Experimental Wear Characterization of Metal-Polyethylene Hip Implant Materials using Designed and Developed Screening Devices

THESIS

Submitted in partial fulfillment
of the requirements for the degree of

DOCTOR OF PHILOSOPHY

by

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BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE, PILANI

2015

BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE, PILANI

CERTIFICATE

This is to certify that the thesis entitled **"Experimental Wear Characterization of Metal-Polyethylene Hip Implant Materials using Designed and Developed Screening Devices"** and submitted by **ANANT CHANDRAKANTRAO KULKARNI** ID No **2005PHXF430G** for award of Ph. D. Degree of the Institute embodies original work done by him under my supervision.

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Acknowledgement

Even though hard work, dedication and perseverance are important in shaping one's career, it is the help from others and generosity of those around you which are often easily forgotten, that make up the fundamental building blocks in that endeavor.

I am grateful to my parents, Shrimad Chandrakant and Shrimati Sunanda for their immense help, motivation and parental support during the completion of my doctorate work. I thank Jyotsna for her support and inspiration during worktime. It is her conviction and faith in the hard work and ability to pursue makes me possible to concentrate and complete my doctorate work. I thank Atharva for sharing those twinkle similes with me and giving me impetus in continuing my work.

I am honored to have had this opportunity to work with my supervisors Professor D.M.Kulkarni. Their inputs, ideas, support and guidance were invaluable and helped me remain on the track. I thank Professor & Head, mechanical department, BITS-GOA for his cooperation and support. I am thankful to Professor Pravin Singru for motivation and support in completing thesis.

I am thankful to work-shop team and departmental colleagues for giving me immense ideas and support in fulfillment of this work. I am thankful to Mr.Narandra Dube and whole DUCOM Team for their ideas and support in completing the work.

I am thankful to all those knowingly and unknowingly contributed in completion of my work.

ANANT.C.KULKARNI

ABSTRACT

Prevention of premature failure of artificial hip implants has been a constant struggle for orthopedic surgeons and engineers. Forty eight years ago, orthopedic community, predicted that artificial hip implant will last long for up to 30 years while enduring a highly active and athletic life. However, as on today average lifespan of hip implants is approximately 10 to 12 years, which is significantly lower than the 30 years goal set by the orthopedic community. The major cause of failure of hip implant is wear. Wear mechanism at the articulating surfaces of the artificial hip joint is highly complex during working conditions.

With an increasing demand for prosthesis hip implantation, there is an increasing need for a more wear resistant implant design. Metal on polymer (UHMWPE) is extensively used as prosthetic pair in total hip replacement. The service life of the artificial implant is still restrained by tiny Ultra-High Molecular Weight Polyethylene (UHMWPE) debris, generated by the long-term friction between the artificial femoral head and the acetabular cup. Presently, wear volume at the articulating surfaces of hip joint is measured with the help of conventional wear measuring test rigs (like pin-on-plate machines). However based upon extensive literature survey, wear results obtained from these conventional wear test rigs are not comparable with clinical (actual) wear. Therefore, there is a need to modify and customize conventional wear screening devices by incorporating motion close to in-vivo motions and serum as a lubricant having cognizant properties, protein content, viscosity as found in natural lubricant (synovial fluid) producing more accurate results on wear which will be comparable to clinical (actual) wear.

In order to obtain clinical wear data an ex-vivo study is carried out on 20 explanted Charnley cups of Indian patients using non-contactable white light interferometer. This retrieval study is found to be more useful to understand the wear distribution and compute wear data like linear wear, volumetric wear, wear rate and wear factor for the duration of functional life of an implant. Patient specific information like age of implantation, time of implant, weight and activity level of patient is utilized to convert this clinical data for comparison with the experimental results. Based on the wear distribution pattern observed from the retrieval study, it is concluded that the motion at the articulating surfaces of hip joint is multidirectional. This multidirectional motion as per the literature could be 8 shaped.

The conventional wear measuring test rig (pin-on-plate), which has either reciprocating or rotating stations, is proposed to modify to account for a multidirectional motion by having a combined reciprocating and rotating (R+R) motion. Design concept and key simulation parameters are proposed to DUCOM Instruments, Pvt. Ltd. Bangalore, which is manufacturing and exporting wear screening devices under a memorandum of understanding with BITS Pilani, K K Birla Goa Campus. The test rig is designed and developed at the industry site and delivered to BITS for the testing and validation. The modified test rig (*pin-on-plate*) is used to conduct a wear test on metal-on-UHMWPE material pair with different dose of cross linking. Wear data like volumetric wear, wear rate, wear factor and surface characterization is generated from this test rig. However, this test rig, being a conventional one is not meant to find key parameters like coefficient of friction and Sommerfeld number.

In order to have a comprehensive wear characterization and achieve more accurate results comparable to clinical wear, it is proposed to modify a conventional tribometer to account for an 8 shaped motion of pin on disc along with serum lubrication which has properties similar to a synovial fluid. In this case also, design concept and key simulation parameters are proposed to DUCOM Instruments, Pvt. Ltd. Bangalore, under another memorandum of understanding with BITS Pilani, K K Birla Goa Campus. The modified tribometer is designed and developed at the industry site and delivered to BITS for the testing and validation. The modified tribometer was renamed as '*advanced bio-tribometer*'. The advance bio-tribometer is used to conduct wear test on metal-on-UHMWPE material pair with different dose of cross linking, similar to the modified wear test rig. Wear data is generated on volumetric wear, wear rate, wear factor and surface characterization. Apart from this data is also generated on coefficient of friction and Sommerfeld number.

Wear data generated from these two screening devices is compared with retrieval study of Charnely cups. By conducting ex-vivo study on the retrieved implants in aboriginal patients we could able to set a standards and limits on the wear parameters or values observed in the Indian community. Every community or a group has peculiar posterior, activity levels and that builds the required straining conditions on artificial hip implant as it is one of the major joint responsible for almost every activity of an individual. The values of wear factor in experimental investigations are in the range of the values found in literatures and ex-vivo investigation results.

Both the test rigs developed are multistation and have generated valuable wear data for analysis. For metal on polyethylene pairs the results of investigations are satisfactory.

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UHMWPE	Ultra-high-molecular weight polyethylene
R	Reciprocating motion mode
R+R	Reciprocating plus Rotational motion mode

Chapter 1 Introduction

1.1 Background

Natural hip joint consists of a femoral head and acetabular cup. Hip joint (Fig. 1.1) is very stable and has a great deal of mobility, thereby allowing a wide range of motion required for activities such as walking, sitting, and squatting. Movements of the femur about the hip joint include flexion–extension, abduction–adduction and inward–outward rotation. It is also a major weight-bearing human joint. In natural hip joint smooth layers of articular cartilage form the load-bearing surfaces and over the period worn out, causing distortion in the shape of the joints. Pain usually results from the sliding of the two rough bony surfaces. Total hip replacement using artificial materials is required to support the natural movements.

Replacing the hip joint consists of the replacement of the femoral head by a ball made of metal alloy or ceramic, and the acetabular cup by a hemispherical lining made up of a polyethylene. Metal on polymer or ceramic on polymer is extensively used as prosthetic pair in total hip replacement (Alhassan and Goswami, 2008, Roychowdury *et al*., 2007). Major cause of failure of hip joint is wear at the articulating surfaces of hip joint. The service life of the artificial implant is still restrained by tiny ultra-high molecular weight polyethylene (UHMWPE) debris, generated by the long-term friction between the artificial femoral head and the acetabular cup. It is well established that the cellular response to wear debris is dependent upon number of particles, shape, size, surface area, and material chemistry (Affatato, *et al*., 2008).

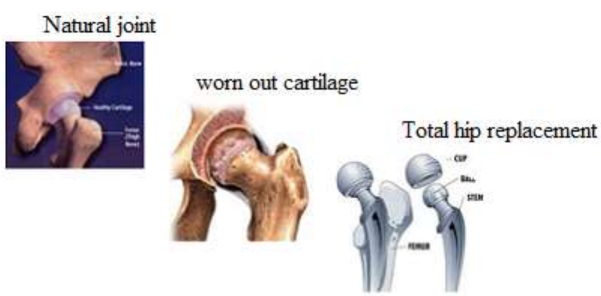


Fig. 1.1 **Total hip replacement**

As the number of cases of patients including young patients is growing exponentially the life of hip implant has become a serious concern. The revision surgery, in which the new prosthesis is implanted by removing the worn-out implant, is costlier, more painful and reduces life span compared to the older one. Each year, arthritis results in nearly 1 million hospitalizations and close to 45 million outpatient visits to health care centers. The data about patients undergoing total hip replacement is unknown in developing country like India but the figures given above will clear about the status and severity of problems related to joint diseases worldwide. People with hip joint damage that causes pain and interferes with daily activities despite treatment may be candidates for Total hip replacement (THR). It is a surgical medical process in which the natural joint is replaced by the artificial implants.

Prevention of premature failure of artificial hip implants has been a constant struggle for orthopedic surgeons and engineers. Forty eight years ago, orthopedic community (Sfantos, and Alibadi, 2007) predicted that artificial hip implant will last long up to 30 years while enduring a highly active and athletic life. However as on today average life span of hip implants is 10 to 12 years, which is significantly lower than the 30 years goal set by the orthopedic community. Wear mechanism at the articulating surfaces of the artificial hip joint is highly complex during working conditions.

In order to understand the complex nature of wear in hip implants Clinical studies, experimental studies and ex-vivo studies of prosthesis are usually carried out (Sagbas, 2012). Generally In preclinical investigation of hip prosthesis the implant material pair is tested on wear screening as well as simulator. With an increasing demand for prosthesis hip implantation, there is an increasing need for a more sophisticated wear testing device which would simulate the geometrical parameters, kinematic motions, load profile and biological lubricating conditions across the highly demanded pair of materials of hip implants. It was jittery that numerous factors affect in vivo wear with respect to the more restrictive and controlled laboratory conditions so that a correlation between in vitro vs. in vivo data remain a challenge.

1.2 Retrieval study

The nature of wear in physiological conditions like hip joint is complex due to multiple attribute interactions. The materials used in pair, the physiology of patient, the weight of patient and surgical acumen ship of surgeons during fixation of implant are considered to be major attributes affecting the qualitative and quantitative characteristics of wear. Therefore it is essential to consummate the retrieval studies of implants to establish bench mark for discussing linear wear, volumetric wear and life expectancy of hip implants.

The retrieval studies are conducted in few of the well-known labs like kingly in London and Aura university Alberta for the patients living in that part of world. The patients living in different part of world differs in their physiology, weight, GAIT cycle pattern and activity level. It is imperative to conduct the retrieval study for patients living in south Asian region so as to establish and characterize wear in implanted prosthesis to relate and compare with the studies carried out in different parts of world. It will help qualitatively to decide the wear index due to difference in life style, walking posture and weight parameters and compare the data with the literature studies.

Various methods are proposed over the years for measurement of wear in retrieved implant. These methods are used alone or sometimes in combination with gravimetric method for validation purpose or to estimate the normalized error in measurement. Some of them are invasive and others are non-invasive. Invasive techniques like radiograph or x ray method are used in clinic and are 2 D methods for wear measurement. Gravimetric method is mostly used in in-vitro studies in which prosthesis prewear or zero cycle data is available. Gravimetric method is also used by many researchers to clinically validate the wear in retrieved or wear tested cup on simulator for finite number of cycles in association with geometric methods. Gravimetric method seems to be ineffective in new potential materials proposed for hip prosthesis. With the introduction of new potential materials proposed, limits of gravimetric methods in discerning wear specific issues seem to be evident. Therefore there is a need to use sensitive methods with higher resolution approaching higher accurate results (Bills, 2005). Recently, few precise and more accurate methodologies based on dimensional measurement and volumetric assessment is incorporated using white light interferometer and coordinate measuring machine. These methodologies are still in the development phase and need validation.

1.3 Wear and Experimental wear test rigs

With an increasing demand for prosthesis hip implantation, there is an increasing need for a more wear resistant implant design. The problems associated with prosthetic failure are mainly related to wear. Presently, preclinical assessment of wear volume at the articulating surfaces of hip joint is accomplished with the help of conventional bio-tribometer and hip simulators. These

Biotribometer are not capable to find the wear volume which can be compared with the clinical (actual) wear data and allow hospitals to take a critical decision on pair of material for the hip implant. Therefore the pre-validation or pre-clinical investigation of the wear performance of pair of materials used in the hip implant is very important. Based upon the wear performance most accurate life of the implant can be predicted.

Wear mechanism at the articulating surfaces of the artificial hip joint is highly complex during working conditions. The wear debris interacts biochemically with body tissues leading to loosening of implant which ultimately reduces the active life of hip implant. The ultra-high-molecular weight polyethylene biomaterial is extensively used as a bearing material in orthopedic implant owing to its superior mechanical toughness, wear resistance and low friction. The service life of the artificial implant is still restrained by tiny ultra-high molecular weight polyethylene (UHMWPE) debris, generated by the long-term friction between the artificial femoral head and the acetabular cup. It is well established that the cellular response to wear debris is dependent upon particle number, shape, size, surface area, and material chemistry, among other factors with smaller and more irregular particles causing the most damage. Therefore the wear simulation and prediction plays a significant role in longevity of metal on polyethylene based implant.

The multi fold gap in the wear result compared between simulator study and clinical results is basically attributed to the assumption of unidirectional sliding motion at the contacting surfaces in hip joint. Hence a review of the simulation studies with the prevalent multidirectional motion at the articulating contact at hip joint is presented along with a novel method is proposed for experimental testing of hip prosthesis material.

Ideally, each new orthopedic material should be characterized for evaluating its wear properties in a device intended to simulate the tribological conditions encountered in the human hip joint and so eliminate undesirable variation in materials properties that could affect the wear process. To characterize these specific materials, a wide variety of machines were developed. In the 1960s, the American Society for Lubrication Engineers listed more than 200 types of wear tests and equipment in use (Saikko, 2014). Recently, the use of multi-axial wear machines was implemented to give a better simulation of the type of motion found in vivo and to be of particular value in the study of biomaterials wear (Joyce, 2000)). Generally, two categories of laboratory wear test equipment are employed as Wear screening devices and wear simulators.

Wear screening devices are easy to manufacture and involves minimum infrastructural cost. It is a machine giving approximately fair wear results for the potential candidate materials. These machines are having advantage of multiple stations to obtain extraneous wear data simultaneously at multiple stations. The motion, load and lubrication can be simulated close to the accrual conditions at hip joint but the geometry of test specimen is in simple form like pins or ball and disc. The commonly available wear screening devices are pin on disc, ball on disc machines but with precise customization it is possible to modify these machines close to the operational and functional features required in the pertinent application.

1.4 Problem definition

Wear of polyethylene and consequent aseptic loosening reduces functional life of hip implant in metal on polyethylene material pair. Therefore there is need to study the complex wear process and estimate the wear parameters in actual hip application using retrieved prosthesis. The wear parameters leading to failure of joint dominantly depends on patient and hip specific activity level apart from surgical skills. Therefore there is a need to investigate the contemporary retrieved implant to understand and estimate reliable, authentic and real clinical wear parameters.

In preclinical investigation, laboratory testing of hip implant material is necessary to determine preliminary wear performance. It is found that there is a large difference in the wear parameters between the estimated clinical ones and predicted by using wear test machines in laboratory. This gap clearly indicates that clinical estimation of wear parameters is 2 to 3 orders on higher side than experimental wear results. Therefore there is a need to predict or estimate the experimental wear index employing more refined and real/close simulation tactics in wear test rigs. According to current literature, multidirectional motion and serum lubrication are essential to reproduce the clinical wear mechanisms. Hence there is a need to improve simulation in experimental wear test rigs in order to bridge the gap existing between the clinical and experimental wear parameter results.

1.5 Aims and objectives:

The study is aimed to analyze contemporary hip retrievals to investigate wear parameters and to develop wear screening devices using in situ simulation parameters for prediction of wear.

In order to carry out the research, following objectives are framed.

1. Perform ex-vivo investigations on retrieved Charnely (metal on polyethylene) cups to understand quantitative and qualitative aspect of wear.
2. Design simulation parameters for customized wear screening device incorporating multidirectional motion profiles which can give wear results at articulating surfaces of hip joint under biological lubricants.
3. Compare wear characterization parameters among various motion profiles in experimental study using designed and developed wear screening devices.
4. Validate the experimental wear characterization with ex-vivo retrieval results.
5. Recommend simulation parameters for wear screening device which can generate more accurate results on wear as compared with the ex-vivo results.

1.6 Organization of thesis

The essence of the thesis is described in a coherent way in different chapters as follows.

Chapter-1 deals with the basic problem of loosening of prosthesis, its reasons and importance of subject from societal angles. The major factor responsible for failure of artificial human hip joint is wear and is necessary to quantify it in natural joint as well as though simulated experimentation so as to deal with the issues hindering the longevity of metal on polyethylene hip implant.

Chapter-2 refers and assimilates the extant literature related to the work done and broadly covering the subject. The literature encompasses four major aspects of present study viz. review of materials used for hip prosthetic application, Retrieval investigations using contemporary methodologies, experimental investigation using laboratory wear test rigs and limitations in considered simulating parameters and output gained using contemporary test rigs.

Chapter-3 broadly outlines various methods and techniques used to investigate the patient specific retrieved Charnley acetabular cups. White light interferometer, non-contact technique and its utilization for gathering coordinate data of points on working surface of polyethylene cup in metal on polyethylene pair is accomplished. Using Wallson Bridge and Dowson method the clinical parameters are converted to experimental parameters to found out wear and using regression wear factor.

Chapter-4 apportions with the customization and wear testing of *pin-on-plate* wear test rig. The ASTM-F732 standards are followed as guideline. Using gravimetric wear measurement, experimental mass loss of polyethylene pins in contact with Co-Cr-Mo alloy metallic counterface and subsequent wear parameters like wear rate, wear factor are conceived for considered pairs of material. The wear characterization is shown using surface characterization and wears particle size analysis.

Chapter-5 reports with the advanced bio-tribometer customized, developed and capable of multidirectional motion simulation. Friction studies are conducted for 8 shaped and square shaped motion patterns to estimate aspect ratio, cross shear ratio and consequent effect of this motion on wear constant. Wear studies are separately conducted using eight motion patterns for UHMWPE/Co-Cr-Mo alloy material pair, according to guidelines ASTM-F732 to calculate mass loss and consequently wear parameters. The wear characterization is made possible using surface characterization and Somerfield plots are drawn to infer and conclude about the lubrication present.

Chapter-6 presents on comparison between the experimental wear studies with same material pairs and different multidirectional motion conducted on two wear screening devices, pin on plate and advanced bio-tribometer. The gaining points related to estimated wear factor and probable wear mechanism will be discussed. The wear parameters investigated in experimental studies are validated with the ex-vivo retrieval studies as bench mark. For Indian patient first time retrieval study is conducted and can established as a major bench mark for comparing he experimental results.

Chapter-7 presents summary, Critical findings, specific contributions, recommendations and future scope of work.

Chapter 2 Literature survey

2.1 Introduction

In 1960s Sir John Charnley pioneered total hip replacement using metal on Polytetra fluoroethylene material pairs. The refinement and alteration in material pairs continued thereafter based on the requirements. The wear resistant Ultra-high-Molecular weight polyethylene material after little success with polytetrafluoroethylene for acetabular cup was used by Charnley. The implant pair metal on polyethylene (Co-Cr-Mo alloy/UHMWPE) is called as gold pair of prosthesis in orthopedic community circles. The reasons are obvious and it is attributed to the easy manufacturing, adequate biocompatibility and required mechanical strength. The literature survey contextual to the work being accomplished is divided into following three sections: 1] Material Pair under Consideration, 2] Ex-Vivo retrieval study 3] Experimental Simulation and Wear Characterization. In experimental wear characterization, literature survey is conducted to cover all aspects of wear.

2.2 Division of literature survey

2.2.1 Material pair under consideration

There are wide number of material pairs being used for hip prosthetic application. Metal on polyethylene is the oldest and identified as low friction arthroplasty pioneered by Charnley (Collin, 1996). Isaac *et al*., (1985) has confirmed that bone cement is important agent behind the loosening of cemented charnely prosthesis. During eighties the lessening of Charnley joint used to be identified as cement disease. As polymeric debris formed due to wear interacts with body tissues, aseptic loosening occurs. These types of failures are referred in literature as poly-disease. Muller (1960) has adopted Charnely concept and brought two changes in the proposed hip prosthesis. He used counterface material as Co-Cr-Mo alloy and increased head diameter of cup to 32 mm. Liverpool *et al* (1990) and Clark *et al* (1997) reported higher wear rate in Muller prosthesis due to increased head diameter.

Weber, (1981) has first time introduced modular prosthesis giving more flexibility using metal on polymer and metal on metal combinations, metal being Co-Cr-Mo alloy and polyethylene is

UHMWPE material. As in metal on polymer pairs the osteolysis is the major factor loosening hip joint, alternative material search has begun.

Mckee-farrrar joint used a configuration of metal on metal and is generally called hard on hard bearing. The pair is made up of Co-Cr-Mo alloy metal. This prosthesis was largely used in sixties and seventies. The hard on hard pair of materials do have minimum wear rate and general functional life of 20 to 30 years. Later Walker and Gold (1971) concluded the loosening of joint because of equatorial binding. However Visuri (1991) has shown that aseptic loosening after 15 years of implantation does need revision in only 17% patients out of cohort of 511 implants

Boutin (1972) first time tried ceramic on ceramic pair of materials in hip prosthesis. Alumina and zirconia are the ceramic materials used for ceramic implants. Ceramic on polymer pair is introduced in 1975 in Germany and Switzerland. An interesting combination of ceramic femoral head and Co-Cr-Mo alloy acetabular cup is reported by Firkins (2000). Ceramic head polishes the metallic cups and very low wear rate is reported for this combination. Vitamin E blended UHMWPE is used to partially compensate for the side effects of irradiation dose used in cross linking. The stabilization of radiations due to cross linking is achieved using anti-oxidant vitamin E and it improves fatigue strength of material. The survey of materials used in hip implant is given according to time line in Table 2.1.

Table 2.1 **Material History and inception**

Material pair	Metal on ptfe	Metal on UHMWPE	Metal on metal	Ceramic on ceramic	Ceramic on metal	Metal on VitaminE XUHMWPE
Year of inception	1952	1963	1952-68	1971	1998	2011

As the considered pair of material in the current study is metal on polyethylene so the discussion hereafter will limit to that pair.

2.2.2 Foremost of Ex-vivo Retrieval study

Several researchers have attempted retrieval analysis in sixties and using the medical radiographic techniques estimated the wear rate for Charnely prosthesis. Among them Atkinson (1986), Dowson and Wroblesky have studied to explain the tendency or pattern of wear for group of retrieved prosthesis (Isaac, *et al*, 1986, Atkinson, *et all*, 1985, Dowson, *et al*., 1984). Investigations of volumetric wear and quantifying the wear depth distribution in retrieved implants have been extensively undertaken by researchers over the last two decades. It is required to identify the aggravating factors for wear and consequent failure of implant. Certainly these studies help in improving the functional life of implants (Buford, 2004).

Charnley cemented fixation is a gold standard in respect of pain free survival & high survival rate compared to uncemented joint (Berry, *et al*., 2002). The equal acceptability of cemented fixation to uncemented fixation is concluded by Clement due to reduced causes of for reoperation in general (Pakvis, *et al*, 2011). The problems like wear, osteolysis and migration are still existing and dominant affecting the survival rate of cemented fixation (Dong, 2014). Initially, it is assumed to be cement as a major factor contributing to osteolysis but there are other factors like wear particles, materials and geometry of implants do contribute in driving inflammatory reaction with the bone and body tissues leading to fixation loosening and subsequent osteolysis (Kumar, *et al*., 2014, Roberts, *et al*., 2014)

Atkinson (1986) has found that the wear depth is three times higher in failed implants as compared to normal working implants. Moreover, the role of cement in aggravating penetration rate is immense due to high wear; chances of impingement are more subsequently leading to more penetration in acetabular cup (Liu, 2013). Surface roughness of femoral head increases as submicronic cement particles abrade it and ultimately increasing the wear (Sawe, 1999). In a clinical study at Wrington hospital (UK) it is found that the penetration of ceramic femoral head in XLP IS 0.29 mm/year for first 8 years and then reduces to 0.022 mm/year (Wroblesky, 1995). Yamagishi (1997) has confirmed in retrieval studies that the multiple wear vectors found clearly indicate that the wear in acetabular cup is taking place in multiple directions and loosening of cup is not essentially the cause of mass wear in clinical investigations. Anneli (2008) has stressed the importance on detection of significant wear so as to address the aseptic loosening and osteolysis. Linear mean wear is assessed using CT scan & coordinate measuring machine (CMM) for metal backed acetabular cup and the difference is varied between 0.39 to 0.09 mm with mean linear wear equal to 0.15 mm. Anneli and Olivercana (2005) has also used CMM as a reference method along with gravimetric method for wear measurement in retrievals. It is assumed that the linear wear is not migration of head in cup but the change in position of cup with respect to cup center. Linear wear varied between 0 to 2.54 mm using CMM and the error between CT and CMM method is 0.12 mm (Bill. 2007). The wear vector angle varied between 85 to 127^{o}C. Anneli (2011) has emphasized on using 3D method for linear wear measurement as there is proven improved accuracy about 10 to 20 % (Martell, 2003a, Sochart *et al*., 1997). Also it is pronounced that the cups with a wear rate less than 0.01 mm/yrs can have a 90% survivorship after 25 years while none of the cups with wear rates above 0.2 mm/yrs. survive that long (Sochart, 1999). The effect of diametrical clearance between the articulating contacting pairs does not account in this study as it may be implied to be the displacement of head inside the polyethylene liner. The maximum depth of linear wear is calculated by fitting a theoretical sphere to unwarned region and the maximum radial distance between the data points on the surface of this sphere and the worn region is calculated (Anelli, 2008).

Smith and Unsworth (1999) combined the method of gravimetric and volumetric wear measurement on simulator using CMM for UHMWPE articulating against Co-Cr & zirconia femoral head and found that the linear wear for cups for both the femoral heads during the first pair of millions cycle is higher and further lowers down from 2 to 5 million cycles. Bills and Brown (1999) have combined gravimetric and geometric method using cmm for studying wear in prosthesis. The wear is higher for first two millions (~2 years) and then variably down to lower rate. Tuke (2010) has proposed an experimental method using roundness machine to measure linear wear in metal-metal implant and emphasized on the need of comparing unworn part of the trace with the worn one for getting required gap data points or wear depth. In the same study the artificial hip profiler is used for estimation of linear and volumetric wear and the depth of notch is and understanding about the wear scar is revealed more as compared to other methods used till date. Hu, (2011) used geometric method with a hypothesis that it is better than gravimetric method for wear measurement their by reducing systematic error in measurement. Roundness machine is used for measuring the geometry of metal–metal retrievals and the results are comparable having close precision in both the methods.

2.2.3 Experimental simulation and Wear Characterization

Experimental test rigs used for wear testing of hip implant material are broadly classified into two types as wear simulator and wear screening device. Wear simulator is a machine which will simulate operating parameters in situ at natural hip joint along with the geometry of prosthesis in complete respect. These machines are costly and test duration is long. The infrastructure cost required for fabrication of these machines is higher (Buford, 2004).

Wear screening devices are the most handy and simple equipment in design and development. The cost required is not much for the fabrication of this equipment. The testing is simple and quick and useful for primary screening the wear performance of material in shorter time. The geometry of test specimen is simple and other simulating parameters like lubricant, load can be customized by suitable changes in the conventional tribometer. The outline of literature survey in current study is limited to screening devices only.

2.2.4 Wear Characterization

1. **Contact pressure**

Saikko (2006) has conducted wear experiment on circularly translating pin on disc machine with metal on polyethylene material pair. The pin is of 9 mm diameter and disc is 40 mm diameter. The load is changed in such a way that various pressures can be applied at contact. It is observed that the wear factor is decreasing with rise in contact pressure. Coefficient of friction is initially increasing up to 2 Mpa and then suddenly drops down. It is recorded that the appropriate range of pressure for wear testing is up to 2 Mpa as clinical wear mechanism and wear is reproduced. In a pin on plate study by Vassilou (2004), it is observed that as contact pressure increases wear factor reduces. Also pin diameter (area) and load will not significantly affect wear factor.

Wang *et, al* (2003) investigated wear contact with different surface roughness. It is found that the contact pressure at asperity is much higher than the nominal contact pressure. Also the deformation is elastic in most of cases, with large roughness of counterface. If the deformation is in elstic-plastic regime then real contact area will increase and consequently asperity ratio too.

2. Cross linking dose

Laraia *et al.*, (2006) has attempted test on multidirectional pin on flat tester, with soak time of test specimen of 129 days. The UHMWPE pins absorbed the lubricant and shown to affect positively in improving wear resistance.

Williams *et al.,* (2007) have advocated for highly cross linked polyethylene. According to his observation the wear rate is inversely proportional to the dose of cross linking although some side effects like oxidation due to cross linking still persists.

3. Conventional motion

Liza (2013) conducted experiment on reciprocating tester for irradiated and unirrdiated specimen in dry and bovine calf serum. The transfer film to counterface in dry atmosphere is more adherent and continuous in case of highly cross linked pin compared with unirrdiated UHMWPE pin material. Under serum lubrication the thickness of transfer film is less as compared to dry conditions. Type of lubrication certainly affects the wear process of polymeric material. Roychowdury *et al., (2004)* conducted tests on pin on flat test rig following ASTM standards. Various pairs of materials including ceramic and UHMWPE as pin material and titanium, ceramic and Co-Cr-Mo as plate material are separately tested for wear ranking. It is found that stainless steel is producing more wear debris and Co-Cr-Mo / UHMWPE is efficient and performing pair of materials.

4. Variable kinematic motion simulation

Ortega-sanez *et al.*, (2007) have clearly specified the reason of existing multidirectional motion in hip joint. During THR, the ligament holding femoral head and cartilage of the acetabulum pelvic cup, LHF are often disrupted consequently leading to micro separation between head and acetabulum in acritical hip joint during walking. This micro-separation may be one of the reasons for elative multidirectional motion between femoral head and acetabular cup.

In a random pin on disc machine Saikko and Jar (2011) have conducted experiment in Adult bovine serum lubricant with static and dynamic load. It is found that for randomly generated wear track the wear factor is higher than the circularly translating motion and attributed to more number of changes in sliding during completion of cycle. The effect of dynamic load on wear factor is unimportant.

The maiden and different attempt of motion simulation was implemented by Joyce (2000). The conventional pin on plate machine is customized to have 2 stations, out of four with additional rotation component of motion. Remaining two stations exhibits the normal reciprocating motion. It is found that wear factor increases due to multiaxial motion simulation. The serum lubricant and Stainless Steel plate on UHMWPE material for testing is prevalent in this study.

Wang (2000) has proposed a theoretical model considering the factor cross linking, cross shear angel and interfacial friction effects. Wang proposed that UHMWPE is maintaining its strength in unidirectional motion but the motion against the primary direction of orientation i.e. cross direction weakens the material leading to less wear resistance and wear factor. The motion in cross direction is associated with the splitting of molecule and rise in friction.

Turell *et al*, (2003) have ventured for kinematic simulation with multiple rectangular shapes covering same distance per cycle. The wear tests are conducted on arthropod tester. The results follow the uniform wear theory proposed by Wang (2000) as wear factor for different geometric rectangular track differs. It is postulated that the cross shear effect is dominating or an important factor giving different wear factor although sliding distance in each wear track is same. It is ultimately shown that during GAIT cycle the trace of path covered by articulating contact is of ellipsoid or rectangular shape and hence the wear rate is strongly affected by the GAIT pattern of individual

Toyce (2007) has considered three pin materials as polyacetal, PTFE and UHMWPE against stainless steel in bovine serum for testing and ranking using multidirectional test rigs. UHMWPE ranked higher in case of wear resistance with wear factor equal to 1.1 x 10^{-6} mm^3/Nm as compared to 37 x 10^{-6} and 3.5 x 10^{-6} mm^3/Nm in case of PTFE and polyacetal material

Saikko (2011) postulated that the dynamic load is insignificant during the wear testing on screening devices. In the current state, multidirection motion and serum lubrication are the two ways to reproduce the clinical wear

Harsha and Joyce (2013) have conducted test on circular translating pin on disc (CTPOD) test rig and confirmed that irradiated specimen shows sufficient wear resistance by comparing with the virgin UHMWPE. It is estimated that for cross linked polyethylene shows 80% reduction in wear compared to virgin UHMWPE, Which matches with the clinical results.

5. New material pairs

Roy Chowdhury *et al.* (2004) have proposed HDPE polymer composites with reinforcement of Kevlar and carbon fibers. These composites are tested for mechanical and Tribological properties. The wear test is conducted on walk simulator and confirmed to be positively significant. Biocompatibility test is giving superior results over the parent HDPE.

Gonzalez-mora *et al*. (2011) have conducted wear test considering variety of Co-Cr-Mo counterface based on manufacturing process used like casting, forging and coated with ZrO2. It is observed that the maximum wear is found in case of coated Co-Cr and least wear is found in casted Co-Cr. The hardness of counterface affect positively and proved to be wear resistance since polyethylene wear gets increase with the scratches or pits on the counterface material.

Roy Chowdhury *et al*, (2007) have developed bio composites by selecting constituent hydorxipapatie, collagen and hyaluronic acid. These tests are conducted on pin on disc and walk simulator in the carboxymethyl cellulose lubricant. The bio composites with 10% hyaluronic acid show good mechanical tribological and acceptable biocompatibility and can be considered as potential material. Magdalena (2010) has empathized the effect of geometric surface conditions prior to testing. The surfaces of contact should be manufactured with state of art process with allowed or permissible values for surface roughnesses

6. Surface roughness

Turell *et al*, (2005) investigated the combination of parameters surface roughness and aspect ratio for considered rectangular wear paths. Two different plates with mild and rough texture are proposed in tests. It is found that maximum wear factor prevails in the conditions when the roughness and aspect ratio are higher.

7. Lubricant

Gispert *et al* (2006) have conducted the wear tests on rotating pin on disc test rig for different material pairs in different lubricant with or without protein content. It is shown that the coefficient of friction increases with time in non-reproducible way due to formation of transfer film on the metallic surface in the presence of lubricant not containing protein. In the presence of protein no transfer film is observed except in case of alumina disc and can be interpreted as more stability of adsorbed film on the metallic surface.

In order to find a cost effective, safe and reliable lubricant Martin *et al*. (2015) have chosen bio lubricant based on the mixture of sodium alginate and gellan gum for testing of material on multidirection test rig. The test result clearly indicates that the wear does not resemble clinical wear and wear factor are deviating a lot from the standard value. The transfer film is observed on the metallic surfaces indicating adhesion or third body wear in the presence of considered lubricant.

Synovial fluid is a natural lubricant having viscosity o.o1 Pa-s. Scholes and Unsworth (1999) have tested hip prosthesis material in different natural and synthetic lubricant. It is found that the coefficient of friction is lesser in bovine and synovial fluid that found in synthetic lubricant. Drawing stribecks curve for every lubricant and material pair it is found that mixed lubrication is present in metal on polyethylene contact pair. The failing friction factor plotted with Sommerfeld number diagonize the mixed fluid film lubrication.

8. Friction

The friction is never responsible for the failure of joint but the values do help us to predict the type of lubrication between the contacting pair. It will help us to design surface roughness optimum to be suitable for the predicted lubrication. Tuckart *et al*. (2014) when conducted wear test with a bunch of unirrdiated and irradiated polyethylene pins on pin on disc machine observed that the CoF for same normal load increases for irradiated specimen compared with unirrdiated specimen at 60^o. It is observed that irradiated polyethylene transfer is little as compared to the case in unirrdiated polyethylene material. The change in CoF between the contacting pair can be explained with little transfer of material and subsequently increase in contact area between the surfaces.

Baykal *et al*. (2010), according to ASTM standard, compared the friction and wear for highly cross linked polyethylene and UHMWPE doped with vitamin E, on multidirectional pin on disc tester. It is found that the wear resistance of highly cross linked polyethylene is more than vitamin E blended UHMWPE with Coefficient of friction found to be lower for blended compared with highly crosslinked polyethylene. It is also observed that there is decrease in roughness for pin and increase for disc after test completion. The micrograph shows more multidirectional scratching for highly cross linked and burnishing’s and protuberances for UHMWPE pin surface.

2.3 Literature gap

The literature gap is explained with the following points.

1. Ex-vivo retrieval analysis:- Bench mark or Validation
2. Wear tests on two indigenous wear screening devices
3. Multistation Test rigs.
4. Use of virgin and cross linked pair of materials

Effective simulation on experimental screening devices is possible when new facts and truths are utilized for it. Motion simulation is one of the important facets in hip screening devices. Lot of good work and experimentation was done and available in the literature and is reporting about qualitative ways to overcome the wear problem in metal-polyethylene pair.

Changing material pair was one option widely discussed and worked on. Hip simulators are developed for predictions of wear. But all these approaches are long term and need lot of time and money investment. There is a need of a test rig which could offer more realistic testing environment and test results in a limited time and reproduce the same wear process as it is observed in clinical arena.

Chapter 3 Ex-Vivo Investigation of Charnley Retrieved Prosthesis

3.1 Introduction

Total hip replacement is one of the most successful surgical methods to alleviate the pains in patient suffering from arthritis (Narinder kumar, *et al.*, 2014, Vernon-Roberts *et al*., 2014). Sir John Charnely has revolutionized the total hip replacement by introducing the principles low friction arthroplasty into practice. Needless to say, the success of THR process is measured in terms of longevity of implant, consequently functional life. Apart from Fixation techniques, the bearing surfaces of prosthesis are one of the most important factors determining the functional life of implant. It is clear from several studies (Unsworth, 2007) that these surfaces get damaged during articulation leading to particle wear debris of sacrificial material. It is important to study the worn out surface of hip prosthesis (In metal on polymer pair, polymer is the sacrificial material leading to particle debris) to understand wear process and estimate wear factors. Therefore Retrieval study is imminent and proposed on Explanted cups assisted with patient specific details

Objective of ex-vivo study is to analyze the gait pattern expressing dominant nature of wear track traced by articulating contact, considering the dominant activity of walking. For a bunch of twenty patients wear analysis is carried out on retrieved cups and as approximate path of sliding track i.e. relative motion between femoral head and acetabular cup retrieval is deduced through studies. The shape of sliding or wear track is useful in simulation of motion in experimental wear test rig. These possible patterns observed in the Indian subcontinent patient will help to understand the aggravating factors of wear. This retrieval study is found to be useful to understand the wear distribution and compute the volumetric wear for the sustained duration of functional life of an implant.

3.2 Material

Charnley has pioneered the work in the field of hip implantation in sixties. Charnley designs with gradual stepped up dimensions of prosthesis are being widely used pair for hip implantation. Cup of bore 22.1 mm diameter and complementing femoral head is the basic design and used mostly in seventies and eighties for implantation (Fig 3.1). The material pair used is Co-Cr-Mo alloy against Ultra high molecular weight polyethylene cup. The polyethylene cups are normally sterilized using a gamma irradiation dose up to 25kGY before packaging and disposal to destination location to avoid contamination (Charnley, 1961).

Fig. 3.1(a) unworn cup (b) Explanted low posterior wall Charnley cup

Cohort of 20 low friction arthroplasty cups is considered in this investigation (Table 3.1). Around 44% cups used are derived from female patients and 56% from male patients. Overall 44% explanted cups are taken from right leg and 56% from left leg. The median value of age at primary surgery is 61 (range = 51 to 67) years. The median for service life of implant is 14 (range = 4 to 27) years. All the cups are low posterior wall Charnley low friction arthroplasty cups having diameter 22.1 mm.

Table 3.1 Patient specific summary of low posterior wall Charnley cup

Sr.no	sex	side	Age at operation in (Years)	Implantation time (Years)	Weight (kg)
1	M	L	57	27	57
2	F	L	61	21	61
3	M	L	61	21	61
4	F	L	65	10	65
5	M	R	51	11	51
6	F	L	58	10	58
7	F	R	67	15	67
8	F	R	63	13	63

9	M	L	55	15	55
10	M	R	61	5	61
11	M	L	63	18	63
12	M	L	58	12	58
13	F	L	55	12	55
14	M	R	59	16	59
15	M	R	62	4	62
16	F	R	63	13	63
17	F	R	65	22	58
18	M	L	67	13	68
19	M	R	58	15	66
20	M	L	60	15	68

3.3 Methodology

White light interferometer is used to obtain wear data. The setup of white light interferometer is shown in Fig. 3.2. Using white light as a source (as shown in Fig 3.3) non-contact scanning is carried out for unworn and explanted cups for retrieval analysis. The white light interferometer used, is integrated with CCD-Camera and manual sensors approach with high precision axis. Twenty units of low posterior wall cups are analyzed for wear characterization. Unworn cup selected is identical to the explanted cup in respect of size and batch of manufacturing so that the basis of comparison on can be used in order to avoid uncertainties in the geometric measurements. Vertical scanning mode is used in order to get artifact free geometrical measurement. Appropriate tolerances zone is selected. The software Geomagic Designis interfaced with scanner and is purpose-built to create geometric model directly from scan data. Before scanning, the left and right side cups are marked for directions considering anototomical coordinate system in order to get uniform wear data. The unworn and retrieved acetabular cups are scanned independently and the point data is collected along with three dimensional coordinates of each points. Around $4x10^5$ to $6x10^5$ points are generated and processed to construct a geometric model using the integrated software with the white light interferometer to estimate the linear and volumetric wear of retrieved cups.

The point data obtained from unworn and retrieved cups is superimposed to determine linear wear, volumetric wear and specific wear pattern using Hypermesh. The specific wear pattern is further utilized to derive a probable wear track (relative motion between femoral head and cup) to analyze the probable wear track by considering the dominant walking activity.

Fig. 3.2 Set up of white light interferometer

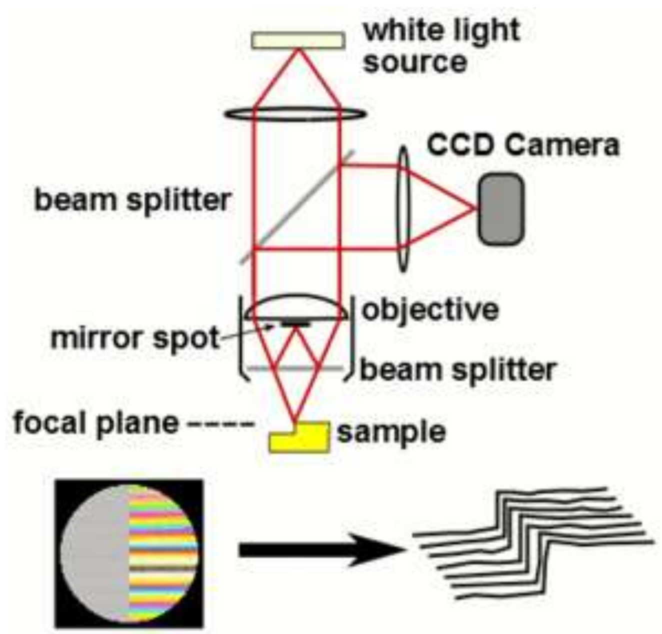


Fig. 3.3 Principle of white light interferometer

3.3.1 Assessment of linear wear

The linear wear varies in different regions of the acetabular cups when it articulates on the femoral head. As a result, the wear depth varies across the bearing surface of the acetabular cup. The wear depth distribution is a plot showing the different regions of the acetabular cup with each representing a specific range of linear wear or wear depth. Researchers have plotted wear depth distribution in different combination of bearing surfaces to evaluate the wear performance qualitatively. The retrieved cups are inspected for impingement mark, location of maximum linear wear and gender and implantation time. Wear scratches and impingement and flange for lpw cup is found to be more for cups having long implantation time. Wear rate is found out on the basis of maximum linear wear in cup.

The integrated software with the machine is capable to read all the point data along with its coordinate. It is also capable to create three dimensional CAD image from the collected geometric point data. All the 20 retrieved cups along with unworn cup are scanned to bring about the point data along with its coordinates. Bearing surface of right retrieved LPW cup required to be scanned is shown in Fig 3.4.

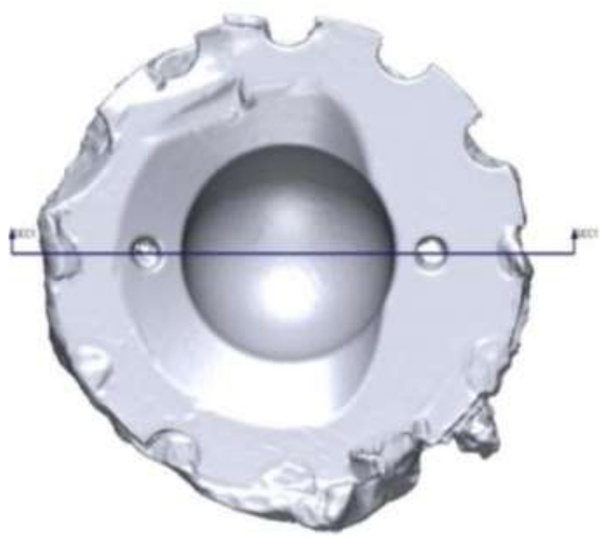


Fig. 3.4 Bearing surface for LPW retrieved cup

The superimposition of original and worn cup is facilitated considering appropriate tolerance zone and coordinate system for left and right implantation as shown in Fig 3.5.

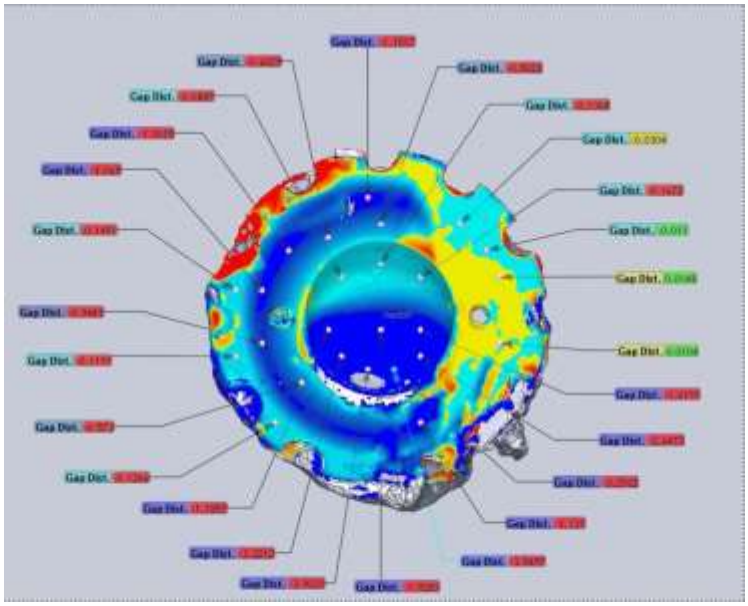


Fig. 3.5 Superimposition of identical unworn and worn cup

Altair Hypermesh version 11.0 has been used to handle the scanned points from scanning white light interferometer. The galaxy of points scanned is used to find the linear wear along the entire bearing surface of each of the retrieved acetabular cup using Hypermesh. Using Tcl command scripts incorporated in the Hypermesh tool, the shortest distance between each of the scanned points and the original point of unworn surface of the acetabular cup is computed as shown in Fig. 3.4 for individual cup. The shortest distance, being considered as a linear wear, is broadly divided into eight distinct divisions, each with a specific range of gap distance values as shown in Fig 3.6.

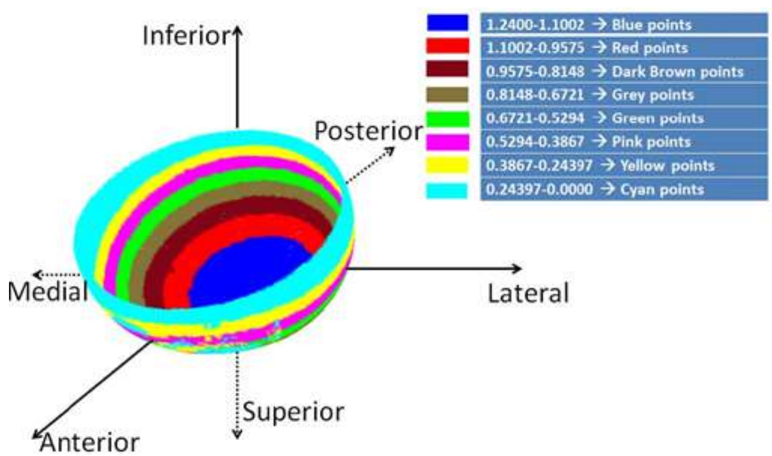
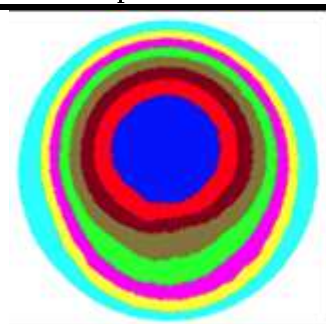
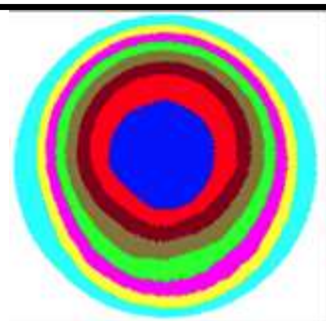
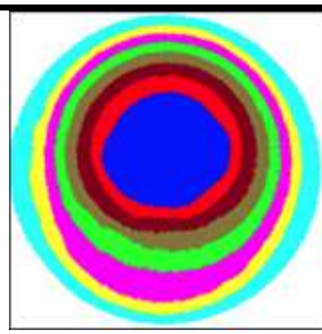
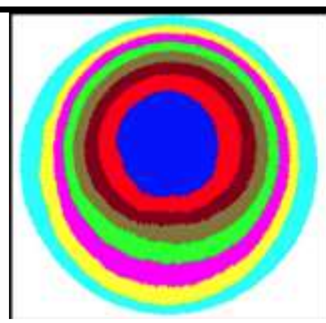


Fig. 3.6 Acetabular cup in anatomical coordinate system with gap distance ranges

Using spherical coordinate system, hemispherical acetabular cup is flattened. The linear wear values with subdivision range for few cups are shown in Table 3.2. The maximum linear wear is found to be at the center of cup and decreases as approaching to flange of cup.

Table 3.2 Wear depth distribution of few flattened cups

Patient no.	Wear depth distribution	Wear depth values
1		3.2400-3.2800 3.2000-3.2400 3.1600-3.2000 3.1200-3.1600 3.0800-3.1200 3.0400-3.0800 3.0000-3.0400 0.0000-3.0000
2		1.2640-1.2800 1.2520-1.2640 1.2400-1.2520 1.2280-1.2400 1.2160-1.2280 1.2040-1.2160 1.1920-1.2040 0.0000-1.1920
3		2.2000-2.2300 2.1800-2.2000 2.1600-2.1800 2.1400-2.1600 2.1200-2.1400 2.1000-2.1200 2.0800-2.1000 0.0000-2.0800
4		1.2400-1.1002 1.1002-0.9575 0.9575-0.8148 0.8148-0.6721 0.6721-0.5294 0.5294-0.3867 0.3867-0.2440 0.2440-0.0000

Anneli, (2008) developed CT scan method for linear wear measurement and estimated mean linear wear is 2.72 (minimum 0.4 mm to maximum 4.2 mm) mm. The mean wear vector angle is 106^o (minimum 57^o to maximum 144^o). The CT method claims to aid in possible detection of patients with increased risk of loosening. Uddin, (2014) for co-cr against XUHMWPE retrievals having implantation time varying between 3 to 10 yrs. calculated mean linear wear to be 0.068 (minimum0.05 to maximum 0.1 mm) mm..In white light studies the linear wear or wear rate are calculated on the basis of maximum wear. The mean linear wear is 1.85 (minimum 0.95 to maximum 4.1 mm) mm for the analyzed group of retrievals. Maximum linear wear is found at the center of cup and decreases away from center to outer periphery of cup.

3.3.2 Assessment of volumetric wear

Shinning 3-D scanner attached to white light source is utilized for scanning the bearing surface of acetabular cup in Charnley prosthesis. The scanned point positions or data points are used to get wear depth distribution for all the cups under investigation.

The volumetric wear of a retrieved cup is estimated by assessing volume contained between the imaginary flap assumed (Fig 3.7) and the working surface of cup for original as well as retrieved cup. The analysis is carried out with an accuracy of 99% and the required output is calculated in kg-mm units. The required mass properties estimated are volume, area, mass, weight and radius of gyration but the required one is volume. For the considered cups the volumes containment in retrieved as well as original cup is found out as follows

V_1- Volume entrapped in retrieved cup and assumed flap

V_2-Volume entrapped in original cup and assumed flap.

As the retrieved inner surface is worn out to some extent therefore the volume V_1 is larger than volume V_2. For the patient 1 considered in this study, volumetric wear is calculated as $\Delta_V = V_1 - V_2 = 4670 - 3825.3 = 844.7\ mn$. Similarly, the process is repeated for each retrieved cups to calculate volumetric wear pertaining to individual retrieved cup.

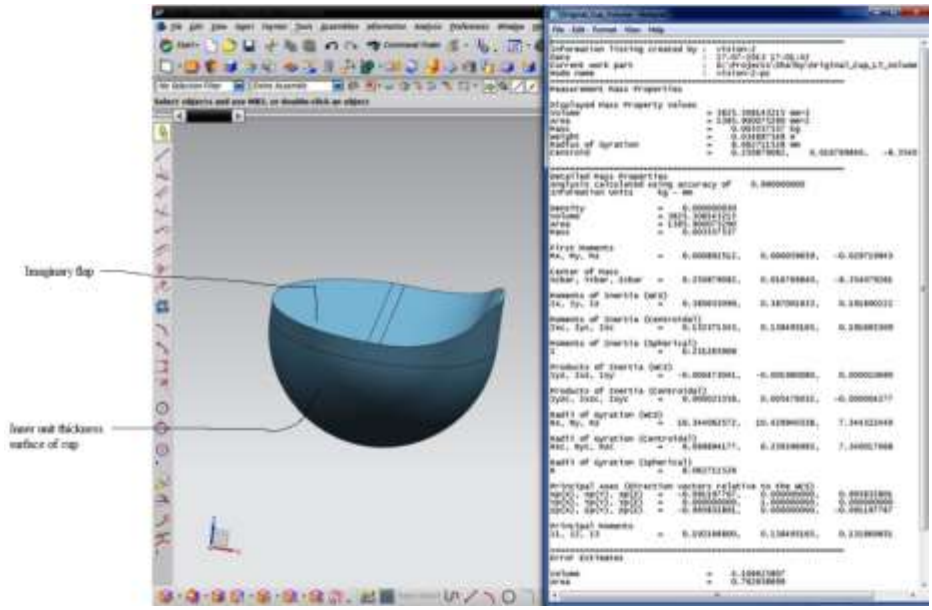


Fig. 3.7 Volume mearurment in cups using imaginary flap

In order to get the net wear it is proposed that unworn acetabular-cup model is used as reference in each case to find the volumetric wear spatially along inner surface of each of explanted cup. The net volumetric wear is the difference, which is easily computed by integrated software and the values are laid down in Table 3.3.

Table 3.3 Scanning output parameters for retrieved acetabular cup

Sr.no	Implantation time (Δ_t) Yrs.	Wear volume (Δ_v) mm^3	Maximum linear wear $(\Delta_x)_{max}$ mm	Minimum linear wear $(\Delta_x)_{min}$ mm
1	4	580.87	0.97	0.02
2	5	633.43	1.24	0.005
3	10	1395.48	0.97	0.02
4	10	1133.48	8	0.023
5	13	1288	1.33	0.004
6	11	968.96	0.95	0.004
7	12	1012	1.28	0.004
8	13	1140.46	0.99	0.003
9	13	1470	0.95	0.002
10	12	1320	2.23	.02
11	15	726.97	0.97	0.02
12	15	936	2.23	0.05
13	16	1832	1.24	0.023
14	22	900	1.77	0.004
15	18	755	3.28	0.004
16	15	1323	6.9	0.003
17	21	900	4.41	0.005
18	21	1288	4.914	0.02
19	22	1323	5.368	0.023
20	27	1300	6.75	0.004

The total volumetric wear is given by the Eq. (3.1) (Wroblewski, *et al*.., 1999, Galvin, 2010)

$$\Delta_v = \Delta_{wear} + \Delta_{creep} \tag{3.1}$$

The creep component is dominant only for the duration of first year of implantation. (Derbyshire, *et al*., 1994). In experimental results on simulator it is effective only for the first millions of cycles run (Derbyshire., *et.al*. 1994).

The estimation of creep component is useful to deduce the net effective wear component and its value is assumed to be 30 mm^3 as mentioned by (Dressler. *et. al*. 2014). In this study, the volumetric wear approximated by removing creep component from total wear (Eq 3.2).

$$\therefore \Delta_v \approx \Delta_{wear} \tag{3.2}$$

Wallbridge and Dowson (1986) has initially proposed converting the evaluated wear in ex-vivo with parameters (patient specific and active implant life) to a basic form comparable to in-vitro wear. The proposition is based on conclusive physical conditions of patient like age at primary surgery, weight of patient and geometrical dimensions of hip prosthesis and later expressed in the form of equations which are widely used to study and compare the in-vivo and in vitro wear results. The correlation between the clinical wear and experimental wear is significant to compare and validate the results. This comparison will estimate and compare the clinical wear between two methodologies and consequential interpretation about the effective simulation used in experimental test rigs. Wallson and bridge (Hall *et al*., 1997) has initiated concept and formulated equation expressing clinical wear involving patient specific parameters with sliding distance quotient term. Further, the same equation is being utilized by various researchers (Purcell, 2015, Sheafi, 2015) for comparing clinical and experimental results. The equation in linear & volumetric form useful for regression purpose is given by Eq. (3.3)

$$\Delta_x = m_{\Delta T} + C \;\; \& \;\; \Delta_v = m_{\Delta T} + C \tag{3.3}$$

Where in Δ& $\Delta$is linear& volumetric wear, Δ is implantation time and C is a factor accounting for creep. If creep is assumed to be negligible the factor $m = \Delta_x / \Delta$is the wear rate or penetration rate. By assuming creep to be negligible if $\Delta$is replaced by volumetric wear term Δ then the factor $m = \Delta_v / \Delta$ is the wear factor and can be expressed as (Atkinson, 1987) shown in Eq. (3.4)

$$K_{Clinical} = \Delta_v / \int_0^l L dx \tag{3.4}$$

Here $I = \int_0^l L dx = 2.376\, NM$ is the sliding distance parameter. Where l is the number of cycles and *L* is load. *N* is the number of cycles, *M* is the mass of patient, *g* gravity constant and *r* is the femoral head radius. The expression of *N* (Eq. 3.5) is very significant for clinical and experimental comparison as it is associated with several patient specific parameters to express the concern of age factor and activity level of any patient & is given by (Hall, 1996).

$$N = 0.5(A_r - A_p)[6.58 - 0.032(A_p + A_r)] \times 10^6 \quad (3.5)$$

Here A_p & A_r are ages of patients at primary & retrieval surgeries.

3.3.3 Ex-vivo wear factor

The wear factor is an index of severity of wear. It is calculated based on the equation given by Wall Bridge (1986) to express clinical data in terms of experimental parameters. In ex-vivo investigation it depends on several parameters fixation technique, activity level of patient and prominently on the surface roughness of femoral head. In cemented fixation it is found that the small particles of bone cement gets abraded with the femoral head surface increasing g its surface roughness. For the considered batch of implants the surface roughness of femoral head is measured before implantation and after retrieval. The clinical wear factor and its relation with surface roughness are widely discussed in the 3.4 (Results and discussion).

3.4 Results and discussions

The patient specific parameters are considered to calculate the sliding distance parameter as enumerated in Eq. (3.4). It refers to weight, age at primary surgery and activity level of patient to calculate the sliding distance parameter. The regression analysis is carried out considering weighing factor as inverse of square of predictor which is sliding factor in this case. The threshold value α is found to be 0.031 which is less than the assumed value of 0.05. The coefficient of determination (R-sq.) is 23.28% with an error of 2.8E-6.The plot of volumetric wear versus sliding distance parameter is shown in Fig. 3.8 and the wear factor is given by the slope of regression line and is 3E-6 mm^3/Nm with y intercept value 386 mm^3. The Pearson correlation factor between the volume and the sliding parameters is 0.466. The clinical wear factor is expressed in both the units as mm^3/cycle and mm^3/Nm and appropriately referred with the earlier studies.

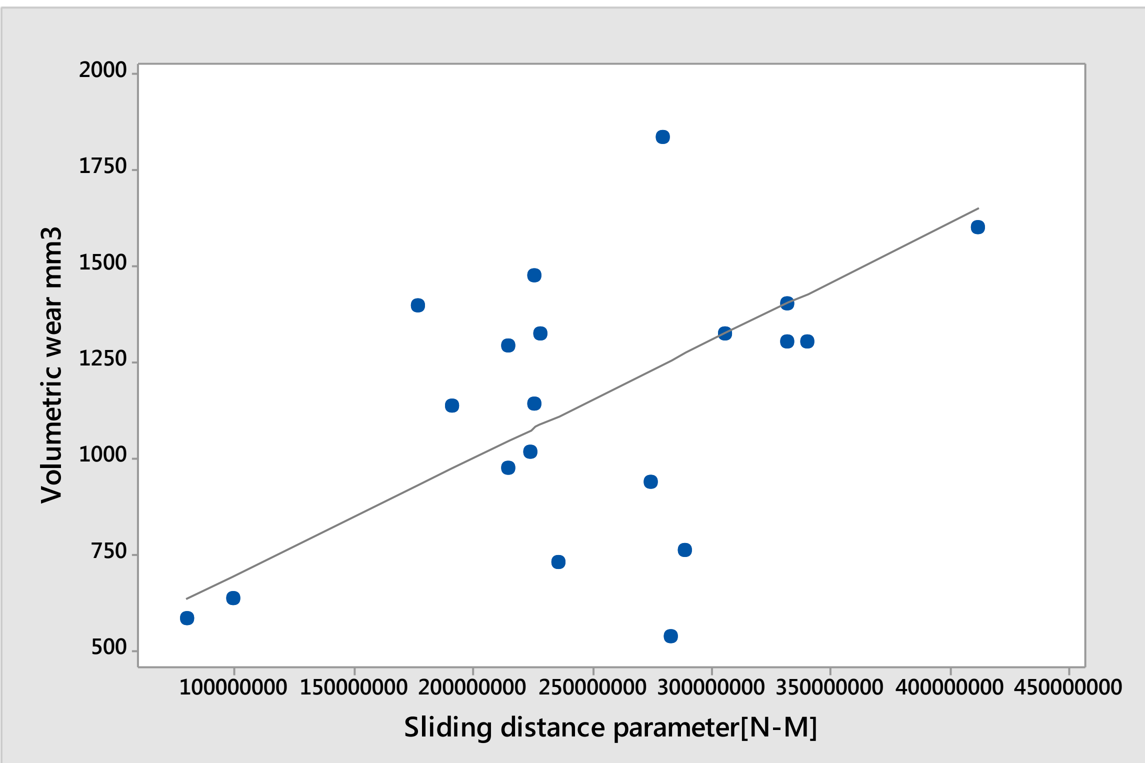


Fig. 3.8 Volumetric wear vs sliding distance parameter for explanted cup

The average number of cycles for the considered batch is 2×10^7 ranging from maximum 3×10^7 to minimum 5×10^6 cycles. Using the mean number of cycles, it is found that the clinical wear factor is $7.2 \times 10^{-5}\, mm^3/Cycles$. Weighted regression is carried out with limiting significant level, with $\alpha < 0.05$ and the wear rate is calculated to be $4.6 \times 10^{-5}\, mm^3/Cycles$. For the same material pair as used in charnely when the tests are carried out on simulator in the presence of bovine serum the wear rate is found to be $5.14\, mm^3/cycles$ (Smith and unsworth, 1995)

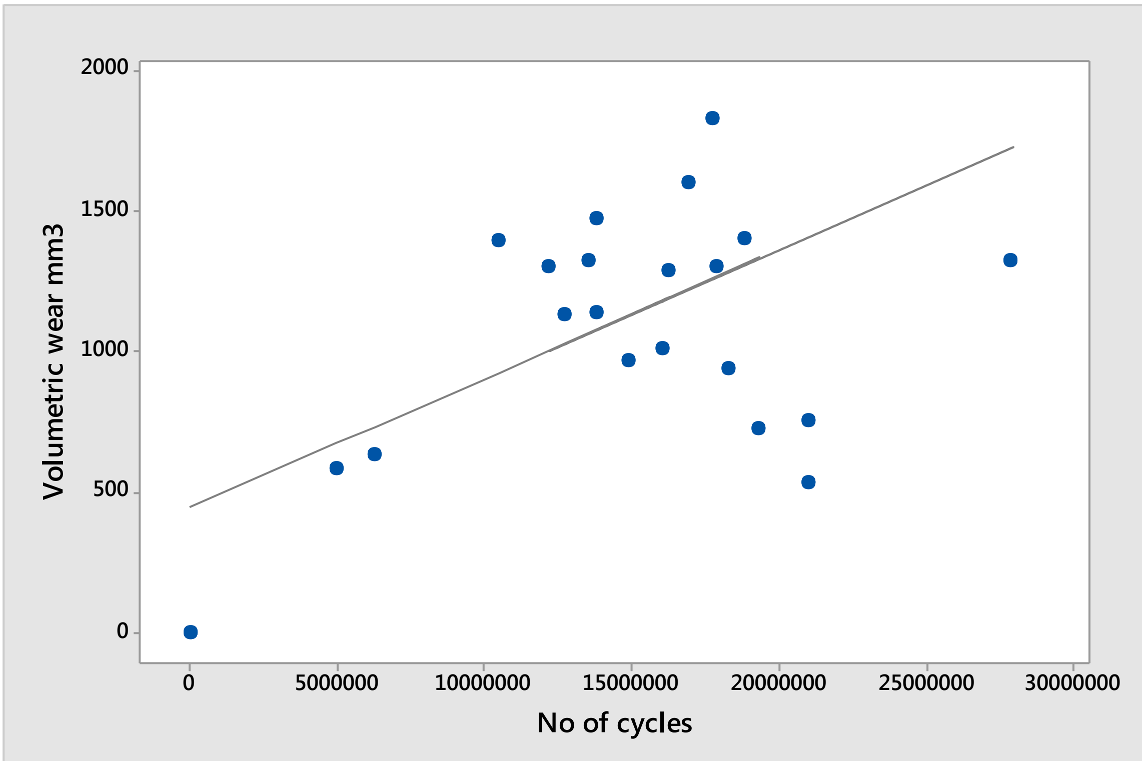


Fig. 3.9 Volumetric wear vs number of cycles undergone by the joint during service

The y intercept of regression line is 365 mm^3 which indicates that the creep factor is not nonzero and is having sufficient value to accept its existence in the wear measurement.

As wear is important factor for better functioning of biopolymer, the mean wear rate of earlier material used for implant that is PTFE is discussed here. The metal on PTEF shows a wear rate of 37×10^{-6} mm^3/N-m.The clinical wear factor value for UHMWPE material is estimated to be $3 \times 10^{-6} \frac{mm}{Nn}$in early studies of Charnley low friction athoplasty implant Hall, using regression estimated wear factor of $2.1 \times 10^{-6}\, mm^3/N$. (Martin *et al.*, 2015)

In similar studies for Charnley classic design, Atkinson estimated the wear factor equal to $2.9 \times 10^{-6} \frac{m}{N}$ (Atkinson *et al*., 1985). In a 100 station simulator Saikko (2005) has estimated wear factor to be equal to $1.19 \times 10^{-6} mm^3/N$. The increase in wear factor in this study is attributed to creep and wear due to bone cement.

The wear angle is defined as the angle between the vectors perpendicular to cup and the presence or location of maximum wear in retrieved cup as shown in Fig 3.10 (Jedenmalm, 2008). The angle of maximum wear estimated for the bunch of cups is ranging from 105^o to 127^o with mean value equal to 112.5^0 and is approximately in the close range with several studies consummated for charnely cups. In studied charnely cup, wear angle for one sample cup is shown in Fig 3.11.

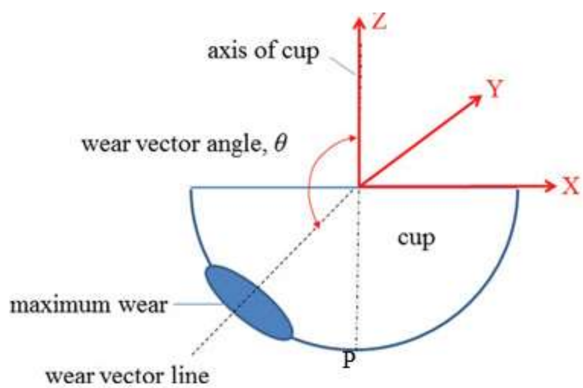


Fig. **3.10** Representation of wear angle on Acetabular cup

A large wear vector angle signifies the close location of maximum wear depth in the vicinity of pole of cup and small wear angle signing or expressing location of maximum wear away from pole and close to edge of cup. Uddin (2014) in his studies using Coordinate measuring machine for explanted cups estimated the wear angle to be 110^0 whereas Jedenmalm (2001) using CT technique estimated to be 105^0. Wear angle in retrieved cup is useful to locate the maximum concentration of wear and it is found to be anterior–posterior segment of cup in human coordinates system.

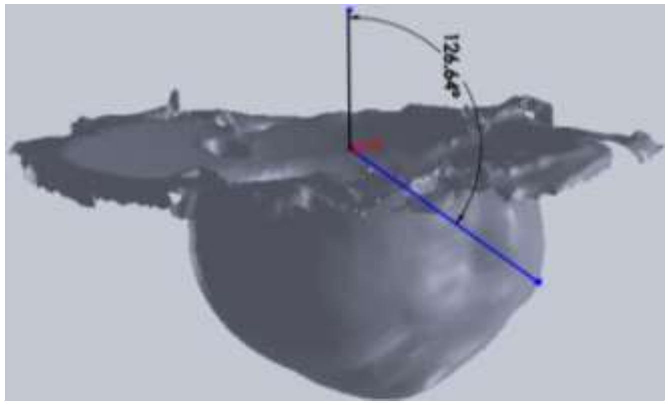


Fig. 3.11 Wear angle measurment on a scanned cup

The linear wear or penetration of femoral head in acetabular cup defines the wear advancement at the articulating contact in hip joint. It is the magnitude of maximum linear wear which has effect on the real estimation of volumetric wear in hip joint. There are two flows of thoughts about the direction of wear vector advancement. Charnley, (1979) reported wear advancement in cylindrical pathways and a single vector. However Motoi., *et al* (1997) has proposed the collegian of multidirectional vectors leading to aggravated wear in clinical conditions. In our studies mean linear wear rate is estimated to be 0.064 mm/yrs. with minimum 0.03 to maximum 0.8 mm/yrs. The linear penetration is higher in certain cups with more implantation time and is in the order of 3.8 mm. It is natural that for larger implantation time there are more chances of migration of femoral head leads to exist multidirectional wear vectors which consequently amount to maximum liner wear (Izquierdo and Avino, 1996, Ohlin *et al.*,1993, Motoi *et al.*, 1997).

Using weighted regression analysis with considered weightage factor equal to reciprocal of square of predictor, the linear wear rate is predicted with 95% confidence interval. The plot of linear wear versus implantation time is shown in Fig 3.12 and the wear rate is given by the slope of regression line and is 0.1438 mm/year.

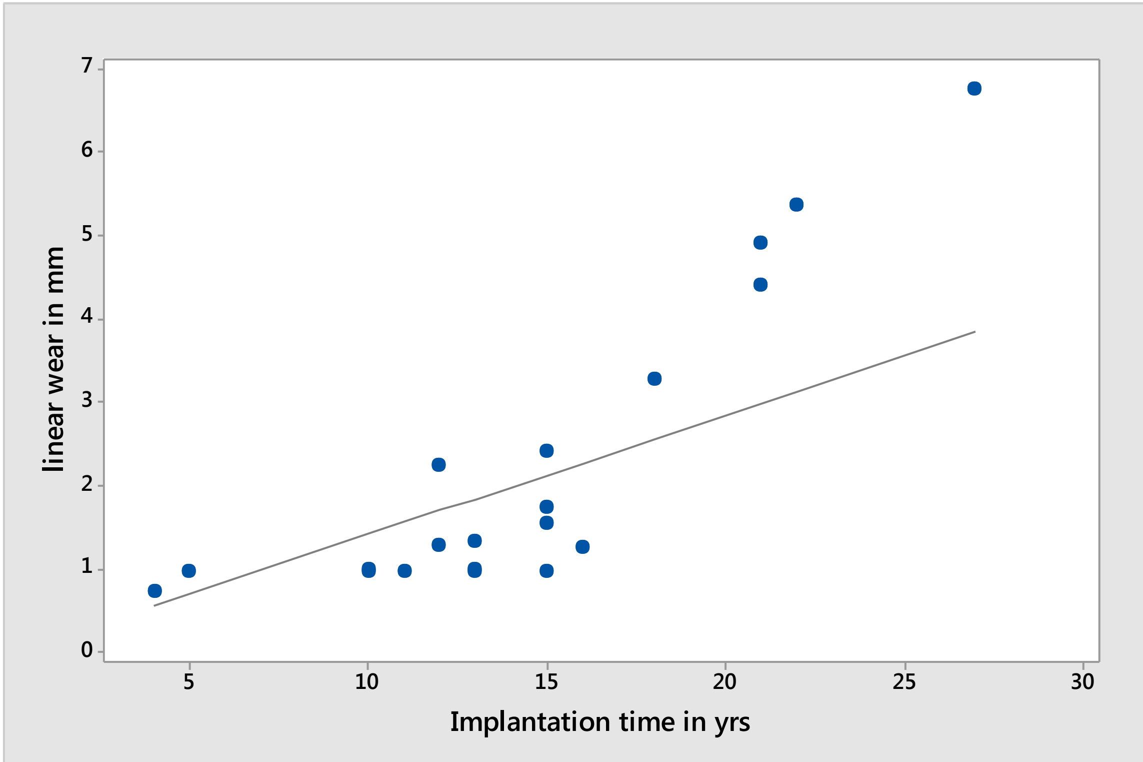


Fig. 3.12 Variation in linear wear with implantation time in yrs

The wear of implant is not only dependent on the implant time but is associated with type of patient, surgical techniques used and activity level of patient, which may affect wear rate significantly. Fig 3.13 shows the variation in linear wear rate with the functional life or survived life for polyethylene cup in body. The average linear wear rate is 0.14 mm/yr. for the considered prosthesis with 80% cups survived up to 20 years for linear wear less than 0.2mm/year. For conventional polyethylene in vivo wear rates are estimated by Sochart (1999) using CT technique and estimated linear wear rate range of 0.1 to 0.2 mm/year. It is intrigued that the acetabular cup having wear rate less than 0.1mm/yr. can survive more than 25 years with a prediction level of 90% (Sochart, 1999, Anneli *et al.*., 2011).

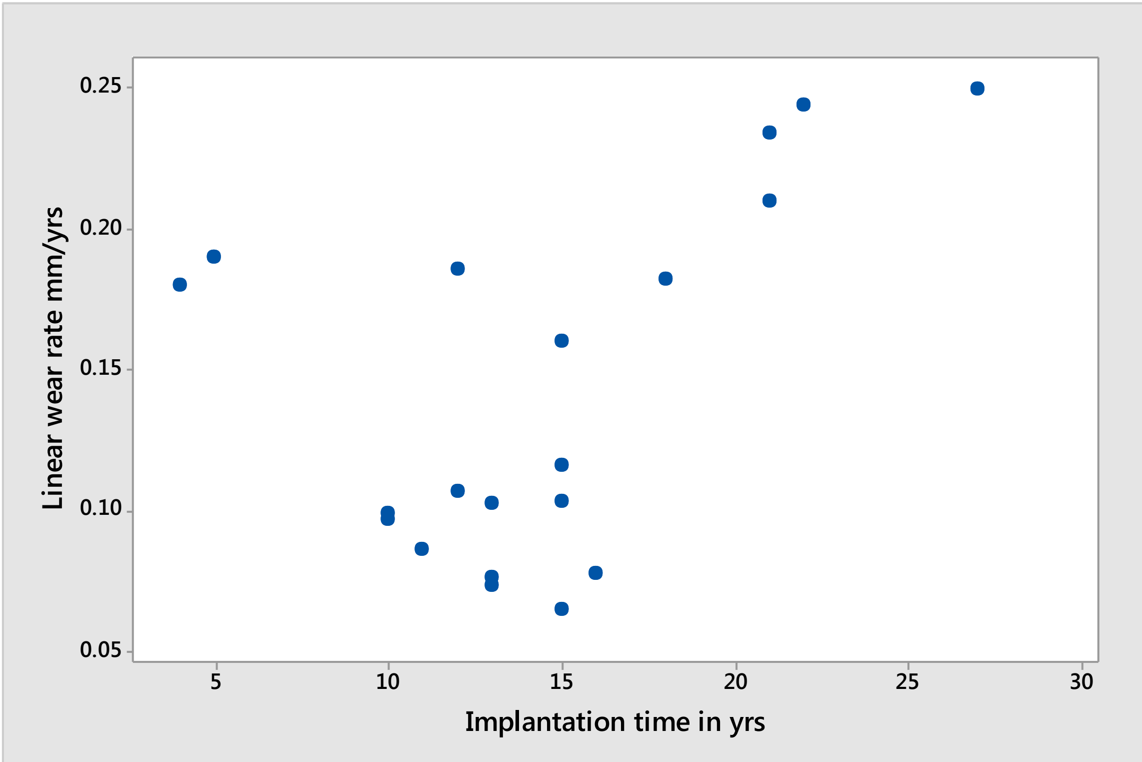


Fig. 3.13 Variation of linear wear rate with respect to implantation time

Chapter 4 Experimental investigation I:Pin on plate test rig

4.1 Introduction

Clinically it is found that wear is one of the important parameter constraining life of hip prosthesis. In order to understand wear, its nature and probability of new candidate material suitable for prosthesis application, experimental methods are appealing (Saikko, 2011). The experimental rigs useful in hip application are broadly classified into Simulators & wear screening devices. Simulators are complex in construction, costlier and needs longer time for testing as the specimens used are geometrically equivalent to actual prosthesis. Practically wear screening test rigs are simple to construct having less incurring cost and shorter time of testing and hence is a first choice in primary investigations of materials. In experimental investigation, two multistation wear screening devices are proposed with different motion profiles for characterizing wear. The concept of close simulation was proposed to Ducom Instruments Bangalore under two MOUs. Accordingly two separate machines were designed and developed as wear test rigs. These are 1] *Pin-on-Plate* test rig 2] *Advanced Tribometer*.

The laboratory wear tests are significant if wear results are to be compared with clinical results. It is categorically proved that motion and lubricant are two important parameters for close simulation of hip application in screening devices like pin on disc machine. The type of motion is multidirectional between articulating contacting surfaces and natural lubricant is synovial fluid (Dowson, 2000). Therefore two pin on disc configurations for wear testing of prosthetic hip material pair are designed considering motion and lubricant simulation parameters with constant contact pressure within physiological limit (2 to 10 Mpa) between the articulating contact of head and cup at hip joint Wear parameters of material found in screening device can be compared with the simulator and clinical wear results.

Several researchers have simulated multidirectional motion in screening devices and confirmed the similarity of wear mechanism as found in clinical investigation (Tower, *et, al*, 2007). The multidirectional motion is achieved through particular well defined wear tracks i.e. the travel of contact between pins and disc. According to uniform wear theory proposed by Wang, (2001) the wear resistance of material decreases when the polymeric pin slides in direction perpendicular to its primary direction of motion (Wang, 2001, Turell 2003). It is proposed to find the cross shear of polymer in such a typically simulated motions and then correlate it with wear parameters and clinical results. An attempt is made to achieve results close to clinical results and understand reasons of joint failure because of complex nature of wear in hip implants.

4.2 Standard for wear test

Out of available standards available for wear testing, ASTM F732-00 (2011) is most suitable for polymeric material using wear screening device (Joyce, 2007). This standard is especially suitable for testing and evaluating friction and wear properties of pair of materials that are being considered for use as bearing surfaces of human joint prosthesis.

The normal load of 127 N is applied and kept constant throughout the test. The frequency of sliding is 2 Hz and the sliding speed of contact is 1 m/s. Pin material is retained in contact with the central area of disc so as to facilitate trouble free fixation and smooth contact during running conditions. The contact pressure is 1.9 < 2 to 3 MPa and does not exceeds the critical pressure limit for hip application (Saikko, 2006). The temperature is maintained at room temperature as there is no consensus about the required limiting temperature during testing.

Test protocols like preparing and precharacterization of bio-specimen, operating parameters on wear test rig, cleaning, rinsing and drying of test specimen and gravimetric mass loss measurement are followed as per the ASTM F732-00 (2011). Finally the test results are compared with the ex-vivo (clinical) results. Both the screening devices are equipped with multistation and hence utilized for generating wear data for unirrdiated (UHMWPE) and variedly cross linked polyethylene (XUHMWPE).

4.3 Materials

4.3.1 Pin material

The UHMWPE pin specimen for this study is available with commercial name GUR1050 from Ticona, Oberhausen, Germany, fabricated into ram extruded rod stock of dimension 40 mm dia × 500 mm length. Later these test specimens are machined and purchased from ORTHOPLASTICS (Lancashire, UK). The medical grade poly extruded rods are machined by turning and milling process. Turning is carried out at 3000-5000 rpm with inserts usually used for aluminum. The milling is carried out at 6000 rpm on vertical milling machine to get the pin specimen of 18 mm diameter with length of 30 mm. To evaluate the sorption component of lubricant during testing control specimens of same dimension and material as test material are dipped in the lubricant outside the test chamber. The portion of test specimen and control specimen in the lubricant during test period is identical and same in order to get the accurate sorption component of lubrication during weight measurement. Control specimens are identically treated just like test specimen except they are not loaded. The properties of UHMWPE material are given in Table 3.1 and the drawing is shown in Fig 4.1.

Table 4.1 Properties of UHMWPE material

Density	Yield Strength	Tensile Strength	Charpy Impact strength
0.93 g/cm^3	17 MPa	720 MPa	210 kJ/m^2

Fig. 4.1 UHMWPE Specimen pin

The required number of pins are subjected to 50 and 75 kGY dose of gamma irradiation (Board of radiation and Isotope technology, Mu, India) and then heated to a temperature of 170^{o}C, well above its melting temperature of 138^{o}C in a convection oven to quench any free radicals and complete the crosslinking process. The resulting cross linked polyethylene pin samples (XUHMWPE) are maintained at this temperature for a period of 4 hours. The temperature was then decreased to 125^{o}C and the XUHMWPE pins were subjected to isothermal crystallization for a period of 48 hours and finally cooled to ambient temperature. In addition to cross linked pins, virgin or non-irradiated pins are also considered for testing purpose.

Cytotoxicity and sterilization with ethylene oxide is done and found in accordance with the consumer article regulation and (Bundersinstitut for Risikobewertung, 2006) BfR recommendations.

4.3.2 Disc material

The metal is a strong contender material to be counterface materials in total hip replacement (THR) prosthetic pair. The potential requirement of prosthesis materials is mechanical strength, corrosion resistance and biocompatibility along with less effective interaction with body tissues. Thermal mechanical processes are used for manufacturing the prosthesis materials. These processes are widely used with sufficient phase transformation and associated mechanical properties. The mechanical properties like deformation depends on the phase formed. The Co-Cr-Mo alloy chemical composition is noted down in Table 4.2 and the mechanical properties are laid down in Table 4.3 as follows.

Table 4.2 Chemical composition of Co-Cr-Mo alloy material

C	Si	Mn	P	S	Cr	Mo	Ni	Co	Ti	Fe	N
0.042	00.44	00.5	0.004	≪0.001	27.74	5.15	0.12	<65.2	0.005	0.5	00.18

Table 4.3 Mechanical properties of Co-Cr-Mo alloy

Material	YS (MPa)	UTS (MPa)	Ym (GPa)	Max elongation (%)
C0-Cr-Mo alloy	241 to 310	793 to 860	210 to 232	20 to 50

4.3.3 Lubricant

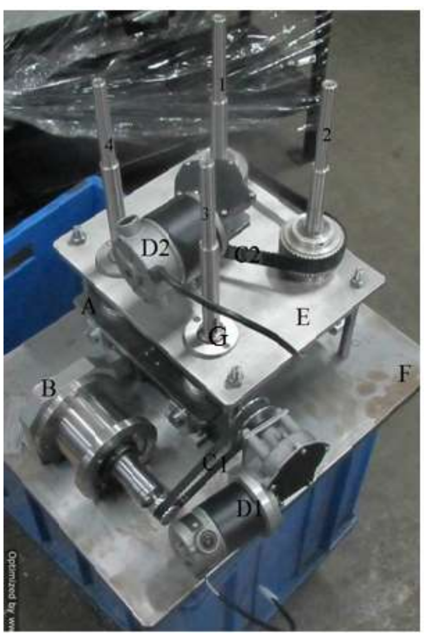
The lubricant preparation is aimed as described in ASTM F732: Standard test method for wear testing of polymeric test material in hip prosthesis. The lubricant is adult bovine serum (RM10907- High media) and is used with a protein concentration of 20 g/lit during tests. The lubricant fulfils the sterility, cytotoxicity tests and virus testing. The adult bovine serum is thawed using the mechanical shakers to bring it in homogenous and liquid state. Deionized water and thawed homogenous lubricant are mixed in 3:1 [volume fraction] proportion and sodium azide and EDTA is mixed to it to retard bacterial degradation and to bind calcium phosphate growth so as to avoid its traces on the bearing surfaces. The properties like viscosity and density are measured using Redwood viscometer and analytical balance. In order to consider the sorption component control specimens are used. The lubricant is prepared in such a way that 50 ml lubricant is sufficiently added to each of the station for test and control specimens. The position of control specimen is adjusted so that the same volume of pin is dipped in both the cases of test and control specimen. The replacement of lubricant is planned in each break of testing. Composition of viscosity and density of lubricant used is mentioned in Table 4.4. The protein content of the serum is also noted down in Table 4.4.

Table 4.4 Protein, albumin and globulin content for adult bovine serum

Total value	a-Globulin value	ß-Globulin value	Globulin value	Albumin value
7.2 g/dl	1.5 g/dl	1.1 g/dl	2 g/dl	2.6 g/dl

Design concept & certain important simulating parameters are proposed to Ducom Instrument Bangalore. The development of test rig is closely monitored and necessary suggestions are given to Ducom during the development process. The loading is mechanical one with contact pressure allowed less than 2 Mpa. Four sliding frequencies are possibly implemented and those are 0.5, 1, 1.5 & 2 Hz. This is made possible by using suitable servo motor and appropriate slider crank mechanism. The rotational speed is designed in such a way that it will cater the 56, 75, 90 & 120 rpm. The provision of few optional values of certain parameters like speed are designed for accelerated wear testing and does not limited up to hip in vivo conditions.

4.4 Pin on plate Test rig



F-Base plate
A-Lower plate
E-Top plate
D1&D2-Motors,imparting reciprocating and rotational motion
C1&C2-V gear belts
1,2,3&4-load carriage & pin guiding spindles
G-Bearings supporting spindle and inherent pin holder

Fig. 4.2 *Pin-on-plate* test rig

The *Pin-on-plate* rig is a four station pin on disc machine developed with basically reciprocating motion of lower plate as shown in Fig. 4.2. Additionally for station 1 & 2 the provision of imparting additional rotational motion is provided by installing motor D2 on the top plate. The mechanical dead weights are used as a means to load the contact and these are mounted on the top portion of stepped spindle. This measuring rig is capable to ration the amount of wear at each break during total intended run.

In the top plate four needle bearings are positioned to guide the spindle till the lower plate. Spindles can freely rotate in the bearings for stations 1&2 accessing the desired rotation al component of motion. The motor is connected to lower plate through crank slider mechanism and is equipped to facilitate four different frequencies as 0.5, 1, 1.5 & 2 Hz of reciprocation. The motor mounted on top plate is equipped to faceplate rotational frequencies from 1 to 2 Hz.

For lubrication purpose acrylic cylinder on each station is used. The disc specimen is fixed at the bottom of acrylic housing using O rings. It is useful to ensure leak proof unit. Four discs are screwed to the lower plate along with acrylic housing. The temperature sensors are positioned in housings to record the temperature of contact. The end of spindle is turned and machined in such a way that it acts as a pin holder. The tightening of the pins in holder is ensured with small screw opening at the end of spindle. The functional view and overall arrangement of electronic reading unit is shown in Fig. 4.3.

Fig. 4.3 *Pin-on-plate* test rig- Functional view

The electronic controls and the electric connections to and from the machine are securely built in read and monitoring box. It is equipped with numbering counter to measure the number of cycles and temperature counter to monitor the rise in temperature during test. Two separate knobs are provided; each one is facilitating the respective change in frequency of either reciprocating or rotation component. The machine is installed with an acrylic cover armed with two window opening to facilitate ventilation, to prevent dust and dirt during the experimentation.

4.4.1 Wear test

The tests on Pin on plate test rig are conducted keeping in view the required output results. The aim of developing this machine is to conduct wear tests for widely used implant material pair: Co-Cr-Mo alloy/XUHMWPE with modifications in the dose of cross linking.

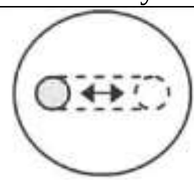
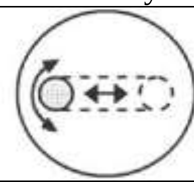
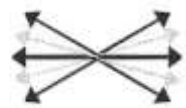
Total four stations are facilitated for simultaneous testing with same or different configuration pertinent to test materials, lubricant and loading to generate wear data generously in a stipulated duration of cycles. All four stations are reciprocating along with additional rotational motion imparted to two stations. The load application is manual and can be varied by changing the dead weight to be applied on the respective stations.

The station 3&4 are developed to run reciprocating motion. In reciprocating motion there is a change in path of polymeric pin after each cycle and the contact is continuous. In order to achieve motion simulation multidirectional motion (reciprocating + rotation) is simulated for station 1&2. The surface points in contact on pin/disc traces a multidirectional path with changing & crossing path by bearing surfaces. In this case the axis of rotation is changing constantly along with the reciprocating motion component and is a multiaxial configuration. The shear of polymeric pin is evident and the purpose of this study is to quantify the effect of additional rotational component on wear output parameters.

Table 4.5 summarizes key details of wear tests to be carried on four work stations, This table also shows that the tests are performed using polymeric pin s with virgin, 50 and 75 kGy grades of irradiation for 2 million cycles, each and for both the type of motions Reciprocating and Reciprocating and rotation.

Table 4.5 Summary of wear test method for multidirectional multistation measuring rig

Wear Specifics	Station 3&4	Station 1&2
Wear test method	Reciprocating PoD (R)	Multi-axial PoD (R+R)
Lubricant	Adult bovine serum	Adult bovine serum
Load and contact	127 N & 2 MPa	127 N & 2 MPa

pressure			
Material Pairs. Each one is tested for 2 million of cycles in R &R+R mode		Virgin UHMWPE pin on Co-Cr-Mo alloy disc	Virgin UHMWPE pin on Co-Cr-Mo alloy disc
		50 kGY XUHMWPE pin on Co-Cr-Mo alloy disc	50 kGY XUHMWPE pin on Co-Cr-Mo alloy disc
		75 kGY XUHMWPE pin on Co-Cr-Mo alloy disc	75 kGY XUHMWPE pin on Co-Cr-Mo alloy disc
Motion of bearing surface			
Relative motion of shear forces w.r.t. polymer surface			
Shear on polymeric pin	Cross path?	No	Yes
	Change path?	Yes	Yes
	Multi-directional ?	No	Yes
Bearing contact at discrete points on Polymer		Continuous	Continuous

The aim of the proposed testing for polymer/metal combination is to investigate the effect of simulated motion on the wear parameters of material pair under consideration. The planned simulation is an attempt to resemble the actual hip contact conditions using *pin-on-plate* test rig for comparing with the ex-vivo results. The results of test is primary investigation and according to ASTEM 732 code further elaborate wear tests can be taken on hip simulator.

4.4.2 Test Method

Wear tests are conducted on pin on plate Test rig incorporating R and R+R motions according to ASTM F732 Standard (ASTM F732, 2011). The replacement of lubricant is planned during testing as per then specified intervals in standards.

To evaluate the sorption component of lubricant during testing, control specimens are proposed, which are of same dimension and material as test material and are dipped in the lubricant outside the test chamber. The portion of test specimen and control specimen in the lubricant during test period is identical in order to get the accurate sorption component of lubrication during weight measurement. Control specimens are identically treated like test specimen except they are not loaded. The test and control specimens are cleaned and rinsed in deionized water before weight measurement. The ultrasonic cleaner is used to remove minute dust and additive particles adhered to test specimens. Each test specimen is kept or processed in ultrasonic cleaner for 20 minutes. After taking out of beaker specimens are wrapped in lint free tissue paper and cleaned. The test and control specimens are air dried in dust free environment as per ASTM F2025 (2006). The sliding distance per cycle is equal to 50 mm.

The initial weight of all the pins is taken using analytical balance having accuracy up to .01 mg. The pin specimens are held properly in the holder and lightly fastened with screw to avoid any loosening effect. The atmospheric temperature and humidity is recorded as 24^oC and 84 %.

As per the standard ASTM F732, four breaks during testing are taken at 0.05, 0.2, and 0.5 and at 1 millions of cycle. Overall the test is conducted for 2 million cycles and at each break the cleaning, drying and weight measurement protocol is followed. Three readings of weights are taken to obtain the closest mean reading.

After each run of 2 million of cycles for individual pair, the post tested lubricant is stored in the zipped bag in refrigerator. The disc and pin surfaces are cleaned and dried before proceeding to observe the morphology under SEM.

4.5 Results and discussion

4.5.1 Volumetric wear rate

The tests are carried out on *Pin-on-plate* test rig considering two separate motion components (R & R+R) and varied cross linked UHMWPE material in contact with Co-Cr-Mo alloy in adult bovine serum. The weighted regression is carried out for three material pairs under consideration with weightage factor equal to inverse of square of predictor i.e. millions of cycles. The statistical determinant considered is 0.05. In all weighted regressions the statistical factors, R_sq is 99% and above and $p<0.05$ are obtained. Fig 4.4 shows variation of volumetric wear with respect to millions of cycles of run and volumetric wear rate (mm^3/mc) is noted down along with figure.

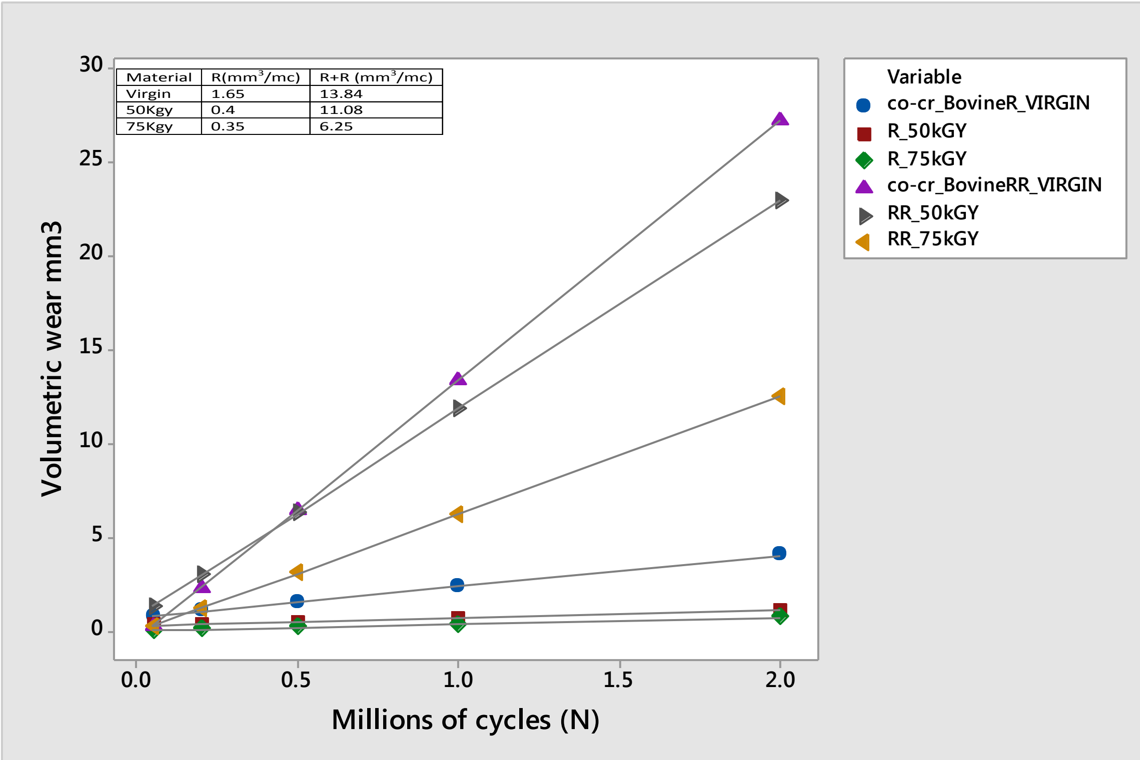


Fig. 4.4 Varation of volumetric wear with respect to number of cycles

The volumetric wear rate for virgin UHMWPE is observed to be higher in R+R motion mode than pure reciprocating motion (R). The volumetric wear rate per million cycles in general for both motion component tests is reducing as the dose of irradiation increases. The volumetric wear rate for virgin UHMWPE pin is found to be 1.65 mm^3/mc in R mode and 13.84 mm^3/mc in R+R motion mode with negligible y intercepts. Subsequently volumetric wear rate of 75 kGY pin is 0.745 and 12.52 mm^3/mc in R and R+R motion mode respectively.

Recently Harsha (2013) has conducted test on CTPOD and found out the wear rate 9.21mg/mc for UHMWPE and 2.06 mg/mc for cross linked UHMWPE. In our study 13.84 mg/mc & 6.25 mg/mc wear rates are established after test duration of 2 million cycles in R+R motion mode. The difference is attributed to the basic difference in circularly translating motion and adopted R+R motion in this study and test of durations. Another reason may be the errors in measuring sorption component of control specimens and length of duration of test.

4.5.2 Wear factor

The wear factor or wear coefficient must be determined under conditions similar to those to which the test specimens are subjected, since it depends on critical factors such as stress, speed, temperature, surface roughness (Saikko, 2014). The wear factor k is defined according to Eq. (4.4).

$$k = \frac{V}{PX}\left(\frac{\text{mm}^3}{\text{Nm}}\right) \tag{4.4}$$

Where; V volumetric wear in mm^3, P is load(N) and X is sliding distance in m

The weighted regression is carried out between the volumetric wear versus sliding distance in reciprocating mode of motion as shown in Fig 4.5.

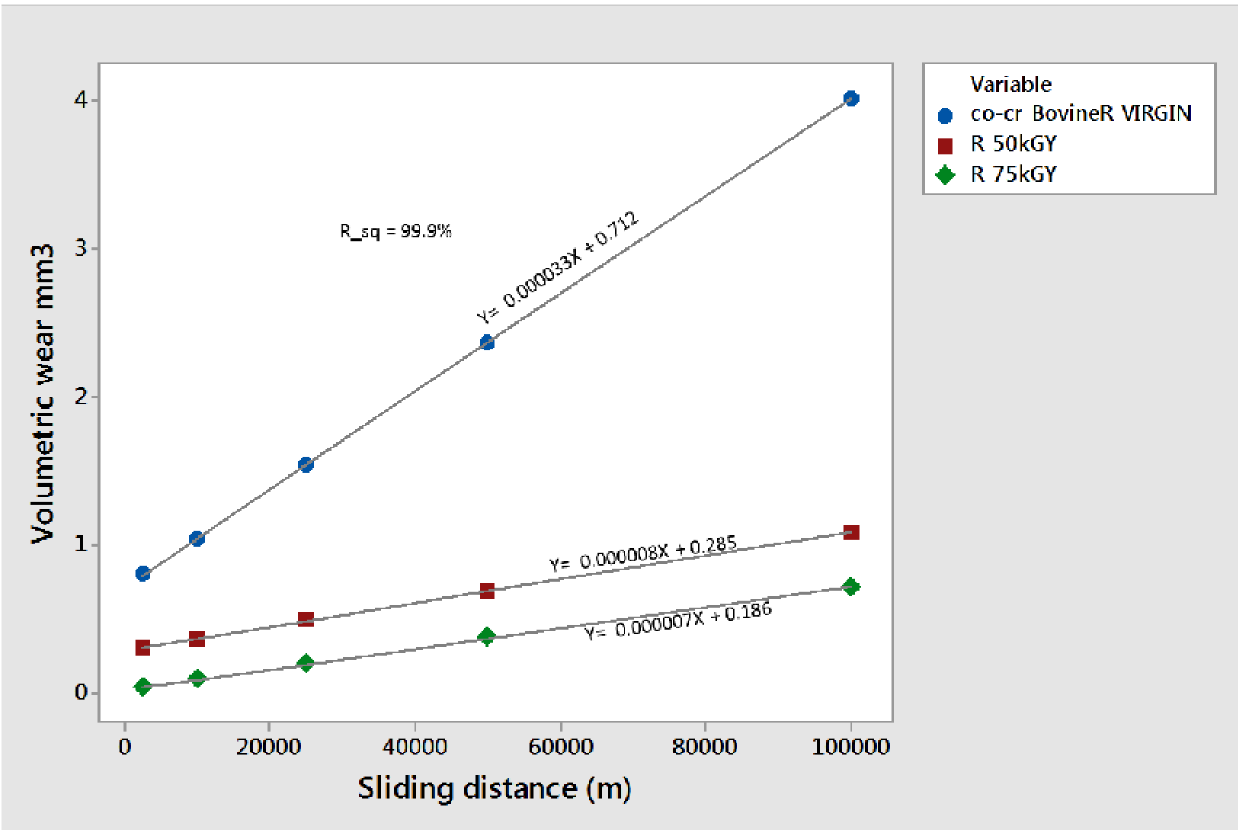


Fig. 4.5 Volumetric wear versus sliding distance in reciprocating motion

It is observed that the wear rate for virgin polyethylene pin is one order higher than in case of 50 kGY & 75 kGY pins. The regression equations are estimated with R_sq value of 99.98%.

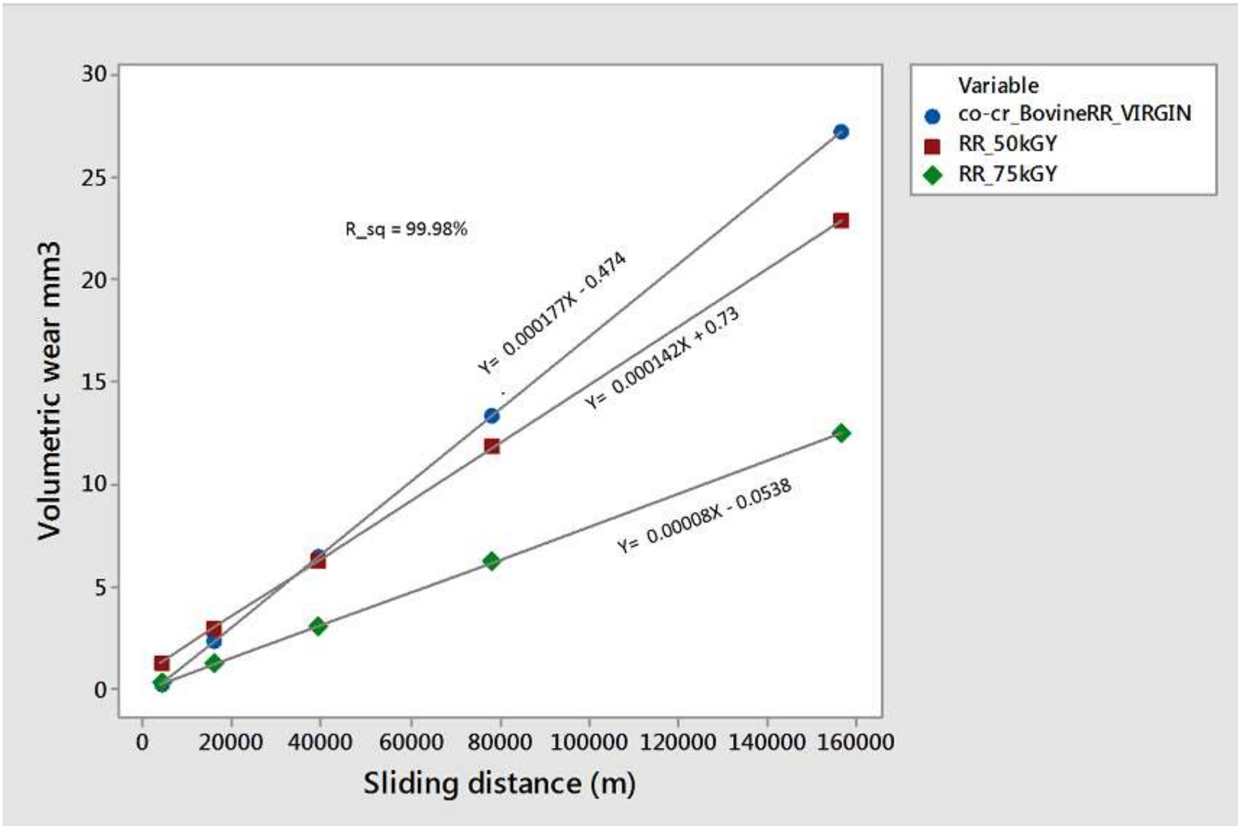


Fig. 4.6 Volumetric wear versus sliding distance in reciprocating plus rotational motion

It is found that the for same number of cycles of running, In R+R motion mode the sliding distance is higher as compared to R mode. It is computed by considering the diameter of pin and rotational speed. The wear rate (mm^3/m) for 75 kGY pin is one order less than the virgin and 50 kGY pin materials.

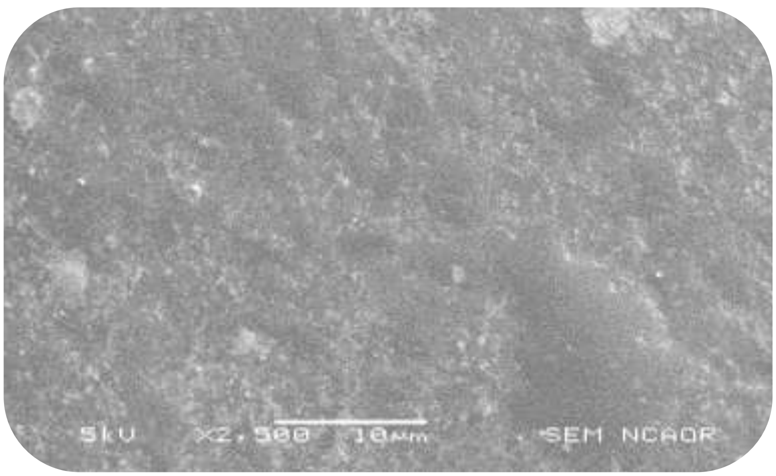
In a similar multidirectional pin on plate rig result conducted by Joyce (2001), the wear factor value for stainless steel/UHMWPE is recorded as 0.085×10^{-6} mm^3/Nm. The value estimated for Co-Cr-Mo/UHMWPE pair in this study is 0.25×10^{-6} mm^3/Nm. The higher value of wear is attributed to the operating conditional parameters like load and surface finish of test specimen and counterface material. It was shown by Roychowdhury (2004) that among the counterface materials wearing against UHMWPE, Co-Cr alloy as a counterface generate less amount of wear debris and proving to be superior in performance than stainless steel. The values of wear amount clearly show that the wear resistance is effectively increased for XUHMWPE and estimates 76% reduction in wear factor and accord to the studies on variably cross linked UHMWPE by Liza (2013).

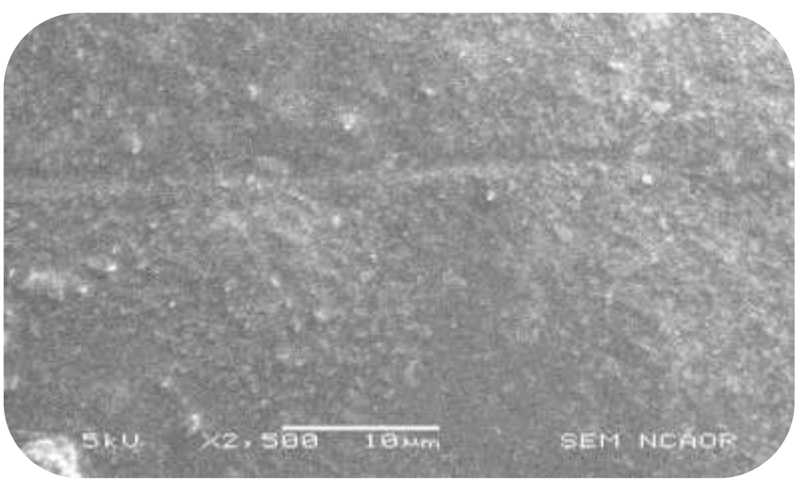
With same material, load and contact area, Turell (2005) has found out 11.6 & 8.9 mg/mc wear rate for square wear track while in this study, wear rate of 13 mg/mc for UHMWPE & 10.41, 5.87 mg/mc for cross linked pins with dose of 50 kGY & 75 kGY is established. Muratoglu (2003) has confirmed, $1 \times 10^{-6} \frac{mm^3}{Nm}$,wear factor for the same cross linked polyethylene material as considered in this study. Saikko (2005) has concluded using CTPOD, wear factor equal to $1.63 \times 10^{-6} \frac{mm^3}{Nm}$ for cross linked pins with circularly translating motion simulation. In this study, the mean wear factor for UHMWPE in R+R motion mode is quite similar to or in the range with the comparable studies simulating different wear paths and is $1.388 \times 10^{-6} \frac{mm^3}{Nm}$ & $1.11 \times 10^{-6} \frac{mm^3}{Nm}$ for UHMWPE & XUHMWPE materials. Although Joyce (2001) found wear factor equal to $1.1 \times 10^{-6} \frac{mm^3}{Nm}$ for XUHMWPE in R+R mode motion, it is based on the stainless steel counterpart material. Therefore naturally the estimated wear factor in this study for Co-Cr-Mo alloy as a counterpart is justified and appropriate since steel counterpart is inefficient in controlling wear of UHMWPE.

4.5.3 Surface characterization

The tests which are conducted on *pin-on-plate* test rig for considered pair of material are incomplete without understanding the wear mechanism and nature of wear occurring in contact. The pin is incessantly dipped in lubricant during test duration.

In surface characterization, it is evident that the nature of wearied out surfaces and its observations are mandatory to analyze the nature of wear. In case of *pin-on-plate* test rig micrographs are taken for both pin (Fig. 4.7) and metallic disc (Fig. 4.8) surfaces using scanning electron microscope. The zooming level is controlled so as to get the finer details of the surface interaction during the test occurrence. The surface of pin is neatly protected in order to avoid any damage or additions during handling. All the bio-specimens are neatly held during the man-handling from station to lab using the gloves to minimize the damage to the wearied surfaces.





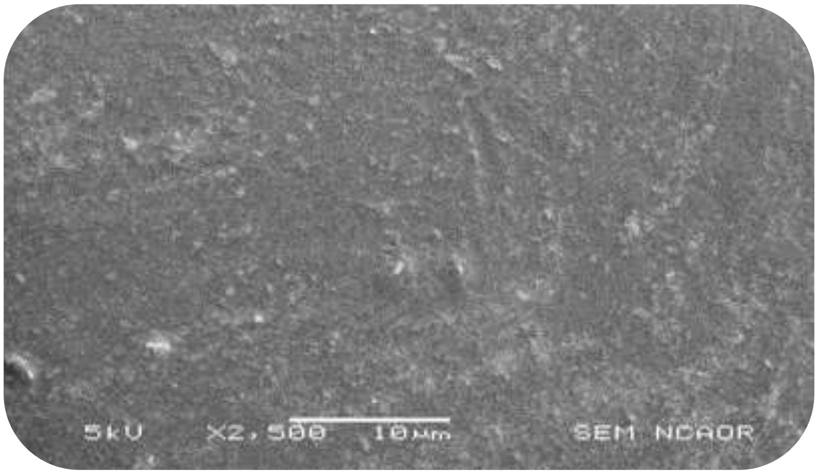
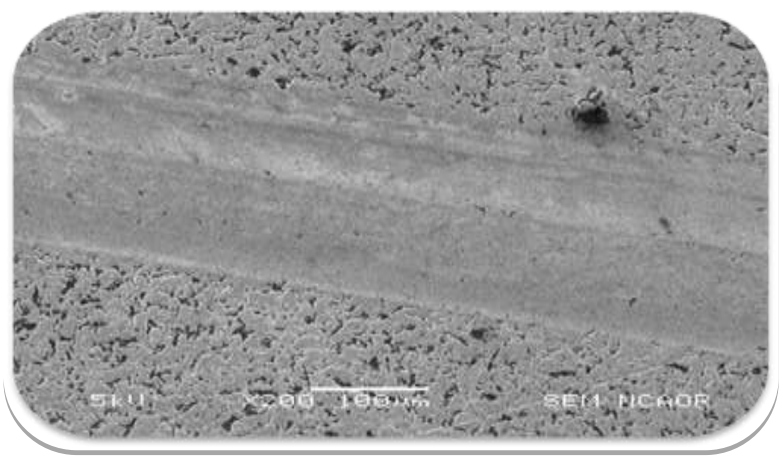


Fig. 4.7 Pin surface micrgraph in reciprocating plus roational mode on *pin-on-plate* test rig

The micrographs for UHMWPE pin material with varied cross linking after completing stipulated duration of 2 million cycles is shown in Fig. 4.6 (a,b & c). The pin surface is clearly indicating that after run the surfaces of pins are polished and led to loosening of vipers or throngs in the form of displacement of macromolecules. The plastic deformations evident and adhesion wear can be confirmed by monitoring the metallic counter face. Partly the wear process seems to be abrasion in the initial phase of run and then over the period of time minor junctions are formed leading to adhesion of polymer to metallic surface. The micrographs for metallic surfaces are shown in Fig.4.8.



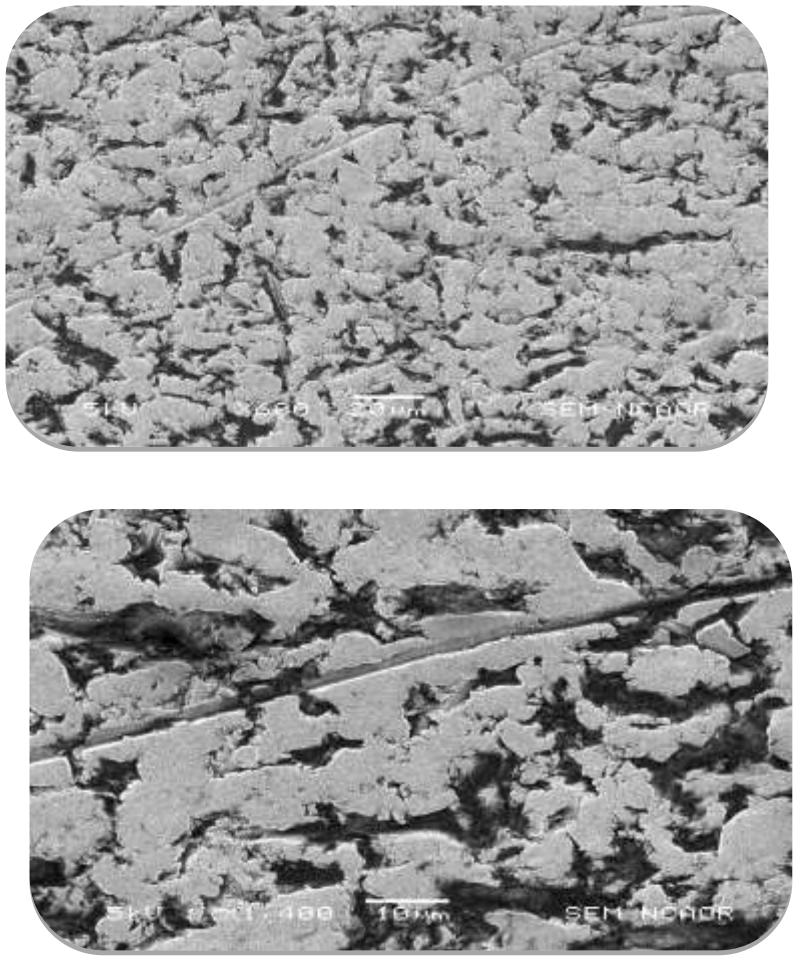
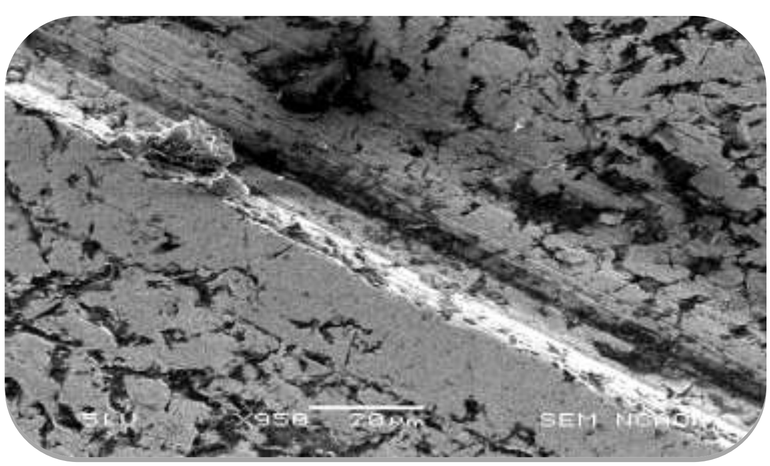


Fig. 4.8 Metallic surface micrograph in reciprocating plus rotational mode on *pin-on-plate* test rig

There is a clear-cut trace that can be observed due to reciprocating plus rotational motion of pin on disc in fig a. small amount of debris and roots or traces can be seen on the surface of disc material. At maximum magnification it is observed that the disc surface does show few pints and minute sliding wear mark on the surface of disc.



In Pin on plate test rig the mode of reciprocation is specifically used for two stations. Both the motion of reciprocation and reciprocation plus rotation is simultaneously carried out on for different stations. The micrograph for reciprocated part of materials is shown below.

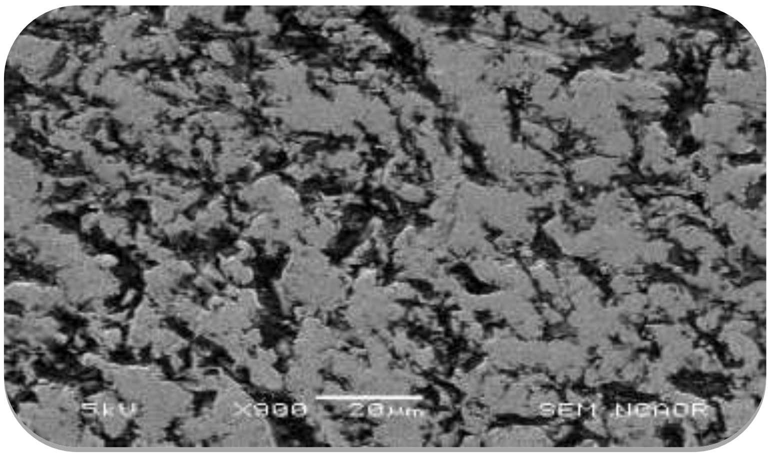


Fig. 4.9 Metallic surface micrograph in reciprocation mode on *pin-on-plate* test rig

The disc surface in micrograph clearly indicates the reciprocating mark created by contact. In fig a. whereas the small to large debris transfer to hard counterface is evident from the adjoin location of track. As the motion is unidirectional the wear is constrained by the orientations of polymer molecules in principal motion direction.

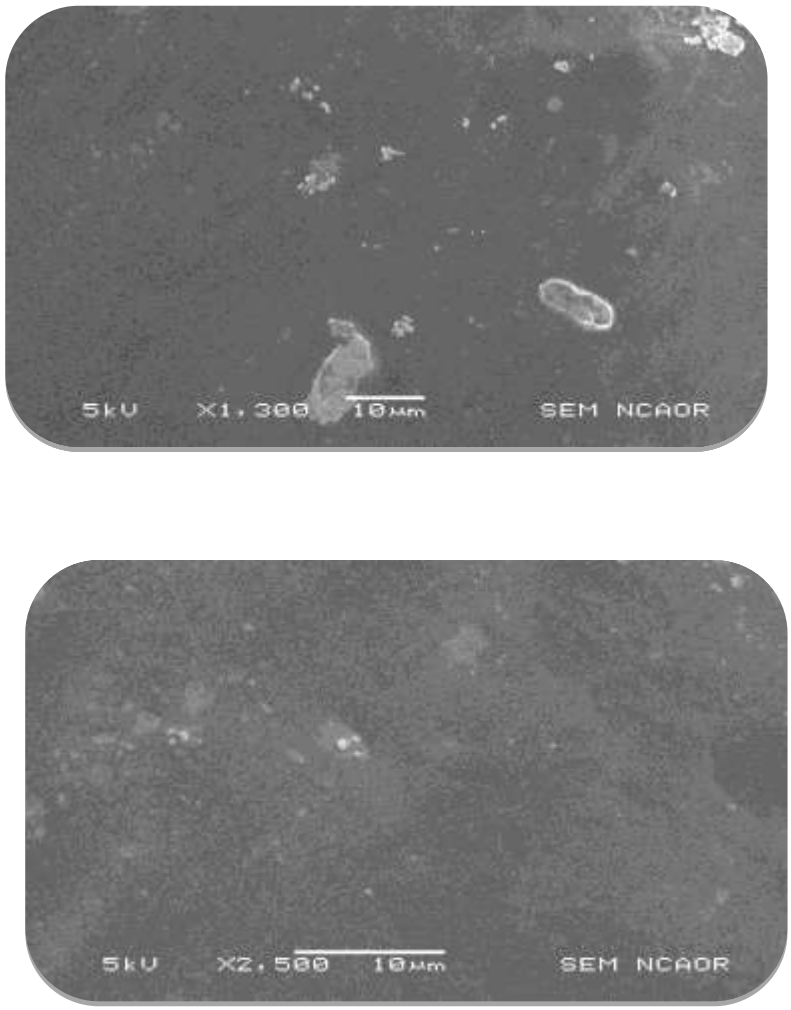


Fig. 4.10 Pin surface micrograph in reciprocating mode on *pin-on-plate* test rig

Chapter 5 Experimental Investigation II: Advanced Biotribometer

5.1 Introduction

The laboratory wear tests are significant if the wear results are comparable to clinical results. Similarly the simulation required in wear rigs should have two classical emphasized parameters like multidirectional motion and serum lubrication (Saikko, 2011). It is observed that in wear screening devices like PoD, stationary load is sufficient and dynamic load does not make any significant difference in getting the desired wear output (Saikko, 2003, 2011).

For hip joint application it is proved that the motion is multidirectional. So variety of attempts by several researchers are carried out during experimental simulation for different motion approximating peculiar multidirectional tracks (Korduba, 2012, Dressler, 2011, Oral, 2010, Saikko, 2014). It is really interesting to find the cross shear of polymer in such a typically simulated motions and then correlate with the output wear parameters as well as clinical results. It is another attempt of experimental simulation to attain comparable closer wear result to clinical results and to understand the wear mechanism failing hip implants.

5.2 Material and methods

The Advanced Tribometer is a six station pin on disc testing unit (Fig 5.1) with three degree of freedom to measure frictional force on 6 stations. The machine is designed to apply load in a range from 0.003 to 3 kN on each station with pin as specimen and with simultaneous linear movement by disc specimen along X & Y axis to generate path of travel in the form of any predetermined profile. This machine facilitates study of friction and wear under sliding either with no-fluid (dry condition) or with fluid at ambient temperature. The machine is interfaced with Winducom 2011 software to control the operating parameters.

Fig. 5.1 *Advanced Biotribometer*

The load, the X-Y linear movement (pre-defined profiles) speed, are pre-set for operation and frictional force along X &Y axis are continuously measured by sensors and values are displayed on software screen. The environment temperature is measured by a portable temperature indicator. As shown in Fig 5.2, all six stations assemblies for clamping specimen pin & applying normal load are mounted on a top plate. The top plate is loosely held on 4 pillars. Four numbers of holes on top plate guiding the pillars have 1 mm diametrical clearance. A step on pillars prevents top plate moving downward and boss on pillar prevents moving upwards. Above the top plate six loading units are mounted vertically on each station.

The housing of each loading unit is guided & locked on top plate, with only the square tube moving down ward on activation of hydraulic cylinder, the square portion is guided inside the bearing flange fitted into housing (as shown in Fig. 5.3). The square tube is connected at the top to hydraulic piston and at bottom a specimen holder is tightened to clamp pin specimen. A flat portion is made on the cylindrical portion on specimen pin to locate & for positive gripping; the specimen is easily changed by unscrewing.

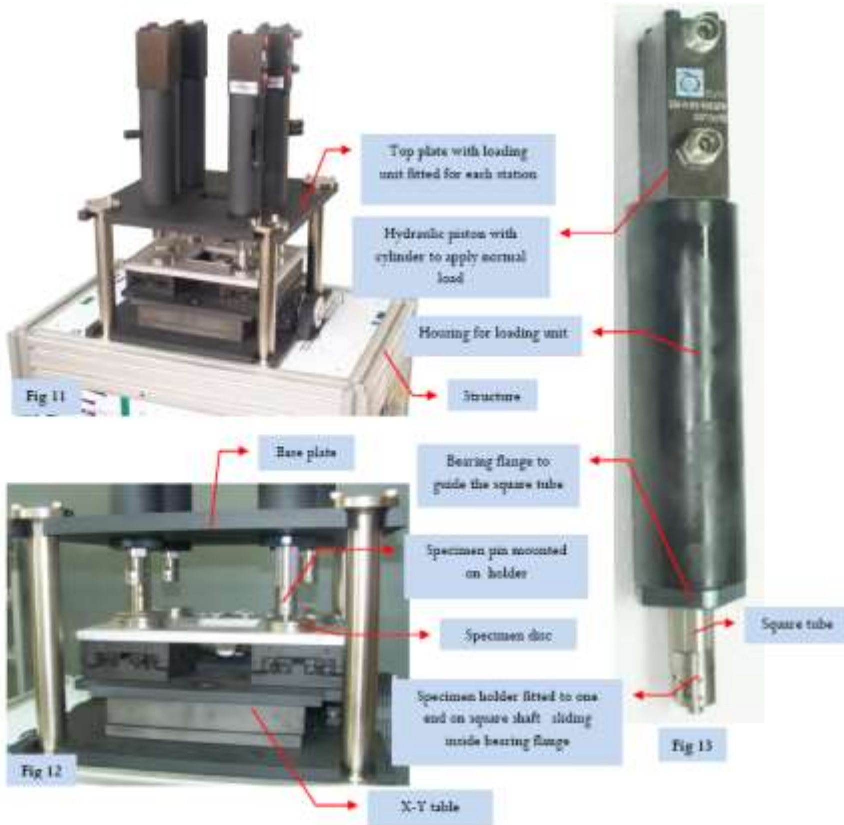


Fig. 5.2 Construction details of *Advanced Biotribometer*

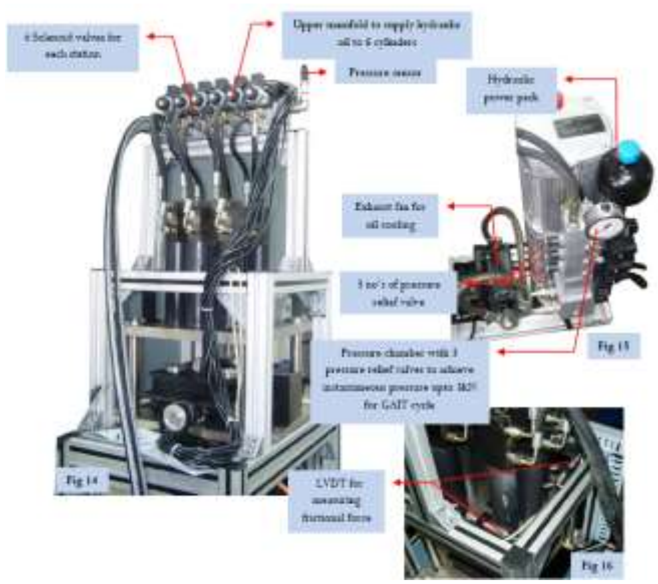


Fig. 5.3 Details of hydrulic ower pack drive system and LVDT for measuring frictional force

Along X & Y axis two number of linear variable differential transformer (LVDT) are mounted with the plunger pressing fixed plates on frame (Fig. 5.3). During test due to friction the loosely held top plate tries to move either along X or Y axis. This displacement is measured by LVDT and converted as frictional force for display on software.

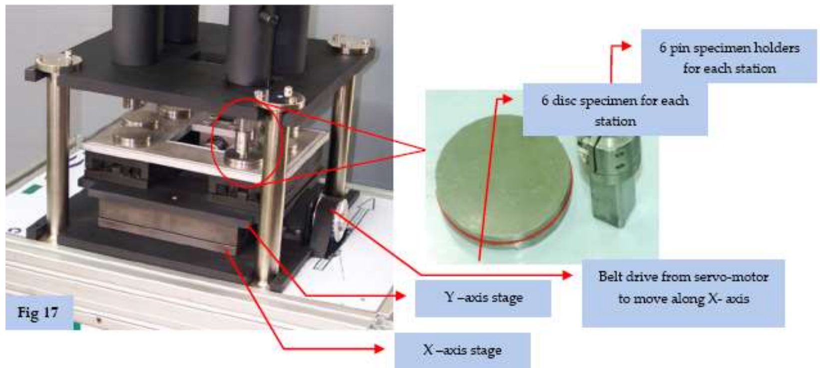


Fig. 5.4 X & Y stages for simulating multidirectional motion of contact & pin holder

Fig. 5.5 Acrylic cylindrical cup as lubricant chamber and sitter for and fixing of disc specimen

Advanced Biotribometer is basically a wear screening device facilitating the characterization of wear for a pair of materials used in human joint prosthesis. It is novel in respect of simulation of multidirectional motion achieved with development of pertinent wear track closure.

In ex vivo investigation of charnely cups the wear parameters are analyzed using white light interferometer. Calonius and Saikko (2002) have conducted test on Drham (mk) hip simulator under physiological loading parameters and found the track shape in the form of figure 8 using computational study which is verified using experimentation. The lubricant is adult bovine serum (RM9981- High media) complies the sterility, cytotoxicity tests and virus testing. The protein content of the serum is noted down in Table 5.1.

Table 5.1 Protein, albumin and globulin content for adult bovine serum

Total value	a-Globulin value	ß-Globulin value	Globulin value	Albumin value
7.2g/dl	1.5g/dl	1.1g/dl	2g/dl	2.6g/dl

The results of this experimental study and output parameters are required to be comparable to clinically observed wear results. The surface roughness of test specimen and control specimen before and after test is noted down. The surface roughness is measured by using Mitutoyo surftest, SJ-412 (4Mn type) along with communication software with computer.

Table 5.2 Test specimen: Material, dimensions and broad test parameter

Set No	Disc	Pin	Contact pressure	Motion component
1	Co-Cr-Mo alloy steel 55ϕ mm	UHMWPE 18ϕ mm	1.1795 MPa	8 shape

Fig. 5.6 Surface roughness evaluation profile for disc

The surface preparation is consummated using cleaning of disc surfaces. The surface of pin is ensured to be clean and free of any dust and dirt particles. The surface roughness along the sliding direction and lay is noted down for the sample length of 4 mm for pin and disc material. The surface roughness prior to test and after test for the test specimens is mentioned in Table No 5.3

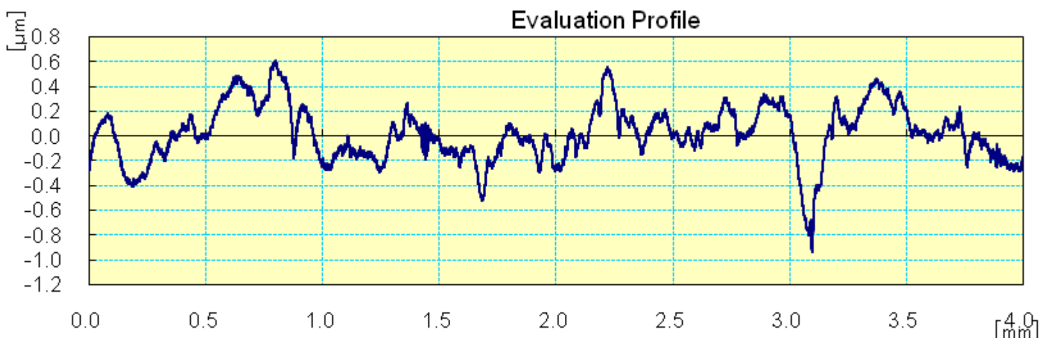


Fig. 5.7 Surface roughness evaluation profile for pin material

Table 5.3 Surface roughness of bio-specimens before and after tests

9mmϕ pin	Eight track		Square track	
	Pin	Disc	Pin	Disc
Initial surface roughness	8.523	1.398 µm	8.523	1.398 µm
Final surface roughness	0.175 µm	1.401 µm	0.552 µm	1.592 µm
18 mmϕ pin				
	Pin	Disc	Pin	Disc
Initial surface roughness	2.509	1.847	1.857	1.943
Final surface roughness	4.834	1.728	2.509	1.847

5.2.1 Friction and cross shear study

One of the reasons for multidirectional motion is micro-separation between the femoral head and acetabular cup during walking conditions after THR (Ortega-saenz, *et al*, 2007 and Richard *et al*, 2002). The multidirection motion of contact pair is basically shearing of material under operating conditions load and lubrication. Cross shear motion is basically a term used for Multidirection motion with interpretation relative to cross shear angle, change in direction and crossing paths during cycle. The main parameter of cross shear motion is direction of sliding. The direction of sliding can be determined by angle of velocity vector. For unidirectional motion paths the sliding angle is constant throughout the cycle. For complex motion paths sliding angle is significantly varying. In case of figure 8 sliding angle changes between the instances of cycle and sliding is combined with rolling and rotation. Therefore the complex motion of figure 8 which is in situ observed in clinical studies is opted for simulation in this study.

Principal molecular orientation (PMO) for UHMWPE pin is always in the direction of major dimension of simulated shape, of sliding. The dimension which is perpendicular to major dimension is called secondary direction of sliding and actual wear for polyethylene takes place due to friction energy dissipated in that direction. Also from literature study it is found that wear rate depends on the wear path pattern (Turell *et al., 2003)*. Therefore in addition to figure 8, square figure is simulated and considered in the frictional studies for estimating of cross shear value.

5.2.1.1 Shape track analysis

The wear tracks under consideration are as shown in figure 5.8

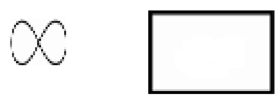


Fig. 5.8 Eight and square wear track under consideration

The cross shear is defined as ratio of frictional work in cross direction to the frictional work spent in PMO direction in a cycle. The total frictional work in respective directions can be calculated by integrating the product of frictional force and length of motion in that direction over the total number of cycles run during the test.

The advanced Biotribometer is capable of measuring the frictional force in both the directions. Using the frictional force $F_{fx} \& F$ in perpendicular and principal direction and a & b arm length of travel in respective direction, the frictional work in perpendicular and principal direction is calculated using Eq.4.1 & 4.2

$$\boldsymbol{W_{fx} = a\int_0^n F_{fx} \times N dn} \tag{5.1}$$

$$\boldsymbol{W_{fy} = b\int_0^n F_{fy} \times N dn} \tag{5.2}$$

Where, a & b are cross directional motion arm & principle direction motion arm respectivelly. N is the total no of cycles run. Total work dissipated in friction in both the direction & cross shear ratio is given by equation 4.3 & 4.4

$$\boldsymbol{W_{ftotal} = W_{fx} + W_{fy}} \tag{5.3}$$

$$\boldsymbol{Cross\ shear = \frac{W_{fx}}{W_{ftotal}}} \tag{5.4}$$

Earlier studies suggesting that sliding motion component in principal direction (Y in our case) leads to plastic deformation and macromolecular orientation while secondary sliding direction (X in our case) leads to material removal by intermolecular splitting. Therefore the energy dissipated in X direction, is only utilized in removing the material and responsible for wear.

The wear rate equation can be expressed as

$$V\alpha\ \mu \times P \times 2a \tag{5.5}$$

P is normal load acting and 2a distance covered in secondary sliding direction per cycles

$$V\alpha\ F_{fx} \times 2a \tag{5.6}$$

The wear factor is defined as volumetric material removal per unit the product of load and unit sliding distance. In our studies for eight shape of wear track the wear factor can be expressed as

$$K = \frac{Wear\ rate\ (\frac{mm^3}{cy})}{Load \times Total\ sliding\ distace\ (\frac{mm}{cy})} = \frac{V}{P \times L} \propto \frac{F_{fx} \times 2a}{P \times L} \tag{5.7}$$

Where L total sliding distance is measured from the eight shapes on similar lines shown below

The equation of wear factor given by orientation softening theory given by Wang and useful to estimate the wear factor of polymer-metal pair of contact is having three terms as laid down below.

$$K = k_a \times [(F_{E\perp}) \div \sum(F_{E\perp} + F_{E\parallel}\ )] \tag{5.8}$$

Where k_a is the wear rate constant and $F_{E\perp}$&$F_{E\parallel}$ are energy dissipated in cross and along principle direction of sliding of polymeric pin.

Frictional work done in ⊥ direction is calculated

$$F_{E\perp} = \mu_x \times F_n \times b \tag{5.9}$$

Where F_n&b are normal force and b cross arm travel during a cycle.

Total frictional work done in a cycle is calculated referring eight shaped wear track shown in Fig.4.7.

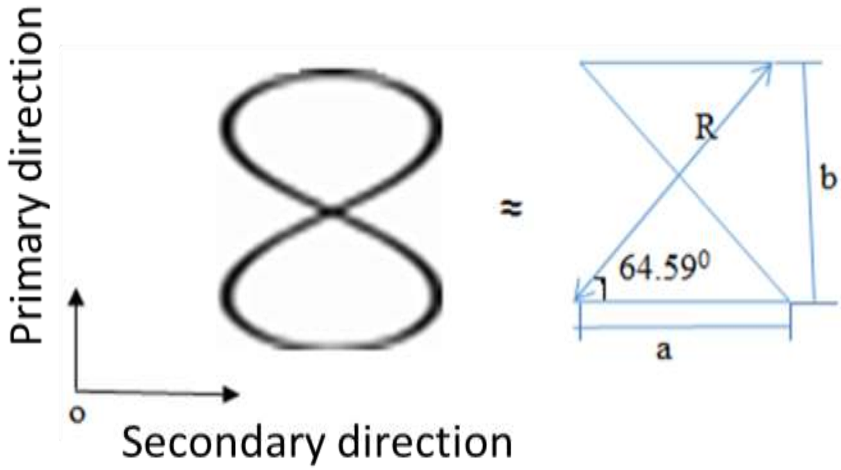


Fig. 5.9 Geometrical feature of 8 shaped wear track

$\sum(F_{E\perp} + F_{E\parallel}) = F_R \times 2R + F_H \times 2b$

(5.10)

Where in 2b is the total sliding in cross direction and 2R is cross path movement

Using equation 4.8 and experimental wear factor the value of wear rate constant for 9 & 18 mm pin diameters are found to be 7.3×10^{-7} *and* 1.66×10 mm^2/N. wear rate constant is an index of severity of wear and which is found to be prominent in case of 18 mm pin.

The cross shear ratio is calculated using the concept of frictional energy as follows

$CS\ Ratio = [(F_{E\perp}) \div \sum(F_{E\perp} + F_{E\parallel})]$ **(5.11)**

The cross shear is calculated by equation 4.11 considering the total run of 2 million cycles. The extensive calculations are consummated statically using excel. The value of cross shear comes out to be in the range of 0.32 to 0.42 considering the breaks during the running of entire test duration.

Turell (2003) has used similar kind of analysis for square wear track. When a femoral head is in contact with the acetabular cup in hip joint, it is found to trace the paths like quasi elliptical or rectangular. Also it depends on poster and activity style, weight of patient. If X in addition to Y are two principle directions of motion along which the travel of contact is consummated and if b>a, b defines the primary component of Motion in X direction of motion and a, defines the cross, secondary component of motion in Y direction. Depending on the values of a, in addition to b, the wear track may be elongated or closed curve for different patients. Another wear track considered for testing is square and the track is specified in following diagram.

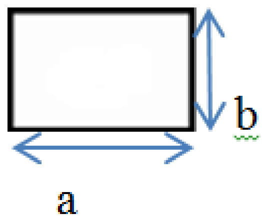


Fig. 5.10 Square wear track

Using similar analysis based on the line of frictional energy disused for eight shaped track, cross shear and friction factor can be estimated using equations for square wear track.

In a particular motion the aspect ratio is defined as dimensions of path traced in principle sliding direction to perpendicular direction of motion. The principle direction of motion is defined as a major direction of sliding in tracing a particular curve. It is found that the UHMWPE got molecular orientation when moving in unidirectional sliding. The combined effect of orientation and strain hardening cultivate additional wear resistance in UHMWPE material in principal siding direction. The material is stronger and wear resistance is more. Consequently the material wear resistance is weak in secondary or perpendicular to primary direction of sliding. The material will wear surrender obviously in the secondary direction. The frictional energy dissipated in secondary direction is utilized completely for initiating and causing wear of polymer whereas total frictional energy is calculated considering total sliding distance covered in one cycle.

5.3 Results and discussions

The approximate eight shaped wear track derived from the ex-vivo investigation is implemented during testing on advanced tribometer. It is important to consider the motion effect on wear parameters of joint materials as it is one of the important factor in the experimental determination of wear rate for polymeric/metallic contact. The allowed sliding speed is 38.4 mm/s between the contact which is close to physiological limits during walking as 30 mm/s (Saikko, 1992, 2014).

The aims of the experiment are friction and wear study of orthopedic golden pair of material on developed advanced biotribometer. Subsequently the simulation developed on test rig in order to mimic the conditions existing at natural hip joint needs to be validated by comparing with the clinical results. The machine is capable of measuring friction in both x & y direction. In advanced biotribometer the tests are carried out for 2 million cycles. The friction is measured continuously and wear is measured at stipulated breaks respectively. The wear factor is calculated using weighted regression between sliding distance and volumetric wear.

The cross shear ratio is calculated based on the frictional energy dissipated during cycle along principal molecular orientation (PMO) or principal direction of sliding and cross direction or secondary direction. The cross shear ratio is calculated for eight and square motion pattern on advanced tribometer.

5.3.1 Frictional studies

In frictional studies using advanced tribometer, coefficient of friction is obtained by conducting 40k cycles for different cross linked pin in contact with Co-Cr-Mo alloy in adult bovine serum. This is shown in fig 5.8. This frictional study is conducted using 12 pins; 6 tests and remaining 6 control pins in 2 rounds each for eight shape and square track. For getting clarity the scheme of testing is explained with the help of following table or diagram.

Table 5.4 Scheme of testing for frictional studies

Test Round	Wear track	Station 1&2	Station 3	Station 4	Station 5&6
		9 mm pin	9 mm pin	18 mm pin	18 mm pin
1	Eight shape	Virgin & 5Mrd	7.5Mrd	7.5Mrd	Virgin & 5Mrd
2	Square shape	Virgin & 5Mrd	7.5Mrd	7.5Mrd	Virgin & 5Mrd

The variation of coefficient of friction with number of cycles of run is for figure 8 and square motion is shown in Fig 5.11 & 5.12. The plot is drawn performing the cubic regression and shows the aspired trend.

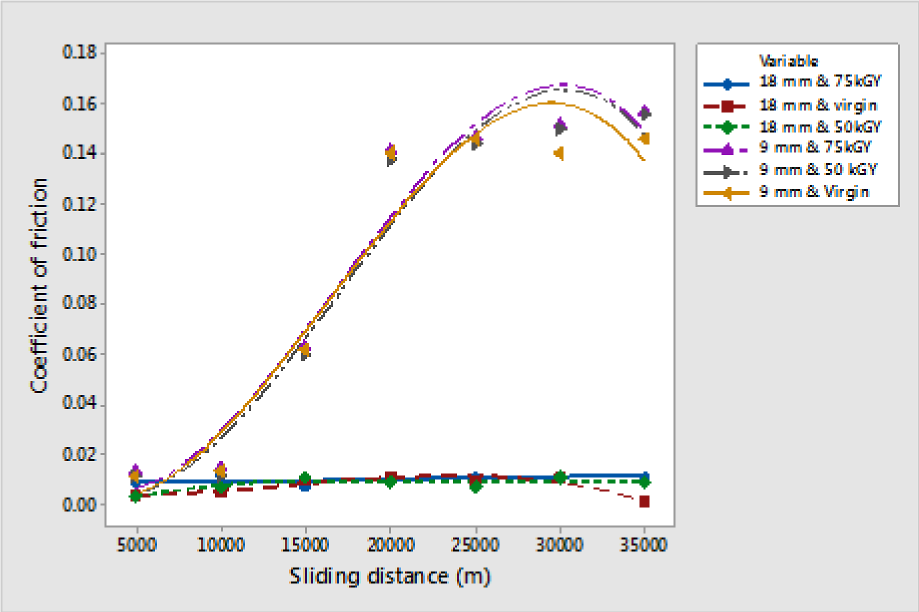


Fig. 5.11 Variation of coeificient of fricion in figure 8 with respect to cycles of run

The value of coefficient of friction increases with the contact pressure for all configurations. Since at relatively high pressures an active protein film gets formed and naturally lubrication turns out to be boundary, increasing the coefficient of friction. At low contact pressure mixed lubrication may prevails reducing the coefficient of friction (Saikko, 1999).

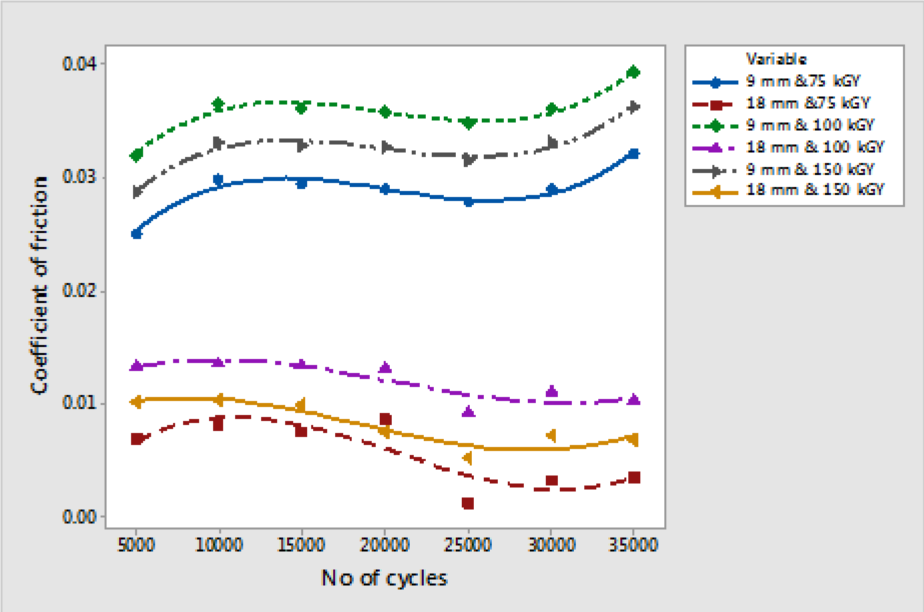


Fig. 5.12 Variation of coeificient of fricion in square motion with respect to cycles of run

The variation of coefficient of friction for eight shape and square motion is shown in Fig. 5.9 &5.10. The mean of coefficient of friction is calculated after stipulated number of cycles and plotted versus number of cycles. The regression is carried out with 95% confidence interval and regression lines are shown for individual pin material in Fig 5.11 & 5.12.

Individually among group of irradiated polyethylene shows slightly higher coefficient of friction in both the simulated motion and as shown in Fig 5.11 & 5.12. Similar observation is observed by Tuckart (2014) after conducting a wear test of polyethylene on rough and smooth surfaces. Although the trend shows rising CoF with dose of irradiation, the net difference between the COF between the variedly cross linked polyethylene is not significant.

Using Eq. (5.8) the wear rate constant k_a and be found out knowing the wear factor from experiment and frictional coefficient form the experimental study.

$$K = k_a \times [(F_{E\perp}) \div \sum(F_{E\perp} + F_{E\parallel})] \quad \textbf{(5.8)}$$

Where k_a is the wear rate constant and $F_{E\perp}$ & $F_{E\parallel}$ are energy dissipated in cross and along

Wear rate constant is also a term indicating the severity of wear. It is an index of severity of wear. The values of wear rate constant for different motion and pins with various diameters are shown in Fig. 5.13. The values of wear factor are calculated from the experimental study of pins for 35000 cycles. The wear rate factor is maximum in case of pin in square motion and minimum value of this factor is observed for 9 mm pin diameter in 8 shape.

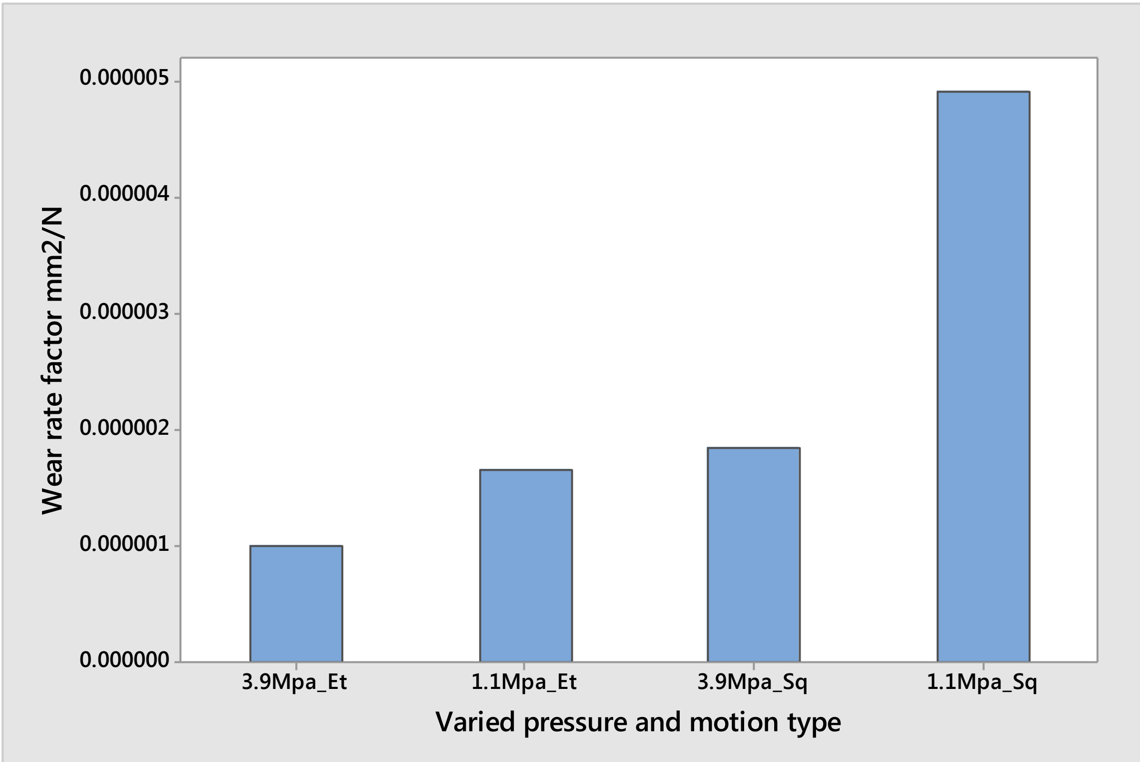


Fig. 5.13 Variation in wear rate factor with different motion

The wear rate factor is a volumetric rate per unit of normal load. It is also usrful as an index of wear. Wear rate factor can be esily compared and having or dertvded unit quualent ot wear factor.

The wear rate factor is double in case of square trak when area is doubled and 1.5 times in case of eight shape when area is doubled. With increase contact pressure & decrease in contact area the wear factor reduces. The similliar type of dependence of pressure on k is observed in studies on CTPOD by saikko and mazzucco (Saikko, 2000, Mazzucco & Spector, 2003)

Table 5.5 Reported values of cross shear for different motion compoenent and diameter of pins

Pin diameter mm	Motion component	
	Square	8
9	0.2837	0.3
18	0.4	0.47

5.3.2 Wear studies

In order to conduct the test for analyzing the wear for UHMWPE/Co-Cr-Mo material pair, ASTM F732 protocol is followed. The mass loss is measured using analytical mass balance to the accuracy of 0.01 mg level. The volume of material is calculated by assuming the density of polyethylene equal to 0.94 mg/mm^3. The volumetric wear for different or varied cross linked polyethylene is plotted against the product of sliding distance and normal load as shown in Fig 5.14. The weighted regression is carried out with a weighted factor considered to be equal to Inverse Square of predictor which is volumetric wear in this case. The regression is carried out keeping the confidence level interval equal to 95% with R_sq value exceeding 95% for all the combination of materials. The y intercept is negligible in all the cases.

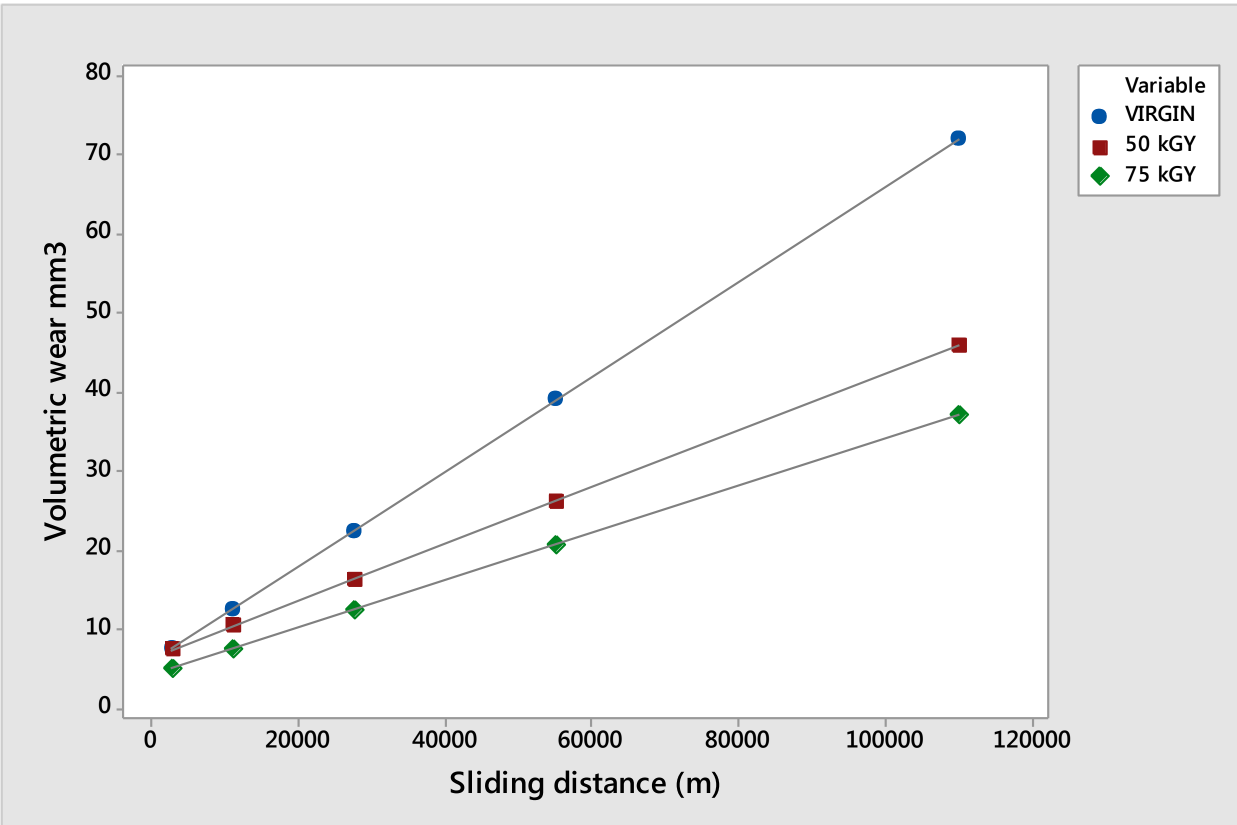


Fig. 5.14 Variation in volumetric wear with respect to product of sliding distance and normal load

The comparison of wear factor for differently cross linked UHMWPE clearly indicated that as the gamma irradiation dose rate increases the wear of polyethylene decreases. The commercially used prosthesis do irradiated as the rate of 50-75 KGy and above it >100Kgy the product or irradiation is called as highly cross linked polyethylene.

The above knitted graph is clearly indicating the effect of cross linking on wear of pins in bidirectional sliding motion. The wear in non- irradiated pin is higher than found in 50 kGY & 75 kGY gamma irradiated pins. The slope of lines is deducing the wear factor over the duration of 2 million cycles. The data of mass loss of polymeric pin is converted to volumetric wear loss by multiplying with a density factor equal to 0.93. The weighted regression analysis is carried out for the wear data considering a weight equal to reciprocal of predictor (product of sliding distance and normal load). The regression is carried out by maintaining the significance level below 0.05.

The least square regression is carried out. The linear relationship is quite strengthful as correlation factor in each of the regression line is 0.9 and above. The linear strength of association between volumetric wear and product of sliding distance and normal load is 99%. The $R_{\_sq}$ value in each regression is ranging from 95- 99%. It means about 99% of variation in response value is accounted for the linear relationship between the x & y values.

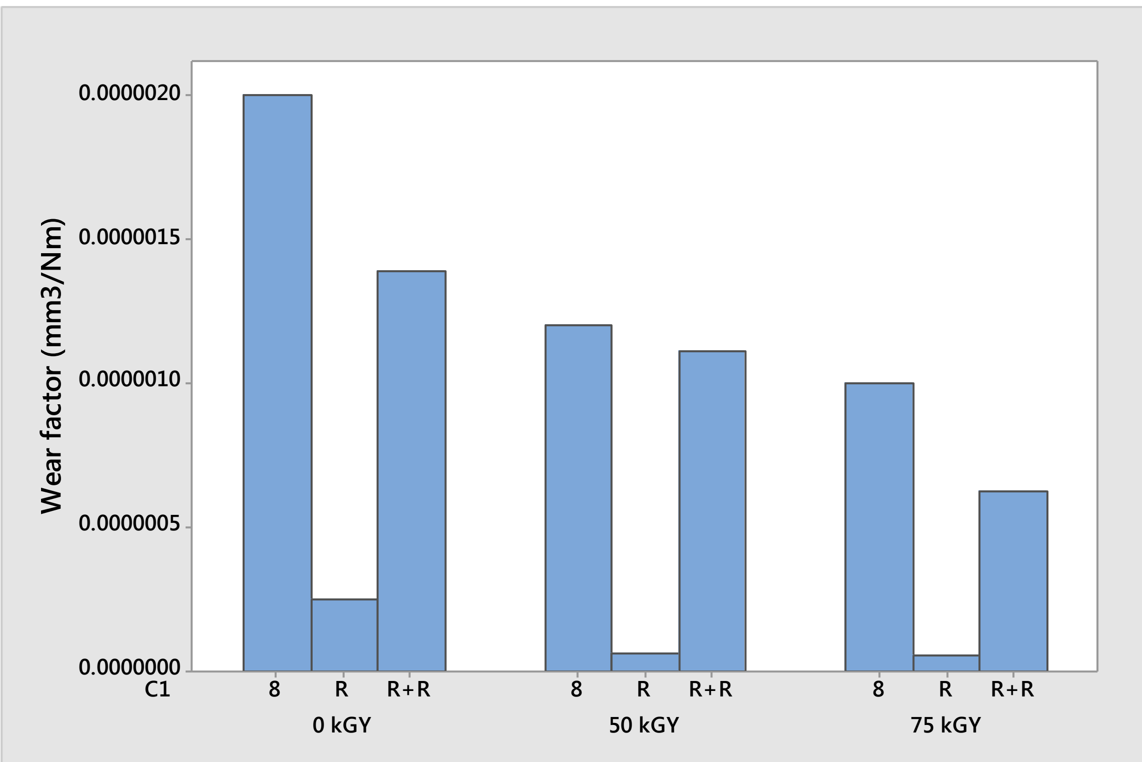
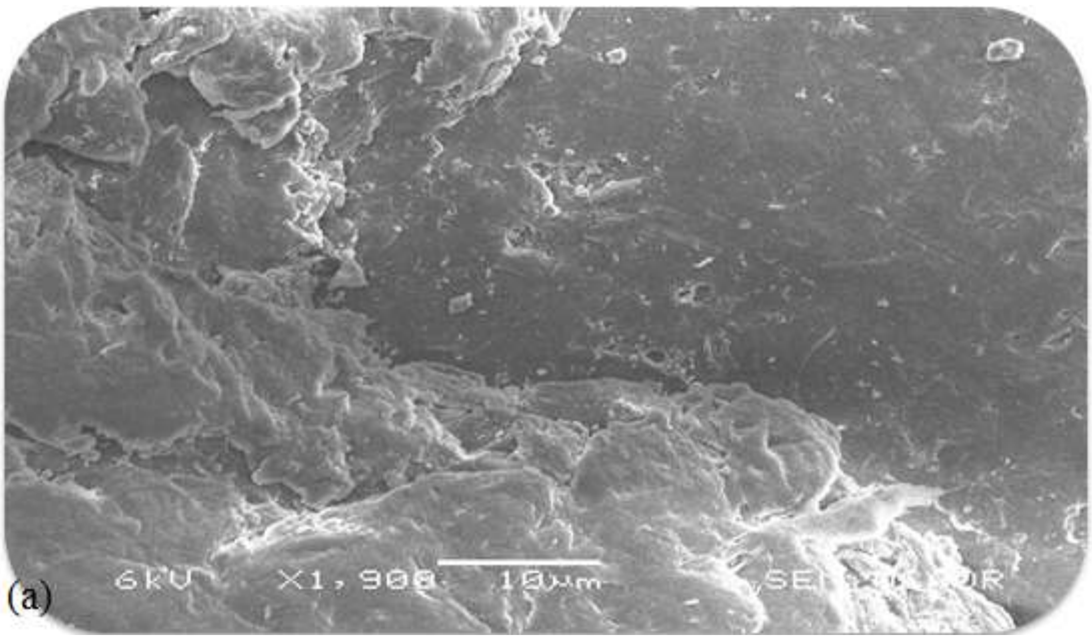


Fig. 5.15 Wear factor vs, cross linking dose in UHMWPE/Co-Cr-Mo alloy material pair

5.3.3 Surface characterization

The pin surface at magnification of 200x clearly indicates the lose threads or distorted microstructure of surface and at higher magnification like 1300 and 2500x, wear debris or lose mico-partilces can be seen to be surrounding or clinging the surface. These particles over the period of time may detach from the surface and aggravate the wear of polymer. For 8 shaped motion component the plastic deformation is large and it can be found that



(a)

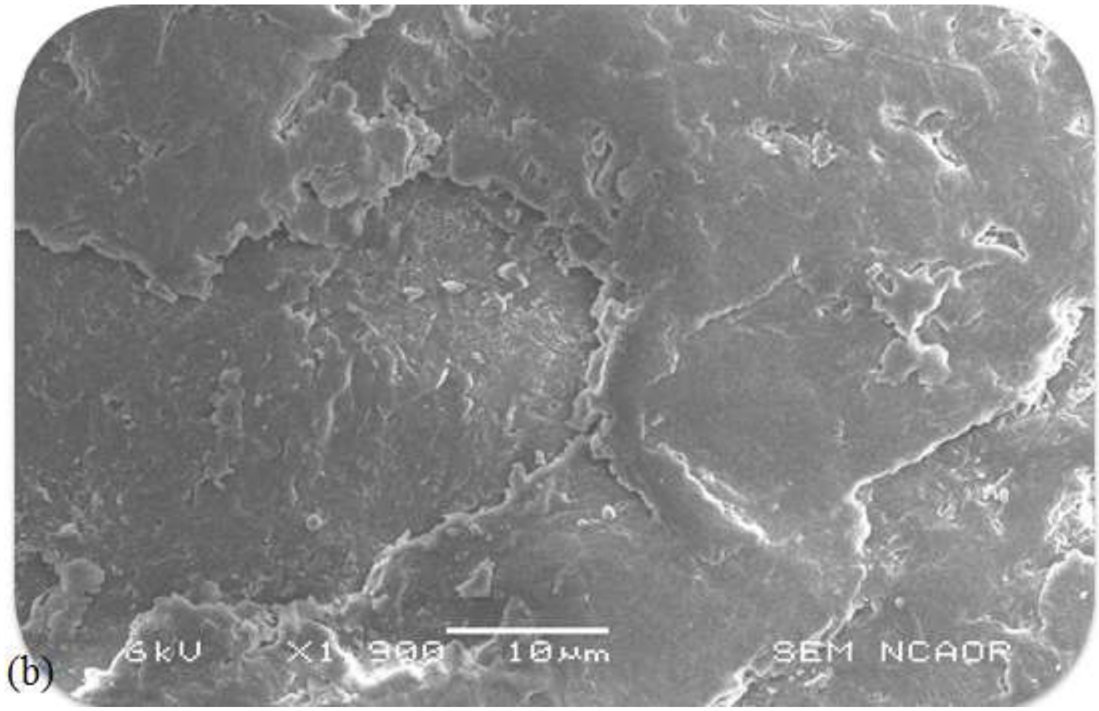
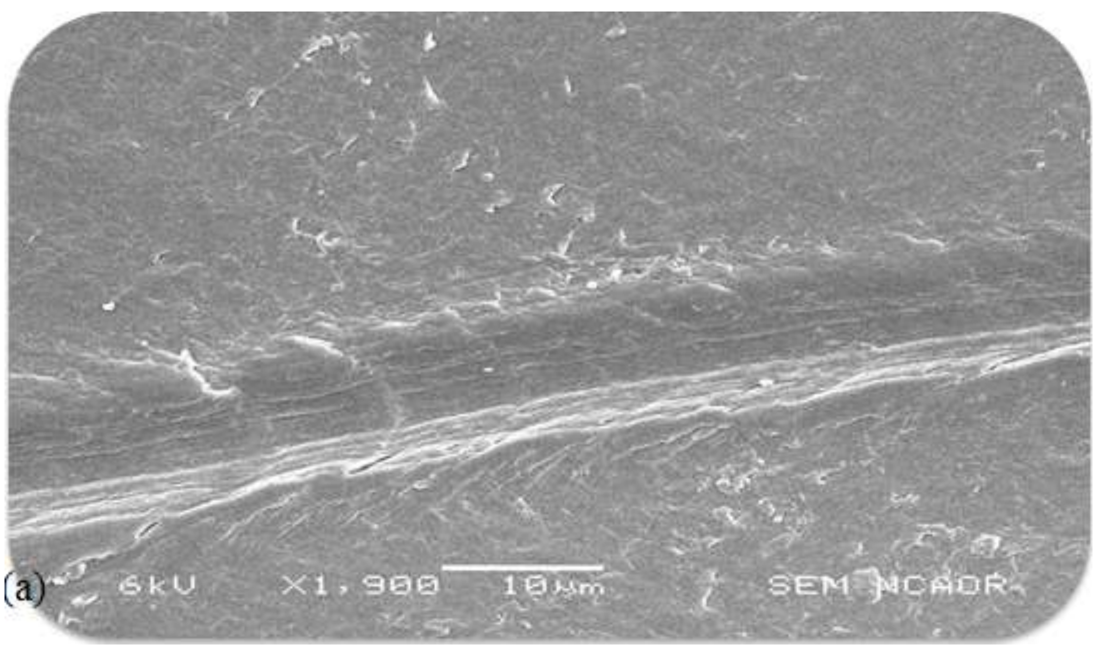
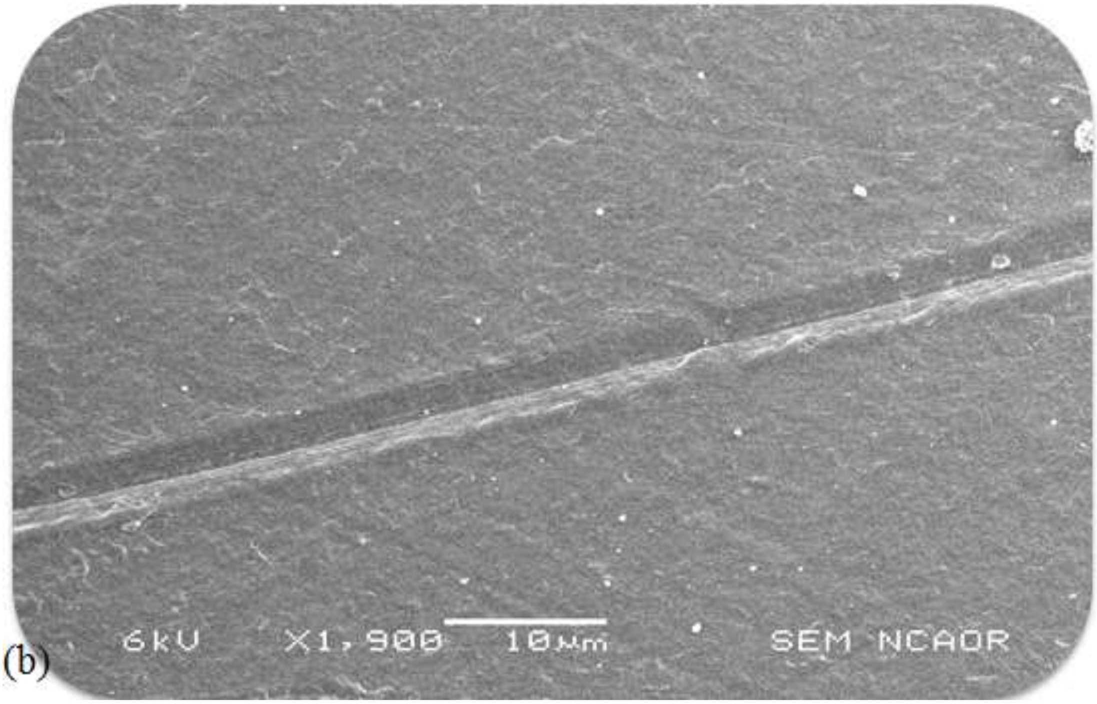


Fig.5.19Pin surface (a &b) micrograph in eight motion pattern on Advanced Tribometer





(b)

Alter running for another 40K cycles while simulating the squire motion the wear tracks are shown as above. It is found that at a magnification of 1900x the material seems to be giving a way for abrasion and little debris or lose particles are seems to be present on the verge of detachment form the surface. At much higher magnification one can see the detachment of particle will get confirmed with little impetus of run.

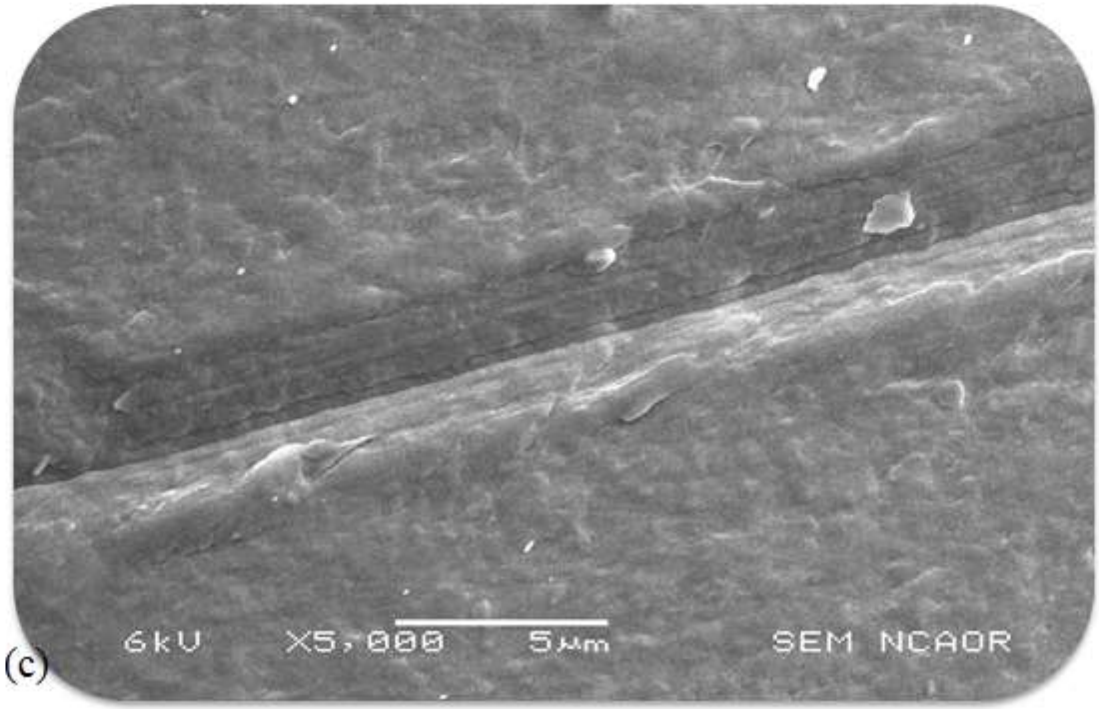


Fig. 5.20 Pin surface (a,b&c) micrograph in Square motion mode on Advanced Tribometer

It can be inferred from the micrograph study from both pin on plate test rig and advanced bio-tribometer that the mechanism of wear seem to be abrasion and adhesion in certain cases. If the adhesion is going to be a dominant factor over the period of run time then it may alter the contact configuration. The contacting objects or material gets altered so that the contact will be sustained between the polymer adhered to metallic surfaces and the polymeric pin. It will surely reduce the total amount of wear in the process. The protein content in the serum is able to control the adhesion wear. The protein content does not allow the adhesion and hamper the process of clinging/adhesion of polyethylene to metallic surfaces.

The bastions wear machismo is a short term and when the surface is fresh or virgin the machining marks on the surfaces get obstructed and leading to the maximum triton. Once these matching marks after certain amount of running gets cleared or got diminished, the surfaces can be called as complimentary and less abrasion wear is evident. In the initial period when the surfaces are fresh the surface rouges is measured using a surface roughness tester and the roughness values are noted down as follows for all the specimens used in *pin-on-plate* test rig and advanced bio-tribometer

In case of advanced bio-tribometer the images 3a, 3b indicates the wear track counter on the metallic surface. The images are gathered using a lens camera by magnifying it to 5X level. The track collected clearly indicates or reveal the shape of the counter simulated on advanced tribometer with reference to the friction studies. These images and their dimensions are selected based on the ex vivo studies on Charnely acetabular cups retrieved from the south Asian subjects/patients. The pin surface micrographs after completing 2 million cycles are shown in the Fig 5.21

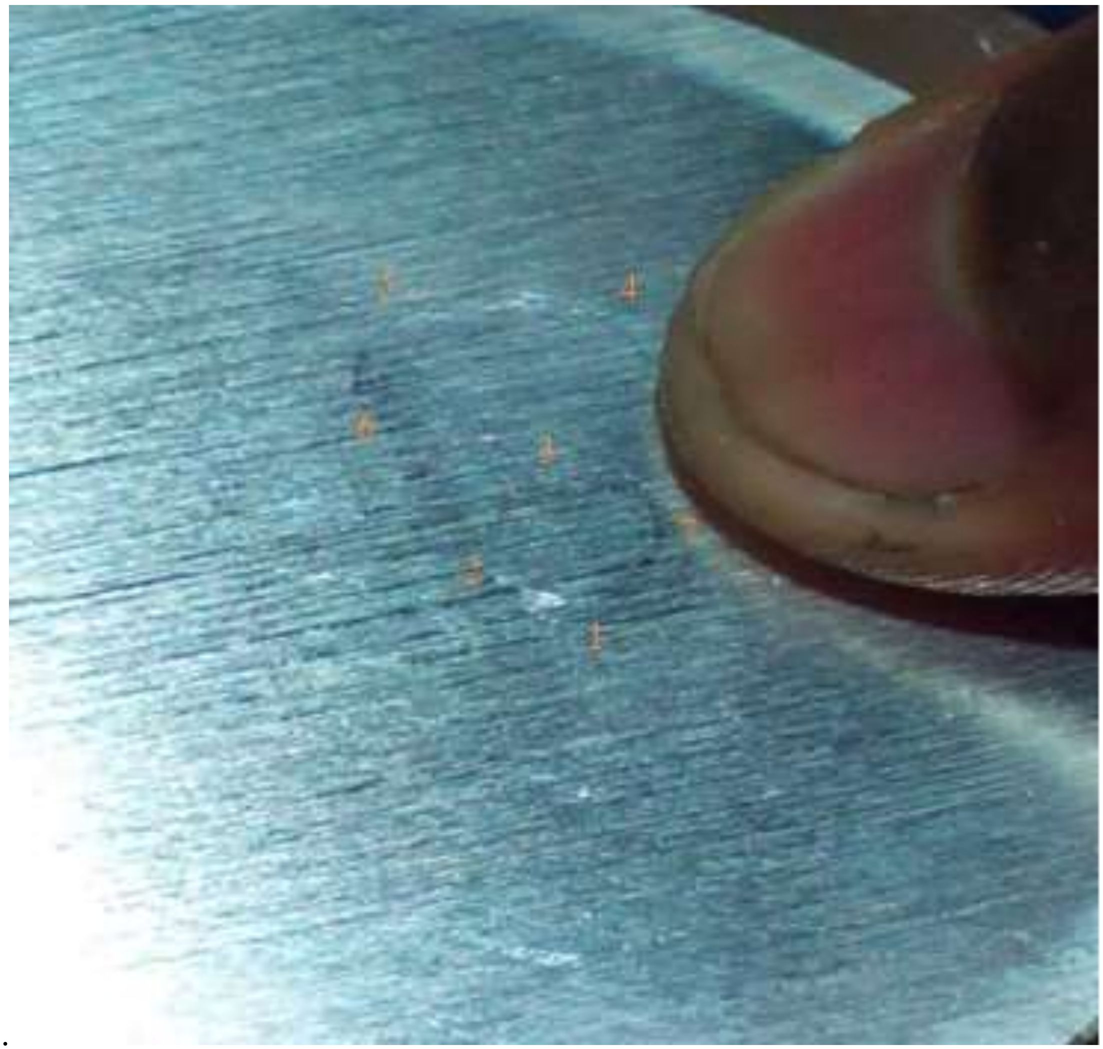


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Fig. 5.21 Pictorial view of the eight shape traced path on CO-Cr-Mo Disc

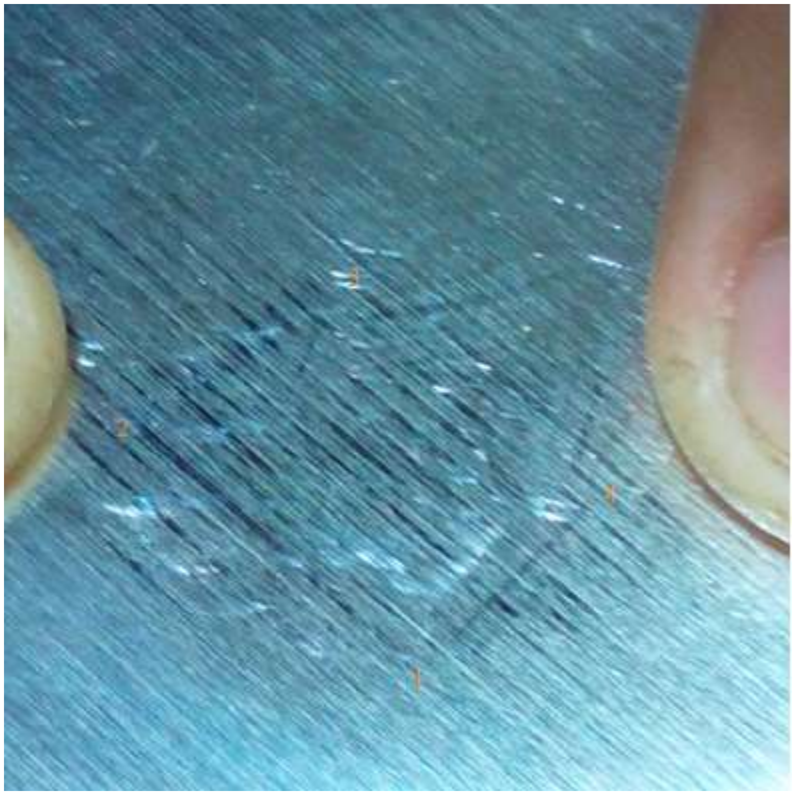

Fig. 5.22 Pictorial view of the square shape traced path on CO-Cr-Mo Disc

5.3.4 The condition of lubrication at the natural joint

It is well known fact from literature that in natural joint the articulating surfaces are never separated by the synovial fluid film and hence friction contact is evident which plays a role in wear process between the polyethylene metal contacts. The Somerfield no is given as $\frac{\eta u}{w}$

Where in η is the viscosity of lubricant, u is the linear velocity of contact, r is the radius of contact and w is the normal load acting in N.

Fig. 5.23 shows variation of coefficient of friction with respect to Somerfield number. The trend clearly indicates that there is a fall in coefficient of friction as Somerfield number increases.

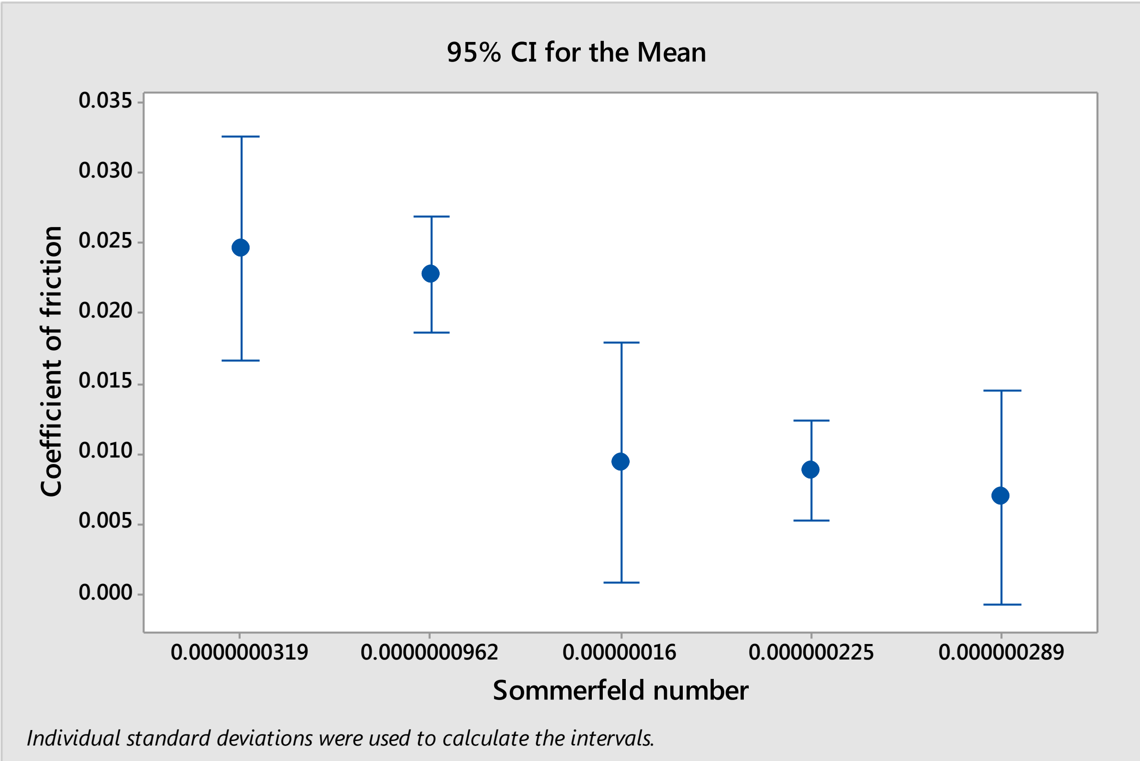

Fig. 5.23 Sommerfield plot for 8 motion pattern

Chapter 6 Overall discussions

COMPARATIVE RESULTS & DISCUSSIONS

This chapter describes the comparison of the results among the wear simulated screening devices using ASTM F732 standard and ex-vivo clinical studies on Charnley cups. The wear factor (mm^3/Nm) makes it possible to quantitatively compare screening, joint simulator, and clinical wear (Saikko, 2011, Atkinson, *et al*., 1985, Hall, *et al*., 1996).

6.1 Ex-vivo clinical studies

The survival rate or functional life of hip implant in metal on polyethylene hip implant material is limited and on an average not more than 10-12 years (Dowson, 2001). Wear of polyethylene is an issue needs to be addressed to understand the nature of complex wear in the hip bearing application. Hence it becomes important to study the retrievals in order to understand changes and nature of wear taking place during the impanation time. Moreover, it is a better practice to compute the actual wear parameters in implants. There are in-vivo methods useful to analyze the performance of implant, positioning, migration if any during the active life and are used by orthopedicians by taking x rays, CT scan and MRI scans during the follow up period. But we prefer to have implant for our study which are taken out of body at the time of revision surgery and cannot be used further in the body. This study called as Ex-vivo study, will helps to compute the linear wear, volumetric wear, wear rate and wear factors. In the community we are living in, it is a great achievement to understand the impact of life style, posterior and gait cycle on the nature of wear qualitatively and quantitatively.

Units of low posterior wall Charnley retrieved cups of 22.1 mm diameter fixed with cementing technology are obtained from the Shalby Hospital Ahmadabad. These cups are collected at the time of revision surgeries of patients. Low posterior wall cups are having a wall or tapered region on the working surface and the design intent is to secure the positioning of cup against the frictional torque due to interfacial contact stress. If the trigonal torque increases during the operating time then it will loosen the cup cement bone interface their by either loosening the cup or migrate the cup from the intended position. The cups are basic design of Charnely and also called as low friction arthroplasty cups. During ex-vivo investigation, after visual inspection it is found that the Poly-methyl-meta-acrylate cement is widespread on the back side of cup. Primafacia femoral head impingement on the tip of flange is dominant as witnessed by wear craters/pits on flanges.

The wear analysis of theses cups are carried out using a most precise, non-contact interferometer which will give the actual positional coordinate of points forming the working surface. The 3D model of both original and retrieved cup is compared to find the volumetric wear contained. The change in volume of cup pertaining to working surface is calculated. The volumetric wear is computed for all the cups under consideration.

The paradox of comparing laboratory and clinical wear rates was first tried to simplify by Atkinson (1986) by an attempt to estimate wear coefficient for clinical retrievals using effective clinical wear factor. The unit of $K_{effecti}$ is $\frac{mi}{N}$ and is estimated using number of steps per year by individual. The main contradiction in comparing the clinical results and laboratory results are two, one is in laboratory experiments the surface of specimen is coated with protective layer and not in vivo (Wallbridge *et al*, 1986) & second is dimensional change in cup due to creep during survival in body. Wallbridge and Dowson (1987) have considered those points and based on the assumptions of maximum creep limited to initial period has put forth a theory or set of equations for comparing clinical and experimental wear rates (John, 1995).

Accordingly considering patient specific parameters the linear and volumetric wear rate along with clinical wear factor is calculated in Chapter-3. After studying 20 Charnley cups, the regressed clinical factor is found to be $3 \times 10^{-6}\frac{mi}{N}$. In classical studies on charnely cups, Atkinson & Hall (1996) has calculated the cynical wear factor $2.9 \times 10^{-6}\frac{mi}{N}$ closely matching with the factor estimated in this study. Moreover it is found that the wear factor estimated using 8 shaped wear track is $2.1 \times 10^{-6} mm^3/N$. The ex-vivo and experimental wear factors estimated on pin-on plate and advanced Biotribometer are $3 \times 10^{-6}\frac{mi}{N}$& $2.1 \times 10^{-6} mm^3/N$ respectively. The difference is in acceptable limits.

The high lights of this study are pointed as follows

By conducting ex-vivo study on the retrieved implants in aboriginal patients we could able to set a standards and limits on the wear parameters or values observed in the Indian community. Every community or a group has peculiar posterior, activity levels and that builds the required straining conditions on artificial hip implant as it is one of the major joint responsible for almost every activity of an individual.

2. It is an important standard since wear is the origin leading to failure of metal on polyethylene hip implant material.

3 These computational work is a set of bench mark and volumetric wear measured pertaining to implant measured by any other method (invasive, secondary) can be validated against the actual values observed in retrieved implants.

6.2 Screening wear simulation

The wear of polyethylene is a major cause of failure in metal on polyethylene implant material (González, 2011). Moreover, it is really difficult to analyze the wear in such a complex biomechanical application on site to understand causes and reasons of the aggressive nature of wear in actual implants. Certain codes for wear testing of hip implant materials are advocating the experimental wear testing of hip implant materials. It is one of the criteria for a material to be used in practice with the pertinent design and material configuration. Metal on polyethylene is in use from last several decades so preclinical evaluation of materials though experimentation is not that important but the success of simulation scheme adopted in vitro on both the test rigs is certainly different and needs to be evaluated by comparing with the ex-vivo studies.

The first test rig designed and developed is based on the kinematic modulation in motion and reciprocating plus rotational motion is imparted to two stations out of four. The remaining two stations exhibit only reciprocating motions. Barber (1999) in his studies specifically reported about the elliptical and quasi-elliptical wear paths to be observed on the cups due to articulation with the femoral head. Taking this lead we have customized a test rig which can cater us the wear track particularly and in order to reproduce the clinical wear using an experimental test rig.

In case of second test rig i.e. *advanced bio-tribometer* the customization of 8 shaped and square shaped wear tracks is incessant. Several authors have reported findings of these types of wear track during their simulator studies on acetabular cups (Tuckart, 2014). We intended additional one i.e. square track (Turell, 2005) and the tests are carried out using ASTM 732 code exclusively framed for wear testing of polymeric materials in hip implants.

Customized pin on disc configuration is used for experimental simulation on *pin-on-plate* rig and *advanced biotribometer*. The UHMWPE pins, virgin and cross linked in the form of cylinder having nominal diameter of approximately 9 and 18 mm with a Co-Cr-Mo disc of 50 mm diameter and 10 mm thickness are used as Bio-specimen during simulated wear testing.

These pins are worn in Pin on plate test rig and advanced *bio-tribometer* having multistation and each station is utilized for testing different test specimen pair, keeping disc material same and changing pin from virgin to cross linked with a gamma irradiation dose as 50 & 75 kGY. The surfaces roughness of counterface disc is maintained in the range 0.04 microns.

The gravimetric wear measurement, mass loss of pins is measured at stipulated breaks using wright balance of 0.01 mg accuracy. The soak control specimen pin is set in to take control of sorption component and weight rise in lubricant. The screening wear tests are carried out using adult bovine serum lubricant on pin on plate test rig and *advanced bio-tribometer*, under a permissible range of contact pressure for hip application. The volumetric wear of the cups was taken to be the pin weight loss after wear, corrected by the weight gain of the soak controls, and converted to volume by dividing by the density of polyethylene ($0.94 mg/mm$).

The objective of the experimental simulation is to reach or closely simulate the conditions existing at articulating surfaces of hip joint. With customized screening devices it is possible to simulate the wear tracks which are close to clinical observations found at articulating contact of cup The combination of rotation and reciprocating motion component do increase the volumetric wear and wear factor compared to pure conventional reciprocating motion. The effect of cross linking to increase the wear resistance is observed to be true, limiting value 100 kGY.

The nature of tracks (8 shaped & square shaped) observed from the hip simulator study and implemented in motion simulation increases the volumetric wear and wear factors compared to conventional wear tracks.

The volumetric wear verses millions of cycles plot for both the test rigs and three different motions component is shown in Fig. 6.1 The volumetric wear, using density functions is converted to mass loss and is recorded in embodied form in the plot. The wear factor (mm^3/MC) is reported in Table 6.1.

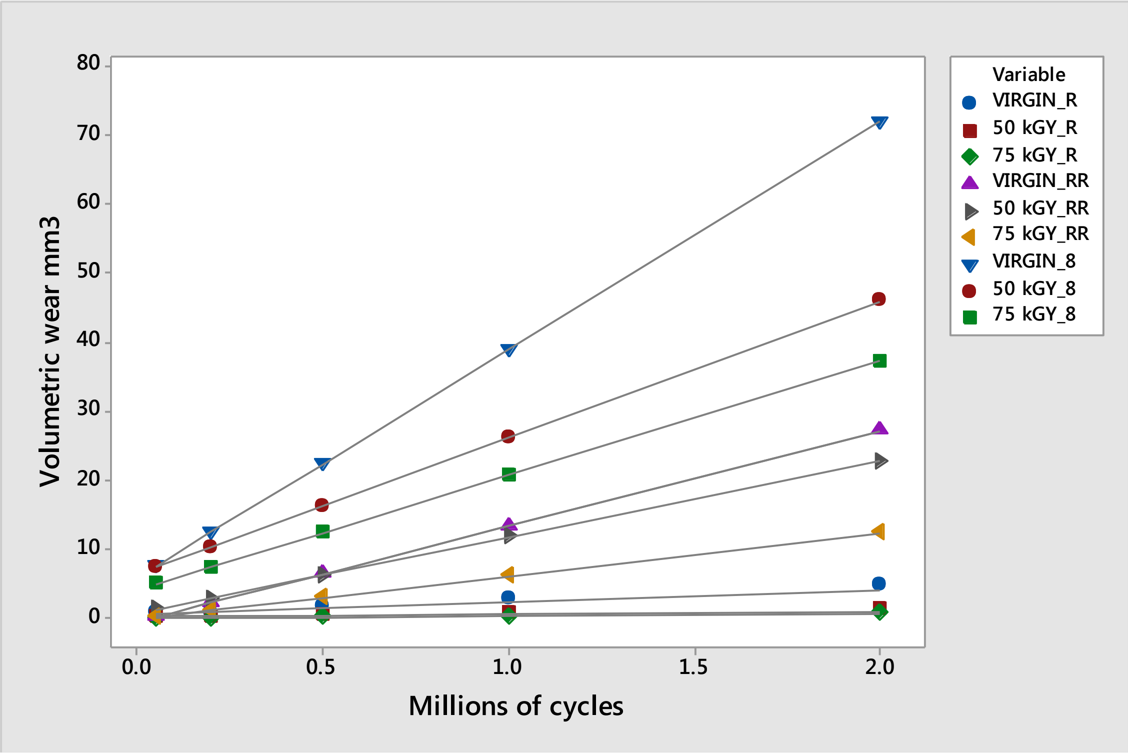

Fig. 6.1 Volumetric wear versus Millions of cycles

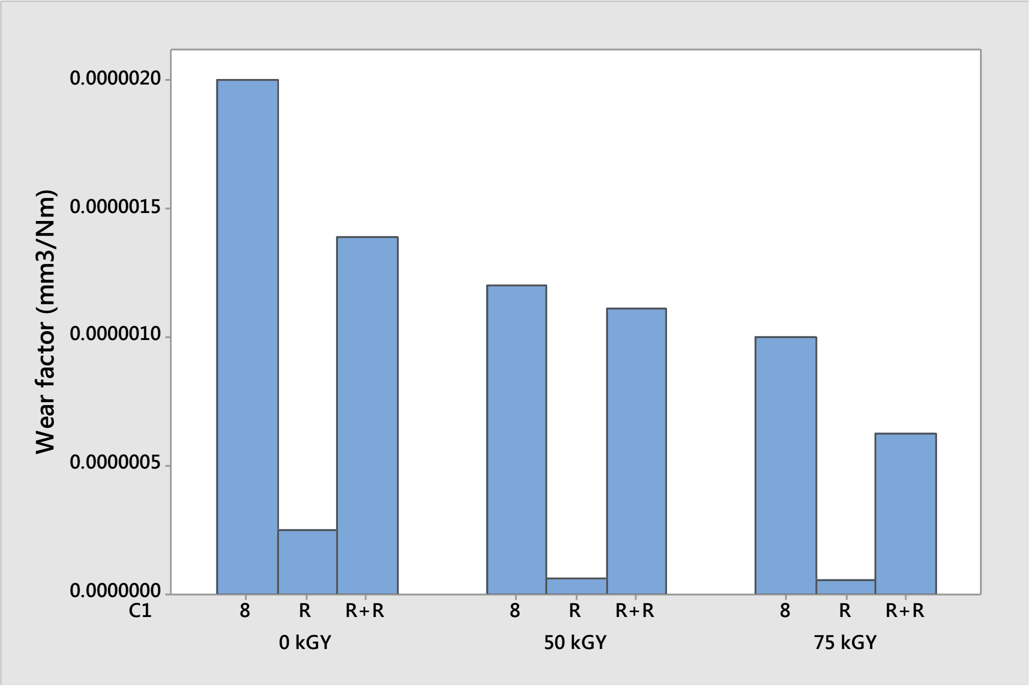

Table 6.1 Estimated wear factor for different simulated motion

6.3 Summary

The combination of results in vitro and ex –vivo are estimated and wear factor measured using advanced bio-tribometer is closer to the wear factor calculated using ex-vivo studies.

Chapter 7

CONCLUSIONS

Summary

The research work presented in this thesis is aimed to perform wear analysis of explanted metal on polyethylene hip implants and develop wear screening devices employing is situ wear simulation. In this study, cohort of twenty retrieved cups is scanned using white light interferometer. The aim of scanning is to map the working surface and irregularities like wear pits, scratching and related damage accounting to wear of surface. Another original cup and from the same batch of production similar in dimension to retrieved cup is also scanned. The CAD models using the point data are prepared using Geomagic software interfaced with the white light machine. Using, original and retrieved CAD geometries, the volumetric wear difference for working surface is estimated. Similar process is continued for all the cups to find the volumetric wear in retrieved cups. Hypermesh software is used to get the linear wear distribution in all the cups. Knowing patient specific data for individual cup, method suggested by Atkinson as well as Wallbridge is employed to convert the clinical data into experimental parametric data. The volumetric wear rate, wear factor are calculated for the retrieval studies.

Two wear screening devices are designed and developed for testing experimental wear properties of Tribological pair of polyethylene pin and metallic disc materials used widely in hip prosthesis. Four station *pin on plate* wear test rig is proposed having two stations with reciprocating motion and two stations reciprocating plus rotating motion. The rotational and reciprocating speeds of base plate are selected in the physiological limit for hip joint.

Six stations advanced bio-tribometer is designed and developed which is capable of simulating all basic motions along with predetermined motion of 8 shaped. The test temperature is monitored using temperature sensors and loads in the physiological limits can be applied though hydraulic powered pack drive.

On both the devices wear tests are conducted according to ASTM F732 standard for two millions of cycles. The protocols specified for test specimen and weighing to measure the mass loss is followed rigorously to find the wear for specified test duration. The mass loss calculated in milligrams is converted to volumetric loss using density function of UHMWPE. The wear rate and wear factor are estimated using both the test rigs. The mean linear and volumetric wear is reported. The surface characterization of worn pin and disc specimen is accomplished using scanning electron microscopy to witness the existing wear mechanism.

Critical findings

Major outcomes of the present research work are summarized below.

The wear studies of hip implant prosthesis can be conducted by two methods. Ex-vivo study is a method in which the retrievals are analyzed using microscopy or coordinate measuring machine for wear estimation and observation to conclude about the wear phenomenon. Another way to study the wear of implant material is simulated experimentation called as in-vitro studies. In this method the experimental test rig and environment like load, lubrication and motion are simulated and tests are conducted using prescribed standards in a controlled environment to analyze the wear phenomenon. In this investigation, ex-vivo and in-vitro approaches are successfully utilized for wear characterization of hip implant material.

Linear wear is investigated in the retrievals and the range is found to be .002 to 4.3 mm in the wide spectrum of patients. Maximum wear is found to be in supero-posterior region of acetabular cup for both left and right leg implantation. Linear wear is found to be maximum at the central region of cups and thinning towards the flanges or outer periphery of cup. The linear wear according to protocol ASTM-732 in UHMWPE is found to be 0.075 mm in R mode and 0.4 mm in R+R mode and 1.08 mm in advanced bio-tribometer using 8 shaped wear track.

The clinical wear factor as estimated in this study is $3 \times 10^{-6} \frac{mm^3}{Nm}$. The wear factor for Charnely cups given by Hall (1996) is considered to be standard in the literature study and is $2.9 \times 10^{-6} \frac{mm^3}{Nm}$. Therefore, clinical wear results are in agreement with the standard. In the development of screening device for wear testing, closer motion simulation is most effective way to mimic the natural hip joint conditions. The development of multistation is one of the most effective ways to compare the wear data for multiple contact pairs. The wear factor estimated for R and R+R mode for UHMWPE material is $0.25\times 10^{-6} mm^3/Nm$ and $1.388\times 10^{-6} mm^3/Nm$. In advanced bio-tribometer, the wear factor obtained using 8 shaped wear track, is $2\times10^{-6} mm^3/Nm$. Therefore, it is clearly observed that the value of wear factor estimated using advanced bio-tribometer for variety of motion simulations is quite satisfying and obeys the literature referred (Saikko, 2014 & Baykal, 2013).

The effect of variably cross linked (virgin, 50 kGY, 75 kGY) UHMWPE is analyzed in wear testing. It is found that the wear resistance is increased with increase in cross linking dose.

In the advanced bio-tribometer study, from the Sommerfeld plot, it is observed that the coefficient of friction decreases as Sommerfeld number increases. Therefore, the type of lubrication is found to be a mixed lubrication. In Co-Cr-Mo alloy / UHMWPE material contact the coefficient of friction is found in the range of 0.02 to 0.06, which is also observed in several literature studies.

In most of the LPW flanged cups the impingement of femoral neck with cup flange is observed giving rise to digs and pits. It is observed to be a common phenomenon in LPW flanged cup.

The creep although found to be major in the initial part of implantation, is major contributory role in this investigation. Around 376 mm^3 volumetric wear is estimated due to change in shape of cup.

The effect of rotational component of motion in addition to reciprocation seems to be immense in the wear estimation. The shear of pin is observed due to change in path and crossing path wherein there is a continuous shift of pin rotational axis, contributing to overall wear.

Specific contributions

1. New method for *ex-vivo* investigation of retrieved hip implants is proposed using non-contactable white light interferometer to understand the wear analysis.
2. Conventional wear measuring test rig (*pin-on-plate*), is modified to account for a multidirectional motion by having a combined reciprocating and rotating (R+R) motion.
3. In order to have a comprehensive wear characterization and achieve more accurate results comparable to clinical wear, conventional tribometer is modified to simulate motion and lubrication conditions at the articulating surfaces of hip joint. This advanced bio-tribometer can be utilized for any joint applications.

Recommendations

1. In order to understand the wear analysis of any candidate pair of materials for any joint applications, white light interferometry is recommended.

2. In order to obtain results more close to the clinical wear, wear screening device like advanced bio-tribometer is recommended, which can simulate the actual motion profile across any joint applications.

Future Scope of Work

- Material pair like Ceramic on UHMWPE, can be tested in hip implant applications, can be tested for the validation of advanced bio-tribometer, which can be compared with clinical wear studies.
- This study can be compared with hip simulator study.
- Effect of change in protein content in bovine serum can be studied in wear analysis.

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List of Publications Based on the Present Work

1. Kulkarni A C & Kulkarni D M (2015): *Wear Depth Distribution at Articulating Surfaces of Hip Prosthesis using Non-Contact Interferometer*. International Conference on Biomechanics and Implant Design, July 27-29, USA, Florida.

2. Anant Kulkarni, Anirudh Dube, D.M.Kulkarni, Amit Ganguli, J.A.Pachore (2014) *Design and Development of Wear Screening Device for Prosthetic Hip Joint Materials using Retrieval Studies.* 2nd International Conference on BioTribology, 11-14 May 2014 | Sheraton Centre Toronto, Toronto, Canada. Organized by Elsevier.

3. Kulkarni A C & Kulkarni D M (2012): *Wear Characteristics of X linked UHMWPE material using Conventional Tribometers and Digital Light Spectrometry*. Asian Tribology Conference, ASIATRIB-2014, 17-20 Feb-2014, organized by Tribological Soc of India (TSI).

4. Kulkarni A C & Kulkarni D M (2012): *Current Experimental Trends in Tribological Testing of Hip Prosthesis Materials and Proposed Novel Method for Experimental Testing TSI812629*. 8th International conference on Industrial Tribology (ICIT 2012), organized by Tribological Society of India at Koregaon Park, Pune (7th–9th Dec 2012)

5. Kulkarni A C, Kulkarni D M, Kudchadkar M S. *Axisymmetric Contact Stress Analysis for Artificial Hip Joint*. Research Book BIO and MEDICAL TRIBOLOGY by Prof. J. Paulo Davim, Department of Mechanical Engineering, University of Aveiro. NOVA Science Publishers, USA. Ch-4, pp: 1-13. (2011)

6. Kulkarni Anant C., Kulkarni D. M. (2011). Miniature Representation of hip joint using image processing and cad software" International conference on Control Instrumentation and Systems Conference (CISCON-11), 3–6 Nov-2011 at Manipal University. 217-219.

Other Publications:

1. S.K. Roy Chowdhury, A.C.Kulkarni (2007): Wear characteristics and biocompatibility of some hydroxyapatite-collagen composite acetabular cups, Wear 262(2007) 1387-1398.

2. Anant.C.Kulkarni (2006): Development of Natural Biocomposites for Hip prosthesis. Presented research paper in the XVI National Society of Biomaterial and Artificial Organs conference. February 24-26, 2006, Indian Institute of Technology Delhi, India.

Special Acknowledgements

1] Authors thank M/S DUCOM Instruments, Pvt. Ltd, Banglore for their financial [INR 15.00 Lakhs] and intellectual support for the project (under MoU, Dated: 29-Sep-2012):

Experimental Investigation of Friction and Wear Mechanism for Hip Prosthesis Material using Multi-Station Orbital Tribometer **[June-2011 to Dec-2013]**

2] Authors thank the funding agency for their financial and intellectual support which is mentioned in below Table for the project:

Experimental Wear Analysis of an Artificial Hip Implant Materials using Advanced Tribometer Customized for Bio-Tribological Studies

#	Funding Agency	Amount (Rs. In Lakhs)
1	Aditya Birla Sci & Technology Center (ABSTC)	10.00
2	DUCOM Instruments, Banglore (under MoU, Dated: 15-Feb-2013)	21.50
3	Department of Sci & Technology (DST, New Delhi)	25.00
4	Shalby Hospital, Ahmedabad (Dr. J A Pachore	Medical Inputs and Retrieved Cups
	TOTAL	56.50

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