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Total Hip Arthroplasty Performed with a Novel Design Type 1 Femoral Stem: A Retrospective Minimum 5-Year Follow-up Study

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Background: The Bencox M stem is a mid-short type 1 stem with additional unique design features. It has a reduced stem length and a lateral shoulder to facilitate minimally invasive surgery, as well as an angular lateral shoulder and a trapezoidal neck to minimize stem-liner impingement. There have been many mid-term reports on type 1 stems, but no results have been reported so far on this novel design type 1 femoral stem. This study presents the clinical and radiological outcomes of total hip arthroplasty performed with the M stem after a minimum 5-year follow-up.

Methods: From July 2014 to February 2015, 125 primary total hip arthroplasties using the M cementless femoral stem were performed on 112 patients in our hospital. Among them, 94 patients (106 hips) were eligible for the study and were followed up for more than 5 years. Our primary outcome was clinical results, which were evaluated by the Harris Hip Score (HHS), thigh pain, noise, and other complications. Secondary outcome was radiological outcomes. Seventy-seven hips were evaluated radiologically with attention to implant fixation, migration, loosening of component, degree of stress shielding, radiolucent lines, focal osteolysis, heterotopic ossification, and the evidence of impingement between the stem and liner.

Results: The average HHS improved from 54.6 points (range, 24–67 points) to 96.8 points (range, 91–100 points) at the latest follow-up. Three hips (2.8%) had intermittent thigh pain, which was tolerable without medication. Five hips (4.7%) had ceramic-related noise. There were no other complications such as infection, nerve injury, dislocation, or revision. All implants showed radiographic evidence of stable fixation by bone ingrowth without migration. Fifty-seven hips (74%) showed mild femoral stress shielding. Distal cortical hypertrophy was detected in 7 hips (9%), and heterotopic ossification was observed in 17 hips (22%). No implant demonstrated focal osteolysis and notching of the femoral neck or shoulder on radiographs.

Conclusions: The minimum 5-year results of total hip arthroplasty performed with the M cementless femoral stem were encouraging clinically and radiologically. A long-term follow-up will be necessary to evaluate its longevity.

Keywords: *Total hip arthroplasty, Cementless, Osseointegration, Type I stem*

Until now, cementless femoral stems have been classified into 6 types according to the bone contact area and fixation site as suggested by Khanuja et al.[1] since 2011. Among them, the Bencox M stem is a single-wedged stem (flat in the anteroposterior plane and tapered in the mediolateral plane) classified as type 1. There are several studies reporting the good clinical and radiological results of type 1 stems.[2-6] As total hip arthroplasty (THA) became a viable option for younger patients, short stems have been developed to preserve the metaphyseal bone stock and facilitate insertion through less invasive approaches and removal when femoral revisions are required. Theoretically,

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short femoral stems cause less pain for patients and less stress shielding on the proximal femur. Cementless short femoral stems show comparable survival rates at long-term follow-up.[7,8]

The Bencox M stem (Corentec, Cheonan, Korea) is a mid-short type 1 stem. It has been used in our institution since July 2014. It was designed to reduce the stem length (95–119 mm) and lateral shoulder width for minimally invasive surgery. The distal part of the stem is shortened by approximately 4–5 cm compared to the conventional type 1 femoral implants such as Bencox ID stem (Corentec, Cheonan, Korea) or Taperloc stem (Biomet, Warsaw, IN, USA). The proximal part of the stem has an angular lateral shoulder profile and a unique trapezoidal neck, designed to minimize stem-liner impingement (Fig. 1). Theoretically, type 1 stems are designed for metaphyseal fixation and preservation of proximal bone stock by transferring the load to the metaphysis, thereby preventing thigh pain and metaphyseal stress shielding.

The aim of the study was to evaluate the clinical outcomes including thigh pain and radiological outcomes including stress shielding, metaphyseal fixation, and stem-liner impingement in patients who underwent primary THA with the M stem with a minimum 5-year follow-up. We also attempted to investigate situations difficult to use this stem.

METHODS

The current study is a retrospective study, and the protocol had prior approval of the Institutional Review Board of Seoul National University Hospital (IRB No. 2004-045-1116). The informed consent was waived as the study was performed retrospectively. Primary THAs performed in 112 patients (125 hips) with the M stem between July 2014 and February 2015 were initially included.

Fig. 1. Photographs of the M stem.

During the same period, the M stem was not used in 5 cases in which mechanical stability was not achieved due to a narrow canal or metaphyseal/diaphyseal mismatch (MDM). In those cases, the Bencox II stem (Corentec), which is one of type 3C, rectangular, tapered, and grit-blasted stems, was used.

During the follow-up period, 9 patients (9 hips) died and 9 patients (10 hips) were lost to follow-up. The remaining 94 patients (106 hips) were evaluated with a minimum follow-up of 5 years (range, 5.0–6.2 years). There were 54 women and 40 men and their mean age was 56.0 years (range, 22.3–85.1 years) at the time of the index THA. The preoperative diagnoses were osteonecrosis of the femoral head (56 cases), degenerative arthritis secondary to acetabular dysplasia (11 cases), posttraumatic osteoarthritis (7 cases), sequelae of Legg-Calves-Perthes disease (6 cases), sequelae of hip joint infection (5 cases), rheumatoid arthritis (4 cases), ankylosing spondylitis (2 cases), residual poliomyelitis sequelae (2 cases), and secondary osteoarthritis related to other causes (13 cases).

The single surgeon (JJY) performed all index surgery except 5 cases. THA was performed in the lateral decubitus position through a modified direct lateral approach in 101 cases and the posterolateral approach in 5 cases. The stem reviewed in this study is an M stem, which is a type 1 stem and made out of titanium alloy. In all cases, the fourth generation alumina-alumina bearing system (BIOLOX Delta; CeramTec AG, Plochingen, Germany) was used. Bencox Mirabo cup (Corentec) was used in 81 cases and Bencox hybrid cup (Corentec) in 25 cases. For the first 6 weeks after surgery, partial weight-bearing with a crutch gait was recommended, followed by full weight-bearing as tolerated. Patients were followed up for 6 weeks, 6 months, 12 months, and then annually after the surgery. Patient demographics data are shown in Table 1.

Clinical evaluation included the Harris Hip Score (HHS) and additional questions about thigh pain, noise, and other complications. The questions were asked in person at the follow-up visits (77 hips) or through telephone interviews (29 hips). The interviewer (HBY) provided the definition of thigh pain as a pain occurring below the hip and above the knee on a telephone interview. The interviewer also asked about the radiating pain pattern in detail and differentiated the spine origin pain from hip pain. The noise was divided into clicking, squeaking, and popping

Table 1. Demographics of 94 Patients (106 Hips)

Variable	Value
Sex	
Male	54
Female	40
Diagnosis	
Osteonecrosis of the femoral head	56 (53)
Arthritis due to hip dysplasia	11 (10)
Posttraumatic arthritis	7 (7)
Sequelae of Legg-Calve-Perthes disease	6 (6)
Sequelae of previous infection	5 (5)
Rheumatoid arthritis	4 (4)
Ankylosing spondylitis	2 (2)
Residual poliomyelitis	2 (2)
Other causes	13 (12)
Age (yr)	56.0 (22.3–85.1)
Duration of follow-up (yr)	5.4 (5.0–6.2)

Values are presented as number (%) or mean (range).

sound. The noise that others could hear was defined as audible noise. Furthermore, complications such as dislocation, infection, and nerve injury were also checked.

As 28 patients (29 hips) had no plain radiographs for the last follow-up, only 77 hips were radiologically evaluated. The implant stability including fixation, migration, loosening of component, and degree of stress shielding were assessed with the criteria described by Engh et al.[9] Furthermore, radiolucent lines, focal osteolysis, heterotopic ossification, and notching of the femoral stem were also evaluated. The location and extent of radiolucent lines and osteolysis were assessed according to zones described by Gruen et al.[10] on the femoral side and described by DeLee and Charnley.[11] on the acetabular side. Osteolysis was defined as a periprosthetic cystic or scalloped lesion larger than 2 mm in diameter that had not been observed on the immediate postoperative radiographs. The criterion of Brooker et al.[12] was used to grade heterotopic ossification. Femoral stem neck or shoulder notching, which is interpreted as evidence of impingement between the metal stem and ceramic liner, was reviewed on serial radiographs.[13-15]

RESULTS

Clinical Results

The average HHS was 54.6 points (range, 24–67 points) before surgery and the mean score was improved to 96.8 points (range, 91–100 points) at the last follow-up. Three patients (3 hips, 2.8%) complained of intermittent thigh pain, which was tolerable without medication.

There were 2 intraoperative femoral cracks (1.3%) during stem insertion. Both patients had relatively narrow canals and osteoporotic cortices, and intraoperative fractures occurred even with gentle femoral rasping. The fractures were confined to the proximal femur and treated with circumferential wiring. They were healed without any problem at the last follow-up.

Five patients (5 hips, 4.7%) complained of transient noise in the hip joint area, of which 2 patients had a clicking sound, 2 patients had a squeaking sound, and 1 patient had a popping sound. None of them had an audible noise. Among them, 2 patients with clicking sound complained of mild pain associated with noise, which did not affect their quality of life. There were no other complications such as infection, nerve injury, dislocation, or revision.

Radiographic Results

All implants showed radiologic evidence of stable fixation by bone ingrowth based on Engh criteria.[9] There was no radiologic evidence of change in implant position such as stem subsidence. Implant loosening, focal osteolysis, and revision cases were not detected on plain radiographs until the last 5-year follow-up. Stress shielding was observed in 57 hips (74%). According to the stress shielding criteria described by Engh et al.,[9] first degree and second degree were noted in 37 hips (48%) and 20 hips (26%), respectively (Fig. 2). There were no cases with third degree or fourth degree stress shielding. Distal cortical hypertrophy at the distal part of the stem was detected in 7 hips (9%), and all of them showed stress shielding; 4 hips for grade I and 3 hips for grade II (Fig. 3).

Heterotopic ossification (HO) was observed in 17 hips (22%), all of which were operated with a direct lateral approach. According to the Brooker classification,[12] 5 hips were grade I and 10 hips were grade II. Two patients (2 hips, 2.5%) had a grade III HO, which means that bone spurs occurred at the pelvis or proximal end of the femur, resulting in a decrease in the space between the opposing bone surfaces to less than 1 cm (Fig. 4). However, they had no complaint with a functional range of motion.

There were no cases demonstrating notching of the femoral neck or shoulder on plain radiographs. Radio-

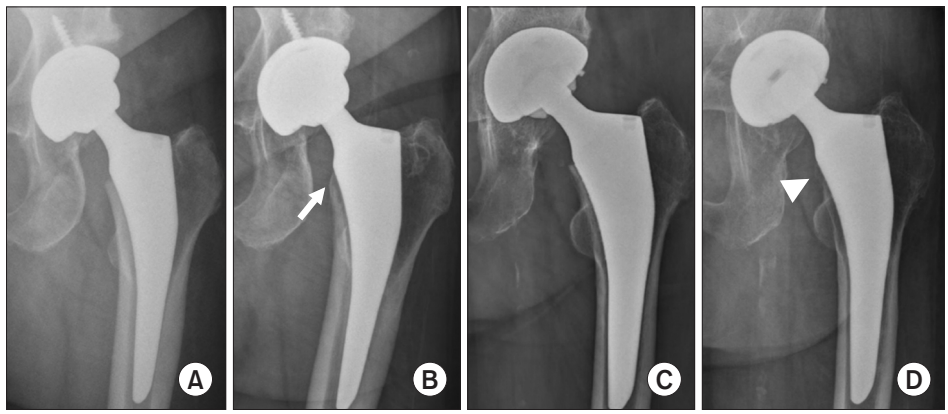

Fig. 2. (A) A 57-year-old woman had total hip arthroplasty (THA) because of degenerative arthritis secondary to dysplastic hip. The immediate postoperative radiograph showed stably fixed implants. (B) The anteroposterior radiograph taken 5.5 years after surgery showed grade I stress shielding (arrow). (C) A 76-year-old woman had THA because of osteonecrosis secondary to a femoral neck fracture. The immediate postoperative radiograph showed stably fixed implants. (D) The anteroposterior radiograph at postoperative 6 years showed grade II stress shielding (arrowhead).

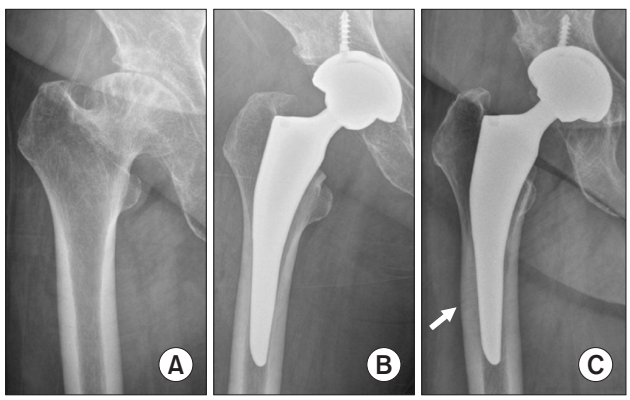

Fig. 3. (A) Preoperative anteroposterior radiograph of a 59-year-old woman with sequelae of Legg-Calve-Perthes disease. (B) The initial postoperative radiograph showed stably fixed implants without any change in cortical density. (C) Distal cortical hypertrophy (arrow) and proximal stress shielding were observed on the plain radiograph at 5.5 years after surgery.

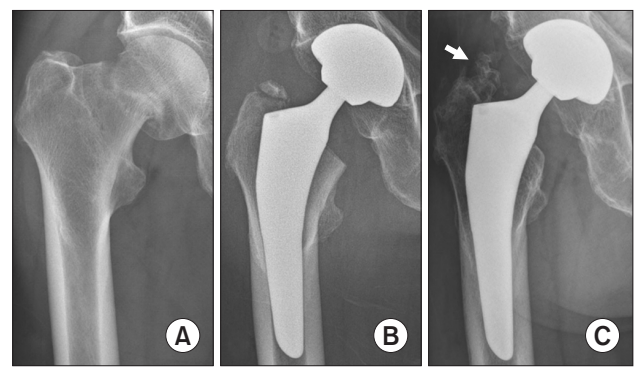

Fig. 4. (A) Preoperative anteroposterior radiograph of a 73-year-old man with a femoral neck fracture. (B) The initial postoperative radiograph showed stably fixed implants without heterotopic ossification. (C) The plain radiograph at postoperative 5 years showed grade III heterotopic ossification (arrow).

graphic results are shown in Table 2.

DISCUSSION

In this study, all patients reported excellent HHS without revision cases. The Bencox M stem is a type 1 stem, which features single-wedged, proximally coated, mid-short length. Furthermore, the reduced lateral shoulder and curved shape of the distal tip are anticipated to reduce bone resection and soft-tissue damage. It is made of titanium alloy, and the flexural rigidity of a titanium alloy is closer to that of bone than that of cobalt-chromium alloy. Even though the etiology of thigh pain after primary THA is multifacorial and still controversial,[16,17] these attempts of changing stem designs have been made to minimize thigh pain and stress shielding.

Three patients (2.8%) in this study complained of mild thigh pain, which was tolerable without medication. A low prevalence of thigh pain has been reported in previous studies involving components with similar tapered, mid-short length stem designs. Gallart et al.[5] reported that none of the 34 patients with the Taperloc Microplasty stem (Zimmer Biomet, Warsaw, IN, USA) complained of thigh pain at a 3-year follow-up. Teloken et al.[6] reported that only 1 out of 42 patients who underwent THA with Trilock stem (DePuy Orthopaedics Inc., Warsaw, USA) complained of thigh pain during 10- to 15-year follow-up, even though the stem was made of cobalt-chromium alloy. By

Table 2. Radiographic Outcome of Total Hip Arthroplasty Using M Femoral Stem

Radiologic finding	Number (%)
Implant fixation	
Stable by bone ingrowth	77 (100)
Stable by fibrous tissue ingrowth	0
Unstable	0
Stress shielding	
Grade I	37 (48)
Grade II	20 (26)
Grade III	0
Grade IV	0
Heterotopic ossification	
Grade I	5 (6)
Grade II	10 (13)
Grade III	2 (3)
Grade IV	0
Others	
Distal cortical hypertrophy	7 (9)
Focal osteolysis	0
Notching	0
Revision	0

contrast, Amendola et al.[18] reported that 16% complained of mild thigh pain and 9% complained of moderate to severe pain in the 2–4 year follow-up of THA using Trilock stem in 238 patients, and they abandoned the short stem design and returned to the conventional one because of concerns about thigh pain. However, considering that there are some reports that thigh pain decreases over time, long-term follow-up may be necessary.[6,19]

All implants demonstrated radiologically stable fixation by bone ingrowth. In addition, there was no implant subsidence, loosening, focal osteolysis, and fretting of the femoral neck. However, there is some concern that 75% of cases demonstrated stress shielding. We detected rounding of the proximal medial edge of the cut femoral neck (grade I) in 48% of cases and some reduction in the proximal medial cortical density (grade II) in 26% of cases. No cases demonstrated severe reduction in the proximal medial cortical density or extensive resorption (grade III or IV). Two previous studies on type 1 stem reported similar results. Amendola et al.[18] showed that stress shielding was mild in 64% and moderate in 0.5%, and there were no severe cases after 2-year follow-up. Teloken et al.[6] reported mild stress shielding in 82%, moderate in 14%, and no severe cases after 15-year follow-up. Engh et al.[9] reported that a stress-related bone loss did not negatively affect the clinical outcome and stress shielding of grade I and II was rarely an issue. A long-term follow-up study is needed to evaluate whether low-grade stress shielding progresses to high-grade and whether such changes cause significant clinical symptoms.

We also observed 7 hips with prominent distal cortical hypertrophy at the distal part of the stem. Considering that type 1 stems are designed for metaphyseal fixation and preservation of proximal bone stock by transferring the load to the metaphysis, this symptom would be contrary to expectation. Khanuja et al.[1] reported that when the femur diaphysis is substantially narrowed, the implant can only engage the distal part and osseointegration may not occur if the proximal porous-coated prosthesis is engaged only under the coating. Kress et al.[20] reported that diaphyseal fixation was unexpectedly observed in a short stem designed for metaphyseal fixation in a study evaluating bone density and contact area using quantitative computed tomography. This suboptimal load transfer led to proximal stress shielding and distal cortical hypertrophy. In other words, bone ingrowth is mainly achieved in the distal part of proximally coated area of the stem, and the uncoated distal part of the stem is caught in the femoral canal. As a result, the proximally coated area was not able to achieve as much bone ingrowth as desired. In the future, it is necessary to evaluate stem longevity in these cases. For the same reason, there were 5 cases where Bencox II stem, a type 3C stem, was used instead of the M stem due to severe MDM. We intraoperatively found that M stem insertion was not possible or mechanical stability was not achieved. In 2 specific cases where severe MDM and osteoporosis both existed, intraoperative femoral fractures were observed as described previously. Therefore, we suggest that it may be difficult to use the M stem in severe MDM or extreme Dorr type A. Stem design modification might be needed for severe MDM patients.

In this study, most of the cases underwent THA with a modified direct lateral approach. Initially described by Hardinge in 1982, the direct lateral approach has been modified several times and is now commonly used. Some studies reported HO was more prevalent in the surgery using the direct lateral approach; prevalence of HO was 5%–18% in posterior or posterolateral approaches, 19% in anterior approaches, and 26%–36% in direct lateral ap-

proaches.[21-25] We observed HO formation in 16 hips that underwent THA with the modified direct lateral approach, which accounts for 23.6% of THAs performed with the modified direct lateral approach. All of them, however, had no discomfort in activities of daily living and had full functional range of motion.

The fourth-generation alumina, BIOLOX Delta bearing, was used in all cases, which was previously reported to reduce the incidence of ceramic head fractures, but not the incidence of liner fractures.[26] Stem neck-liner impingement is one of the risk factors for ceramic liner fractures.[13,14,26] Lee et al.[15] reported that impingement between the stem and ceramic liner occurred on the shoulder of the stem, as well as on the neck in a considerable proportion. The M femoral stem was designed to have a trapezoidal neck and an angular lateral profile shoulder to minimize stem shoulder-liner impingement, as well as stem neck-liner impingement. Neither type of impingement was found in the current study.

The incidence of noise phenomenon in ceramic-on-ceramic THA was reported between 0.7% and 20.9%.[27] Walter et al.[28] suggested the increased edge loading to the acetabular component was a significant cause of the noise. Cup abduction of the patients with noise was 39.6° on average (range, 35°–43°) and cup anteversion was 20.6° on average (range, 14.8°–23.5°) by the method of Bachhal et al.[29] Lee et al.[15] reported that the incidence of noise was significantly higher in cases with stem-liner impingement. Steinhoff et al.[13] reported that noise phenomenon was associated with ceramic liner fracture, as well as with stem-liner impingement. In the current study, 5 patients reported noise, but it was tolerable since the noise was mild, intermittent, inaudible to others, and almost painless. The etiology and clinical implications of noise problems after THA have not been clearly established and are still controversial, so further follow-up study is required.

There are several limitations to this study. First, this is a retrospective study with its intrinsic limitations. Future randomized prospective trials involving comparison with other stems are required. Second, there was inconsistent quality of plain radiographs, as well as interobserver and intraobserver variability, in radiological evaluation. To overcome this, all radiographic results were evaluated by three orthopedic surgeons and were scrutinized with the use of an established grading system. Finally, since the minimum follow-up period of 5 years was relatively short, a longer follow-up with a multi-center setting is required to investigate the effect of confounding variables.

Mid-term results of THA performed with the Bencox M cementless femoral stem were encouraging with excellent clinical and radiological outcomes. All patients reported good-to-excellent HHS without severe complications. All implants showed radiologic evidence of stable fixation by bone ingrowth. There was no evidence of implant subsidence, loosening, focal osteolysis, or notching of the femoral stem. However, a high prevalence of proximal stress shielding still remains a matter of concern. Further studies with a large number of patients and a long-term follow-up would be needed to evaluate the stem longevity.

CONFLICT OF INTEREST

The corresponding author (JJY) has patent arrangement from Corentec company manufacturing Bencox M stem. The other authors certify that he or she has no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

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