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Effects of Material Thickness and Surface Modification of Cross-linked Polyethylene with Poly(2-Methacryloyloxyethyl Phosphorylcholine) on Its Deformation Behavior, Wear Resistance, and Durability Under Repetitive Impact-to-sliding Motion

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ABSTRACT[1]

Background: Large femoral heads and thin cross-linked polyethylene (CLPE) acetabular liners are required for preventing dislocation in total hip arthroplasty (THA). However, the wear resistance and durability of thin CLPE liners in severe physiological conditions has not been fully understood.
Methods: In this study, we investigated the wear and fatigue properties of untreated CLPE (50 kGy gamma-ray irradiated and annealed) and poly(2-methacryloyloxyethyl phosphorylcholine)-grafted CLPE (PMPC-grafted CLPE) disks that were 3 mm and 6 mm in thickness and subjected to a repetitive impact-to-wear test using a pin-on-disk testing machine.
Results: PMPC grafting reduced the gravimetric wear of 3 mm and 6 mm thick CLPE disks, but did not affect volumetric changes at the impact area. However, the volumetric change for 6 mm thick PMPC-grafted CLPE disks in areas subjected to high pressure was significantly less than that for CLPE. The thickness of CLPE did not affect its gravimetric wear, whereas volumetric changes at both bearing and backside surfaces of 3 mm thick disks were significantly larger than those of 6 mm thick disks. The results of finite element analysis indicated that the maximum von Mises stress of 3 mm thick CLPE disks near the backside hole was greater than its yield stress, which resulted in cold flow. Delamination and fracture did not occur for any disks.
Discussion: Under impact-to-wear conditions, PMPC grafting and CLPE substrate with sufficient thickness brought wear and fatigue resistance; those are favorable candidates for bearing material under the severe physiological conditions present in reconstructed hip joints.

1. Introduction

Total hip arthroplasty (THA) is widely used to reconstruct degenerative hip joints that result from conditions such as rheumatoid arthritis, osteoarthritis, or femoral neck fracture [1–4]. Greater longevity and superior stability of artificial hip joints are required for high activity daily life. One of the issues affecting the longevity of artificial hip joints is periprosthetic osteolysis causing aseptic loosening, which is the major reason for revision surgery in THA [5]. As periprosthetic osteolysis is caused by polyethylene (PE) wear particles, the reduction of PE wear is important [6,7]. Cross-linking is widely applied to improve the wear resistance of PE; however, the problem of osteolysis in THA still remains [8,9]. The Australian Orthopaedic Association National Joint Replacement registry reported that the revision rate of CLPE, including antioxidation CLPE, was 5.2% during the last 14 years, and loosening/osteolysis was the second reason for revision surgery (21.2%) [10]. To enhance the wear resistance of cross-linked PE (CLPE), we have developed a surface modification technology with poly(2-methacryloyloxyethyl phosphorylcholine [MPC]) (PMPC) grafting for a CLPE acetabular liner (PMPC-grafted CLPE) [11–14]. The

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surface modified liner has shown high wear resistance and excellent short-term clinical results [14–17].

In addition to periprosthetic osteolysis, dislocation is one of the main complications associated with THA [18], and so the discussion surrounding the treatment of the problem has intensified. Dislocation is mainly caused by the impingement of the femoral stem neck and acetabular liner [19], which potentially can be avoided by using large-diameter femoral heads [20] or dual mobility bearings [21]. A large-diameter femoral head increases the femoral head/neck diameter ratio, consequently increasing the range of motion and jumping distance necessary for preventing dislocation [22,23]. However, a thin acetabular liner has to be used in conjunction with a large-diameter femoral head because the volume of the acetabulum is limited.

In vivo motion of an artificial hip joint was studied using several methods [24,25]. Lombardi et al. reported on the separation and collision of the interface between the femoral head and the PE acetabular liner occurring in a cycle of walking [25]. Therefore, repetitive impact loading for a PE acetabular liner at heel-strike is a consideration. Using a thin PE acetabular liner poses considerable risks of wear [26] and/or fatigue [27] during daily activities. Several studies reported the relationship between the wear and thickness of CLPE [28,29]. However, the wear under impact-to-sliding motion has not been fully understood. Hence, we focused on the effect of CLPE thickness on wear and fatigue properties by carrying out impact-to-sliding motion experiments.

In this study, we evaluated the wear and impact fatigue resistance of PMPC-grafted CLPE disks with 3 mm and 6 mm thicknesses under repetitive impact-to-sliding motion tests, which simulated severe physiological conditions. We attempted to find the answers to two questions: (1) Will surface modification with PMPC grafting affect the wear and fatigue resistance of CLPE under the severe physiological condition of repetitive impact-to-sliding motion? (2) Will the thickness of the CLPE substrate affect the wear and fatigue resistance of CLPE under this severe physiological condition?

2. Materials and Methods

2.1. Materials

A compression-molded PE (GUR1020 resin; Quadrant PHS Deutschland GmbH, Verden, Germany) stock bar was irradiated in N_2 gas with 50 kGy gamma rays to induce cross-linking and was annealed at 120 °C for 7.5 h in N_2 gas. This material was referred to as CLPE. The cross-linking condition was the same for both the CLPE acetabular liner (Excellink; KYOCERA Corp., Kyoto, Japan) [30] and the PMPC-grafted CLPE acetabular liner (Aquala; KYOCERA Corp.) [15–17]. The CLPE disks with thicknesses of 3.0 mm and 6.0 mm were machined from the bar. We chose 6 mm thick disks for this study because generally the thinnest acetabular liner products are around 6 mm. The 3 mm thick disks were chosen as specimens to simulate an extremely thin acetabular liner. Some of the CLPE disks were immersed in an acetone (Kanto Chemical Co., Inc., Tokyo, Japan) solution containing 10 mg/mL of benzophenone (BP, Wako Pure Chemical Industries Ltd., Osaka, Japan) for 30 s and then dried in the dark at room temperature to remove the acetone. MPC (NOF Corp., Tokyo, Japan) was dissolved in degassed pure water to a concentration of 0.50 mol/L. Subsequently, the CLPE disks coated with BP were immersed in the MPC aqueous solution. Photoinduced graft polymerization was performed on only the bearing surface of the CLPE disk, using ultraviolet irradiation (UVL-400HA ultra-high pressure mercury lamp; Riko-Kagaku Sangyo, Funabashi, Japan) with an intensity of 5.0 mW/cm^2 at 60 °C for 90 min. After polymerization, the PMPC-grafted CLPE disks were washed with pure water and ethanol (Kanto chemical Co., Inc.) and dried at room temperature. This material is referred to as PMPC-grafted CLPE. Both CLPE and PMPC-grafted CLPE disks were sterilized with 25–40 kGy gamma rays in N_2 gas. The PE for all disks thus received 75 kGy gamma rays in total.

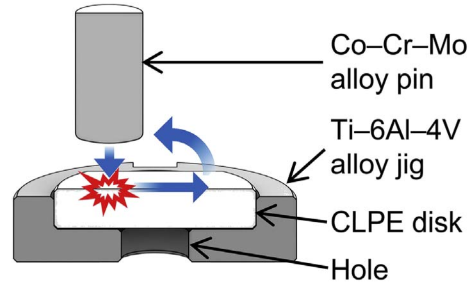

Fig. 1. Schematic illustration of impact-to-wear test.

2.2. Impact-to-wear Testing

Impact-to-wear testing (n = 3) was conducted using a pin-on-disk testing machine (Ortho-POD; AMTI, Watertown, MA, USA) (Fig. 1) [31]. The disks were attached to the pin-on-disk machine with a titanium–6 aluminum–4 vanadium (Ti–6Al–4V) alloy jig (KYOCERA Corp.) that had an 8 mm diameter hole to simulate an acetabular shell with screw holes. The surface of ASTM F75 low carbon cobalt–28 chromium–6 molybdenum (Co–Cr–Mo) alloy pins with diameters of 9.53 mm (KYOCERA Corp.) and curvature radii of 30 mm had a roughness of R_a < 0.012 μm, which is the same smoothness as that of femoral heads used in artificial hip joints. A mixture of 27% fetal bovine serum (Bio west, Nuasllé, France) at 37 °C was used as a lubricant.

Impact-to-wear testing was performed on a repetitive impact and one-way straight sliding track with a half-sine profile and an applied load peaking at 150 N, along with a sliding distance of 10 mm, a sliding speed of 20 mm/s, and a frequency of 1 Hz for a maximum test duration of 2.0×10^6 cycles. Each experimental parameter was referred to ASTM F732-00 appendix 3. The disks were weighed and the lubricant was replaced at the cycles of 0.5×10^5, 0.2×10^6, 0.5×10^6, 1.0×10^6, and 2.0×10^6. The gravimetric wear was determined by weighing the disks with an electronic balance (XP-205; Mettler-Toledo GmbH, Grifensee, Switzerland) with a resolution of 0.01 mg. Weight change was converted into volume by assuming a CLPE density of 0.94 g/cm^3 [13] for the calculation. Control soak testing (n = 3) was conducted simultaneously to perform correction for the weight increments by water absorption. All disks used for the impact-to-wear and control soak tests were pre-soaked in the lubricant for 4 weeks before the tests.

Surface morphologies of the bearing and backside surfaces of the disks were observed using a non-contact three-dimensional profiler with a 0.01 nm height resolution (Talysurf CCI Lite; Taylor Hobson Ltd., Leicester, UK) to evaluate their volumetric change [32]. The volumetric change for the bearing surface of the disks was analyzed by dividing it into three parts: impact area, lower pressure area (Hertzian contact pressure: 25.8–33.5 MPa), and higher pressure area (33.5–38.5 MPa). The wear factor (k) was defined from volumetric change using Archard's equation, as shown below.

$$k = W / (P \times L)$$

W = volume of worn material (mm^3)
P = the applied load (N)
L = the total sliding distance (m)

The applied load is defined as the average of the dynamic vertical load in each area.

The significant differences (p < 0.05) of gravimetric wear and volumetric change for 4 comparative groups (CLPE disk vs. PMPC-grafted CLPE disk with 3 or 6 mm thicknesses, and 3 mm thick disks vs. 6 mm thick disks of CLPE or PMPC-grafted CLPE) were determined