From THE DEPARTMENT OF MOLECULAR MEDICINE AND SURGERY SECTION OF ORTHOPAEDICS AND SPORT MEDICINE
Karolinska Institutet, Stockholm, Sweden

ESTIMATING POLYETHYLENE WEAR IN TOTAL HIP ARTHROPLASTY BY USING COMPUTED TOMOGRAPHY AND ALTERNATIVE RSA TECHNIQUES

Dov Goldvasser

Stockholm 2014

Published by Karolinska Institutet.
Printed by Universitetsservice US-AB

ISBN 978-91-7549-658-0

Department of Molecular Medicine and Surgery

Estimating Polyethylene Wear in Total Hip Arthroplasty by Using Computed Tomography and Alternative RSA Techniques

THESIS FOR DOCTORAL DEGREE (Ph.D.)

By

Dov Goldvasser

Defense of the thesis will take place on Friday 17 October at 9.00 in Granitsalen, Eugeniahemmet T4:00, Karolinska University Hospital, Solna

Principal Supervisor:
Lars Weidenhielm, Professor
Karolinska Institutet
Department of Orthopaedic Surgery
Division of Molecular Medicine
and Surgery

Co-supervisor(s):
Henrik Malchau, Professor
Harvard University
Massachusetts General Hospital
Harris Orthopaedic Laboratory
Department of Orthopaedic Surgery
Henrik Olivecrona, MD PhD
Karolinska Institutet
Department of Orthopaedic Surgery
Division of Molecular Medicine
and Surgery
Charles Bragdon, PhD
Harvard University
Massachusetts General Hospital
Harris Orthopaedic Laboratory
Department of Orthopaedic Surgery

Opponent:
Leif Ryd, Docent
Lund University
Department of Orthopaedics
Division of Medicine

Examination Board:
Hans Berg, Docent
Karolinska University
Department of Clintec
Orthopaedics and Biotechnology
Rüdiger Weiss, Docent
Karolinska University
Molecular Medicine and Surgery
Division of Orthopaedics
Elena M. Gutierrez-Farewik, Docent
Inst. for Mekanik, KTH
KTH Mechanics
Royal Institute of Technology

TO MY FAMILY

ABSTRACT

Introduction: Traditionally Total Hip Arthroplasty (THA) components performance, and in particular the performance of the polyethylene liner, is evaluated in 2D by examining plain radiographs or in 3D using Radio Stereo-metric Analysis (RSA). While 2D techniques require only a plain radiograph, they are less accurate. RSA systems, on the other hand, are more accurate but are more complicated to set up and require dedicated equipment. CT scanners are widely available and can measure THA performance in 3D. These techniques fail to estimate wear when tantalum cups are implanted, and alternative methods are needed.

Specific Aims: Validate a Computerized Tomography (CT) technique for evaluating THA wear, develop and test algorithms to estimate wear in THA when tantalum cups are implanted.

Methods: To validate the 3D CT data and software, a supine hip phantom fitted with a 3-axis micrometer tower was scanned, first (as a feasibilty study) in an experimental ultra-high resolution flat panel CT scanner and then in a multi-detector CT scanner. The micrometers were displaced in the x, y, and z axes, displacement of the micrometers (femoral head) was estimated and then compared to the actual micrometer readings (studies I and II). Wear was also estimated from clinical CT data of patients that had their THA revised: images were analyzed and compared to a coordinate measurement machine (CMM) and a micrometer (study III). For the analysis of liner wear when tantalum cups are used, four methods were tested: standard RSA, Model Based RSA, RSA-Helical axis, and RSA Center of Rotation. To test these methods a supine hip phantom was used and the femur was abducted. The center of the femoral head was calculated using these four methods (Study IV).

Results: Study I - Measuring femoral head displacement using a phantom in the high resolution flat panel CT scanner, the mean difference between the actual micrometer displacement and the CT readings was found to be -0.14±0.12 mm (-0.06 to -0.21 mm 95% CI). In study II, similar to study I, a hip phantom was placed in a multi-detector CT and the femoral head displacement was compared between readings from CT data and the actual micrometers displacement. The mean accuracy and precision for the individual axis x, y, and z was 0.159±0.056 mm, 0.113±0.029 mm, and 0.209±0.036 mm respectively, with combined accuracy of 0.285 mm. In study III, we compared CT wear measurement to the actual wear of the same retrieved implant. Ex-planted liners were measured using CMM and micrometer, the average differences and standard deviations were: CMM-CT 0.09±0.29mm, CMM-Micrometer 0.01±0.32, and micrometer-CT 0.11±0.44. In study IV, comparing alternative techniques of calculating femoral head center when tantalum cups are used, the 2D average head-cup distance was calculated by: standard RSA 0.41mm, Model Based RSA 0.38mm, RSA RSA-HAT 0.96mm, and RSA-COR 1.41mm.

Conclusion: Under ideal conditions, with no soft tissue or motion artifacts, and with a high-resolution flat panel scanner it is possible to record femoral head penetration to a clinicaly acceptable level.When considering the clinical application of current CT technology and measurement techniques, the expected wear measurement accuracy should be 0.3 mm. In cases where CT technology does not provide an adequate solution for wear measurement (when tantalum cups are implanted), model based RSA provides the closest agreement to gold standard RSA and should be considered as a viable solution for wear measurement.

LIST OF SCIENTIFIC PUBLICATIONS

I. **Measuring Polyethylene Wear In THA Using a High-Resolution Flat Panel CT Scanner and Dedicated Software. A Feasibility Study.**
Dov Goldvasser, Michael Doerner, Charles Bragdon, Rajiv Gupta, Henrik Malchau. Manuscript.

II. **A New Technique for Measuring Wear in Total Hip Arthroplasty Using Computed Tomography.**
Dov Goldvasser, MSc, Marilyn E. Noz, PhD, G.Q. Maguire Jr., PhD, Henrik Olivecrona, MD, PhD, Charles R. Bragdon, PhD, Henrik Malchau, MD, PhD. J Arthroplasty. 2012 Oct; 27(9): 1636-1640.e1. doi: 10.1016/j.arth.2012.03.053. Epub 2012 May 31

III. **In-vivo and Ex-vivo Measurement of Polyethylene Wear in Total Hip Arthroplasty Comparison of Measurements Using a CT Algorithm, a Coordinate Measuring Machine, and a Micrometer.**
Dov Goldvasser, Viktor J Hansen, Marilyn E Noz, Gerald Q Maguire Jr., Michael P Zeleznik, Henrik Olivecrona, Charles R Bragdon, Lars Weidenhielm, and Henrik Malchau. Acta Orthop. 2014 Jun; 85(3): 271-5. doi: 0.3109/17453674.2014.913225. Epub 2014 Apr 23

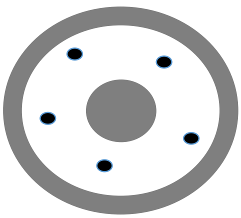
IV. **Alternative Methods for Calculating the Center of the Femoral Head when Radio-Opaque Cups are Used in Total Hip Arthroplasty.**
Goldvasser D., Wang J. H., Kaptein B. L., Kärrholm J., Malchau H., Bragdon C. R. Manuscript.

CONTENTS

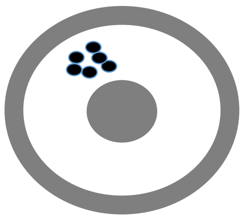
LIST OF ABBREVIATIONS AND DEFINITIONS

CAD	Computer Aided Design
CMM	Coordinate Measurement Machine
CT	Computerized Tomography
MDCT	Multi Detector CT
RSA	Radio-Stereo-Metric Analysis
THA	Total Hip Arthroplasty
Accuracy	How close is a measurement to the “true” value
Precision	The degree to which repeated measurements produce similar results

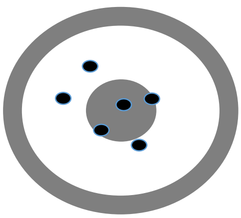
The following diagram illustrates the definitions of accuracy and precision:



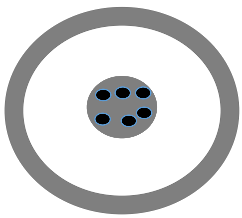
Low accuracy and
Low precision



Low accuracy and
High precision



High accuracy and
Low precision



High accuracy and
High precision

1 INTRODUCTION

Total hip arthroplasty (THA) procedures provide pain relief in cases of hip joint failure, and are used in a range of indications including: osteoarthritis, rheumatoid arthritis, hip fractures, and bone tumors. The most common indication for THA is osteoarthritis, and it is predicted that in the USA by 2030 the demand for THA will increase by 174% to 572,000 [1, 2]. Surgical interventions to alleviate pain caused by hip arthritis have been reported as early as the 1800's. The most common THA procedure involves replacing the acetabulum articulating surface with an artificial/synthesized material, as well as replacing the femoral head and neck with artificial components [3]. Over the years some of the materials used to replace the acetabulum surface included: glass, Vitallium (a mainly cobalt-chrome alloy), and Bakelite [4]. In 1956 Sir John Charnley started implanting polytetrafluoroethylene (PTFE), both on the acetabular and femoral sides. However, shortly after, it was discovered that the wear rate of PTFE was 0.5 mm per month. In addition the wear particles induced a severe foreign body reaction [5, 6]. As a result, a new material was introduced, ultra-high molecular weight polyethylene (UHMWP), and the first hip was implanted with this material in November 1962. Unbeknown to clinicians and researchers, particle disease was still a problem and the relationship between wear particles and osteolysis took some time to uncover [6-9]. The next evolution in polyethylene bearing surfaces was the introduction of the highly cross-linked polyethylene [10, 11], and the first hip was implanted in December 1998. As history demonstrate [12], *in-vivo* surveillance of implant performance is a critical component in the process of developing and implanting new polyethylene materials.

In-vivo surveillance of polyethylene performance is traditionally measured with the help of x-ray imaging. Discovered by Wilhelm Röntgen in 1895, x-ray imaging is used to produce a planar (2D) density contrast image (the radiograph) of the object of interest.

Over the years a number of radiographic techniques were developed to take advantage of Röntgen's discovery and monitor *in-vivo* performance of THA implants.

The first adaptation of x-ray technology to the acquisition of data from radiographic images, came as early as 1898 [13]. However, it was not until 1974 when Göran Selvik introduced a system based on x-rays, which he called Roentgen Stereo-photogrammetry [14-16] and was later named RSA, that it was possible to quantify 3D femoral head displacement in a systematic way. In this RSA system, tantalum beads are inserted in the bone and the edge/rim of the polyethylene cup, together with a calibration cage and computer software, allowing measurement and tracking of relative changes in the THA implants. In this system the tantalum beads increase the accuracy and precision of the RSA measurements [17]. For the purpose of wear measurements edge detection algorithms are used to identify the center of the acetabular cup and femoral head. The RSA system has been modified since it was first introduced by Selvik; today RSA is considered the gold standard for measuring the performance (head penetration, and component loosening) of total hip arthroplasty. Due to the requirement to implant tantalum beads and the use of a special radiographic suite to capture RSA images, RSA studies are usually limited to a small cohort and small number of medical centers that can perform these studies. While RSA is useful for wear measurements in research, it is not a practical tool for a widespread clinical use involving large patient cohort [18, 19].

Other techniques based on a single plain radiograph have also been developed [20-24], and use edge detection algorithms to identify the location of the center of the head and acetabular cup, and there by infer wear [25]. These techniques require no special equipment and can be used by simply capturing an anterior-posterior radiograph of the pelvis. Special software is required to analyze the images and calculate wear [21, 26]. Single plain radiographs present some unique challenges for wear measurements. These are due to the change of pelvic orientation between patient visits, the focal distance and the location of the central beam [27-36].

A third performance diagnostic tool for total hip arthroplasty is the computerized tomography (CT) machine. The catalyst for the development of the CT was the inability to differentiate between the densities of comparable tissues. A conventional x-ray image represents the total attenuation of the tissue between the x-ray source and the image-capturing element. The development of the CT is credited to Godfrey Hounsfield and Allan Cormack, who won the 1979 Nobel Prize for its development [37, 38]. The first patient was scanned, for an alleged brain tumor, in a CT in South London in October of 1971. Earlier versions of CT machines had lower image resolution, with voxels 3 x 3 x 13mm with an 80 x 80 detector matrix, and required a significant amount of time to acquire an image, 4.5 to 20 minutes. Technology, however, evolved quite rapidly and with the introduction of the spiral/helical CT in 1990 the path was clear for the CT to become a ubiquitous tool for medical imaging. Furthermore, recent developments in flat panel CT (fpCT) technology [39-41] introduced the use of high-resolution CT scanners to clinical applications, and possibly the use of O-Arm [42] scanner in pelvic imaging.

These advances in CT technology [43-45] and the global presence of CT machines in all modern hospitals presented an opportunity for the development of new clinical tools. Some of these advancements included using CT data to reconstruct a 3D volume from the captured images [46-49]. These reconstructed images (volumes) can be used in a variety of ways [50, 51]: including re-orienting the pelvis to a standard position, as well as orientating the acetabular cup, which eliminates the uncertainty of patient re-positioning. These 3D CT techniques help overcome some of the technical limitation of x-ray imaging [52, 53]. In the current studies we used hip (THA) phantoms combined with CT scanners (3D data) and image processing software [54, 55] to analyze the ability of CT scanners to estimate wear in total hip arthroplasty.

For patients with implanted tantalum cups [56-59], using plain radiographs, CT or RSA wear measurements are impractical, therefore other methods are required. Tantalum cups used in THA present a unique challenge due to the difficulty in identifying the center of the femoral head. Traditional wear estimation methods [60, 61] fail due to the high density of tantalum metal, which makes it radio-opaque. To overcome these difficulties some alternatives can be considered [62-64]. We compared model based RSA, helical axis RSA and center of rotation RSA techniques, to identify the best alternative technique (to the gold standard RSA) for wear measurement when tantalum cups are used.

2 AIMS

Overall aims were to investigate, using a phantom and retrieved polyethylene components, the application of computerized tomography to the measurement of polyethylene wear. We also aimed to investigate alternative wear measurement techniques for cases when radio-opaque acetabular cups are implanted and current radiographic and CT techniques fail.

I The aim of this feasibility study was to evaluate the precision and accuracy of an experimental high resolution flat panel CT scanner to detect wear in total hip arthroplasty. A hip phantom was used to simulate wear, and dedicated software was used to analyze the data.

II The aim was to evaluate the precision and accuracy of a clinically used multi-detector CT scanner to detect wear in total hip arthroplasty. A hip phantom was used to simulate wear, and advanced software was used to analyze the data.

III The aim was to compare, via precision analysis, wear measurements obtained from *in-vivo* CT to the same actual explanted acetabular cups (as was measured by CT). In addition, *ex-vivo* measurements were obtained and compared using a point micrometer and CMM machine.

IV The aim was to test alternative techniques for THA wear measurements for those cases where a radio-opaque (tantalum) acetabular cup was implanted. In such circumstances, CT and common wear measurement radiographic techniques fail. We used a hip phantom to test a number of alternative techniques, comparing these techniques and identifying the one that will produce results that most agree with the gold standard RSA technique.

3 MATERIAL AND METHODS

3.1 STUDY I

To simulate polyethylene wear in THA we used a hip phantom (Figure 1). The phantom was constructed of a hemi-pelvis and proximal femur that were made of sawbones, and were mounted to a clear Plexiglas stand. THA components were attached to the hemi-pelvis and proximal femur. A tri-axial micrometer tower, with a resolution of 0.01mm, was used to displace the femoral head into the acetabular cup. One full rotation of the micrometer dial represented a linear displacement of the femoral component by 0.5 mm.

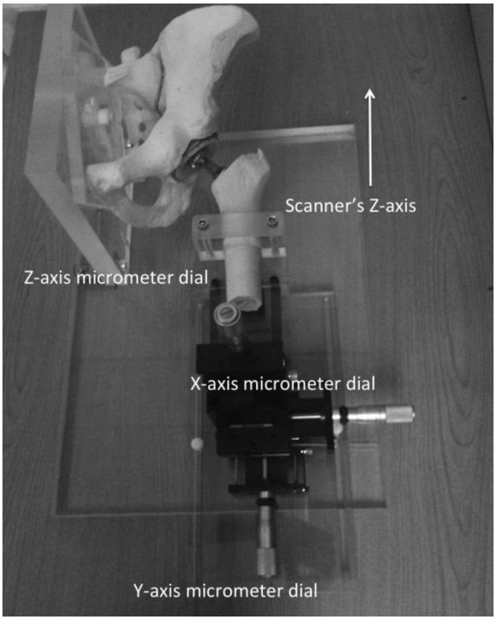


Figure 1 - Phantom assembly showing the hemi-pelvis tower with acetabular cup implanted, the femoral component attached to the micrometer tower assembly.

The assembly was positioned in the high-resolution flat panel CT scanner. The CT scanner settings were 100 kVp and 29 mA, the spatial resolution was cubic at 0.2 mm with a detector matrix of 512x512 elements, in total 301 slices were collected.

The phantom assembly was placed on the scanner's bed and the Z-axis was visually aligned with the Z-axis of the scanner. The table was moved into the gantry, a scan was obtained and the table was moved out to re-adjust the micrometers. The micrometers were always moved in the same (clockwise) direction. Without moving the phantom assembly the bed was moved back into the gantry for another image acquisition. In the end of a series scan the micrometers were dialed back to their original position. Two series were collected.

Using dedicated software two readers analyzed the data. Virtual markers were placed by moving the computer's cursor (using the mouse) over the virtual representation of the surface of the cup. Each reader independently placed virtual markers on the surfaces of the acetabular cup and femoral head. For the cup about, 850 markers were placed and for the head about 870 markers. These markers were used to calculate the center of the femoral head and acetabular cup. In total, two readers each read two scan series, there were a total of four groups of data each containing 14 position measurements and 13 head-cup distance measurements.

An iterative numerical algorithm used the virtual (surface) data points to calculate the estimated centers of the femoral head and acetabular cup. Using these centers the 3D Euclidian distance between the head and the cup was calculated. The calculated (based on CT) distance was compared to the actual Euclidian distance as recorded by the micrometers. Under ideal conditions the differences between the micrometers' displacement and the CT readings would be zero.

3.2 STUDY II

In this study we used a hip phantom similar to the one that was used in study I. Slight modifications to the phantom base were made to be able to better align the micrometers axes with those of the scanner. The micrometers tower was the same as the one in study I. A clinical CT scanner (Siemens SOMATOM Definition Flash) was used. The settings were 100 kVp, 24 mA; the slice thickness was 0.6 mm; and the pixel spacing was a square of 0.35 mm per side.

The hip phantom was constructed of 3 main components: the base, the micrometer tower, and the hemi-pelvis tower. The base's top surface was machined to be flat. The tower assembly for the hemi-pelvis was perpendicular to the base. The micrometer tower z-axis was aligned with the long axis of the base using specially designed grooves. A circular 2-axis level (bubble level) was used to align the phantom base plane with the CT table plane.

The phantom was positioned on the scanner table and aligned with the scanner coordinate system by using the circular level and the scanner's laser alignment beam. The laser beam was used to align the z-axis of the scanner with the alignment groove on the base of the phantom, and thus, the micrometer tower z-axis was aligned with the CT scanner z-axis. The center of the femoral head/acetabular cup assembly was (visually) placed in the geometric center of the scanner, which was accomplished with the help of the laser alignment beams.

Once the phantom was positioned on the scanner's table, the scanning protocol was implemented. Each of the micrometers was adjusted independently. Between each scan the table (and the phantom) was moved out of the CT gantry, the micrometer(s) were adjusted, and the table was moved back into the gantry (i.e., the table was returned to the same offset in the CT scanner z-axis as shown on the gantry's display).

A computer algorithm was used to place (in 3D space) a large number of virtual markers on the femoral head (~1600 markers) and acetabular cup (∼15000 markers). These virtual markers were used to estimate the best possible location for the center of the femoral head and acetabular cup, as well as the head and cup radii. Once the centers (head and cup) were determined, an error calculation was performed.

Two observers analyzed results independently. Each observer repeated the measurements twice. Data collected were analyzed using mean, median, histogram distribution, and Q-Q plots. Intra-observer and inter-observer data were analyzed using a 2-sample t-test. Retrospectively, we analyzed the alignment of the micrometer tower with the coordinate system of the CT.

3.3 STUDY III

We identified 10 patients for whom both a pelvic CT scan and a polyethylene liner explant were available. Liners were explanted as part of revision surgery that occurred due to polyethylene wear, osteolysis, or instability. Only CT scans with a slice thickness of 1.6 mm or less were included.

3.3.1 CT method

To analyze the data, we used a 3D processing tool. To identify the surface of the acetabular cup, the software detects the surface of the cup and places landmarks on that surface. To identify the surface of the femoral head the software detects the surface of the femoral head and places landmarks on that surface. A numerical algorithm is then used to estimate the radius and center of the head and cup.

3.3.2 CMM method

For the CMM measurements, the same polyethylene liners that were analyzed using the CT method were analyzed *ex-vivo* using a CMM. Each cup was programmed individually using the specialized CMM software. The complete internal surface of each cup was measured with a line scan at 3° intervals, and two points per mm. The average number of points per cup was about 4,700.

These data points were imported into CAD software. Two spheres were created to simulate the position of the femoral head in the cup. The diameter of the spheres was determined based on actual measurements of the explanted femoral heads, which was measured using a caliper. For each of the CMM-scanned liners, two observers independently aligned the two spheres such that one sphere was positioned in the original position of the femoral head (pre-wear position) and the second sphere was positioned at the location of maximum wear. Once the two spheres were optimally positioned, the distance between their centers was calculated. This process was repeated five times for each cup, by each of the five observers.

3.3.3 Micrometer method

In addition, nine cups were analyzed using a point micrometer. Each of the nine cups was analyzed by locating the thickest and thinnest portions of the liner wall. Ten measurement points were averaged around each of those locations. The difference between the thickest and thinnest portions was considered to be the amount of wear in the liner. Two observers performed the observations independently.

3.4 STUDY IV

The hip phantom configuration in this study was different than the previous studies, and can be seen in Figure 2. The phantom consists of a support structure, a sawbones hemi-pelvis, a sawbones femur that consisted of a femoral component, a radiolucent acetabular cup, and a polyethylene liner. A radiolucent cup was used to identify the femoral head in a standard RSA analysis. This construction allowed the joint to rotate freely, while keeping a secure contact between the femoral head and the polyethylene liner. Tantalum beads (0.8 mm) were inserted in the pelvis (in the vicinity of the cup), in the femur, and in the rim of the polyethylene liner.

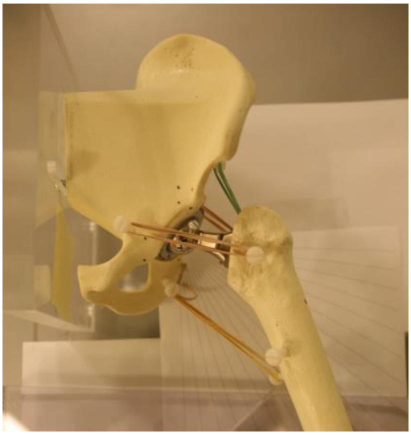


Figure 2 - Hemi pelvis with proximal femur and femoral stem and head. This configuration allowed the free rotation of the femur.

The phantom was positioned on the X-ray table in the RSA suite. Radiographs were taken in three abduction angles of about 0°, 10°, and 20°. The experiment was repeated five times resulting in a total of 15 images. The pelvis was not moved between one image exposure and the next: the femur was the only segment that was displaced (abducted) during this experiment.

Theoretically the calculated x, y and z position of the head and cup should be identical for all images. Position data (x, y and z) were used to compare between the different techniques. Assuming that these centers are perfectly aligned in this specific hip implant, if all techniques produce flawless results the position difference and the difference in scalar distance between the centers of the head and cup should be zero. The scalar distance was calculated both in 3D and in 2D (x-y plane, abduction / adduction).

Four different methods were used to analyze the data:

3.4.1 Standard RSA

RSA uses radio-stereo metric images to identify the position and center of the acetabular cup and the center of the femoral head. We identified all the tantalum markers in the phantom including the markers that were imbedded in the cup rim. Using the RSA software the beads in the rim of the cup together with the cup contour were used to identify the cup center, while the head contour was used to identify the head center.

3.4.2 MBRSA – (Model-based RSA)

MBRSA uses a laser scan model of the femoral stem, head and acetabular cup. Then, edge detection techniques are used to identify the edges of the femoral stem, femoral head and acetabular cup. Optimization algorithms are then employed to estimate the best pose of the components based on the minimum distance between the edge detection of the components in the radiographs and virtually projected contours of the scanned models of the components. Tantalum cup use was simulated by only using parts of the femoral head that were visible outside the cup. The positions of both the cup and head center were calculated as x, y, and z locations.

3.4.3 RSA-HAT (Helical axis technique)

With RSA-Hat a helical axis describes the instantaneous motion of a rigid body in terms of rotation around and translation along a unique axis. To calculate the helical axis the position of a rigid body needs to be known in two different locations. For the purpose of estimating the center of the femoral head, the intersection of two helical axes is required. Errors in calculating helical axis are inversely related to the magnitude of rotation, therefore the magnitude of femoral rotation was set to approximately 10°. The intersection of these two helical axes represents the estimated location of the center of the femoral head. Eleven tantalum beads inserted in the femur were used as the rigid body for helical axes calculation. The position of the femoral head was calculated as x, y and z location.

3.4.4 RSA-COR (Center of Rotation)

Eleven tantalum beads in the femur were used to calculate the center of rotation of the femoral head. For each tantalum bead displacement a plane was defined as a perpendicular to the line of motion and passing through the bisector of the line that connects a bead between its two positions. The intersection of these planes denotes the center of rotation of the femur.

4 SUMMARY OF RESULTS

4.1 STUDY I

Mean, standard deviation, accuracy, precision and 95% confidence interval values are listed in Table 1. ANOVA analysis indicated that there was no statistical difference (p=0.95) between the head-cup expected distances to the head-cup calculated distances. The overall (all readings) mean was -0.14±0.12 mm, the overall accuracy and precision was respectively 0.29mm and 0.41mm, the 95% CI was between -0.06 and -0.22 mm.

Table 1 - Head - Cup distance statistic.

	Reader 1 Series 1	Reader 1 Series 2	Reader 2 Series 1	Reader 2 Series 2
Mean	-0.14	-0.13	-0.18	-0.12
SD	0.12	0.15	0.11	0.09
Accuracy	0.22	0.25	0.37	0.32
Precision	0.31	0.35	0.52	0.46
+95% CI	-0.09	-0.06	-0.08	-0.01
-95% CI	-0.18	-0.20	-0.29	-0.23

4.2 STUDY II

Table 2 displays the average of the results from the two observers for the difference between actual and calculated displacement.

Table 2 - Combined observers' mean difference between the actual micrometer displacement and the image-based calculated displacement

	Combined observers' mean					
	X	SD	Y	SD	Z	SD
Displacement error (mm)	-0.032	0.213	0.049	0.035	0.015	0.021
All error (mm)	0.000	0.217	0.039	0.035	0.039	0.051
Zero error (mm)	0.010	0.232	0.036	0.033	0.046	0.055
STDErr All	0.058		0.026		0.020	
STDErr Zeros	0.077		0.034		0.026	
STDErr displacement	0.123		0.053		0.039	
Accuracy (mm)	0.159		0.113		0.209	
Precision (mm)	±0.056		±0.029		±0.036	

Accuracy for the x-, y-, and z-axes was calculated to be 0.159, 0.113, and 0.209 mm, respectively; precision for these axis were calculated to be 0.056, 0.029, 0.036 mm, respectively.

4.3 STUDY III

When comparing the CMM readings between the two observers, the mean difference was 0.02 mm (CI: –0.02 to 0.08; $p = 0.7$; interclass correlation coefficient: 0.99). When comparing micrometer readings between the two observers, the mean difference was 0.05 mm (CI: 0.02 to 0.08; p = 0.2; interclass correlation coefficient: 0.99). The mean differences in wear measured using the three different methods (with CIs) are summarized in Table 3.

Table 3 - Mean difference between the three methods, with range and confidence intervals

	CT – CMM (mm)	CMM – Micrometer (mm)	CT – Micrometer (mm)
Mean difference	-0.09 (-0.38 to 0.20)	0.01 (-0.31 to 0.33)	0.11 (-0.33 to 0.55)
95% CI	-0.15 to -0.02	-0.05 to 0.08	0.19 to 0.21

Between CMM and micrometer the accuracy was 0.19 mm, and between CT and micrometer accuracy was calculated to be 0.30 mm.

4.4 STUDY IV

Table 4 summarizes the results. The number of readings/permutations (n) for each method varies based on the method used.

Table 4 – Standard RSA, MBRSA, RSA-HAT, and RSA-COR Head-Cup distance difference for three and two (XY plane) dimension (n=number of observations)

Standard RSA (n=105)	Head-Cup distance 3D (mm)	Head-Cup distance 2D (mm)
Average Distance	0.46	0.41
Standard Deviation	0.11	0.12
Precision	0.21	0.23
Model Based RSA (n=78)		
Average Distance	0.38	0.28
Standard Deviation	0.15	0.11
Precision	0.29	0.22
RSA-HAT (n=125)		
Average Distance	5.92	0.96
Standard Deviation	8.21	0.30
Precision	16.10	0.59
RSA-COR (n=25)		
Average Distance	18.88	1.41
Standard Deviation	12.32	1.52
Precision	24.15	2.80

5 DISCUSSION

5.1 STUDY I

Imaging a hip phantom in a high-resolution flat panel CT scanner we estimated the displacement of the femoral head into the acetabular cup. The mean difference for all estimates was -0.14±0.12mm with confidence interval (95%) of -0.06 mm to -0.22 mm. The accuracy and precision were calculated to be 0.29 mm and 0.41 mm respectively.

Estimating 3D wear of the polyethylene component is currently limited to RSA studies. In their 2002 RSA phantom study Bragdon et al. [65] estimated that wear can be measured in 3D with an accuracy of 0.055 mm and precision of 0.014 mm. Their experiment was accomplished under ideal setup with optimal conditions, and is considered the gold standard for wear measurements in THA.

The lower precision in this study can be attribute to the manual nature of placing markers on the surface of the cup, and the fact that the surface of the cup was not smooth but porous. As a result some virtual markers were placed on locations farther away from the center, while other markers were placed on locations closer to the center.

The process of marking the surface of the acetabular cup and the femoral head requires an extensive amount of user input, mainly in placing the virtual markers on the surface of the cup and head. We therefore developed a more automatic version [55] of the software that requires minimal user interface and the process of cup and head surface identification is standardized and automated.

We believe that when considering some fpCT features like: the lower radiation, the high-resolution capabilities, and the increase in availability, these make flat panel CT technology an attractive alternative to 2D radiographic measurements. 2D measurements are based on one (AP) projection, which is the only image that is used to estimate femoral head penetration. When using only the AP projection certain assumptions are made, for example that wear in the Anterior Posterior direction is minimal and other assumptions are related to the location of the x-ray source and the geometry of calculating the AP projections. CT technology provides the opportunity to estimate femoral head penetration in 3D without any of the limitations of the 2D methods. It is our conclusion that flat panel CT technology is a viable alternative to spiral CT for THA clinical wear measurements. Our results show that flat panel CT imaging can be used as a tool in clinical wear measurement of polyethylene liners implanted in THA. Nevertheless the method may not be precise enough to evaluate early wear in new liner materials.

5.2 STUDY II

The combined mean displacement error of 0.026 mm with a combined mean SD of 0.101 mm for all 3 axes indicates that under ideal conditions, small amounts of displacement (wear) may be detected by using a clinically available high-resolution CT scanner such as the one used in this study. Our hypothesis that precision and accuracy of polyethylene wear using CT imaging would be comparable with those of RSA was only partially correct. Although precision measurements were comparable with those of RSA, accuracy measurements were higher than those of RSA. However, the calculated displacement, that is, the implicit detection level of wear, in this experimental study is sufficient for clinical follow-ups.

When comparing the radius of the acetabular cup in the CMM to the CT scanner, a difference of 0.554 mm was observed, whereas measurements of the femoral head radius produced a difference of 0.140 mm. The type of cup used for this experiment can explain the variation between CMM and CT measurements of the acetabular cup. The trabecular mesh/in-growth cup that was used limits the ability of the CMM probe to measure only the outer surface of the cup. Computed tomography data of the acetabular cup surface included data points from both the base surface of the cup and the outer diameter of the trabecular mesh interface. For the purpose of wear measurement, the difference between CMM measurement and CT measurement of head and cup radius is not relevant as long as this difference is consistent throughout the scans. In our experiment the data indicates that the measurement of head and cup radii was very consistent.

5.3 STUDY III

We validated our hypothesis that the differences between the means of the three wear measurement techniques CT, CMM, and micrometer were not statistically significant. In a previous publication, we investigated the use of a high resolution CT scanner to estimate the displacement of the femoral head in a THA phantom. We found that the 3-axis accuracy was 0.28 mm. This result is in agreement with our current study.

A potential major concern using this (CT) technique is increased risk of radiation. New protocols for reduced CT radiation exposure can make CT technology a viable option for future clinical studies of THA performance. Another shortcoming led to the exclusion of liner seven from CT measurements, as the CT calculated wear was greater than the thickness of the liner. We have repeated the CT measurement for that liner a number of times, with the same outcome. This error can be explained by the large amount of wear of the polyethylene. In this case, in the CT imaging, the femoral head was in contact with the acetabular cup, which introduced difficulty for the computer algorithm to differentiate between the acetabular cup and femoral head. This can be solved with software modifications. Another source of error between CT measurement and CMM and micrometer measurements is the implant time in vivo after imaging. It is likely that some additional wear took place during this period (115 days on average).

The ability to follow implant performance clinically (with an accuracy of 0.3 mm) in vivo in 3D— in a large cohort with clinically available tools and avoiding the need for special procedures—should be of some interest.

5.4 STUDY IV

In cases where radio-opaque (tantalum) cups are implanted it is not possible to identify the center of the femoral head. The inability to identify the center of the head prevents the *in-vivo* measurement of wear. To overcome this limitation we investigated the use of alternative techniques for identifying the center of the femoral head. We measured the estimated location (x, y, and z) of the femoral head using other techniques. We also calculated the 3D and 2D distances between the head and acetabular cup.

Measurements taken in this experiment were calculated under ideal conditions with no soft tissue or other factors (e.g. patient motion) that can diminish the quality of the analysis. Under clinical conditions it should be expected that soft tissue and motion artifacts would introduce additional errors in the measurements.

In each of the (measurement) systems we used all the available information for the analysis. Each system calculates the center of the head and cup in a different way and thus we are not comparing the way the centers are calculated but rather examining the outcomes of these calculations.

When compared to RSA the average head-cup distance was closer using the helical axis technique than when using the center of rotation technique. When calculating the location of the head by the center of rotation method, as well as the helical axis method, a large error is expected in the Z direction. This is due to the mathematical solution of intersecting planes and the planar displacement of the femur. For these cases we therefore also compared 2D head-cup distance. It is possible that both the RSA-HAT and RSA-COR estimations of the center of the head will improve by replacing one abduction rotation with a flexion and external-internal rotation examination. The Model-based RSA head-cup mean difference (in 3D) was 0.38 mm, which is 0.08 mm smaller than the difference found with standard RSA (0.46 mm). Calculations assume that the true difference between the center of the cup and the center of the head is exactly zero; however there might be a small offset in this value.

6 CONCLUSION

Estimating 3D wear of the polyethylene component ***in vivo*** in total hip arthroplasty is currently limited to RSA studies, and therefore to a small patient cohort. The use of CT technology for clinical wear estimation will make these wear studies possible for more THA patients (in which polyethylene is used as the articulating surface).
The first three studies in this thesis are dedicated to estimating the limits of CT technology for measuring polyethylene wear in THA. We conclude that for using current multi detector CT technology for clinical applications [66] the expected limits of detection should be on the order of 0.3 mm.
For those patients with tantalum (radio-opaque) cups we examined alternative methods since available techniques are not capable of estimating wear. We concluded that model-based RSA is the method of choice for wear measurements when implants with tantalum cup are used.

Study I – This feasibility study, using a flat panel CT and a hip phantom, was conducted to explore wear detection level of the flat panel CT. We conclude that fpCT is suitable for clinical wear measurements, although not precise enough for early wear detection. The accuracy and precision were 0.29 mm and 0.41 mm respectively.

Study II – Wear in the polyethylene liner of a total hip arthroplasty was estimated using a multi detector CT and a hip phantom. Accuracy calculation indicates that multi detector CT is capable of detecting wear to a clinically acceptable level, with accuracy for the x-, y-, and z-axes was calculated to be 0.159, 0.113, and 0.209 mm, respectively; precision for these axis was calculated to be 0.056, 0.029, 0.036 mm, respectively.

Study III – In this retrieval study we validated *in-vivo* CT wear measurements by comparing them to actual measurements of the same (explanted) polyethylene cups. *Ex-vivo* cups were measured using a CMM and micrometer. Comparing micrometer data to CT data indicate that MDCT can detect wear to a clinically acceptable level, with accuracy of 0.3 mm and 95% CI of 0.01 to 0.21 mm.

Study IV – We investigated alternative wear measurement techniques for those patients where tantalum cups are implanted and current techniques fail. These (alternative) techniques rely on the availability of radio-stereo-metric images. The conclusion is that model based RSA provides the closest results to those produced by the gold standard RSA, with a difference between the two methods of 0.08 mm.

7 ACKNOWLEDGEMENTS

I would like to take the opportunity to convey my heartfelt appreciation to those whom without, this thesis would not have been possible. In particular:

Lars Weidenhielm – for making this international collaboration a possibility, and as the main supervisor providing valuable resources, guidance and feedback.

Henrik Malchau – for assembling the team, providing resources and support, and helping to make this thesis a reality.

Marilyn Noz and Gerald Q. Maguire – for support with analyzing the data, modifying the code, looking at the results, and reviewing the manuscripts.

Charles Bragdon – for help with this work and the thesis committee.

Michael P. Zeleznik – for critical reading of the manuscripts.

Henrik Olivecrona – for help with this work and the thesis committee.

Rajiv Gupta – for support and resources.

Bart Kaptein – for the insight, comments, and review of the manuscript.

Johan Kärrholm – for the insight, comments, and review of the manuscript.

To my co-authors – for their hard work and contributions.

The Harris Lab at the Massachusetts General Hospital, for generously providing time and resources in support of this work.

Rochelle Sugarman – for being “in the groove”, thank you for reading and commenting on this dissertation.

Jay Rosenheim – thank you for reading and commenting on this dissertation.

Elaine, my wife and partner, thank you – you are the best.

8 REFERENCES

1. Kurtz, S., et al., *Projections of primary and revision hip and knee arthroplasty in the United States from 2005 to 2030.* J Bone Joint Surg Am, 2007. **89**(4): p. 780-5.

2. Abe, H., et al., *Jogging after total hip arthroplasty.* Am J Sports Med, 2014. **42**(1): p. 131-7.

3. Callaghan, J.J., A.G. Rosenberg, and H.E. Rubash, *The adult hip*. 2nd ed. 2007, Philadephia: Lippincott Williams & Wilkins.

4. Gomez, P.F. and J.A. Morcuende, *Early attempts at hip arthroplasty--1700s to 1950s.* Iowa Orthop J, 2005. **25**: p. 25-9.

5. Gomez, P.F. and J.A. Morcuende, *A historical and economic perspective on Sir John Charnley, Chas F. Thackray Limited, and the early arthoplasty industry.* Iowa Orthop J, 2005. **25**: p. 30-7.

6. Schmalzried, T.P., et al., *The mechanism of loosening of cemented acetabular components in total hip arthroplasty. Analysis of specimens retrieved at autopsy.* Clin Orthop Relat Res, 1992(274): p. 60-78.

7. Harris, W.H., et al., *Extensive localized bone resorption in the femur following total hip replacement.* J Bone Joint Surg Am,1976.**58**(5):p. 612-8.

8. Harris, W.H., *Osteolysis and particle disease in hip replacement. A review.* Acta Orthop Scand, 1994. **65**(1): p. 113-23.

9. Harris, W., *The Problem is Osteolysis.* Clinical Orthopaedics and Related Research, 1995. **311**: p. 46-53.

10. Muratoglu, O.K., et al., *Surface analysis of early retrieved acetabular polyethylene liners: a comparison of conventional and highly crosslinked polyethylenes.* J Arthroplasty, 2004. **19**(1): p. 68-77.

11. McKellop, H., et al., *Development of an extremely wear-resistant ultra high molecular weight polyethylene for total hip replacements.* J Orthop Res, 1999. **17**(2): p. 157-67.

12. Harris, W.H., *The first 50 years of total hip arthroplasty: lessons learned.* Clin Orthop Relat Res, 2009. **467**(1): p. 28-31.

13. Karrholm, J., *Roentgen stereophotogrammetry. Review of orthopedic applications.* Acta Orthop Scand, 1989. **60**(4): p. 491-503.

14. Selvik, G., *Roentgen stereophotogrammetry. A method for the study of the kinematics of the skeletal system.* Acta Orthop Scand Suppl, 1989. **232**: p. 1-51.

15. Selvik, G., *Roentgen stereophotogrammetric analysis.* Acta Radiol, 1990. **31**(2): p. 113-26.

16. Selvik, G., *A stereophotogrammetric system for the study of human movements.* Scand J Rehabil Med Suppl, 1978. **6**: p. 16-20.

17. Borlin, N., S.M. Rohrl, and C.R. Bragdon, *RSA wear measurements with or without markers in total hip arthroplasty.* J Biomech, 2006. **39**(9): p. 1641-50.

18. Bragdon, C.R., et al., *Comparison of femoral head penetration using RSA and the Martell method.* Clin Orthop Relat Res, 2006. **448**: p. 52-7.

19. Kaptein, B.L., et al., *Model-based RSA of a femoral hip stem using surface and geometrical shape models.* Clin Orthop Relat Res, 2006. **448**: p. 92-7.

20. Martell, J.M. and S. Berdia, *Determination of polyethylene wear in total hip replacements with use of digital radiographs.* J Bone Joint Surg Am, 1997. **79**(11): p. 1635-41.

21. Devane, P.A. and J.G. Horne, *Assessment of polyethylene wear in total hip replacement.* Clin Orthop Relat Res, 1999(369): p. 59-72.

22. Kabo, J.M., et al., *In vivo wear of polyethylene acetabular components.* J Bone Joint Surg Br, 1993. **75**(2): p. 254-8.

23. Sychterz, C.J., et al., *Radiographic evaluation of penetration by the femoral head into the polyethylene liner over time.* J Bone Joint Surg Am, 1997. **79**(7): p. 1040-6.

24. Hui, A.J., et al., *Validation of two and three-dimensional radiographic techniques for measuring polyethylene wear after total hip arthroplasty.* J Bone Joint Surg Am, 2003. **85-A**(3): p. 505-11.

25. Clarke, J.C., et al., *Can wear in total hip arthroplasties be assessed from radiographs?* Clin Orthop Relat Res, 1976(121): p. 126-42.

26. Martell, J.M., et al., *Comparison of two and three-dimensional computerized polyethylene wear analysis after total hip arthroplasty.* J Bone Joint Surg Am, 2003. **85-A**(6): p. 1111-7.

27. Lewinnek, G.E., et al., *Dislocations after total hip-replacement arthroplasties.* J Bone Joint Surg Am, 1978. **60**(2): p. 217-20.

28. Ghelman, B., *Radiographic localization of the acetabular component of a hip prosthesis.* Radiology, 1979. **130**(2): p. 540-2.

29. Ghelman, B., *Three methods for determining anteversion and retroversion of a total hip prosthesis.* AJR Am J Roentgenol, 1979. **133**(6): p. 1127-34.

30. Malchau, H., et al., *Accuracy of migration analysis in hip arthroplasty. Digitized and conventional radiography, compared to radiostereometry in 51 patients.* Acta Orthop Scand, 1995. **66**(5): p. 418-24.

31. Pettersson, H., et al., *Radiologic evaluation of the position of the acetabular component of the total hip prosthesis.* Acta Radiol Diagn (Stockh), 1982. **23**(3A): p. 259-63.

32. Herrlin, K., H. Pettersson, and G. Selvik, *Comparison of two- and three-dimensional methods for assessment of orientation of the total hip prosthesis.* Acta Radiol, 1988. **29**(3): p. 357-61.

33. Herrlin, K., G. Selvik, and H. Pettersson, *Space orientation of total hip prosthesis. A method for three-dimensional determination.* Acta Radiol Diagn (Stockh), 1986. **27**(6): p. 619-27.

34. Sutherland, C.J. and S.J. Bresina, *Measurement of acetabular component migration using two-dimensional radiography.* J Arthroplasty, 1992. **7 Suppl**: p. 377-9.

35. Yao, L., J. Yao, and R.H. Gold, *Measurement of acetabular version on the axiolateral radiograph.* Clin Orthop Relat Res, 1995(316): p. 106-11.

36. Lu, M., et al., *Reliability and validity of measuring acetabular component orientation by plain anteroposterior radiographs.* Clin Orthop Relat Res, 2013. **471**(9): p. 2987-94.

37. Beckmann, E.C., *CT scanning the early days.* Br J Radiol, 2006. **79**(937): p. 5-8.

38. Mamourian, A.C. and L. Ebook, *CT Imaging: Practical Physics, Artifacts, and Pitfalls*. 2013, Oxford: Oxford University Press, USA.

39. Gupta, R., et al., *Experimental flat-panel high-spatial-resolution volume CT of the temporal bone.* AJNR Am J Neuroradiol, 2004. **25**(8): p. 1417-24.

40. Gupta, R., et al., *Ultra-high resolution flat-panel volume CT: fundamental principles, design architecture, and system characterization.* Eur Radiol, 2006. **16**(6): p. 1191-205.

41. Zbijewski, W., et al., *A dedicated cone-beam CT system for musculoskeletal extremities imaging: design, optimization, and initial performance characterization.* Med Phys, 2011. **38**(8): p. 4700-13.

42. Sembrano, J.N., E.R. Santos, and D.W. Polly, Jr., *New generation intraoperative three-dimensional imaging (O-arm) in 100 spine surgeries: does it change the surgical procedure?* J Clin Neurosci, 2014. **21**(2): p. 225-31.

43. Morsbach, F., et al., *Reduction of metal artifacts from hip prostheses on CT images of the pelvis: value of iterative reconstructions.* Radiology, 2013. **268**(1): p. 237-44.

44. Chen, M.Y., S.M. Shanbhag, and A.E. Arai, *Submillisievert median radiation dose for coronary angiography with a second-generation 320-detector row CT scanner in 107 consecutive patients.* Radiology, 2013. **267**(1): p. 76-85.

45. Liu, P.T., et al., *Metal artifact reduction image reconstruction algorithm for CT of implanted metal orthopedic devices: a work in progress.* Skeletal Radiol, 2009. **38**(8): p. 797-802.

46. Noz, M.E. and G.Q. Maguire, Jr., *QSH: a minimal but highly portable image display and handling toolkit.* Comput Methods Programs Biomed, 1988. **27**(3): p. 229-40.

47. Olivecrona, L., et al., *Standard orientation of the pelvis: validation on a model and ten patients.* Acta Radiologica (Stockholm, Sweden : 1987), 2005. **46**(1): p. 74-82.

48. Olivecrona, H., et al., *Stability of acetabular axis after total hip arthroplasty, repeatability using CT and a semiautomated program for volume fusion.* Acta Radiologica (Stockholm, Sweden : 1987), 2003. **44**(6): p. 653-661.

49. Olivecrona, H., et al., *A new CT method for measuring cup orientation after total hip arthroplasty: a study of 10 patients.* Acta Orthopaedica Scandinavica, 2004. **75**(3): p. 252-260.

50. Noz, M.E., et al., *A versatile functional-anatomic image fusion method for volume data sets.* J Med Syst, 2001. **25**(5): p. 297-307.

51. Olivecrona, L., et al., *Acetabular component migration in total hip arthroplasty using CT and a semiautomated program for volume merging.* Acta Radiologica (Stockholm, Sweden : 1987), 2002. **43**(5): p. 517-527.

52. Jedenmalm, A., et al., *Validation of a 3D CT method for measurement of linear wear of acetabular cups.* Acta Orthop, 2011. **82**(1): p. 35-41.

53. Jedenmalm, A., et al., *A new approach for assessment of wear in metal-backed acetabular cups using computed tomography: a phantom study with retrievals.* Acta Orthop, 2008. **79**(2): p. 218-24.

54. Vandenbussche, E., et al., *Measurement of femoral head penetration in polyethylene using a 3-dimensional CT-scan technique.* Acta Orthop, 2010. **81**(5): p. 563-9.

55. Maguire, G.Q., Jr., et al., *A new automated way to measure polyethylene wear in THA using a high resolution CT scanner: method and analysis.* ScientificWorldJournal, 2014. **2014**: p. 528407.

56. Flecher, X., et al., *Do tantalum components provide adequate primary fixation in all acetabular revisions?* Orthop Traumatol Surg Res, 2010. **96**(3): p. 235-41.

57. Macheras, G.A., et al., *Radiological evaluation of the metal-bone interface of a porous tantalum monoblock acetabular component.* J Bone Joint Surg Br, 2006. **88**(3): p. 304-9.

58. Christie, M.J., *Clinical applications of Trabecular Metal.* Am J Orthop (Belle Mead NJ), 2002. **31**(4): p. 219-20.

59. Jafari, S.M., et al., *Do tantalum and titanium cups show similar results in revision hip arthroplasty?* Clin Orthop Relat Res, 2010. **468**(2): p. 459-65.

60. Martell, J.M., J.J. Verner, and S.J. Incavo, *Clinical performance of a highly cross-linked polyethylene at two years in total hip arthroplasty: a randomized prospective trial.* J Arthroplasty, 2003. **18**(7 Suppl 1): p. 55-9.

61. Karrholm, J., et al., *Radiostereometry of hip prostheses. Review of methodology and clinical results.* Clin Orthop Relat Res, 1997(344): p. 94-110.

62. Woltring, H.J., et al., *Instantaneous helical axis estimation from 3-D video data in neck kinematics for whiplash diagnostics.* J Biomech, 1994. **27**(12): p. 1415-32.

63. Ramsey, D.K. and P.F. Wretenberg, *Biomechanics of the knee: methodological considerations in the in vivo kinematic analysis of the tibiofemoral and patellofemoral joint.* Clin Biomech (Bristol, Avon), 1999. **14**(9): p. 595-611.

64. Hurschler, C., et al., *Comparison of the model-based and marker-based roentgen stereophotogrammetry methods in a typical clinical setting.* J Arthroplasty, 2009. **24**(4): p. 594-606.

65. Bragdon, C.R., et al., *Experimental assessment of precision and accuracy of radiostereometric analysis for the determination of polyethylene wear in a total hip replacement model.* J Orthop Res, 2002. **20**(4): p. 688-95.

66. Smith, P.N., R.S. Ling, and R. Taylor, *The influence of weight-bearing on the measurement of polyethylene wear in THA.* J Bone Joint Surg Br, 1999. **81**(2): p. 259-65.