The aims of the current study were to examine polyethylene particles in synovial fluid at an early stage, and to compare a newly introduced medial pivot total knee prosthesis with an established posterior-stabilized total knee prosthesis. Synovial fluid was obtained 1 year after knee arthroplasty from 17 patients with well-functioning prostheses (22 knees, 11 posterior-stabilized prostheses and 11 medial pivot prostheses) under complete sterile conditions. Polyethylene particles were isolated and analyzed by scanning electron microscopy. Particle size (equivalent circle diameter) was 0.78 ± 0.08 μm (mean ± standard error) in posterior-stabilized prostheses and 0.67 ± 0.06 μm in medial pivot prostheses. Particle shape (aspect ratio) was 2.30 ± 0.22 in posterior-stabilized prostheses and 1.90 ± 0.16 in medial pivot prostheses. The total numbers of particles were 1.16 ± 0.57 × 10⁸ in posterior-stabilized prostheses and 9.01 ± 2.95 × 10⁶ in medial pivot prostheses. Particles were smaller and rounder in medial pivot prostheses than in posterior-stabilized prostheses, but the differences were not significant. The difference in the common logarithm of particle number was significant. The medial pivot prosthesis generated less wear particles than the posterior-stabilized prosthesis, and these findings may have an impact on the incidence of osteolysis and aseptic loosening.

It generally is accepted that polyethylene wear particles induce a macrophage response, which leads to osteolysis and aseptic loosening in total joint arthroplasties. In the 1990s, wear of polyethylene components and osteolysis after total knee arthroplasties were reported with increased frequency. Generation of polyethylene wear particles is one of the most important factors that affects mid-term and long-term results of total knee arthroplasties. The geometry of the articulating surface in total knee arthroplasties affects the character-
istics of polyethylene wear particles. Therefore, many designs for total knee arthroplasty prostheses recently have been introduced based on new concepts in wear reduction. Although newly introduced total knee prostheses theoretically provide low wear, no clinical information is available concerning the characteristics of polyethylene wear particles in such knee prostheses. It particularly is important to examine in vivo polyethylene wear generation in such new total knee prostheses before they are used widely.

The aims of the current study were to examine the size, shape, and number of polyethylene particles in synovial fluid at an early stage, and to compare a newly introduced total knee prosthesis such as medial pivot total knee prosthesis with an established posterior-stabilized total knee prosthesis.

MATERIALS AND METHODS

Synovial fluid was obtained 1 year after surgery from 17 patients who had a total knee arthroplasty (22 knees) under complete sterile conditions. Informed consent was obtained from all patients and the ethical committee in the authors’ hospital authorized to use of this procedure.

Eleven knees had a posterior-stabilized total knee prosthesis (five I-BII, Zimmer, Warsaw, IN; six Osteonics Scorpio PS, Stryker Osteonics Howmedica, Rutherford, NJ), and 11 had a medial pivot total knee prosthesis (Advance Medial-Pivot Knee, Wright Medical Technology, Arlington, TN). The manufacturing methods for polyethylene inserts were a compression molded sheet for the I-BII (GUR4050) prosthesis, and ram extrusion for the Scorpio PS (GUR1050) and the Advance Medial-Pivot Knee (GUR4050) prostheses. Sterilization of the polyethylene insert was done with 2.5 Mrad γ-rays in nitrogen gas for the I-BII and the Scorpio PS prostheses, and ethylene oxide gas for the Advance Medial-Pivot Knee prosthesis. The mean patient age at the time of surgery was 65 years (range, 55–73 years) (posterior-stabilized prostheses, 63.8 ± 2.1 [mean ± standard error] years; medial pivot prostheses, 67.0 ± 2.3 years). The difference was not statistically significant (p = 0.323). Nine patients were men and six patients were women. The preoperative diagnosis of all patients was osteoarthritis. The patients were assessed preoperatively and postoperatively using the Hospital for Special Surgery knee score and Knee Society score. Preoperative and postoperative activity level was evaluated using the University of California Los Angeles activity-level rating. Quantitative assessment of walking activity was calculated as steps per day. Steps per day was estimated from a University of California Los Angeles activity score and the linear regression line described by Zahiri et al. The knee scores and activity level of each design were investigated by two physicians with experience in total knee arthroplasty (AK, 11 posterior-stabilized prostheses; KI, 11 medial pivot prostheses).

Polyethylene wear particles were isolated using a previously described technique. All solutions were filtered through a 0.2-μm pore nylon filter (150–0020, Nalge Company, Rochester, NY) to avoid contamination of extraneous particles. Synovial fluid was in each case digested with the same amount of 10 mol/L sodium hydroxide at 65°C for 12 hours, applied to sucrose density gradients (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 G) at 4°C for 3 hours (CP100α, P28S1014 rotor, Hitachi Koki Co, Ltd). The top layer was collected and applied to isopropanol-water density gradients (0.90, 0.96 g/mL) in a 40-mL tube (40PA tube, Hitachi Koki Co, Ltd) and ultracentrifuged again at 28,000 rpm (103,200 G) for 1 hour (CP100α, P28S1004 rotor, Hitachi Koki Co, Ltd). Polyethylene particles were collected from the interface between two layers and filtered through 0.1-μm polycarbonate filters (VCTP 013–00, Millipore Corporation, Bedford, MA). The filter was dried, attached to an aluminum specimen mount (M4, Nissin EM Co, Ltd, Tokyo, Japan), and coated with platinum (E-1030 ion sputter, Hitachi Science Systems Ltd, Tokyo, Japan) for scanning electron microscopic examination (S-4700SI, Hitachi Ltd, Tokyo, Japan) (Fig 1). The images were analyzed with a computerized image analyzer (Mac Scope, Minami Co, Tokyo, Japan).

The retrieval ratio of this extraction method was determined using normal synovial fluid and commercially-available high-density polyethylene powder (mean particle size, 3.5 μm) (S-395, Shamrock, Petaluma, CA).

It practically is impossible to aspirate completely all synovial fluid in a joint with one puncture. Therefore, the synovial fluid collection ratio
was calculated to estimate polyethylene wear particles in the residual synovial fluid in joint capsules. After simple aspiration, 20 mL of saline was injected into the joint capsule and then reaspirated with residual synovial fluid. Polyethylene wear particles in simple aspirated fluid and reaspirated fluid from seven knees were analyzed. The fluid collection ratio was defined as:

\[
\text{Synovial fluid collection ratio} = \frac{A}{(A + B)} \times 100\% 
\]

where A is the total count of polyethylene wear particles in synovial fluid with simple aspiration, and B is that with reaspiration.

The total number and concentration of polyethylene wear particles in the synovial fluid were calculated from (1) the number of particles on the filter; (2) the retrieval ratio; (3) the synovial fluid collection rate; (4) the amount of synovial fluid used for the extraction process; and (5) total amount of synovial fluid. Particle size was expressed using equivalent circle diameter, which is the diameter of a circle having the same area as the particle. Particle shape was determined by the aspect ratio (length/breadth) and roundness (perimeter\(^2/4\pi \times \text{area})^{26}

Statistical analyses of differences between the types of prostheses were done using the nonpaired \(t\) test and Mann-Whitney \(U\) test with a statistical software package (StatView 4.5, Abacus Concepts Inc, Berkeley, CA).

**RESULTS**

The knee scores and activity levels are shown in Table 1. The differences in postoperative Hospital for Special Surgery knee score (\(p = 0.0001\)) and postoperative Knee Society score (knee score, \(p = 0.0004\); function score, \(p = 0.005\)) between the two designs were statistically significant. However, the differences in postoperative University of California Los Angeles score (\(p = 0.470\)) and postoperative steps per day (\(p = 0.400\)) between two groups were not significant.

The retrieval ratio of polyethylene particles was 65.2%. The synovial fluid collection ratio was 92.3%.

The volume of synovial fluid was 11.0 ± 2.3 mL (mean ± standard error) for posterior-stabilized total knee prostheses and 4.7 ± 1.7 mL for medial pivot total knee prostheses (\(p = 0.040\)). The concentration of particles was 1.23 ± 0.62 \(\times 10^7\)/mL for posterior-stabilized total knee prostheses and 4.52 ± 2.41 \(\times 10^6\)/mL for medial pivot total knee prostheses. The total particle number contained in synovial fluid was 1.16 ± 0.57 \(\times 10^8\) for posterior-stabilized total knee prostheses and 9.01 ± 2.95 \(\times 10^6\) for medial pivot total knee prostheses (Table 2). The common logarithm of total particle number generated in medial pivot total knee prostheses was smaller than in posterior-stabilized total knee prostheses, and the difference between groups was statistically significant (\(p = 0.004\)) (Fig 2A). The difference in the common logarithm of particle concentration between groups was not statistically significant (\(p = 0.155\)) (Fig 2B).
TABLE 1. Scores and Activities in Patients with Posterior-Stabilized and Medial Pivot Total Knee Prostheses

<table>
<thead>
<tr>
<th>Score</th>
<th>Operative status</th>
<th>PS TKA (n=11)</th>
<th>MP TKA (n=11)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital for Special Surgery</td>
<td>Preoperative</td>
<td>67.4 ± 1.2</td>
<td>34.2 ± 3.7</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Postoperative</td>
<td>93.1 ± 0.9</td>
<td>85.8 ± 1.2</td>
<td>0.0001</td>
</tr>
<tr>
<td>Knee Society</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Preoperative</td>
<td>68.1 ± 1.5</td>
<td>18.2 ± 1.0</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Postoperative</td>
<td>93.5 ± 0.8</td>
<td>88.4 ± 0.8</td>
<td>0.0004</td>
</tr>
<tr>
<td>Function</td>
<td>Preoperative</td>
<td>71.4 ± 2.3</td>
<td>28.3 ± 6.2</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td></td>
<td>Postoperative</td>
<td>95.5 ± 1.6</td>
<td>87.2 ± 2.1</td>
<td>0.005</td>
</tr>
<tr>
<td>UCLA Activity Level</td>
<td>Preoperative</td>
<td>3.5 ± 0.2</td>
<td>2.8 ± 0.1</td>
<td>0.028</td>
</tr>
<tr>
<td></td>
<td>Postoperative</td>
<td>4.5 ± 0.2</td>
<td>4.3 ± 0.1</td>
<td>0.470</td>
</tr>
<tr>
<td>Quantitative Activity</td>
<td>Preoperative</td>
<td>3167 ± 108</td>
<td>2729 ± 84</td>
<td>0.005</td>
</tr>
<tr>
<td>(Steps per Day*)</td>
<td>Postoperative</td>
<td>3854 ± 108</td>
<td>3729 ± 97</td>
<td>0.400</td>
</tr>
</tbody>
</table>

PS = posterior-stabilized; MP = medial pivot; TKA = total knee arthroplasty; UCLA = University of California Los Angeles

*Calculated from UCLA Activity Score

TABLE 2. Concentration and Number of Polyethylene Wear Particles in Posterior-Stabilized and Medial Pivot Total Knee Prostheses

<table>
<thead>
<tr>
<th>Parameter</th>
<th>PS TKA (n=11)</th>
<th>MP TKA (n=11)</th>
<th>p Value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number</td>
<td>1.16 ± 0.57 × 10⁶</td>
<td>9.01 ± 2.95 × 10⁶</td>
<td>0.004</td>
</tr>
<tr>
<td>Concentration (/mL)</td>
<td>1.23 ± 0.62 × 10⁷</td>
<td>4.52 ± 2.41 × 10⁶</td>
<td>0.155</td>
</tr>
</tbody>
</table>

*Common logarithm was used for statistical analysis

PS = posterior-stabilized; MP = medial pivot; TKA = total knee arthroplasty

Fig 2A–B. (A) Comparison shows the polyethylene wear particle number (total count per knee) between posterior-stabilized prostheses and the medial pivot total knee prostheses. A common logarithm was used for statistical analysis. (B) Comparison shows the polyethylene particle concentration between posterior-stabilized prostheses and the medial pivot total knee prostheses. A common logarithm was used for statistical analysis.
The size and shape of the particles in each group are shown in Table 3. Particle size expressed using equivalent circle diameter was 0.78 ± 0.08 μm in posterior-stabilized total knee prostheses and 0.67 ± 0.06 μm in medial pivot total knee prostheses (p = 0.260). Particle shape determined by the aspect ratio was 2.30 ± 0.22 in posterior-stabilized total knee prostheses and 1.90 ± 0.16 in medial pivot total knee prostheses (p = 0.158). Particle shape determined by the roundness was 2.52 ± 0.36 in posterior-stabilized total knee prostheses and 1.80 ± 0.17 in medial pivot total knee prostheses (p = 0.075). Medial pivot prostheses tended to generate smaller and rounder particles. However, the difference was not significant. Particle size distributions expressed by equivalent circle diameter of each group are shown in Figure 3. For posterior-stabilized and medial pivot total knee prostheses, 0.4 to 0.6 μm was the range with greatest frequency.

**TABLE 3. Size and Shape of Polyethylene Wear Particles in Posterior-Stabilized and Medial Pivot Total Knee Prostheses**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>PS TKA (n = 11)</th>
<th>MP TKA (n = 11)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ECD (μm)*</td>
<td>0.78 ± 0.08</td>
<td>0.67 ± 0.06</td>
<td>0.260</td>
</tr>
<tr>
<td>Shape</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspect ratio</td>
<td>2.30 ± 0.22</td>
<td>1.90 ± 0.16</td>
<td>0.158</td>
</tr>
<tr>
<td>Roundness</td>
<td>2.52 ± 0.36</td>
<td>1.80 ± 0.17</td>
<td>0.075</td>
</tr>
</tbody>
</table>

*ECD = equivalent circle diameter; PS = posterior-stabilized; MP = medial pivot; TKA = total knee arthroplasty

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**Fig 3.** Size distribution shows wear particles in posterior-stabilized prostheses and medial pivot total knee prostheses.
DISCUSSION

There have been only four reports concerning polyethylene particles in synovial fluid of failed total knee prostheses. Although polyethylene wear particles from failed knee prostheses yield important information, wear particles in such failed knee prostheses are generated in extreme conditions and might be affected by unstable interface and third bodies. In the current study, polyethylene wear particles in synovial fluid of total knee prostheses that were functioning well were investigated.

Polyethylene wear particles are generated at the articulation and dispersed into synovial fluid. Some particles then are captured in the capsule and other particles migrate in interface tissue, causing osteolysis and aseptic loosening. Although the number of polyethylene particles in synovial fluid is not necessarily the same as the number of particles generated in countersurface, the number of particles in synovial fluid is related to particles generation and particle deposition in interface tissue. Therefore, generation of large numbers of polyethylene particles may result in great numbers of particles in the joint fluid, the capsule, and the interface tissue. These differences may not affect the short-term and midterm results, but would have impact on the long-term stability, which is required in modern designs for total knee arthroplasty prostheses.

As reported by Stern and Insall, posterior-stabilized prostheses first were introduced in 1978. The tibial post and femoral cam provide a functional substitution for the posterior cruciate ligament. Posterior-stabilized prostheses have feature problems such as dislocation, cam wear, and patella clunk syndrome. However, it has been reported that polyethylene wear is lower than in other types of prostheses and survivorship is approximately 95% at 15 years. Posterior-stabilized total knee prostheses, therefore, have been recognized as among the few to achieve excellent long-term clinical results.

Medial pivot prostheses have been developed based on a unique concept. A large medial ball and socket joint provide a large contact area and low stress. Less congruent lateral articulation reproduces pivotlike movement, as in normal knees. Although a medial pivot prosthesis theoretically reduces wear, there have been no reports concerning long-term clinical results.

In the current study, wear particles tended to be smaller and rounder in medial pivot total knee prostheses than in posterior-stabilized total knee prostheses. However, this difference was not statistically significant. The common logarithm of the total particle number in synovial fluid in medial pivot total knee prostheses was smaller than in posterior-stabilized total knee prostheses, and the difference was statistically significant. The concentration of polyethylene wear particles tended to be smaller in medial pivot total knee prostheses than in posterior-stabilized total knee prostheses, but the difference between groups was not statistically significant. The synovial fluid was a buffer system for polyethylene wear particles. Therefore, the total particle number may correlate with the amount of particles generated at the articulation, whereas the concentration highly depends on the volume of the synovial fluid. These differences may not affect the short-term and mid-term results, but would have impact on the long-term stability, which is required in modern designs for total knee arthroplasty prostheses.

The differences in the postoperative Hospital for Special Surgery knee score and the postoperative Knee Society score between the two groups were statistically significant. The knee scores and activity levels of patients with each design were investigated separately by two physicians with experience in total knee arthroplasty. Variance between investigators could have affected the differences in the Hospital for Special Surgery knee score and the Knee Society score between the two designs. However, the rating system for the University of California Los Angeles Orthopaedic Research Institute is designed to account for interobserver variability.

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Angeles activity score is much simpler and variance between investigators can be minimized using the University of California Los Angeles activity score. Outcome evaluations of joint reconstructions in lower extremities should include an assessment of patient activity. In vivo wear assessments of total joint prostheses should be based on a measure of use. The modern electronic, digital pedometer can be a satisfactory means of quantifying the use of joints in the lower extremities. The University of California Los Angeles activity score had a strong correlation with the average steps per day as recorded by modern pedometers in 100 patients with total joint replacements. The University of California Los Angeles activity score is valid for activity assessment in a clinical setting. The differences in the postoperative University of California Los Angeles activity score (p = 0.470) and steps per day as postoperative quantitative activity (p = 0.400) between two designs were not statistically significant. Therefore, the difference in total number of particles between two designs might not be influenced by the difference in patient activity level.

In the early stage, the medial pivot prosthesis generated less wear particles than the posterior-stabilized prosthesis. However, careful followup of patients with the medial pivot total knee prosthesis is mandatory, because polyethylene wear and osteolysis after total knee arthroplasty are multifactorial. The current authors think that extraction analyses of particles in the early postoperative period generated in well-functioning prostheses provide particularly important information of newly introduced total knee prostheses.

References
20. Insall JN, Ranawat CS, Aglietti P, Shine J: A


