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Prevalence and Predictors of Post-Operative Coronal Alignment Outliers and Their Association With the Functional Outcomes in Navigated Total Knee Arthroplasty

Madhav Chowdhry [b], Ankur B. Bamne, MS [a], Young Gon Na, MD [a], Yeon Gwi Kang, MS [a], Tae Kyun Kim, MD, PhD [a]

[a] Joint Reconstruction Center, Seoul National University Bundang Hospital, Bundang-gu, Seongnam-si, Korea
[b] Jawaharlal Nehru Medical College, Aligarh Muslim University, Aligarh, India

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ABSTRACT

We aimed to determine the prevalence and predictors for being an outlier after navigated TKA and asked whether navigated TKAs with perfect coronal alignment have better functional outcomes than those without it. Alignment was measured in 124 patients (191 knees) with navigated TKAs who were available for 1 year functional outcome assessment. The outcomes were compared among the 3 subgroups divided by the deviation of mechanical axis from neutral (0°): the perfect, 0° or within 1°; the acceptable, 1°–3°; and the outlier, beyond 3°. The prevalence of outliers was 20.4%, and the severity of preoperative varus deformity was the strongest predictor. Accuracy of coronal alignment in radiographs did not correlate consistently with functional outcomes.

Proper limb alignment is crucial for good function of either a native or a replaced knee. Postoperative coronal limb alignment is often considered as an outlier if it is beyond 3° from a neutral mechanical axis after total knee arthroplasty (TKA) [1–3]. Application of computer-assisted navigation technology has been documented to improve the coronal limb alignment in TKA [4–6], with fewer reported outliers as compared to conventional TKA [7–11]. However, whether the use of navigation is universally effective in preventing the occurrence of outliers remains controversial. Multiple studies reported that despite having no navigation-assessed outliers during surgery, there is a high incidence of radiographic outliers in coronal alignment [12,13]. Furthermore, few predictors for outliers are reported which may help surgeons to anticipate the occurrence of outliers in coronal alignment in an effort to improve functional outcomes and implant longevity [14,15].

In theory, improved coronal alignment should translate into better post-operative outcomes. A few studies have reported that navigated TKAs have better functional outcomes at short-term follow-up than conventional TKAs [1]. However, other studies comparing conventional and navigated TKAs have found that navigated TKAs, despite improvements in limb alignment, did not have better functional outcomes than conventional TKAs [14,16–19]. Therefore, whether improved alignment by the use of navigation technology translates into better functional outcomes remains controversial.

We aimed to determine the prevalence of outliers in coronal limb alignment and to identify their predictors in navigated TKAs. We also attempted to determine how well the radiographically assessed coronal limb alignments correlate with the functional outcomes. We hypothesized that the outliers in radiographic coronal alignment occur with high prevalence, and that the degree of preoperative coronal deformity would be a predictor for an outlier. It was also hypothesized that the correlation of radiological limb alignment to the functional outcomes would be weak.

Methods

In total, 191 consecutively navigated TKAs performed in 124 patients with advanced osteoarthritis of the knee from January of 2004 to December of 2007 were included in this study. All patients were followed up for more than 12 months. One hundred eighty three TKAs (95.8%) were performed in 119 female patients, and 8 TKAs (4.2%) in 5 male patients. The mean age was 69.1 years (range 55–83), and the mean body mass index (BMI) was 26.6 kg/m^2 (range 18.9–41.3). Navigated TKAs performed during the same study period were excluded if patients were older than 85 years, had a diagnosis other

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Reprint requests: Tae Kyun Kim, MD, PhD, Joint Reconstruction Center, Seoul National University Bundang Hospital, 300 Gumi-dong, Bundang-gu, Seongnam-si, Gyeonggi-do (463-707), Korea.

E-mail address: osktk@snubh.org (T.K. Kim).

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than primary osteoarthritis, or refused to participate in this study. To determine whether our sample size had sufficient statistical power, a prior power analysis was performed using the two-sided hypothesis test at an alpha level of 0.05. Sixty four knees were found to be required to detect a 5° difference in motion arc and a 5% difference in outcome scales, which we considered to be clinically significant. Thus, the sample sizes used were regarded as adequate. This study was approved by the Institutional Review Board of our hospital, and all patients provided informed consent for the use of their radiographs and medical records.

All surgeries were performed by a single surgeon (TKK) via the medial para-patellar approach using an image-free navigation system (Orthopilot 4.2; B. Braun-Aesculap, Tuttlingen, Germany). The surgeon had performed more than 200 navigated TKAs using the same navigation system before this study was initiated. Fifty seven TKAs were performed as a unilateral procedure, and 134 knees were performed as staged bilateral procedures where the second TKA was carried out at an interval of 1–2 weeks after the first TKA. A single mobile bearing system (e.motion-PS; B. Braun-Aesculap, Tuttlingen, Germany) was implanted in all cases. The navigation system was properly applied to the surgical procedures by following the system's technical manual with consideration of intraoperative information. The transmitter was fixed with a 4.5 mm bicortical self-tapping screw through a separate incision in the proximal tibia and through the primary incision in the distal femur. Another transmitter was fixed onto the foot using a rubber band. After the transmitter placement, the kinematic registration was carried out to determine the joint centers of the hip, ankle and knee. Anatomical registration followed to determine the key anatomical landmarks: the medial tibia plateau, the lateral tibia plateau, the center of the proximal tibia (knee joint center), the medial and lateral posterior femoral condyles, the anterior femoral cortex, the medial and lateral femoral epicondyles, the medial and lateral malleoli, and the ankle center. Bone resection started with the proximal tibia. The target thickness was typically 8 to 10 mm from the well-preserved tibia plateau. The target alignment was neutral to make bone resection perpendicular to the mechanical axis in the frontal and sagittal planes. The femoral resection was planned by the simulation program in the system. The typical targets for the distal femoral resection were 7 mm to 12 mm in thickness and perpendicular to the mechanical axis. After completing bone resection, the resection thickness, the coronal alignment, and the sagittal alignment were measured with the checking plate and recorded in the datasheet. If the difference between the planned resection and the executed resection was zero or deviated within 1 mm or 1°, the execution was accepted. If the deviation was greater than 1 mm or 1°, repeated resection was attempted after the cutting block was repositioned with the aid of the navigation system. Patella was routinely resurfaced. After bone resections were completed, trial components of a chosen size were positioned in place, and the overall limb alignment, the range of motion, joint stability, and patellar tracking were evaluated with the aid of navigation. All implants were fixed with cement (Palacos; Heraeus Kulzer GmbH, Hanau, Germany). The order of implantation was as follows: the tibial component, the femoral component and the patellar component. After the cement was hardened completely, residual cement debris was removed, and arterial bleeders were coagulated with the tourniquet deflated. The polyethylene insert was inserted, and the coronal limb alignment and extension degree were measured with the navigation system. The mechanical axis assessed at the end of surgery using the navigation system was within the acceptable range (≤3°) in all the cases. After operation, a compressive dressing was applied without immobilization for the first 24 h. Knees were then placed in a continuous passive-motion machine. All patients began walking with crutches or a walker and started active and passive range-of-motion exercises on the second postoperative day. Knee range of motion and weight bearing were gradually increased.

All clinical information was prospectively collected using pre-designed datasheets and maintained in our database by an independent investigator (YGK). This included information on demographics, preoperative clinical status, and postoperative outcomes evaluated at 12 months after surgery. Preoperative clinical status and postoperative outcomes were evaluated using knee motion arc (flexion contracture and maximum flexion), American Knee Society (AKS) knee and function scores [20], Western Ontario McMaster University Osteoarthritis Index (WOMAC) scores [21], and Short Form-36 (SF-36) scores [22]. An independent investigator (one of the authors) measured flexion contracture and maximum flexion to the nearest 5° using a standard 38 cm goniometer, with the patients in supine position.

Radiographic measurements to determine the coronal limb alignment were performed using a long leg weight bearing anteroposterior radiograph covering the hip–knee–ankle joint (Fig. 1). All radiographs were taken with the patella facing forward using a special device to control foot position. Preoperative mechanical axis was measured as the angle between the line connecting the hip center and the apical midpoint of the femoral intercondylar notch, and the line connecting the midpoint of the medial and lateral tibial eminences and the midpoint of the talus dome. Postoperative mechanical axis was measured as the angle between the line connecting the hip center and the apical midpoint of intercondylar notch of the femoral

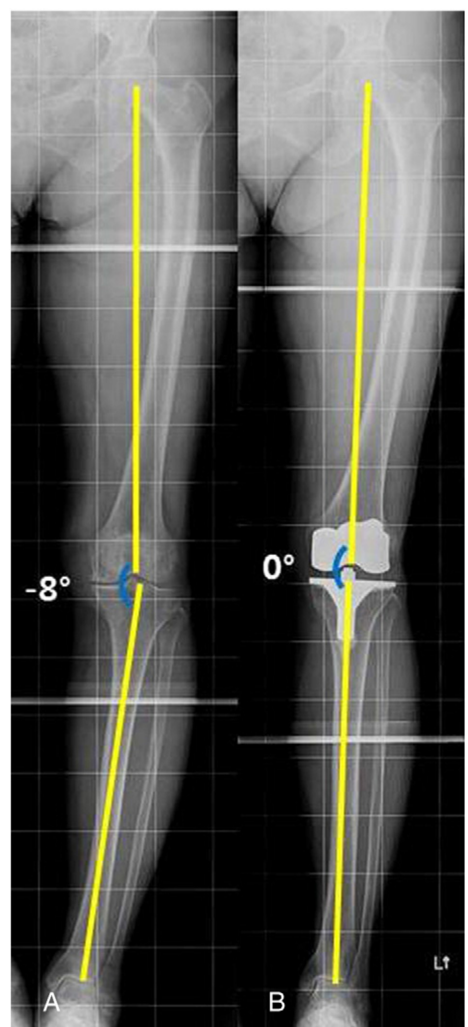

Fig. 1. Radiograph showing method used for measurement of coronal alignment (mechanical axis) on a long leg standing radiograph, pre-operative (A) and post-operative (B).