

Comparison of in vivo polyethylene wear particles between mobile- and fixed-bearing TKA in the same patients

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Abstract

Purpose Polyethylene wear particle generation is one of the most important factors that affects the mid- to long-term results of total knee arthroplasties (TKA). Mobile-bearing total knee prostheses were developed to reduce polyethylene wear generation. However, whether mobile-bearing prostheses actually generate fewer polyethylene wear particles than fixed-bearing prostheses remains controversial. The aim of this study was to compare, within individual patients, the in vivo polyethylene wear particles created by a newly introduced mobile-bearing prosthesis in one knee and a conventional fixed-bearing prosthesis in other knee.

Methods Eighteen patients receiving bilateral TKAs to treat osteoarthritis were included. The synovial fluid was obtained from 36 knees at an average of 3.5 years after the operation. The in vivo polyethylene wear particles were isolated from the synovial fluid using a previously validated method and examined using a scanning electron microscope and an image analyser.

Results The size and shape of the polyethylene wear particles from the mobile-bearing prostheses were similar to those from the conventional fixed-bearing prostheses. Although the number of wear particles from the mobile-bearing prosthesis (1.63×10^7 counts/knee) appeared smaller than that from the fixed-bearing prosthesis (2.16×10^7 counts/knee), the difference was not statistically significant.

Conclusions The current in vivo study shows that no statistically significant differences were found between the polyethylene wear particles generated by a newly introduced mobile-bearing PS prosthesis and a conventional fixed-bearing PS prosthesis during the early clinical stage after implantation.

Level of evidence Therapeutic study, Level III.

Keywords Total knee arthroplasty · Polyethylene wear particle · Mobile-bearing prosthesis · Fixed-bearing prosthesis

Introduction

Polyethylene wear particles induce macrophages to release cytokines, which can lead to osteolysis and aseptic loosening of total joint prostheses [4, 13, 14, 17]. Generation of polyethylene wear particles is one of the most important factors that affects the mid- and long-term clinical results after total knee arthroplasty (TKA) [2, 6]. Therefore, to achieve better long-term results for patients with high levels of activity, the materials and design of total knee prostheses have been modified to reduce polyethylene wear particles after TKA. The mobile-bearing prosthesis was expected to produce fewer polyethylene particles than the conventional fixed-bearing prostheses. However, only a few reports on the in vivo polyethylene wear from mobile-bearing prostheses have been published [19, 20]. Therefore, whether mobile-bearing prostheses lead to a reduction in wear remains controversial.

Recently, a highly conforming mobile-bearing posterior stabilized (PS) prosthesis (Vanguard RP; Biomet, Warsaw, IL, USA) was introduced. Because it takes decades to establish the long-term performance of such a newly

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introduced total knee prosthesis, it is particularly important to report early feedback on the *in vivo* polyethylene wear generation before the prosthesis is used widely. However, measuring the *in vivo* polyethylene wear using post-operative TKA radiographs is difficult. To provide such early feedback, we have established a method for measuring the *in vivo* polyethylene wear by isolating and analysing the polyethylene wear particles in the synovial fluid from well-functioning knees after TKA. The characteristics of the *in vivo* polyethylene wear particles generated between different types of total knee prostheses have been compared previously [10, 11, 18–22]. One previous report [19] compared an old mobile-bearing cruciate-retaining prosthesis (MBK, Zimmer, Warsaw, IN, USA) and an old PS prosthesis (IB-II, Zimmer, Warsaw, IN, USA), but those prostheses are no longer used. There have been no reports on contemporary mobile-bearing PS prostheses.

Thus, the aim of this study was to compare the *in vivo* polyethylene wear particles generated by a newly introduced mobile-bearing PS TKA prosthesis in one knee and a conventional fixed-bearing PS TKA prosthesis in the other knee within individual patients. It was hypothesized that the number, size, and shape of the polyethylene wear particles generated by a newly introduced mobile-bearing PS TKA prosthesis and a conventional fixed-bearing PS TKA prosthesis would be significantly different.

Materials and methods

Patients who had bilateral TKAs at our university hospital between 2008 and 2012 were eligible to participate in this study, and patients with primary osteoarthritis and varus deformity of the knee were included. The exclusion criteria included inflammatory arthritis, post-traumatic osteoarthritis, osteonecrosis of the knee, and valgus deformity of the knee. A total of 18 patients who had bilateral TKAs agreed to participate in the present study. Twelve of the patients had simultaneous bilateral TKAs, and six patients had staged bilateral TKAs at an interval of 0.2 ± 0.2 years (mean \pm standard deviation). All of the patients received a mobile-bearing PS prosthesis (Vanguard RP, Biomet) in one knee and a conventional fixed-bearing PS prosthesis (Vanguard PS; Biomet) in the other knee (Figs. 1, 2). The Vanguard RP prosthesis is characterized by its unique saddle-shaped post-cam design and large contact area. A previous report showed that this prosthesis has a much larger contact area on the upper surface of the polyethylene insert and a much lower contact stress throughout the full range of motion than other fixed-bearing PS prostheses [26]. The saddle-shaped post-cam mechanism is in contact during the early phase of flexion and prevents the paradoxical anterior movement of the femoral component [16]. The lower

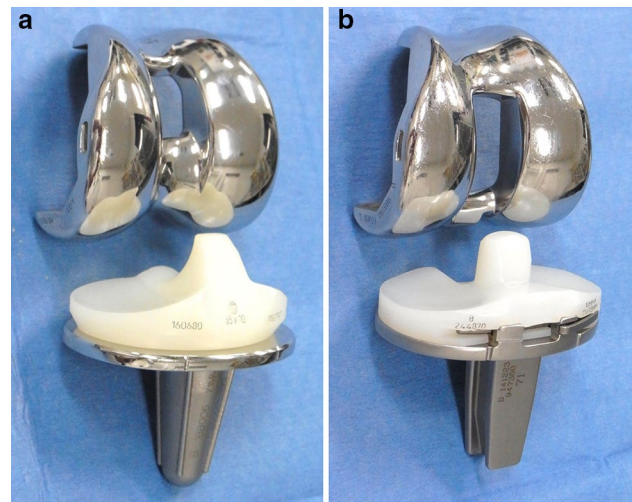


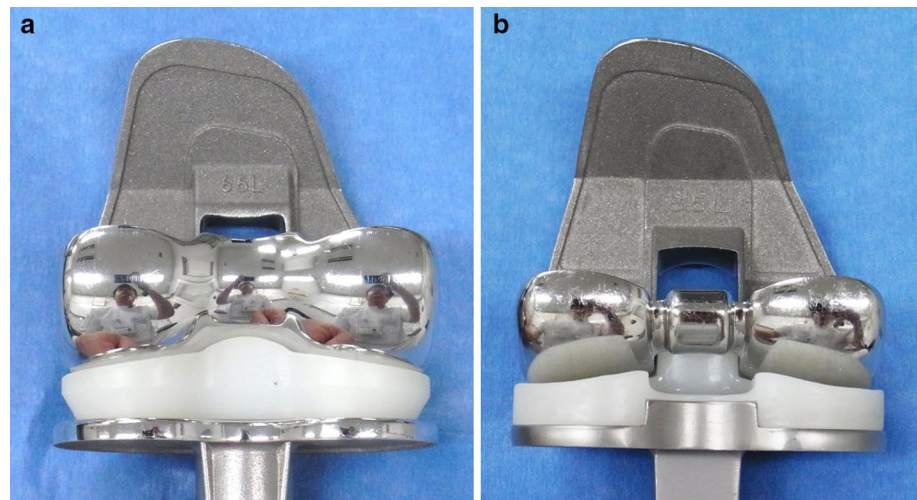
Fig. 1 Images of **a** the newly introduced mobile-bearing PS prosthesis (Vanguard RP) and **b** the conventional fixed-bearing PS prosthesis (Vanguard PS). In the mobile-bearing prosthesis, the polyethylene insert freely rotates about its cam, seated within a hole in the tibial tray. The operative instruments, operative technique, shape of the bone cut surface, fixation method for the prosthesis, and the maximum flexion angle without impingement between the posterior edge of the femoral component and polyethylene insert were identical between the mobile-bearing and fixed-bearing prostheses

surface of the polyethylene insert contains a polyethylene stem and tibial baseplate hole-type mobile-bearing mechanism and induces medial pivot motion after the operation [16]. The surface of the tibial tray was polished in the mobile-bearing PS prosthesis, but was not polished in the fixed-bearing PS prosthesis.

All of the patients were female, and all of the operations were performed by a single surgical team using the medial parapatellar approach. Besides the design of the articulating surface, the prostheses in these two groups were identical. The femoral and tibial components were made from Co–Cr alloy, and the tibial insert was conventional polyethylene (ArCom, Biomet). All of the components were secured with bone cement. Synovial fluid was obtained from all 36 of the knees at an average of 3.5 years after the operation.

The *in vivo* polyethylene wear particles were isolated from the synovial fluid samples using previously validated methods and examined using a scanning electron microscope and an image analyser [12, 19–23]. Each synovial fluid sample was digested with the same amount of 10 M sodium hydroxide at 65 °C for 12 h, applied to a sucrose density gradient (5, 10, 20 %) in a 14-mL tube (14PA tube, Hitachi Koki Co., Ltd., Tokyo, Japan), and then ultracentrifuged at 28,000 rpm ($103,700\times g$) at 4 °C for 3 h (CP100 α , P28S1014 rotor, Hitachi Koki Co., Ltd.). Next, the top layer was collected and applied to an isopropanol-water density gradient (0.90, 0.96 g/mL) in a 40-mL tube (40PA tube, Hitachi Koki Co., Ltd.) and ultracentrifuged again at

Fig. 2 Images showing the post-cam design of **a** the mobile-bearing PS prosthesis (Vanguard RP) and **b** conventional fixed-bearing PS prosthesis (Vanguard PS). The Vanguard RP has a unique *saddle-shaped* post-cam design and large contact area



28,000 rpm ($103,200 \times g$) for 1 h (CP100 α , P28S1004 rotor, Hitachi Koki Co., Ltd.). The polyethylene particles were collected from the interface between the two layers and filtered through 0.1- μ m polycarbonate filters (VCTP 013-00, Millipore Corporation, Bedford, MA, USA). The filters were dried, attached to an aluminium specimen mount (M4, Nisshin EM Co., Ltd., Tokyo, Japan), and sputter-coated with platinum (E-1030 ion sputter, Hitachi Science Systems Ltd., Tokyo, Japan) for scanning electron microscopic examination (S-4700SI, Hitachi Ltd., Tokyo, Japan).

The total number of polyethylene wear particles in each knee joint was calculated from (a) the number of particles on the filter, (b) the retrieval ratio (65 %) [19], (c) the synovial fluid collection ratio (92 %) [19], (d) the amount of synovial fluid used for the extraction process, and (e) the total volume of synovial fluid. Particle size was expressed as an equivalent circle diameter, which is the diameter of a circle having the same area as the particle. Particle shape was determined from the aspect ratio (length to width) and roundness as $\text{perimeter}^2 / (4\pi \times \text{Area})$ [11, 19–23]. Particle size and shape were determined with a digital image analyser (Mac Scope, Minami Co., Tokyo, Japan).

The pre-operative and post-operative activity levels of each patient were evaluated using the University of California Los Angeles (UCLA) activity-level rating [1]. The Knee Society score [11], extension and flexion angles of the knee joint [15], post-operative implant alignment according to the Knee Society grading [7], and mechanical axis using full-length leg radiography were also evaluated. The extension and flexion angles of the knee joint were determined with a standard clinical goniometer according to the method of Kim et al. [15]. A single expert observer (Y.M.) evaluated these parameters for all patients.

The protocol for this study was approved by the Institutional Committee on Human Research at Osaka City University Graduate School of Medicine (number of approval:

1281). Informed consent was obtained from all of the patients before their enrolment.

Statistical analysis

The significance of differences between the two prostheses was assessed using the paired *t* tests with a commercially available software package (StatView 4.5; Abacus Concepts Inc., Berkeley, CA, USA). *P* values <0.05 were considered statistically significant. A sample size calculation showed that 16 knees in each group would allow detection of a difference of 1.5×10^7 polyethylene wear particle counts/knee with a power of 0.8 at an α of 0.05 for a standard deviation of 2×10^7 counts/knee.

To determine the interobserver reliability of the measurements, intraclass correlation coefficients (ICCs) were calculated using the method of absolute agreement and with a single measurement as the unit of analysis using the SPSS ver. 13.0 (SPSS Inc., Chicago, IL, USA) for 6 patients. ICCs below 0.4 represented poor reliability, those from 0.4 to 0.6 represented moderate reliability, those from 0.6 to 0.8 represented good reliability, and those from 0.8 to 1.0 represented very good reliability, according to Bland and Altman [3]. Total number (ICC = 0.85; 95 % CI [confidence interval], 0.12–0.98), ECD (ICC = 0.98; 95 % CI, 0.87–0.99), aspect ratio (ICC = 0.75; 95 % CI, 0.52–0.96), and roundness (ICC = 0.87; 95 % CI, 0.24–0.98) had very good or good interobserver reliability.

Results

All of the patients analysed were female. The average age at the time of the operation was 75 ± 7 years, and the average height and body weight were 148 ± 4 cm and 58 ± 8 kg. Additional salient patient data for both

Table 1 Radiographic outcome, range of motion, Knee Society score, and UCLA activity-level score

Parameter	Mean (and standard deviation)		<i>P</i> value
	Mobile-bearing	Fixed-bearing	
	PS TKA	PS TKA	
Post-op periods (years)	3.4 ± 1.6	3.5 ± 1.5	n.s.
Component size			
Femur	57.5:1, 60:6, 62.5:5, 65:4, 70:1	57.5:1, 60:6, 62.5:6, 65:4, 67.5:1	n.s.
Tibia	63:3, 67:13, 71:3	63:5, 67:11, 71:2	n.s.
Thickness of PE insert	10 mm:17, 12 mm:1	10 mm:10, 12 mm:6 14 mm:1, 18 mm:1	0.011
Patella	31:12, 34:2, NR:3	28:2, 31:9, 34:6, NR:1	n.s.
Pre-op hip–knee–ankle angle	12 ± 4	13 ± 5	n.s.
Post-op hip–knee–ankle angle (degrees valgus)	1 ± 1	2 ± 1	n.s.
Post-op implant alignment (°)			
α	96 ± 1	96 ± 1	n.s.
β	89 ± 1	90 ± 1	n.s.
γ	−0 ± 2	−1 ± 3	n.s.
δ	87 ± 2	87 ± 2	n.s.
Pre-op extension (°)	−8 ± 8	−7 ± 6	n.s.
Pre-op flexion (°)	120 ± 15	119 ± 14	n.s.
Post-op extension (°)	−1 ± 2	0 ± 0	n.s.
Post-op flexion (°)	133 ± 12	134 ± 12	n.s.
Pre-op KSS knee	27 ± 11	27 ± 11	n.s.
Pre-op KSS function	43 ± 12	43 ± 12	n.s.
Post-op KSS knee	99 ± 2	99 ± 2	n.s.
Post-op KSS function	85 ± 18	85 ± 18	n.s.
Pre-op UCLA activity-level score	4 ± 1	3 ± 1	n.s.
Post-op UCLA activity-level score	6 ± 1	6 ± 1	n.s.

NR non-resurface, PE polyethylene, TKA total knee arthroplasty, KSS Knee Society score, UCLA University of California Los Angeles

Table 2 Quantity, size, and shape of wear particles in the mobile-bearing prosthesis and the fixed-bearing prosthesis

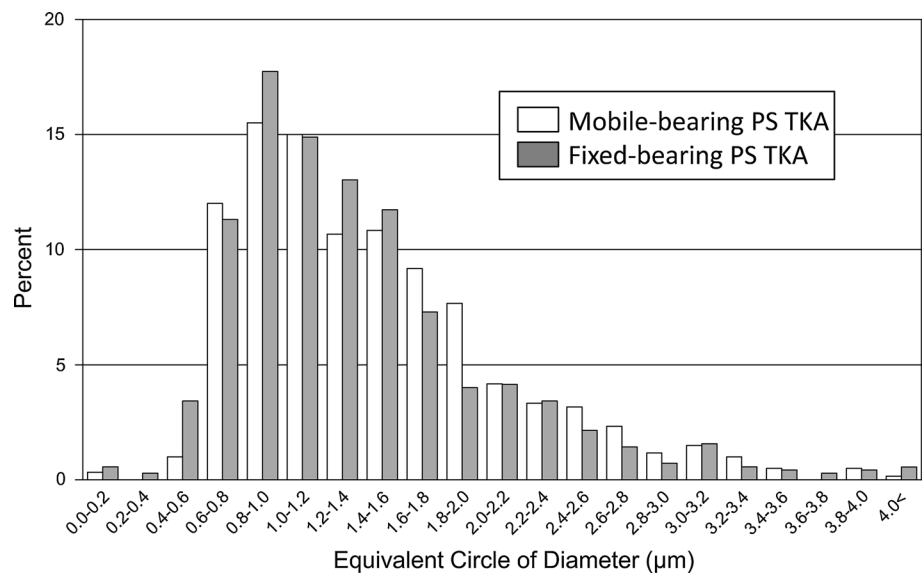
Characteristics	Parameter	Mean (and standard deviation)		<i>P</i> value
		Mobile-bearing PS TKA	Fixed-bearing PS TKA	
		(<i>n</i> = 18)	(<i>n</i> = 18)	
Quantity	Total number	(1.6 ± 1.9) × 10 ⁷	(2.2 ± 2.6) × 10 ⁷	n.s.
Size	ECD (μm)	1.5 ± 0.2	1.5 ± 0.3	n.s.
Shape	Aspect ratio	1.4 ± 0.1	1.4 ± 0.1	n.s.
	Roundness	1.4 ± 0.1	1.4 ± 0.0	n.s.

ECD equivalent circle diameter, TKA total knee arthroplasty

groups are shown in Table 1. The polyethylene insert was thicker in the mobile-bearing than in the fixed-bearing PS prosthesis ($p = 0.011$), but the differences in other pre- and post-operative parameters were not significant. There was no significant difference between the synovial fluid volumes collected from the mobile-bearing (6 ± 3 mL) and fixed-bearing (7 ± 3 mL) PS prostheses.

The quantity, size, and shape of the polyethylene wear particles from each group are shown in Table 2. The total number of polyethylene wear particles obtained from the knees with the mobile-bearing PS prosthesis tended to be less than that obtained from those with the fixed-bearing PS prosthesis, but the difference was not statistically significant. The size distribution of the polyethylene wear particles is shown in Fig. 3. Particles of size 0.8–1.0 μm

Fig. 3 Size distribution of the polyethylene wear particles isolated from the synovial fluid of knees implanted with the mobile-bearing and with fixed-bearing prostheses



occurred most frequently in both groups. The differences in the size and shape (aspect ratio and roundness) between the groups were not statistically significant.

Discussion

The most important findings of the present study were that the number, size, and shape of the *in vivo* polyethylene wear particles generated from a newly introduced mobile-bearing PS prosthesis were not statistically different than those generated from a conventional fixed-bearing PS prosthesis. Although the number of wear particles of the mobile-bearing PS prosthesis tended to be less than that of the fixed-bearing PS prosthesis, the difference was not statistically significant.

One previous report analysing the *in vivo* polyethylene wear particles also found that the number, size, and shape of the *in vivo* polyethylene wear particles generated by a mobile-bearing prosthesis were not statistically different from those generated by a fixed-bearing prosthesis [19]. However, the prosthesis investigated in that study was an old mobile-bearing cruciate-retaining prosthesis, which is no longer used. In fact, different mobile-bearing prostheses were assessed, and thus the clinical results were varied with the various mobile-bearing prostheses. Therefore, the results of the previous study could not be applied to the recently introduced mobile-bearing prosthesis examined in the present study.

Although several studies have reported simulations of the *in vitro* wear of mobile-bearing total knee prostheses, the results remain controversial. In mobile-bearing prostheses, the reduction in contact stress on the polyethylene caused by the large contact area may be offset by the

increased number of articulating surfaces. Several studies reported advantages of mobile-bearing prostheses over fixed-bearing prostheses [5, 8, 18], but others did not [9, 24, 27]. However, there have been no studies on the newly introduced mobile-bearing PS prosthesis, which was investigated in the present study. The results reported here show that the mobile-bearing PS prosthesis did not generate more *in vivo* polyethylene wear particles than the conventional fixed-bearing PS prosthesis.

There are several strengths to the present study. First, we analysed polyethylene wear particles from patients who received a mobile-bearing PS prosthesis in one knee and a conventional fixed-bearing PS prosthesis in the other knee. The level of physical activity and body weight of patients strongly influence the amount of polyethylene wear after TKA. Here, the activity level and body weight were identical for the two different prostheses, which almost removed the influence of such factors on the polyethylene wear particle generation. Second, we used the same brand of prostheses for the two groups; only the design of the articulating surface was different between the mobile-bearing and fixed-bearing prostheses. Previous reports have shown that the materials used for the femoral component [20] and tibial insert [12] also influence *in vivo* polyethylene wear particle generation. Here again, the materials used for the femoral component, tibial component, and tibial insert were identical between the two different prostheses. Thus, we were able to eliminate the influence of the materials and properly evaluate the isolated effects of the difference in articulating surface on the *in vivo* polyethylene wear particle generation.

This study has several limitations. First, there may be a selection bias. The patients who agreed to participate in the present study showed good clinical results, with high Knee

Society and UCLA activity-level scores and improved knee joint flexion angles post-operatively. The number of in vivo polyethylene wear particles may be smaller in other patients with lower activity scores and smaller flexion angles in the knee joint. Therefore, the results of this study may apply to active patients with high activity levels, but not to patients with low active levels. Second, the polyethylene wear particles analysed were not from the soft tissue, but from the synovial fluid. However, it is unethical to harvest soft tissue from well-functioning patients. Polyethylene wear particles are generated from the prostheses and dispersed into the synovial fluid. Some particles are captured in the capsule, while others migrate to the tissue interface and cause osteolysis and aseptic loosening. Previous report showed that the concentration of polyethylene wear particles in the synovial fluid was significantly correlated with the number of particles and histiocytes observed by histological analysis and the degree of osteolysis found during revision TKA [25]. Therefore, the number of polyethylene wear particles in the synovial fluid is related, but not necessarily equal, to the number of particles generated from the prosthesis and deposited at the tissue interface. Comparing the polyethylene wear particles in the synovial fluid of knees with the newly introduced total knee prosthesis and those with the established total knee prosthesis design for which long-term clinical results are already available may also be predictive of the incidence of osteolysis. Besides total hip arthroplasty, it is difficult to measure polyethylene wear using radiographs after joint replacement because the articulation of the joints is not ball and socket shape and the posture of the knee joint (extension–flexion and rotation) changes the contact area between the femoral component and the polyethylene insert. Therefore, in vivo polyethylene wear particle analyses on synovial fluid samples after TKA were performed. Third, the polyethylene inserts could not be observed in the present study. Therefore, the different types of polyethylene wear, such as abrasive, adhesive, cracks, and delamination, could not be distinguished. Further studies would be needed to determine the relationship between the characteristics of the polyethylene wear particles and the types of polyethylene wear. Fourth, it was difficult to make an accurate sample size calculation for this study. The characteristics of in vivo polyethylene wear particles are influenced by both the type of prosthesis and the patient activity level, and no reports on the relationship between the number of particles in the synovial fluid and clinical outcomes were available. Thus, the data from a recent study on contemporary fixed-bearing PS prosthesis [23] were used to make the sample size calculation. This may not be the best approach, but no better method was available. Fifth, the polyethylene insert was thicker in the mobile-bearing group than in the fixed-bearing group. This difference in thickness between the groups

may have affected the characteristics of the in vivo polyethylene wear particles.

Although the newly introduced mobile-bearing PS prosthesis did not reduce the amount of in vivo polyethylene wear particles generated compared to a conventional fixed-bearing PS prosthesis in the early clinical stage after implantation, there were no adverse effects of the newly introduced prosthesis either. Therefore, there is currently no reason to abandon the newly introduced mobile-bearing PS prosthesis. However, further follow-up studies on the generation of polyethylene wear particles should be performed to determine whether there are advantages to the mobile-bearing PS prosthesis.

Conclusions

The current in vivo study shows that no statistically significant differences were found between the polyethylene wear particles generated by a newly introduced mobile-bearing PS prosthesis and a conventional fixed-bearing PS prosthesis during the early clinical stage after implantation.

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