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Effect of stem alignment on long-term outcomes of total hip arthroplasty with cementless Bi-Metric femoral components

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ABSTRACT

We investigated the effects of varus-valgus alignment on the long-term outcomes after cementless total hip arthroplasty (THA) using a porous coated version of Bi-Metric® femoral stems. The Kaplan-Meier survival analysis was performed in 71 hips. The survival rate with femoral revision for aseptic loosening as the end point was 100% at 17 years. Nevertheless, the initial stem alignment was more valgus in patients with the Engh grade III–IV stress shielding than patients with the Engh grade I–II. Our results suggest that valgus misalignment of cementless Bi-Metric stem might be a potential risk factor for the progression of stress shielding.

1. Introduction

Cementless total hip arthroplasty (THA) is becoming increasingly popular due to a marked improvement of femoral stem components in regard to material property, surface treatment (porous coating), and shape conformity to various types of medullary cavity morphology.[1–4] Bi-Metric® total hip system (Biomet, Inc., Warsaw, IN) has been clinically introduced since 1985 in US and 1987 in Japan, which consists of a femoral stem made of forged titanium alloy (Ti-6Al–4 V) with a plasma-sprayed porous coating on its proximal one-third portion.

Several authors reported promising short to mid-term outcomes of cementless Bi-Metric stems.[5–8] Nevertheless, there are a few reports concerning about stress shielding and bone resorption. One study performed by Robertsen et al.[5] showed that calcar remodeling was present in 90% of the patients (88% atrophy and 2% hypertrophy) only at 2.9 year follow-ups after 50 primary THAs using collared type Bi-Metric stems. Meding et al.[8] reported that patients experienced a severe stress shielding classified as the Engh grades III (prevalence rate, 53%) and IV (17%) at 10.4 year follow-ups after receiving collarless type Bi-Metric stems (105 hips).

The stem malpositioning is a potential risk factor for the progression of stress shielding, which is often associated with a distal press-fit of stems and a reduced load transfer at a proximal part of femur.[9,10] In this context, we hypothesized that varus-valgus positioning of cementless Bi-Metric stem (even in the small variation) has a significant adverse effect on the fixation stability. In the present study, we conducted the 12–17 year long-term follow-up of 71 cementless THAs using a porous-coated version of Bi-Metric stems at a single institution, and analyzed the effects of varus-valgus misalignment on the long-term clinical and radiological outcomes.

2. Methods

This retrospective study was approved by the Institutional Review Board (IRB) of our institute. Between March 1997 and July 2002, 95 primary THAs were performed in 89 patients with the use of a collarless, proximally porous-coated, cementless Bi-Metric® femoral stems (Biomet, Inc., Warsaw, IN) without hydroxyapatite coating. All the operations were performed by four surgeons (TS, TM, TT, KY) at a single center. 10 patients (10 hips) died during the study period due to causes unrelated to THA. 14 patients alive either had changed hospital (2 patients, 2 hips) or were lost to followup (12 patients, 12 hips). Thus, 65 patients (71 hips) were included for clinical and radiographic analyses (Table 1). Of these patients, there were 11 males and 54 females with underlying diseases, including osteoarthritis (63 hips), osteonecrosis of femoral heads (7 hips), and rheumatoid arthritis (1 hip). Their mean age and body mass index (BMI) at the time of surgery were 60 years (range, 33–83 years) and 24.9 kg/m^2 (range, 17.5–39.0 kg/m^2). The mean follow-up period was 14.0 years (range, 12–17 years).

All the patients received standard proximal profile (SPP) Bi-Metric stems with a 3° proximal-to-distal taper, 0° anteversion, and 135° stem-neck (CCD) angle, and Ti-6Al-4V plasma-sprayed porous coated cups

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Table 1
Patient demographics.

Variable	Value
Number of hips	71
Number of patients	65
Number of women	54
Initial diagnosis (number of hips)	
Osteoarthritis	63 (89%)
Osteonecrosis	7 (10%)
Rheumatoid arthritis	1 (1%)
Age at surgery (years)	60 (range, 33–83)
BMI (kg/m^2)	24.9 (range, 17.5–39.0)
JOA hip score	48 (range, 22–72)
Follow-up period (years)	14 (range, 12–17)

BMI: body mass index; JOA: Japanese Orthopaedic Association.

with 4 fins on the rims (Mallory-Head®, Biomet, Inc.). The acetabular liners were 33-kGy γ-irradiated conventional ultra-high molecular weight polyethylene (PE) (ArCom®, Biomet, Inc.), which were captured by the cups with a Ring-Loc® mechanism (Biomet, Inc.). The counter-faces used were cobalt chrome alloy or monolithic zirconia (3Y-TZP) femoral heads with the diameter of 28 mm. A posterior approach without trochanteric osteotomy was adopted in all hips. Radiographs were taken before and immediately after THA, and the follow-up radiography was then performed weekly within one month. Subsequently, patients were evaluated at every 3 or 6 months at the first postoperative year, and at every 6 months or 1 year after the second year.

The preoperative and postoperative outcomes were assessed according to the Japanese Orthopaedic Association (JOA) score (100 points is the maximum score).[11,12] Stress shielding was classified as grade I–IV according to the criteria of Engh et al. [13]. The grade I–II and III–IV were regarded as mild and severe shielding in this study. Radiolucent lines at bone-implant interfaces were classified using three acetabular zones of DeLee and Charnley[14] (zones I–III) and seven femoral zones of Gruen[15] (zones 1–7). Distal cortical hypertrophy of bone on medial and lateral portion of femur was evaluated. The fixation and stability of the stems were assessed by the Engh's scoring system (the maximum scores of fixation and stability are 10 and 17 points, respectively).[16] The Kaplan-Meier analysis of the survival of the stem components was conducted in all hips. The stem failure was defined as aseptic loosening, and revision for any reason.

Radiological loosening was defined as 2 mm or more of radiolucency around the entire prosthesis[17] or any migration of the implant.[16] The total and annual linear wear[18] of PE acetabular liners were assessed to correlate with aseptic loosening. Stem alignment was determined as the angle between the longitudinal axes of the femoral intramedullary canal and the femoral component stem on anteroposterior radiographs.[19] Statistical analysis was performed with the Mann-Whitney *U* test to investigate the relationship between osteolysis and liner wear, as well as stress shielding and stem alignment. The analysis was conducted using software package SPSS (SPSS, version 17, Chicago, IL, USA). Statistical significance was set at a confidence level of $P < 0.05$.

3. Results

The mean JOA hip score improved from 48 points (range, 22–72 points; SD, 11) preoperatively to 93 points (range, 78–100 points; SD, 5) at final follow-up, and there were no patients remaining thigh pain after six months from the operation. The postoperative complications included: a late infection, and recurrent dislocation. One hip was revised as a result of periprosthetic infection. The Kaplan-Meier analysis with aseptic loosening of the stem as the end point showed 100% survival at 17 years (Fig. 1). On the other hand, the Kaplan-Meier analysis with revision of the stem for any reason (infection) as the end point showed 98.6% survival at 17 years (Fig. 1).

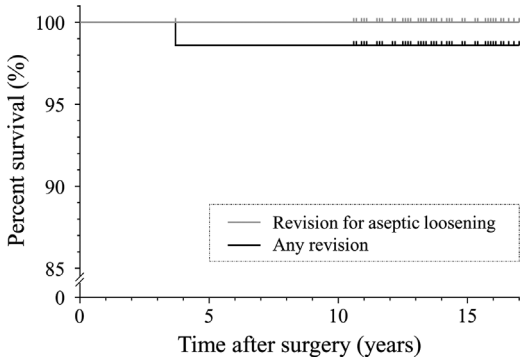

Fig. 1. Kaplan-Meier survival curves for cementless Bi-Metric femoral components at a mean of 14 years.

The average cup inclination and anteversion were measured as 41° and 19.1° in the postoperative AP radiographs. The average total and annual linear wear of PE acetabular liners were assessed as 1.25 ± 0.75 mm and 0.090 ± 0.049 mm/year, respectively. Pelvic osteolytic lesions were noted in acetabular zones I–III, and these prevalences were 35, 30, and 9% of 69 hips (excluding one infected hip and one dislocated hip), respectively.

All stems were placed within ± 4° from neutral alignment (Fig. 2). There were no measureable changes in varus-valgus positioning for any stems at any follow-up. The femoral stems were placed within ± 1° from neutral alignment in 77% of 69 hips. The average Engh's scores for stem fixation and stability were both favorable (9.6 points [range, 5–10 points, SD, 1] and 16.9 points [range, 14.5–17 points, SD, 1]), suggesting the successful bone ingrowth in all patients.

Stress shielding of the Engh grade I, II, III and IV was noted at 27, 61, 9, and 3%, respectively, and 88% of 69 hips (excluding one infected hip and one dislocated hip) were mild grade I–II (Fig. 3). A cortical hypertrophy was noted in 6 hips (9%). The initial stem alignment was more valgus in patients with the Engh grade III–IV stress shielding than patients with the Engh grade I–II ($P < 0.0001$). (Fig. 4). The femoral osteolysis was observed at the proximal zones (13, 7, 11% of 69 hips in zones 1, 6, 7), but no femoral components were revised for osteolysis.

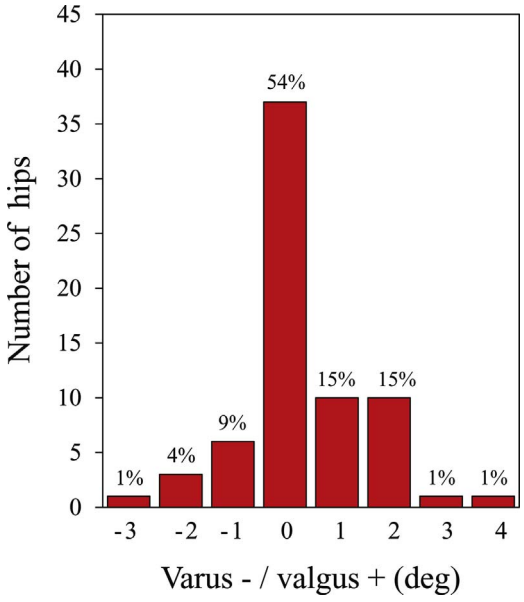

Fig. 2. Relationship between number (percentage) of the hips and the initial stem alignment.