Assessment of Acetabular Cup Wear with
Computed Tomography and Influence of
Surface Roughness on Wear of Materials for
Hip Prostheses

Licentiate Thesis
by
Anneli Jedenmalm
Stockholm, Sweden
2006

Department of Materials Science and Engineering
School of Industrial Engineering and Technology
Royal Institute of Technology (KTH)
SE - 100 44 Stockholm, Sweden
Assessment of Acetabular Cup Wear with Computed Tomography and Influence of Surface Roughness on Wear of Materials for Hip Prostheses

A dissertation submitted to Royal Institute of Technology, Stockholm, Sweden, in partial fulfillment of the requirements for the degree of Technical Licentiate.

ISBN 91-7178-448-9
ISRN KTH/MSE--06/56--SE+MEK/AVH

© Anneli Jedenmalm 2006
This thesis is available in electronic version at: http://media.lib.kth.se
Printed by Universitetsservice US AB, Stockholm
Assessment of Acetabular Cup Wear with Computed Tomography and Influence of Surface Roughness on Materials for Hip Prostheses

ANNELI JEDEMALM
Department of Materials Science and Engineering
School of Industrial Engineering and Technology
Royal Institute of Technology (KTH)
SE - 100 44 Stockholm, Sweden


ABSTRACT

Over one million hip prostheses are implanted in patients worldwide each year and the need is increasing as the patient group of younger and more active patients is increasing. Many parameters affect the longevity of the implant, where aseptic loosening caused by wear debris is the most common reason for revision. To be able to monitor wear in vivo and also to predict the longevity of new materials for hip prostheses are therefore important issues in this interdisciplinary research area. This thesis comprise a true non-invasive 3D method for determination of acetabular cup wear using Computed Tomography (CT) intended for clinical routine use in order to plan for a revision. It also comprises investigations of the influence of surface roughness and sterilization method in wear testing of materials for hip prostheses. Mainly wear of ultra high molecular weight polyethylene (UHMWPE) was investigated since it is the most common soft bearing in hip prostheses. The 3D-CT method was found to be easy to use and showed an accuracy and repeatability at a clinical relevant level for acetabular cup wear. It should lend itself well to semi-automation. The influence of surface roughness was investigated with both a multidirectional pin-on-disk machine and with a hip simulator. A new low friction coating, Micronite, was also evaluated with the pin-on-disk machine. This coating showed potential for use in artificial joints, but further investigations are needed. In the hip simulator test, it was found that not only a rougher counter surface increased wear, but also sterilization by \( \gamma \)-irradiation increased wear of UHMWPE cups.

Keywords: Hip prostheses, Computed Tomography; Surface roughness; UHMWPE; Wear; Coating; \( \gamma \)-irradiation; pin-on-disc; hip simulator
LIST OF PAPERS AND AUTHOR CONTRIBUTION IN EACH PAPER

This thesis is based on the following papers, referred to by Roman numerals in text:

I. Tribological investigation of coatings for artificial joints
   Hoseini, M., Jedenmalm, A. and Boldizar A.
   *Submitted to Wear*, May 2005.

II. Assessing wear of the acetabular cup using computed tomography: an ex vivo study

III. Effect of surface roughness and sterilization method on wear of UHMWPE acetabular cups: preliminary hip joint simulator results
    Jedenmalm, A., Leardini, W., Zavalloni, M., Affatato, S. *ASME conference ESDA 2006*, Torino, 4<sup>th</sup>-7<sup>th</sup> July 2006, Italy.

IV. A new approach for assessment of acetabular cup wear with computed tomography: a phantom study
    Jedenmalm, A., Olivecrona, H., Olivecrona, L., Noz, M.E., Stark, A.
Paper I
The author supervised Hans Magnusson’s Master of Science Thesis work and together planned and performed AFM (Atomic Force Measurement) surface roughness measurements and particle debris analysis. The paper was discussed with Mohammed Hoseini and the author wrote some of the parts regarding surface roughness and particle debris analysis.

Paper II
The work was planned together with the co-authors. The author planned, and evaluated the CMM measurements analysis and planned, performed and evaluated the micrometer measurements.

Paper III
The author planned, performed and evaluated the experimental work. The hip simulator experiment was discussed with the co-authors, and Walther Leardini and Mara Zavalloni also aided with some practical issues. The paper was mainly written by the author and the co-authors aided with the discussion and introduction.

Paper IV
This is a continuation of paper I and the author planned the experiments together with the co-authors, and evaluated the CMM measurements and results including statistics and wrote the paper in close co-operation with the co-authors.
CONTENTS

1 ABBREVIATIONS ........................................................................................................ 11

2 INTRODUCTION ........................................................................................................ 13
  2.1 Hip Prosthesis ....................................................................................................... 13
  2.2 Aims of thesis ....................................................................................................... 14

3 WEAR TESTING OF MATERIALS FOR HIP PROSTHESES .. ........................................ 17
  3.1 Different wear test machines .................................................................................... 18
    3.1.1 Pin-on-disk ........................................................................................................ 18
    3.1.2 Hip Simulator .................................................................................................... 18
  3.2 Wear debris ............................................................................................................. 19
  3.3 Materials for Hip Prostheses .................................................................................... 20
    3.3.1 UHMWPE ......................................................................................................... 20
    3.3.2 Metals ............................................................................................................... 21
    3.3.3 Ceramics .......................................................................................................... 21
    3.3.4 Titanium nitride coating ...................................................................................... 21
    3.3.5 Micronite coating ............................................................................................... 22
    3.3.6 Diamond-like carbon coating ............................................................................. 22
  3.4 Sterilization of UHMWPE ........................................................................................ 22
  3.5 Tribology of Hip Prostheses ..................................................................................... 23
    3.5.1 Wear ................................................................................................................... 23
    3.5.2 Friction .............................................................................................................. 24
    3.5.3 Lubrication ....................................................................................................... 24
  3.6 Surface Roughness .................................................................................................. 24

4 ACETABULAR CUP WEAR ASSESSMENT FOR CLINICAL USE ......................................................... 27
  4.1 Computed Tomography ............................................................................................ 27
  4.2 In vivo Wear ............................................................................................................. 28
  4.3 Different Radiographic Methods .............................................................................. 29

5 EXPERIMENTAL ........................................................................................................ 31
  5.1 Materials ................................................................................................................ 31
    5.1.1 Pin-on-disk ........................................................................................................ 31
    5.1.2 3D-CT ............................................................................................................... 32
    5.1.3 Hip Simulator .................................................................................................... 32
  5.2 Methods .................................................................................................................. 33
    5.2.1 Pin-on-disk wear test ........................................................................................ 33
    5.2.2 AFM surface roughness measurements ............................................................ 34
    5.2.3 Wear debris characterization .............................................................................. 34
    5.2.4 Computed Tomography ..................................................................................... 35
    5.2.5 CMM ............................................................................................................... 37
# Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AFM</td>
<td>Atomic Force Measurement</td>
</tr>
<tr>
<td>AP</td>
<td>Anterior Posterior</td>
</tr>
<tr>
<td>CMM</td>
<td>Coordinate Measurement Machine</td>
</tr>
<tr>
<td>CoCr</td>
<td>Cobalt Chromium alloy</td>
</tr>
<tr>
<td>CoCrMo</td>
<td>Cobalt Chromium Molybdenum alloy</td>
</tr>
<tr>
<td>CT</td>
<td>Computed Tomography</td>
</tr>
<tr>
<td>2D</td>
<td>Two dimensional</td>
</tr>
<tr>
<td>3D</td>
<td>Three dimensional</td>
</tr>
<tr>
<td>EBRA</td>
<td>Ein Bild Roentgen Analysis</td>
</tr>
<tr>
<td>In vitro</td>
<td>In the laboratory and not in a living organism</td>
</tr>
<tr>
<td>In vivo</td>
<td>Taking place in a living organism</td>
</tr>
<tr>
<td>RSA</td>
<td>RadioStereometric Analysis</td>
</tr>
<tr>
<td>SEM</td>
<td>Scanning Electron Microscope</td>
</tr>
<tr>
<td>THR</td>
<td>Total Hip Replacement</td>
</tr>
<tr>
<td>UHMWPE</td>
<td>Ultra High Molecular Weight Poly-Ethylene</td>
</tr>
</tbody>
</table>
2 INTRODUCTION

Hip joint prostheses are needed when the natural hip joint is destroyed either by accident or by some disease. The most common reason for total hip arthroplasty (THA) is arthritis, inflammation of the joint [1]. For example, osteoarthritis destroys the joint cartilage, causing severe pain in the hip since bone is rubbed against bone, and by replacing the entire joint, pain is relieved. The outcome is very good for elderly patients, but for younger and more active patients the implant often needs to be replaced.

2.1 Hip Prosthesis

Hip prostheses consist mainly of a stem, ball (referred to as head) and a socket (referred to as cup), Figure 1. The cup and stem can either be press-fitted into the bone or cemented. The press-fit design involves a porous coating usually made of titanium or hydroxyapatite that enhances bone ingrowth. For the cemented design a kind of bone cement usually made of polymethyl-methaacrylate (PMMA) is used to attach the implant to the bone.
In 1959 sir John Charnley, an English surgeon introduced a hip prosthesis where the cup was made of polytetrafluoroethylene (PTFE). It had such high wear that it had to be replaced by another material and in 1962 Charnley introduced UHMPWE as a new bearing material [2]. The design and material are still used today with some small changes.

There are many different materials and material combinations that are used today, but the most common material combination is a titanium stem, a CoCr head and an UHMWPE cup with a titanium backing. Other couplings for the articulating surfaces are for example: CoCr – CoCr, Alumina or Zirconia sliding against UHMWPE, Alumina – Alumina, Zirconia – Zirconia. All the above mentioned materials may also differ in material processing and alloy composition.

Even though THA is considered as a successful treatment of destroyed hips, the numbers of failures and the longevity are not satisfactory. After ten years less than 10% will fail and after 20 years less than 30% [1]. Consider that about 800 000 (exact numbers are not available because of insufficient international registry) patients receive a hip prosthesis each year in the world the number of revisions are quite high [3]. The most common reason for hip joint revision surgery (replacement surgery of an implant) is usually not that the implant mechanically wears out but rather by aseptic loosening (mechanical loosening) [1]. This loosening process, often called osteolysis, is believed to be triggered by wear debris [4, 5].

Even though there is over forty years of experience and research about hip prostheses there are problems to solve. One of the most important issues is to improve the longevity of the implant in order to improve younger and more active patients’ quality of life and in order to reduce the number of revisions and hence health care costs.

### 2.2 Aims of thesis

There were two main purposes for this thesis. One was to validate a method for in vivo wear determination of acetabular cups using CT. The method would enable planning of revision at an early stage. The other was to investigate the influence of surface roughness and sterilization method in wear testing of materials for hip prostheses. This is important in order to develop more severe wear testing of new materials in order to predict their performance and longevity. The outline of the thesis is shown in Figure 2.
Figure 2  Outline of thesis.
3 Wear Testing of Materials for Hip Prostheses

It is difficult to validate hip implants because of the many parameters to consider, where the most obvious ones are listed in figure 3. For example, it doesn’t matter how wear resistant a material is if it causes negative biological reactions in the body.

**Input Parameters**
-Surface Roughness
-Sterilization method
-Design
-Size
-Diametrical clearance
-Materials
-Lubrication

**Testing of hip prosthesis**

**Output parameters**
-Wear
-Wear debris
-Corrosion
-Ageing and oxidation of materials
-Biological response

*Figure 3* The most obvious parameters to consider for wear testing of materials for hip prostheses.
A hip prosthesis might be in the body for 10 to 25 years. This time frame is not suitable for testing of commercial products, and therefore simplified and accelerated wear testing is used. However, history has shown that more severe testing is required, especially for new materials intended for younger and more active patients that require a more long lasting implant.

3.1 Different wear test machines
Wear test machines for materials for hip prostheses tries to mimic the physiological motion of the hip. Usually normal gait is simulated and the motion is simplified. A normal hip joint moves in three different planes: flexion-extension, abduction-adduction, and rotation, and has a double-peak load profile. The load may increase with four times the bodyweight during walking. The most common wear test methods to simulate these motions are pin-on-disk machines and hip simulators. For both methods bovine serum is considered to be the best lubricant to simulate the synovial fluid that normally is in human joints.

3.1.1 Pin-on-disk
Pin-on-disk machines are fast and good for screening of new materials. Modified pin-on-disk machines also take into account the multidirectional wear path which is especially important for polymers. Otherwise the wear can be underestimated. The drawback with these machines is that they tend to exaggerate the influence of surface roughness, since the contact area is small and thus just one scratch may have great impact [6]. They also only test the material and surface texture, not the design.

3.1.2 Hip Simulator
Hip simulators try to mimic the normal walking of a human. The tests can be performed with ready to implant designs. These tests take longer time than the simplified pin-on-disk experiments and are more expensive. The standard testing requires simulated walking and not running or walking slow. One million cycles is considered to correspond to one year of walking and the tests are usually run for about 2 to 5 million cycles. For an active patient it would be more appropriate to stipulate that 3 million cycles correspond to one year.
These tests are however used with as new implants and without the many parameters occurring in vivo, such as 3rd body wear. The problem with using 3rd body particles in hip simulator tests with polymer cups is that the particles may be embedded in the polymer, which makes it difficult to measure the wear of the cup. Some of the other parameters such as sickness and thus changed joint fluid are by obvious reasons difficult to simulate. Since younger and more active patients require a more long lasting and wear resistant hip prosthesis it is evident that more severe testing conditions are needed.

3.2 Wear debris

A successfully implanted hip prosthesis will be in the body for about ten years or more before it is needed to be replaced, most likely because of aseptic loosening [1]. Wear is considered to be one of the most important limiting factors for a long implant life, even though very few implants mechanically wear out. Instead, the wear debris generated during normal wear of UHMWPE may cause substantial negative biological effects [4, 5, 7]. Wear debris is transported to the soft tissue surrounding the implant and causes chronic inflammation. Continuous irritation caused by UHMWPE particles activates inflammatory cells (macrophages) that stimulate bone resorptive cells (osteoclasts) and eventually lead to loosening of the implant [4, 5, 7].

Shanbag et al. [8] reported from an in-vitro study that the mean particle size of wear debris from UHMWPE acetabular cups was 0.5 µm with a predominantly spherical shape, and that 90 % of all particles were submicron in size. Particles with a size of 10 µm and larger were also found. Tipper et al. [9] showed that less than 0.1 % of all particles had a diameter larger than 10 µm. Typical size distributions of wear debris reported from in-vivo experiments [10-12] are:

- Spherical particles 0.1 - 0.5 µm (mean diameter)
- Clusters of small irregular particles 0.25 × 10 µm (rectangular)
- Flakes and platelets 50 × 80 µm
- Elongated particles 2 × 100 µm

It has been demonstrated in several studies that the macrophage reaction to wear debris depends on a number of factors including size and concentration
of the debris. It was also shown that wear debris of a smaller size and higher concentration stimulated macrophages more [12, 13].

It is also well known that abrasive conditions at the articulation may be due to both two-body and three-body abrasions. Third-body particles could easily abrade the softer UHMWPE and produce a greater amount of wear debris, about billions of sub-micrometer wear particles annually [14].

3.3 Materials for Hip Prostheses

There are several materials and material combinations that are used for hip prostheses. They all have their pros and cons for this particular application, but hey all have in common that they have to function in the body and withstand the body load for a long period of time.

3.3.1 UHMWPE

Currently there are several types of Ultrahigh molecular weight polyethylene (UHMWPE) acetabular cups that differ in material properties and sterilization methods [10]. UHMWPE is a semicrystalline, linear homopolymer of ethylene. High wear resistance, low coefficient of friction, high impact strength and toughness, low density and good biocompatibility and biostability are properties of UHMWPE that makes it the number one choice of material for acetabular component in artificial joints [15].

UHMWPE is a tough material that can undergo great plastic deformation before break, but in artificial joints continuous deformation leads to embrittlement and finally breach, also called fatigue wear. Oxidative wear refers to the environmental issues, like oxidation from artificial aging that changes the mechanical properties of the polymer and might increase wear rate.

UHMWPE have a very high strain rate to failure with greater wear resistance than other polymers, nevertheless the polymer wears. Normal wear rate in acetabular cups can be as low as 50-100 microns a year [10], but still a large number of submicron particles are generated (>10^{10}), which cause negative biological effects.
3.3.2 Metals
Stainless steels, CoCr alloys and titanium alloys are the most common metallic biomaterials used in artificial joints. These metallic materials have typical metallic advantages like high tensile and fatigue strength but also disadvantages such as chemical and mechanical wear.

There have been many tribological studies on the wear of UHMWPE - stainless steel couplings used for artificial joints but relatively few studies on the wear of alternative material combinations. Stainless steel was the original stem and femoral head material for the Charnley prostheses. Stainless steel is also alloyed with nickel, which may cause allergies. A typical stainless steel, 316 L, consists of several different elements, where L denotes a low carbon content (316L: Fe bal, 17-19% Cr, 12-14% Ni, 2-3% Mo, <2%Mn, <0.03%C). Nowadays, it is often replaced with CoCr-alloys because of their improved corrosion properties. CoCr alloys have been used in surgical implant applications for more than sixty-five years [16].

3.3.3 Ceramics
Ceramic materials like alumina and zirconia, are used in artificial joints as femoral heads because of their high damage resistance and their polished surface. High strength (could cause stress shielding) and their brittle nature makes these ceramics not the first choice for load applications like bulk material for artificial joints. The manufacturers are refining their methods in order to make components without pores and defects that cause the brittleness, but still long-term in vivo results with this new generation of joint implants are not available yet.

3.3.4 Titanium nitride coating
Titanium nitride (TiN) is the most common coating material for physical vapour deposition (PVD) today. In industry, TiN coating is used to improve tribological, corrosive and high temperature properties. The gold-coloured coating can also be used for esthetic applications [17]. Raimondi et al. [18] reported from a tribological study on TiN-coated femoral heads that some of the coatings had distinct surface scratches, which were believed to be the result of third body abrasive wear from bone cement particles. Coating breakthrough in femoral heads coated with other coating materials was also reported. One reason for this coating breakthrough is the high stresses that arise from contact with hard particles trapped
between the two articulating surfaces (acetabular and femoral head). If the coating is locally damaged, this will accelerate failure, causing extensive wear and breakthrough of the coating, even under low loads [18]. Impact studies of TiN-coated titanium have shown that coating failure depends mainly on the substrate properties. When plastic deformation of the substrate occurs, the coating itself cannot carry the entire load and failure takes place [19].

3.3.5 Micronite coating

Recently, some new surface engineering techniques have been developed which may be interesting for extending the lifetime of artificial joints. Micronite is a specially treated TiN-coating with a significantly lower coefficient of friction, according to a study performed with oil as lubricant (in accordance with ASTM G99-95a (2000) e1) [20]. Micronite (Patent Pending) is made by introducing a high molecular material into the substrate that consists of a specially treated PVD-coated TiN. This material combination has a low coefficient of friction and low wear.

3.3.6 Diamond-like carbon coating

Diamond-like carbon (DLC) is known to have some properties similar to diamond, e.g. hardness, elastic modulus and chemical inertness [21, 22]. Results from in-vitro experiments on DLC-coated components are contradictory. Today the two major areas for DLC-coated materials in-vivo are blood-contacting (heart valves) and tribological applications (artificial joints). Blood-contacting applications are commercially available. In 2001, a company sold artificial joints with a DLC-coated femur part. Within a short time, some of these implants showed failure due to increased wear and coating delamination and had to be replaced [12].

3.4 Sterilization of UHMWPE

The sterilization method is known to sometimes affect the material properties and wear resistance of the polymer cups [10, 12, 23]. Examples of sterilization methods are: ethylene oxide (EtO) gas, gas plasma, and $\gamma$-irradiation. Historically, UHMWPE components for THA (Total Hip Arthroplasty) were sterilized by ethylene oxide (EtO) gas, but for practical reasons, this technique was to a great extent supplanted by exposure to $\gamma$-
irradiation, typically at doses ranging from 2.5 to 4.0 MRad, with the components packaged in air [10]. Today it has become common knowledge that $\gamma$-irradiation of UHMWPE may result in bond scission and formation of free radicals in the presence of oxygen [10]. Therefore inert atmosphere such as nitrogen is used instead of air. Furthermore, due to the presence of long-lived free radicals, oxidation may increase for years after irradiation, sometimes reaching a maximum in a zone located below the surface of the component [10, 24]. Degradation continues after irradiation and subsequent implantation in the body [24, 25]. Numerous clinical studies have considered the effects of different sterilization methods on UHMWPE components of joint implants [10, 23, 26, 27]. Unfortunately, the results do not produce a fully conclusive conclusion.

3.5 Tribology of Hip Prostheses

Tribology is the science and technology of interacting surfaces in relative motion, which is an interdisciplinary subject that embraces physics, chemistry and material science. It is the study of friction, lubrication and wear.

3.5.1 Wear

Wear is characterized by the progressive loss of material from the surface of a solid body owing to mechanical action. There are four main wear mechanisms: abrasive-, adhesive-, fatigue-, and oxidative wear. Abrasive wear is sometimes subdivided into two-body and three-body abrasive wear. In two-body wear material is removed by micro cutting from hard surface asperities, in three-body abrasive wear material is removed from hard particles that have embedded themselves into a soft surface that plough grooves into the opposing softer surface. Adhesive wear is material transfer between two surfaces, or loss from either surface, due to localized bonding between the contacting asperities that break molecular forces. Abrasive wear is the most common wear mode in hard joint bearings, while all four wear modes can be found in joint implants with soft bearings.
3.5.2 Friction
Friction is the resistance to motion that arises from interaction of solids at the real area of contact. It can be desirable (brakes) and undesirable (bearings). The degree of friction is often represented by the coefficient of friction, \( \mu \), defined as the ratio of the tangential force to the normal force.

For artificial joints, friction forces arise mainly from adhesion and deformation. Adhesion occurs because of molecular interaction between the two surfaces. Frictional force from deformation arises from the energy loss needed to deform the polymer because material asperities. Friction also occurs because viscous losses to the lubricant [28].

Friction and wear is related to each other in the sense that frictionless processes will not cause wear. On the other hand, increasing friction forces do not automatically imply increasing wear loss [29].

3.5.3 Lubrication
The articulating surfaces in the artificial joint are lubricated with pseudo-synovial fluid or bursal fluid with a complex and variable biological composition. However, it is clear that this fluid does not have the rheological properties of healthy synovial fluid. Artificial joint articulates with mixed or boundary lubrication regime (250 nm film) generated by hydrodynamic action not enough to separate the two surfaces. Hence direct contact and wear of the bearing surfaces occur [9].

3.6 Surface Roughness

Retrieved metal femoral heads have been found to be scratched and roughened which can accelerate the wear of the UHMWPE cup [30-32]. The scratches have been found to be multidirectional, and especially in the area of contact between head and cup [33, 34]. Surface scratches in vivo are mainly believed to be caused by third body wear from particles of bone, cement and/or metal [30].

Since there are so many parameters to consider in the \textit{in vivo} situation it has been difficult to correlate the head surface roughness to the acetabular cup wear in the patient [31].
Many surface roughness studies for hip prostheses have been performed, but with very various results [30, 31, 35, 36]. Some authors have found a relationship between surface roughness of retrieved femoral head and the wear volume of the cup, while others have found a much weaker relationship than that tested *in vitro*. Most of these studies used the arithmetic mean roughness parameter, $R_a$, for evaluation of the head surface roughness even though this parameter alone cannot distinguish between different surface profiles.

The 3rd body particles may also be the reason why the femoral heads are roughened *in vivo* and thus accelerating the wear of the UHMWPE cup. Today more young and active patients also receive hip prostheses and therefore it is important to include this roughening factor in the long-term wear prediction.
4 ACETABULAR CUP WEAR ASSESSMENT FOR CLINICAL USE

Assessment of acetabular cup wear is important in order to know when it is necessary to replace the implant. Several studies have concluded that early migration is a good predictor for late failure and that measurements of the migration would enable the orthopedic surgeon to plan for a revision [37-40]. Thus, reliable wear measurement methods for the clinical situation are essential in order to predict failure. Higher precision and accuracy of clinically available wear measurement methods would also improve the power of clinical studies of new implants and detection of clinically significant wear differences at an earlier stage.

Several radiographic methods exist, but the ones used in clinical practice are not accurate enough to detect wear at an early stage. The most common ones are based on simple X-ray radiographs. There exist more accurate methods for research, such as radiosteremetric analysis (RSA), but they are too complicated and expensive for use in clinical practice.

4.1 Computed Tomography

With computed tomography (CT) it is possible to obtain cross sections of patients. Attenuation profiles are taken in a number of projections and thereafter a computer can reconstruct the image of the investigated plane. Every image element (pixel) in the memory matrix corresponds to a certain volume element (voxel) in the patient. To diminish the investigation time, several detectors are arranged in a circle section and the X-ray tube is centered in the opposite direction of that circle. The different projections are obtained by rotation of the whole package of X-ray tube and detectors [41]. An image of a CT scanner is shown in figure 4.
CT is the modality of choice for assessing periprosthetic osteolysis. Serial CT scans have been proposed as a method for monitoring osteolysis, thereby facilitating the planning and timing of revision surgery [42]. Previous studies have shown that CT can be used for evaluating acetabular cup position and migration [43-45]. Ideally a CT examination of a THA patient should also provide data on wear of the implant.

A very high contrast can be obtained compared to ordinary X-ray. For visual assessment in both 2D and 3D, current multi-slice Computed Tomography (CT) offers an accurate spatial volume resolution without significant distortion and gives correct geometry. Metal artefacts, historically contraindicating CT examinations in the presence of implants, are now suppressed by software algorithms provided by the CT manufacturers. Therefore, there is potential for measuring the relationship between the implant components. The advantage of CT measurements of wear is that they are truly three-dimensional and independent of the wear direction and patient position during examination. On planar radiographs, wear out of the plane of the radiographs can be undetected. Using CT, wear in any direction will be detected.

4.2 In vivo Wear

Several studies have concluded that early migration is a good predictor for late failure and that measurements of the migration would enable the orthopedic surgeon to plan for a revision [37-40]. In vivo wear rate values of conventional UHMWPE acetabular cups ranges from 0.13 mm/year to
0.23 mm/year and total wear at revision is about 1 to 3.5 mm [14]. A common wear profile of an acetabular liner is shown in figure 5.

![Figure 5](image)

**Figure 5** A schematic profile of a worn acetabular liner with radius, $r$, and head penetration depth, $d$.

### 4.3 Different Radiographic Methods

Several wear measurement techniques have been developed, ranging from simple single radiographic techniques to more advanced 3D (three dimensional) techniques. They have their respectively pros and cons. For example the common method of using AP (anterior-posterior) radiographs for monitoring wear is difficult in the clinical routine practice since the position and orientation of the wear tract must be guessed and the accuracy tends to be less than in laboratory conditions [46]. A recent phantom study reported 1.3 mm for accuracy, and 0.13 mm for mean measurement error of using digitized AP radiographs combined with dedicated computer software [47], while a study resembling clinical routine by Clarke et al. reported errors (2 SD) ranging from $-1.8$ to $+1.2$ mm for 1 mm wear and from $-4.4$ to $+0.8$ mm for 4 mm wear for manual assessment of wear when comparing two AP radiographs [46]. There is also a difference between individuals in the interpretation of the radiographs and the quality of the X-ray film. Another drawback that also applies for all 2D methods is that there is a risk that the wear vector might be out of the plane of the radiograph and that the magnitude of the error depends on the degree of anteversion of the cup [11]. Some 3D methods
have therefore been developed by adding a lateral view to the AP radiographs [48, 49]. In vivo measurements have shown that 3D wear monitoring analysis has a higher accuracy and detects about 10-20% more wear than 2D methods [40, 48, 49]. The precision of the 3D technique is however lower than for the 2D [49]. Also the lateral view is often obstructed by the prosthesis, and can therefore be difficult to obtain. The most accurate and true 3D wear monitoring method today is considered to be radiostereometric analysis (RSA) [1]. In a study by Schewelov et Al. [47], the accuracy of the RSA digital measurements was 0.42 mm with a mean measurement error of 0.01 mm. However, such methods are normally not available in clinical practice since it requires special equipment and also implantation of small tantalum balls on the implant and surrounding bone.
5 EXPERIMENTAL

5.1 Materials

Wear of UHMWPE was estimated in all experiments. The same medical grade was used, but with different treatments and shapes.

5.1.1 Pin-on-disk
For the pin-on-disk experiment, the pins were made of UHMWPE, while stainless steel was used for the harder counter-surface disks that served both as a reference and a substrate for coatings. The UHMWPE was compression-molded medical grade GUR 1020 (produced by PolyHI Solidur, Germany and provided by Scandimed AB, Sweden). The pins were machined to cylindrical pins of length 20 mm and a diameter of 8 mm. One end was truncated according to Figure 6, and aged for 23 days at 80°C in a heat chamber.

![Pin geometry](image)

Figure 6 Pin geometry

The discs were made of 316L stainless steel (provided by Vattenfall Ringhals AB, Sweden) and had a diameter of 80 mm and a thickness of 4 mm. The disks were polished mechanically with number 500 abrasive papers
to a surface roughness ($R_a$) of about $0.025\pm0.005 \, \mu m$. This was the surface roughness of all the discs before surface coatings were applied. Three different coatings (made by Micromy, Stockholm, Sweden), titanium nitride, Micronite, and diamond-like carbon, were applied on the discs using magnetic sputtering PVD at 300°C with a coating thickness of about 3µm.

In the first stage, the tribological experiments were performed on surfaces having the same surface roughness on the substrate before the coating. In the second stage, tribological experiments were performed on surfaces having similar roughnesses after the coating. Based on the result from the first stage, Micronite and TiN sample were chosen for the latter investigation. The stainless steel discs were polished mechanically with abrasive papers to reach the same surface roughness, $R_a$, as the Micronite- and TiN-coated samples.

### 5.1.2 3D-CT

Eight explanted acetabular cups (Romanus acetabular cup, Biomet, Warsaw, IN, USA) and matching femoral heads were used in the CT studies. This implant consists of a hemispherical titanium alloy shell, a polyethylene liner with a hexagonal locking device, and a 28 mm modular femoral head component. The outer diameter of the titanium shells ranged from 52 mm to 58 mm.

### 5.1.3 Hip Simulator

A total of 15 commercially available acetabular cups, whereof 7 were $\gamma$-sterilized (3 Mrad) in nitrogen, the other cups were non-sterilized, and 11 femoral heads were investigated. The cups were made of compression molded GUR1020 UHMWPE (Sulene™ PE, ISO 5834-2), with an inner diameter of 28mm and outer diameter of about 46 mm. The heads were made of Durasul wrought CoCrMo (protasul 20, ISO 5832-12) with a diameter of 28 mm. The diametrical clearance between each head and cup coupling was measured with a Coordinate Measurement Machine (Wenzel LH44, Wenzel, Wiesthal, Germany) and was estimated to 0.51 mm ± 0.01 (mean ± standard deviation). All but three heads were manually roughened with P320 grit SiC paper producing circular multidirectional wear tracks, prior wear test. The average initial head surface roughness was measured with a white light profilometry to 15 nm ($R_a$) and those heads are referred
to as smooth. The average surface roughness of the roughened heads was about 400 nm ($R_a$). One rough- and one smooth head were kept as controls for the roughness measurements.

5.2 Methods

5.2.1 Pin-on-disk wear test
The multidirectional pin-on-disk machine measured the accumulated wear and friction of a loaded test specimen sliding against a rotating disc. The significant recorded quantity, the wear of the UHMWPE pin, was defined as the reduction in pin length [$\mu$m]. A number of modifications of the pin-on-disc machine were made in order to mimic the in-vivo tribological conditions. In particular, the polymer pin was allowed to slide over a stainless-steel rotating disk and also to rotate around its own axis, figure 7.

![Figure 7 Principle of a pin-on-disc wear test machine with loaded test specimen pin and rotating disc.](image)

This gave a bidirectional motion and the strain-hardening behavior of polyethylene due to unidirectional sliding was reduced [50]. The reduction in sample length was measured in real time with a displacement transducer in order to obtain continuous information about the wear process. The frictional force between the test specimen and the rotating disc was recorded with a load cell. The temperature of the bovine serum used as the
lubricant and the room temperature were continuously recorded during measurement.

The specific wear is here defined as wear per sliding distance, i.e. \( \mu \text{m/km} \), a dimensionless number typical of the pin and disc combination. The parameters used during the wear measurements, as in previous studies, were [50-52]:

- Sliding velocity 60 rpm, 100 mm/s
- Running period 48 hours, 17.3 km
- Contact pressure (load/area) 9 MPa
- Contact area 7 mm\(^2\)
- Temperature 37 ± 1 °C

Bovine serum was used as lubricant in all the tribological experiments. The serum was diluted with phosphate-buffered saline with a physiological pH of 7.4 at 25 °C in a ratio of 2:1, since the protein content of calf serum Sigma C 6278 (5-8 per cent) is much higher than that of synovial fluid (2 per cent). Sodium azide, 0.02 %, was added to prevent microbial growth.

### 5.2.2 AFM surface roughness measurements

The surface roughnesses (\( R_a \) and \( R_{\text{max}} \)) of the discs were measured using AFM Nanoscope 3100 (ThermoMicroscopes now Veeco Instruments Inc, NY, USA) in the contact mode with the autoprobe M5 with Large area scanning head (100x100µm). The data acquisition software was ProScan 1.51b with Image Processing Software IP2.0. Before scanning, all the discs were ultrasonically cleaned with ethanol. One disc from each material group was analyzed at five positions outside the wear track circle and five on the wear track.

### 5.2.3 Wear debris characterization

The wear debris generated from the pin-on-disc experiments were collected by filtering the bovine serum according to the protocol used by Affatato et al. [12]. Each serum sample with wear debris was dissolved in 6N KOH for 24h at 60°C during continuous stirring. Then an equal amount of ethanol was added and after a further 24h the samples were filtered through 0.2 µm Isopore polycarbonate membrane filters.
(Millipore). The filters were dried and sputtered with gold for examination in a Scanning Electron Microscope (SEM, JEOL JSM 840), using secondary electrons with energy of 5-20 keV. For the compositional investigation of unknown materials, the energy dispersive mode was used with electrons of 20 keV.

5.2.4 Computed Tomography
Two examinations were obtained of each implant, using a CT scanner (LightSpeed QX/I, General Electric Medical Systems, Milwaukee, WI, USA). Volumes were acquired with 1.25 mm collimation and a pitch of 3 (0.75 mm/rotation), at 40 mA, 120 kV. Slices were reconstructed with 1.25 mm increment. To mimic different patient positions, the position of the implant in the CT-scanner was altered between the scans. External pliers were used to seat the femoral head in the cup.

The image analysis of the CT volumes was performed on a laptop using a previously extensively validated 3D volume fusion tool, co-developed with RADH Oncology Products [53-55]. Two different approaches were used, one based on superimposed circles on three different planes and one with selected landmark points. The latter approach was developed after the circle method.

CT image analysis – circle approach
The center of the prosthetic femoral head and the center point of the cup were determined in the CT volumes. The measurements were made using a 3D sphere superimposed on the axial, sagittal, and coronal slices simultaneously. The sphere was positioned using the computer’s pointer device. When designated, the coordinates of the sphere’s center were output. The sphere size was set by specifying the radius and, when applicable, re-sized with the computer’s pointer device. Isolines were superimposed on the images to define the metal–bone interface. The software also features 3D-isosurface display of the implant. First, the linear penetration depth of the femoral head into the cup was measured. A sphere was designated encompassing the femoral component head and a second encompassing the outer shell of the acetabular cup. The sphere sizes were chosen to match the known size of the components (diameter 28 mm for the head and 52–58 mm for the cup, depending on the specific prosthesis). The distance between the centers was computed using the
Pythagoras theorem in 3D. In a non-worn cup of this type these centers coincide, therefore the distance represents the linear penetration depth of the head into the cup in the given CT volume, i.e. the length of a linear wear tract. Second, a measurement of the thickness of the remaining polyethylene liner was made. Starting with the previously designated sphere on the femoral component head, a second sphere was superimposed on the first and expanded until it reached the inner surface of the cup shell. The difference in radii between the two spheres was calculated. This represented the remaining polyethylene liner thickness. In a test–retest procedure these experiments were performed on each of the 16 CT volumes twice on different days (trials 1 and 2) by two independent examiners. Examiner 1 was a radiologist, examiner 2 an orthopedic surgeon. The time used for analysis of each image was restricted to between 5 and 10 min.

**CT image analysis – landmarks approach**
In the CT volumes, the center of the prosthetic femoral head and the center point of the cup were determined along with the orientation of the normal axis to the cup opening surface. The measurements were made with the use of a 3D point mode. The computer pointing device was dragged to a point of interest on the screen, and when designated, generated the coordinate point on the displayed 3D-isosurface. 200 evenly distributed coordinate points corresponding to the outer surface of the cup metal shell and the femoral head were designated respectively using this 3D point mode. Secondly 20 coordinate points on the cup opening face were designated using the same approach. The time used for each image analysis was restricted to 20 minutes. Using locally developed software and linear algebraic solutions these point sets were used to fit spheres to the cup and femoral head, and to compute the orientation of the normal axis to the cup opening plane.

The algorithms used for this have previously been reported [45]. To filter out metal artifacts, the calculations for fitting the spheres were performed in two iterations; first a preliminary sphere was fitted to each point set, second all landmark points with a distance of more than 0.5 mm (i.e., approximately one standard deviation) from the sphere surface were eliminated, and a final sphere was fitted.
The wear vector was defined as the vector originating from the center of the cup to the center of the head. The angle between this wear vector and the normal axis was calculated using the basic linear algebra formula for an angle between to vectors (u and v), equation (1).

\[
\cos \theta = \frac{u \cdot v}{\|u\|\|v\|}
\]

(1)

**5.2.5 CMM**

The inside of the polyethylene liners of the cups were examined with a coordinate measuring machine (CMM) using 8000 evenly distributed digitizing points. Points on the cup opening collar and on the hexagonal locking device surfaces were also acquired to enable calculation of the wear vector angle. Locally developed software was used to calculate the maximum linear wear depth. A sphere was fitted to the unworn region, and the maximum radial distance between the data points on the surface of this sphere and the worn region was calculated.

The wear vector was defined as the vector originating from the center of the unworn cup to the most worn point on the cup inner surface. The angle between this wear vector and the normal axis of the acetabular cup opening plane was calculated in order to validate the possibility to use CT for determination of the wear direction. For the calculation of the angle, Equation (1) from paragraph 5.2.4 *Computed Tomography* was used.

**5.2.6 Micrometer**

The thickness of the polyethylene liners was measured with a Giga IP54 digital micrometer (Giga, China). The thinnest part of the polyethylene liners was measured and the thicknesses were recorded in millimeters. These measurements were repeated three times.

**5.2.7 Hip simulator**

All cups were pre-soaked in distilled water for four weeks prior to wear test in order to stabilize the soak rate. They were ultrasonically cleaned, blow-dried with nitrogen gas, vacuum dried for 30 minutes, and then
weighed four times in rotation with a Sartorius microbalance (resolution ± 0.01 mg and accuracy ± 0.1 mg) every 5th day at room temperature.

A total of nine acetabular cup and head pairs, were wear tested in inverted position in a 12-station hip joint simulator (Shore Western Inc, Monrovia, CA, USA) for 2 Million cycles (Mc) at room temperature. Lubricant was 25 % sterile filtered bovine calf serum balanced with distilled water and 0.2 % sodium azide added to retard bacterial growth and EDTA (Ethylenediaminetetraacetic acid) was added with a concentration of 20mM in order to minimize precipitation of calcium phosphate. A sinusoidal load curve was applied with load maximum of 2 kN at a frequency of 1 Hz. Wear was determined by weighing of all cups every 0.5 Mc with the same procedure as during pre-soak and serum was replaced with fresh serum after each weighing. Wear volume was calculated by dividing the gravimetric data with the density of GUR1020 UHMWPE (935 kg/m3). The seven rough heads were paired with four sterilized - and three non-sterilized cups and the two smooth heads were paired with two non-sterilized cups. Control soaks (3 sterilized and 3 non-sterilized cups) were kept unloaded in distilled water in the same room, since loaded soak stations weren’t available.

5.2.8 Profilometer surface roughness measurements
The head surface roughness of all heads was measured with a Zygo NewView 5010 (Zygo Corporation, Middlefield, Connecticut, USA) non-contact white light interferometry profilometer before and after wear test. Each head were measured with 10 approximately evenly distributed measurement areas of 0.26 mm × 0.35 mm with more than 300 000 measurements points. The parameters Rₚ, Rₜ, Rₜ and Rₚₙ were recorded.
6 RESULTS AND DISCUSSION

Wear testing and assessment are complex, expensive and elaborate work, since there are so many parameters to consider. Still it is important to perform these studies since the need and requirements of the implants are increasing and by that also the requirements on the materials are getting higher.

6.1 Wear Testing of Materials for Hip Prostheses

For both the hip simulator test and the pin-on-disk it was confirmed that surface roughness of the harder counterpart increased wear of the softer counterpart. It was also confirmed that the pin-on-disk machine showed a much higher wear increase with higher surface roughness compared to the hip simulator. The surface roughness of the 316L stainless steel disk increased after wear testing, while the coated disks as well as the CoCr femoral heads did not change significantly after wear testing.

6.1.1 Multidirectional pin-on-disk

The specific wear of the 316L was about four times higher than that of TiN and more than five times higher than that of Micronite. The specific wear of 316L increased more than 15 times when the Ra-value was increased from 0.03 µm to almost the same level as that of the coated material. Although there was no significant difference in the Ra-value between Micronite and TiN, the specific wear and µ for TiN were more than 30% and 10% respectively higher than for Micronite. The counter-surface material DLC gave a considerably higher wear and friction than the other counter-surface materials tested. There were no significant differences in µ between the Micronite and TiN. The counter-surface material 316L gave the lowest µ and the lowest specific wear when the surface roughness was the same before coating, but when the surface roughness was similar for the different substrates, the results were the opposite. In the latter case the µ for Micronite was about 30% lower than that for 316L and almost 10% lower than that for TiN.
The deposition of a thin coating layer (few µm) increased the surface roughness of the disks. The highest surface roughness were noted for DLC and Micronite followed by TiN. The higher surface roughness is believed to be the main reason for the higher specific wear on the coated counter-surfaces. Results of the study with the same surface roughness after the coating confirmed this statement.

The wear track after the pin was clearly visible for the 316L discs, while wear marks on the coated discs were almost invisible. The surface roughness of 316L changed on the wear track during wear test while the coated discs remained unchanged. This phenomenon could be due to the higher hardness for the PVD-coated material. This is important for the longterm survivorship of the implant.

The width of the particle size distribution of the wear debris increased with higher surface roughness and both smaller and larger particles were found. The larger particles were mostly flaky and elongated whereas the smaller ones had mostly an irregularly spherical shape. The mean particle sizes from the test with the same surface roughness on the substrate before coating are shown in Table 1. The debris exhibited the typical morphology and also the typical size and shape of wear debris reported from numerous hip simulator studies, indicating that the modified pin-on-disk method may be regarded as a reliable method to study the wear properties of material used in artificial joints [9-12, 56]. The amount of large debris as well as the specific wear was higher for the TiN, Micronite and DLC surfaces. The amount of debris for the DLC sample was significantly higher than that of the other counter-surfaces, which corresponds to the higher total wear rate. Fisher et al. [57] stated that debris below 1 µm was the most biological active, and therefore stainless steel can be expected to give more biologically active debris per unit volume, according to the study with the same surface roughnesses on the substrate before the coating. The FBA can be expected to be larger for the coated counter-surfaces than for the 316L, due to the higher total amount of wear debris below 1 µm.
Table 1  Mean particle size and amount below 1 µm from the study with the same surface roughness on the substrate before coating.

<table>
<thead>
<tr>
<th>Material</th>
<th>Mean size, µm</th>
<th>&lt; 1 µm, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>316L</td>
<td>0.46</td>
<td>98.7</td>
</tr>
<tr>
<td>TiN</td>
<td>0.72</td>
<td>70.6</td>
</tr>
<tr>
<td>Microntie</td>
<td>1.15</td>
<td>51.8</td>
</tr>
<tr>
<td>DLC</td>
<td>2.34</td>
<td>56.4</td>
</tr>
</tbody>
</table>

6.1.2 Hip Simulator

The hip simulator wear results indicate that the wear of UHMWPE acetabular cups is significantly increased due to the increase in head surface roughness. This study showed a 2-fold increase in wear rate with a roughened head (Ra = 0.4 µm, Rt = 3.15 µm) compared to a smooth head (Ra = 0.015 µm). In comparison to studies by other authors, both stronger and weaker relationships have been found between surface roughness and wear [6, 36, 58-61]. Their experimental set-ups differ in different ways, but for example Bowsher et Al [61] used a very similar experimental set-up with similar roughness values (Ra = 0.38 µm, Rt = 3.14 µm) but found a 8-fold increase in wear rate. There could be several reasons for the discrepancy in the results of these kinds of studies. One reason for this is that there are different instruments for measuring the surface roughness values and these can give different values. Also the Ra value is often the only parameter considered in these kinds of studies although it is not enough to describe the surface roughness by only one parameter. Two surfaces may have the same Ra value but different surface profiles and the magnitude of peaks and valleys and the shape and magnitude of the scratches also may differ. Therefore, the magnitude of surface roughness is questionable and discrepancy between results obtained with different procedures and different methods of roughness measurement are possible.

In orthopaedics applications roughness determined by peaks elevating from the surface will be aggressive and wearing fast, while the same Ra determined by valleys will increase the lubrication, optimizing the coupling of the surfaces and not increase wear. An attempt was made in this study to characterize the surfaces with more parameters, in order to be able to perform more controlled accelerated wear testing with roughened heads in the future. Hall et Al. [31] are among the few authors that have
done more comprehensive surface characterizations of femoral heads. In that study retrievals were investigated with several surface parameters and a relationship was found between the clinical wear factor and the two parameters $R_{sk}$ and $R_a$. It is difficult to make a completely scientific comparison between \textit{in vitro} and \textit{in vivo} wear results especially since the number of cycles in vivo is estimated from the number of years \textit{in vivo} and patients tend to be more or less active. The trends can however be compared and discussed and in the aforementioned retrieval study the $R_{sk}$ value was in the same range as for the smooth heads in this study, while the $R_a$ value showed that the heads had been roughened \textit{in vivo} but not as much as the roughened heads. Most importantly the wear rate in this hip simulator was higher than the \textit{in vivo} result which is good from a safety point of view.

Another difference factor is different sterilization methods. In this study the $\gamma$-irradiated cups both had significantly higher soak- and wear values than the non-irradiated cups. By a study by Affatato et Al. [58], where non-sterilized cups were compared to EtO and, $\gamma$-irradiated (in air) cups, the $\gamma$-irradiated cups also had higher soak values, while the wear rates of the $\gamma$-irradiated were lower than EtO-sterilized cups. There was little difference in soak rate between the EtO sterilized cups and the non-sterilized cups.

6.2 3D-CT

The main results of both CT experiments are summarized in Table 2. No significant differences were found between trials, repeated CT scans, or examiners, except for measurement of remaining polyethylene thickness, where a difference was found between the examiners. These differences were due to different interpretation of metal artefacts in the volumes. The results and landmark points were normally distributed. A slight systematic difference was found for the head diameter measurements, where the head diameter was slightly underestimated by the CT method.

Linear wear of the eight cups assessed with direct measurements (CMM) varied between 0.21 and 4.58 mm, and direct measurements (micrometer) of remaining polyethylene thickness varied between 0.89 and 3.82 mm.
The wear vector angles varied between 86° to 127°. The heads had also been worn and the head diameters varied between 27.48 and 27.94 mm.

Accuracy of the head migration measurements was in the clinical relevant level of 1 mm for both CT methods, while the accuracy of remaining polyethylene was not as reliable due to metal artifacts.

Table 2  Repeatability, accuracy, and interval estimate of bias at 95% confidence level in millimeters (in degrees for angle measurements) for CT measurements of retrieved acetabular cups.

<table>
<thead>
<tr>
<th></th>
<th>Repeatability</th>
<th>Accuracy</th>
<th>Interval estimate of bias</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CT method based on circles</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Linear wear, examiner 1</td>
<td>0.53</td>
<td>0.60</td>
<td>-0.07 ± 0.18</td>
</tr>
<tr>
<td>Linear wear, examiner 2</td>
<td>1.00</td>
<td>1.04</td>
<td>-0.04 ± 0.18</td>
</tr>
<tr>
<td>Residual thickness, examiner 1</td>
<td>1.04</td>
<td>1.30</td>
<td>-0.26 ± 0.18</td>
</tr>
<tr>
<td>Residual thickness, examiner 2</td>
<td>0.92</td>
<td>0.99</td>
<td>0.07 ± 0.16</td>
</tr>
<tr>
<td><strong>CT method based on landmarks</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Linear wear</td>
<td>0.40</td>
<td>0.55</td>
<td>-0.15 ± 0.33</td>
</tr>
<tr>
<td>Wear vector angle to normal axis</td>
<td>26.3°</td>
<td>27.0°</td>
<td>-0.66 ± 2.06</td>
</tr>
<tr>
<td>Head diameter</td>
<td>0.27</td>
<td>0.80</td>
<td>-0.53 ± 0.25</td>
</tr>
</tbody>
</table>

The examiners regarded the method based on circles as easy to use, even without detailed information on the prosthesis. The wear results of the CT methods were comparable. However, in the method based on circles two outliers were found arising from examiner interpretation of metal artefacts. This was not an evident problem with the landmark method, since those areas can easily be avoided when selecting landmarks and the largest deviations from a sphere are also removed by filtering.
There are many designs and materials for cups in THA. Metals have a good radiographic contrast, while polymers are more difficult to detect without increasing the radiation dose. Therefore metal-backed PE cups such in this study are well suited for CT measurements while ceramic-on-ceramic and metal-on-metal hip prostheses are not. There is also a possibility that PE-on-ceramic articulations may work as well for wear detection with CT, but this has not been investigated yet. The accuracy of wear detection may also be different for different designs and materials.

These CT methods for linear head penetration measurements presumes that the center of the femoral head coincide with the center of the non-worn acetabular cup. This is true for many hip prostheses designs but not for all. Sychtertz et Al. [62] found a mean difference of 1.1 mm between the centers from 3 weeks postoperative radiographs. It is also common that there is a diametrical clearance of about 0 - 0.5 mm between head and cup even though it is not stated by the manufacturer [63]. This would imply an initial displacement of the head inside the polyethylene liner if a diameter of 28 mm was used for the cup. This was not accounted for in these studies. The way to address this issue is to perform a postoperative scan to attain a reference value for subsequent scans. This would improve accuracy, since the diameters given by the manufacturer is not precise and also the problem with centers not coinciding from the beginning may also be overcome by software algorithms.

Also, the method measuring remaining polyethylene thickness is useful for all implants, since it does not require the center of cup and femoral component head to coincide initially or the implant to be spherical. Significant differences were however found between examiners, and this was because of different interpretations of metal artifacts in the images. Differences were due to measurement errors of more than 1 mm in cups 1 and 8. A review of these volumes showed the presence of spicule-shaped metal artifacts that coincided with the wear tracts. Since some cups feature metallic locking devices embedded within the polyethylene, differentiating these from metal artifacts without specific knowledge of the cup configuration can be difficult. Therefore, it was a matter of individual interpretation whether to include these structures in the measurements or not, and here the two examiners made different choices. Accuracy of this method was not as good as for measurements of linear penetration depth.
This was a limited study with a small number of subjects and therefore the data should be interpreted with caution. Moreover the backside wear is not measured with CMM but with CT. Only the angle between the cup normal axis and the wear vector could be compared across the methods because of the hexagonal locking mechanism between shell and liner allows for six different positions. In a clinical situation this would not be a problem because the wear direction would be measured either relative to the pelvis or relative to a cup coordinate system.

The advantage of CT measurements of wear is that they are truly three-dimensional and independent of the wear direction and patient position during examination. However, as in any radiographic method, the relationship between the metallic part of the cup and the metallic head of the femoral component is measured, not the actual thickness of the polyethylene liner. Therefore, the linear penetration depth can be underestimated if the femoral component head is not positioned in the most worn part of the polyethylene liner during the CT examination, as was the case with one of the examined cups.

The median total wear of the retrievals in this study was 3.2 mm. Sochart et Al [40] found in a study that the wear rates of the revised components were twice that of the surviving ones. This would imply that an accuracy and repeatability level of within 1 mm for linear wear detection would be enough to plan for a revision. The direction of wear in these retrieved cups was roughly perpendicular to the normal axis of the cup. Assuming that the cups were implanted in a normal position, i.e., around 45° of inclination and moderate anteversion, a significant part of the wear would not be accounted for on standard AP-radiographs.
7 CONCLUSIONS

A new 3D method for measurements of head penetration into acetabular cups using CT allowed for reliable wear detection at a clinically relevant 1 mm accuracy level. The method was easy to use and should lend itself well to automation.

Measurement of remaining polyethylene thickness on CT volumes is promising, since this does not require the head and cup centers of the implant to coincide initially and could therefore be useful for all cups, even non-spherical cups. Yet, based on this study, the method needs improvement or possibly more experienced examiners, since its accuracy and repeatability is still not reliable for clinical use.

It is possible to use CT for wear direction, but a larger sample study is needed to confirm the accuracy and repeatability level.

For the multidirectional pin-on-disk experiment, the width of the size distribution of the wear debris increased with higher surface roughness and both smaller and larger particles were found. The larger particles were mostly flaky and of an elongated shape, whereas the smaller ones had mostly an irregularly spherical shape.

AFM analysis showed that coating of the substrate using the PVD-technique changed the surface topography and that the deposition of a 3 µm thick coating layer increased the surface roughness of the coated materials. The surface roughness of the 316L disc changed on the wear track, whereas the surface roughness of coated materials did not change during the wear experiments. This is important for the long-term performance of a femoral head. The specific wear for 316L was about four times higher than that for TiN and more than five times higher than that for Micronite, despite the lower surface roughness of the 316L surface.

The specific wear and the µ value for TiN were more than 30% and 10% respectively higher than the value for Micronite, when the surface roughnesses were about the same. The new type of coating, Micronite, was in this respect a successful surface engineering method of enhancing the tribological properties of TiN, since Micronite is a specially treated TiN-coating. Considering the potential of Micronite and TiN coatings for
artificial joints, further study is required at surface roughness levels similar to those used in artificial joints.

The specific wear for 316L increased more than 15 times when the Ra was increased 4-5 times in the pin-on-disk experiment.

The increased head surface roughness from 15nm to 400nm (R\textsubscript{a}) increased the acetabular cup wear 2-fold in the hip simulator experiment.

The $\gamma$-irradiated cups wore more than the non-radiated cups when tested in a hip simulator.

The sterilization also effects the diffusion of lubricant into the polymer cup. In this study the $\gamma$-sterilized cups gained more weight than the non-sterilized cups.
8 SUGGESTIONS FOR FUTURE WORK

There is a possibility to optimize the CT method to a more automated method that may aid to identify patients with increased risk of aseptic loosening. The idea is to generate the surface automatically or semi-automatically in order to make the method more easy to use and to minimize interpretation errors. A much larger quantity of landmark data points is also recommended in order to improve precision and accuracy of the software optimizing calculations. If the centers are more accurately determined the measurements of the wear direction will also be more accurate.

The next step for the CT method for acetabular wear detection would be to do a larger study with implants that are measured before and after wear testing. After that a clinical study on patients would be desirable in order to validate its potential in a clinical routine setting.

Considering the potential of Micronite and TiN coatings for artificial joints, further study is required at surface roughness levels similar to those used in artificial joints.

Since it was found that the gamma-irradiated cups had a higher wear rate and gained more weight during soak than the non-sterilized cups it would be interesting to investigate the relationship between serum diffusion and the mechanical properties. It would also be interesting to compare to retrieved cups, since the time in vivo is much longer than the time in the in vitro experiments.

Oxidation is another parameter that could influence the mechanical properties and wear resistance of UHMWPE and therefore an oxidation level comparison between new cups tested in a hip simulator and revised cups would be of interest.

Since it was found that the roughened surfaces in the pin-on-disk experiment influenced the size and shape of the wear debris it would also be advisable to perform a wear debris characterization of wear debris from a hip simulator experiment with roughened heads and compare to in vivo wear debris.
9 ACKNOWLEDGEMENTS

Thanks to Stefan Jonsson, my main supervisor, for giving me the opportunity to start with this interesting project. I would also like to thank my supervisors: Karin Jacobson at KIMAB for great support and André Stark at Karolinska Hospital for his enthusiastic support and for giving me the opportunity to learn more about medical technology.

A special thank to the number of people that have aided with the different technical equipments:

Attila Temun – CMM, KTH
Mikael Sundin – YKI for teaching me the profilometer.
Mohammed Hoseini – Borås, pin-on-disk
Walther Leardini – Bologna, hip simulator
Saverio Affatato – Bologna, hip simulator
Mara Zavalloni – Bologna, hip simulator
Henrik and Lotta Olivecrona – CT at Karolinska hospital
Hans Magnusson – KTH, pin-on-disk
Hans Bergqvist - SEM
Oskar Karlsson – KIMAB, FEGSEM

I would also like to thank for the financial support from Sven Norén foundation, and also Lorenz Carlsson’s scholarship fund for travel to Bologna.

A special thank to Henrik Olivecrona for motivating me with the medical CT discussions. Thanks to all nice working colleagues and friends at MSE. My office room mate Malin for fun discussions and encouragement. Finally I would like to thank all my friends and family.
REFERENCES


[34] B. M. Wroblewski, Revision Surgery in Total Hip Arthroplasty, Springer-Verlag, London, 1990,


56
[41] B. Jacobson, Medicin och Teknik, Studentlitteratur, Lund, 1995,


