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***In-vitro* wear assessments of fixed and mobile UHMWPE total knee replacement**

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1. ABSTRACT

This work discusses the wear behaviour of two different ultra-high-molecular-weight-polyethylene (UHMWPE) tibial component designs. Mobile and fixed bearings were tested on a knee wear simulator for 5 million cycles using bovine calf serum as lubricant. We correlated the wear results with the chemical characterization of the investigated materials: Fourier Transformed Infra Red Spectroscopy analyses, Differential Scanning Calorimetry and cross-link density measurements were used to assess the chemical features of this polyethylene.

Mobile and fixed polyethylene inserts showed a different wear behaviour: the mobile designs components showed lower weight losses than the fixed components (109 ±6 mg and 163 ±80 mg, respectively). Significant statistical differences were observed in wear rate ($P = 0.035$, Kolmogorov-Smirnov Test for two samples).

From a molecular point of view, typical radiation-induced oxidation profiles were observed in all the tested polyethylene samples, but the overall degradation was more significant in the fixed bearing inserts and this is likely to play a role on the wear performances.

Keywords: wear; mobile TKR; fixed TKR; FTIR analyses; crystallinity.

2. INTRODUCTION

It is well known that the oxidative degradation of ultra-high-molecular-weight-polyethylene (UHMWPE) decreases its mechanical properties, leads to the formation of wear debris and consequently may induce biological responses that cause osteolysis and implant loosening [1-5]. The goal is to develop improved materials in order to extend the lifetime of orthopaedic implants up to 30 years. Several new and pending products aim to address this issue and laboratories wear test can help on this matter.

The objective of wear evaluation is to determine the wear rate and its dependence on the test conditions (i.e. load, range of motion, lubricant and temperature). Under the same material chemical characteristics, wear of knee prosthesis depends on its geometry, kinematics conditions, and absence or presence of soft-tissue. A wear test reproducing *in vivo* working conditions must be performed to obtain realistic results.

Wear mechanisms at the articular surfaces of knee prostheses, are influenced by many factors (including load, motion pattern, component geometry, absence or presence of soft-tissue, etc.) that can cause knee failures [6, 7]. Contact kinematics has been identified as the dominant factor affecting UHMWPE wear in total knee replacement (TKR) [8, 9]. Nevertheless contradictory results are often found in the literature as far as wear on the polyethylene is concerned when mobile or fixed bearing inserts are implanted/tested [10-14]. However, in most of the studies on this subject, almost little or no attention was paid to the material chemical characteristics, such as oxidation, degree of crystallinity and cross-link density, which have often been demonstrated to strongly influence the wear performances [3, 15, 16]. In particular, oxidative degradation is known to reduce the wear resistance of ultra-high molecular weight polyethylene, while cross-linking improves it [17, 18].

TKR implants include both mobile- and fixed-bearings designs. As of now, there is controversy over which design provides superior results [19-21]. Fixed-bearing (FB) knee prosthesis is a knee arthroplasty in which the tibial component is fixed to the tibial bone and does not allow movement of the bearing surface. On the other hand, the concept of the mobile-bearing (MB) knee prosthesis was developed in order to create a dual surface articulation, with a polyethylene insert that articulates in between a metallic femoral component and a tibial tray [22]. This leads to larger contact areas, lower contact stresses and, theoretically, better wear advantages over the fixed bearing. Nevertheless, both designs show excellent survival rates of up to 95% in

10-year follow-up [23-25] and comparative studies could not demonstrate the superiority of one or the other design [26-29].

To gain more insight into this subject, the present study is aimed at comparing the *in vitro* wear behaviour of mobile and fixed UHMWPE TKR designs, using the same knee simulator under bovine calf serum as lubricant. Furthermore, we aimed at investigating if and how the physico-chemical characteristics of radiation-sterilized UHMWPE can influence the wear performances. The wear behaviour of mobile and fixed UHMWPE bearings was comparatively evaluated by gravimetric measurements, while chemical analyses were performed at a molecular level. At this regard, Fourier Transformed Infra Red Spectroscopy (FTIR) Microscopy, Differential Scanning Calorimetry (DSC) and cross-link density measurements were used in order to monitor chemical properties across the tibial insert section.

3. MATERIALS AND METHODS

3.1 Specimens tested

The wear behaviour of TKR fixed and mobile bearing UHMWPE knees (Size #2, 4 specimens for each batch) was investigated using commercially available designs. Each polyethylene tibial insert was coupled with CoCrMo femoral and tibial components. A schematic draft of the mobile and fixed bearing design is showed in Figure 1. The conventional polyethylene resin (GUR 1050) was surgical grade consolidated by compression moulding (according to ISO 5834/2) and γ-sterilised (30 ±4KGy).

Following a standardized protocol [30], all the UHMWPE inserts were pre-soaked for four weeks before the wear tests was performed. This was conducted in order to achieve a steady level of fluid absorption as recommended by (ISO 14243) international standard.

3.2 Wear test details

A wear test with the same knee simulator and the same kinematics was performed for each design (fixed and mobile). In particular, each wear test ran for five millions cycles using a "three-plus-one" stations simulator (Shore Western Mfg., Monrovia, USA). Three specimens were placed on three different stations while the fourth station was taken by the soak control specimen. Testing was performed to estimate the total change in mass due to lubricant absorption, according to ISO 14243-3. Alignment and load components (axial load, anterior/posterior translation, intra/extra-rotation, flexion/extension) reproduced a simplified gait cycle, as it is usually applied in our laboratory [31-34] and according to ISO 14243-3. Load was applied vertically (perpendicular to the tibial tray), and oscillating in the range 168 to 2600 N to reproduce a physiological profile. The applied kinematics was in displacement control for the following degrees of freedom:

a. flexion/extension (F/E) angle oscillating between 0° (neutral) and 58° (flexion) synchronously with the load;

b. anterior/posterior (A/P) translation oscillating between 0.0 mm (neutral) and 5.2 mm (posterior);

c. intra/extra-rotation (I/E) oscillating between 21.9° (extra-rotation) and 5.7° (intra-rotation).

The soak control station allows only synchronous axial load of the same amplitude of the one applied on the three test specimens.

The lubricant used was 25% (v/v) sterile bovine calf serum (SIGMA, St. Louis, MI) balanced with deionised water and 0.2% sodium azide (E. Merck, Darmstadt, Germany) to prevent bacterial degradation. The lubricant was maintained at a constant temperature of 37 ± 2 °C during the entire test. Each wear test was run at a frequency of 1.1 Hz. Gravimetric wear of the tibial specimens was assessed at 500,000 cycle intervals. Weight loss was measured using a microbalance (SARTORIUS AG, Göttingen, Germany) with an uncertainty of ±0.01 mg. Each weight measurement was made in triplicate.

A statistical analysis (Kolmogorov-Smirnov non parametric test [35]) was applied to correlate the wear behaviour among all polyethylene samples tested in this study. Statistical significance was set at $P < 0.05$.

3.3 FTIR spectroscopy

A FTIR Microscope (Spectrum Spotlight 300, Perkin-Elmer, Shelton, Connecticut, USA) was used to investigate the chemical characteristics through the thickness of the components. A series of 180 μm thick slices of UHMWPE was microtomed perpendicularly to the articulating surface. A PolyCuts Microtome (Reichert-Jung, NuBlock, Germany) was used at a rate of 10 mm/s in air at room temperature. Line-scan spectra were collected by setting the area of analysis at 100 x 100 μm^2; the spectra were recorded every 100 μm along the mapping direction, starting from the articulating surface towards the bulk. For the worn inserts, two separate line scans were collected: the first one was performed starting from the most worn area of the bearing surface, the second one was collected starting from the unworn surface of the same sample. We assumed that the analysis of the unworn area could give a reliable picture of the chemical characteristics of each specimen surface prior to wear testing. All spectra were run in the transmission mode with a 4 cm^{-1} resolution and 16 scans per spectrum, and were normalised at 2020 cm-1 at an absorption of 0.05, corresponding to a film thickness of ca. 100 μm. The peak at 2020 cm^{-1}, a combination band associated with the twisting of CH_2, was used as an internal standard, since it can be regarded as unaffected by minor changes in the polymer structure [36].

The molar concentration of trans-vinylene double bonds was calculated from the 965 cm^{-1} absorption band, using the molar absorptivity proposed by De Kock and Hol [37].

The FTIR ketones absorption at 1718 cm^{-1} was used to characterize the oxidation in the specimens. An oxidation index was calculated, in accordance to ASTM F2102, as the area ratio of the carbonyl peak (between 1650 and 1850 cm^{-1}) to the 1370 cm^{-1} reference peak (between 1330 and 1390 cm^{-1}) from the FTIR spectra.

The surface oxidation index (SOI) was calculated as the average of the oxidation indices of the first 3mm of the sample, while the maximum oxidation index (OI) was calculated as the local oxidation index corresponding to the strongest ketones absorption.

3.4 Determination of crosslink density.

The crosslink density was quantified by gravimetric measurements. Small cylinders with diameter of 3 mm and approximate weight of 15 mg were cut out of the inserts and soaked in xylene at 135°C for 3 hours. Two separate measurements were taken on each sample: one specimen was obtained from the unworn region of the bearing surface, the other was cut from the inner bulk. All the experiments were run in triplicate.

The swell ratio (ρ) was calculated as:

$$\rho = \frac{(V_s + V_x)}{V_s} \quad (1)$$

where V_s is the initial volume of the sample, calculated by dividing the initial weight of the sample by the density of UHMWPE (assumed to be 0.93 g/cm^3), and V_x is the volume of the absorbed xylene, calculated by subtracting the initial weight of the sample from its final xylene-swollen weight and dividing the result by the density of xylene (0.75 g/ cm^3).

The measured ρ values were used to determine the crosslink density, ν_d. The molecular weight between crosslinks, M_c, was calculated using the equations reported by Muratoglu [38].

3.5 Crystallinity.

The crystallinity of the tested samples was determined using a DSC (DSC 6- Perkin-Elmer, Waltham, Massachusetts, USA) at a heating rate of 10°C/min. Again, two distinct regions were tested, one representative of the surface layer (depth < 1mm, unworn area) and the other one of the bulk region (depth > 3mm). All the experiments were run in duplicate. The sample weights varied around 5 mg. The heat of fusion was calculated by integrating the DSC endotherm from 60 to 160°C. The crystallinity was calculated by normalizing the heat of fusion to the heat of fusion of 100% crystalline polyethylene (293 J/g) [39].

4. Results

All commercial knee specimens completed all tests. The cumulative (medial plus lateral) weight loss for the two different designs (mobile and fixed) was generally lower for the UHMWPE mobile bearings; an average mass loss of 109 ±6 mg and 163 ±80 mg was measured for the MB and FB specimens, respectively. The variation in volumetric wear versus the number of cycles for all inserts is plotted in **Figure 2**. The MB configurations showed wear differences compared to the FB configuration (P = 0.035, Kolmogorov-Smirnov Test for two samples). However, it must be stressed that one FB specimen (#2) wore significantly more than the other ones.

Visual and microscopic examinations of the bearing surfaces revealed a large damaged areas (16*20 mm) on both medial and lateral condyle for each design; the femoral components showed similar surface features: unidirectional scratches were observed, on both medial and lateral condyle for each design, and along the A/P direction (**Figure 3**). The tibial insert showed longitudinal scratches along the A/P direction and burnishing phenomena indicating a predominance of adhesive wear (**Figure 4**), in agreement with findings by Barnett and co-workers [10].

FTIR measurements showed the presence of a trans-vinylene absorption at 965 cm^{-1}, which is well known to be related to irradiation [40, 41]. The trans-vinylene absorption was constant through the inserts cross section, indicating an homogeneously distributed irradiation dose. The trans-vinylene concentration varied between 2,8 mmol/l and 3,3mmol/l among the different samples.

Figure 5 (Parts a and b) shows the FTIR line-scan collected along the cross-section of the unworn and worn region of FB#2, respectively. The strong absorption centered at 1718 cm^{-1} can be attributed to the presence of oxidation products (ketones), whose concentration is maximum at the bearing surface and decreases towards the bulk. Previous studies have shown that absorption of lipids from the synovial fluid in vivo or from the calf serum used as lubricant during in vitro testing may result in a well-defined ester peak absorbing at 1740 cm^{-1}. Besides interfering with the calculated gravimetric wear rate [42], this absorption may complicate the interpretation of the spectra and the calculation of the oxidation index [16, 43]. We verified that the carbonyl peak at the unworn surface of our inserts primarily consisted of a single ketone peak (see

Figure 5). We also soaked thin sections cut from the inserts in boiling cyclohexane for up to 6 hours and we found no significant changes to the oxidation profiles after extraction.

Evidences of oxidation were observed on all samples, although to different levels. No significant differences in oxidation were observed among the worn MBs. The results of MB#2 are then commented hereafter as representative of the MBs group. The maximum oxidation index (OI) calculated on the worn and unworn region of each investigated sample, and the average surface oxidation index (SOI) calculated on the unworn region are reported in Table 1. In all cases, the maximum OI was located right at the surface level. The degree of crystallinity of the polyethylene inserts was constantly higher on the surface than in the bulk (**Table 2**). The cross-link density of the bulk region of the inserts, measured in term of molecular weight between cross-links (M_c), varied between 13500 g/mol for the most heavily oxidized FB#2 and 11000 g/mol for the mildly oxidized control sample MB#4. In contrast, while trying to measure the cross-link density of the surface region of the inserts, we observed that a significant fraction of polyethylene was dissolved into xylene, thus making a reliable calculation of cross-link density impossible.

5. Discussion

Given the long term issues of polyethylene wear in TKR, clinicians are increasing their interest in new designs. A debate remains about the clinical difference between fixed or mobile bearing TKR. In this study, we were wondering whether mobile TKR design would result in a similar/altered/different wear mechanism with respect to a fixed TKR using the same knee simulator, the same kinematics, and the same size of the UHMWPE inserts. We have also investigated the chemical properties of the tested UHMWPE, in order to evaluate their influence on the observed wear performances.

The UHMWPE components were gamma sterilized, but details such as sterilization atmosphere (air or inert) were not specified, as it often happens in commercial products. We used the trans-vinylene groups concentration calculated from the FTIR spectra to assess the actual absorbed radiation dose, following a standardized internal procedure. Radiation doses ranging between 26 and 31 kGy were calculated, in accordance with the manufacturer declaration.

All the UHMWPE inserts, including the control unworn samples, showed a characteristic oxidation profile (**Figure 5**), which can be attributed to the radiation sterilization in the presence of oxygen [44, 45]. Nevertheless, significant differences in the oxidation levels were observed among different samples (Table 1). In particular, while the MB samples showed similar and lower oxidation indexes, significant variations were observed among the FBs, with FB#2 having the highest OI and SOI in the unworn region, followed by FB#1 and FB#3, respectively. The observed differences are not surprising, since it is widely known that the development of a specific oxidation profile results from a combination of heterogeneous parameters, such as irradiation dose rate, temperature of the sterilization facility, oxygen availability, etc. [44]. This often result in significant differences in the oxidation level, even among samples that have identical characteristics (starting material, manufacturing cycle, design, etc.), except for the sterilization batch.

The OI observed in the worn region of all tested samples was constantly lower than that of the unworn region, probably because degraded material had been previously removed from the surface by wear, as suggested by the comparison of Figure 3a with 3b. The absence of an FTIR absorption centered at 1740 cm^{-1} on both the worn and the unworn region indicates that diffusion of lipids from the lubricant into UHMWPE was not significant in the present conditions. This is in contrast with previous findings [42].

The observed surface oxidation was accompanied by an increase in crystallinity (**Table 2**). A slight increase in crystallinity is always observed in irradiated UHMWPE, being the result of “tie” chain scission, due to irradiation, and rearrangement of those chains into the crystalline structure [46]. Nevertheless, the higher crystallinity observed here on the surface of the inserts, compared to that of the bulk, is a result of further rearranging of smaller chains formed as a part of the oxidation and chain scission cascade [47, 48].

The existence of a low molecular weight polyethylene fraction created by radiation-induced degradation is confirmed by the results of the cross-link density measurements: while the cross-link density found in the bulk of the inserts is more or less consistent with a moderately cross-linked, radiation sterilized UHMWPE [38], the same measurement on the oxidized surface region resulted in solubilisation of a significant fraction of the material.

It is well known that a correlation between the molecular structure of polyethylene and its wear resistance exists and highly cross-linked polyethylene has been developed to address the need of a higher-molecular weight polyethylene with improved wear performance [15]. Thus, the observed degradation is certainly detrimental for the wear performances of UHMWPE.

Although consistent literature on TKR wear tests became available in the last years, to the authors' knowledge, there are not many reports describing in detail both the wear performances and the chemical characterization of implants with different designs, tested with the same knee simulator. The chemical characterization of our samples indicates that the fixed bearings have a more significant degradation in both their upper and lower surfaces. This molecular degradation is likely to be responsible for an increased wear rate of UHMWPE, as well as the multidirectional motion pattern in the femoral articulation of the fixed design, which, as observed by other authors [49, 50], results in a cross-shear stress on the polyethylene contact surface. Moreover, degraded polyethylene on the lower surface of the insert can also exacerbate the backside wear phenomenon, to which fixed bearing designs are known to be particularly subjected [51]. These observations appear in agreement with the wear test findings, which indicate a better wear behaviour (in terms of weight loss) of the mobile design, even if the mobile components are free to move in any direction on the tibial tray, resulting in having two articulating interfaces and, therefore, the potential of increased UHMWPE wear. Although large damaged areas were observed on both medial and lateral condyle for each design, as well as a burnishing phenomena indicating a predominance of adhesive wear during knee wear simulation, gravimetric results showed that mobile components worn less than fixed components: the mean gravimetric wear rates were 21.9 mg/million cycles for the mobile and 32 mg/million cycles for the fixed knee design, respectively. These results were in agreement with other studies that compared mobile ***vs***. fixed designs using displacement and force control simulators [14, 51, 52].

The oxidation trend (FB#2> FB#1> FB#3 > MBs) basically reflects an inverse wear resistance trend, even if a moderately higher oxidation level for FB#2 does not account completely for the dramatic difference observed in the wear test. Also, the significant difference in oxidation between FB#3 and MBs does not support the practically insignificant differences in wear. These observations suggest that a more complex set of parameters must be taken into account to determine the wear performance.

In conclusion, mobile and fixed bearing designs showed significant statistical differences in wear rate: the mobile bearings exhibited a better wear behaviour, but this may be due either to a more advantageous design or to better material chemical characteristics (i.e. less oxidative degradation) or to a combination of the two.

It is recognized that the small number of specimens is a limitation of this study, even if such wear test is expensive and time consuming. Also, it could be questionable if an extended sample size would be sufficient to distinguish the wear behaviour between the two configurations. In particular, the overlapping of two concurrent variables (surface chemical characteristics and design) always makes the overall interpretation of the wear performance a difficult task.

6. Conclusions

This study demonstrated significant differences in the oxidation levels between mobile and fixed TKR designs. All the UHMWPE inserts, including the control unworn samples, showed a characteristic oxidation profile which can be attributed to the radiation sterilization in the presence of oxygen.

The overall results of the physical and chemical characterization indicate that the oxidized surfaces of the inserts were already chemically degraded before the wear test. Moreover, they suggest that the present wear experiment, as well as the majority of those involving commercial products, radiation-sterilized in the presence of oxygen, has been performed on samples exhibiting different starting levels of oxidation (i.e. different starting mechanical properties). Overall, we are unable to draw a definite conclusion regarding the advantage of one configuration over the other: the wear experiments seem to indicate a more favourable behaviour of the MB configuration, but the chemical characterisation demonstrated that the FB specimens were more degraded from a chemical point of view and this has certainly influenced the wear performances, independently on the design.

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Tables & Figures Captions

Table 1 – Average surface oxidation indexes (SOI) and Maximum oxidation indexes (OI) of representative samples.

Table 2 – Peak melting points and percentage of crystallinity of representative samples.

Figure 1 – Total knee prosthesis tested using a knee simulator: Parts A) & B) show the mobile and fixed designs, respectively.

Figure 2 – Wear behaviour of mobile vs. fixed UHMWPE bearings design tested using a knee simulator.

Figure 3 – Unidirectional scratches were observed, on both medial and lateral condyle for each design, and along the A/P direction. Part A) and Part B) show the femoral components for the fixed and the mobile design, respectively.

Figure 4 – Longitudinal scratches along the A/P direction and burnishing phenomena were observed on both medial and lateral condyle for each design, and along the A/P direction. Part A) and Part B) show the polyethylene menisci for the fixed and the mobile design, respectively.

Figure 5 – FTIR line-scan collected on the specimen FB#2, along the cross-section of the unworn (Part A) and worn region (Part B).

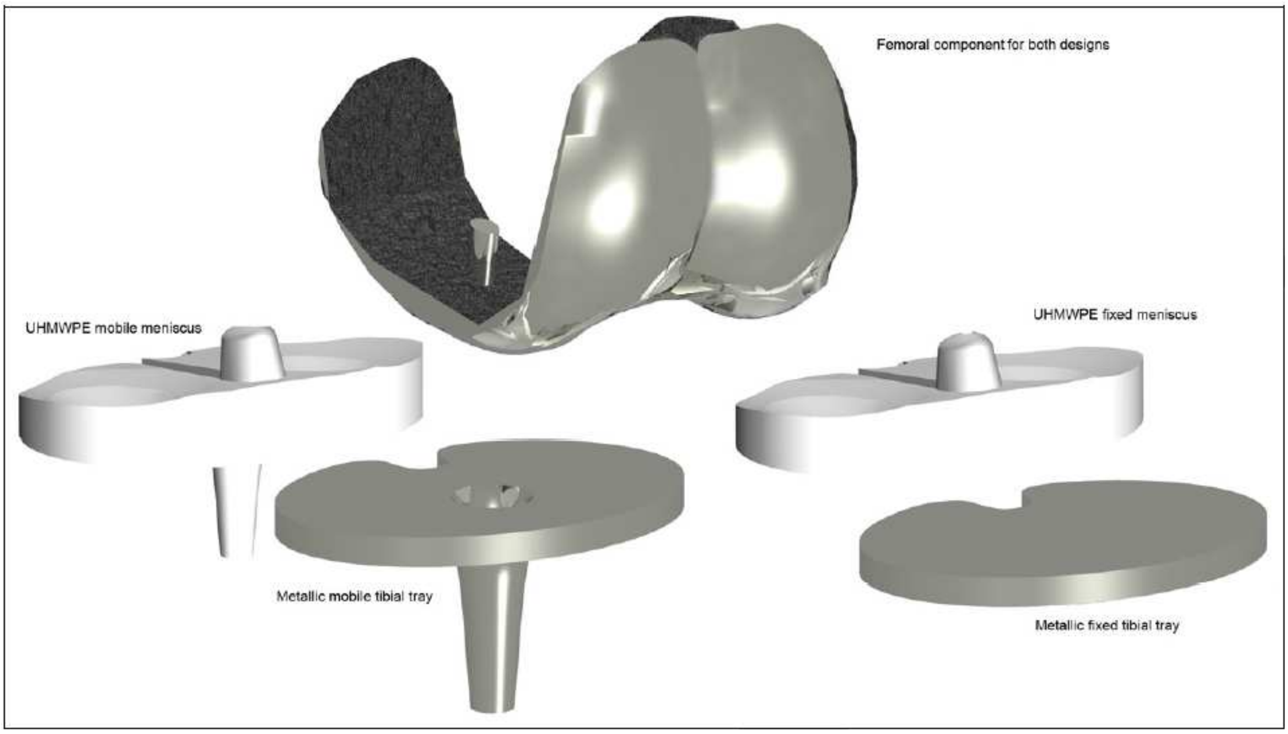


Figure 1 – Total knee prosthesis tested using a knee simulator: Parts A) & B) show the mobile and fixed designs, respectively.

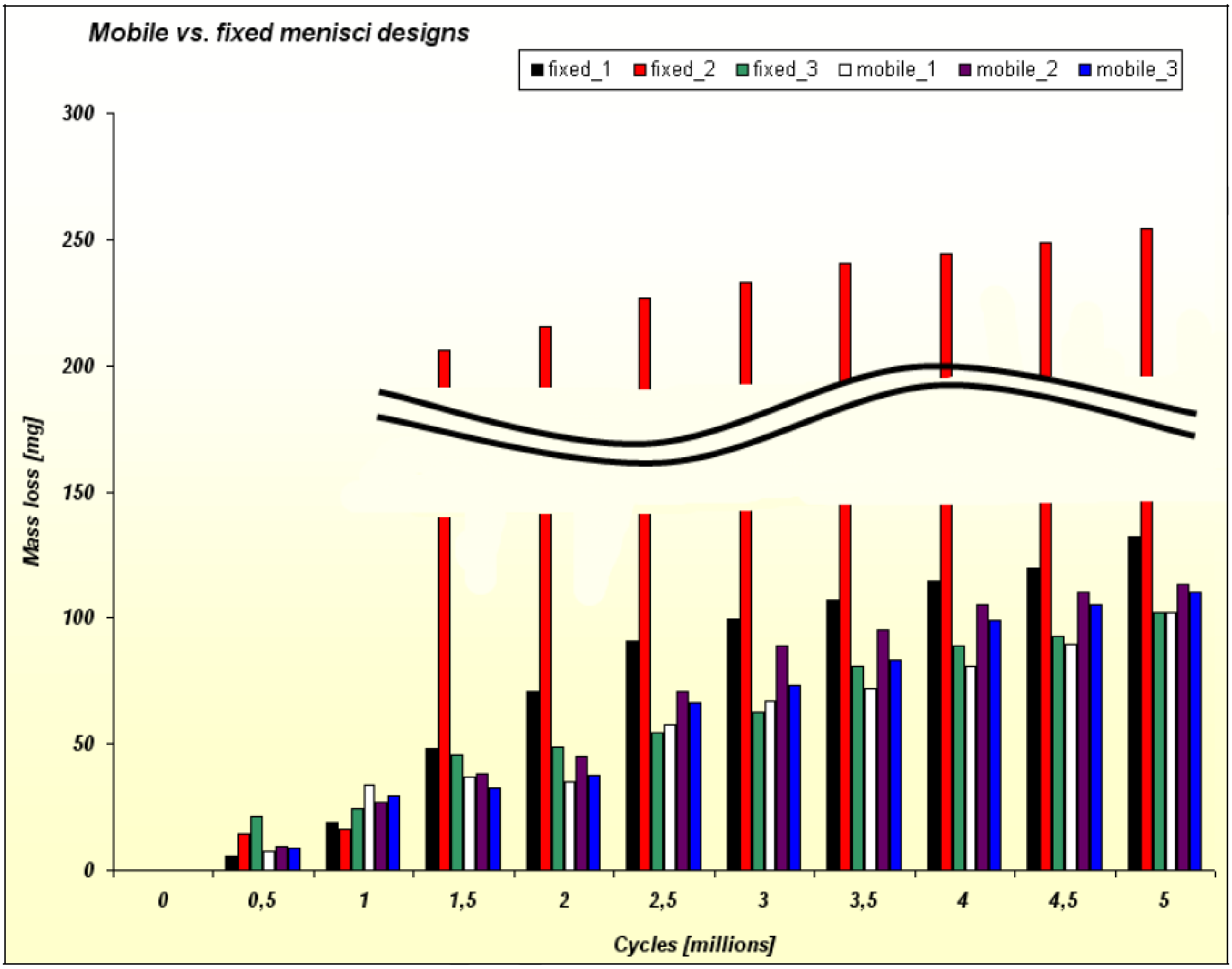


Figure 2 – Wear behaviour of mobile vs. fixed UHMWPE bearings design tested using a knee simulator.

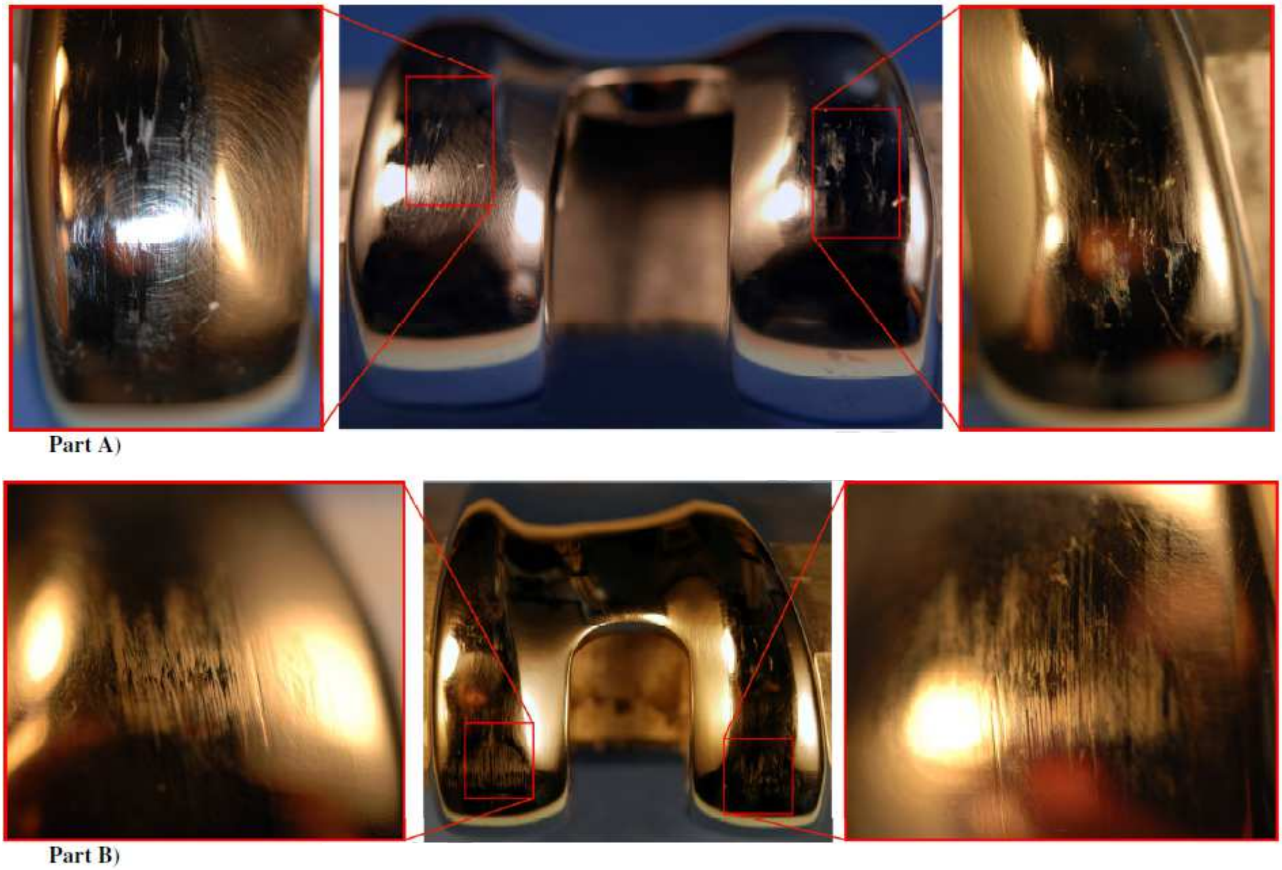
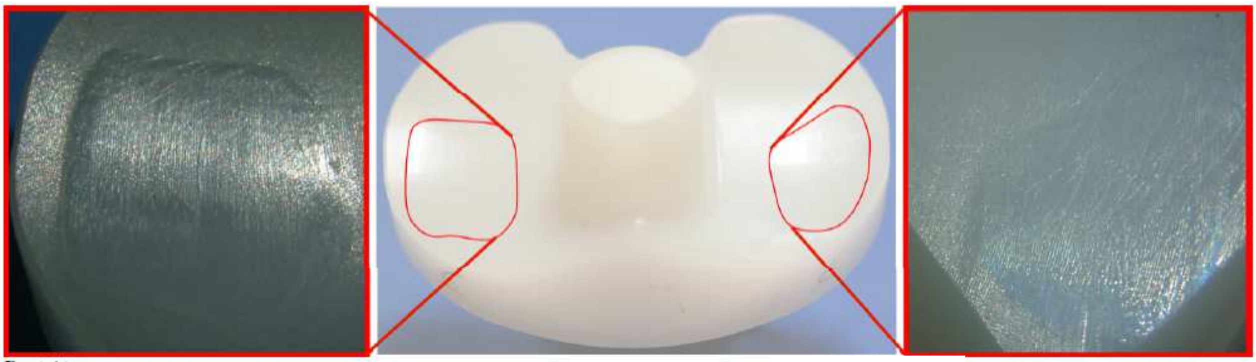
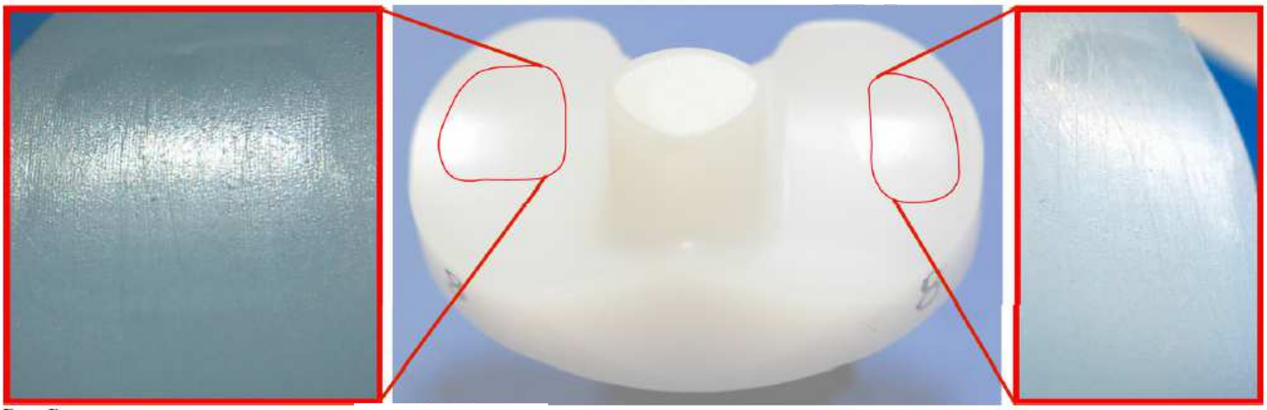


Figure 3 – Unidirectional scratches were observed, on both medial and lateral condyle for each design, and along the A/P direction. Part A) and Part B) show the femoral components for the fixed and the mobile design, respectively.



Part A)



Part B)

Figure 4 – Longitudinal scratches along the A/P direction and burnishing phenomena were observed on both medial and lateral condyle for each design, and along the A/P direction. Part A) and Part B) show the polyethylene menisci for the fixed and the mobile design, respectively.

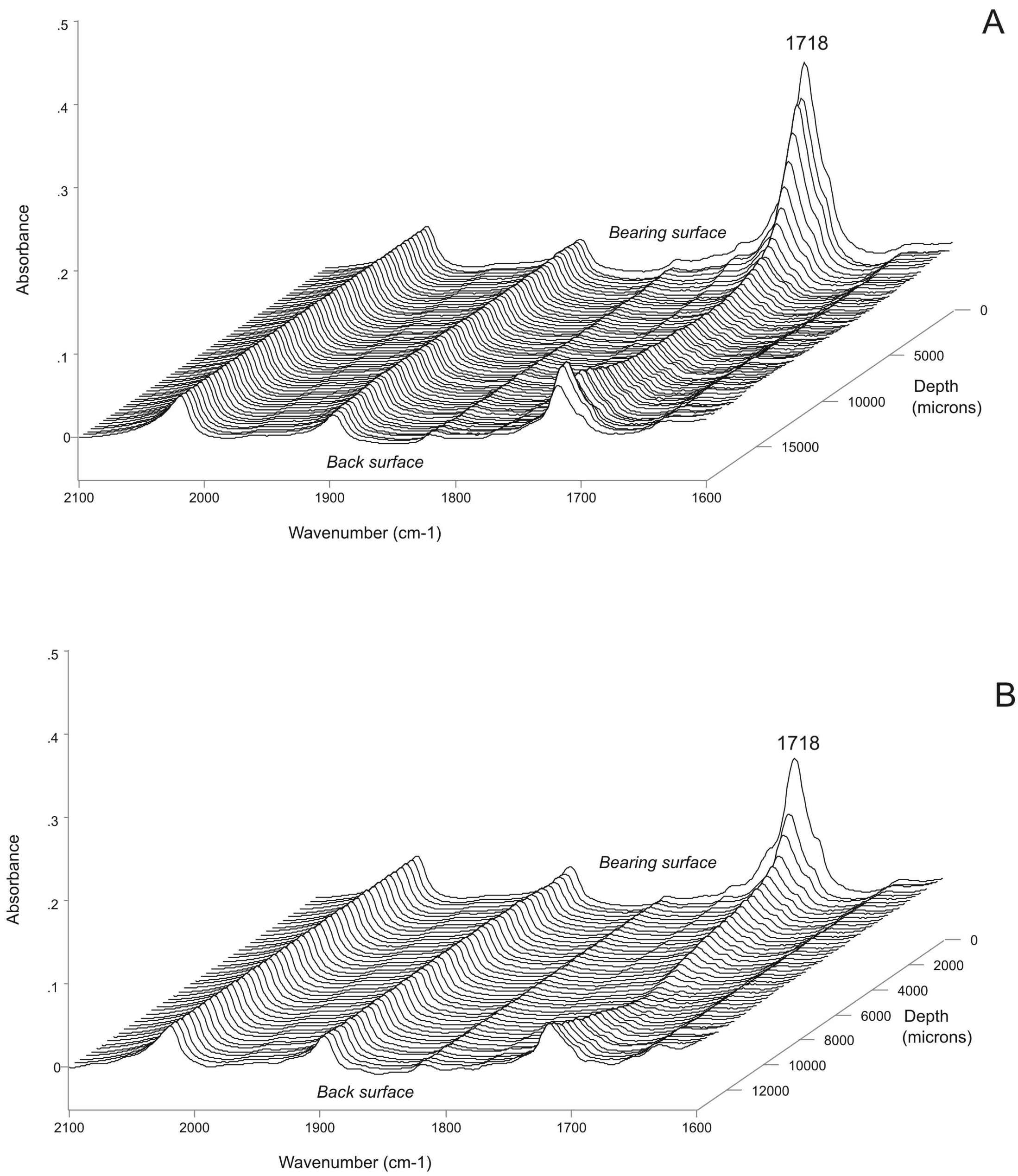


Figure 5 – FTIR line-scan collected on the specimen FB#2, along the cross-section of the unworn (Part A) and worn region (Part B).

Sample	Average Surface Oxidation Index (SOI) Unworn region	Maximum Oxidation Index (OI) Unworn region	Maximum Oxidation Index (OI) Worn region
Fixed_1	0.8	1.8	1.5
Fixed_2	1.0	2.5	1.2
Fixed_3	0.5	1.0	0.9
Mobile_2	0.2	0.5	0.4
Mobile_4(CTRL)	0.2	0.6	-

Table 1 – Average surface oxidation indexes (SOI) and Maximum oxidation indexes (OI) of representative samples.

	T_m (°C)	% Crystallinity
FB#2 unworn surface	135 ±1.0	53,6±1.2
FB#2 bulk	138± 0.8	48,6±0.9
MB#2 unworn surface	139±0.5	53,6±1.0
MB#2 bulk	137±0.6	49,4±0.7
MB#4 CTRL surface	138±0.5	53,1±1.0
MB#4 CTRL bulk	136±0.7	48,8±0.5

Table 2 – Peak melting points and percentage of crystallinity of representative samples.