**In Vivo Wear of Highly Cross-linked Polyethylene against Ceramic Femoral Head by Radiographic and Retrieval Studies**

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### Introduction

Osteolysis caused by wear debris of ultra-high molecular weight polyethylene (UHMWPE) in joint arthroplasty has emerged as a serious issue. Reduction of the wear debris from UHMWPE is essential to prevent osteolysis, and different bearing interfaces as well as improvement of the bearing material have been attempted. Clinical application of highly pure alumina ceramics in total hip prostheses (THPs) started in Europe and Japan in the 1970s in order to reduce the UHMWPE wear debris. Clinical results have proved efficiency in wear resistance of the ceramics. Several types of highly cross-linked polyethylene (CLPE), with the irradiation of 50 to 105 kGy, have been launched and extensively used since 1998. In previous studies, such CLPE exhibited an 80 to 90% reduction in wear rate compared with conventional polyethylene (PE) [1]. In this study, the in vivo wear of a CLPE against alumina ceramic femoral head was evaluated by radiographic and retrieval studies.

### Materials and Methods: Acetabular cups

The CLPE (Aeonian; Kyocera Corp., Kyoto, Japan) acetabular cups were manufactured using the following process: The compression-molded UHMWPE (GUR1050 resin) sheet stock was gamma-ray irradiated with 35 kGy in air and annealed at 110°C in N₂ for 12 hours. The cups were then machined from this sheet stock and then gamma-ray sterilized with a dose of 25 to 40 kGy in N₂. Thus, the total dose of gamma-ray irradiation was 60 to 75 kGy.

**Clinical data**

An alumina ceramic femoral head (Kyocera Corp.) of 28 mm in diameter was used in all patients. The CLPE acetabular cup was fixed by the interface bioactive bone cement (IBBC) technique in all cases. The clinical data consisted of 61 joints operated between July 2000 and January 2001. The average age of the patients was 60 years (20–78 years) at the time of operation, and the average follow-up period was 46 months (25–59 months). Primary diseases were osteoarthritis of the hip in 56 joints, femoral head necrosis in 3 joints, congenital dislocation of the hip in 2 joints. Distribution of the cup thickness in the 61 joints were: 1 of 7 mm, 4 of 8 mm, 26 of 9 mm, 23 of 10 mm, 5 of 11 mm and 2 of 12 mm.

**Radiographic analysis**

The in vivo wear of the CLPE cups was measured using frontal view plain radiographs. The femoral head center was determined using a computerized algorithm provided by Vector Works 10.5 (A&A Corp., Tokyo, Japan). Three points on the femoral head contour were used for analysis by the software. The data from the previous study for PE cups (n = 73) sterilized with ethylene oxide gas were used for comparison [1].

**Retrieval study**

Four retrieved CLPE cups of average clinical use for 32 months (11–70 months) were examined. The reasons of revision were: 2 for infection, 1 for repeated dislocation and 1 for pelvic fracture.

The linear wear of the retrieved CLPE cups was measured using a threedimensional coordinate measurement instrument (BHN-305; Mitsutoyo Corp., Kawasaki, Japan).

The worn surface of retrieved CLPE cups was observed by a scanning electron microscope (SEM) (S-3400N; Hitachi Ltd., Tokyo, Japan) at the acceleration voltage of 15 kV.

**Results**

The CLPE showed a high initial linear wear rate of 0.236 mm/year, and the steady wear rate was close to zero (~0.007 mm/year) by radiographic analysis (Figure 1). In PE cups, there was virtually no difference between initial and steady linear wear rates (0.104 and 0.098 mm/year for the former and the latter, respectively). No significant difference was found in the linear wear rate among groups of different thickness (8, 9, 10, and 11 mm), but the tendency of higher wear was observed in the 8 mm group.

The linear wear of retrieved CLPE cups was: 0.21 mm (retrieved after 11 months), 0.05 mm (12 months), 0.09 mm (33 months) and 0.04 mm (70 months) respectively, being similar to the results given by radiographic analysis. In the worn surface of the retrieved CLPE cup retrieved after clinical use of 12 months, machine marks were observed (Figure 2(A)). It indicates extremely low wear (including creep deformation) of this cup. In contrast, the worn surface of the retrieved CLPE cup after clinical use of 70 months was smooth (Figure 2(B)). It indicates creep deformation having occurred to some extent, because the linear wear of retrieved CLPE cup after clinical use of 70 months is extremely low.

**Discussion**

The CLPE cups showed a high initial wear rate, but after one year post operation, it became low and stable. It is known that creep resistant properties are generally improved in the CLPE annealed below the melting point [2]. Hopper reported that the initial wear rate (0–2 year follow-up data) of PE is higher than that of CLPE [3]. We hence speculate that creep deformation of the PE should be higher than creep deformation of CLPE because the PE is not highly cross-linked. However, such a low initial wear rate of the CLPE was not detected in this radiographic study.

The results of radiographic analysis in this study showed a notable reduction in wear of the CLPE cups of clinical use over 36 months against alumina ceramic femoral head, compared to that of the PE cups. The linear wear of retrieved CLPE cups was remarkably low, being consistent with the results of radiographic analysis. We expect that the CLPE has favorable wear properties in long term clinical use, though detailed follow-up is required.

**References**