THE INFLUENCE OF STERILIZATION ON IN VIVO OXIDATION AND WEAR OF RETRIEVED TOTAL KNEE PROSTHESIS

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INTRODUCTION:
Ultra-high molecular weight polyethylene (UHMWPE) is one of the most popular bearing materials for artificial joint system. Since 1990s, the sterilization and packaging of UHMWPE has been a controversial topic. Gamma-ray irradiation in air is the typical sterilization method for the UHMWPE component of an artificial joint. The previous studies reported that the gamma-sterilized polyethylene containing free radicals degraded with substantial oxidation in vivo [1]. It was a source of concern that oxidatively degraded UHMWPE might decrease wear resistance. Thereafter, sterilization method of the major orthopedic manufacturers switched to gamma irradiation in an inert gas, or ethylene oxide gas (EOG) or gas plasma sterilization in total hip prosthesis (THP), because of several indications that gamma sterilization in air causes oxidative degradation of chemical and mechanical properties of UHMWPE during long-term shelf storage. However, the oxidation index of the degraded polyethylene was lower in vivo than in vitro. It has also been reported that the oxygen content might be almost zero in the body and that the oxidation index was lower in the worn area than in the unworn area in THP [2].

In this study, we evaluated the influence of sterilization on in vivo oxidation and wear of retrieved total knee prosthesis (TKP). Especially, comparisons between gamma and EOG sterilization, and worn and unworn areas were made.

METHODS:
Prosthesis Six retrieved UHMWPE inserts of clinical use for 6-23 years were studied. Three each inserts were EOG and gamma sterilized, respectively. The clinical data are summarized in Table 1.

<table>
<thead>
<tr>
<th>No</th>
<th>System</th>
<th>Sterilization</th>
<th>Clinical use (year)</th>
<th>Degradation (Fracture)</th>
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<tr>
<td>1</td>
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<td>Gamma (air)</td>
<td>16.8</td>
<td>Fracture</td>
</tr>
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<td>IBI (Zimmer)</td>
<td>Gamma (air)</td>
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<td>Degradation</td>
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<td>4</td>
<td>KU3 (Kyocera)</td>
<td>EOG</td>
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<td>N.A.</td>
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<td>EOG</td>
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<td>N.A.</td>
</tr>
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</table>

Oxidation analysis by FT-IR The oxidation index of the retrieved UHMWPE inserts was measured by a microscopic Fourier transform infrared (FT-IR) spectrophotometer. Thin slices of the cross-section of worn and unworn (intercondylar) area were prepared from each insert. The oxidation index was defined as the ratio of the area of the carbonyl absorption peak (1720 cm⁻¹) to the area of the methylene absorption peak (1360 cm⁻¹), and calculated according to ASTM F2102.

Linear wear analysis by shape tracer The shapes of the medial and lateral areas of the UHMWPE inserts were determined by a shape tracer. By comparison of the shape of the retrieved component with that of the original one, which was estimated from marginal (i.e. unworn) shape of insert, linear wear was calculated.

RESULTS AND DISCUSSION:
In the worn area, the oxidation index of gamma sterilized insert was slightly high compared with that of EOG sterilized one (Figure 1(a)). In the unworn area, especially for subsurface, the oxidation index of insert was substantially higher in gamma sterilized insert than in EOG sterilized one (Figure 1(b)). The linear wear of gamma sterilized inserts was not so different compared with that of EOG sterilized one (Figure 2).

The oxidative degradation of worn area proceeded more rapidly compared with unworn area, because the TKP insert was fully exposed to body fluid. The contact of insert with oxygenated body fluid is assumed to be a mechanism of in vivo degradation with respect to the above considerations. Of course, free radicals produced by gamma sterilization are also responsible for oxidative degradation. In this study, while the advantage of gamma sterilization as to wear resistance was not found, the risk of delamination and/or fracture was perceived.

In conclusion, the sterilization methods affect in vivo oxidation, and gamma sterilization has an undesirable influence (e.g. delamination and fracture) upon wear resistance of UHMWPE TKP inserts.

REFERENCES:

LISTING FOR ADDITIONAL AUTHOR AFFILIATION:
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Figure 1: Oxidation index of retrieved UHMWPE inserts with gamma or EOG sterilization. (a) Worn area (medial and lateral, n=2), (b) unworn area (n=1). The subsurface is 0.5 mm in depth and the interior is 2.5 mm in depth form the surface.

Figure 2: Linear wear of retrieved UHMWPE inserts with gamma or EOG sterilization.

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