Long-term in-vitro wear performance of an innovative thermo-compressed cross-linked polyethylene

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LONG-TERM *IN-VITRO* WEAR PERFORMANCE OF AN INNOVATIVE THERMO-COMPRESSED CROSS-LINKED POLYETHYLENE

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NOMENCLATURE

PE-A	conventional PE GUR-1020 (EtO-sterilized)
PE-B	conventional PE GUR-1020 (γ-sterilized)
PE-C	conventional PE GUR-1050 (γ-sterilized)
XLPE	cross-linked PE GUR-1020 (EtO-sterilized)
XLPE-RT	cross-linked-Thermo-Compression PE GUR-1050 (EtO-sterilized)
Mc	Million cycles
KW	Kruskal-Wallis non-parametric statistical tests
KS	Kolmogorov-Smirnov non-parametric statistical tests

1 ABSTRACT

New cross-linked polyethylene acetabular cups, obtained by thermo-compression process, were compared with conventional and traditional commercially available cross-linked polyethylene in terms of wear behavior in a hip simulator for 10 millions cycles using bovine calf serum as lubricant.

Gravimetric measurements revealed significant differences between the wear behaviors of the five sets of acetabular cups. In particular, this new type of thermo-compression crosslinked wore more than the traditional cross-linked polyethylene but exhibited a wear rate about four times lower than conventional UHMWPE.

The FTIR analyses indicate that oxidation to various extents appears as a consequence of γ-irradiation in presence of oxygen.

Keywords*:* PE GUR-1020; PE GUR-1050; Wear, Long-term wear behavior; Conventional UHMWPE; FTIR analysis; Oxidation.

2 INTRODUCTION

The research to improve the life of a patient that had a hip implant remains **a** major concern **of** scientists in the world. It is well know that ultra-high-molecular-weight-polyethylene (UHMWPE) is the most commonly used material in orthopaedics implants even if wear due to this material represents a serious clinical problem [1]. Excessive wear may lead to gross mechanical failure such as fracture and disassociation [2] and the release of particulate wear debris may induce biological responses that cause implant loosening [3, 4]}. Medical grade resins are described as GUR-1020 e GUR-1050 depending on their molecular weights. The requirements for medical grade UHMWPE powder are specified in ASTM standard F648 and ISO standard 5834-1. These standards characterize powders on molecular weight, trace impurities of titanium, aluminium, and chlorine (residuals from catalysts), and ash content. No analysis is required on the final form that can be achieved by different processes [5-7]; these may not produce uniform conditions in the manufactured shape and there is still no consensus on which resin and conversion method would be universally proposed as the best choice for all the orthopaedic applications.

At the moment, the focus of research in total joint arthroplasty has shifted to improve the wear performance of conventional UHMWPE and increase its mechanical properties, such as yield stress and Young's modulus. To this end, increasing the cross-linked density is well established as a promising solution to improve the wear resistance and durability of polyethylene [3, 8]. The molecular chain structure at the articulating surface of polyethylene is believed to undergo a reorganization process due to strain accumulation caused by surface traction [9]. This altered polyethylene responds to stresses favourably if loaded along the fiber axis but unfavourably if loaded off axis [10]. Several different manufacturing processes have been developed to increase the wear characteristic of conventional polyethylene in order to achieve the so-called cross-link polyethylene (XLPE). The industrial process consists to treat the UHMWPE with high-energy radiation, peroxide, or silane treatments [3, 8, 11]. The common factor of these aforementioned processes, is the treatment with γ-irradiation or e-beam at dose between 40 to 100 kGy [1, 3, 8, 9, 11-14]) before the machining of PE bar into the final form; this increase the crosslinking density and improve wear resistance of the conventional polyethylene. Radiation-induced cross-linking of UHMWPE has been shown to improve wear resistance by up to 5 fold if compared to conventional polyethylene [15-17]. This decrease in wear has been observed in clinical studies [18, 19], in laboratory tests using hip joint simulators [8, 20, 21], and under both ideal and severe wear conditions [14, 22].

However, as the level of polyethylene cross-linking increases, the mechanical properties, such as the ductility, yield strength, and elongation to failure decreases [1, 11, 23-25]. Moreover, this result in a decrease in the toughness [1, 26] and acetabular cups fabricated from these materials might present a risk for wear increase and catastrophic failure [24]. At this concern, improvements in the forming process of XLPE acetabular cups were implemented. In particular, a thermo-compression process, at a temperature above the melting point, follows the irradiation phase completing the manufacturing of the articulating surface of the acetabular cup. As a consequence, mechanical machining of the articulating surface is avoided and higher material homogeneity and superficial finish achieved. Absence of machining marks on the surface of the polyethylene should reduce the abrasion and this could end in improved wear resistance of the XLPE cups.

With this in mind, in this work we asked whether new cross-linked PE acetabular cups, obtained by thermo-compression process (XLPE-RT), would result in less wear than XLPE and conventional UHMWPE.

In particular, two outcomes were used as the basis for comparing wear behavior:

- Wear rate (determined from sequential gravimetric measurements during the course of the test) my be influenced by material composition (different GUR) and sterilization;
- Degree of oxidation of the acetabular cups (determined from FTIR measurements).

On the basis of an initial analysis [27] it was decided to continue testing up to 10 million cycles (Mc) in order to evaluate the long-term wear effects. This study provides additional important information to that already described [27], since it clarifies the characteristics of the long-term wear resistance of the materials.

3 MATERIALS AND METHODS

3.1 Specimens tested

The wear behaviour of 20 different polyethylene acetabular cups (28-mm inner x 44-mm outer; 4 specimens for each batch) coupled with 28-mm CoCrMo femoral heads were investigated using a hip joint simulator. The conventional PE and the XLPE resins studied were surgical grade consolidated by compression moulding according to the ISO 5834/2. More details are shown in Table 1.

Following a standardized procedure [22, 28-30], another 10 acetabular cups (two for each type of material used) were stored (non-loaded) in bovine calf serum to compensate for weight chances due to fluid absorption. All specimens were tested three months after their sterilization. All polyethylene acetabular cups were pre-soaked for four weeks prior the wear tests.

3.2 Experimental wear details

Wear tests were performed using a 12-station hip joint simulator (Shore Western, USA). The simulator set-up followed is described in details elsewhere [27, 31, 32]. Each articulating station was subjected to a sinusoidal loading (max 2 kN) with a frequency of 1.1 Hz, according to the rotation test frequency under room temperature (23 ±1 °C) conditions.

The weight loss of the cups was determined every 0.5 Mc until five Mc and every one Mc from 5 to 10 Mc. A SARTORIUS microbalance (AG, Germany) with a precision of ±0.1 mg was used to measure the weight loss during the experiments.

The effects of the different polyethylenes on wear were evaluated using ***KW*** and ***KS*** statistical tests. Statistical significance was set at $P < 0.05$.

3.3 Roughness measurements

The surface roughness of all the femoral heads was measured using a contact profilometer Hommel Tester T8000 (Hommel Werke, Germany). Scanning operations were performed identifying three planes according to previous standardized protocol [33]. Sampling lengths were taken using a cut-off of 0.08 mm. Two parameters (R_a and R_t), used to qualify the surface roughness, were taken into consideration as previously reported [33]. In particular, R_a is the arithmetic mean of the sum of roughness profile values (DIN EN ISO 4287 - 1997) and does not indicates if valleys or peaks cause the roughness. R_t is the vertical distance from the deepest valley to the highest peak of the roughness profile over the sampling length. The measurements were acquired at 0, 5, and 10 Mc.

A statistical analysis (factorial ANOVA, analysis of variance, statistical significance was set at $p < 0.05$)[34] was performed to find out whether the various surface profile parameters (R_a and R_t) of the femoral heads could predict the variance observed in the weight loss of the acetabular cups measurements. A linear regression analysis was performed between each roughness parameter and the weight loss measurements; the linear regression intercept coefficient and squared linear regression coefficient R^2 are reported.

3.4 FTIR spectroscopy

The most worn polyethylene acetabular cups (one for each batch) were cut perpendicular to the articulating surface; from the cross section a series of ca. 180 μm thick slices was obtained using a PolyCuts Microtome (Reichert-Jung) at 10 mm/s in air at room temperature. A FTIR Microscope (Spectrum Spotlight 300, Perkin-Elmer, Shelton, Connecticut, USA) was used to map the oxidation. For collecting the line-scan spectra, the area of analysis was set at 100 x 100 μm^2 and the spectra were recorded every 100 μm along the mapping direction, starting from the articulating surface towards the bulk. Each line scan was collected starting from the worn area of the bearing surface. All spectra were run in the transmission mode with a 4 cm^{-1} resolution and 16 scans per spectrum. All the spectra were normalised at 2020 cm-1 at absorption of 0.05, corresponding to a film thickness of 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 [35]. The degree of oxidation of samples was determined by the ketones absorption at 1718 cm^{-1}. Hydroperoxides were detected after reaction with nitrogen monoxide (NO) for 15 hours in a dark reaction vessel. Under these conditions, hydroperoxides in polyethylene are converted into more easily detectable nitrates at 1630 cm^{-1} as reported by Lacoste et al. [36, 37].

4 RESULTS

All the acetabular cups and the femoral heads completed the planned 10 Mc.

Compared to the different cup configurations, the XLPE-RT combination wore more than the XLPE but maintained a lower weight loss than the other conventional PE during the whole test (Fig. 1).

Significant statistical differences ($p < 0.0001$) were observed between all the polyethylene cups using the KS statistical test. The same significance (KW, $p < 0.05$) was also observed between the two cross-linked PE materials and between the three conventional PE acetabular cups. Significant statistical differences ($p < 0.05$) were also found considering the type of resin (PE-A vs. PE-B) and between the groups with the same sterilization (PE-B vs. PE-C).

The mean roughness measurements (± Standard Deviation) of the parameters (R_a, R_t) for the femoral heads under investigation at zero Mc, 5 Mc, and 10 Mc are reported in Table 2.

The coefficient of correlation between the weight loss and the two roughness parameters (R_a and R_t) for the femoral heads coupled with the various different polyethylenes are plotted in Figs. 2 & 3.

The average roughness R_a for the heads coupled with the cross-linked PE showed the lower coefficient of linear regression ($R^2 = 0.45$) in comparison with the conventional PE ($R^2 = 0.81$). The same correlation was observed with the R_t parameter ($R^2 = 0.27$ ***vs***. $R^2 = 0.84$).

The FTIR line-scan spectra measured on the aforementioned polyethylene acetabular cups are shown in Fig. 4. All samples show diffusion of apolar products from the bovine serum, as indicated by the ester absorption at 1740 cm^{-1} found in all spectra. However, this phenomenon was found to be more superficial than in samples retrieved after in vivo implantation [38, 39]. The FTIR spectrum of PE-A shows only a slight oxidation, evidenced by the hydroperoxides absorption at 1630 cm^{-1}. Samples B and C show the same oxidation profile, but the oxidation level of sample B is much higher. The presence of oxidation is also confirmed by the absorption of ketones at 1718 cm^{-1}. The oxidation found in these samples can be attributed to a poor packaging storage, in agreement with other study that observed this phenomenon [40].

The two-crosslinked samples show different oxidation level: a minimal absorption of both ketones and hydroperoxides indicates quite a low oxidation for XLPE. On the contrary, a high concentration of ketones and hydroperoxides indicates a high oxidation level of XLPE-RT, comparable to that of PE-B.

Evidently, not all hydroperoxides were eliminated due to a too short thermal treatment. In addition, the higher oxidation level found in XLPE-RT can be explained with the lack of mechanical machining after irradiation. Thus, if from one hand the absence of machining marks on the articulating surface could reduce the abrasion, on the other end, eliminating the mechanical machining also means failing in removing the superficial layer of polyethylene, which have been oxidized during irradiation.

5 DISCUSSION

Interest in an improved polyethylene that present wear resistance for orthopaedic implants is an open challenge. The wear performance of five different polyethylenes coupled with CoCrMo femoral heads was evaluated for 10 million cycles. In particular, we asked whether new XLPE-RT acetabular cups, after long-term wear tests, would result in less wear than long-term wear tests would result in less wear than XLPE and conventional UHMWPE after UHMWPE and to determine the degree of oxidation of these specimens.

We found a reduced wear rate for the XLPE configurations in comparison to the conventional PE. In particular, the XLPE and XLPE-RT cups showed a significant 80% to 90% wear reduction compared with the conventional PE (Fig. 1). XLPE-RT acetabular cups showed higher weight losses than XLPE (50%). It was stressed that our initial hypothesis related to the absence of machining marks on the surface of the polyethylene should be reduce the abrasion and this could ends in improved wear resistance of the cups doesn't verified but the high oxidation level observed on these new XLPE-RT cups could altered the results observed.

Significant differences ($p < 0.05$) were observed between all the polyethylene cups. In particular, the results of this investigation clearly showed a reduced wear for the two types of XLPE with respect to the conventional UHMWPE components.

Hip simulator studies have indicated that cross-linking can reduce the type of wear (>95%) that occurs in acetabular components in *in-vitro* tests [11, 41-45]. These results are also confirmed from *in-vivo* follow-up studies: a significant decrease in the femoral head penetration into the highly cross-linked polyethylene acetabular liners compared with the conventional UHMWPE liners was observed by Martell and D'Antonio [15, 46]. Regarding the sterilisation treatments, we found that our γ-irradiated PE-B specimens continued to wear about four times faster than the EtO sterilised of the same composition (Fig. 1). The oxidation level of PE-B, partially crosslinked by radiation sterilization, is much higher than that of the EtO sterilized sample (PE-A). Thus, the oxidation induced by irradiation in air led to a decrease in the molecular mass.

A concern about the same sterilisation method but different material show the PE-B cups (γ-irradiated) wore about 3 times than the PE-C cups sterilised under the same conditions. This result can be explained by the different oxidation levels found in the two samples, according to the mechanism proposed by Costa et al. [4]. In particular, a decrease of molecular weight may involve abrasion.

Concerning the roughness measurements, R_a and R_t were taken into account because, as better explained in a previous work [33], the femoral heads implanted in patients could be scratched at various stages and variations of the roughness during the life of the prosthesis may not change in a systematic manner [47]. Profiles of different surfaces could have the same roughness average (R_a) and wavelength but have different shapes. In this sense, R_t is the other parameter that can better correlate with the wear rate, when femoral heads with substantially different surface conditioning are compared. A slight increase in R_a may be observed from 5 to 10 Mc for all the combinations (Table 2). Conversely, an appreciable increase in R_t is observed for all the configurations. It was stressed that the PE-B group presents higher R_a and higher R_t with respect to the other polyethylenes. Probably that isolated scratches on the PE-B acetabular cups increased the wear rate significantly more than generalized roughness of the metallic counter-face and could also change the wear performance ranking of various polyethylene formulations. A correlation between wear that occurs at 10 Mc and weight loss is observable only for high weight loss (conventional polyethylenes with $R^2 > 0.8$). Regarding the cross-linked PE the model is not able to describe a correlation between the roughness and the weight loss because the variations are smaller than measurements accuracy.

6 CONCLUSIONS

All the acetabular cups (cross-linked and conventional PE) showed significant differences between them in respect to the wear behavior. Weight loss was found to decrease for the XLPE than the other configurations. However, this study is limited in predicting clinical wear rates. It is stressed that these wear tests were conducted in a laboratory under controlled conditions on a hip simulator. The FTIR analyses indicate that oxidation to various extents appears as a consequence of γ-irradiation in presence of oxygen and therefore the XLPE cups in our study showed the most variability in wear rates, whereas the conventional PE cups showed much more uniform wear behavior.

Differences in the wear behaviour could be correlated to different oxidation levels. In fact, while these levels increase for the cups, the roughness values keep constant as to indicate that improvement in manufacturing process influences the quality of substrate rather then the surface. Further studies are in progress to better investigate the reasons of different oxidation levels and to correlate the wear behaviour to the spatial distribution of the oxidation.

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Table 1 – Description of the five groups of polyethylene tested in this study.

Type of resin	Manufacturing process	Irradiation dose	Final sterilization
PE-A**	Mechanical machining from bar extrusion to obtain the final form.	---	EtO
PE-B**	Mechanical machining from bar extrusion to obtain the final form.	---	γ 3 ±0.5Mrad (Dose in vacuum packed)
PE-C**	Mechanical machining from bar extrusion to obtain the final form.	----	γ 3 ±0.5 Mrad (Dose in vacuum packed)
XLPE **	Machining into the final form. Washing and packaging under controlled environment (standard procedure for biomedical components).	γ-irradiation dose in the range 67.5 ÷ 82.5 kGy (nominal dose 100kGy) Annealing at 150°C under nitrogen for 6 hours.	EtO
XLPE-RT**	Thermo-compression according to ISO 5834/2 into a cylindrical pre-form, which allows obtaining the concavity of the cup with no need of further machining.	γ-radiation dose in the range 82.9 ÷ 97.5 kGy (nominal dose 100kGy) Annealing at 150°C under nitrogen for 6 hours.	EtO

** *More details about the type of resin is given in the Nomenclature section.*

Table 2 - Mean roughness (± Standard Deviation) for R_a and R_t parameters at zero, 5, and 10 million cycles.

Cycles (Mc)	R_a (μm)			R_t (μm)		
	0 Mc	**5 Mc**	**10 Mc**	**0 Mc**	**5 Mc**	**10 Mc**
PE-A	0.01 ± 0.01	0.02 ± 0.01	0.02 ± 0.01	0.05 ± 0.01	0.17 ± 0.09	0.16 ± 0.05
PE-B	0.01 ± 0.01	0.02 ± 0.01	0.05 ± 0.03	0.07 ± 0.01	0.15 ± 0.04	0.36 ± 0.21
PE-C	0.01 ± 0.01	0.01 ± 0.01	0.01 ± 0.01	0.05 ± 0.01	0.11 ± 0.03	0.10 ± 0.01
XLPE	0.01 ± 0.01	0.01 ± 0.01	0.02 ± 0.01	0.05 ± 0.02	0.16 ± 0.07	0.21 ± 0.03
XLPE-RT	0.01 ± 0.01	0.01 ± 0.01	0.02 ± 0.01	0.05 ± 0.01	0.11 ± 0.04	0.17 ± 0.05

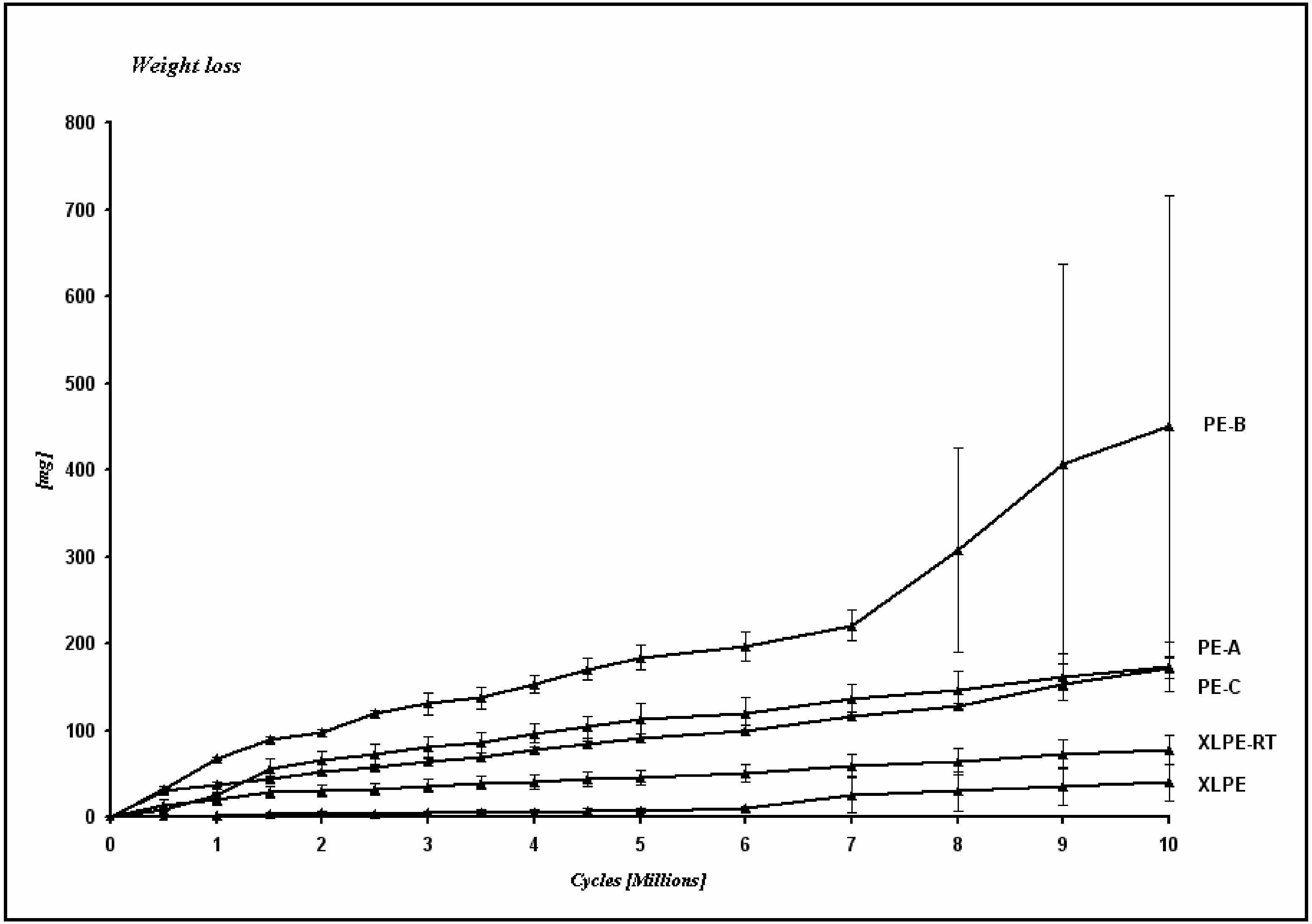

Figure 1 – The picture shows the weight loss (± standard deviation) for five different polyethylenes. The cross-linked PE wore less than the other ones. Between 5 and 10 million cycles, wear reduced with respect the initial trend. The PE-B continued to show the worst wear behavior.

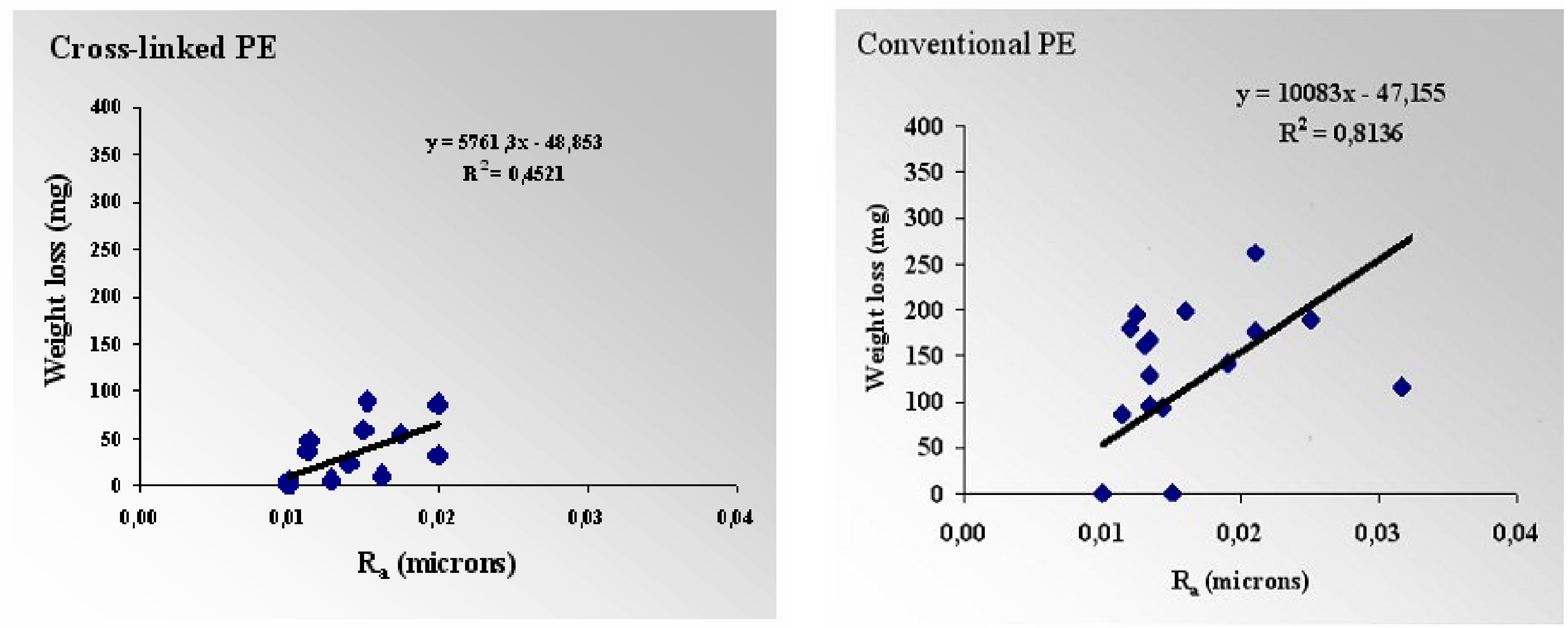

Figure 2 – Weight loss of the different polyethylenes **vs**. R_a from zero to 10 Mc. The solid line represents a simple linear regression fit, whereas the points represent each data value.

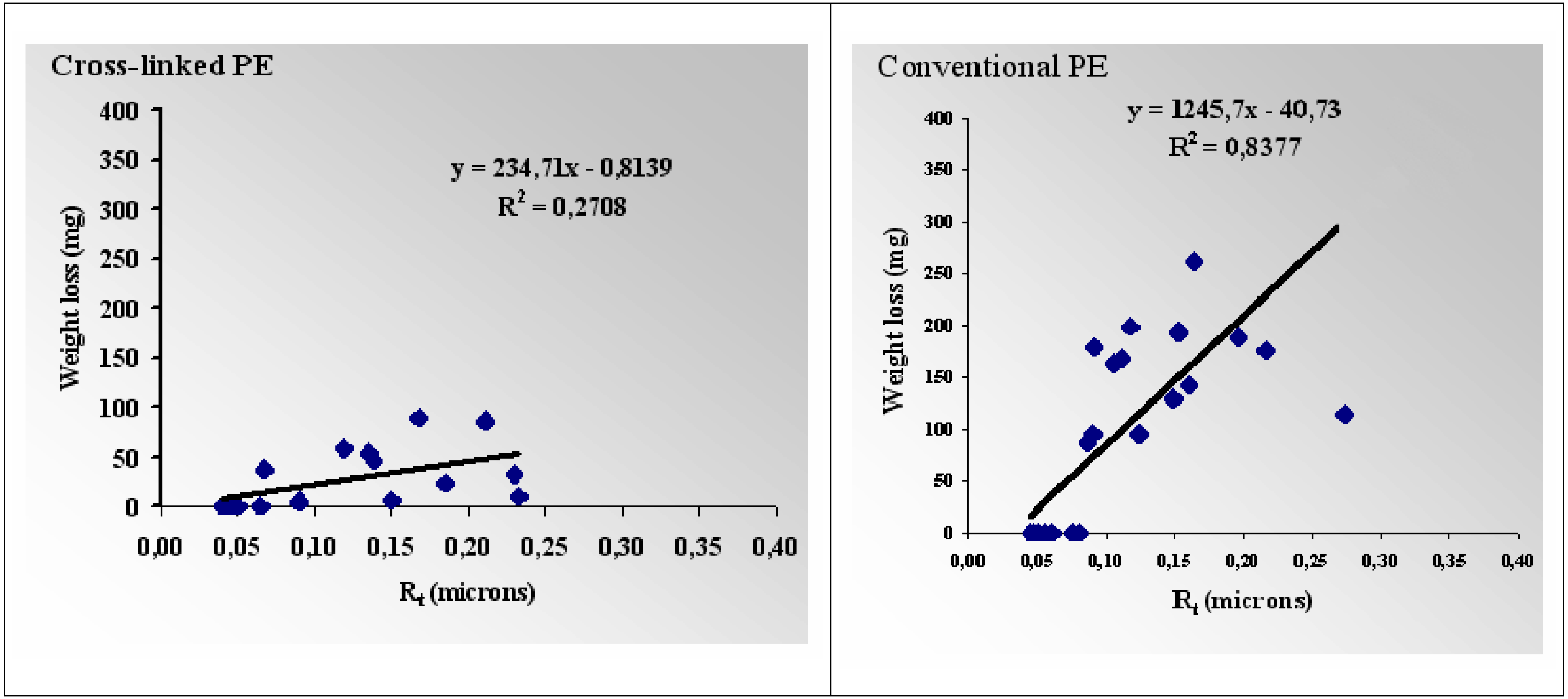

Figure 3 – Weight loss of the different polyethylenes **vs**. R_t from zero to 10 Mc. The solid line represents a simple linear regression fit, whereas the points represent each data value.

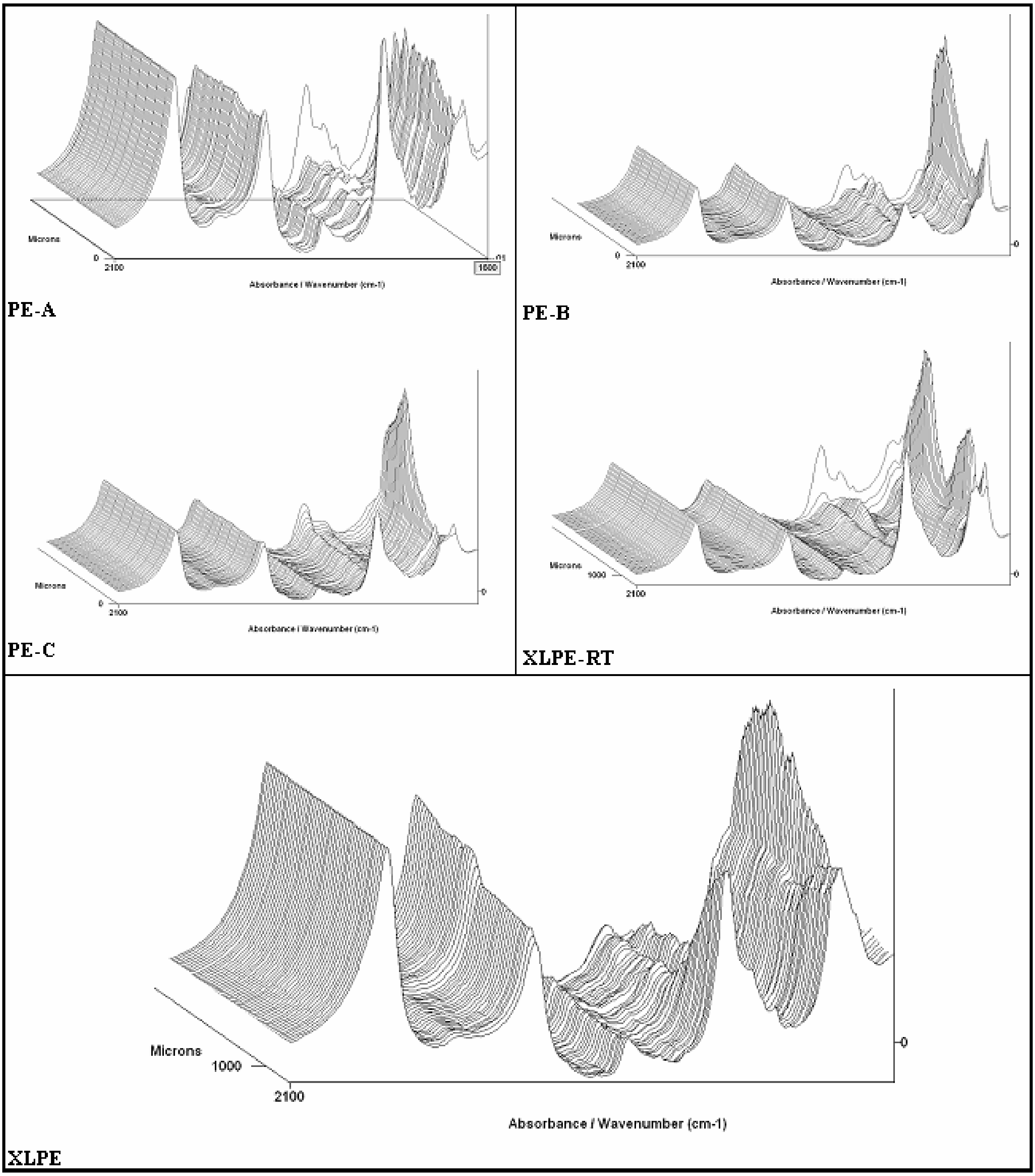

Figure 4 – FTIR spectra of the most worn polyethylene acetabular cups.