Clinical Results of the Wear Performance of Cross-Linked Polyethylene in Total Hip Arthroplasty

Prospective Randomized Trial

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Abstract: To investigate the clinical results of cross-linked polyethylene (CLPE) and to compare the CLPE wear against zirconia and stainless steel heads, we studied the radiographic wear after a minimum 3-year follow-up in total hip arthroplasty (THA). Ninety-four hips were randomly implanted with a 22.225-mm head cemented THA—the group of non-CLPE against zirconia and CLPE against 2 different zirconias and stainless steel. The linear wear rate was significantly lower in the group of CLPE against zirconia (0.067, 0.059 mm/y) and against stainless steel (0.068 mm/y) compared with non-CLPE against zirconia (0.170 mm/y). In the short-term results, the wear performance of CLPE against zirconia was superior to that of non-CLPE; however, it did not show a better wear rate than CLPE against stainless steel. Furthermore, long-term investigations will be necessary for understanding CLPE wear in vivo. **Keywords:** wear, cross-linked polyethylene, total hip arthroplasty, clinical result, prospective randomized trial.

Long-term results of total hip arthroplasty (THA) have been improving year by year [1-3], but many problems still need to be resolved. Among them, the major problem that influences the long-term results of THA is periprosthetic osteolysis and subsequent loosening of the prosthesis [4-5].

One of the possible causes of aseptic loosening is considered to be induced by an immunologic response [6-8]. Some literature suggests that the more the acetabular polyethylene (PE) liner is worn, the more frequent the occurrence of periprosthetic osteolysis in THA [9-11].

To resolve the excessive wear of PEs, cross-linked polyethylene (CLPE) has been developed, and CLPEs are now produced by several manufacturers. The clinical use of sockets made of CLPE has become widespread in recent years. Some of the CLPEs have shown excellent wear resistance in vitro [12] and in vivo [13]. However, not all CLPEs are equal because they are produced by various methods. For such reasons, the wear performance of CLPE is still unclear.

In this study, we investigated the clinical results of CLPE and compared the wear performance of it against zirconia and stainless steel heads by analyzing radiographic wear after a minimum 3-year follow-up in THA.

Patients and Methods

From November 1999 to December 2001, 94 hips were implanted with a 22.225-mm head, primary, cemented THA in our hospital. The patients were randomly divided into 4 groups using a sealed envelope technique. All the sockets were all PE cemented acetabular components without a modular metal shell. Twenty-six hips in 23 patients (1 male and 22 females) of group A were implanted with conventional non-CLPE sockets against zirconia heads (BC socket and PHS head, Kyocera Corp, Kyoto, Japan) as control. All the other sockets were made of CLPE (Aeonian socket, Kyocera). The other femoral prostheses were divided into the following 3 groups: 25 hips in 17 patients (1 male and 16 females) of group B were implanted with Kyocera zirconia heads (PHS head, Kyocera), 23 hips in 20 patients (all females) of group C were implanted with Kobelco zirconia heads (HHZ head, Kobelco, Kobe Steel Ltd, Kobe, Japan), and 20 hips in

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17 patients (2 males and 15 females) of group D were implanted with stainless steel (Ortron-90) heads (Elite head, DePuy Inc, Warsaw, Ind). The surface finish of the heads are similar (Ra, <0.02 μm; Ry, <0. 2 μm; the data were provided by its manufacturers).

A preoperative diagnosis was as follows. In group A, 21 hips were secondary osteoarthritis as a result of developmental hip dysplasia, 3 hips were rheumatoid arthritis, and 1 hip was idiopathic avascular necrosis of femoral head (ANF) and postseptic arthritis of one hip. In group B, 24 hips were secondary osteoarthritis as a result of developmental hip dysplasia, and 1 hip was steroid-induced ANF. In group C, 22 hips were secondary osteoarthritis as a result of developmental hip dysplasia, and 1 hip was arthrodesis. In group D, 17 hips were secondary osteoarthritis as a result of developmental hip dysplasia, 2 hips were systemic lupus erythematosus, and 1 hip was steroid-induced ANF. The preoperative and postoperative activity level of the patients was classified by using the UCLA activity level index [14].

Among these groups, patients' demographics such as mean age at operation, follow-up period, the body weight before surgery, the preoperative and postoperative activity level index, and socket abduction angles were not statistically different as shown in Table 1.

The conventional BC sockets used were made of non-CLPE. They were made from GUR415, with stearic acid by ram extrusion and sterilized by ethylene oxide gas. Their average molecular weight was 7.3×10^6. The CLPE, Aeonian socket was made from GUR1050 without the use of stearic acid by compression molding. Their average molecular weight is 7.3×10^6. Cross-linking was accomplished by annealing the material at 110°C after irradiation (3.5 Mrad). These sockets were sterilized by γ irradiation (2.5 Mrad) in nitrogen.

All operations were performed by using a direct lateral approach with a trochanteric osteotomy (Dall's approach) [15]. In dysplastic hips, the femoral head was used for the graft [16]. The grafts were screwed to the superolateral aspect of the acetabular roof with poly-L-lactic acid (PLLA) screws (Fixsorb, Takiron Co Ltd, Osaka, Japan). The acetabular sockets were fixed with vacuum-mixed bone cement (Endurance, DePuy), and the femoral stems were also inserted with bone cement and a cement gun, the so-called third-generation technique [17].

Radiologic Analysis of PE Wear

Polyethylene wear was measured radiologically by determining the penetration of the center of the head relative to the center of the acetabular socket, based on the computer-aided technique described by Sychterz et al [18] and modified by Tanaka et al [19]. The analytical methods used in this study, including the digitization of radiographs and the use of software, are the same as those previously reported and verified by retrieved specimens [19].

Table 1. Patients' Demographics

Group	Acetabular Socket (Manufacturer)	Inner Head (Manufacturer)	Femoral Stem (Manufacturer)	n	Age at Operation, y (±SD)	Follow-Up years, y (±SD)	Body Weight, kg (±SD)	Activity Level Index (Preoperative/Postoperative) (Points ± SD)	Socket Abduction Angle, Degrees (±SD)
A	BC socket, non-CLPE (Kyocera Corp)	PHS head, zirconia (Kyocera Corp)	KC stem (Kyocera Corp)	26	60.0 ± 9.4	4.04 ± 0.99	52.3 ± 6.2	3.6 ± 0.9/5.2 ± 0.8	44.3 ± 4.6
B	Aeonian socket, CLPE (Kyocera Corp)	PHS head, zirconia (Kyocera Corp)	KC stem (Kyocera Corp)	25	61.6 ± 7.9	3.80 ± 0.68	50.7 ± 6.7	3.6 ± 0.7/5.2 ± 0.9	43.5 ± 4.7
C	Aeonian socket, CLPE (Kyocera Corp)	HHZ head, zirconia (Kobelco, Kobe Steel Ltd)	K-max stem (Kobelco, Kobe Steel Ltd)	23	62.7 ± 9.6	3.73 ± 0.54	51.0 ± 9.4	3.7 ± 0.6/5.3 ± 0.7	43.7 ± 3.9
D	Aeonian socket, CLPE (Kyocera Corp)	Elite head, stainless-steel (DePuy Inc)	C stem (DePuy Inc)	20	60.9 ± 7.9	4.07 ± 0.43	54.7 ± 12.6	3.7 ± 0.8/5.2 ± 0.9	44.0 ± 4.7
P					.76	.27	.34	.86/.94	.94