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Biotribology of a vitamin E-stabilized polyethylene for hip arthroplasty – Influence of artificial ageing and third-body particles on wear

Thomas M. Grupp [a,b,*], Melanie Holderied [a], Marie Anne Mulliez [a], Rouven Streller [a], Marcus Jäger [c], Wilhelm Blömer [a], Sandra Utzschneider [b]

[a] Aesculap AG Research & Development,Tuttlingen, Germany
[b] Ludwig Maximilians University Clinic for Orthopaedic Surgery, Campus Grosshadern, Munich, Germany
[c] Clinic for Orthopaedic Surgery, University of Essen, Germany

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ABSTRACT

The objective of our study was to evaluate the influence of prolonged artificial ageing on oxidation resistance and the subsequent wear behaviour of vitamin E-stabilized, in comparison to standard and highly cross-linked remelted polyethylene (XLPE), and the degradation effect of third-body particles on highly cross-linked remelted polyethylene inlays in total hip arthroplasty. Hip wear simulation was performed with three different polyethylene inlay materials (standard: γ-irradiation 30 kGy, N_2; highly cross-linked and remelted: γ-irradiation 75 kGy, EO; highly cross-linked and vitamin E (0.1%) blended: electron beam 80 kGy, EO) machined from GUR 1020 in articulation with ceramic and cobalt–chromium heads. All polyethylene inserts beneath the virgin references were subjected to prolonged artificial ageing (70 °C, pure oxygen at 5 bar) with a duration of 2, 4, 5 or 6 weeks. In conclusion, after 2 weeks of artificial ageing, standard polyethylene shows substantially increased wear due to oxidative degradation, whereas highly cross-linked remelted polyethylene has a higher oxidation resistance. However, after enhanced artificial ageing for 5 weeks, remelted XLPE also starts oxidate, in correlation with increased wear. Vitamin E-stabilized polyethylene is effective in preventing oxidation after irradiation cross-linking even under prolonged artificial ageing for up to 6 weeks, resulting in a constant wear behaviour.

1. Introduction

The biological response to polyethylene wear particles released by orthopaedic implants is a key factor in periprosthetic osteolysis and subsequent implant loosening [1–5]. In hip wear simulations highly cross-linked polyethylenes (XLPE) have been shown to improve wear resistance and, for this reason, have been introduced as bearing materials in orthopaedic joint replacements [6–8]. After a decade of use in total hip arthroplasty, highly cross-linked polyethylenes are now clinically established as the material of choice for acetabular liners in articulation with cobalt–chromium or ceramic heads [9–12].

These liners have been proved to reduce significantly wear [13–15] and osteolysis [15–18]. Analysing the incidence of acetabular osteolysis in young patients (25–55 years old) by computer tomography, with a mean follow-up of 7.2 years (range 5.1–10.9 years), Mall et al. [17] reported apparent osteolysis in 24% of the patients with standard polyethylene components compared to 2% in the XLPE group. In a systematic review of wear and osteolysis outcomes in hip arthroplasty, Kurtz et al. [15] calculated a mean linear rate of femoral head penetration of 0.042 mm year^{-1} for XLPE liners (n = 1503 hips, 28 studies) and of 0.137 mm year^{-1} for standard polyethylene (n = 695 hips, 18 studies). Based on a pooled odds ratio of 0.131 across nine studies, they estimated an 87% lower risk of osteolysis [15].

To improve the oxidation resistance, highly cross-linked polyethylenes have to be thermally treated by annealing or remelting after irradiation [6,7,19]. Annealing of XLPE substantially reduces the residual free radicals, but the remaining minor fraction still persists in the material, with the consequence of further oxidation [12]. Wannomae et al. [20] found in vivo oxidation by residual free radicals in irradiated and annealed XLPE acetabular components retrieved 4–33 months after implantation, a result corroborated by Kurtz et al. [21]. While annealing leads to the retention of the remaining oxidation potential, only post-irradiation remelting is effective at eliminating the residual free radicals [12]. However,

* Corresponding author at: Aesculap AG Research & Development,Tuttlingen, Germany. Tel.: +49 7461 95 2667; fax: +49 7461 95 382667.
E-mail address: thomas.grupp@aesculap.de (T.M. Grupp).

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remelting substantially affects the mechanical properties of XLPE [21,22] due to the loss of crystallinity [16], a possible reason for structural material fatigue in vivo [24–26]. Furthermore Muratoglu et al. [27] described two potential mechanisms which might reduce the oxidative stability of irradiated and remelted XLPE in vivo – cyclic loading and absorption of liquids. Increasing oxidation leads to a concomitant decrease in cross-link density and increase in crystallinity [27] which, according to Carpentieri et al. [28], plays a major role on the post-irradiation oxidative effects of polyethylenes.

For this reason, the stabilization of highly cross-linked polyethylene by diffusion [22] or blending [29,30] of the antioxidant vitamin E was developed to enhance oxidation resistance [31] and improve fatigue strength by the avoidance of post-irradiation melting [16,32]. Highly cross-linked polyethylene stabilized by diffusion of vitamin E showed superior oxidation resistance, equivalent wear behaviour and enhanced mechanical properties in comparison to an irradiated and remelted XLPE with the same dose level (100 kGy) [16,22].

2. Objectives

The objective of our study was to evaluate the influence of prolonged artificial ageing on oxidation resistance and the subsequent wear behaviour of vitamin E-stabilized, in comparison to standard and highly cross-linked, remelted polyethylene, and the degradation effect of third-body particles on XLPE inlays in total hip arthroplasty.

3. Materials and methods

In vitro wear simulation was performed using acetabular cups (Plasmacup® DC ∅ 52/54 mm, Aesculap AG Tuttlingen, Germany) made out of Ti6Al4 V alloy in combination with three different polyethylene inlay materials machined from GUR 1020. The standard polyethylene inlays (STD) were packed under nitrogen atmosphere and sterilized by γ-irradiation (30 ± 2 kGy). The highly cross-linked and remelted polyethylene inlays (REM) were cross-linked by γ-irradiation (75 kGy) and sterilized by ethylene oxide (EO). The highly cross-linked and vitamin E (0.1%) blended polyethylene inlays (VitE) were cross-linked by an electron beam (80 kGy) and sterilized by EO.

In the comparative wear simulation, the highly cross-linked polyethylene inlays (REM, VitE) were used at a size of ∅ 36/52 mm and combined with modular heads of ∅ 36 mm (taper 12/14) made out of zirconia toughened aluminia ceramic (BIOLOX®*delta*, Aesculap AG, Tuttlingen, Germany) or out of $CoCr_{29}Mo_6$ alloy (Aesculap AG, Tuttlingen, Germany). The STD were used as the clinical established reference at a size of ∅ 36/52 mm and combined with modular heads of ∅ 36 (taper 12/14) made out of aluminia ceramic (BIOLOX®*forte*, Aesculap AG, Tuttlingen, Germany).

All polyethylene inserts beneath the virgin reference components were subjected to artificial ageing according to ASTM F2003–02 (parameters: 70 °C, pure oxygen at 5 bar, duration 2, 4, 5 and 6 weeks). Therefore the inserts were put into a pressure vessel (Millipore Corp. 6700P05, Merck KgaA, Darmstadt, Germany) at room temperature that was filled with pure oxygen at an initial pressure of 5 bar (73 ± 1 psi), which was then oven heated to a target temperature of 70 °C to reach a target pressure of 5.79 bar (84 psi). At these conditions, one standard ageing cycle (2 weeks) has a duration of 336 + 1 h. All polyethylene inserts were soaked prior to wear simulation in serum-based test medium until the incremental mass change over 24 h was less than 10% of the previous cumulative mass change to allow for saturated fluid absorption (Table 1).

To determine the oxidation state of the polyethylene inserts after artificial ageing, slices were cut using a Microtome (Leica Microsystems Type RM2255, Wetzlar, Germany), stepwise in increments of 100 μm from the articulating surface down to 500 μm and at 1000 μm, and oxidation index measurements were performed by Fourier transform infrared spectroscopy (FTIR; Perkin Elmer Spectrum Image-Spotlight 200, Rodgau, Germany). For each absorbance spectrum, the total area of the peak absorptions between 1650 and 1850 cm^{-1} (A_{Ox}) was calculated, together with the reference peak for polyethylene (between 1330 and 1396 cm^{-1}, A_{Ref}), for each reference inlay prior to wear testing. The oxidation index (OI) was calculated in accordance with ISO 5834–4:2005 by division of the area A_{Ox}/A_{Ref}.

3.1. In vitro wear simulation

In vitro wear simulation was performed on a customized 6 + 2-station servo-hydraulic hip simulator (EndoLab GmbH Thansau, Germany) with kinematic and load patterns according to ISO 14242-1:2012 (E).

Three acetabular cups per test group were fixed with epoxy resin and mounted on the wear test stations. In each test group a reference that was submitted only to axial force for loaded soak control was tested in parallel. The femoral heads were fixed via a stainless steel tube with a 12/14 taper connection. The STD, REM and VitE groups were tested through five million cycles with a frequency of 1 Hz in a lubricant of newborn calf serum (Biochrom AG, Berlin, Germany) diluted with deionized water to achieve the target protein content of 30 g l^{-1}. The lubricant was incubated at 37 °C, pH-stabilized with ethylene diamine tetraacetic acid and replaced at intervals of 0.5 million cycles. Patricine was added to prevent fungal decay.

To test for wear in the presence of third-body particulate debris, particles of poly(methyl methacrylate) (PMMA) bone cement with a mean size between 125 and 150 μm and a particle concentration of 5 g l^{-1} were used. They were generated out of Palacos® R bone cement (Heraeus Medical, Wehrheim, Germany) containing zirconium dioxide as a radiopaque material. After the completion of 5 million cycles, the highly cross-linked polyethylene test groups in virgin condition ($REM_{virgin\ delta}$, $REM_{virgin\ CoCr}$, $VitE_{virgin\ delta}$, $VitE_{virgin\ CoCr}$) were again tested for 3 million cycles under third-body conditions in articulation with BIOLOX®*delta* ($REM_{third\text{-}body\ delta}$,$VitE_{third\text{-}body\ delta}$) and CoCrMo ($REM_{third\text{-}body\ CoCr}$, $VitE_{third\text{-}body\ CoCr}$) femoral heads of 36 mm diameter (Fig. 1).

At each measurement interval (0.5, 1, 2, 3, 4 and 5 million cycles for STD, REM and VitE groups and 5.5, 6, 6.5, 7, 7.5 and 8 million cycles for $REM_{third\text{-}body}$ and $VitE_{third\text{-}body}$ groups), the devices were cleaned as prescribed in ISO 14242-2:2000(E) protocols for gravimetric wear assessment of hip joint articulations. Wear of the polyethylene inlays and of the modular femoral heads was determined gravimetrically using an analytical balance (Sartorius CPA225D, Göttingen, Germany) to a precision of 0.01 mg, taking air buoyancy and lubricant absorption into account. All bearing surfaces were inspected with a stereo microscope (Leica MZ 16, Bensheim, Germany). The component sets were rotated across stations after each half million cycles to minimize the effect of inter-station kinematic variability.

A geometrical assessment of plastic deformation (creep) and wear was performed after 5 million cycles for the test groups STD, REM and VitE with a three-dimensional measuring machine (Zeiss UMM850, Oberkochen, Germany) in a tactile measuring mode (1500 points per scan). The geometrical changes were displayed vertically to the transversal plane of the polyethylene inlays with a pseudocolour mode, the colours being spread between red = +0.05 mm and purple = −0.3 mm for the articulating surface of the polyethylene inlays.

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