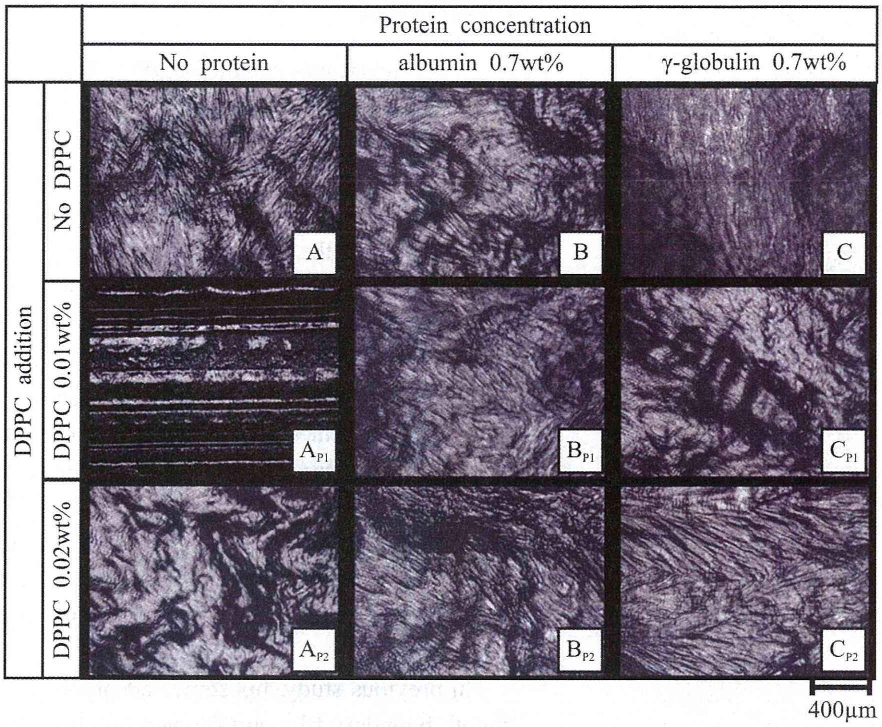

Fig.8 Worn surface of PVA hydrogel as upper specimens

3.2 TEM observation of lubricant components

TEM images of lubricant constituents are shown in Fig.9. Liposomes in lubricant A_{P1} are sized in several hundreds nanometers. In lubricant A_{P2} that contained twice as much DPPC as lubricant A_{P1}, some liposomes fused together and grew in size. When DPPC and proteins coexisted and concentration of DPPC was 0.01wt%, liposomes got distorted but remained their spherical structure. However, when the concentration of DPPC became higher as 0.02wt%, some liposomes aggregated and some lost their spherical structure and collapsed. Therefore, it was confirmed that DPPC/protein concentration in lubricant was key factor for the structure of liposomes and DPPC bilayers.

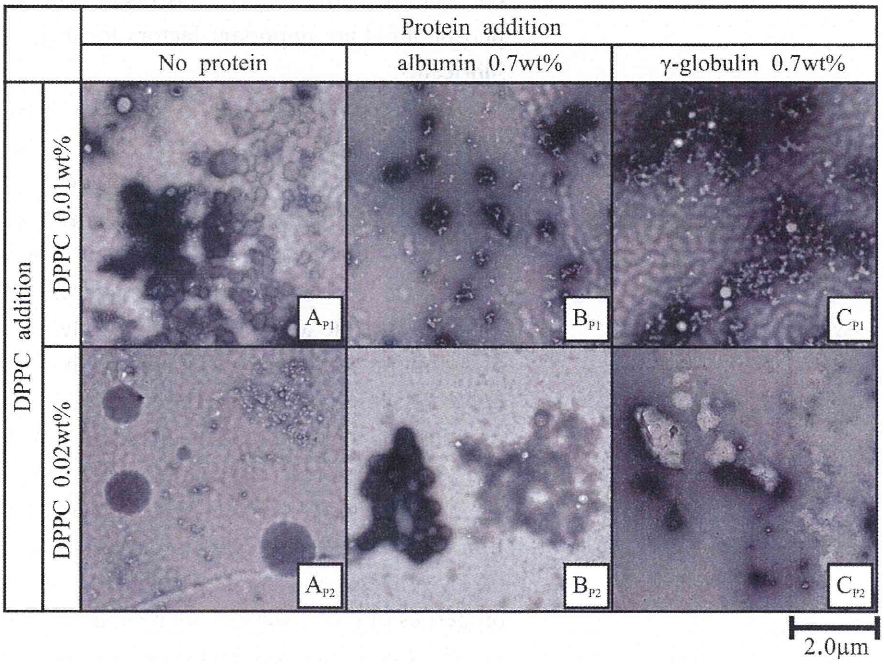

Fig.9 TEM images of lubricant components

4. Discussion

When lubricants contained DPPC but no proteins, friction coefficient was reduced by DPPC addition and wear pattern was shifted from adhesive to abrasive wear. In addition, wear of PVA hydrogel was suppressed by addition of DPPC with high concentration. Therefore, DPPC has role of reduction of the adhesivity and shear resistance between PVA hydrogels. The boundary lubricating ability of multi-lamellar film of phospholipids was reported(28), and the authors indicated the lubricating mechanisms of multi-lamellar film formed by friction-induced spread of liposomes(24). In lubricant that contained 0.01wt% DPPC, small liposomes easily collapsed and formed lamellar film based on the bilayer structure. In multi-lamellar film composed by phospholipid, water layer exists between each bilayer(29) and it is considered that this layer functions as a low shearing resistance layer. Although lubricant A_{P2} that contained 0.02wt% DPPC showed wear reduction of PVA hydrogel as compared to lubricant A_{P1}, there was little difference in friction coefficient at steady state between lubricants A_{P1} and A_{P2}. In general, liposomes are stabilized by fusion and enlargement. Therefore, wear of PVA hydrogel was reduced by increase of liposomes intervening between rubbing surfaces but additional effect of friction reduction was not obtained by suppression of forming multi-lamellar film due to the stabilization of liposomes.

In previous study, liposomes adsorbed on the rubbing surface were spread and formed smooth boundary film and showed low friction and the smooth sheet-like adsorbed matters that are composed of DPPC and albumin formed under rubbed condition(24). It was reported that the liposomes made by neutral phospholipids such as DPPC have high affinity to albumin (30) and there are influences of DPPC/protein concentration on maintaining and collapsing the structure of liposomes and phospholipid bilayers(31).When concentration of liposomes in lubricant is low, the structures of liposomes and bilayers maintained and the liposomes did not become larger. And then, the liposomes were spread and formed lamellar film and functioned as boundary lubricant. When concentration of liposomes in lubricant is high, liposomes fused, grew in size and stabilized. Therefore, it is considered that liposomes in lubricants A_{P2}, B_{P2}, C_{P2} could not be easily spread by frictional loading and could not form multi-lamellar films. And thus, lubricating function of phospholipid was not fully utilized and adhesive wear pattern became obvious. These results indicated that not only concentration of single constituent but also relative concentration of proteins and phospholipid are important factors for these constituents to function as excellent boundary lubricants.

The effect of additives to lubricant on suppression of wear was not confirmed on the upper specimens. The contact area of upper specimens was not changed during reciprocating friction test. PVA hydrogel is the biphasic material that contains about 80% water and has biphasic lubrication property. It is indicated maintaining of water content and interstitial fluid pressure are important to maintaining the biphasic lubrication mechanism (32) and friction coefficient of PVA hydrogel as biphasic material increases with increase of loading time due to the exudation of internal water (33). There was little chance of recovery of hydration for upper specimen and it is considered that biphasic lubrication ability of upper specimens decreased during the test. Therefore, it is indicated that adsorbed film by proteins and phospholipid itself could not protect sufficiently the upper surface of PVA hydrogel with contact zone under continuous loading.

Thus, the establishment of the synergistic function of boundary lubrication by adsorbed film and biphasic lubrication is an important factor for reduction in both friction and wear of PVA hydrogel. The improvements in boundary lubrication and biphasic lubrication properties of PVA hydrogel are planned in further study.

In this study, concentration of proteins in lubricant was relatively low within physiological concentration. In addition, natural synovial fluid contains other lubricating components such as hyaluronic acid. Therefore, influence of the addition of hyaluronic acid and protein concentration would be researched in future study.

5. Conclusion

In this study, influence of phospholipid and protein constituents on friction and wear behavior of PVA hydrogel as artificial cartilage was investigated. It was indicated that DPPC contributes to reduction of friction of PVA hydrogel and the appropriate coexistence of DPPC and proteins significantly reduces wear of PVA hydrogel. In addition, both the concentration and the relative ratio of proteins and phospholipids are important factors for these constituents to function as excellent boundary lubricants for PVA hydrogel. These findings would contribute to the elucidation of the wear mechanisms of PVA hydrogel in synovial fluid and improvement of material properties of PVA hydrogel considering the influences of synovial fluid as lubricants.

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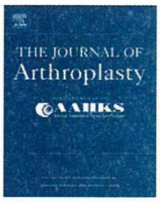

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An Additional Reference Axis Improves Femoral Rotation Alignment in Image-Free Computer Navigation Assisted Total Knee Arthroplasty

Hiroshi Inui MD, Shuji Taketomi MD, Kensuke Nakamura MD, Takaki Sanada MD,
Sakae Tanaka MD, Takumi Nakagawa MD

Department of Orthopaedic Surgery, Faculty of Medicine, The University of Tokyo, Tokyo, Japan

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ABSTRACT

Few studies have demonstrated improvement in accuracy of rotational alignment using image-free navigation systems mainly due to the inconsistent registration of anatomical landmarks. We have used an image-free navigation for total knee arthroplasty, which adopts the average algorithm between two reference axes (transepicondylar axis and axis perpendicular to the Whiteside axis) for femoral component rotation control. We hypothesized that addition of another axis (condylar twisting axis measured on a preoperative radiograph) would improve the accuracy. One group using the average algorithm (double-axis group) was compared with the other group using another axis to confirm the accuracy of the average algorithm (triple-axis group). Femoral components were more accurately implanted for rotational alignment in the triple-axis group (ideal: triple-axis group 100%, double-axis group 82%, $P<0.05$).

Total knee arthroplasty (TKA) has become one of the most successful surgical procedures in orthopedic surgery [1,2]. The success of this procedure depends on many factors, including surgical techniques and the design and material of the components. With regard to surgical techniques, implant positioning and soft tissue balancing are very important. Malpositioning of any component can lead to an increased risk of loosening, instability, patella subluxation, and residual pain [3–5].

Computer-assisted navigation systems have been designed to increase the accuracy of implantation and have become much more accepted and prevalent in recent years. Several studies have demonstrated superior alignment of components in the coronal plane in navigated TKA compared with conventionally implanted TKA [6–8]. However, with regard to the accuracy of rotational alignment, few studies have demonstrated an improvement in computer-assisted navigation as compared with conventional methods. In particular, using image-free navigation systems, many authors have reported variability in identifying the surgical transepicondylar axis (SEA) for femoral rotation [9–11]. The Whiteside axis is generally assumed to be perpendicular to SEA and therefore a reliable axis of reference [12,13]. However, criticism of this landmark also includes difficulty in identification in case of trochlear dysplasia or destructive arthritis [14,15]. Using an average algorithm between the determined angle of the registered Whiteside axis and transepicondylar axis has been recommended, and Stockl et al. showed that image-free navigation using this algorithm improved femoral rotational alignment [15,16]. However, much room for improvement in femoral component rotation control remains in the use of image-free navigation systems.

To reduce the registration errors, we believed that there is a need for an additional reference axis to confirm the accuracy of the rotational axis calculated by the image-free navigation system using an average algorithm. If the additional axis contradicts the rotational axis calculated by the image-free navigation system, it shows the necessity to re-register such landmarks as the medial sulcus, lateral epicondyle, and femoral AP axis. The posterior condylar axis (PCA) is known to be one of the most common axes during conventional total knee arthroplasty procedure. However, there are differences among patients in the angle between SEA and PCA, which is often called the condylar twist angle (CTA); therefore, CTA must be measured preoperatively to accurately set the rotational cutting guide in the conventional technique. Indeed, the use of computed tomography (CT) or magnetic resonance imaging (MRI) is recommended to detect CTA, but this accompanies some disadvantages, including the additional cost of CT and MRI and the additional radiation dose associated with CT. However, there have been some reports on methods that can help us to predict PCA and CTA preoperatively from radiography alone [17–19]. Just one additional radiograph is less of a disadvantage than CT or MRI.

The purpose of this study was to clarify whether the accuracy of the femoral rotational axis derived from an image-free navigation

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Reprint requests: Hiroshi Inui, MD, Department of Orthopaedic Surgery, Faculty of Medicine, The University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan.

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system using an average algorithm could be confirmed by calculating another reference axis determined by PCA and CTA predicted from one additional radiograph, and also whether this improved femoral rotational alignment. We therefore hypothesized that this confirmation using the additional axis would improve femoral rotational alignment.

Materials and Methods

Institutional review board approval was received for this study. All patients provided written informed consent.

Of a total of 162 consecutive primary TKA procedures performed in 146 patients between January 2009 and September 2011, 158 knees were replaced using the Stryker 4.0 image-free computer navigation system (Stryker Orthopedics, Mahwah, NJ) equipped with an average algorithm derived from the registered the Whiteside axis and SEA.

Between January 2009 and June 2010, femoral rotational alignment was determined according to this navigation algorithm (double-axis group: 78 knees) and between July 2010 and September 2011, femoral rotational alignment was determined by the navigation system and confirmed by the additional axis (triple-axis group: 80 knees). With power set at 0.80 and a 2-sided P-value of 0.05, we calculated 24 patients would be needed in each group to detect the accuracy of the femoral rotational alignment. Thirty-eight knees in the double-axis group and 26 knees in the triple-axis group were assessed by axial CT imaging after surgery. Preoperative variables were recorded, including age, sex, body mass index, preoperative diagnosis, frontal alignment, and range of motion. Pre-operative scores were obtained using the Knee Society Score (KSS) [20]. There was no statistically significant difference between the groups in terms of demographic characteristics (Table 1).

Pre-Operative Planning

Preoperatively, in the triple-axis group, one radiograph of the distal femur was taken by the method of Kanekasu et al. [17], and we contrived to see the epicondyles and posterior condyles of the femur by radiography as accurately as by axial CT imaging. We measured the angle between the clinical epicondylar axis (CEA) and PCA on the radiograph (Fig. 1). Then, we considered the influences of two things. One was the angle between CEA and SEA which had been reported to be 3° [18]. The other was the residual articular cartilage of the posterior condyle which the radiograph was unable to detect (Fig. 2). Takashiro et al. [19] demonstrated that the articular cartilage wear of the posterior femoral condyle affected CTA and that the articular cartilage wear of the posterior femoral condyle of patients with varus knees was mainly localized in the posteromedial condyle. We assumed that the cartilage wear would localized in the posterolatelal condyle of patients with valgus knees and the cartilage wear of the posteromedial and posterolateral condyle of patients with neutral knees would be equal, and that the angle affected by the cartilage wear was 1° [19]. Therefore, we subtracted 4° (=3°+1°) from the measured angle for varus knees, 3° for neutral knees, and 2° (=3°−1°) for valgus knees in this study to attain the predicted condylar twist angle (p-CTA) (Fig. 2). The average p-CTA was 3.7°±1.0° of external rotation [mean±standard deviation (SD), range: 1°–7° of external rotation].

Table 1
Preoperative Demographic Data.

	Double-Axis Group	Triple-Axis Group	*P*-Value
Number of patients	38	26	
Sex (female/male)	32/6	21/5	
Diagnosis (OA/AN)	36/2	24/2	
Age (years)	76.8±4.6	79.6±5.1	n.s.
Pre-operative FTA (°)	185.6±9.6	186.5±6.0	n.s.
Pre-operative KSS	36.4±10.1	34.9±9.7	n.s.
Maximum extension (°)	−10.9±6.7	−9.4±6.1	n.s.
Maximum flexion (°)	120.3±14.2	120.0±11.8	n.s.
Body mass index (kg/m^2)	25.6±3.9	25.2±3.5	n.s.

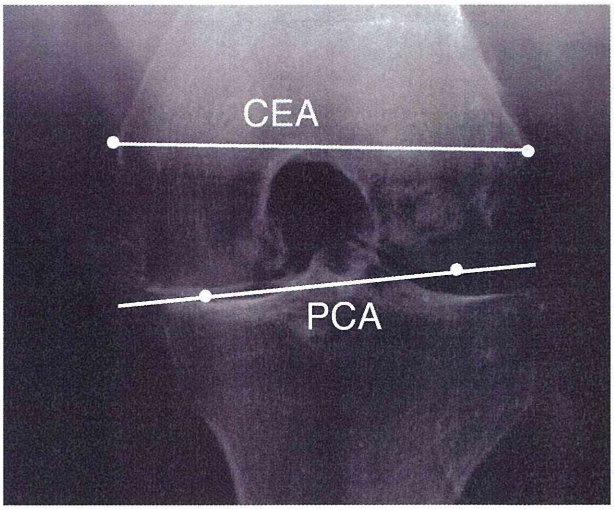

Fig. 1. Axial radiograph of the distal femur taken by the method of Kanekasu et al. [17]. CEA is the line connecting the medial and lateral epicondylar prominences; PCA is the line connecting the posterior margins of the medial and lateral femoral condyles.

Surgical Procedure

The Stryker 4.0 Navigation System was used for computer-assisted implantation. The system was image-free and used infrared cameras and light-emitting diodes. Surgery was performed under a tourniquet. A midvastus approach was used for varus and neutral knees and a medial parapatellar approach was used for valgus knees. The patella was everted in all patients. Landmarks comprised the center of the femoral head, the distal femur, the proximal tibia, the ankle, the Whiteside axis, the epicondylar axis (lateral epicondyle, medial sulcus), the anterior surface of the distal femoral cortex, the condylar surfaces of the femur and tibia, and the tibial AP axis. The femoral rotation axis on the navigation system (navi-FRA) was defined as the average rotational axis of the transepicondylar axis and the axis perpendicular to the Whiteside axis in the double-axis group (Fig. 3).

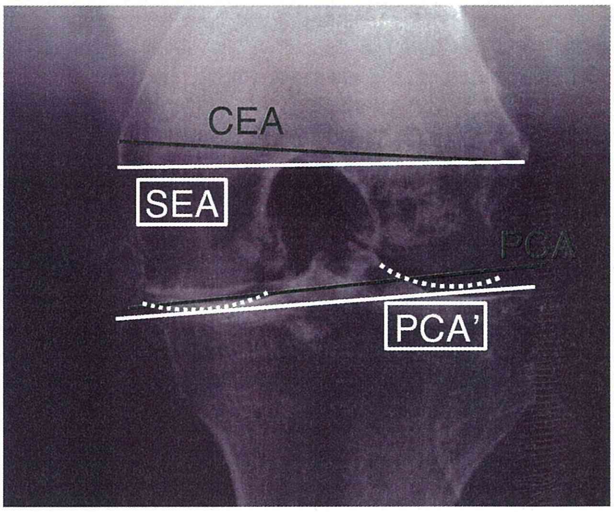

Fig. 2. Predicted condylar twist angle (p-CTA). P-CTA is the angle between SEA and PCA'. PCA' is the line connecting the posterior margins of the two dotted curves which are the assumed posterior femoral condyles with the articular cartilage included.

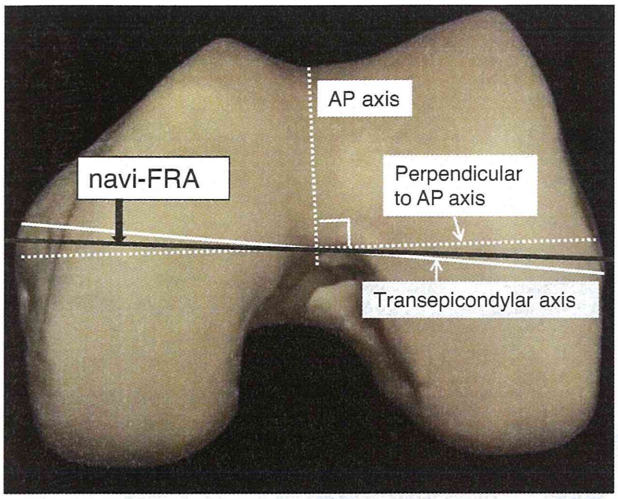

Fig. 3. The femoral rotation axis on the navigation system ("navi-FRA"). Navi-FRA is defined as the average axis of the transepicondylar axis and the axis perpendicular to the AP axis. AP axis = Whiteside's line.

In the triple-axis group, after cutting the distal femur, the posterior reference guide was set. Using the posterior reference guide, we drew two blue lines, one of which was "p-CTA − 2°" externally rotated from PCA and the other was the "p-CTA + 2°" externally rotated (Fig. 4). We measured the angles between navi-FRA and the two lines intraoperatively using the navigation template drilling guide. The guide was one of the specific adapted instruments of the Stryker 4.0 system which was developed to calculate the angle between PCA and the line connecting two drill holes or between PCA and the lower end of the guide (Fig 5). If the former angle was displayed as "internal" and the latter as "external," we concluded that navi-FRA was set as accurately as possible since the differences between navi-FRA and the axis determined by PCA and p-CTA were within 2° (Fig. 5). If both angles were displayed as internal or external, we assumed that the registration had not been performed accurately, and we re-registered the three landmarks (lateral epicondyle, medial sulcus, and the Whiteside axis). After one more registration, we followed navi-FRA and set the 4-in-1 cutting block.

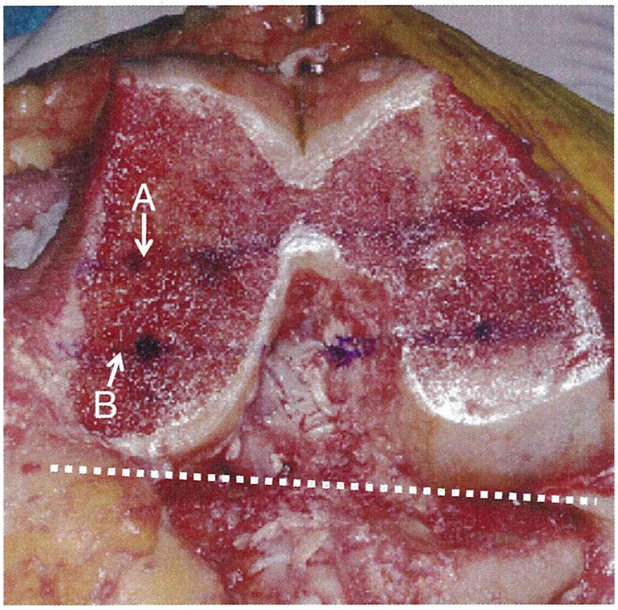

Fig. 4. Axial cross-section of the right distal femur. A: a blue line "p-CTA + 2°" externally rotated from PCA. B: a blue line "p-CTA − 2°" externally rotated from the PCA. PCA is the dotted line in this figure.

One surgeon (TN) took part in all procedures as the chief surgeon or first assistant. All implants used in both groups were Stryker Scopio NRG total knee implants.

Postoperative Evaluation

Rotational alignment of the femoral component was evaluated by CT. Knees were positioned in full extension. The rotational femoral component (RFC) angle was defined as the angle between the line through the center of both fixation pegs and SEA (Fig. 6). The ideal rotational femoral component angle was defined as falling within 3° of the target angle (0°) [9]. All CT scans were measured twice at 3-month intervals by two observers (HI and TS). Postoperative scores (KSS) and range of motion were recorded 1 year after operation.

Statistical Analysis

Data were analyzed using the EXCEL statistics 2008(SSRI Co., LTD., Tokyo, Japan) software package for Microsoft Windows. The Mann–Whitney U-test was used to compare the two groups. Fisher's exact probability test was used to compare the rate of optimally implanted components between the two groups. All significance tests were two-tailed, and a significance level of $P<0.05$ was used for all tests. The chance-corrected κ-coefficient was calculated to determine the intra- and inter-observer agreements. Kappa values of intra-observer reliability, inter-observer reliability (HI), and inter-observer reliability (TS) were 0.84, 0.91, and 0.92, respectively.

Results

The average RFC angle was −0.1° ± 2.4° [mean ± SD, range: 7° of internal rotation to 4° of external rotation] for the double-axis group and 0.3° ± 1.7° (3° of external rotation to 3° of internal rotation) for the triple-axis group. With regard to the average RFC angle, there were no statistically significant differences observed between the two groups.

Thirty-one cases (82%) were implanted ideally (within 3° of neutral) in the double-axis group, whereas all 26 cases (100%) were implanted ideally in the triple-axis group. There was a statistically significant improvement in the triple-axis group ($P<0.05$) (Fig. 7).

In the triple-axis group, a second registration was necessary for 8 cases (31%). After re-registration, navi-FRA was set accurately in all cases. There were 2 cases in which both of the angles between navi-FRA and the two blue lines after the second registration were displayed as internal and one case in which they were external.

The mean post-operative KSS was 91.7 (range: 79 to 100) for the double-axis group and 93.5 (75 to 100) for triple-axis group. The mean post-operative functional score was 72.2 (5 to 100) for the double-axis group and 74.7 (30 to 100) for triple-axis group. With regard to range of motion, the average maximum extension angle and flexion angle were −2.1° (−20° to 5°) and 115.8° (90° to 135°) for the double axis group, while −1.8° (−10° to 5°) and 118.2° (95° to 135°) for the triple-axis group. No significant difference was detected in these values for the two groups. There was one case of patella subluxation in the double-axis group which needed an additional operation of arthroscopic lateral release, the femoral component of which was 6° internally implanted.

Discussion

Malpositioning of any component can lead to an increased risk of loosening, instability, and pain [3,4]. Restoration of the tibiofemoral angle to within 3° of neutral during TKA is thought to be associated with a better outcome [4–6,21,22]. Computer-assisted navigation systems are designed to increase the accuracy of implantation, and have become much more accepted and prevalent in recent years.

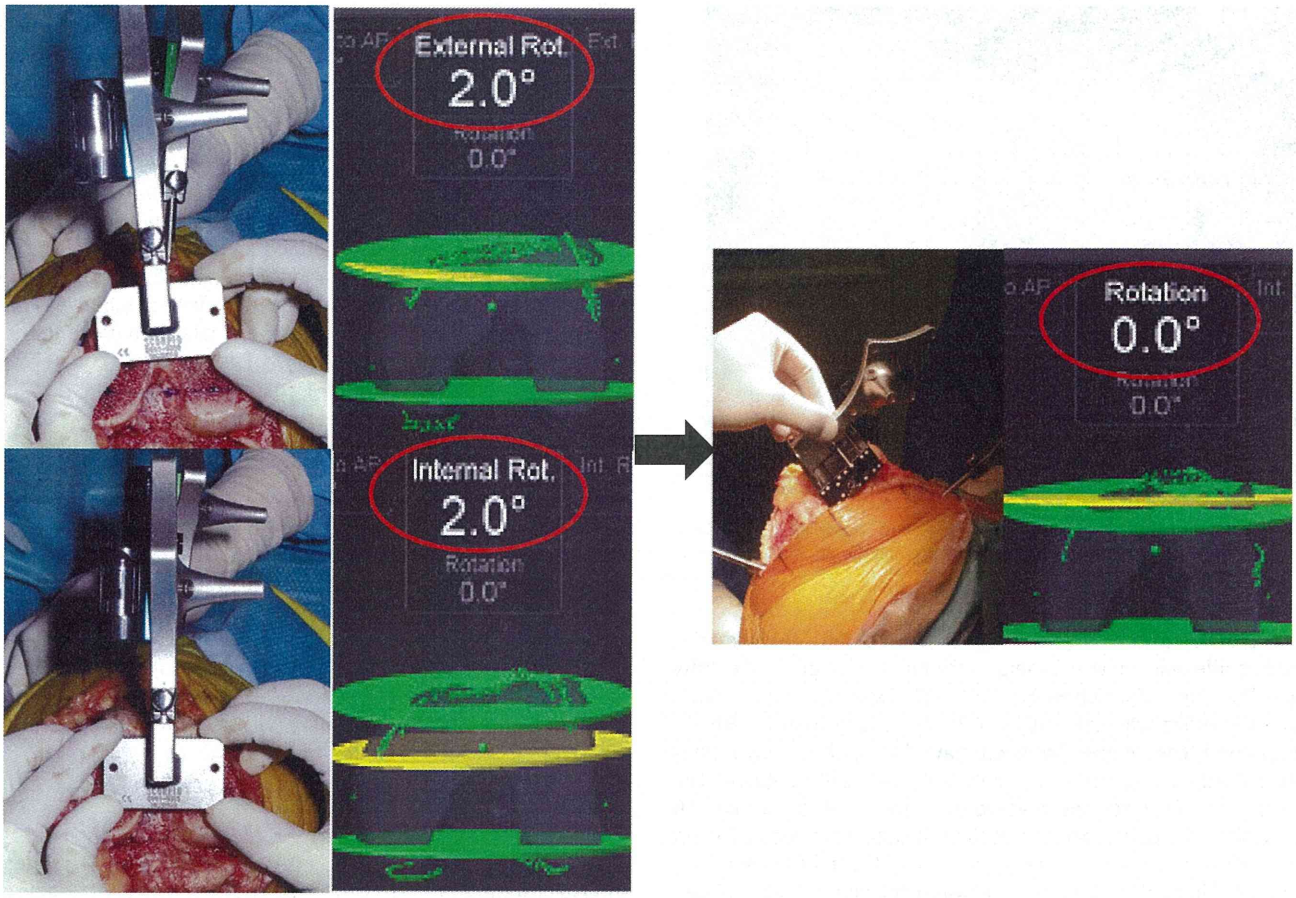

Fig. 5. Measurement of the angles between navi-FRA and the two lines (shown in Fig. 3) using the navigation system. If the two angles were displayed as "internal" and "external," we assumed navi-FRA to be accurate and set the 4-in-one cutting block in the neutral position.

Several studies have demonstrated superior alignment of the components in the coronal plane in navigated TKA compared with conventional implanted TKA [5,21,22].

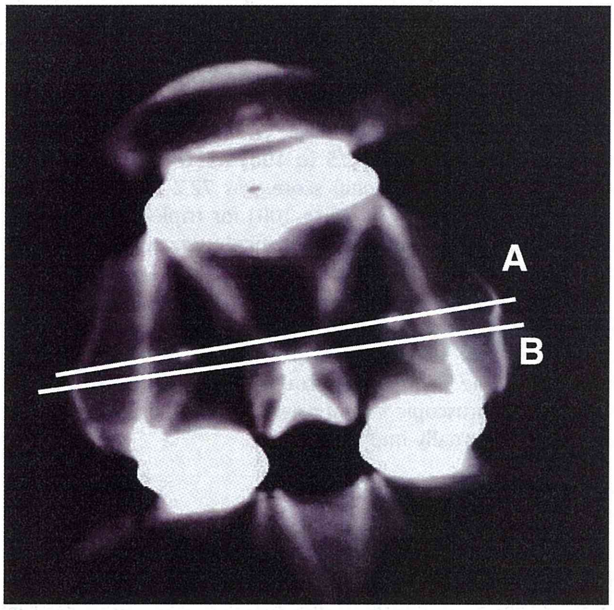

Fig. 6. Evaluation of rotational alignment of components on CT images. The rotational femoral component angle is defined as the angle between lines A and B. (A: Line through the center of both fixation pegs. B: Surgical epicondylar line).

Accurate rotational alignment of the femoral component is also considered important [5,9,10,18]. However, few studies have demonstrated an improvement in the accuracy of femoral rotational alignment with computer-assisted navigation, in particular image-free navigation, compared with conventional methods [9,10,16]. Many authors have reported variability in the identification of the transepicondylar axis [11,23]. Yau et al. [11] found that using the image-free navigation system, the maximum combined error was 8.2° with 5.3° at the medial and 2.9° at the lateral femoral epicondyles in the transepicondylar axis. Some authors have speculated that this variability is caused by soft tissue coverage [13,24]. However, in a cadaveric study, Siston et al. [25] demonstrated high variability even after all soft tissues had been stripped.

In our current series, eighty-two percent of femoral components in the double-axis group (31 of 37 knees) were implanted ideally. This result appears superior to those reported in previous studies using conventional techniques and that may be partly because of the average algorithm equipped with the Stryker 4.0 image-free navigation system [9,16,26]. However, Mizu-uchi et al. [9] demonstrated that 89.3% of femoral components were implanted within 3° of the ideal rotational alignment in the CT-based navigation group, and they reported that the image-free navigation systems are more widely used than the CT-based navigation systems not because of the accuracy of the former but because of the necessity of the latter for pre-operative CT scans and planning time.

In the current study, 100% of femoral components were implanted ideally in the triple-axis group, representing a statistically significant improvement ($P<0.05$). This result demonstrates that each reference axis (transepicondylar axis, Whiteside's axis, and posterior condylar axis) has some variability and is not always reliable; however,

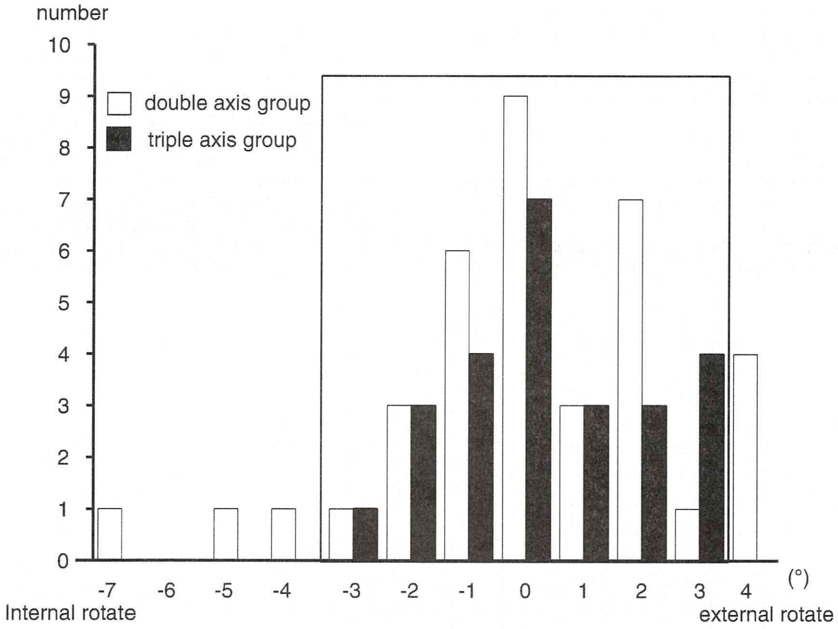

Fig. 7. Distribution of the rotational femoral component angle. The box represents the ideal alignment (±3° of neutral).

combination of a triple reference axis reduced variability, enabling the femoral component to be ideally implanted each time with respect to rotational alignment.

In the triple axis group, we could confirm the accuracy of the femoral rotational registration by another reference axis. Re-registration of the landmarks was performed if necessary. As a result, all femoral implants were implanted ideally with regard to rotational alignment. Based on this result, it is speculated that it is not the navigation system itself but the surgeons' registration error which is mainly responsible for the inaccuracy of the femoral rotational alignment.

There are some limitations to the current study. One limitation is that as we couldn't assess every patient's CT, there might be some potential selection bias. Follow-up CT was performed to those who consented in spite of the demerits of the additional cost and radiation dose associated with CT. Therefore, the patients evaluated by CT might be possessing a better outcome and more motivated than those who did not consent. The mean post-operative KSS, functional score, maximum extension angle and flexion angle of those who didn't consent were 90.9, 73.1, −1.5° and 115.1° (double-axis group, 40patients) and 92.2, 73.8, −1.8° and 116.8° (triple-axis group, 52 patients) respectively. No significant difference was detected between those who consented and those who didn't in both groups. Therefore, we think there might not be any potential selection bias in this study. However, we should have evaluated every patient's CT. Another limitation is that surgery in the two groups was performed at different times. Some studies have shown that there is a so-called learning curve in navigated surgery, especially in early cases. Twenty to thirty implantations are said to be necessary before surgeons become accustomed to the navigation system and the average operating time reaches a plateau [27,28]. At our institute, 63 implantations using the image-free navigation system (Stryker 3.1) had been performed by the end of December 2008; therefore, our result might not have been affected by the learning curve. Furthermore, 79% of femoral implants were ideally implanted with respect to rotation using the Stryker 3.1, which was equipped with the same average algorithm. There might have been no learning curve with regard to identification of the femoral transepicondylar axis and the Whiteside axis.

In conclusion, our study demonstrates that the accuracy of femoral rotational alignment with the image-free navigation system, which uses the average algorithm between the transepicondylar axis and the Whiteside axis, can be significantly improved by the addition of another reference axis determined by PCA and CTA, and this can be predicted not by CT or MRI but from just one radiograph.

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