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Polyethylene wear particle generation in vivo in an alumina medial pivot total knee prosthesis

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Abstract

Polyethylene wear particle generation is one of the most important factors affecting mid- to long-term results of total knee arthroplasties. It has been reported that the medial pivot total knee prosthesis (MP) design and alumina ceramic femoral component reduce polyethylene wear. The aim of this study is to evaluate in vivo polyethylene wear particle generation in the newly introduced alumina MP, in comparison with a metal MP. Synovial fluid was obtained from 11 knees with alumina MP and 15 knees with metal MP at nine months after the operation. Polyethylene particles were isolated, and examined using scanning electron microscope and image analyzer. Total number of particles in each knee was $7.10 \pm 2.86 \times 10^6$ in alumina (mean ± standard error), and $5.70 \pm 2.82 \times 10^7$ in metal MP ($p = 0.048$). Particle size (equivalent circle diameter) was $0.78 \pm 0.04\,\mu m$ in alumina, and $0.66 \pm 0.06\,\mu m$ in metal MP ($p = 0.120$). Particle shape (aspect ratio) was 1.52 ± 0.05 in alumina, and 1.88 ± 0.11 in metal MP ($p = 0.014$). Apart from the femoral component, the material and manufacturing method of polyethylene insert differed between the two groups, although the sterilization method was the same. Alumina MP generated fewer and rounder polyethylene wear particles than metal MP in early clinical stage, and could potentially reduce prevalence of osteolysis and aseptic loosening.

Keywords: In vivo test; Polyethylene; Wear debris; Alumina; Knee replacement

1. Introduction

Polyethylene wear particles induce macrophages to release cytokines, which leads to osteolysis and aseptic loosening in total joint arthroplasties [1–4]. Generation of polyethylene wear particles in total knee arthroplasties is one of the most important factors that affect mid- and long-term clinical results [5,6]. Certainly, in case of elderly patients with lower activity levels, even total knee prostheses with conventional design and materials have achieved excellent mid- and long-term results. Polyethylene wear particle generation in total joint prostheses is correlated to the activity level of the patients [7]. Greater demands are recently placed on total knee arthroplasties for younger, more active patients [8]. Therefore, to reduce polyethylene wear generation and to achieve better long-term results for patients with higher activity levels, many new designs and materials have recently been introduced for total knee prostheses.

Regarding the design of the articulating surface of total knee prostheses, reduced wear generation of the medial pivot design has been reported [9]. Regarding the material of the articulating surface of total knee prostheses, reduced polyethylene wear of alumina ceramic has been reported [10–12]. Thus, to reduce polyethylene wear generation, we combined the design (medial pivot) and the material (alumina ceramic), and developed a new total knee prosthesis, alumina ceramic

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medial pivot total knee prosthesis (MPK; Kyocera, Tokyo, Japan) (Fig. 1).

It takes decades to study the long-term results of newly introduced total knee prostheses. Thus, it is particularly important to examine in vivo polyethylene wear generation in such new prostheses before they come into widespread use. Apart from total hip arthroplasty, it is difficult to determine the in vivo polyethylene wear using postoperative radiographs. We have developed a method to measure in vivo polyethylene wear by isolating and analyzing polyethylene wear particles in synovial fluid from well-functioning knee after total knee arthroplasty [9,13].

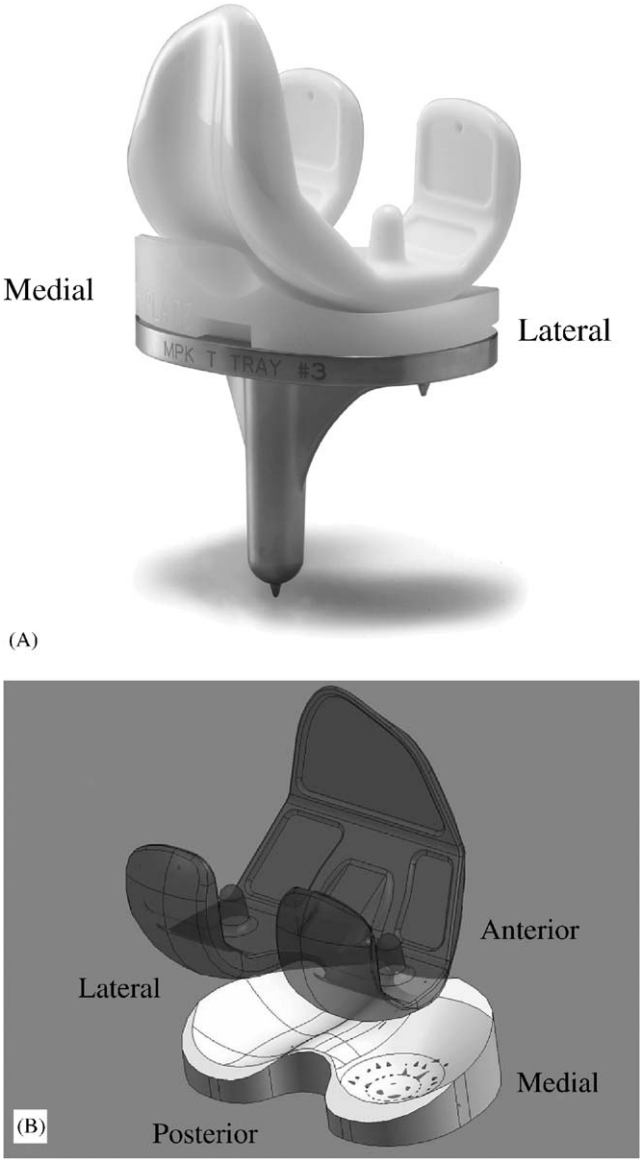

Fig. 1. Photograph (1-A) and diagram (1-B) of the Medial Pivot Knee. Note the ball and socket joint in the medial compartment and the less congruent articulation in the lateral compartment. The femoral component is made of alumina ceramic. The tibial tray is made of titanium alloy.

The aims of the current study were to determine the size, shape, and number of polyethylene wear particles isolated from the synovial fluid of newly introduced alumina ceramic medial pivot total knee prostheses in comparison with metal medial pivot total knee prostheses.

2. Methods

Synovial fluid was obtained from 22 patients who had total knee arthroplasty (27 knees) under complete sterile condition in an operating room on nine postoperative months. This study was approved by our institutional committee on human research. All subjects gave informed consent at enrollment. Eleven knees had alumina ceramic medial pivot total knee prosthesis and 15 knees had metal medial pivot total knee prosthesis (Advance medial-pivot knee; Wright medical technology, Arlington, TN, USA).

The materials used for the femoral component were high purity current alumina ceramic (Bioceram; Kyocera, Tokyo, Japan) for the alumina ceramic medial pivot prosthesis, and Co–Cr alloy for the metal medial pivot prosthesis. Roughness (Ra) of femoral component surface is 0.02 μm for the ceramic medial pivot prosthesis, and 0.127 μm for the metal medial pivot prosthesis. Character of alumina ceramic is shown in Table 1. The manufacturing methods used for the polyethylene inserts were compression molded sheet (GUR 1050) for the ceramic medial pivot prosthesis, and ram extrusion (GUR 4050) for the metal medial pivot prosthesis. The polyethylene inserts were sterilized with ethylene oxide gas for both of the prostheses. All components were fixed with bone cement.

The preoperative diagnosis of all patients was osteoarthritis. Preoperative and postoperative activity levels were evaluated using the University of California Los Angels (UCLA) activity-level rating [14]. Quantitative assessment of walking activity was calculated as steps per day. Numbers of walking activity was estimated from UCLA activity score and a linear regression line as described by Zahiri et al. [7]. The activity level of each group was investigated by three physicians with experience in total knee arthroplasty (AK, KI, and YK).

Table 1
Material character of current alumina ceramic

	Current alumina[a] (1987–)
Alumina content (%)	>99.5
Bending strength (MP)	640
Average grain size (μm)	1.4
Density (g/cm^3)	3.97

[a]Bioceram; Kyocera, Tokyo, Japan.