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The Influence of Steam Sterilization on Retrieved UHMW-PE Parts

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INTRODUCTION:

Ultra high molecular weight polyethylene is an important material for the construction of bearing surfaces in hip or knee implants. However it is also a contributing factor to the failure of total joint replacements. For example aseptic loosening due to wear particles or fatigue damage causing fracture of polyethylene parts has been observed in hip and knee replacements, respectively. The explanted polyethylene parts can provide valuable information on the reason for revision, whether it was related to the raw material, the design of the implant, the sterilization procedure etc. Usually the complete explanted joint system is autoclaved in the clinic using hot steam (134°C). The goal of this research was to investigate the influence of this steam sterilization on the properties the polyethylene. Therefore a revised hip inlay was split into two parts, one half was cleaned without a thermal treatment, and the other half was sterilized using hot steam. On both parts, the chemical properties were analyzed using infrared spectroscopy.

METHODS:

A hip inlay (ABG, Benoist Girard France) which was articulating against a 32 mm zirkonium ball head, was revised after 9 years. This cup was γ-sterilized in air [1]. The hip cup was split into two parts. One half was desinfected for 15 minutes in an ultrasonic cleaning bath using a 5% Stammopur DR2 solution. The other half was sterilized in a unisteri 446-steam sterilisator (MMM, Germany) at 134°C. The sterilisation time was 20 minutes, however the whole cycle, (heating–evacuation–sterilization–cooling) takes approximately 3 hours. After the sterilization or cleaning, the oxidation index of the polyethylene was measured using Fourier transform infrared spectroscopy (FTIR). Thin (150 microns) microsections were cut from the inlay in the non-loaded regions from both halfs of the cup (which used to be connected to each other). The microsections were cut as a function of the distance from the surface of the inlay and were used with and without extraction of the components that diffused into the polyethylene. The microsections were extracted for 48hrs in cyclohexane at 80°C to extract the absorbed body fluids. All microsections were scanned in the FTIR spectrometer with a resolution of 4 cm-1. The oxidation index was measured by deviding the area of the carbonyl peaks at 1720 cm-1 by the area of the internal reference peak at 1370 cm-1 [2].

RESULTS AND DISCUSSION:

A photograph of the retrieved hip cup is shown in Figure 1. The part of the inlay which was subjected to the hot steam (right), does not fit anymore to its cleaned counterpart (left). During clinical use, there is wear and plastic deformation (creep) of the polyethylene. Heating the polyethylene in the autoclave close-to, but below the melting temperature (137°C) results in partial recovery of this plastic deformation.

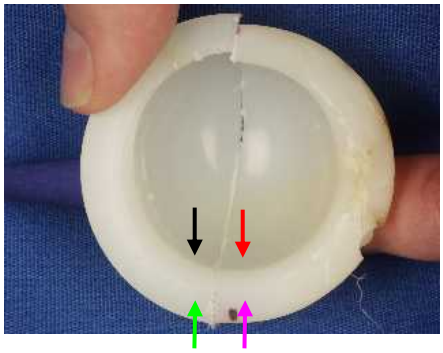

Figure 1: Top view of retrieved hip inlay after 9 yrs implantation. One half as received (left) and one half after steam sterilization (right). Arrows indicate the locations where the oxidation indices were measured.

The oxidation indices (OI) as a function of the depth in the material are shown in Figure 2.

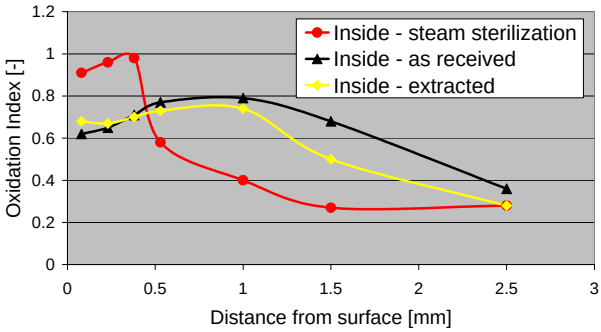

Figure 2: Oxidation index profile (OI in the non loaded zone on the inside of the cup (see Figure 1)

The oxidation index in the non-loaded zone of the inlay after cleaning (black curve) shows a maximum at 1 mm below the surface of the inlay.

This subsurface maximum is typical for γ-sterilized polyethylene parts, aged on the shelf and during clinical use [3]. The oxidation is a result of oxygen which reacts with the free radicals present in the polyethylene. The free radicals are formed during the γ-sterilization and the oxygen difuses into the polyethylene surface, either on the shelf or via the body fluids during clinical use.

These body fluids difusing into the surface also have carbonyl groups and therefore might lead to erroneous (high) oxidation values. However a comparison of the the oxidation profile before (black curve) and after extraction (yellow curve) shows that there are only minor differences, i.e., the oxidation is dominated by reactions between oxygen and free radicals and not strongly influenced by the absorbed body fluids.

Steam sterilization of the same area has a strong influence on the oxidation level and on the profile (red curve versus black curve). The oxidation maximum shifts towards the surface and to higher values (OI ~ 1). The heat during the sterilization activates both chemical reactions and difusion processes. The differences in oxidation index are probably the result of oxidative reactions occuring of free radicals still present in the material and/or due to diffusion of oxidized species towards the surface. The latter is possible due to the increased mobility at 134°C in combination with a vacuum of 65 mbar in the autoclave.

The influence of steam sterilization on the oxidation index curves measured on the OUTSIDE of the inlay is even more pronounced (see green and violett arrows in Figure 1):

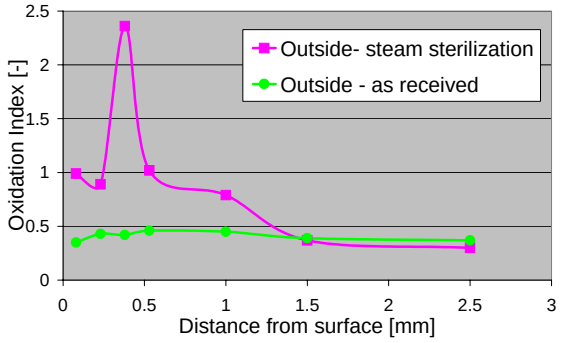

Figure 3:Oxidation index profile in the non-loaded zone on the outside of the cup (see Figure 1)

Also on the outside, the steam sterilization shifts the oxidation maximum towards the surface. However, there is a very sharp subsurface maximum which was not observed on the inside of the inlay. An explanation might be that on the outside more residual free radicals are present which then react very fast due to the thermal activation during autoclaving.

CONCLUSIONS:

- The steam sterilization procedure affects the dimensions of explanted polyethylene parts due to partial release of stresses built-up in the material during use.
- The heat, vacuum and steam adversely affect the oxidation index present directly after explantation which might lead to erroneous conclusions.
- Chemical analysis and dimensional measurements on revised PE parts are virtually impossible after steam sterilization.
- Attention should be paid when comparing oxidation values from literature of retrieved UHMW-PE implants.

REFERENCES:

[1] MDA /2004/011
[2] oxidation index was measured after ASTM F21002-01
[3] “The UHMW-PE Handbook”, ed. S. Kurtz, Chapter 11, Elseviers Academic Press, 2004