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Vitamin E stabilised polyethylene for total knee arthroplasty evaluated under highly demanding activities wear simulation

Thomas M. Grupp [a,b,*], Bernhard Fritz [a], Ines Kutzner [c], Christoph Schilling [a], Georg Bergmann [c], Jens Schwiesau [a,b]

[a] Aesculap AG Research & Development, Tuttlingen, Germany
[b] Ludwig Maximilians University Munich, Department of Orthopaedic Surgery, Physical Medicine & Rehabilitation, Campus Grosshadern, Munich, Germany
[c] Julius Wolff Institute, Charité Universitätsmedizin Berlin, Germany

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ABSTRACT

As total knee arthroplasty (TKA) patients are getting more active, heavier and younger and structural material fatigue and delamination of tibial inserts becomes more likely in the second decade of good clinical performance it appears desirable to establish advanced pre-clinical test methods better characterizing the longterm clinical material behaviour. The questions of our study were 1) Is it possible to induce subsurface delamination and striated pattern wear on standard polyethylene TKA gliding surfaces? 2) Can we distinguish between γ-inert standard polyethylene (PEstand.30kGy) as clinical reference and vitamin E stabilised materials (PEVit.E30kGy & PEVit.E50kGy)? 3) Is there an influence of the irradiation dose (30 vs 50 kGy) on oxidation and wear behaviour?

Clinical relevant artificial ageing (ASTM F2003; 2 weeks) of polyethylene CR fixed TKA inserts and oxidation index measurements were performed by Fourier transform infrared spectroscopy prior testing. The oxidation index was calculated in accordance with ISO 5834-4:2005 from the area ratio of the carbonyl peak (between 1650 and 1850 cm^{-1}) to the reference peak for polyethylene (1370 cm^{-1}). Highly demanding patient activities (HDA) measured in vivo were applied for 5 million knee wear cycles in a combination of 40% stairs up, 40% stairs down, 10% level walking, 8% chair raising and 2% deep squatting with up to 100° flexion. After 3.0 mc all standard polyethylene gliding surfaces developed noticeable areas of progressive delamination. Cumulative gravimetric wear was 355.9 mg for PEstand.30kGy, 28.7 mg for PEVit.E30kGy and 26.5 mg for PEVit.E50kGy in HDA knee wear simulation. Wear rates were 12.4 mg/mc for PEstand.30kGy in the linear portion (0–2 mc), 5.6 mg/mc for PEVit.E30kGy and 5.3 mg/mc for PEVit.E50kGy. In conclusion, artificial ageing of standard polyethylene to an oxidation index of 0.7–0.95 in combination with HDA knee wear simulation, is able to create subsurface delamination, structural material fatigue in vitro, whereas for the vitamin-E-blended materials no evidence of progressive wear, fatigue or delamination was found.

Statement of Significance

As total knee arthroplasty patients are getting more active, heavier and younger and structural material fatigue and delamination of polyethylene tibial inserts becomes more likely in the second decade of good clinical performance, it appears desirable to establish advanced pre-clinical test methods better characterizing the longterm clinical material behaviour. Various studies reported in literature attempted to artificially create delamination during in vitro knee wear simulation.
We combined artificial ageing to clinically observed oxidation of gamma inert and vitamin E stabilised polyethylene inserts and highly demanding patient activities knee wear simulation based on in vivo load data. With this new method we were able to create clinically relevant subsurface delamination and structural material fatigue on standard polyethylene inserts in vitro.

* Corresponding author at: AESCULAP AG Research & Development, Am Aesculap-Platz, D-78532 Tuttlingen, Germany.
E-mail address: thomas.grupp@aesculap.de (T.M. Grupp).

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1. Introduction

Failure of total knee arthroplasty (TKA) is relatively rare and the most common causes for revision are aseptic loosening, septic loosening and implant wear [1–4]. During the last decade and a half substantial research efforts have been undergone to improve polyethylene bearing materials for hip and knee arthroplasty by highly cross-linking [5,6] and anti-oxidative stabilization [7–11] in regard to ageing resistance and wear [6,12,13]. Highly cross-linked polyethylene (XLPE) inserts have shown significant improvements in decreasing wear and osteolysis in total hip arthroplasty [14–16]. In contrast to that, XLPE gliding surfaces have not shown to reduce the risk for revision, aseptic loosening or wear in total knee arthroplasty based on clinical outcomes [17], patient registries [18,19] and basic research [20,21].

As total knee arthroplasty is being increasingly performed on heavier, younger and more active patients [22,23], it appears desirable to reduce surface and delamination wear to improve survival rates in the next decade [24,25]. Articular gliding surface damage is based on two main clinical failure mechanism: abrasive/ adhesive surface wear and subsurface delamination [26,27]. Delamination is caused by high contact stresses and subsurface stress concentrations in combination with degradation of the polyethylene due to radiation-induced oxidation [28–32]. The structural fatigue failure of knee gliding surfaces caused by oxidation-induced embrittlement, degradation and crack concentration below the articulating surface has been widespread seen for γ-irradiation in air [28,29,31,33], but also occurred in a pronounced manner for γ-irradiation under inert atmosphere and barrier packaging [24]. Oxidative degradation leading to subsurface white banding, pitting, cracking and substantial material loss has currently been described for highly cross-linked polyethylene tibial bearings sequentially irradiated and annealed [34,35], which prevents shelf oxidation before implantation [36]. Testing sequentially irradiated and annealed polyethylene tibial bearings in a knee simulator favourable wear behaviour and high oxidation resistance has been found in vitro [37,38], but not in vivo [34,35,39,40]. Searching for polyethylene materials optimized for total knee arthroplasty, pre-clinical testing is limited today [41–43], due to the fact that current ISO 14243 series wear testing is not dedicated to produce demanding wear conditions as given in patients service under daily in vivo loading conditions [44–47]. One major limitation is that current in vitro wear testing is mainly focused on abrasive-adhesive surface wear due to level walking test conditions and does not reflect subsurface delamination as an essential clinical failure mode [25,31,48–52].

2. Objectives

The objectives of our study therefore attempts to answer the following questions:

1) Is it possible to induce subsurface delamination and striated pattern wear on standard polyethylene TKA gliding surfaces in a combination of clinical relevant artificial ageing and highly demanding activities (HDA) wear simulation?
2) Is the HDA method able to distinguish between standard polyethylene (γ-irradiation 30 kGy under nitrogen) as clinical reference and vitamin E stabilised materials?
3) Is there an influence of the irradiation dose (30 kGy versus 50 kGy) on the oxidation and wear behaviour under HDA wear simulation conditions?

3. Materials and methods

A cruciate retaining fixed bearing TKA design (Columbus® CR) with femoral and tibial components made out of cobalt-chromium was used in an intermediate femoral size F4L combined with a tibial tray T3 and polyethylene gliding surfaces (size T3, height 10 mm) machined from GUR 1020 resin. Standard polyethylene gliding surfaces as clinical reference (PEstand.30kGy) were packed under nitrogen atmosphere and sterilised by γ-irradiation (30 ± 2 kGy; Co60 source 1.1732 & 1.3325 MeV) as clinical reference, instead of electron beam normally applied in serial production [52], whereas experimental compression molded GUR 1020 tibial inserts blended with 0.1% vitamin E (PEVit.E30kGy & PEVit.E50kGy) were packed under nitrogen atmosphere and irradiated by electron beam (30 ± 2 kGy & 50 ± 2 kGy; 10 MeV).

3.1. Artificial ageing and oxidation index measurements

All tibial inserts were used after artificial ageing according to ASTM F2003-02 (parameters: 70 °C, pure oxygen at 5 bar, duration 336 + 1 h (2 weeks)) and soaked prior to wear simulation in serum-based test medium at 37 °C for 30 days to allow for saturated fluid absorption. Oxidation index measurements were performed prior wear testing on additional tibial inserts – being in the same oxidation pressure vessel (Millipore Corp. 6700P05, Merck KgaA, Darmstadt, Germany) as the specimens for wear testing. 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 0.1, 0.2, 0.3, 0.4, 0.5 and 1.0 mm from the superior femoral contact surface, and oxidation index measurements were performed by Fourier transform infrared spectroscopy (FTIR)(Perkin Elmer Spectrum Image-Spotlight 200, Rodgau, Germany) (10 measurement points for each depth). For each absorbance spectrum, the total area of the peak absorptions between 1650 and 1850 cm^{-1} (A_{Ox}) as well as the reference peak for polyethylene (1330 cm^{-1} and 1396 cm^{-1}) (A_{Ref}) were calculated 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}.

3.2. Optical and geometrical wear surface analysis

The bearing surfaces were inspected optically with a stereo microscope (Leica MZ 16 Bensheim, Germany) and to evaluate the geometrical changes during the test the gliding surfaces were scanned before and after the test with a 3D measuring machine (UMM850, Zeiss Oberkochen, Germany) with a resolution of less than 3.5 μm at a minimum of 7500 points on an equidistant grid covering the bearing areas of the tibial inserts. The scans were superimposed and the geometrical changes were calculated (Holos NT 2.4.12, Zeiss Oberkochen, Germany) and displayed in pseudo-colors in a plane transversal view.

3.3. High demanding activities knee simulation and gravimetric wear measurements

HDA knee wear simulation was performed on a load controlled 4 station knee wear simulator (EndoLab Thansau, Germany) with a 60–40 medio-lateral load distribution adapted from ISO 14243-1:2009(E) on three test samples and one soak control. Daily patient activity profiles derived from flexion kinematics and load data of 8 patients, normalized to a patient weight of 100 kg (“High100” loads) measured by Bergmann et al. [53] in vivo, were applied for 5 million knee wear cycles (mc) in a combination of 40% stairs up, 40% stairs down, 10% level walking, 8% chair raising and 2% deep squatting with up to 100° flexion [44,54]. For walking, stair ascent and stair descent the cycle frequency was 1 Hz and, for the high flexion activities chair raising and knee bending, the frequency was 0.5 Hz [44,54]. The load profiles were applied in a loop repeated 500 times during the test consisting of 4000 cycles stair