Comparison of total knee arthroplasty using patient specific instruments versus conventional instruments

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Component alignment is an important factor affecting the long-term outcome of total knee arthroplasty (TKA). Especially, malalignment in coronal plane exceeding 3 º tends to result in increased risk of component loosening. Computer navigation assisted TKA was introduced in order to minimize these outliers in component positioning and alignment, and reported to be effective in many studies. In addition, the risk of fat embolism and the amount of bleeding expected to be smaller compared to the conventional method, because of sparing of an intramedullary canal of the femur. Osteoarthritic knees with the deformed femur or any hardware in the femur can be effectively addressed with navigated TKA. However, navigated TKA takes more operation time compared to the conventional method, and there is increased risk of infection and pin site loosening or fracture. Patient specific instruments were developed to improve the accuracy of implant placement without negative aspects of navigated total knee arthroplasty[1, 2]. Preoperative CT or MRI data of the knee was obtained through the lower extremity including the hip center and the ankle center. The manufacturer creates bone models of the distal femur and proximal tibia from the image data using a rapid prototyping technique. Jigs or cutting guides were then made to fit on the distal femur and proximal tibia based on the information on resection levels, which reflects proper component positioning in relation to the mechanical axis and appropriate component sizing. The purpose of this study is to compare the accuracy of postoperative alignment between TKA using patient specific instrument and TKA using conventional instruments.

We designed a randomized controlled study with ninety consecutive knees which were planned to undergo total knee arthroplasties. Forty five primary osteoarthritic knees were allocated to the group of patient specific instruments (Signature group, n = 45), and the other 45 knees to the group of conventional instruments (Conventional group, n = 45). CT based *Signature*™ personalized patient care system (Biomet, Warsaw, IN) was applied to the patient in the Signature group. All surgeries were performed with use of single type of implants (Vanguard® PS mobile bearing knee, Biomet, Warsaw, IN). Bone models and patient specific jigs were produced by Materialise (Leuven, Belgium).

In Signature group, initial target position of the implants were set at perpendicular position to the mechanical axis of the lower extremity in coronal plane, 3º flexion from the mechanical axis of the femur and 3º posterior slope to the mechanical axis of the tibia in sagittal plane. Femoral component rotation was set at parallel position to the clinical transepicondylar axis. We measured and analyzed postoperative mechanical tibio-femoral angle with fully weight borne long cassette plain radiograph and coronal, sagittal alignments of each individual component were also measured from postoperative CT scan. Rotation of the femoral component was assessed with CT scan by comparing the posterior condylar axis of the implant and clinical transepicondylar axis. The amount of postoperative drainage and operation time were recorded. The outcome on postoperative alignment is evaluated by assessing the frequency of outliers in each parameter. The outlier was defined as >3º off from the mechanical axis in coronal plane and >3º off from initial target angles in sagittal plane. Every case of the Signature group was thoroughly cross checked with conventional instruments on its intraoperative alignment and femoral component rotation. We tried to record and analyze every unexpected event during the surgery including conversions into conventional instruments.

There was no difference in preoperative demographics, clinical and radiographic data between the groups. The mechanical axis of the leg was varus 0.6±2.5° in Signature group and valgus 1.0±1.8° in conventional group. Femoral coronal alignment (varus 1±1.5° versus varus 0.06±1.4°) and tibial coronal alignment (varus 0.1±1.4° versus valgus 1.0±1.5 °) were similar between two groups. Femoral

sagittal alignment (3.1° flexion versus 3.6° flexion) and tibial sagittal alignment (3.1° posterior slope versus 3.6° posterior slope) were also similar between the groups. The prevalence of outliers in the mechanical axis of the leg was 17% in Signature group and 14% in conventional group (p=0.705). The percentage of outliers in the femoral (5.7% versus 2.8%, p=0.614) and the tibial alignment (0% versus 5.6%, p=0.493) in coronal plane was also similar between the groups. Femoral components of Signature group were placed average 0.5° internally from the clinical transepicondylar axis, while it was 1.2° internally from the axis in the conventional group. (p=0.171) Blood loss via postoperative drain was not significantly different, however operation time was significantly longer in the Signature group due to the cross checking procedures.

There were twelve cases of modification of surgical procedures in the Signature group. Eight cases in the Signature group experienced intraoperative conversion into the conventional femoral guide because of excessive external rotation. In four cases, proximal tibial cutting was performed again with the conventional extra-medullary tibial guide. Among them, two cases had shown unacceptably decreased posterior slope and other two had presented with varus cut of the tibia.

TKA using Signature system provided acceptable accuracy in implant positioning and alignment, which was comparable to that of the conventional TKA. Further clinical validations are needed for safer use. Still, patient specific instrument including Signature system seems to be a useful alternative in cases with extra articular deformities or retained hardware around the knee by avoiding the femoral canal breaching