knees. Correlation coefficients between the FMA angle and the distal–lateral distance of the medial condylar resection from the femoral sulcus were assessed using Pearson's correlation analysis. A test–retest analysis was performed to determine intraobserver reliability between the measurements made initially and >1 month after the first measurement. Pearson's correlation coefficient was also used to calculate the test–retest reliability for the distances of the distal–lateral and distal–medial condylar resections from the femoral sulcus. Correlation coefficients ($r$) ranged from −1.0 (negative correlation) to +1.0 (positive correlation), $0.1 \leq r < 0.3$ between two variables was considered weak, $0.3 \leq r < 0.7$ was considered moderate, and $0.7 \leq r < 1.0$ was considered strong. Stata software (version 13; Stata Corporation, College Station, TX, USA) was used for the statistical analyses.

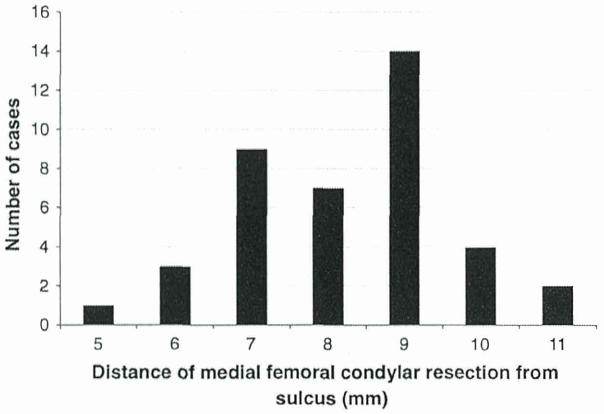


**Fig. 4** Graphical representation of the distribution of the distance of the distal medial resection from the femoral sulcus

## Results

The correlation coefficients of test–retest reliability for the distances of the distal–lateral and distal–medial condylar resections from the femoral sulcus were 0.91 and 0.96, respectively, indicating strong correlations for both measurements. The mean distance of the distal–lateral condylar resection from the femoral sulcus was 7 mm [standard deviation (SD) 1; range 5–9 mm] (Fig. 3). The mean distance of the distal–medial condylar resection from the femoral sulcus was 8 mm (SD 1; range 5–11 mm) (Fig. 4). These differences in the distances between the distal–lateral condylar resection and the distal–medial condylar resection from the femoral sulcus were significant ($P = 0.01$).

In men, the mean distances of the lateral and medial condylar resections were 7 mm (SD 1; range 5–8 mm) and 9 mm (SD 1; range 7–11 mm), respectively. In women, the respective mean distances of the lateral and medial condylar resections were 7 mm (SD 1; range 5–9 mm) and 8 mm (SD 1; range 5–10 mm). These values did not differ significantly between men and women (lateral, n.s.; medial, n.s.).

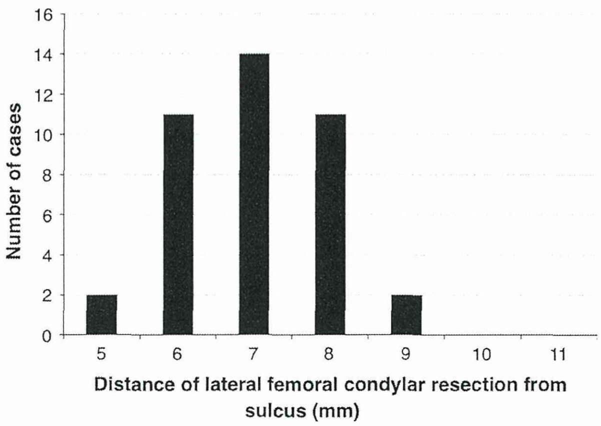


**Fig. 3** Graphical representation of the distribution of the distance of the distal lateral resection from the femoral sulcus

Table 1 shows the mean distances of lateral and medial condylar resections for the knees according to the component sizes. There was no significant difference between the component sizes.

The mean FMA angle was 5.5° valgus (SD, 2.0), and the FMA angle ranged from 0.4° valgus to 9.9° valgus. There was a slightly positive correlation between the FMA angle and the distance of the distal–lateral condylar resection from the femoral sulcus ($r = 0.33$) (Fig. 5). However, the FMA angle did not correlate significantly with the distance of the distal–medial condylar resection from the femoral sulcus ($r = -0.23$) (Fig. 6).

## Discussion

The most important finding of this study was that the sulcus cut technique cuts bone 7 mm from the lateral condyle and 8 mm from the medial condyle in the average varus-deformed arthritic knee. The trochlear groove of the femur is one of the most easily accessible and useful anatomical landmarks for the femur because this feature is less affected by osteoarthritis. Previous studies have reported on the importance of the femoral sulcus as a rotational and medial–lateral landmark in TKA [2, 10, 21, 32]. The results of the current study suggest that the sulcus of the distal femur can be used as a reliable landmark for distal cutting of the femur in TKA.

Determining the level of distal femoral resection is essential for a successful outcome of TKA. Distal shift of the joint level with distal femoral resection is considered

**Table 1** Number of lateral and medial condylar resections using the sulcus cut technique for knees according to component size

| Component size | *N* | Lateral condylar resection (mm) | | | Medial condylar resection (mm) | | |
|---|---|---|---|---|---|---|---|
| | | Mean | SD | Range | Mean | SD | Range |
| Standard | 8 | 7 | 1 | 6–8 | 8 | 1 | 6–9 |
| Large | 9 | 7 | 2 | 5–9 | 8 | 2 | 5–10 |
| Extra-large | 23 | 7 | 1 | 5–8 | 9 | 1 | 6–11 |

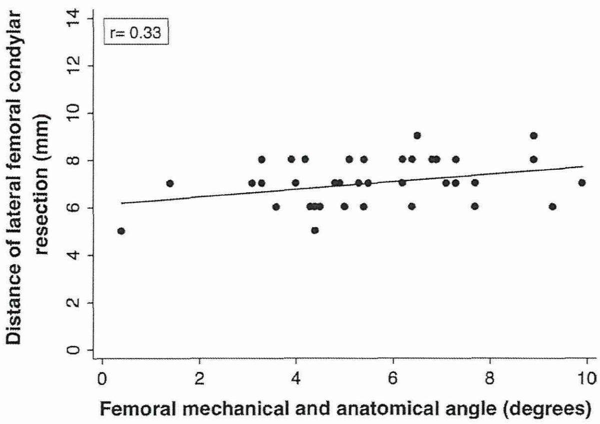


**Fig. 5** Graphical representation of the correlation between the femoral mechanical and anatomical angle and the distance of the distal lateral resection from the femoral sulcus

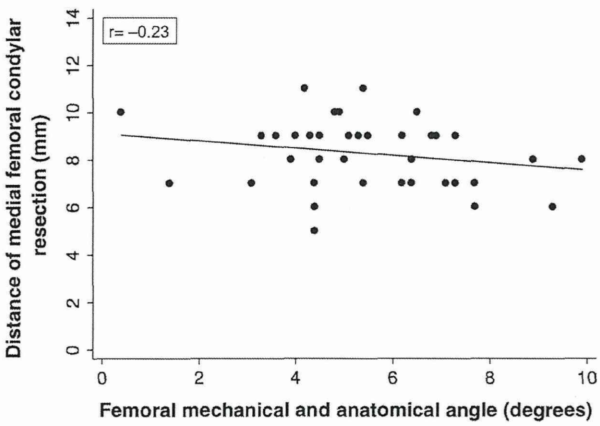


**Fig. 6** Graphical representation of the correlation between the femoral mechanical and anatomical angle and the distance of the distal medial resection from the femoral sulcus

a risk factor for developing a stiff knee [8, 22, 29, 35] and excessive wear of the ultra-high molecular weight polyethylene [20, 36]. By contrast, proximal shift of the joint level with distal femoral resection can lead to symptomatic joint laxity [22, 27] and anterior knee pain [14, 18]. Although some surgeons intentionally raise the joint line to achieve an equal flexion–extension gap using the gap-balancing technique [4, 7, 19, 34], it is necessary to have a useful landmark for distal femur resection. Undesired distal femoral resection can happen when using a general distal femoral cutting block on the distal end of the femur and might require additional bone resection.

To investigate ways of improving precision, several studies have used the ratio of the transepicondylar width of the femur and the distance from the medial (or lateral) epicondyle to the joint line tangent [13, 16, 31, 33]. This technique is useful and is the only applicable method in revision TKA, but it is too complex for primary TKA. Navigation systems have been reported to achieve more accurate component alignment during TKA, but few studies have focused on the accuracy of joint line reconstruction using such navigation systems [5, 17]. Jawhar et al. [17] reported that the joint line was shifted proximally by >8 mm in 6 % of nonnavigated versus 6.8 % of navigated primary TKAs, but this difference was not significant. However, that study did not describe the detailed surgical planning with the navigation system. Even with the navigation system, precise bone resection cannot be achieved without adequate surgical planning.

In the current study, the most frequent distances of the distal–lateral and distal–medial condylar resection were 7 mm (35 % of cases) and 9 mm (35 %), respectively. The patients in the current study had almost no deformities of the femoral lateral condyle in the CT images, and we found only slight degeneration of the femoral lateral cartilage during surgery. Previous studies have reported that the cartilage thickness in the femoral lateral condyle was about 2 mm [1, 3]. Based on the findings of the current study, the original "cartilaginous" joint line of the distal–lateral condyle would be 9 mm on average from the deepest point of the femoral sulcus. In other words, when a femoral component with 9 mm distal thickness was used, the sulcus cutting of the distal femur would maintain the lateral joint line. These results also suggest the high precision of this technique because 90 % of the cases were within the variance of ±1 mm from the mean value. On the other hand, it can be difficult to estimate the original medial distal joint level because of severe articular deformity. Even if only the cartilage is worn out in the absence of bony damage, the sulcus cut technique would slightly elevate the joint line at the medial side compared with that of preosteoarthritis.

The current study also showed that this technique is uniformly effective regardless of sex and size of the component, although the surgeon must pay close attention to prevent overresection of the distal–lateral condyle if the FMA angle is >10°. These findings suggest that the sulcus cut technique possesses high clinical reliability for determining the desirable distal femoral resection level in TKA for almost all varus knees without severe femoral bowing.

The main limitation of this study is that only varus osteoarthritic knees were included; however, valgus osteoarthritic knees are uncommon. Because of hypoplasia of the lateral condyle in the valgus knee [23], the distance of the distal–lateral condylar resection from the femoral sulcus in the valgus knee might be less than that in the varus knee. The other limitations of this study are that the number of patients was small, the study population was limited to Japanese patients, and there was intraobserver bias.

## Conclusions

This study showed that the sulcus cut technique is a reliable and effective method that works uniformly well regardless of sex and component size. This technique can be used to determine the desirable level of the distal femoral resection in relation to the distal thickness of the commonly used femoral components.

**Conflict of interest** The authors declare that they have no conflict of interest.

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The Journal of Arthroplasty 29 (2014) 2352–2356

Contents lists available at ScienceDirect

The Journal of Arthroplasty

journal homepage: www.arthroplastyjournal.org

# Tibial Rotational Alignment Was Significantly Improved by Use of a CT-Navigated Control Device in Total Knee Arthroplasty

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ARTICLE INFO

*Article history:*
Received 15 January 2014
Accepted 24 June 2014

*Keywords:*
total knee arthroplasty
rotational alignment
tibial component
developed instrument
CT-based navigation system

ABSTRACT

This study compared the accuracy of three methods to set tibial component rotational alignment: (1) conventional method, the anteroposterior (AP) axis was determined by the surgeon using anatomical landmarks; (2) partial-navigation method, the tibia was prepared according to the AP axis using a CT-based navigation system and the component was manually positioned; (3) full-navigation method, the tibial component was positioned and fixed with cement under the control of navigation using a newly developed instrument. The conventional method showed considerable deviation (range, −18.6° to 14.7°), and the partial-navigation method also showed considerable deviation (−11.3° to 8.1°). In contrast, the full-navigation method significantly improved the accuracy of alignment (−2.9° to 2.1°). The tibial component can become malaligned during cement fixation, even after proper bone preparation.



Rotational malalignment of the tibial component can lead to altered joint kinematics and painful total knee arthroplasty (TKA). Excessive malrotation of the tibial component can result in various complications after TKA such as painful knee [1–4], stiff knee [5,6], patellofemoral instability [7–11], or excessive wear of the ultrahigh molecular weight polyethylene of the tibial component [12,13]. Precise rotational placement of the tibial components is, however, difficult to accomplish with a conventional technique because anatomical landmarks for deciding tibial rotational alignment can be obscured and are variable in nature compared with those for femoral rotational alignment [14,15]. Previous studies have shown that internal rotational errors of more than 25° for the tibial component can occur in conventional TKA [4,9]. Even when a navigation system is used, the deviation from the optimum rotational angle decided during preoperative planning is greater for tibial alignment than for femoral alignment [16–19].

Errors in aligning the tibial component can occur during bone preparation and component fixation. First, the accuracy of the conventional method using anatomical landmarks is extremely low because it is a very subjective way to determine the appropriate position. Second, even if an image-based or image-free navigation system is used, the system cannot assist with rotational alignment of the tibial component during the cementing procedure. The position and orientation of the tibial component can possibly change during fixation with cement. We have developed a custom instrument to control rotational alignment with a computer navigation system during the cementing procedure (Fig. 1).

This study examined the accuracy of rotational alignment of the tibial component with and without CT-based computer navigation. We also evaluated whether accuracy was improved with the developed instrument.

## Materials and Methods

The study group contained 70 consecutive knees in 59 patients (48 women, 11 men) undergoing primary posterior cruciate-substitute (PS) TKA (Scorpio NRG PS, Stryker Orthopaedics, Mahwah, NJ, USA) by several surgeons between February 2010 and February 2013. A CT-based navigation system was used in all patients. We excluded two patients because the preoperative plan for tibial rotational alignment was changed intraoperatively due to severe deformity. Finally, data from 68 knees were available and the preoperative diagnosis was osteoarthritis in 61 knees, and rheumatoid arthritis in 7 knees. The mean age of the patients at the time of operation was 74.7 years (range, 59–88). This study was approved by the Institutional Review Board, and all patients provided informed consent for these operative procedures and risk of radiation exposure. All patients were assessed using preoperative and postoperative CT scans for rotational alignment of the tibial component.

The Conflict of Interest statement associated with this article can be found at http://dx.doi.org/10.1016/j.arth.2014.06.016.

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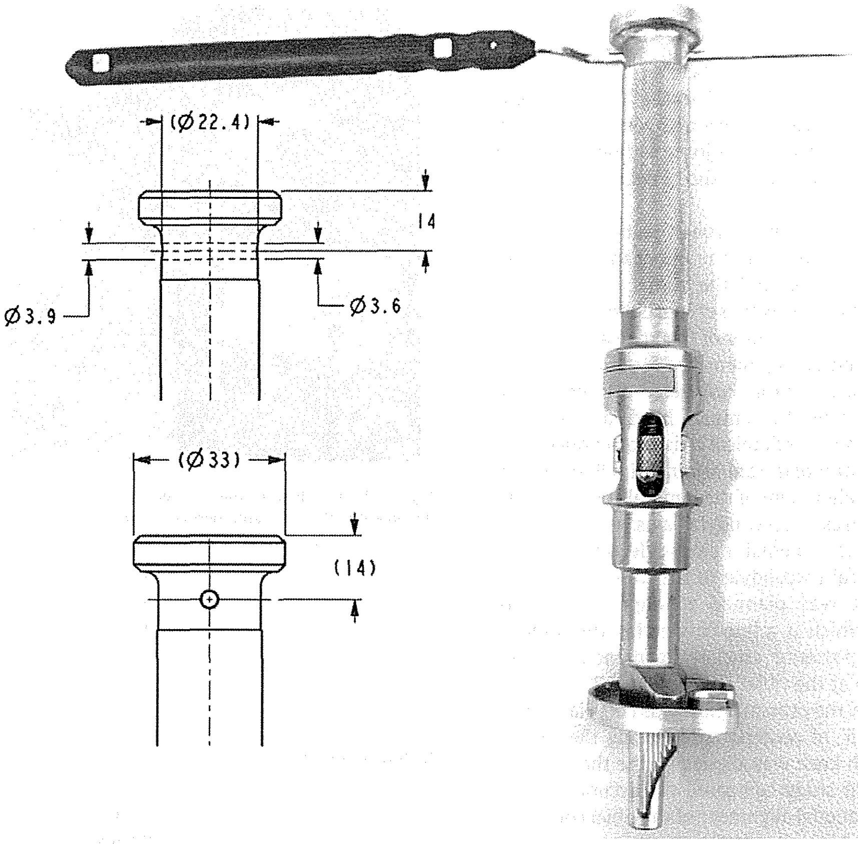


**Fig. 1.** A custom instrument designed to allow examination and control of rotational alignment with a computer navigation system. A small and truncated conical hole was made in the handle of the tibial component fixator to be a perfect fit for the diameter of the navigation pointer. The hole was located 14 mm from the top of the handle and finely adjusted in parallel and anterior–posterior direction to the tibial component. The diameter of the hole at the entry point (anterior side) was 3.9 mm, and that at the exit point (posterior side) was 3.6 mm. The hole length was 22.4 mm.

**Fig. 2.** We determined the tibial anteroposterior axis manually using anatomical landmarks after the proximal tibial cut (conventional method).

*Preoperative Planning and Surgical Technique*

We used a CT-based navigation system (Vector Vision Knee 1.6.; Brain LAB Inc., Heimstetten, Germany). For the initial CT scans (Toshiba Aquilion; Toshiba Medical Systems Co., Tochigi, Japan), the femoral head, the knee joint, and the ankle joint without the femoral shaft and tibial shaft were scanned with a slice thickness of 2 mm in immediate succession.

To align the components in the coronal plane, the femoral component was set perpendicular to the mechanical axis that connected the center of the knee and the center of the femoral head, and the tibial component was set perpendicular to the mechanical axis that connected the center of the knee and the center of the ankle joint. For the sagittal alignment, the femoral component was aligned to the mechanical axis that connected the center of the lateral knee and the center of the femoral head, and the tibial component was aligned to the mechanical axis that connected the center of the knee and the center of the ankle joint with 5° of posterior slope. The neutral rotational alignment of the femoral component was aligned according to the surgical epicondylar axis, which is a line connecting the sulcus of the medial epicondyle and the most prominent point of the lateral epicondyle of the femur [20,21]. The tibial rotational alignment was planned to align to the tibial anteroposterior (AP) axis, which is a line connecting the middle of the tibial insertion of the posterior cruciate ligament and medial border of the patella tendon at the tibial attachment [22].

For the surgical technique, the proximal tibia was cut relative to the tibial mechanical axis with 5° of posterior slope using the CT-based navigation system. Then each knee was aligned by the three different methods in turn. The current study compared the accuracy of three methods for determining rotational alignment of the tibial component.

1. Conventional method — The surgeon manually determined rotational alignment of the tibia as the tibial AP axis using anatomical landmarks and marked the line of the tibial AP axis on the tibial cutting surface by a radio knife (Fig. 2). The rotational alignment resulting from the conventional method was evaluated by the navigation system (Fig. 3).
2. Partial-navigation method — The rotational direction of the bone preparation instrument was set relative to the tibial AP axis using the navigation system. After the keel hole of the tibia was prepared (Fig. 4), the tibial component was temporarily held in position by hand (Fig. 5). The rotational alignment with the partial-navigation method was evaluated with the navigation system.
3. Full-navigation method — Finally, the tibial component was positioned under control of the navigation system using the developed instrument during the cementing procedure. The final position of the component with the full-navigation method was evaluated again by the navigation system. Postoperatively, we evaluated the tibial rotational alignment using an axial CT scan with a slice thickness of 2 mm. The same examiner performed the same measurement three times and the mean value of the three rotational angles resulting from these measurements was used in this study.

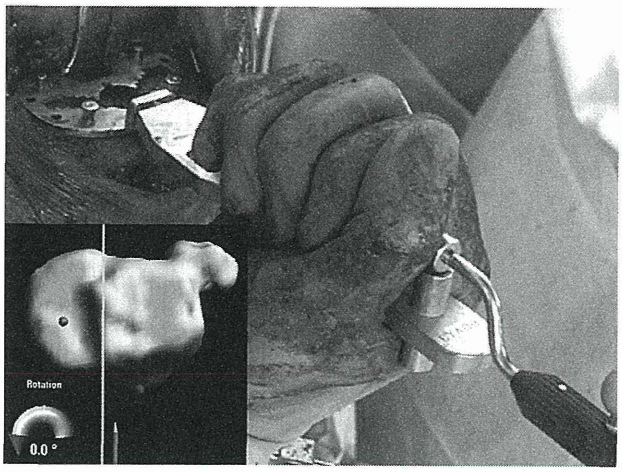

**Fig. 4.** The keel hole of the tibia was prepared exactly by matching the rotational alignment of the tibial anteroposterior axis using the navigation system.

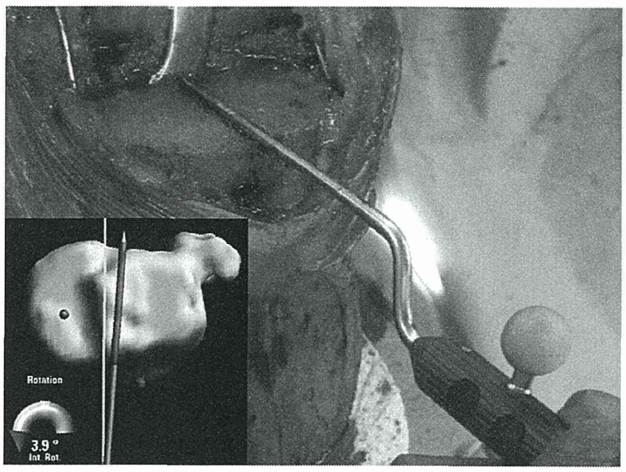

**Fig. 3.** The accuracy of the conventional method for determining the tibial anteroposterior axis was evaluated using the navigation system.

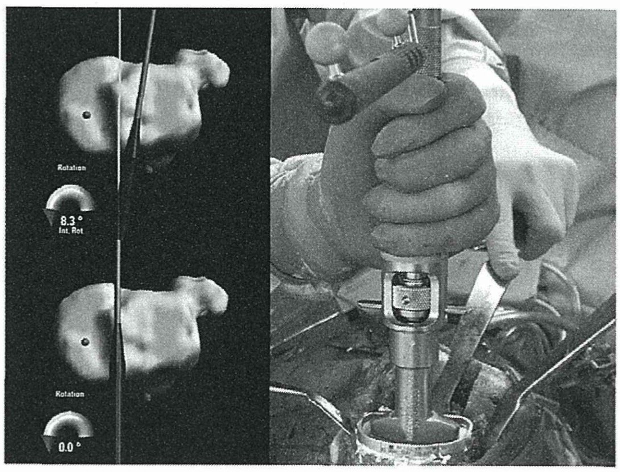

**Fig. 5.** The tibial component was temporarily positioned by hand (partial-navigation method), and was then positioned using the custom instrument relative to the tibial anteroposterior axis with the navigation system during the cementing procedure (full-navigation method).

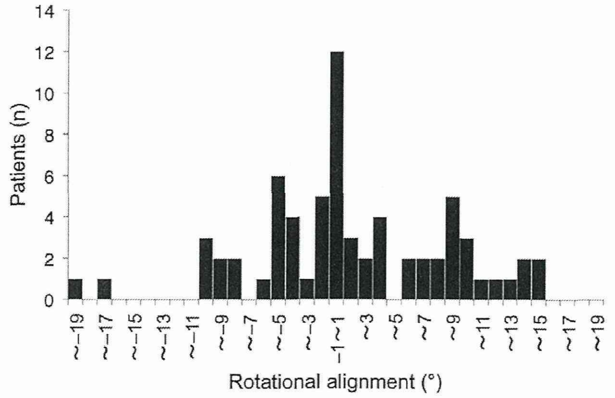


**Fig. 6.** Distribution of the rotational alignment values of the tibial component resulting from the conventional method.

### Statistical Analysis

Differences between measured alignments were determined using the nonparametric Mann–Whitney *U* test for independent samples. Computer software (Stata software version 13; Stata Corporation, College Station, TX, USA) was used for statistical analysis. The significance level was set at 5%.

## Results

The rotational alignment with the conventional method was highly variable and ranged from 18.6° of internal rotation to 14.7° of external rotation, and the mean rotation (SD) was 1.1° (7.1°) (Fig. 6). The rotational alignment with the partial-navigation method also showed a wide range of rotational deviation, between 11.3° of internal rotation and 8.1° of external rotation, and a mean (SD) of −1.7° (3.9°). In particular, more than 3° of tibial internal malrotation occurred in 26 cases (38%) (Fig. 7). In contrast, rotational alignment of the tibial components set with the full-navigation method and the newly developed instrument, significantly improved compared with the other methods. The rotational deviation was between 2.9° of internal rotation and 2.1° of external rotation with a mean (SD) of −0.1° (0.6°) ($P < .001$) (Fig. 8). The tibial rotational position on the postoperative axial CT scans showed high accuracy, as did the final intraoperative position, with the postoperative scan measurements for tibial rotation having a mean (SD) of 0.7° (1.5°) and a range from 3.1° of internal rotation to 4.1° of external rotation (Fig. 9).

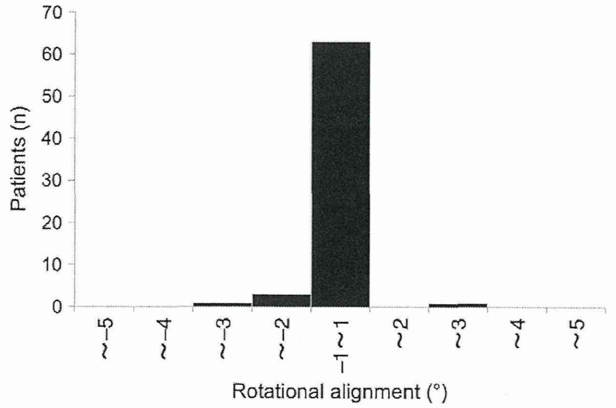


**Fig. 8.** Distribution of the rotational alignment values of the tibial component resulting from the full-navigation method.

## Discussion

Rotational alignment of the tibial component is recognized as an important factor influencing patient symptoms after TKA [1,4,5,8,13]. However, several references for setting rotational alignment of the tibial component can be very ambiguous compared with the surgical epicondylar axis used to align the femoral component [4,9,14,15].

Akagi et al [22] reported a tibial AP axis that was very useful and has provided a consensus reference for rotational alignment of the tibial component. The tibial AP axis is more accurate than extra-articular references such as the transmalleolar axis of the ankle and the second metatarsal bone axis of the foot [23]. The definition of the tibial AP axis includes the tibial insertion of the PCL as an intraarticular reference, but the majority of the tibial PCL insertion may be removed during the proximal tibial cut [24,25]. As a result of this effect, the current study showed that tibial rotation was highly variable, at up to −18.6° with the conventional method. A low level of accuracy of implantation was also reported when other anatomical references were used. Maximum internal rotational errors of the tibial component using the tibial tuberosity and the geometric center of the knee as landmarks were 25.4° and 27.7°, respectively [4,9]. Nicoll et al [4] discussed that the cause of internal malrotation might be an

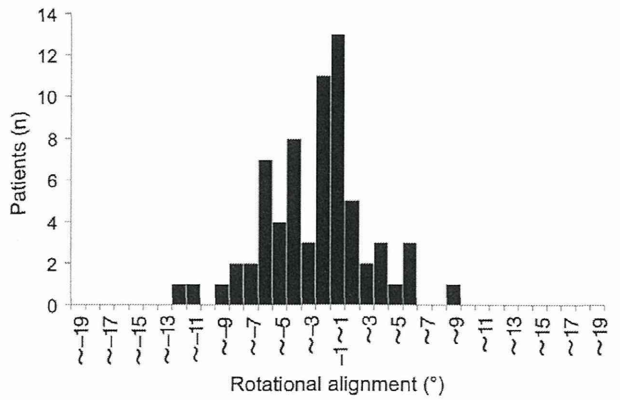


**Fig. 7.** Distribution of the rotational alignment values of the tibial component resulting from the partial-navigation method.

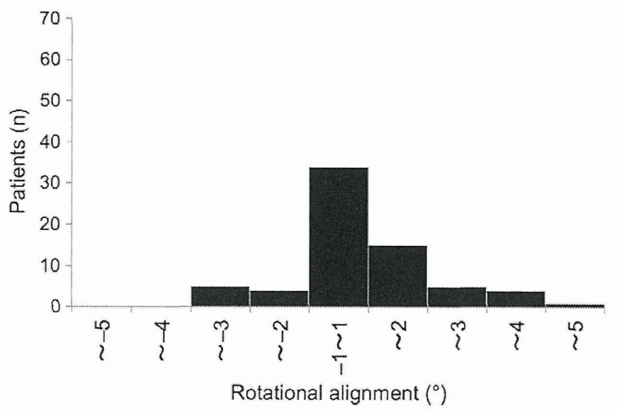


**Fig. 9.** Distribution of the rotational alignment values of the tibial component measured on the postoperative axial CT scan.

attempt to avoid impingement of the popliteus tendon or to obtain better cover of the cut tibial surface. Consequently, accurate rotational positioning of the tibial component is very hard to accomplish with manual positioning methods, even if a variety of landmarks is used.

Most of the image-free navigation systems cannot support rotational alignment of the tibial component [16–18]. Matziolis et al [18] reported that the tibial components showed a greater range of rotational deviation, with between 21.2° of internal rotation and 11.0° of external rotation, using an image-free navigation system, and these results were not significantly different from those with the conventional implantation method. On the other hand, CT-based navigation systems can support rotational alignment of the femoral and tibial components. However, even if the CT-based navigation systems are used, the variation from the ideal rotational angle is larger for tibial alignment than for femoral alignment. Mizu-Uchi et al [19] reported that a rotational tibial component angle within ±3° of the ideal was obtained in 78.6% (22 of 28) of knees using a CT-based navigation system. We also showed that rotational tibial component angles within ±3° from the ideal were obtained in only 50% (34 of 68) of knees when it was manually positioned, even after the keel hole of the tibia was prepared exactly relative to the tibial AP axis using the navigation system (partial-navigation method). We suggest that a possible reason for this variability in tibial rotational alignment might be that a small space is allowed for the cement mantle surrounding the keel, or it may be due to fragility of the cancellous bone after bone preparation. In addition, the present study clearly showed that the tibial component position often deviated, particularly in the internally rotated direction. Intraoperatively, the femoral lateral condyle may interfere with the position of the tibial component fixator, or the tibial component itself may impinge with the popliteus tendon. These effects would tend to align the tibial component in internal rotation.

Fixation of the tibial component under navigation control with the newly developed instrument (full-navigation method) significantly improved the accuracy of rotational alignment. The full-navigation method was useful to confirm a reference state for rotational alignment and to collect the rotational error measurements in real time on the navigation system monitor. Since postoperative CT scans also showed a high degree of accuracy of rotational alignment (3.1° of internal rotation to 4.1° of external rotation), we found that utility of the new instrument when used with the CT-based navigation system was high. No previous studies have systematically investigated the causes of malrotation of the tibial component. This is the first study that has detected major error sources of the tibial rotational alignment and, more importantly, found that the cementing procedure is the most critical step in ensuring correct alignment of the tibial component.

Our study has some limitations. First, there are potential sources of errors introduced by each surgeon when determining the tibial AP axis for preoperative CT planning on the navigation system. This may be because of unclear images or conditions such as severe deformity or osteoporosis. Although we double-checked each plan as much as possible, we excluded two patients because the preoperative plan for tibial rotational alignment was changed intraoperatively due to severe deformity. Second, intraoperative rotational alignment was evaluated using the CT-based navigation system. The navigation system has its own measurement error. We did not allow any errors greater than one millimeter and one degree during registration. Considering that the intraoperative measurements and postoperative CT evaluations of the final position were very close, we consider that the navigation system was accurate enough for intraoperative evaluation. Third, although we used a commonly used tibial component, the results of this study cannot generally be applied to all tibial component designs because of features such as asymmetric elements or uncemented components.

In conclusion, when surgeons determined the rotational alignment of the tibial component to the tibial AP axis using anatomical landmarks, the results were found to be highly variable. In addition, surgeons should know that the tibial component can become malaligned during fixation of the component. The new instrument used in this study, when combined with the navigation system, was found to be very useful in controlling the tibial rotation within ±3° of the planned position.

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# Osteoinduction on Acid and Heat Treated Porous Ti Metal Samples in Canine Muscle

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## Abstract

Samples of porous Ti metal were subjected to different acid and heat treatments. Ectopic bone formation on specimens embedded in dog muscle was compared with the surface characteristics of the specimen. Treatment of the specimens by $H_2SO_4$/HCl and heating at 600°C produced micrometer-scale roughness with surface layers composed of rutile phase of titanium dioxide. The acid- and heat-treated specimens induced ectopic bone formation within 6 months of implantation. A specimen treated using NaOH followed by HCl acid and then heat treatment produced nanometer-scale surface roughness with a surface layer composed of both rutile and anatase phases of titanium dioxide. These specimens also induced bone formation after 6 months of implantation. Both these specimens featured positive surface charge and good apatite-forming abilities in a simulated body fluid. The amount of the bone induced in the porous structure increased with apatite-forming ability and higher positive surface charge. Untreated porous Ti metal samples showed no bone formation even after 12 months. Specimens that were only heat treated featured a smooth surface composed of rutile. A mixed acid treatment produced specimens with micrometer-scale rough surfaces composed of titanium hydride. Both of them also showed no bone formation after 12 months. The specimens that showed no bone formation also featured almost zero surface charge and no apatite-forming ability. These results indicate that osteoinduction of these porous Ti metal samples is directly related to positive surface charge that facilitates formation of apatite on the metal surfaces in vitro.

**Citation:** Kawai T, Takemoto M, Fujibayashi S, Akiyama H, Tanaka M, et al. (2014) Osteoinduction on Acid and Heat Treated Porous Ti Metal Samples in Canine Muscle. PLoS ONE 9(2): e88366. doi:10.1371/journal.pone.0088366

**Editor:** Christof Markus Aegerter, University of Zurich, Switzerland

**Received** September 25, 2013; **Accepted** January 6, 2014; **Published** February 10, 2014



**Funding:** The authors have no support or funding to report.

**Competing Interests:** Kenji Doi is employed by Osaka Yakin Kogyo Co., ltd. This does not alter the authors' adherence to all the PLOS ONE policies on sharing data and materials.

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## Introduction

Various types of porous materials have been found to exhibit osteoinduction, which is ectopic bone formation on a material without the addition of living cells and/or growth factors such as bone morphogenetic proteins. Although the exact mechanisms of osteoinduction by materials remain largely unknown, there is considerable interest for potential clinical applications.

Most of the materials in which osteoinduction has been found are based on calcium phosphate [1–6]. However, Fujibayashi found that porous titanium metal with no calcium phosphate can also exhibit osteoinduction, if it is subjected to certain chemical and heat treatments [7]. A porous titanium (Ti) metal specimen produced by plasma-spray deposition exhibited osteoinduction when embedded in dog muscle, following: NaOH and heat treatments; NaOH and water treatments; NaOH, HCl and water treatments [8]. Untreated samples did not exhibit osteoinduction. The degree of osteoinduction was greatest for the NaOH, HCl and water treated samples and the NaOH treated samples exhibited the least growth. All of the porous Ti metal subjected to these chemical and heat treatments also showed apatite formation on their surfaces in a simulated body fluid (SBF) with ion concentrations almost equal to those of the human blood plasma [8]. These results indicate that osteoinduction is facilitated by the formation of apatite on the metals surfaces in vivo, as has been speculated for other osteoinductive materials [9].

Porous Ti metal produced by sintering of a Ti fiber mesh did not exhibit any osteoinduction, even when subjected to NaOH and water treatments, although apatite formation occurred on its surface in SBF [7]. This result indicates that osteoinduction of porous Ti metals specimens depends not only upon the formation of apatite on the sample surface, but also the morphological characteristics of the porous structure.

In recent studies we found that Ti metal specimens subjected to a simple acid treatment followed by heat treatment without an initial NaOH treatment also formed apatite on their surface in SBF [10]. The Ti metal specimen that was acid and then heat treated showed micrometer-scale roughness [10,11], whereas a specimen treated by NaOH and then heat-treated showed nanometer-scale surface roughness [12–15]. The Ti metal specimen that was acid and then heat treated was found to be strongly bonded to living bone, when it was implanted into rabbit tibia in the form of a rectangular plate [11], and was deeply penetrated with newly grown bone when it was implanted into rabbit femur as a porous structure [16]. It was speculated that the