RSA studies (e.g. use of a treadmill in front of an RSA system) would facilitate future studies and the validation of the OTS system.

Further comparisons between OTS recordings and simultaneous measurements with dynamic RSA, including joints other than the hip, should be performed.

Another possible way to improve the resolution is to find mathematical algorithms that are able to compensate for soft-tissue artefacts. These algorithms should be validated against dynamic RSA studies of the corresponding joints.

Further studies are needed to evaluate the extent to which gait analyses could be used to distinguish patients who report remaining problems after THA due to mobility complaints with causes that can be related to implant positioning or insufficient muscular function from those who are dissatisfied for other reasons.

Further studies should be conducted to determine whether gait analyses using a more finely tuned approach are able to distinguish different functional deficiencies after THA and relate these findings to possible reasons for their presence. If so, this method should occupy a firmer position in the diagnosis and treatment of remaining problems and complications after THA.

Further studies of motion analysis systems that are not based on reflective markers should be conducted. If data from these systems (e.g. IMU based) are able to provide relevant information with sufficient resolution, this would facilitate studies of larger patient populations.

In order to make gait analysis easier to use, models without reflective markers, using the body shape together with BMI, should be used when developing new software.

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## **APPENDIX**

### HARRIS HIP SCORE mm. Personnr. Sida Höger Vänster Gångsträcka 11. Obegränsad 8. 1.5 – 2 km Undersökningsdatum 5. 0.5 – 1 km 2. <500m, mest inomhus 0. Säng, rullstolsbunden Klinik 15. Mölndal ADL - trappgång Använder ej ledstång/räcke Använder ledstång/räcke Tid efter op år 1. Klarar med svårighet 0. Klarar ej trappor Medicinering med bisfosfonat (eller motsv.) 2. Ja, ange preparat + dos .... ADL - påklädning Tar på sig skor och strumpor 4. Utan svårighet Medicinering med kalcium +/- D-vitamin 2. Med svårighet 1. Nej 2. Ja, ange preparat + dos 0. Kan ej ADL - sitta 5. Bekvämt i stol 3. På hög stol i 30 min Medicinering med cortison 0. Kan ej sitta bekvämt 1. Nej 2. Ja, ange preparat + dos ADL – använder allmänna kommunikationsmedel 1. Ja 0. Nej Medicinering med NSAID (tom 1 v. preop) Höftrörlighet 2. Ja, ange preparat + dos Extension extensionsdefekt = neg. värde Flexion Inatrotation om fix utatrotation = neg. värde Smärta 0-44 44. Ingen, eller obetydlig 40. Lätt, begränsar dock ej aktivitetsnivån 30. Lätt smärta, ej påverkan daglig aktivitet, ibland analgetika Utåtrotation Abduktion om fix adduktion = neg. värde 20. Smärtan begränsar aktiviteter, regelbundet analgetika Adduktion 10. Uttalad smärta stark begränsning av aktiviteter Invalidiserad, vilovärk Benlängdskillnad i mm 100 Nej Hälta 2. Hö längre i mm 11. Ingen 3. Vä längre i mm 8. Lätt 5. Måttlig Trendelenburg 0. Uttalad 1. Negativ Positiv 3. Osäker Gånghjälpmedel 11. Inget 7. Käpp vid långa promenader eller motsv.5. Käpp, nästan alltid eller alltid Charnleyklass 1. 1 höft sjuk, i övr. frisk 3. 1 krycka 2. Bilat höftsjd, i övrigt frisk 2. 2 käppar, rullator

UPPFÖLJNING

0. 2 kryckor, rullstol

3. Flera leder påverkade, annat gånghandikapp
4. Bilat höftsjd, en höft opererad

5. Bilat höftproteser

VAS skala belastningssmärta	Fysisk aktivitetsnivå	
VAS skala vilovärk	Inget     Promenad     Simning     Cykling	
Nytillkommen komplikation	4. Löpning, joggning 5. Kombination; annat	
0. Ingen	, , , , , , , , , , , , , , , , , , , ,	
Luxation (endast en)     Luxation (2 eller fler)	Frekvens av fysisk aktivitet	
3. Infektion (protes kvar)	1. Dagligen	
Radiol lossning cup	2. 2-5 ggr/vecka	
Radiol lossning stam	3. 1 gång per vecka	
6. 4+5	4. < 1 gång/vecka	
7. Annat ange	 5. Vill/kan ej motionera	
	 Patientens åsikt om operationen	
	1. Nöjd	
	2. Tveksam	

3. Missnöjd

Rev 070905



Svensk version

(Swedish version for Sweden)

Kryssa under varje rubrik bara i EN ruta som bäst beskriver din hälsa I	)AG
RÖRLIGHET	
Jag har inga svårigheter med att gå omkring	
Jag har lite svårigheter med att gå omkring	
Jag har måttliga svårigheter med att gå omkring	
Jag har stora svårigheter med att gå omkring	
Jag kan inte gå omkring	
PERSONLIG VÅRD	
Jag har inga svårigheter med att tvätta mig eller klä mig	
Jag har lite svårigheter med att tvätta mig eller klä mig	
Jag har måttliga svårigheter med att tvätta mig eller klä mig	
Jag har stora svårigheter med att tvätta mig eller klä mig	
Jag kan inte tvätta mig eller klä mig	
VANLIGA AKTIVITETER (t ex arbete, studier, hushållssysslor, familje-	elle
fritidsaktiviteter)	
Jag har inga svårigheter med att utföra mina vanliga aktiviteter	
Jag har lite svårigheter med att utföra mina vanliga aktiviteter	
Jag har måttliga svårigheter med att utföra mina vanliga aktiviteter	
Jag har stora svårigheter med att utföra mina vanliga aktiviteter	
Jag kan inte utföra mina vanliga aktiviteter	
SMÄRTOR/BESVÄR	
Jag har varken smärtor eller besvär	
Jag har lätta smärtor eller besvär	
Jag har måttliga smärtor eller besvär	
Jag har svåra smärtor eller besvär	
Jag har extrema smärtor eller besvär	
ORO/NEDSTÄMDHET	_
Jag är varken orolig eller nedstämd	
Jag är lite orolig eller nedstämd	

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Jag är ganska orolig eller nedstämd

Jag är mycket orolig eller nedstämd

Jag är extremt orolig eller nedstämd

# Bästa hälsa du kan tänka dig • Vi vill veta hur bra eller dålig din hälsa är IDAG. • Den här skalan är numrerad från 0 till 100. • 100 är den bästa hälsa du kan tänka dig. 0 är den sämsta hälsa du kan tänka dig. • Sätt ett X på skalan för att visa hur din hälsa är IDAG. • Skriv nu i rutan nedan det nummer du har markerat på skalan. DIN HÄLSA IDAG = Sämsta hälsa du

100

95

75

70

65

60

55

50

45

40

35

30

25

20

15

10

kan tänka dig

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