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Working principle of the dual mobility (total hip replacement): wear mechanisms and design optimization LAURIANNE IMBERT

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SUMMARY

The dual mobility concept for hip implants was invented in the 70s to address the issue of postoperative dislocations. The idea was to mix the Charnley "Low Friction Principle" that recommended a small head, i.e. decreasing of wear due to small diameter, and the benefit on the dislocation rate of a big head closer to the native one. Thus a polyethylene insert was added between the metallic metal back and the femoral head but some concerns remained, particularly the cup wear.

To keep on improving the dual mobility cup, the first point was to understand how it is working. Therefore explants analysis and studies on simulators were carried out on several series of samples. Analysis techniques like surface profilometry or 3D profiling with a Coordinate Measuring Machine (CMM) were then performed to measure roughness and wear. It was of interest to be able to compare the results given by different techniques to draw more reliable conclusions from the comparison. Indeed it was possible to conclude that wear was significant for some explants and not for the others which gave information about the wear mechanisms. It was also possible to give more reliable ranges for the average volumetric wear.

Given observations made during the previous studies, an ellipsoidal shape was thought to improve the dual mobility longevity and reduce wear. Indeed the polyethylene deformed under loading with time which resulted in a blocking of the insert at its equator and an increase in wear. The idea was to increase the thickness at the average load application point which corresponded to a reduced clearance thus a higher contact area during loading. It resulted in a more uniform contact pressure distribution and lower maxima in stress and pressure. The final effect would be a slower deformation and the blocking effect would be avoided. Obviously it would go together with a reduced wear which was the major goal of that shape optimization.

Keywords: dual mobility, total hip replacement, wear, shape optimization

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GLOSSARY

Acetabulum: It is the concave part of the pelvis where the femoral head is in rotation to form the hip joint.

Arthrofibrosis: As a result of injury or trauma, scar tissue will form excessively preventing motion of the joint. Regarding the dual mobility issue, this painful response of the body is responsible for the blocking of the mobility between the insert and the metal-back.

Aseptic loosening: It is the process by which the implant is less and less anchored into the bone due to bone resorption caused by the wear particles.

Dislocation: The femoral head is extracted from its socket.

Explant: A device that was implanted and has been removed from patients.

Femoral stem: It is the part of the implant inserted into the femur.

Intraprosthetic dislocation: It is a kind of dislocation happening in the dual mobility case, precisely it is the fact that the metallic head is extracted from the insert and stays in the metal-back.

Metallosis: It is the inflammatory response to the release of metallic debris into the soft tissues of the body.

Microseparation: The femoral head is separating by few millimeters from the prosthetic acetabular cup.

Osteoclasts: Type of bone cells responsible for bone removal. They are opposed to osteoblasts in charge of bone formation.

Osteolysis: Bone resorption.

Stress-shielding: the bone does not bear most of the load during human gait when an implant is inserted. The implant supports most of the load and the bone is not rebuilt.

THA: Total hip arthroplasty

THR: Total hip replacement

UHMWPE: Ultra high molecular weight polyethylene

1. INTRODUCTION

Total hip arthroplasty* (THA*¹) represents about 1.5 million surgeries performed worldwide each year. It is one of the most successful procedure, some concerns remain though. The two main total hip replacement (THR*)-related issues are dislocation and wear. Dislocation* may be described as the extraction of the replaced femoral head from the acetabular cup. The ligament in charge of preventing this phenomenon in the native hip is no longer present in the operated hip. To address this particular problem of dislocation, Pr. Gilles Bousquet and André Rambert shared their knowledge to invent the dual mobility concept patented in 1975. This innovation has enabled to improve the range of motion and to significantly reduce the number of dislocations even though this postoperative complication depends on several factors other than design-related ones. Thus this solution seems to be promising for reducing the risk of instability. However, intraprosthetic dislocation* has appeared as a new issue and wear still remains a concern. Indeed wear is known to entail osteolysis* because of the particles release. Therefore the concept of dual mobility has to be kept improving, it is the reason why a global strategy of optimization has been decided by SERF, the company created by André Rambert, the purpose of this strategy is to improve the dual mobility cup longevity.

This report explains the different aspects of my work which was part of that optimization approach. It starts with a theoretical background from the hip joint to the dual mobility prosthesis, then all the materials and methods used for the four tasks carried out during this thesis work are detailed followed by the results and discussion parts. From them it is possible to draw some conclusions and to establish the work that might be performed in the future to continue the investigations made during this work. But, first of all, it is worth giving some theoretical background starting by the native hip joint.

¹ * means that a definition can be found in the glossary

2. THEORETICAL BACKGROUND

The hip joint is what is commonly called a ball-and-socket joint since the femoral head is moving inside the acetabulum* to generate a wide range of motion. Unfortunately this motion is sometimes hindered by cartilage degeneration or fracture for instance, and when it is too serious one may need to support a surgery in order to replace the diseased or broken parts. In total hip arthroplasty the surgeon replaces both the femoral head and the acetabulum. Even though nowadays it is a common procedure, there are still some related problems; one of the most frequent is the dislocation that is the extraction of the femoral head from the acetabular cup.

As it will be explained in this part, to avoid this kind of postoperative complications great care must be taken of many factors like the patient's condition, the materials, the implant's design and so forth. Therefore there are some solutions to reduce the risk of instability after surgery and a very promising one seems to be the dual mobility hip replacement. However, to understand the principle of hip replacements, and particularly those with a dual joint, one needs to start by looking at the natural hip joint.

2.1 The hip joint

When people talk about hip, they might mean the region between the waist and the thigh as well as the joint. In this theoretical review it refers to the hip joint also called acetabulofemoral joint (or coxo-femoral joint) as it is the joint between the femur and the acetabulum* of the pelvis (Figure 1).



2.1.1 Description

Figure 1: Schematic of the hip [1] with permission

The acetabulum is the socket in the lateral side of the iliac bone in which the head of the femur can move. The femur (thigh bone) is divided in several parts, the ball is the femoral head linked to the rest of the long bone by the femoral neck (also called collum). The bumps on the femur are the greater and lesser trochanters; they enable the attachment of abductor and illiopsoas muscles. The hip joint is not only composed of bones, it is actually a synovial joint since the bones in contact are covered with a hyaline cartilage lubricated by synovial fluid. The synovial fluid consists of water, hyaluronan, proteoglycans, lipids and proteins. The most abundant protein is albumin but others are known to have an influence on friction [2]. The cartilage is composed of a matrix of collagen and proteoglycans along with water and inorganic salts. The proteins of collagen play the role of hydraulic bumpers and enable to support great loads, the fluid load support might be the highest for normal walking and the lowest for going downstairs, the load is first supported by fluid pressurization and as the fluid gradually exudes out of the contact area, the solid matrix supports more and more of the load [3]. The collagen fibres are known to be efficient in tension so, as the cartilage is mainly loaded in compression, they will resist lateral expansion thus enhancing pressurization [4]. The cartilage is not vascularized, it cannot repair itself (last step of cells growth), however, walking and running seem to be of importance to keep a good cartilage thickness [5]. Almost half of the femoral head is contained within the cup-like acetabulum which enables a good grip. This latter is enhanced by the acetabular labrum, a fibrocartilaginous ring that extends the acetabulum beyond the femoral ball equator, and an articular capsule composed of fibrous tissues and ligaments that covers the whole joint. Besides a ligament attaches the femoral head to the socket which prevents dislocation. Finally there are other means of union that is the surrounding muscles; they enable movements in all spatial planes [6].

2.1.2 Movements and biomechanics

The surrounding muscles enable a lot of movements which makes this articulation a difficult assembly to change, above all if we want to keep that same great range of motion. Table 1 presents a list of the possible motion and the associated angles.

Hip movements	Angle
Extension	15°
Flexion	120° leg bended, 90° leg straight
Abduction	45°
Adduction	30°
Extern rotation	45°
Intern rotation	35

 Table 1: Table of hip movements for a normal person [7]

The joint articulation is made to support several times the body weight either in static or dynamic situations; indeed Pauwels established that the hip joint has to support about four times the body weight. To understand where it comes from, it is important to first understand the biomechanics of the hip joint [8-10], so let us see the forces applied on it by taking a simplified view of the system. The hip acts as a center of rotation for a lever system. The forces to take into account are the body weight counterbalanced by the force exerted by the gluteal muscles (in reality other muscles play a role) in order to keep the pelvic straight (figure 2). The force supported by the hip joint is then the sum of the two.



Figure 2: Forces supported by a hip joint

When the velocity is low, less muscle contraction is needed to counterbalance the inertia so the peak pressure may be lower [11]. Besides the factors influencing the joint pressure are the body weight, the neck length, the position of the fulcrum, the distance of the line of supported body weight and the utilization of walking stick [8]. An important thing is also the contact area between the femoral head and the acetabulum, the larger the contact area, the lower the pressure on the hip joint. The resultant of the forces is coming oblique to the joint and its direction changes with the person's activity. But actually, depending on the body weight. Indeed the maximum force supported during fast walking is 7.6 times the body weight and it is 7.2 and 7.1 when you go upstairs and downstairs [12]. Besides, it is worth noticing that a walking cycle applies a double maximum force on the hip joint [12], therefore it will be wise to have the same kind of dynamic loading during hip walking simulation.

2.1.3 Hip problems

The hip joint is a great construction that can last decades without failing but, as the rest of our body, it ages, the cartilage wears, the bones and muscles weakens, it can finally result in a need for a replacement. The two main problems are primary osteoarthritis and hip fracture due to aging [13].

Surgeons decide to replace the bad hip by prosthesis when there is no other choice for restoring the mobility of patients. There are many different implants and the choice of the appropriate one is based on several factors such as the patient's condition (age, activity level, metal intolerance, etc.), the surgeon's method of operating and so forth.

It has just been explained that there is sometimes the need for a hip implant to replace the natural one, the next part develops the different hip prosthesis that have been used and the associated issues but let us start with a bit of history.

2.2 Hip replacements

Nowadays, the hip replacement is one of the most successful procedures, according to Avicenne Développement more than 1.3 M are performed each year. It aims at reducing pain and restoring a good range of motion. As we will see, these goals are quite achieved today but, as almost every technology, it had to be improved over time and still have to be.

2.2.1 History

In 1939 Harold Bohlman created the first femoral prosthesis (THR), it was in Co-Cr-Mo alloy (Vitalium[®]) discovered in 1936.

The first prosthesis implanted in many people in France is from the Judet's brothers in 1946 who replaced the femoral head by a ball in poly(methyl methacrylate) (PMMA), material abandoned in 1949 because of the wear debris and failures of PMMA. In 1950 Austin Moore proposed a new method to fix the femoral head; it consisted of a stem implanted into the medullar canal of the femur.

In 1951 Mac Kee implanted for the first time the total hip replacement invented 10 years before. However the two implants in stainless steel loosened in less than one year. Then he proposed a Vitalium[®] stem with a large femoral ball in an acetabular cup in Vitalium[®]. The reason of the numerous loosenings, that is the reaction of the body to the debris, would be found only in 1974.

In the 1960' Sir John Charnley introduced a revolutionary principle still used today, the "low friction arthroplasty". He decided to change the material to use one with a low friction coefficient, in 1959 he chose Teflon[®] but he had to abandon it because of necrosis, he opted for polyethylene in 1962. He also decreased the femoral head diameter from 41mm to 22mm to reduce friction. That same year he introduced his third revolutionary idea, namely the use of an acrylic cement to fix the prosthesis. Finally to decrease the risk of dislocation he proposed a new surgery approach called trochanterotomy.

At that same time Farrar joined Mac Kee, they firstly changed the design of the neck and in 1974 they change materials and chose high density polyethylene but the wear was still too fast.

In 1973 André Rambert created the company SERF (Société d'Etudes, de Recherche et de Fabrication) after the success of a knee prosthesis fabrication [14].

In 1975 the concept of dual mobility was patented and first prosthesis using this innovation and a 22.2mm diameter started to be implanted.

In 1979, SERF produced the cementless tripod cup NOVAE® (figure 3) that Gilles Bousquet used during his entire career.



Figure 3: Tripod cup NOVAE® (SERF) [15] with permission

It is said that Gilles Bousquet wanted to mix the "low friction" principle of Charnley and the stability due to a large head in the Mac Kee Farrar prosthesis.

Between 1970 and 1980 work was done on methods of fixation without cement and a new friction couple: ceramic-on-ceramic [16]. This hard-on-hard couple was developed even more in the 2000' together with another one that is metal-on-metal. The fixation methods used raised relief patterns on the stem and acetabular component of hydroxyapatite layer to help osseointegration. New surgery techniques have appeared like the mini invasive technique or more recently the computer assistance, in order to provide more accuracy in the placement of the implant which is one of the numerous important issues.

2.2.2 What is it composed of and how is it placed?

A total hip replacement is composed of two parts: the femoral and the acetabular parts (figure 4).



The femoral stem* may be in Titanium alloy (Ti-6Al-4V), 316L or 316 LN stainless steel, there are not a lot of materials used in that field since the requirements are numerous and strict like mechanic and biocompatibility. The stem is the part inserted into the thigh bone and it is linked to the ball by the neck. It can be in one block, which is called monoblock, or the pieces can be removed and changed individually, in that case it is called a modular device. The acetabular cup can be made of one material, mostly Co-Cr alloy, or it can be composed of a UHMWPE* liner inside a metallic back up. In the first case we would have a metal-on-metal implant whereas in the second case it would be a metal-on-polyethylene prosthesis. Ceramics like alumina or composites made from alumina and zirconia can also be used sometimes for the ball and the cup.

The polyethylene (PE) has been used for hip replacements for a long time, coupled with a metallic femoral head it constitutes the "gold standard". There are several grades of polyethylene, first the high density PE was used, it is produced using a Ziegler catalyst and has its density and crystallinity increased [18]. Then the UHMWPE has been used since the 1960s because of its interesting properties like low friction coefficient, high resistance to wear and stability in the body [19]. Then, crosslinked UHMWPE has been used for that same application (e.g. AltrX[™] AltraLink[™] Polyethylene developed by DePuy Orthopaedics) as they are known to be more wear resistant [20]. During crosslinking the material becomes weaker in terms of mechanical properties, the color changes, the crystallinity decreases [18] but it has a better wear resistance. The crosslinking can be carried out by gamma irradiation; it results in the C-H and C-C bonds breaking and the formation of free radicals. These radicals can react with oxidants but they are also able to recombine to create bonds between atoms, i.e. crosslinking, which is

favored when the irradiation is performed under vacuum or in inert atmosphere [19,20]. The material can be annealed to make the residual radicals (those that have not recombined) disappear [13]. The ideal is to avoid both short-term and long-term oxidation. Some studies report that highly crosslinked UHMWPE has a better wear resistance and it would exhibit a lower functional biological activity which means a lesser osteolysis* [21]. In appendix 1 one can find a table of several kinds of crosslinked UHMWPE with some characteristics.

The total hip replacement surgery can be performed by several approaches (anterolateral, posterolateral...even using computer-assistance) but the same steps will be achieved. The surgeon proceeds by cutting off the femoral head, then places the femoral stem in the medullary canal, prepared by drilling and reaming, using bone cement or not. The acetabular component is placed in the reamed acetabulum* using cement or impaction. The orientation and articulation are checked before suturing the tissues. Indeed a malposition can shorten greatly the implant longevity and entail pain; particularly studies have shown that a cup inclination superior to 45° could result in increased wear [22].

Obviously the fixation of the components is an important issue accounting for the longevity of the implant, it can be achieved by mechanical (bone cement for stems, screws for cups...), biological (allows tissue to grow into the pores) or direct fixation ways and other newer techniques are emerging like the use of electromagnetic field stimulation. Bone cement was trendy in the 1970s but today it is known to have problems like shrinkage or the creation of another interface but it is still used, mostly in elderly. Short and long-term fixation must be taken into account, it is the reason why some implants have a layer of hydroxyapatite known to enhance short-term fixation and a layer of titanium to ensure long-term fixation since this material is known for its osseointegration property.

2.2.3 <u>Postoperative problems</u>

Several kinds of problems may happen after this type of hip surgery. One of the most common one is the dislocation. It is the fact that the femoral ball gets off the acetabular cup, it results in a lot of pain and the incapacity for the patient to move. It is mainly due to the fact that during a movement of too large amplitude the femoral neck is going to bump into the socket rim [23], hence it will also cause the liner's wear, it is a femoroacetabular conflict. Another phenomenon that results in dislocation is microseparation*. An index is used to quantify the risk of dislocation, the distance AB, because when the head has travelled this distance dislocation has happened. But many factors must be taken into account like the surgery approach; indeed the posterior approach seems to be associated with a higher rate of dislocation. So the factors can be surgery-related but also patient- and implant-related, for example dislocation is more

common in females or people with a prior hip surgery or neuromuscular conditions that lead to weak muscles around the hip [24].

Wear is another recurrent problem with hip joints, and joints in general, as it means motion of surfaces in contact. When a metallic head is moving inside a polyethylene liner, the polymer is going to wear and some zones can even become free of PE. Obviously it needs to be changed to keep a painless hip. It is defined as the "progressive removal of material from the prosthesis" and it is influenced by many factors (design, patient, processing, materials, sterilization, packaging ...) and split into four wear modes: adhesive wear, not intended rubbing, abrasive wear and fretting wear [13].

It is a true issue to assess and measure wear in vitro and in vivo, a first idea is to perform a finite element analysis [25] but it is not enough. Another solution is to make simulation with a hip simulator [26,27] following the standard ISO 14242. For example J.G Bowsher and J.C. Shelton in [26] studied the influence of patient activity on the wear of crosslinked UHMWPE. They applied series of walking, stumbling and jogging to be closer to real living conditions of young patients and prove that with smooth heads, short periods of increased speed or load have a small effect on PE wear. But there is a debate about the necessity of complex load profiles to simulate physiological wear [28]. In vitro several other methods are used like gravimetric, geometrical or volumetric methods, these last two are achieved using a Coordinate Measuring Machine (CMM). Radiographs and radiostereometric methods can be used to measure wear in vivo. But for now the results obtained from *in vitro* and *in vivo* methods are not comparable. To assess the wear particles size and distribution a study [21] reported the use of the high resolution FEG-SEM. It is also possible to work on explants* like the case in a study carried out by J. Geringer et al. on a series of 250 explants* [29], where 3D profilometry, Scanning Electron Microscopy and CMM were used to characterize wear.

The wear of PE can have another significant consequence, it has been proven that UHMWPE wear debris can promote aseptic loosening*. Indeed the debris entail an immunogenic reaction and the release of several proteins and enzymes (cytokines...) responsible for bone resorption. The wear debris activate macrophages that release the cytokines and other proteins responsible for the stimulation of osteoclasts*. The particle size that has the most impact on the macrophages and bone resorption is between 0.3 and 1 μ m (0.1 and 1 μ m according to [21]) and the critical wear threshold is 0.3 mm/year [13]. Moreover screwholes could promote the migration of the wear debris thus enhancing implant loosening. The osteolysis* due to the wear particles is said to be likely when the wear rate is more than 0.1mm/year and very unlikely when it is less than 0.05mm/year [30].

Aseptic loosening* can be a cause for revision, a second operation is needed to ensure the fixation again. There are many other causes for revision, one of the main causes is

dislocation and sometimes dislocations keeps on happening, this is called recurrent dislocation or recurrent instability.

Other issues are related to hip prosthesis like corrosion, fretting-corrosion, stressshielding*, etc. But as they are not in direct correlation with the subject of the master's thesis, they will not be detailed. It is just worth bearing in mind that the bone is a viscoelastic composite material composed of inorganic ceramic and collagen. There are different kinds of bone but for the human cortical bone, the longitudinal elastic modulus is about 17.4 GPa and the tensile yield stress in the longitudinal direction is about 115 MPa [31]. It is very different from metallic implants thus resulting in stress shielding (table 2).

Materials	E (GPa)	σ _y (MPa)
UHMWPE	0.2-1.2	20-40
PEEK CF 30 %	10-20	160-250
316L	190-210	170-800
Ti-6Al-4V	100-115	950-1400
Co-Cr-Mo alloy	200	450-2200
Al ₂ O ₃	300-400	Shear 330
		compression 2200-2600

Table 2: Table of Young's modulus, E, and yield strength, σy, for a few materials used for THR [32-39]

As a second surgery constitutes an extra period of time in hospital, an extra pain and substantial extra charges, it is essential to succeed the primary surgery and to avoid all the complications that can occur.

2.2.4 Solutions to hip replacement related problems

Several solutions have been thought over time to reduce wear and instability, the two main causes for revision. For example it could be interesting to design a raised edge or screw as a stop for movement but it is not enough to ensure total stability. Another solution is to make the femoral head larger to enhance the range of motion, thus to reduce the risk of dislocation. But a bigger femoral ball might mean more wear debris as well which will entail aseptic loosening except if the materials are changed.

During their study J.G Bowsher and J.C. Shelton in [26] showed that a very important factor for active patients was the head surface (it must be as smooth as possible to decrease wear), therefore they proposed to use harder or more wear resistant materials than CoCrMo for active patients. Besides, instead of UHMWPE bearing new wear couples have been thought like the metal-on-metal couple. This hard-on-hard couple enables to make a larger femoral ball but there is still some concern about the risk of metallosis* and the diffusion of metallic ions in the body, the long-term effects of such a couple are not known so other materials for bearing are considered like the use of ceramics. Indeed several implants are composed of alumina (the ball or the ball and the socket) but it is known to be brittle and the final product is more expensive than the

product with metals or polyethylene. Alumina-polyethylene might be more resistant than metal-polyethylene but none in vivo study can confirm that in vitro observation. Nevertheless ceramic is recommended for young and active patients because of its outstanding wear resistance. The friction couple metal-on-metal is said to have an even better wear resistance but the reaction to debris and ion release make it risky. Indeed the effects of ion release over time are unknown and the metal wear debris are considered more active [30]. It explains why polyethylene is still used a lot. Some addition to the crosslinked UHMWPE like vitamin E could hindrance even more its degradation since it could prevent oxidative degradation without remelting hence decreasing the mechanical properties [13,30]. Some manufacturers also used a process of thermo-compression to improve the wear properties [40], it wears more than traditional crosslinked UHMWPE but exhibits a wear rate four times lower than the usual UHMWPE. New materials like zirconia toughened alumina, ZTA, and new couples like ceramic-on-metal are being studied [30]. Finally composites are being studied together with a horseshoe-shaped design like the Cambridge Cup (Howmedica) or MITCHTMPCR Cup (Stryker SA) which use carbon reinforced polymer (Polybutylene terephthalate PBT and Polyether ether ketone PEEK) as bearing surfaces [30,41,42]. This flexible material accounts for a significant reduction in stress shielding* given the stresses and strains are more physiologic. In addition, a FE (Finite Element) study reported that both designs have similar biomechanics and that they both enable stimulation of bone remodeling towards formation over a larger area [43]. Even a composite with quasicrystals has been investigated [44].

So none seem to have unanimity, and we lack of data to assess the wear of the new cross linked UHMWPE in a long-term period to be sure it is the material to use. Besides, according to [45] CLPEs (cross-linked polymers) depend a lot on the process, the results from *in vivo* studies are still controversial and they seem to make smaller particles which could enhance osteolysis*. D.G. Campbell reported in a preliminary study in 2010 [46] the wear performance of a second generation highly cross linked X3TM PE. A new process of sequential irradiation and annealing is used to improve the elimination of free radicals while keeping the mechanical properties. He reported a wear rate of 15 μ m/year, measured by penetration of the femoral head in the liner, which is 58% less than the first generation and definitely less than the osteolysis* threshold of 0.1mm/year. But as the results are in the same range as the radiostereometric analysis (RSA) accuracy, studies over a longer period of time must be carried out. Therefore further studies are needed to form a clear view on these CLPEs.

Another solution against instability is the constrained tripolar cups that enable a larger range of motion. They are said to have reduced the risk of dislocation but to be associated with a quite high loosening rate due to the increased strains [47]. On the contrary the

unconstrained dual mobility cup could improve stability without increasing loosening rate. Let us explain the principle in the part 2.3 of this theoretical part.

2.3 Dual mobility hip replacements

The concept of dual mobility was created in the 1970s by Professor Gilles Bousquet and André Rambert to provide stability and a higher range of motion than traditional implants thanks to a unique principle. As SERF is the creator of the concept and has the knowledge, the next part will focus on its case, other examples will be quoted though.

2.3.1 Description

The concept of dual mobility is based on the fact that simple mobility implants with small head can dislocate too early when the femoral neck comes bumping into the acetabular cup's rim. The dual mobility implant keeps the small head stemming from the Charnley's hip prosthesis to have little wear but an added UHMWPE insert acts as a big femoral ball and allows a wider range of motion. The femoral head slides against the inner surface and the outer surface slides against the metallic shell.

The first design created by Pr. Gilles Bousquet and André Rambert (figure 5) shows a retentivity to prevent the femoral ball from leaving the insert, so the head must be forced into the liner by impaction. Besides the rim of the shell was not round-shaped and there were three fixation points, so it was called a tripod implant. The insert and the metal-back have different centers, some manufacturers have opted for this system to counterbalancing the tilting, like the Medial Cup1 of Aston® which is an evolution of the Bousquet's design, even though Pr. M.H. Fessy thinks it is useless [48].

Some studies have shown, using the wear marks, that the major motion occurs between the femoral head and the inner surface, but there is still little motion between the insert and the shell [22]. F.L. Langlais *et al.* [47] confirm that most movement happens in the inner joint of the dual mobility cup (Aston's cup), they add that during abduction/adduction or rotation the movement starts in the inner articulation, at 25° the femoral neck impinges on the insert rim and the second articulation starts until the impingement on the metallic shell at 54° which provides a total range of motion of 108°. Nevertheless a study performed on 250 explants of SERF products [29] demonstrated that the triggering of the second mobility is influenced by arthrofibrosis*. It proposed also a mechanism for the dual mobility; during loading the insert and the shell come in contact which deforms the insert, it goes thinner at the apex where the force is maximum and thicker at the equator. This thickening entails the blocking of the insert into the shell and the increased of wear in that area marked by a typical wear stripe. It leads to a higher wear rate of the first mobility as well. Consequently the authors pointed out the need of an improved design. Another article [25] refers to the importance of the contact surface

between the insert and the shell; a larger contact area might mean a distribution of the stress and consequently a decrease in wear.

The NOVAE® system has not changed a lot. Its geometry can be seen on the figure 5.



Figure 5: a) Schemes of the new and former design of NOVAE® (in blue the pole erased of 0.5 mm, in grey a variable zone for the equatorial press-fit) [15] with permission b) Novae® Evolution® TH [49] with permission

The metallic shell is a half sphere augmented by a cylinder of 3mm. There is a removal of material at the pole to favor the press fit. At the equator there is a special macrostructure to ensure primary stability but some NOVAE® products still have the tripod fixation established in the first version. Compared to the first version the lateral edges have been removed to make the implant fit easier into the bone. The cup is now completely symmetrical which allow a better adaptation. Besides, the insert was modified by adding a chamfer to decrease contact stress and increase retentivity [50]. An excentration was added to compensate the natural tilt of the femoral ball by another torque.

In his study, Pr. M.H Fessy indicates that there is less wear using a stainless steel shell (316L or 316 LN) than using a Cobalt-Chromium shell [15]. But the stainless steel is not well appreciated by the human body since *in vivo* it is rapidly covered with a fibrous membrane. To avoid this unfavorable phenomenon SERF has used since 1979 an alumina spray-coating to isolate the stainless steel. Pr. Gilles Bousquet did not like cement, so in collaboration with Pr. Jean Rieu, in charge of the biomaterials laboratory at the Ecole des Mines de Saint-Etienne, they developed this alumina coating [14]. This ceramic is bioinert so it is well tolerated by the body, apart the question of submicrons particles, but it does not give rise to a strong bonding. This is the reason why SERF is also using titanium coating which has osseoconductive properties. On top of this coating they spray a hydroxyapatite layer to promote short-term integration. In some versions the fixation can be enhanced by the original tripod system.

The series of products includes revision implants as well that are NOVAE® COPTOS®, NOVAE®Stick/K and NOVAE®arm. Indeed these implants provide a better primary

fixation which is a key point in case of revision. The choice of the implant depends a lot on the bone destruction, indeed the more there is healthy bone, the larger will be the contact area between the bone and the implant, the more efficient will be the fixation by bone growth that is cementless implants.

Several French companies are using this concept of dual mobility to make their product, among them Aston in Saint-Etienne or Amplitude in Neyron, but others world-wild are doing the same like Stryker, DePuy, Aesculap, Zimmer GmbH or Wright Medical.

This concept has been recognized more and more the last years, as a consequence it is more and more used, it would represent 30% of the total hip arthroplasty (THA) in France.

2.3.2 Advantages

This concept has two main advantages: a great range of motion [51,52] and an outstanding stability because it delays lever-out dislocation [53]. Pr. M.H. Fessy says in [15] that the abduction adduction can go up to 126°, it is 186° for the flexion extension and 220° for rotation. It is the system that provides the greater range of motion and also the better stability. Indeed if we judge the stability by the dislocation risk index, Pr. M.H Fessy showed that it was the greatest for the dual mobility system compared to another tripolar and a bipolar system [36].

It has been proven in several studies to constitute a promising solution against dislocation in primary surgery. Indeed the literature reports a mean figure of 3.5% for dislocation and it can be higher in some cases like a neck fracture where it lies between 8% and 14% [15].For the first generation NOVAE® (SERF) design cementless and alumina-coated, Pr. F. Farizon [54] reported a cumulative survival rate of 95.4% at 12 years follow-up which proves the benefit of this first generation dual mobility cup (table 3). Pr. Claude Vielpeau [50] reported in 2010 an experience of 663 dual mobility sockets, 437 implants were the original design whereas 231 were the second generation cups NOVAE® E (SERF). There were 5 dislocation cases in the first group with a min follow-up of 15 years and 0 case in the second group with a min follow-up of 5 years. The survival rate at 5 years for the second generation is $99.6\% \pm 0.4\%$ and the total dislocation rate is 1.15%with a 16.5 years follow-up which is less than the values found in the literature for other implants. R. Philippot et al. evaluated the incidence of instability after primary surgery in a series of 384 cases with a mean follow-up of 15 years using the NOVAE®-1 acetabular cup (SERF) [55]. There were 14 cases of intraprosthetic dislocation (3.6%) and 13 cases of aseptic loosening (3.3%). The cumulative survival rate at 15 years was $96.7 \pm 3.3\%$ which is another proof of the benefit of dual mobility in terms of stability. O. Guven et al. studied the unconstrained tripolar implant SaturneTM (Amplitude) for primary THA in 163 patients with high risk of instability [24]. No dislocation was observed in the mean follow-up of 40.2 months.

Working principle of the dual mobility	(total hip	replacement):	wear	[•] mechanisms	and	design	optimization
LAURIANNE IMBERT							

Study	Acetabular cup's type	Primary THR (P)/ Revision (R)	Dislocation	Survival rate	Follow up
[54]	135 NOVAE®	Р		95.4%	12 years
[50]	437 original design 231 second generation cups NOVAE® E	Р	5 0	84.4% 99.6%	15 years min 5 years min
[55]	384 NOVAE®-1	Р	14	96.7 %	15 years
[24]	163 Saturne™	Р	0		40.2 months
[47]	88 Medial Cup®	R	1	94.6%	2 and 5 years
[56]	163 NOVAE®	R	6	96.1%	7 years
[57]	23 Collégia™	R	2		2-10 years
[58]	51 Medial Cup®	R	2	96%	2 years min

Table 3: Summary of some studies results

Its potential to provide stability during revision has also been studied even though the risk of instability is increased in that case. Indeed the risk of dislocation in revision is reported to range between 5.1% and 14.4% for patients of an average of 63 years old [47] or more generally also found in the literature between 5% and 30% [56]. F.L. Langlais et al. reported a study of 88 hip replacements in THA revision for patients at high risk of dislocation, with a two and five years follow-up. Only one patient had dislocation and two early loosening [47]. Similarly R. Philippot carried out a study on 163 revision THAs [56], the use of the NOVAE[®] (SERF) dual mobility cup resulted in a dislocation rate of 3.7% and a survival rate of 96.1% at seven years follow-up. P. Massin and L. Besnier [57] reported the utilization of the CollégiaTM dual mobility cup (Wright Medical France) in 23 THA revisions, 6 cases were for recurrent instability and 16 for aseptic loosening. There were two cases of dislocation. M. Hamadouche et al. reported the use of a cemented dual mobility cup to treat recurrent dislocation [58], the Medial Cup[®] (Aston) was used to restore complete stability in 45 patients over 47. All these results are summarized in table 3. There are other studies detailing the efficacy of dual mobility cups to manage instability [59]. Obviously this concept is very promising in hip arthroplasty but some concerns remain.

2.3.3 <u>Concerns about the dual mobility implant</u>

One of the main issues with the dual mobility is the intraprosthetic dislocation, which is when the femoral ball leaves the insert and comes in contact with the metallic shell. Since it is specific to dual mobility, it must be as rare as possible not to lose the benefit obtained from the stability. Anyway Pr. M.H. Fessy insists on the rarity of this phenomenon saying that it occurred only 63 times in 12 years in Pr. Gilles Bousquet's service where this concept was used systematically [48]. R. Phillippot, F. Lecuire, S. Leclerc and F. Farizon et al. confirm this infrequency [54-56]. Obviously the age of implantation has an impact since 95% occurs in patients implanted when they were less than 70 [48]. Besides, there are two phenomena resulting in intraprosthetic dislocation, a homogeneous wear of the insert rim due to the impingement of the neck on the retentive chamfer and an asymmetric degradation due to the insert tipping under gravity [47, 48]. An optimal head neck ratio enables to delay the homogeneous degradation but not the asymmetric degradation. Moreover, this latter is 5 times faster than the symmetric degradation so Pr. M.H. Fessy recommends a head of 22.2 mm and a neck with a specific design to delay both degradations. Large cup diameter, neck roughness and calcification are said to be other favoring factors.

The dual joint prosthesis raises concern about the wear of the insert, as there are two bearing surfaces one might think that the wear is higher which would mean a non-negligible possibility of loosening. Even though some people have shown the fact that the motion is mostly between the head and the insert, there is still motion between the insert and the metallic shell which may cause additional wear. However a study performed by P. Adam in 2005 on 40 explants showed that the total insert wear was 82 μ m/year, which is not more than for other implants [15]. Similarly J. Geringer *et al.* [29] explained that the total wear of a dual mobility system is equivalent to the wear obtained from a traditional implant.

Nevertheless one is looking for reducing wear even more, it could be achieved by a new design of the acetabular cup. Q. Meng *et al.* [60] have been following the works of John Fisher about aspherical bearing surface. Indeed, in this article they reported the performance of Alpharabola, a metal-on-metal hip implant with aspherical bearing surface. They investigated the effect of the minimum radius of curvature of the inner metallic cup R2 and the variation in the radius, characterized by α , on the dry contact and hydrodynamic pressures. First, they noticed that the maximum pressure was not at the center of the contact zone but had an annular shape. They also found that the higher R2 and α , the lower the dry contact and hydrodynamic pressures due to an enlarged contact area (better conformity).Therefore, the higher R2 and α , the higher the film thickness which meant a better lubrication, hence a lesser wear. Their design includes a larger equatorial clearance to avoid clamping. This article also quotes the UltimaTM and MetasulTM prosthesis for other innovative designs.

The wear is difficult to measure in that case of dual mobility *in vivo*, which is the reason why so few data exist. However, some recent studies about radiostereometric analysis RSA [61] may open the road to an easy way to quantify the wear, thus to ensure the benefit of the dual mobility concept. For now this tripolar implant, as it can be called in articles, is recommended only for the 70 year-old and more and for patients with high risk of dislocation [47,58].

2.4 Conclusion, Aims and limitations

The hip joint and the surrounding can be affected by a disease or a fracture that requires the replacement of this particular ball-and-socket joint, which is done using a total hip replacement (THR). This procedure is one of the most common and successful as it is demonstrated by the increasing number of such surgeries world-wild each year. Several types of THR are currently used, they vary in the materials, the geometries, the number of mobility and so on. There is not unanimity about one kind of THR since many factors must be taken into account, among them a lot are patient-related. Moreover there are several issues in THR, particularly wear but also restoring stability and large range of motion. Traditional simple mobility implants have helped to achieve these goals so far but dual mobility implants seem to exhibit better performance.

This concept was invented in the 1970s by Pr. Gilles Bousquet and André Rambert, the idea was to use an insert to provide a second mobility between the insert and the metallic shell. That way they mixed the "low friction" principle of Charnley together with the effect of a big femoral head of Mac Kee. It enables to delay the dislocation and restore a large range of motion. The original design has not evolved much but some key aspects have been further developed to improve the performance.

Obviously this concept is very promising in hip arthroplasty but some concerns remain, wear and intraprosthetic dislocation primarily; thus there is a need for additional long-term data to definitely prove its great benefits. Besides, the number of intraprosthetic dislocations has decreased since the first dual mobility cup due particularly to new design; similarly the wear problem could be addressed by optimizing the cup shape as it was done by M. Mak *et al.* for cup rims in ceramic-on-ceramic prosthesis to respond microseparation "stripe wear" due to head translation [62] or even closer to our subject the work of Q. Meng *et al.* who studied contact mechanics and elastohydrodynamic lubrication in a metal-on-metal hip implant with an aspherical bearing surface [60]. The work done during this thesis was aiming to serve as a starting point for this optimization. Obviously the numerical modeling is nowadays a necessary step when one wants to start to investigate a new product, it is powerful but does not replace the *in vitro* and *in vivo* experiments, therefore one has to be critical with the results and keeps in mind the assumptions made to get them. They could be seen as limitations for the use of the model but they cannot be avoided, the point is to make the most appropriate ones regarding the

problem. Next part about materials and methods gives the details of the reasoning and the assumptions used for the construction of the model.

3. METHODS AND MATERIALS/ EXPERIMENTAL WORK

This thesis work is in line with the project of optimization of the dual mobility concept. The present work was divided in several parts, all aiming at participating to the enhancement of this Pr. G. Bousquet's invention. The main part consisted of a finite element analysis of the dual mobility cup when the insert is more and more aspherical, all the progression to construct the models and get results are explained in the first part. The second part deals with the methodology used to set up a new tool of wear calculation. It is important to be able to calculate the wear to know the starting parameters before the optimization and to enable the comparison of the progress due to the optimization. Moreover the visualization of the wear location on and in the insert by surface reconstruction enabled to gain understanding about the working principle of the dual mobility cup. This understanding is of course a key point to be able to optimize the cup properly. The third part explicates the method used to compare two profiling techniques. This technique of surface analysis is of interest to characterize wear as well since it gives the roughness profile of a surface. The last part is the experimental one where the extraction tests and the associated protocols are detailed. These tests aimed at gaining understanding on the role of the retentive chamfer during extraction by measuring the force needed to do so. It can help optimize the design of this chamfer which is a key part of the insert to prevent dislocation.

3.1 Design optimization by finite element modeling (FEM)

It has been widely noticed that under stress the insert will deform, it becomes thinner where the resultant load is applied and it thickens at the equator, as a consequence the clearance is progressively modified which results in changes regarding the friction and the contact area hence the wear. Moreover there is a point at which the insert cannot move anymore in the metal back hence one mobility is blocked because of the polyethylene deformation, it has a consequence on the wear and on the longevity of the implant. Therefore the aim of this finite element analysis is to study the change in shape of the insert in UHMWPE, the idea is to see the effect of making it aspherical on the stresses and on the contact area for starting, to conclude if it could be beneficial to change the shape and give hints on the direction to follow. The strategy was to start with a simple model before trying to expand it with more complex issues like the appropriate number of element or the shape optimization to get useful results.

3.1.1 Model construction

First of all the software used for that FEA was Abaqus/CAE[®] 6.10. Even though Abaqus[®]/explicit is said to be more accurate for contact simulation, Abaqus[®]/implicit was chosen because it is easier to use and still give reasonably good results.

The model consisted of three parts: the metal back, the polymeric insert and the metallic head. Two of them were imported as .igs files, due to confidential agreement sketches and exact dimensions will not be detailed in this study. The metal back was imported as a discrete rigid body and the head as a deformable homogeneous solid part. The insert has been made as a deformable homogeneous solid part with the sketch module of Abaqus/CAE[®] and the dimensions of the 2001 design. Therefore changing the shape from spherical to ellipsoidal was possible on the insert with that sketch module. A constraint of rigid body was later applied on the head, indeed the Young's modulus of the metallic parts allowed to consider them as rigid bodies. That way we considered only the UHMWPE deformed and we saved computational time. Many authors used this assumption for one or both components [63-67]. The global origin in the part module was used to define the reference points of the rigid bodies. The materials of the insert and the head had to be created and assigned to the corresponding part. The head was in Cobalt Chromium (CoCr) alloy and the insert in UHMWPE. The assumption made was to use elastic properties for all the materials, using just the density, the Young's modulus and the Poisson's coefficient. Some authors used that same assumption during their studies [63,68]. The materials properties are summarized table 4.

Materials	Density (g/cm ³)	Young's Modulus (MPa)	Poisson's coefficient		
UHMWPE	0.900	900	0.4		
CoCr	8.300	210 000	0.3		
Table 4: Materials properties used in the FE model [63,66,68]					

All the instances were made dependent and they were positioned using coincident point constraint, rotation and translation. The instances were all tilted of 45° to be in a position close to reality. All the parts were tilted 45° since it is the most probable situation, several authors used this tilting angle too [64, 68]. The insert can be tilted because of gravity but we do not know the frequency of that event. The anteversion was kept to zero like T.A. Maxian *et al.* did in 1995 for one of the first reported finite element analysis for wear simulation [68]. The starting point was a non-contact situation, then one defined two steps where the contact between the metal back and the cup and then between the cup and the head would be established by imposing a displacement. Indeed there were too many problems when imposing just a load. The displacement applied was actually a part of the simulation but they aimed at helping the convergence. A step "load" was also created, all the steps were defined as a static general load for which the "nlgeom" was toggled on. The time period was set to 1.

The output conditions needed to be selected, we focused on the stresses (S, CPRESS), the contact area (CAREA) and the status (CSTATUS and COPEN) of the nodes to know if

there was contact or not. Let us note that CPRESS was used by other authors in the same kind of study [60].

Then the contact was defined, first of all the surfaces (inner MB, inner Insert, outer Insert, outer Head) that were to be in contact during loading were defined. The metallic surfaces were chosen as the master surfaces as they had the highest Young's modulus. Then a mechanical normal behavior ("hard contact" with surface separation allowed) and tangential behavior were chosen as definition of the interaction property. Several authors agreed on an assumption of frictionless contact as the joint was considered welllubricated [62, 68]. But due to convergence problem some friction was included since without friction there was not a unique solution. Therefore a penalty friction of 0.038 was added as it was used by several authors [65, 67] for a metal-on-polyethylene couple as well. Two contact interactions were defined using the following options: surface-tosurface contact (implicit) [60], finite sliding [65, 60], two configurations contact tracking and no smoothing. A slave adjustment surface and a contact control with an automatic stabilization factor of 0.001 were added for each step but the initial one. The lubrication was not likely to be negligible in the reality but it could not be modeled properly in an element finite analysis as it was not the same scale, it was the same issue as the roughness [69]. Indeed the lubrication had a pressure effect near the contact zones but it was not at the millimeter scale so it would require too many elements to take it into account properly. It could explain why it was very rare to find articles where the wear and the lubrication were simultaneously taken into account as it was explained in the review written by L. Mattei et al. [70]. Besides, the periprosthetic fluid is obviously different from the synovial fluid [2] and its properties have not been clearly identified yet. The only relevant solution was to use a low enough friction coefficient like 0.038 used in other studies mentioned earlier. Anyway a frictionless contact might not the best definition as M.Z. Jin highlighted it [63]. Indeed the frictional force had an effect on the local stress distribution thus on the wear too. Frictional heating was neglected since the friction coefficient was low [71].

Then boundary conditions and load were created. The external surface of the metal back was clamped as it was done by others [71] since backing effect could be neglected. Two displacements were imposed during the two first steps to establish the contact firmly. These displacements were deactivated during the last step of load application, just the rotation of the femoral ball was constrained to save some computational time and avoid convergence difficulties. A concentrated force was applied on the reference point of the head in the plane with an angle of 12° with the vertical, it is a first approximation since the load direction is known not to be constant and the average direction not to be vertical [72]. A load of 2500 N, as it is 3-4 times the body weight [62, 63], was applied. Meshing was a very important issue since all the results depended on the quality of the mesh so it was important to think of the appropriate number and type of elements. A coarse mesh and linear tetrahedral elements C3D4 proposed by Abaqus[®] together with the free

technique were used for the model construction. To get reliable results mesh refinement was necessary. It resulted in an insert with hexahedral (C3D8R) and wedge (C3D6) elements and the head with both hexahedral (C3D8R) and tetragonal (C3D4) elements. Many articles reported the use of hexagonal elements [64, 66, 67]. When using hexagonal elements there was much less element distortion. The appropriate number of elements was chosen thanks to a short convergence study that will be detailed in the next part but before note that the strategy used to solve the problems regarding this model can be found in appendix 2.

3.1.2 <u>Convergence study</u>

The idea is to found the optimal number of elements, i.e. the number of elements that give the most accurate results in the least time. As the model was constituted of three parts and not much time was left, that study was simplified. It was decided to look at different number of elements in the spherical case for the insert and also for the metallic shell and head (the same number was taken for both), eliminate those that did not give a physical response and choose a situation in the physically acceptable range. This number would not be the real optimal number but it would give a physical response, accurate enough in a short enough time. The size of mesh, i.e. the number of elements, was defined by the "global seeds" chosen during meshing; there were 9 different "global seeds" for the insert and for each of them several "global seeds" for the pair metallic shell/head. For each simulation one looked at seven parameters thought to be appropriate for this contact analysis, the contact area (CAREA) at the end of the load application, the mean contact pressure (CPRESS), the mean von Mises equivalent stress (S) and their maximum on the inner and outer surfaces of the insert. It is worth bearing in mind that the von Mises equivalent stress must be measured at the integration point of the element whereas the contact pressure is measured at the nodes. Once an appropriate number of elements were chosen the shape optimization part could be addressed.

3.1.3 Shape optimization

The most important issue was to change the shape of the outer surface insert. For this step the quotations and sketches from 2001 and the sketch module of Abaqus[®] were used. In the sketches from 2001 where there is an excentration which means that the centers of the inner and outer spheres are not coincident. This "excentration" aims at reducing the torque that makes the insert rotate. With this design the contact between the insert and the neck is avoided. The aim of changing the shape is to make the zone where the load is applied thicker to have an insert that lasts longer (we could think it would also create

more wear debris but as the wear is now very small, there might be more benefit to make this change) (figure 6).



Figure 6: Sketch of the spherical insert. In green is a rough illustration of how ellipsoidal the insert would be (sketch used with permission of SERF but the quotations have been erased for a confidentiality issue).

Besides by reducing the clearance, identified as a key parameter [60, 63], at this point the contact area was increased so the maximum pressure was expected to decrease and also not to be concentrated at the center of the contact zone like it was observed for another aspherical cup [60], a more uniform pressure distribution was observed as well. Obviously without any deformation the contact area is larger for the spherical implant at equal clearance but it might be less obvious if the clearance is decreased. Anyway one might have thought that since the clearance was smaller and the insert thicker, it would deform more and the contact area after deformation would be larger. This would result in a lower contact pressure and a reduced wear. It was also of interest to avoid the blocking in the equatorial region due to the deformation of the insert. The general idea was that the insert would be compressed the most where the load was applied that was at 45° - 12° = 33° since it was positioned at 45° and the load was applied with an angle of 12° . At this location the insert was thicker. Hence the outer surface was made ellipsoidal where the inner surface was kept spherical.

The spherical insert had the dimensions 22.30 mm for the external diameter which induced a clearance of 0.20 mm. For the others the minimal radius for the external ellipsoid was chosen to be 22.20, 22.25 and 22.30 mm to see the effect of increasing the clearance at the equator where the blocking happened. The major radius was 22.305, 22.32, 22.35, 22.40, 22.45, 22.457, 22.46, 22.49 mm which corresponded to a clearance of respectively 0.195, 0.18, 0.15, 0.10, 0.05, 0.043, 0.04, 0.01. Jin *et al.* said this clearance must be in the range 0.025 mm and 0.14 mm when they identified the parameters to reduce the peak contact stress in polyethylene [63].

The results will be showed in the corresponding part but let us detail the methods corresponding to the other important issue of this work that was analysis of wear mechanism to understand more the working principle of the dual mobility.

3.2 Surface reconstruction and wear calculations

To explain this part and the next one properly it is of importance to keep in mind a related study made by J. Geringer et al. [29] where a series of 12 explants* and a blank cup were analyzed thoroughly using particularly a coordinate measuring machine (CMM) and a mechanical profiler. The idea was to make some assumptions about the working principle of the dual mobility cup because it was unclear when and how each mobility was triggered. The CMM palpated the surfaces, both inner and outer surface of the polymeric insert, and the output data were series of three dimensional points. The CMM measurements campaign was carried out at SERF, then they used the software Pro/Engineer[®] to reconstruct the surface and calculate the wear volume by comparison of the palpated volume within the reconstructed surface with the theoretical volume. The first thing was that the calculations made by the software were totally hidden so one did not know how it was done which might make the results less trustable. The idea was to use the software Matlab[®] to construct codes capable of doing the same job, the interest was double. Firstly it offered possibility to see the code and act on it, the results were then expected to match the previous ones in order to confirm them. The second interest was to have two sources for the results, their comparison enabled stronger and more reliable conclusions.

The first thing was then to reconstruct the surfaces starting with three dimensional scattered points. It was done by two ways, triangulation and interpolation. It was important to keep in mind that we wanted to reconstruct a surface Z=f(X,Y) in a 3D space. The simplest was to link the points by triangulation, for instance "DelaunayTri" is a Matlab[®] function that can do that, it builds a triangulation from a set of points in a way that no points are contained in the circumcircle for any triangles of the triangulation. The minimum angle among the three angles of the triangles is maximized. In higher dimension it would be tetrahedrons. The result was plotted using the Matlab[®] function "tetramesh". The function "convhulln" or "delaunayn" are also used to perform a

triangulation and plotted with "trisurf" function. A second way to reconstruct surfaces from 3D points was by interpolation. It was carried out using "griddata" and "TriScatteredInterp" recommended because generally more efficient. As we have scattered points, a regular grid had to be defined first ("meshgrid") and then "griddata" gridded the data to it. The interpolation method was chosen, it corresponded to the type of surface to use, 'cubic' gave the best result here; it was triangle-based. Then the gridded data were plotted using "mesh". With "TriScatteredInterp" one first constructed an interpolant F=TriScatteredInterp(X,Y,Z) that was then evaluated on the grid and plotted using "mesh" as well. Besides a package of functions to use the nurbs surfaces (Nonuniform rational basis spline) could be downloaded, they are a generalization of nonrational B-splines defined by an order, a set of weighted control points and a knot vector. They can be curves or surfaces; they use polygons to reconstruct the surface. The control points were the data but they had to be assembled in a way quite difficult to understand so it was done like the examples using loops. The knot sequence determined where and how the control points affected the NURBS surface. The curve or the surface was represented by a polynomial of degree one less than the order. The first interest of the interpolation was to increase the number of points describing the worn surface in order to get a more accurate definition thus a more accurate wear calculation. The second interest of the surface reconstruction was to be able to visualize the surface after wear, in order to see if the wear was symmetrical or asymmetrical. That way it was possible to validate or not the assumption made in the next step which consisted of considering the worn volume as a spherical segment. Moreover it helped gain understanding about the wear mechanism.

Then the wear was calculated, to do so the volume within the reconstructed surface had to be measured and compared to the theoretical volume. The latter was calculated from the dimensions ordered by SERF, that was 22.2 $^{+0.1}$ $_{+0.3}$ mm for 8 explants, 26 $^{+0.1}$ $_{+0.3}$ mm for 2 explants and $28^{+0.1}_{+0.3}$ mm for the last two, these dimensions corresponded to the inner part of the insert, that was the part the coded were firstly built for. To calculate the volume within the reconstructed surface of the insert, two strategies were envisaged. A first strategy was to approximate the worn volume to a spherical segment. The radius of that approximating sphere was found by two methods: either roughly by choosing manually a sphere that superimposed well enough, or by optimization, this last method was better. Note that an algorithm of that whole reasoning can be found in appendix 3. First the center of that sphere needed to be found, it was done by calculating the distances between an initial center and all the points. Then the Matlab[®] function "fminsearch" searched for the minimal difference between the maximum and minimum distances since when the center is found the distances must be equal and this difference null. The centers were approximated to be (0,0,Cz) for a simplification matter. To find the optimal radius the Matlab[®] function "Isqnonlin" was used to find the minimum of the difference

between the distance points-center and the radius. Only the 840 points from the CMM were used at first. Then, one also used 15,300 points given by "nrbmak", the constructor of the interpolation surface in a NURBS toolbox. Finally more than 35,000 points given by "TriScatteredInterp" were used as well.

This optimal radius had to be then replaced in an appropriate formula to get the volume. In the first method (called method 1,2 and 3 in the following according the number of points used for the radius calculation, first 840, then 15,300 and finally more than 35,000), the formula used was

$$V = \frac{\pi}{3}h^2\left(3R - h\right)$$

for a spherical cap (appendix 3) where h is the height of the cap, it was calculated from the radius and from the segment's height that was used in the Pro/Engineer[®] method.

In a second method (called method 4) the formula used was the formula of a spherical segment (appendix 3)

$$V = \frac{\pi}{2}h\left(r^2 + r'^2 + \frac{h^2}{3}\right)$$

where r and r' are the radii of the circles resulting from the intersection of the sphere with two planes. Like the radius of the sphere, they were found by optimization. This time h was the height of the spherical segment. For the volume before implantation r and r' were calculated with the Pythagoras formula, the sphere radius and the height.

In the second strategy there was no approximation by a sphere but each polygon given by the CMM for a particular altitude was considered instead, and the enclosed area was calculated with the function "polyarea". This area was then multiplied by the above half height and the below half height. To be relevant the theoretical volume was calculated the same manner using the parametric equation of a circle since each theoretical curve was a circle (the implant being spherical). There were 7 or 8 circles in total; the radius was calculated from the height and the sphere radius with the Pythagoras formula (method called method 5).

For both strategies the theoretical minimum and maximum volumes (i.e. before implantation) were calculated the same way. The difference with the palpated volume was made to access the total wear. Finally to get the volumetric wear per year the total wear was divided by the survival time in years. Fewer techniques were used for the second mobility wear but the principle was the same as for the first mobility.

The results are presented in the corresponding part but let us going on with the second technique used for the explants analysis mentioned before: the profiling technique.
3.3 Profiling methods comparison

During the original analysis of the twelve explants and the blank cup performed by J.Geringer *et al.* [29], a mechanical profiler SOMICRONIC® was used to measure roughness parameters on three zones (apex, no-worn and worn) and thus access information about wear and the working principle of the dual mobility. Table 5 groups the conditions of that measurements campaign with the mechanical profiler.

Number of cups	Number of measures on the apex	Number of measures on the no-worn zone	Number of measures on the worn zone	Total number of measures per cup
13 (12 explants + 1 blank cup)	1	5	5	11

Table 5: Number of cups and measures involved in the first profiling measurements campaign [29]

It used a stylus diamond that came into contact with the surface [73]. Its vertical position was recorded as it moved horizontally. This method was independent of optical properties of the analyzed material and it could go through the pollution on the surface easily. However several problems questioned its use. First it took about 40 minutes to make one measure, it could not measure roughness on every surface (for example on a very smooth or very rough sample) and it damaged the surface due to the stylus impact. The idea was then to use an optical profiler on the thirteen same cups. Obviously it was a very different technique as it was non-contact using monochromatic or polychromatic light beam. In the related study [29] they used white light and a Wyko NT 9100 machine (Bruker Nanoscope-Veeco Instruments, Inc.). The principle is that an incident white light goes through a semi-reflective splitter to be split into two waves. The first one will be reflected by a mirror and the second one will be reflected by the sample surface. The two rays will recombine but, as a path difference has been introduced, the recombination results in constructive and destructive interferences. This recombination gives rise to a pattern of interference fringes recorded by a CCD camera. The analysis of a series of interferograms captured during the vertical translation of the system enables to determine the surface height at each pixel i.e. a roughness profile of the surface. It is fast, it can measure all kind of surfaces and the vertical resolution is lower than 1 micrometer whereas it is about 4 micrometers for the mechanical method. However the area measured is limited by the optical system and can be quite small when the magnification is high. Nevertheless it was thought to be more accurate than the mechanical profiler, the idea was to compare both methods specifically for the application of wear characterization on this type of explants. Only the results analysis was carried out in that work not the measurements. First question asked: was one method better than the other?

It was interesting to answer it but it was even more interesting to use the comparison to draw useful conclusions about the wear mechanisms of these explants related directly to their working.

The most relevant parameters identified during the already-mentioned study [29] were chosen to compare the methods: Sa, St, Sq, Sdr, Srk and Ssk. Sa and Sq characterize the mean roughness, they are not sensitive to the texture unlike St (sum of the largest peaks and valleys) and even more Sdr since it is the developed interfacial area ration. SRk is the depth of the working part and Ssk, the skewness, tells if there is more peaks or more valleys. A more complete explanation of these parameters can be found in appendix 4. Several comparisons were performed to be able to get the more information as possible.

The first information was to know if the methods gave similar results when all the cups were considered at the same time. To do so one considered the series of thirteen cups and compared the mean of every parameter in each studied zone. For the apex only one measure was taken so it did not have a statistical weight, it was the reason why we focused on the worn and no-worn zones. ANOVA (Analysis Of Variance) method was used to conclude if the mean values of a particular parameter for a series of thirteen cups measured with both techniques were different or not. More information on ANOVA can be found in [74].

The second type of information wanted was to know if a difference in roughness parameter was significant enough to be considered as wear. The idea was to compare the worn and no-worn zones, if a significant difference existed it could be concluded that the implant had actually worn. This comparison was made for each parameter, each cup and each technique. ANOVA tests were performed again but that time the series of five measures were taken into account.

The third type of information one was looking for was about the wear mechanisms. To do so the cup were ranked from the highest to the lowest mean value for the mechanical method for each parameter and the worn and no-worn zones. ANOVA tests were performed to know if some cups in the ranking could be considered as similar or significantly different which changed the ranking. The position in this new ranking compared to the blank cup gave information about the wear of the explants. The five measures were taken into account and every cup was compared to the other for the same zone and the same method.

The commonly used Bonferroni test was performed for all multiple comparisons. In this method the significance level for each pair comparison is α/n where n is the number of comparisons and α is the significance level used for a single comparison test, usually 0.05. This method avoids the increase in the number of type 1 errors saying it is different when it is not. For more information see [75].

3.4 Experimental work: extraction experiments

The goal of these series of experiments was to access the force needed to extract the head from the cup depending on the retentive chamfer machined with different wear levels. The protocols and samples to be tested were decided before the start of this thesis work. It was intended to test two series of cups with two different experiments, on one hand one was interested by the force required to impact and extract the head from the cup, on the other hand one wanted to know the torque involved during dislocation.

There were two series of two times four cups called series A and B. For both series the retentive chamfer was machined to simulate different wear levels, typically 20%, 40%, 60 % and 80%, there were two specimens for each wear level (table 6).

	A0	A1	A2	A3	A4	B0	B1	B2	B3	B4
Number of samples	1	2	2	2	2	1	2	2	2	2
Wear level	0%	20%	40%	60%	80%	0%	20%	40%	60%	80%
Test	Push- in/pull- out	Push- in/pull- out	Push- in/pull- out	Push- in/pull- out	Push- in/pull- out	Lever- out	Lever- out	Lever- out	Lever- out	Lever- out

Table 6: Table of all the samples tested during the extraction experiments

For the series A the retentive chamfer was machined from interior to exterior. A higher and higher wear level meant a head more and more pulled out in the vertical axis. It was the opposite way for the series B but for confidentiality issue one cannot say more about the machining of the chamfers. The higher the wear level, the more dislocated the head and the more tilted the stem. One blank cup was added to each series which corresponded to the wear level 0%.

The inserts were a model CIE 51/22.2 from SERF (Décines, France) that is in UHMWPE. To avoid any problems during the device adaptation three dimensions were measured. The external diameter was found to be 45.8 mm in all the sixteen cases. The stem used for the lever-out experiment was a SERF product as well: a Sagitta EVL 3 i.e. a stem in stainless steel to be cemented. It has a short neck on which was placed a head SCC 22.2/+4 (SERF, Décines) in cobalt-chromium.

To carry out the experiments a device built by SERF was provided, for a question of time and handiness it was decided to reproduce it. However, some adjustments had to be made since the samples to be tested have a particular shape and the device was planned to be used on a tensile machine Instron model 1186. Therefore, before carrying out any tests a new device had to be thought, sketched and machined. It was composed of seven parts illustrated in the following figures 7, 8 and 9.



Figure 7. On the top left the device during a push-in/pull-out test. On the top right the same device but adapted to a lever-out experiment. At the bottom the tool used to center the device. All the sketches were made by Nicolas Curt, technician for the health center at the Ecole des Mines de Saint-Etienne. The workshop of the EMSE machined the parts. 1: base of the device, 2: support for the cup bottom, 3: support for the cup top, 4: cone with the head for the pull-out test, 5: lever for the lever-out test, 6: adapter, 7: holes to place the support accurately and 10 mm spaced between the two tests, 8: the cup, 9: the stem, 10: tool used to center the device by lowering the head within the hole.

A load cell (figure 8) of 20 kN range was used together with a displacement sensor to record the force and the displacement respectively thanks to the software AllTest II. In all experiments a velocity of 0.1 mm/s was used, the test had to be short enough to avoid the creep effect of the polyethylene.



Figure 8. Photograph with the load cell (1), the displacement sensor (2), the computer during a pull-out test.

For the series A, all the cups were submitted to three push-in/pull-out tests, it was expected that the repetition had an important effect on the deformation of the insert but one had to check this assumption. Indeed if the chamfer was not too damaged after one test we could reproduce it three times and use the three results to get more accurate data. A block of four step was programmed, a first fast descent, then a descent at a velocity of 0.1 mm/s, and the climb up with the same two velocities. The height was adjusted with the first sample, the idea was that the head had to pass the retentive chamfer but not touch the bottom of the cup before going up. The force needed to insert and extract the head was recorded.

The device was then placed in the off-axis position to carry out the lever-out experiment (figure 9). The head was fixed on the stem. Every cup was submitted to one lever-out test with a lever arm of 10 mm. The height was adjusted before each test, and then a program made press on the stem at a velocity of 0.1 mm/s until another height (the dislocation had happened before it was reached) and the arm went up at a faster velocity of 1 mm/s. The force needed to dislocate the head was recorded. Text files with all the points were obtained and it was possible to reconstruct the curves using the Matlab[®] software as one will see in the next part about the results.



Figure 9. Lever-out experiment (1:cup, 2:stem, 3: device to push on the stem)

The materials and methods have been detailed for the four tasks carried out during this thesis work, the next part will give the results of each one.

4. RESULTS

4.1 Design optimization by finite element modeling (FEM)

4.1.1 <u>Convergence study</u>

Several criteria were used to justify the solution was physical or not by looking at the results. Indeed if the contact, characterized by CSTATUS (different colors if the node was open or closed), showed too many non-contacting nodes within contacting ones it was not physical. Or any case the contact seemed not physical. Besides, the situation was judged not physically acceptable when there were several maxima, above all it was showed that there is one maximum for the pressure in the spherical case [60]. Another non physical situation is when there is a local maximum representing a stress concentration due to the wedge element (figure10).



Figure 10: a) CSTATUS when the "global seeds" was put to 1.5 for the insert and 2.5 for the metal-back and the head. b) Several maximum for the contact pressure inside the cup when the "global seeds" was set to 2.0 for the cup and 2.8 for the metal-back and the head. Red means about 24 MPa and green means about 12 MPa c) Peak of stress due to the wedge element for the "global seeds" set to 2.0 for the cup and 3.0 for the metal-back and the head

On the opposite when the stress distribution was uniform the situation was thought to be physically acceptable and even likely to happen. It was the case for the "global seeds" of 0.8 for the polymeric cup and 0.85 for the other two parts (figure 11). It was the reason why these "global seeds" were chosen for the simulations with the aspherical models.



Figure 11: von Mises stress distribution inside the cup for a "global seeds" set to 0.8 for the cup and 0.85 for the metal-back and the head

The variables measured in each case were plotted to distinguish a range of physically acceptable solutions (figure 12). The non-acceptable solutions according to the previous criteria are marked with a red circle.





Figure 12: a) Final CAREA for the contact metal-back/insert. b) S mean as a function of "global seeds" for the pair metal-back, head

CAREA seemed to converge to about 600 but there was not a range in which the solution was always acceptable, one could define a range just from a metal-back (MB)/head "global seeds" of 2.0, from that limit it looked like the solution was acceptable when the CAREA was between 530 and 600. The same observation could be done for every parameter. The solutions may have become acceptable from a certain "global seeds" from the metal-back and the head of about 2.0. Regarding the variable S mean, all the solutions between 1.55 and 1.59 seemed acceptable from that limit of 2.0.

4.1.2 Shape optimization

Once the mesh size was chosen it had to be applied to all the aspherical models. First it was important to check that the damping due to the stabilization parameter was negligible compared to the frictional energy.

Then we focused on the same parameters as the convergence study to be able to compare the different cases. The following figures (13-19) present the results obtained.



Figure 13. Final CAREA, the contact area at the end of the load application for both contact zones as a function of the insert size



Figure 14. CPRESS mean in MPa as a function of the insert size



Figure 15. S mean in MPa as a function of the insert size



Figure 16. CPRESS maximum on the inner surface of the insert in MPa as a function of the insert size



Figure 17. S maximum on the inner surface of the insert in MPa as a function of the insert size



Figure 18. CPRESS maximum on the outer surface of the insert in MPa as a function of the insert size



Figure 19. S maximum on the outer surface of the insert in MPa as a function of the insert size

First of all the order of magnitude found was the same as for the one involved in other studies, for instance Q. Meng *et al.* reported a maximum value of dry contact pressure of about 28MPa [60] and H. Yoshida *et al.* found a maximum peak pressure of 9.36 MPa during the simulation of sitting down [11].

Then one can see that for the final CAREA (figure 13) between the head and the insert, the insert size did not seem to have an influence. Regarding the final CAREA between the insert and the metallic shell, the more aspherical the higher the final contact area between both parts. That tendency was confirmed with the analysis of CSTATUS or COPEN

Then the two interesting means showed a minimum for the spherical case (figure 14 and 15) which was not very conclusive for our study since we expected a minimum in an aspherical case.

The maxima on the inner part of the cup seemed to be the highest for the most aspherical cases. The maximum contact pressure was the lowest for the size 22.30/22.49 and the maximum von Mises stress was the lowest for the case 22.25/22.40 (figure 16 and 17). The maximum contact pressure on the outer part was the smallest for the insert size 22.30/22.40 while the stress maximum was the smallest for the case 22.30/22.40 while the stress maximum was the smallest for the case 22.30/22.40 while the stress maximum was the smallest for the case 22.30/22.40 while the stress maximum was the smallest for the case 22.30/22.40 which were both aspherical (figures 18 and 19).



It can be seen that the pressure distribution for the spherical case (figure 20) had a maximum in the center of the contact zone as it was said in previous studies [60]. The pressure distribution was more uniform for aspherical cases.

4.2 Surface reconstruction and wear calculation

The surface reconstructed by triangulation is presented in figure 21 a) for one sample and the surface reconstructed by interpolation is presented in figure 21 b) and c).



Figure 21.a) Example of surface reconstructed using Delaunay triangulation. .b) Surface reconstructed using NURBS package for I3 .c) Surface reconstructed using "TriScatteredInterp" for I3.

The results from the triangulation and NURBS seemed satisfying but it was not the case for "griddata" and "TriScatteredInterp" since there were too many holes in the surface. However all the results seemed to give relevant results as no aberrant points appeared.

Regarding the wear calculation the comparison of the 5 methods and Pro/Engineer[®] was performed in order to select the best ones. To do so one focused only on the worn volumes at first. To be able to compare them, relative errors were calculated by taking the absolute value of the difference between the worn volumes of the method and

Pro/Engineer[®] divided by the palpated volume given by Pro/Engineer[®] and multiplied by one hundred. These relative errors are presented in table 7.

Explants	Method 1	Method 5	Method 2	Method 3	Method 4
12	0.09	0.61			0.96
13	0.18	0.67	0.99	14.88	1.14
15	0.64	0.85			5.68
16					
17	0.20	0.71	0.61	0.50	14.61
I4	0.10	0.57	2.68	1.53	0.34
18	0.09	0.45	0.61	0.86	
I1	0.18	0.61	0.62	1.84	2.10
T4	0.14	0.68	0.72	1.00	
Т3	0.14	0.49	0.69	0.86	
Т2	0.09	0.68	0.75	0.65	0.85
T1	0.24	0.58	0.71	0.05	

Table 7: Relative errors of the worn volume (in %) for the five methods compared to Pro/Engineer® results.

Method 1 and 5 clearly gave the smallest relative errors which indicate they gave the closest results to Pro/Engineer[®]. To visualize this comparison figure 22 presents the worn volumes given by these two methods and Pro/Engineer[®].



Figure 22: Comparison of first mobility palpated volumes for Pro/Engineer® and methods 1 and 5.

Obviously the results given by these three techniques were very close, it was the reason why the methods 1 and 5 were prioritized and validated for this application case (volume calculations from three dimensional scattered points).

Then they were used to calculate the annual wear as it was described earlier. The results are presented in table 8 and figure 23.

Characteri stics	Explants	Implant survival (years)	First mobility average 3D annual wear (mm ³ /yea r) Pro- engineer®	First mobility Range/2 (mm ³ /yea r) Pro- engineer®	First mobility average 3D annual wear (mm ³ /yea r) Matlab® method 1	First mobility Range/2 (mm ³ /yea r) Matlab® method 1	First mobility average 3D annual wear (mm ³ /yea r) Matlab® method 5	First mobility Range/2 (mm ³ /yea r) Matlab® method 5
MB SS	12	11.417	22.4	2.9	22.2	4.8	21.5	4.8
316L	I3	10.417	41.9	1.9	93.0	2.8	93.0	2.8
	15	9.33	132.2	3.6	135.1	6.2	138.2	6.2
	I6	9.08	No data	No data	No data	No data	No data	No data
	17	7.25	-0.4	2.1	22.2	3.8	22.3	3.8
MB SS	I4	10.25	0.2	1.1	19.3	2.7	19.1	2.7
316L arthrofibro sis (AF)	18	6.33	10.1	4.4	11.9	6.1	11.8	6.1
MB SS 316L High brooker	I1	12	15.2	1.7	7.0	2.4	7.1	2.4
MB Ti-6Al-	T4	6.17	-7.9	3.2	-8.2	4.6	-8.3	4.6
4V (AF)	T3	7.25	0.5	2.7	-0.3	3.9	-0.3	3.9
MB Ti-6Al-	T2	13.92	25.2	1.4	4.2	2.3	4.0	2.3
4V	T1	15.5	4.0	1.3	3.5	1.8	3.6	1.8

Table 8: Results of annual wear given by Pro/Engineer® and the two Matlab® methods for the firstmobility of a series of twelve explants.



Figure 23: Comparison of the results of first mobility annual wear for the three methods.

It was visible that the results given by method 1 and method 5 were not significantly different because the error bars overlapped in each case, then they could be considered as similar. Compared to the results from Pro/Engineer[®], there were significant differences in five cases: I3, I7, I4, I1 and T2, when the error bars were clearly not overlapping.

The method 1 could be easily adapted to calculate the annual wear for the second mobility whereas the method 5 was not practical to use in that case since it required a lot of time because of the elevated number of points. Therefore it was adapted only twice to confirm the results. They are presented in Table 9 and Figure 24.

Characteristi cs	Expla nts	Implant survival (years)	Second mobility average wear (mm ³ /ye ar) Pro- engineer ®	Second mobility range/2 (mm ³ /year) Pro- engineer®	Second mobility average wear (mm ³ /year) Matlab® method 1	Second mobility range/2 (mm ³ /ye ar) Matlab® method 1	Second mobility average wear (mm ³ /year) Matlab® method 5	Second mobility range/2 (mm ³ /year) Matlab® method 5
MB SS 316L	12	11.417	0.1	8.3	4.3	16.6		
	13	10.417	74.8	7.1	62.3	14.1		
	I5	9.33	44.1	17.5	27.4	17.5		
	I6	9.08	75.2	8.8	58.2	17.6	59.8	17.8
	I7	7.25	1.2	16.2	-14.6	15.7		
MB SS 316L arthrofibrosis	I4	10.25	24.3	4.7	7.0	9.3		
(AF)	18	6.33						
MB SS 316L High brooker	I1	12	32.9	6.0	14.5	11.0		
MB Ti-6Al-4V (AF)	T4	6.17	76.2	15.1	50.2	30.1		
	Т3	7.25	46.9	25.7	32.0	25.6		
MB Ti-6Al-4V	Т2	13.92	15.0	5.9	12.4	11.8		
	T1	15.5	13.2	2.8	6.3	6.3	6.4	6.3

 Table 9: Results of annual wear given by Pro/Engineer® and the two Matlab® methods for the second mobility of a series of twelve explants.



Figure 24: Comparison of the results of second mobility annual wear for the three methods.

The same observation as the first mobility case could be made, that was the methods 1 and 5 were not significantly different. The comparison with the wear volumes from Pro/Engineer[®] showed a significant difference in two case I4 and I1.

4.3 Profiling methods comparison

ANOVA, analysis of variance, enables to compare means of two or more series of samples under some hypotheses: normal distribution, equal variance and if they are independent and random. First ANOVA is known to be robust to the first two assumptions above all if the number of measures is equal for all the series which was the case. Besides the last two assumptions were fulfilled since the measures were taken randomly and independently. Therefore ANOVA was considered usable.

4.3.1 Global technique comparison

The comparison of all the results for two techniques resulted in only one significant difference which was for the parameter Sdr and for the worn zone. The difference was said to be significant when the answer of the comparison was "YES". That means that for every other parameter and zones, both profilers gave similar results.

4.3.2 <u>Worn/no-worn zone comparison</u>

As said earlier the idea was to know which profiler distinguished wear for what cup. It was thought that a cup cited by both profilers could be considered as truly worn. The results are shown in the following table.

	Sa	St	Sq	Sdr	Ssk	SRk
Mechanical profiler	13, 15, 16	13, 15, 16	13, 15, 16	13, 15, 16	NONE	13, 15, 16
Optical profiler	13, 15	15	NONE	13, 15	NONE	13, 15

Table 10: Results of ANOVA tests (p=0.05) between the worn and no-worn zones to know in what cases
the two profilers distinguish wear

The mechanical profiler distinguished wear for three cups I3, I5 and I6 in five cases up to 6. The optical profiler distinguished wear for I5 in 4 cases and for I3 and I5 in 3 cases. The results were similar but the optical profiler was said not able to detect wear in I6 and sometimes in I3 as well.

4.3.3 <u>Cups comparison</u>

The mean values of the five measures for the thirteen cups were compared by pair to show what cups were significantly different from the others. The idea was to make a new ranking and to get some information about wear thanks to the position of each cup in that ranking. One had to focus on the most relevant rankings since there were 12 of them, 13 cups in each and not all of them could give useful results since some results said none significant difference between any cups. The first parameter one focused on was the general roughness parameter Sa because it was thought to be the most known of every parameters and consequently it was commonly used for roughness characterization. Figure 25 shows Sa on the no-worn zone for both profilers and the ranking is made according to the mechanical one.



Figure 25. Sa values for every cup and both techniques on the no-worn zone ranked according to the mechanical technique

ANOVA resulted in no significant difference between any of the thirteen cups for the optical profiler. So it could be concluded that no ranking was possible for the optical technique and it brought no information about the techniques comparison. However the fact that none cup was significantly different from the blank cup for both methods was relevant with the fact that the measures were taken on the no-worn zone.

The figure 26 and tables 11-12 show the results for the Sa parameter in the worn zone.







 Table 11: ANOVA results (p=0.05) for the mechanical profiler on the worn zone for the parameter Sa, yellow indicates no significant difference, red indicates a significant difference



 Table 12: ANOVA results (p=0.05) for the optical profiler on the worn zone for the parameter Sa, yellow indicates no significant difference, red indicates a significant difference

First of all, the order was never exactly the same when both techniques were compared, however it looked like the highest values corresponded, as did the lowest ones. I2 looked like an exception but because of the error bar it was not possible to say it for sure. That kind of uncertainty was a justification for the use of ANOVA. Based on the pair comparison it was possible to make a new ranking for the mechanical technique: - I3, I6

- I5, I7

- the others (not different from I7 but different from I5)

And for the optical technique:

- 15, 13, 17, 16

- T1, T2, T3, Blank cup (not different from I7 and I6 but different from I3 and I5)

- I1, I2, I4, I8, T4 (not different from blank cup but different from I7)

They were similar.

The second parameter looked closer upon in this work was Sdr given it was the most differential when the results for the first measurements campaign with the mechanical profiler were treated. That meant it was the most significant for distinguishing between cups. The exact same conclusion as the Sa parameter could be made for the no-worn zone. For the worn zone the figure 27 shows Sdr on the worn zone for both techniques. The tables 13-14 show the results from multicomparison tests carried out with ANOVA and the Bonferroni method.



Figure 27. Sdr values for every cup and both techniques on the worn zone ranked according to the mechanical technique



 Table 13: ANOVA results (p=0.05) for the mechanical profiler on the worn zone for the parameter Sdr, yellow indicates no significant difference, red indicates a significant difference

	Blank cup	I1	12	13	I4	15	16	17	18	T1	T2	Т3	T4
Blank													
cup													
I1													
12													
13													
I4													
15													
I6													
17													
18													
T1													
T2													
T3													
T4													

 Table 14: ANOVA results (p=0.05) for the optical profiler on the worn zone for the parameter Sdr, yellow indicates no significant difference, red indicates a significant difference

Again it was possible to make some groups considering that within each group there was no significant difference.

The new ranking for the mechanical profiler was:

- I3, I6

- I5

- the others

For the optical profiler:

- I5, I3, I7

- I6 (different from I5 and I3 but not different from I7)

- T1 (even though T1 is not different from I6 but different from I7)

- the others

Again they were similar.

4.4 Experimental work: extraction experiments

The figures 28 and 29 present the results of the push-in/pull-out tests for each wear level of the A series, where the chamfer was machined from the interior. All the three repetitions are plotted. There are 8 figures in total but as the tendency is the same only two of them are displayed.



Figure 28. Three repetitions of the push-in/pull-out test on A1-2 in green the first test, in blue the second test and in purple the last test



Figure 29. Three repetitions of the push-in/pull-out test on A3-1 in green the first test, in blue the second test and in purple the last test (the negative force correspond to the compression of the load cell and the positive forces correspond to a tensile force on the load cell)

The first conclusion was that in all cases the force needed for impacting the head inside the cup was higher than the force for extracting the head. Secondly, as it was expected, the retentive chamfer was altered by each test since the force recorded was lower and lower. It is the reason why in the following only the first attempt will be considered.

The next result (figure 30) is the comparison of the forces involved for each wear level for this same test. One can bear in mind that the samples called A1 corresponded to the lowest wear level; hence a higher force was expected.



Figure 30. Push-in/pull-out results

First of all the results of A1-1 were not plotted since the first extraction was not recorded and as it was proved one test altered the sample a lot. One can see that the two samples with the same chamfer wear level have similar curves above all during the insertion part. Indeed the curves superimpose very well for negative forces which corresponds to the impaction of the head inside the cup. Secondly it seemed that the higher the wear level of the retentive chamfer, the lower the force except for A1 and A2 for which the difference was not obvious. A0 was another exception given it was between A1 and A3. The following table (table 15) shows the maxima for each step and each sample.

	A0	A1-2	A2-1	A2-2	A3-1	A3-2	A4-1	A4-2
Wear level	0%	20%	40%	40%	60%	60%	80%	80%
Insertion	898	1016	1045	1055	879	859	439	420
Extraction	772	762	703	801	625	674	371	391

Table 15: Maxima of the force (N) needed for each of the two steps
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This table confirms that there was not a large difference between A1 and A2 by opposition to the other two. Besides the maximum force reached during extraction was 801 N whereas it was 1055 N during insertion.

The lever-out tests provided the results on figure 31.



Figure 31. Lever-out results (note that the displacement scale was different for B0 it is the reason why the curve is displaced compared to the others)

It can be observed in the previous graph that the lower the wear of the retentive chamfer, the higher the force needed to dislocate the head. Again the difference between the wear level 20% and 40% was not as obvious as for the other two wear levels. This time the wear level 0% was very similar to 20% and 40%. The table 16 shows the maxima for each cup.

	B0	B1-1	B1-2	B2-1	B2-2	B3-1	B3-2	B4-1	B4-2
Wear level	0%	20%	20%	40%	40%	60%	60%	80%	80%
Maximum	254	254	264	244	254	225	234	186	186
force (N)									

Table 16: Maxima of the force reached during the lever-out test for each sample

The maximum force reached during lever-out test was 264 N for the lowest wear degree.

Many results have been observed, the next part helps drawing conclusions from them.

5. DISCUSSION

5.1 Design optimization by finite element modeling (FEM)

5.1.1 <u>Convergence study</u>

A general observation was that the smaller the "global seeds" of the three parts, the more often the solutions were acceptable. It was not possible to define a range of acceptable solution without considering first a limit of "global seeds" for the metal-back and the head. This limit was put to 2.0 since above this value the great deal of the solutions was not physically acceptable (according to the criteria mentioned previously) and below which most of the solutions were acceptable.

Then it was important to choose a solution that enabled to get good enough results in a reasonable time, it was the common trade-off between the time and the accuracy of the results. Here one did not increase the number of elements until clearly constant results because it took a lot of time so the challenge was to take a compromise between the time and the number of elements for which the results were close enough to consider them reliable and similar to what would be obtained by keeping on increasing the number of elements. Therefore this convergence study was not exhaustive but it made a good sorting. As for a cup "global seeds" of 0.8 and for a "global seeds" of 0.85 for the other two the solution looked the most uniform and the closest to reality in addition to the fact that it was physically acceptable and did not last more than 20 minutes so these "global seeds" were chosen. It resulted in a number of elements close to 80 000 for the insert, 20 500 for the head and 15 458 for the metal-back.

Obviously one could think to a complete study to get even more accurate results. It could even be possible to use optimization algorithms to find these optimal numbers. A resulting limitation is that the number of elements was chosen to be the same for the metal-back and the head yet there was no reason for it. It could even be thought that since the convexity is higher in the inner of the insert, the size of the elements of the head could be smaller than the elements of the metal back.

5.1.2 Shape optimization

One saw that the more aspherical the higher the final contact area between the insert and the metal-back, it was consistent with what was expected. Indeed it was said that we add some material where the force applied was the highest so that the resulting deformation filled the holes.

For four parameters (maximum of von Mises equivalent stress and maximum of the contact pressure on both the inner and outer surfaces) the aspherical shape seemed to have an influence since the minimum for each was not for the spherical case. Particularly the sizes 22.25/22.40, 22.30/22.40, 22.30/22.46, 22.30/22.49 seemed to stand out. As the

final contact area was the highest for the last two cases previously quoted it might have been thought that the situation with a minor ellipse radius of 22.30 mm was the best suited for the purpose of this work.

For the means of the contact pressure and the stress, they were found to be minimal for the spherical case which was not in agreement with the expectations. However we were not sure the variations were significant so it was not enough to conclude the spherical case was the best.

There are several limitations to that finite element model. A first limitation is on the material properties, an elastic definition was used but it is not the actual, case for UHMWPE. To get more accurate results it could be relevant to define the UHMWPE as elasto-plastic, even viscoelastic. For the first case one could say perfectly plastic at a certain stress, for the second definition one would need test data. Another thing regarding the polymer is its time-dependent property; maybe it would be relevant to take into account creep or to use a stress-dependent modulus. An elastic definition overestimates the contact pressures [69]. Besides head penetration is frequently used as an estimation of wear but it is not due to wear only, indeed as explained by S.L. Bevil et al. [64], creep plays an important role in head penetration, according to S.L. Bevill et al. it would represent 10% to 50% of initial penetration. Several other authors [76] reported an initial bedding-in period during which the wear rate is high and creep would be one of the first causes of it, then wear would dominate. Obviously creep entails a change in contact area so in contact pressure too. Therefore even though it does not change a lot the predicted volumetric wear [64], creep might be of importance for the present issue as the initial deformation is of interest. During the assembly the metal back was tilted 45° to respect the anatomical position but the insert and the head were positioned at 0° whereas their position would normally be random, however a preferred position was easier to reproduce. Besides an anteversion angle between 5 and 25° might be added [65]. The mesh quality might not be optimum while it was observed to have a great influence on the results. For instance a too straight demarcation between the two types of elements for the mesh of the head might result in distortions and poor results at this location. It may require specific software to make a better mesh and a lot of time. Indeed S.H. Teoh et al. spent some time on the meshing to have a very good mesh [66].

Obviously these models have assumptions and only one simulation was done to get these final results so one has to be careful about what to say. Nevertheless the results were in agreement with what was expected since the contact area was increased, the stress and contact pressure maxima decreased and the pressure distribution was more uniform. Therefore one can conclude that an aspherical shape may be advantageous in terms of contact area, contact pressure and stress distribution. It was a first study about the shape

optimization, the idea was to set the basis, of course further work is needed to confirm that first conclusion.

5.2 Surface reconstruction and wear calculations

The results from the interpolation were expected to be better than triangulation where no points were added. But figure 21 showed more satisfying results using the triangulation, it could mean there were enough points. Besides for just the observation of wear (uniformity, asymmetry) and tell if the assumption of sphere was valid the triangulated surface was enough. However, as no point seem aberrant in the interpolated surface it still could be used for the purpose of wear calculation as it will be seen later.

The first conclusion that one could make was for the selection and validation of methods made in the first mobility case. That conclusion was method 1 and 5 were the most appropriate to calculate the worn volumes given they gave the results the closest to the results given by the software Pro/Engineer[®]. It is worth noting that these two methods used only the 840 points given by the CMM, therefore this number of points seemed sufficient for the calculations, there were no need for additional points from interpolation. Of course these conclusions were made according to the application that meant under certain specific conditions and could be wrong in other cases.

Strangely, even if the worn volumes from Pro/Engineer[®], and method 1 and 5 were quite similar since the largest relative error was 0.64% for method 1 and 0.85% for method 5, the average annual wear could be significantly different. This difference must have come to another error source than the algorithms or at least it was amplified by another parameter. Indeed two small errors in opposite direction entail a bigger error. This second parameter may have been the tolerances together with the scale difference since it was the only additional step made from to the first worn volume calculations. It was thought that the fact they were taken into account added inaccuracy given the actual diameter could have been known after manufacturing. The ideal situation would be to have the actual volume of the implant so it would have to be measured and written down into the file but unfortunately it is not done for now so this inaccuracy cannot be avoided.

As mentioned earlier methods 1 and 5 were validated, therefore their results could be considered as valid as the one from the software Pro/Engineer[®], hence all of them had to be taken into account to give volumetric wear. As a result the range was quite large, for instance for the first mobility of the explant named I3, the average annual wear was between 41.9-1.9=40 mm³/year and 93.05+2.8=95.85 mm³/year. Nevertheless it was not possible in that situation to be more accurate. Moreover as there was no one manner to wear for all the implants it seemed closer to reality to give this type of range. Besides the values found were in agreement with the ones from the literature, for example 21.49 \pm

3.21 mm³/Mc (1 million cycle Mc is equivalent to one year with a simulator) for a dual mobility prosthesis in a hip simulator [22] or 21.5 mm³/Mc for a simple mobility implant under smooth conditions in a hip simulator as well simulating normal walking [26]. Finally the approximation of spherical segment did not seem to rough since the results from methods 1 and 5 were very close. Besides it did not seem to be a critical hypothesis since even for the largest asymmetrical wear (figure 21 b)) the results given by the methods 1 and 5 were close to the volumes calculated by Pro/Engineer[®].

5.3 Profiling methods comparison

The results obtained from the three comparisons enabled to make some conclusions and assumptions presented below.

5.3.1 Global technique comparison

As mentioned in the results part, ANOVA found only one significant difference for the first comparison: that was for Sdr on the worn zone. It was relevant with the fact that this particular parameter was the one that exacerbated the errors the most and it was in the most irregular of the three zones since the no-worn zone did not suffer abrasion and the apex zone was more flattened than peaked. Therefore it was possible to conclude that both techniques gave similar relevant results.

5.3.2 <u>Worn/no-worn zone comparison</u>

The first conclusion from this comparison was that both methods distinguished wear for 13 and 15 for most parameters which tended to prove that they were the most damaged cups. But obviously they were not the only worn cups since twelve cups out of thirteen were explants hence supposed to have been deteriorated during the implantation period. Actually it was relevant not to detect wear when the cups where in contact with a Ti-6Al-4V metal back given the wear mechanism was different, just a little rubbing happened and wear was very slight. Besides there were at least four cases of fibrosis (I4, I8, T3 and T4), the second mobility was blocked so it was relevant not to find wear on the outer surface of the insert. I2 was suspected to be in an intermediary state of fibrosis which would explain why the two methods failed to distinguish wear for this cup. The remaining cases are I6 and I1. The wear of I1 for the second mobility was measured and mentioned earlier (table 9), it was small which would explain why it has not been detected. Finally the mechanical profiler distinguished wear for I6 unlike the optical one; that would tend to prove that the mechanical method was more accurate in that case since I6 had worn. Obviously there was a difference in results between both profilers that could be due to the contact that dug the surface so the mechanical profiler overestimated the

wear compared to the optical one and this might have been enough to reach the limit of wear distinction. But it could also come from the optical method that cannot detect holes and valleys if the slope is too straight. Therefore one might think that not one technique was always giving more reliable results than the other, and the mechanical profiler was not necessarily less accurate but it was the complementarities of both techniques that could lead to useful conclusions.

5.3.3 <u>Cups comparison</u>

For both techniques and both parameters it appeared that the no-worn zone for every cup was not worn indeed since the profilers could not make a significant distinction between the explants and the blank cup. This point was reassuring regarding the techniques; they did not detect wear when there was no wear.

Regarding the worn zone for the Sa parameter the profiling technique and ANOVA helped to make groups of explants which could be considered to have worn similarly. The two methods made quite the same groups which enabled to be sure that wear did occur and occurred the same way within a same group. It would tend to prove that the use of one of the technique could give good results. They both showed that in the ranking I3, I5, I6 and I7 were on the left of the blank cup, it corresponded to more striated samples than the blank cup which would be consistent with an implantation time equal or higher than 9 years. It was not the case for I7 but I7 was not different from the blank cup as well so it was a special case. The others were thought to be more polished than the blank cup which corresponded to a survival time lower than 9 years. It was not true for I2, I4, T1 and T2. However I4 corresponded to a patient with fibrosis, I2 was suspected to be in the same case. T1 and T2 were separate cases since the wear mechanism was different when the shell was in titanium, indeed the abrasive wear was very slight.

The second significant parameter was Sdr, it was thought to be interesting as it exacerbated the differences and allowed a distinction between flat and peaked surfaces. There was a general tendency showing the results from the mechanical profiler smaller than the results from the optical one. That tendency could be explained by the fact that the stylus used in the mechanical machine squashed the surface, the asperities were not seen and the developed area was smaller than reality. The results were similar for the ones obtained with the Sa parameter, for the worn zone the cups for which the methods distinguished wear were significantly different from the blank cup so it was relevant. Besides the ranking was similar too since the most altered cups (I3, I5, I6) were separated from the blank cup and the cups more polished. The optical profiler said different from the mechanical one for I6 and I7. To have information about the texture it was interesting to look at the Ssk value that showed if there were more peaks or more valleys. The mechanical profiler gave a higher Ssk value for I6 than the optical one (0.67 and 0.02), it was relevant with the fact that the mechanical profiler distinguished wear for I6 and not the optical one. But the Ssk values for the I7 cup on the worn zone were closer (0.28 and

0.20) so it confirmed that I7 seemed to be at the limit of wear domain, thus it was difficult to be sure about the location of I7 in the wear process.

5.4 Experimental work: extraction experiments

On the figures 28-30 we could see that at the end of the impaction step the force became positive which correspond to a tensile load whereas we expected only compression for the step. And it was the reverse for the second step, the extraction of the head finished by a compression of the load cell. It could be related to an opposite force created by the chamfer once it had been passed over. Therefore it could stem from the elastic release of the chamfer but it also might have been related to the working of the load cell.

It was said that the force needed for inserting the femoral ball was higher than the force needed for extracting it, it was a relevant result given during the impaction the air inside the cup was compressed which entailed the need of applying a higher force. The maximum force reached during insertion and extraction was respectively 1055 N and 801 N. It is relevant with the fact that forces about 250 N reached during daily activities are not enough to extract the head from the cup. Besides, as expected the lower the wear level the higher the force required for the insertion and extraction of the head. However the difference was not obvious between a wear level of 20% and a wear level of 40% which might have meant that until the wear level the retentive chamfer could ensure its function as efficiently as before. The same conclusion could be made about the lever-out test. The blank cup showed no conclusive results but only one blank cup was tested for each experiment and it was not coming from the same batch as the others so it was not easy to compare anyway.

That lever-out experiment involved much lower forces due to the fact that a lever arm was used. The maximum and the minimum were 264 N and 186 N and were reached respectively for the lowest and the highest wear level which was consistent. The forces involved seemed quite low which might be worrying but it is worth bearing in mind that the velocity imposed during the tests was quite low compared to reality; therefore the forces recorded were lower than the forces required in reality at real velocity.

There are some limitations to these experiments like the fact that the load cell was not the most suitable since the forces measured were too small, indeed there were around 200 N and the uncertainty was about 20 N. It may be also the reason why the graphs seemed to have some noise. Besides the number of samples with the same wear degree was not high enough to get statistically reliable data. Nevertheless these experiments were the first of a series that will take these limitations into account. They were aiming at giving a first idea and many other experiments of that type will be carried out to be able to draw interesting and reliable conclusions about the retentive chamfer. It is already possible to say that the retentive chamfer had a positive effect on the dislocation rate since it entailed the necessity of a higher force to extract the head from the cup.

Results and discussion for each of the four tasks enabled us to draw some general conclusions about the work performed during this thesis work.
6. CONCLUSIONS

That master's thesis had two objectives, firstly one wanted to get a better understanding of the working of the dual mobility, it could be done by analyzing wear. One part was to quantify it and the other was to observe the mechanisms. The second objective was to study tracks of optimization, one of them was about the insert shape, and the idea was to use finite element analysis to see the effects of such a change on some parameters. Another track of optimization was about the retentive chamfer, the idea was just to measure the forces involved in impaction and extraction of the ball from the cup.

About the experimental work it has been seen that the retentive chamfer is indeed a key parameter to avoid dislocation since the force needed for the extraction decreased as the wear degree increased. Of course the force required for the lever-out was lower than for the push-in/pull-out test and the force needed for the impaction was higher than the one needed for the extraction. But the important was that even after a certain amount of wear the retentive chamfer still seemed to be efficient which suggested that its design was already in a good way but it could be improved, for instance it could be interesting to achieve a more gradual decrease.

The other task about optimization of the dual mobility showed that an aspherical shape could have benefits in terms of stresses and contact area. Indeed it could help decrease the maximum stresses and make the contact pressure more uniform.

The other important issue was the wear analysis through the analysis of explants and a blank cup with several machines. A CMM gave three dimensional data on both the inner and outer surfaces of the cups. The surface reconstruction and wear calculations enabled to get qualitative (asymmetrical wear happened for I3) but mostly quantitative information that was the average annual volumetric wear. Two methods built with the software Matlab[®] were validated on the inner surface before being further used on both surfaces to get wear measures. The comparison of these methods and Pro/Engineer® resulted in quite large range for the wear but more realistic as well. It was possible to confirm the first results obtained with Pro/Engineer[®] and the assumptions made from them. However, it should be kept in mind that they were just minimum limits and that the true wear must be higher since not the whole surface could have been palpated. The stylus contact is a drawback of mechanical techniques as one saw for the profiling methods as well. The idea was to compare the results from a mechanical profiler with the results from an optical one. The results were similar from each other but the mechanical profiler initially suggested as less accurate showed a better wear distinction. Therefore for that precise kind of application it should not be neglected. But the more reliable information came from the complementarities of the results, indeed when both profilers distinguished wear we could be sure the samples had worn. It was particularly the case for I3 and I5. The cups comparisons together with the ANOVA tests enabled to make groups of similar wear mechanisms, then looking at the material of the associated metal

back, the implantation time and other information like the presence of fibrosis, helped build assumptions and understanding about the working of the dual mobility which is of interest when one is looking for further improvement and optimization.

Several conclusions have been done from this thesis work but it is worth bearing in mind that they are all related to the conditions and assumptions used. Consequently future work must be carried out to generalize these conclusions.

7. FUTURE WORK

7.1 Design optimization by finite element modeling (FEM)

In future work limitations mentioned in part 5A could be addressed. Besides wear could be one of the outputs of that simulation, it could be done by implementing the Archard's law or a modified Archard's law [68,76]. It would then be important to measure the sliding distance using only flexion/extension [68] or more advanced definition.

Besides the loading conditions can be more complex to reflect more the actual conditions, it could be dynamic and cyclic loading or even several steps of static loading. For instance in the T.A. Maxian's article [68] they explained how they simulated the walking conditions by using 16 discrete instants per cycle, assuming that one million cycles represent one year. They used only the flexion/extension but we could think of using the other movements or other postures (some articles describe up to 9 postures studied to be closer to real conditions but not all seem to be of interest). [76] also used only flexion/extension and a dynamic loading constituted of 16 load stages with different loading direction representing the walking activities but many authors used several stances for dynamic loading as [64] where they wanted to characterize creep and wear during simulated gait. Another point is to take into account the effect of muscles [72,77] and even more accurate would be the capsule representation as it has been done by K.J. Stewart *et al.* [65] aiming at improving the fidelity to the real cases to further help to make design and surgery decisions. The capsule presence might increase the torque required to flex the hip joint but it may be not of primary importance for this study.

Even though the time simulation was not too long, one might think of reducing it further if more elements are to be used in the future. In that case, auto-remeshing or mass increased artificially might help.

7.2 Surface reconstruction and wear calculations

The future work might be here to adapt the algorithms used for the points obtained with the CMM machine for the information given by the new machine using a scanning process.

7.3 Profiling methods comparison

It might be of interest to make this comparison for a new series of explants to make sure what we have concluded is true again and above all to get the most information about the wear of the explants. Indeed this comparison could help validate the assumptions of working made during the analysis of the first series of explants.

7.4 Experimental work: extraction experiments

The retentive chamfer was said to be altered by successive tests but one does not know what are the proportions of each mode (elastic deformation, plastic deformation) so changing the protocols like the time between each test could bring information about that proportion. Besides, other tests on larger series are expected to acquire knowledge on the chamfer deformation.

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APPENDIX

Appendix1: Table of several crosslinked UHMWPE with some characteristics

Material	Manufacturer	Resin	Crosslinki ng process	Annealing	Yield stress (Mpa)	UTS (Mpa)	Elongatio n (%)	Tm (°C)
ArCom®	Biomet	1900H	Gamma 2.5-4 Mrad	None	24-25	59-40	240-300	142
Marathon ™	Depuy/Johnso n&Johnson	1050	Gamma 5 Mrad	Above Tm	21	56	300-290	136
Reflection™ XLPE	Smith&Nephe w	1050	Gamma 5 Mrad	At Tm	20-21	56-58	300	136
Crossfire™	Stryker HowmedicaOst eonics	1050	Gamma 7.5 Mrad	Below Tm	22-24	53-48	230-280	141
Durasul™	SulzerOrthopa edics	1050	Electron 9.5 Mrad	Melt anneal	19-20	34-30	330-280	140
Longevity™	Zimmer	1050	Electron 10 Mrad	Melt anneal	21	43	250-240	138- 140
Х3тм	Stryker	1020***	3 cylces 3 Mrad***	3 cycles 130°c***	25* 24***	54* 56***	270***	
E1®	Biomet				24**	43**		
ASTM UHMWPE					19	27	250	

Source [78]

When there are two figures it means as-received and after aging

*source [79]

**source [80]

***source [81]

Appendix 2: Strategy used to solve the problems faced during the construction of the finite element models

There were several warnings indicating "excessive distortion of elements", "negative eigenvalues" or "numerical singularities". With the files provided while running Abaqus it was noticed that during the whole job severe discontinuities occurred, they were due to openings and overclosures. The penetration and contact force errors were compared to tolerances and establish if the severe discontinuity was small enough. When it was not it entailed new attempts for an increment and eventually the limits of attempts or time increment would be reached. So, one of the problems had to be related to the contact definition. Besides the convergence was very slow and the job aborted while just an infinite fraction or even none fraction of the load was applied.

The strategy to solve the problems was to simplify the model and understand the warnings and errors. Abaqus manuals and the Internet provided a lot of advices and guidance concerning the contact (convert SDI, decrease time increment, use C3D10M elements, check surface normals, use unsymmetric solver, use contact controls), for instance when using contact and a complex geometry it was helping to add surface adjustment. This option "surface adjustment tolerance of zero" to remove penetration was also the one adopted for the investigation of the dry contact in the study about the aspherical design of Q. Meng [60].

At the beginning the fact that the contact characteristics appeared at the first attempt of the first increment meant that there was already contact between the two surfaces. The strategy was then to translate the insert outwards and make a simulation to measure exactly when the contact occurred, this displacement would be used in a first step to establish the contact. It was also a common practice to add stabilization that is a non-physical damping helping for convergence. The choice of the damping factor was a tradeoff between the number of increments required for job completion (time cost) and sufficiently small ratios ALLSD (energy dissipated by viscous damping)/ALLFD (frictional energy). Indeed it was important to check that this artificial damping was negligible.

The second main source of problems was the "rigid body" definition. Indeed the job aborted with many warnings "numerical singularities" typical of rigid body motion, another warning was "zero pivots" indicating overconstrained problem. Moreover the head went through the insert without "seeing" it. It was also due to the rigid body definition. The solution was to constrain all the degrees of freedom and to import the head as deformable and then use a rigid body constraint. The boundary conditions and loads must be applied to the reference points in order to avoid the overconstraints. A contact control was added for each step to help prevent rigid body motion and enhance convergence as it is commonly suggested for contact problems instead of the stabilization in the step definition. However one has to check it does not have an incidence on the

results by checking that the energy due to this stabilization is well below the frictional energy.

Appendix 3: Algorithm of the strategies used for wear calculations.



the Matlab® methods

Use the same methods to calculate the minimal and maximal volumes given the tolerances, make the subtraction to get the total volumetric wear and divide by the implantation time to access the average annual wear

Appendix 4: explanation of the roughness parameters (from the "WYKO Vision Help")

Sa, Sq and Ssk are amplitude parameters, St is a spatial parameter, SRk is an Abbott-Firestone parameter and Sdr is a hybrid parameter. They are all 3D parameters; they have a more accurate surface characterization than with 2D parameters. Sa is the mean roughness and Sq is the root mean square roughness. They are unable to differentiate a plane surface from a peaked surface hence they are insensitive to the texture. Ssk is the skewness that is the degree of asymmetry of a surface height distribution about a mean plane. It is interesting for wear measurements since a positive Ssk indicates more peaks and a negative Ssk more valleys. A peak is defined as a point above its eight nearest neighbors and a valley is defined as a point below its eight nearest neighbors. St is the sum of the largest peaks height and the largest valleys depth, therefore it is more sensitive to the surface texture than Sa or Sq. SRk (or Sk) is the depth of the working part of the surface that is the main flat part. Sdr is the developed interfacial area ratio, it is a percentage defining the additional surface area due to the texture compared to the plane surface of the same size. The difference in Sa can be small together with a large difference in Sdr so this latter parameter enables to differentiate surfaces with similar mean roughness but a difference in texture.