A Patient-Specific Instrument for Femoral Stem Placement During Total Hip Arthroplasty

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Abstract: To ensure that the femoral stem is placed in the proper position during total hip arthroplasty, the authors developed a patient-specific instrument. A total of 10 total hip arthroplasties were performed with the assistance of the patient-specific instrument during this study. The mean accuracy of stem tilt, varus/valgus, and anteversion was 2.1°±1.2°, 1.0°±0.7°, and 4.7°±4.1°, respectively. No complications were observed and no reoperations were required for any of the patients who underwent surgery included in this study. The results support the feasibility of this patient-specific instrument for use during stem placement in total hip arthroplasty. [Orthopedics. 2017; 40(2):e374-e377.]

Accurate alignment of implants during total joint arthroplasty is important to avoid reoperation and poor clinical outcomes. To reduce malalignment of implant placement, various computer navigation systems have been introduced; however, most of these systems require considerable time and money. Patient-specific instruments have been developed as an alternative to navigation systems. Although many clinical reports of patient-specific instruments for total knee arthroplasty have been published, few reports of patient-specific instruments for total hip arthroplasty (THA) of the acetabular cup are available. Furthermore, no study about the clinical use of patient-specific instruments for femoral stem placement has been published.

The authors used a rapid prototype technique on the basis of 3-dimensional preoperative planning data to develop a unique patient-specific instrument for femoral stem placement during THA. The patient-specific instrument has a guidance function that enables surgeons to simulate the femoral stem placement before undertaking the actual operation. In this study, the authors conceptualized a patient-specific instrument for femoral stem placement during THA. They report on the feasibility of using this novel patient-specific instrument as part of the surgical procedure.

Materials and Methods

Patients

Institutional review board approval was obtained for this study, and it was performed in accordance with the ethical standards detailed in the 1964 Declaration of Helsinki. All patients provided informed consent to participate. Between April and August 2013, the authors performed THAs in 10 hips of 10 patients using the patient-specific instrument for femoral stem placement. All 10 patients were women, with a mean age of 58 years (range, 46-77 years) and a mean body mass index of 23.4 kg/m² (range, 18.9-28.1 kg/m²). The reason for surgery was osteoarthritis in 9 hips and osteonecrosis of the femoral head in 1 hip.

Preoperative Planning

For preoperative planning, computed tomography scans (Aquilion ONE; Toshiba Medical, Tokyo, Japan) at a slice thickness of 0.6 mm of the pelvis and femur were obtained at least 3 weeks prior to surgery.
These scans were transferred to a 3-dimensional template software (Zed hip; LEXI, Tokyo, Japan) so that the authors could plan the size and alignment of the implant. Planning of the femoral stem placement was performed to achieve the fit and fill for the femoral canal and the calcar, and to restore the center of the native femoral head to the extent possible. The neck osteotomy level was adjusted by considering leg length and offset.

The authors used an anatomical coordinate system of the femur that was based on the recommendations of the International Society of Biomechanics. Angles of stem tilt, varus/valgus, and anteversion in preoperative planning were recorded for the postoperative evaluation and measured with respect to the proximal axis of the femur. The 3-dimensional template software automatically defined the proximal axis of the femur as the approximated straight line, based on the fourth and sixth sections of the 14 computed tomography slices of the whole femur. Stem tilt was measured as the angle between the proximal axis of the femur and the axis of the femoral stem on the sagittal plane of the stem. Anterior tilt (positive value) was defined when the stem was tilted as the femoral head shifted forward. Similarly, stem varus/valgus was measured as the angle between the proximal axis of the femur and the axis of the femoral stem on the coronal plane of the stem. Valgus angle was defined as the positive value of stem varus/valgus angle. Stem anteversion was defined by the angle between the femoral neck of the stem and the posterior condylar axis.

**Production of the Patient-Specific Instrument**

The patient-specific instrument was designed for use in preoperative 3-dimensional planning, via computer-aided design software (Solidworks; Dassault Systèmes SA, Vélizy-Villacoublay, France) and 3-dimensional modeling software (Geomagic Freeform; 3D Systems, Rock Hill, South Carolina) (Figure 1). The patient-specific instrument consists of a base part, which overlaps the surface of part of the greater and lesser trochanters, and a guide part that is combined with the base part, which has holes to allow insertion of 2-mm Kirschner wires.

The patient-specific instrument has a function that indicates the neck resection level, the entrance point for the femoral canal, and the appropriate alignment for stem placement. The neck resection level is indicated by the cranial edge line of the base part. The Kirschner wires are inserted into the patient-specific instrument to guide the direction of the initial reaming, rasping, and stem insertion (Figure 2). The patient-specific instrument itself was manufactured from photosensitive medical-grade resin using a rapid prototype machine (Eden250; Objet Geometries Ltd, Rehovot, Israel) (Figure 3). Prior to intraoperative use, patient-specific instruments were sterilized with the STERRAD Sterilization System (Advanced Sterilization Products, Irvine, California).

**SURGICAL TECHNIQUE**

All operations were performed with patients in the lateral decubitus position, and through a posterior approach, with a 10- to 15-cm skin incision...
All femoral and acetabular components were made with cementless devices. QSLP acetabular and J-Taper stem systems (Kyocera Medical Corp, Osaka, Japan) were used in 9 hips and Mallory-Head acetabular and Taperloc stem systems (Biomet, Warsaw, Indiana) were used in 1 hip.

After the femoral head was dislocated, the base part of the patient-specific instrument was placed to overlie the trochanter as well as the neck of the femur. Then, the surgeon (H.I.) marked the line of the neck resection level and performed the osteotomy of the femoral neck. After the acetabulum procedure was undertaken, the patient-specific instrument was again placed on the femur, for rasping. The surgeon removed the bone from around the entrance point of the femoral canal and performed the initial reaming with the aid of the patient-specific instrument. Next, rasping and implantation of the stem were performed according to the guidance of the patient-specific instrument (Figure 4).

**Radiographic and Clinical Evaluation**

All patients had a computed tomography scan 1 week postoperatively, and the scans were transferred to the postoperative evaluation software (Zed hip). The authors determined the difference in the stem position (tilt, varus/valgus, anteverision) between the preoperative planning and the postoperative measurement, with the absolute difference defined as the accuracy of stem placement. Cases that were identified as having a significant difference from the preoperative planning in stem alignment—defined as extending beyond 3° of tilt and varus/valgus and 5° of anteverision—were considered outliers. The incidence of accuracy outliers was analyzed. Surgical data were also recorded, including operative time, intraoperative estimated blood loss, need for reoperation, and presence of complications such as infection, venous thromboembolism, and dislocation. All patients were followed for a

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**Table:**

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minimum of 3 months postoperatively to identify complications.

RESULTS
Femoral stems were placed with the guidance of the patient-specific instrument and fit the bone surface in all cases. The values for stem position during preoperative planning and postoperative evaluation are listed in the Table.

The mean operative time was 111 minutes (range, 88-135 minutes), and the mean estimated blood loss was 356 mg (range, 100-350 mg). No complications were observed and no reoperations were required.

DISCUSSION
To evaluate the feasibility of this novel patient-specific instrument for femoral stem placement, the authors investigated the placement accuracy and adverse events through this preliminary study. The results indicate that this patient-specific instrument for femoral stem placement is safe and effective.

Studies have discussed the position of the acetabular cup during THA in terms of prevention of dislocation\(^1\text{-}\text{14}\); however, the importance of stem anteverision has received attention because the concept of combined anteverision has become more prevalent.\(^15\) Hirata et al\(^16\) showed that the mean absolute surgeon error in performing the intraoperative estimation of stem anteverision in THA using the lower-leg axis as a reference was 7.3\(^\circ\), and the estimation differences in 60% of cases were beyond 5\(^\circ\). Kitada et al\(^6\) reported that the accuracy of stem anteverision placement with a computed tomography–based navigation system was within 5\(^\circ\) in 60% of cases. In the current study, 7 of 10 cases (70%) achieved accurate stem anteverision to within 5\(^\circ\), which may indicate that the patient-specific instrument could be a valuable guide for stem anteverision as part of a computed tomography–based navigation system.

The novel patient-specific instrument that the authors developed enables guidance considering these parameters in addition to the angle of stem tilt, varus/valgus, and anteverision. Thus, they propose that this is a useful device for the accurate placement of a femoral stem.

This study had several limitations, including the small number of patients and the absence of a control group. However, this was a feasibility study. A large-scale, double-armed clinical study to evaluate the effectiveness of the patient-specific instrument will be performed subsequently.

CONCLUSION
This is the first report of the clinical application of THA by using a patient-specific instrument manufactured based on preoperative 3-dimensional planning, for accurate placement of a femoral stem. The results of this study support the feasibility of this patient-specific instrument for use during stem placement in THA.

REFERENCES