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Original Article

Coronal Instability after Total Knee Arthroplasty using Bi-Surface type 3: An Averaged 10 Year Follow-up Study

Kim Mindae, Toshifumi Watanabe, Takeshi Muneta, Toshiyuki Ohara, Ichiro Sekiya and Hideyuki Koga

Medical Hospital, Tokyo Medical and Dental University, Tokyo, Japan

Abstract

The stability of the knee joint affects the outcome of total knee arthroplasty. Among the knees with Bi-Surface type 3 (BS3), some showed progressive mediolateral (ML) displacement in the tibiofemoral joint on the standing anteroposterior (AP) radiographs, which indicated ML instability. We aimed to clarify the coronal instability and related factors with it.
We compared radiological and clinical outcomes of the 26 knees with BS3 and 38 knees with NexGen LPS (LPS). All surgeries were performed with the same surgical techniques at our institution. Radiological evaluation included the component shift ratio, which indicated coronal instability. Correlations of the component shift ratio at latest follow-up with radiological and clinical measurements were also assessed.
Greater component shift ratios in the BS3 group were found, while clinical outcomes showed no significant differences in both groups. The component shift ratio increased with the posterior tibial slope, the femorotibial angle, the implant extension angle, and the knee extension at the latest follow-up.
BS3 knees exhibited coronal instability on radiographs, although clinical outcomes were similar to LPS knees. Understanding the design characteristics of BS, avoiding excess posterior tibial slope, and paying attention to the soft tissue balance would be the keys to prevent the instability with this prosthesis.

Key Words: Coronal instability, Mediolateral displacement, Component shift ratio,

Introduction

Instability is one of the main causes for the revision surgeries after total knee arthroplasty (TKA), accounting for about 20 % in the previous reports[1, 2], ranging from 7% to 26 %[3-5]. The cause of the instability following TKA includes several reasons[6, 7]. Implant designs and surgical techniques greatly affect postoperative stability. In posterior-stabilized (PS) prostheses, the post-cam mechanism plays an important role for stable femoral rollback during flexion with a small amount of valgus/varus rotation throughout the range of motion[8]. The conformity of the prosthesis including the shape of the tibial insert also affects the joint stability. For surgical techniques, mediolateral (ML) soft tissue imbalance and flexion/extension gap mismatch can result in unstable knee[6, 7].

Bi-Surface knee system (BS, Kyocera, Kyoto, Japan) is a unique total knee prosthesis that has a ball-and-socket structure instead of the post/cam mechanism (Fig 1a)[9, 10]. The ball-and-socket surface helps smooth deep flexion with axial rotation, keeping the large contact area between the femoral component and tibial insert[9-11]. The femoral component is made of alumina ceramics. Together with the ultra-high molecular weight polyethylene inserts, the ceramic femoral component would decrease polyethylene wear and improve

Corresponding Author: Toshifumi Watanabe, MD. ,Ph D.
Department of Orthopaedic Surgery Medical Hospital, Tokyo Medical and Dental University 1-5-45 Yushima, Bunkyo-ku, Tokyo 113-0034, Japan
Tel & Fax: +81-3-5803-4675
E-mail: watanabe.orj@tmd.ac.jp
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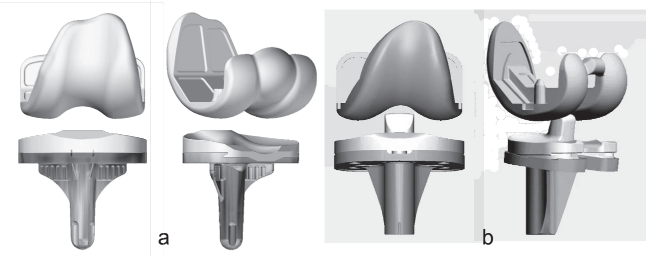

Figure 1.

a. Bi-Surface type 3 has a unique ball and socket structure in the mid-posterior area of the femoral and tibial components.
b. LPS has a conventional post/ cam structure.

long-term prosthesis durability[12]. Excellent range of motion and patient satisfaction were achieved with this prosthesis[11, 13], and long-term durability was also confirmed[14, 15]. We started applying BS type 3 (BS3) in 1999 at our institution and continued using it for several years. However, among these cases, some knees showed progressive mediolateral (ML) displacement in the tibiofemoral joint on the standing anteroposterior (AP) radiographs. One of these cases ended up with gross instability and underwent revision surgery at 6 years after the primary TKA (Fig. 2). Knees with another prosthesis with post/cam mechanism (NexGen LPS, Zimmer, Warsaw, IN, Figure 1b) used during the same period of time at our institution did not demonstrate such coronal instability. Based on this, we hypothesized that instability might occur because of the unique implant feature in BS3.

Therefore, we compared radiological and clinical outcomes of the knees with two different designs (BS3 and LPS) to clarify whether the coronal instability occurred in prosthesis specific and if this was the case, what affected the shift and whether the shift affected the clinical outcomes including patient satisfaction.

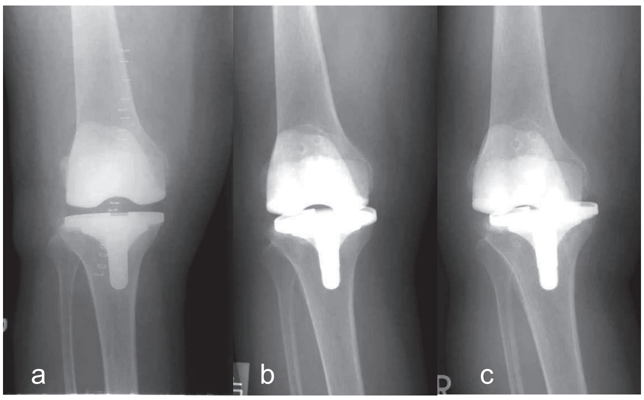

Figure 2.

The progressive medial shift of the tibial side and varus deformity is demonstrated on the anterolateral radiographs: a. 1 week, b. 1 year, and c. 6 years after the surgery.

Methods

Subjects

We retrospectively assessed a total of 64 knees in 42 patients who underwent BS3 (26 knees, BS3 group) or LPS (38 knees, LPS group) and were followed up 2 years or more (Table1). Out of 42 patients, 22 patients underwent bilateral TKA: 6 patients with two-stage bilateral TKA and 16 patients with simultaneous bilateral TKA. The prosthesis for each knee was selected by the primary surgeon for unilateral TKA, while for bilateral TKA, BS3 and LPS were used for each side. Again, the selection of the side is determined by the primary surgeon for the patient. The cohort consisted of osteoarthritis without preoperative valgus knee deformity. From January 1999 to December 2002, a total of 225 primary TKAs in 160 patients were performed at our institution, including 89 knees with LPS or BS3. Excluding knees with a preoperative diagnosis of rheumatoid arthritis (8 knees) or aseptic necrosis (1 knee), or femorotibial angle (FTA) less than 170° (1 knee) left 79 knees. Out of 79 knees, 68 knees (86%) were followed-up for more than 2 years. Finally, 64 knees in 42 patients were analyzed excluding a patient with bilateral TKA who underwent a revision surgery for one side because of infection and a patient with bilateral TKA who got knee injury after surgery. The subjects include a patient with a unilateral TKA with BS3 who showed instability at 1 year after surgery and underwent revision surgery at 6 years (Fig. 2). Preoperative characteristics of both groups were similar (Table 1).

Table 1. Preoperative profiles of 2 groups

Factors	Bi-Surface 3	NexGen LPS	P value
Number of knees	26	38	-
Timing and side of surgery (simultaneous / two-stage / unilateral)	16 / 6 / 4	16 / 6 / 16	0.077
Sex (female / male)	25 / 1	35 / 3	0.461
Age at surgery (years)	72 ± 6	72 ± 6	0.700
Knee extension (°)	-12 ± 11	−12 ± 9	0.822
Knee flexion (°)	109 ± 17	113 ± 19	0.408
Knee Society knee score	34 ± 17	35 ± 19	0.940
Knee Society function score	45 ± 31	41 ± 29	0.655
Self-assessment (/100)	15 ± 20	13 ± 18	0.454
Femoro-tibial angle (°)	188 ± 6	189 ± 6	0.534
Follow-up period (year)	10 ± 5	9 ± 5	0.538

Data are shown as an average ±standard deviation or as numbers.

Prostheses

Both BS3 and LPS are posterior-stabilized prostheses that do not need functional posterior cruciate ligament (Fig. 1). BS3 has a unique ball and socket structure, which enables femoral rollback avoiding posterior impingement between the femoral component and tibial insert[9, 10], but does not work from extension to mid-flexion. On the other hand, LPS has a conventional post/cam structure, which induces femoral rollback after post/cam engagement, and works as an ML stabilizer throughout the range of motion. BS3 aimed at deep knee flexion of 150°, whereas LPS were designed to flex up to 125°. The ball and socket joint in BS3 starts working at 60° knee flexion, while the post/cam engagement in LPS occurs at 75° theoretically. The tibial inserts in both systems had relatively flat low-constrained symmetrical medial and lateral surface, which allow relatively free axial rotation and femoral rollback.

Surgical Procedures and Postoperative Management

All surgeries were performed based on the same surgical techniques by 4 surgeons. An air tourniquet was applied during surgery, which was released before skin closure. A midline skin incision followed by the midvastus approach was applied. Measured bone resection based on anatomic landmarks was used for all knees. An intramedullary alignment rod for the femoral cut and an extramedullary guide system for the tibial cut were used. Mechanical alignment was aimed at in the coronal plane for both femur and tibia. In the sagittal plane, the distal femoral cut was made parallel to the distal femoral shaft to avoid anterior notch, and approximately 5° of the posterior tibial slope was aimed at for both systems. After the bone resection, the soft tissues were released on a case-by-case basis to obtain ML balance[16], and all the components were fixed with cement. The patella was replaced for all knees. No knee showed remarkable ML or extension-flexion imbalance during surgery.

The same postoperative management was applied for all cases. Patients were allowed to start and gradually progress a range of motion and full weight-bearing gait exercise on the day after surgery.

Radiological and Clinical Outcome Assessment

We compared radiological and clinical outcomes of both groups. In the radiological assessment, component angles (α, β, γ, and δ angle) and the radiolucent line were evaluated based on the Knee Society roentgenographic evaluation system[17]. The FTA, the implant extension angle, and the component shift were measured at 1 year after surgery and at latest follow-up. The FTA was examined on the standing anteroposterior (AP) radiograph of the knee. The implant extension angle was measured on the supine lateral radiograph of the knee at full extension (Fig. 3a). The ML shift between the femoral and tibial component was measured on the standing AP radiograph of the knee, and the component shift ratio was calculated (Fig. 3b). The component shift ratio indicates ML instability near knee extension.

For clinical outcomes, knee extension and flexion, Knee Society knee score (KS) and function score (FS), and Self-assessment of the involved knee (0-100) were examined at 1 year after surgery and at latest follow-up.

We also assessed correlations of the component shift ratio at latest follow-up with radiological and clinical measurements in both groups to clarify the factors which related to the component shift.

An orthopaedic surgeon (the first author) performed all measurements on the radiographs. Intraclass correlation coefficients (ICC) were examined to determine the inter- and intra-observer reproducibility for the component shift ratio using SPSS Statics 21 (IBM, Armonk, NY, USA). To check the inter-observer reproducibility, randomly selected 20 knees were measured independently by another orthopaedic surgeon (one of the authors) as a second observer. The ICCs for the inter-observer reproducibility were 0.92 and 0.82 in BS and LPS group, respectively. To assess the intra-observer reproducibility, randomly selected 20 knees were mea-

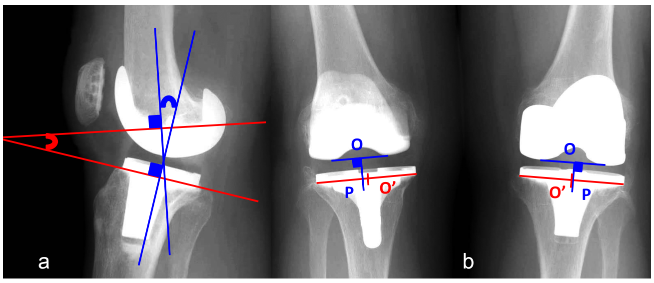

Figure 3.

a. The implant extension angle was measured.
b. The lateral shift between the femoral and tibial component was measured, and the component shift ratio was calculated. The center of the femoral component was determined as the center of the distal femoral line connecting the lowest point of the medial and lateral condyle (O). The center of the tibial component was determined as the center of the mediolateral (ML) line on the lower border of the baseplate (O'). The intersection between the line perpendicular to the distal femoral line and passing the point O, and the ML line on the baseplate was determined as the point P. Then, the distance between the point P and O' was measured with the medial direction of the point P to O' being positive. Finally, the component shift ratio was calculated by dividing the PO' length by ML length of the baseplate.

sured twice by the first author. The ICCs for the intra-observer reproducibility were 0.93 and 0.85 in BS and LPS group, respectively.

Statistical analysis

For statistical analysis between the two groups, Student's t-test and Mann-Whitney U test were applied for numerical data based on the distribution of the data, and chi-square test and Fisher's exact test were used for categorical data. Spearman's rank correlation coefficients were also examined. A probability value less than 0.05 was considered to be significant. Statistical software, SPSS Statics 21 was used for all analyses.

Results

In the radiographic assessment, we found greater component shift ratios in the BS3 group compared with LPS group at 1 year after follow-up (1.1±1.0, 0.0±1.1, respectively, p<0.001) and at the latest follow-up (2.4±2.9, 0.0±1.1, respectively, p<0.001, Table 2). No knees showed the ratio more than 3 % at 1-year follow-up in both groups. However, 6 knees in BS group demonstrated the component shift ratio more than 5%, while no knee in LPS group showed the shift of more than 5% (p<0.001, Fig. 4). When we examined the radiographs of these 6 knees in detail, the component shift ratio exceeding 5% first appeared at 8 ± 5 years after surgery. The FTA and the implant extension angle were not significantly different between the two groups either at one year or at latest follow-up. The incidence of the radiolucent line 1mm or more was significantly higher in the BS3 group (5 knees, 20%) compared with LPS group (0%, p=0.009). None of the 5 knees with the radiolucent line in BS3 group exhibited component shift ratio of more than 5% at the latest follow-up. The femoral and tibial component position was also similar in BS and LPS groups: (*α*, 95±2, 96±3, p=0.548; *β*, 90±3, 89±2, p=0.151; *γ*, 3±2, 4±2, p=0.183; *δ*, 85±2, 85±1, p=0.365, respectively).

In clinical assessment, no significant differences were found in terms of knee extension or flexion, KS, FS, or self-assessment either at 1-year follow-up or at the latest follow-up between the two groups (Table 3).

Three radiographic measurements correlated with the component shift ratio at latest follow-up in BS3 groups (Fig. 5). The component angle of *δ* showed a negative correlation with the component shift ratio at the latest follow-up in the BS3 group (r= -0.454, p= 0.020), but not

Table 2. Femorotibialangle, implant extension angle, and component shift ratio at 1-year and the latest follow-up

Factors		Bi-Surface 3	NexGen LPS	P value
At 1-year follow-up	Femorotibial angle (°)	174±3	175±3	0.788
	Implant extension angle (°)	8±7	6±8	0.303
	Component shift ratio (%)	1.1±1.0	0.0±1.1	<0.001*
	Component shift ratio > 5 % (N)	0	0	-
At the latest follow-up	Femorotibial angle (°)	175±4	175±3	0.779
	Implant extension angle (°)	10±9	8±7	0.481
	Component shift ratio (%)	2.4±2.9	0.0±1.1	<0.001*
	Component shift ratio > 5 % (N)	6	0	0.003*

Data are shown as an average ± standard deviation or as numbers.
* P < 0.05.
Fisher's exact test was applied to compare the Component shift ratioover 5%.

Table 3. Clinical outcomes at the latest follow-up

Factors		Bi-Surface 3	NexGen LPS	P value
At 1-year follow-up	Knee extension (°)	-4±5	-3±3	0.250
	Knee flexion (°)	117±12	121±11	0.522
	Knee Society knee score	93±5	93±7	0.528
	Knee Society function score	77±15	80±13	0.473
	Self-assessment (/100)	83±8	84±10	0.553
At the latest follow-up	Knee extension (°)	0±2	0±3	0.485
	Knee flexion (°)	119±13	120±11	0.966
	Knee Society knee score	94±9	95±9	0.458
	Knee Society function score	68±22	70±24	0.537
	Self-assessment (/100)	81±19	78±19	0.621

Data are shown as an average ±standard deviation.

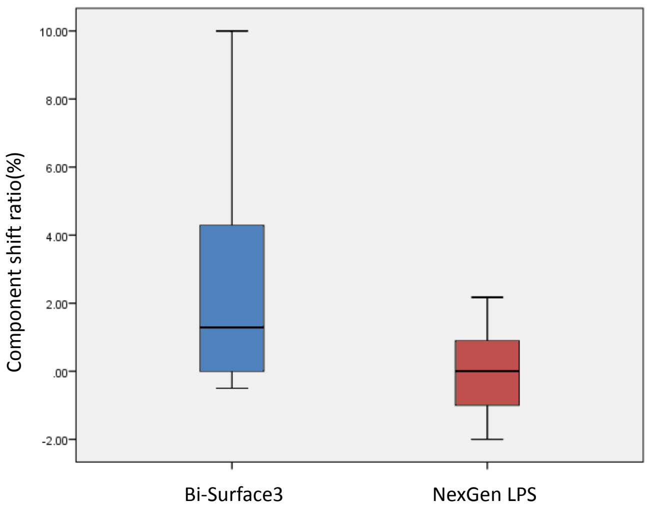

Figure 4.

Component shift ratio at the latest follow-up in both groups are shown. BS3 group shows a non-normal distribution toward medial shift of the tibia, while LPS group has a normal distribution.

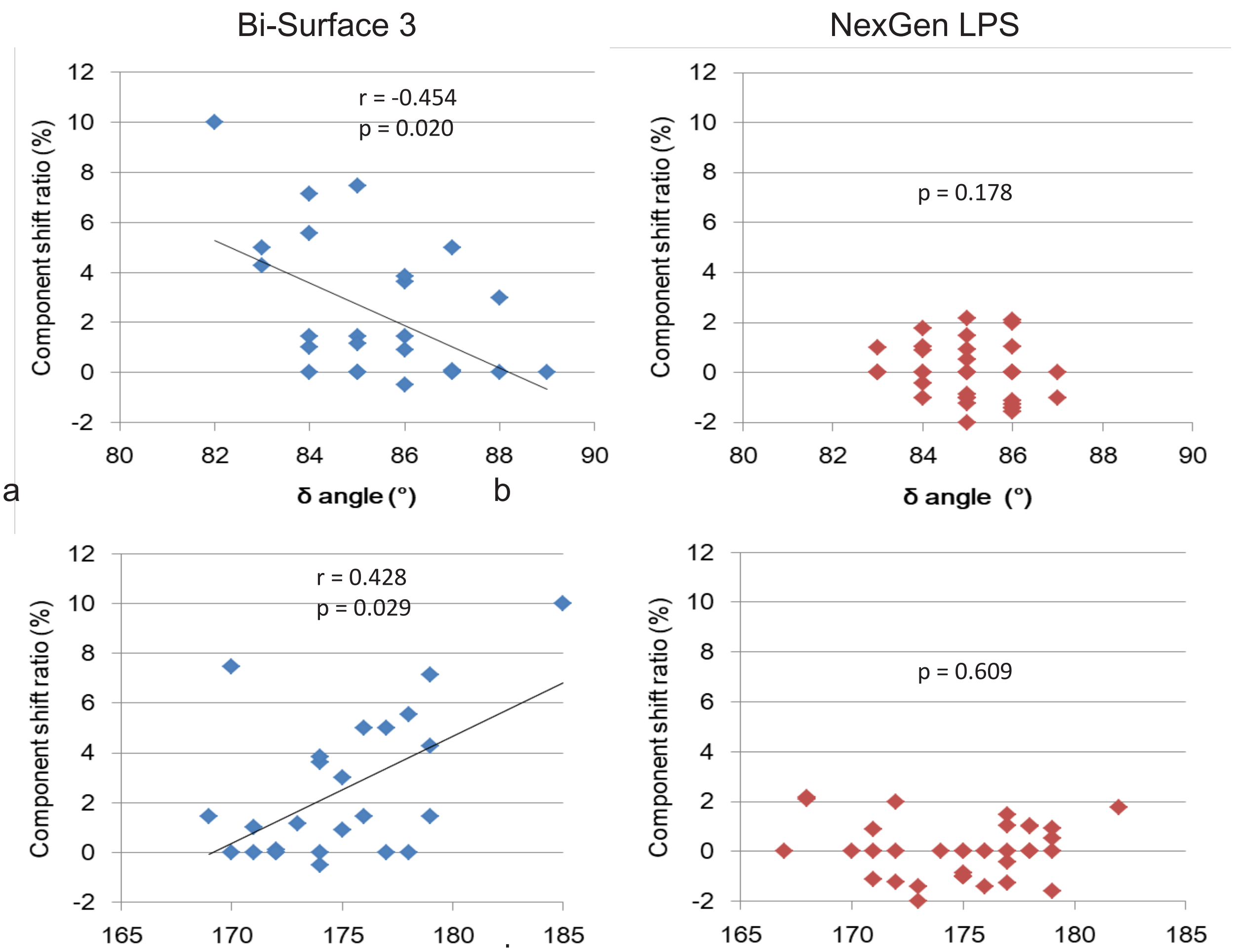

Figure 5.

Correlation of component shift ratio at latest follow-up with femorotibial angle, implant extension angle, and component position of δ are shown.

in LPS group (p=0.178). The FTA at the latest follow-up demonstrated a positive correlation with the component shift ratio at the latest follow-up in the BS3 group (r= 0.428, p= 0.029), but not in LPS group (p=0.609). The implant extension angle at the latest follow-up also exhibited positive correlation in BS3 group (r= 0.456, p= 0.019), but not in LPS group (p=0.755). We found no correlation of the component shift ratio at the latest follow-up either in BS3 or LPS group with the preoperative FTA (p=0.073, p=0.339, respectively), the α angle (p=0.681, p=0.310, respectively), the β angle (p=0.273, p=0.691, respectively), or the γ angle (p=0.737, p=0.386, respectively).

One clinical measurement correlated with the component shift ratio at the latest follow-up in BS3 group, which was knee extension at the latest follow-up (r= 0.508, p= 0.008), but not in LPS group (p=0.750). We found no correlation of the component shift ratio at the latest follow-up either in BS3 or LPS group with the age at surgery (p=0.425, p=0.176, respectively), follow-up period (p=0.918, p=0.092, respectively), knee flexion (p=0.990, p=0.986, respectively), KS (p=0.847, p=0.804, respectively), FS (p=0.214, p=0.676, respectively), or self-assessment (p=0.306, p=0.863, respectively) at the latest follow-up.

Discussion

The primary outcome in this study was that the tibial side significantly shifted medially in BS3 group compared with LPS group on standing AP radiographs at 1 year after surgery and at the latest follow-up, which suggests more instability in BS3 knees near extension. We performed all the surgeries in both groups with the same surgical techniques including bone cutting and soft tissue releasing, and postoperative FTA and component angles confirmed the same bone resection in both groups. However, the component shift ratios were significantly different, indicating different implant designs would affect the coronal instability. The component shift ratio in both groups fell within 3% at 1 year after surgery, while 6 knees in the BS3 group showed the component shift ratio more than 5% at the latest follow-up, which indicated the progress of the shift in BS3 group during this period of time. The other radiographic assessments except the radiolucent line were similar between the two groups including the implant extension angle. The implant extension angles were around 10° greater than clinical knee extension because of the femoral bowing (5°) and posterior tibial slope (5°)[18].

The component shift ratio correlated with δ angle, FTA, implant extension angle, and knee extension at the latest follow-up in the current study. Knees with greater postoperative FTA are considered to have more lateral laxity compared with the medial side, which would result in higher component shift ratio[19]. A previous study suggested that preoperative severe deformity can induce postoperative instability[20], and so as in BS knee[21]. Care should be taken to the knees with preoperative severe deformity, although the preoperative FTA did not affect the component shift ratio in this study. The component angles in the coronal plane (*α*, and *β*) did not correlate with the ratio, while one of the sagittal angles (*δ*) had negatively correlated with the ratio. The increasing tibial posterior slope resulted in increasing component shift ratio. The implant extension angle and the knee extension connected to the laxity or instability near extension[22]. A surgeon can control these factors by avoiding steep posterior tibial slope, excessive soft tissue release, and leaving too much laxity. Nevertheless, the significantly higher component shift ratio in BS knees would greatly depend on its component design because other radiographic outcomes including FTA, component angles, and implant extension angle were similar in both groups.

BS3 would have more coronal instability near extension compared with the LPS. Both BS3 and LPS have relatively flat symmetrical tibial insert to allow great axial rotation and femoral rollback. The prominent difference between the 2 prostheses is the ball-and-socket structure in BS3 and the post/cam mechanism in LPS. BS3 knees heavily depend on the medial and lateral collateral ligament and other soft tissues for ML stability from extension to 80° flexion where the mid-posterior socket surface starts working[11]. Gap balancing throughout the range of motion is also important to maintain stability from extension to mid-flexion and make the ball-and-socket mechanism work properly in deep flexion[11]. Iida et al. reported 3 cases of ball-and-socket joint dislocation out of 115 knees in 95 patients (2.6%) in their study on BS type 4 with an average follow-up of 2.3 years[21]. In 3 knees, 1 case had multiple surgeries before TKA, and another case had severe preoperative deformity with FTA of 195°. Akagi et al. reported 2 knees with revision surgery due to instability and 2 knees with ML subluxation out of 182 knees (4 knees, 2.2%) in their study on BS types 1 and 2 with an average follow-up of 5.8 years[13]. We also have a case with the severe coronal instability that underwent revision surgery out of 26 knees (4%) in our series with an average follow-up of 10 years. The knee has poor preoperative flexion of 75°, and flexion/extension gap balancing and ML soft tissue balancing were challenging. In the latest version of BS type 5, the new design with both post/cam structure and a ball-and-socket joint surface is available.

The radiolucent line of 1mm or more was observed in 5 knees in BS3 group, while no knee exhibited the radiolucent line in LPS group in this cohort. Implant loosening has been reported in the high flexion prostheses[23]. BS3 was developed to aim high flexion for Japanese population, which may carry the risk of implant loosening. On the other hand, LPS does not put emphasis on high flexion, which may have benefits on the loosening. It is interesting that no knees with the radiolucent line showed component shift ratio of more than 5% in BS3 group. The sheer force on the femorotibial joint would be absorbed by the ML shift in the cases with obvious instability, while the force would directly work on the implant bone surface, resulting in the radiolucent line in the cases without instability. In BS3, excellent long-term results were reported even in knees with a wide range of motion and the ratio of over 20% of the radiolucent line[14, 15]. The partial radiolucent line in BS3 may not necessarily connect with the poor outcome.

Clinical outcomes include knee flexion and patient satisfaction were similar in both groups, despite the significant differences in the component shift ratio in this study. BS3 did not exhibit a better range of motion compared with the non-high flexion PS prosthesis although BS3 aimed at deep knee flexion. A previous study reported average knee flexion of 138.5° at 1 month after surgery with BS prosthesis for the knees with preoperative average flexion of 132.2°[11]. Preoperative knee flexion of our cohort in BS3 averaged 109°, which would limit the postoperative flexion averaged 117°[24]. A previous study reported 20% of patients with BS types 1 and 2 felt loose in activities of daily living[13]. The high component shift ratio indicates coronal instability in the tibiofemoral joint and may affect the clinical results that can be detected by the detailed assessments on daily activity in a larger cohort.

Several limitations should be considered. First, the cohort is osteoarthritis because we excluded rheumatoid arthritis to eliminate the specific soft tissue features which may affect the joint stability[25]. The results may not generalize the patients with rheumatoid arthritis. Second, we applied midvastus approach, independent bone resection followed by step by step soft tissue release to obtain ML balance. Different surgical procedures may induce different outcomes. Third, the prosthesis was selected by a primary surgeon for the patient, not randomized manner. However, the preoperative characteristics of two groups were similar. Fourth, detailed clinical evaluations including patient-based assessments for knee symptoms and functions were not carried out in this study. Finally, a small number of the subject would affect the outcomes. Still, long term follow-up revealed the progressive ML instability in BS3, achieving the primary aim of this study.

In conclusion, BS3 knees exhibited coronal instability on standing AP radiographs, although clinical outcomes were similar to LPS knees. The component shift ratio increased with the posterior tibial slope, FTA, implant extension angle, and knee extension at the latest follow-up. Understanding the design characteristics of BS, avoiding excess posterior tibial slope, and paying attention to the ML and flexion/extension balance would be the keys to prevent the instability with this prosthesis. The latest version of the BS prosthesis with post/cam structure should be considered for the cases with preoperative severe deformity or contracture that require large surgical corrections with aggressive soft tissue releases.

Acknowledgments

This study was approved by the research ethics committee and the clinical research conflicts of interest committee of Tokyo Medical and Dental University.

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Compliance with Ethical Standards

This study was also approved by the clinical research conflicts of interest committee and the clinical research conflicts of interest management committee of Tokyo Medical and Dental University.

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