

Influence of design and bearing material on polyethylene wear particle generation in total knee replacement

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Abstract

Periprosthetic osteolysis is one of the main reasons for revision of arthroplasty. The osteolytic reaction is influenced by the dose, size and shape of the wear particles. For arthroplasty, a low number and biologically less active particles are required. This is the first study which analyzes the impact of different knee designs, combined with crosslinked polyethylenes (sequentially irradiated and annealed as well as remelted techniques), on the amount, size and shape of particles. Overall, six material combinations, four of them with crosslinked polyethylene (XPE) and two of them with ultra-high molecular weight polyethylene (UHMWPE) inserts, including fixed and mobile bearings, were tested in a knee joint simulator. After isolation nearly 100,000 particles were analyzed in size, shape and number by scanning electron microscopy and image analysis. For all the designs, the wear was predominantly smooth and granular with few fibrillar particles. The Scorpio[®] design with the X3[™] insert, the Natural Knee[®] II design with the Durasul[™] insert and the LCS[®] design, also combined with a crosslinked polyethylene insert, generated statistically significant ($P < 0.05$) lower particle numbers. The particle size was independent of the radiation dose. The wear generated by the LCS[®] knee design (XPE and UHMWPE) had a higher percentage fraction of particles $>1 \mu\text{m}$ in size (equivalent circle diameter). The NexGen[®] design, tested with the Prolong[™] insert, showed a high number of particles in the biologically active size range compared with the other crosslinked designs, which could be a predictor for higher biological reactivity.

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1. Introduction

Prosthetic wear plays a central role in the initiation and development of osteolysis, which leads to the loosening of total joint replacements [1–3]. Numerous factors can influence the cellular response to wear particles, including the size, dose, volume, shape and composition of the particles [1–3].

For total knee arthroplasty, conventional ultra-high molecular weight polyethylene (UHMWPE) is the material

of choice for tibial inserts [4,5]. However, UHMWPE is now widely perceived as the most significant factor in wear-induced bone resorption [6–8]. The characteristics of polyethylene particles associated clinically with an osteolytic response by histiocytes have been shown and detailed in the literature [3,9,10]. Crosslinked polyethylene (XPE) was developed to reduce volumetric wear in both total hip and knee prostheses [11–16]. Furthermore, some studies have shown that XPE wear particles could be different from UHMWPE particles in size and volume [2,17,18].

Principally, there are two ways of crosslinking UHMWPE which may reduce the mechanical properties of polyethylene [19]. Annealing after irradiation creates free

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radicals or highly energized unpaired electrons, which may lead to late oxidation of the polyethylene [19,20]. Otherwise, remelting the polyethylene after irradiation removes the free radicals but also reduces fatigue strength [20].

In addition, in the knee a range of design and kinematic variables have to be considered, as they can markedly influence wear, regardless of the type of polyethylene used [21]. Current tibial component designs in total knee arthroplasty can be subdivided into two different groups: fixed bearing and mobile bearing. The mobile-bearing knee implant was designed to minimize contact stress on the bearing surface and to reduce polyethylene wear [22,23]. Although the mobile-bearing design has theoretical advantages over the fixed-bearing implant, there is little evidence that mobile-bearing implants lead to better clinical results [24].

In considering the benefits of using XPE in the knee, the nature of the debris has to be considered. Therefore, the purpose of this study was to determine the size, morphology and number of polyethylene particles for six different current knee designs. Different XPE, including fixed- and mobile-bearing inserts, made by remelting as well as by sequential irradiation and annealing, were compared.

2. Materials and methods

2.1. Materials

Six different types of tibial inserts (four XPE inserts and two UHMWPE inserts; shown in Table 1) were used with the appropriate femoral and tibial component recommended from the particular manufacturer. Whereas the material combinations A–C, E and F are actual product devices, D is an experimental combination and not a commercially available product.

2.2. Knee simulator testing

The experimental knee designs (three inserts/material) were tested on a knee simulator (Stallforth/Ungethuem, Germany), involving three simultaneously running test stations over 5×10^6 cycles. Before the measurements, the

inserts were left at 37 °C for 30 days to reach thermal equilibrium and dimensional stability [25]. The physiologic load, flexion/extension (0–60°) motion, anterior/posterior translation waveforms were taken from the recommended ISO kinematics of the knee during normal gait [26]. The compressive load applied to each knee was offset 5 mm medially from the tibial axis [26], and the simulator was run at a frequency of 1 Hz. The lubricant was changed every 6 days. This lubricant used for testing was 25% (v/v) newborn calf serum (Heraeus Kulzer, Berlin, Germany) with 0.1% (m/v) sodium azide solution (Sigma–Aldrich, Munich, Germany) in sterile water [26]. Wear was determined gravimetrically at every 0.5 million cycles, for up to 5 million cycles of testing, by the technique outlined by the ISO [27]. Volumetric wear of the bearings was calculated from weight loss data converted to volumetric data (by material density).

One load-soaked insert was used to correct for fluid absorption in the polyethylene inserts. The load-soaked inserts were subjected to the same cyclic load profile without motion and with the femoral component flexed by 10° to coincide with the peak load during gait. All other test conditions were the same for the load-soak inserts. The load-soak corrected weight loss data were fitted with a linear regression in the steady-state weight increase region (steady state occurred between 0.5 and 2 million cycles). The slope of the regression was recorded as the gravimetric wear rate.

2.3. Isolation of the particles

The particles were separated from the lubricant using the acid digestion method [28]. Then, 10 ml of each serum sample were added to 50 ml of hydrochloric acid (37% v/v; Merck, Darmstadt, Germany) and mixed with a magnetic stir bar at 60 °C for ~1 h. Then, 3 ml of this digestion solution was added to 150 ml of methanol (Merck, Darmstadt, Germany) and filtered through a 0.02-µm polycarbonate membrane (Anodisc 47, Whatman plc, Maidstone, Kent, UK). The filter membrane was then dried for at least 6 h and sputter-coated with gold.

Table 1
Types of knee designs including tibial inserts that were tested in the knee simulator.

Material combination	Knee design	Type of polyethylene	Manufacturing process
A	Scorpio® (Stryker)	XPE (crosslinked polyethylene) (X3™)	Fixed-bearing CR 24 mm, GUR 1020, 3 × 30 kGy gamma irradiation, annealed and sequential irradiated, Gasplasma sterilized
B	Natural Knee® II (Zimmer)	XPE (Durasul™)	Fixed-bearing <i>ultra-congruent</i> 19 mm, GUR 1050, 95 kGy E-beam, remelted, EtO sterilized
C	NexGen® (Zimmer)	XPE (Prolong™)	Fixed-bearing CR 14 mm, GUR 1050, 65 kGy E-beam, remelted, Gasplasma sterilized
D	LCS® (DePuy)	XPE	Mobile-bearing (rotating platform) 15 mm, GUR 1020, 50 kGy gamma irradiation, remelted, gas plasma sterilized (experimental combination: not a commercially available product)
E	LCS® (DePuy)	Conventional UHMWPE	Mobile-bearing (rotating platform) 15 mm, GUR 1020, 25–40 kGy gamma irradiation under vacuum in foil (GVF)
F	Natural Knee® II (Zimmer)	Conventional UHMWPE	Fixed-bearing congruent 13 mm, GUR 1050, gamma sterilized

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