Computer-assisted total knee arthroplasty: Does the tibial component remain at malposition risk?

J.-C. Bové*

Val-de-Sambre Multispecialties Private Hospital, 162, route de Mons, 59600 Maubeuge, France

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Summary
Objectives: The development of computer-assisted surgery in total knee arthroplasty continues its search for better accuracy in the spatial positioning of prosthetic components and in achieving the best ideal ligament balance. Many studies have underscored the value of computer-assisted navigation in obtaining precise bone cuts in terms of both orientation and location, which would optimize bone resection and thereby fulfill ligament balancing requirements. Yet improving bone cut accuracy can be undermined by positioning errors of the component at the final stage of implantation. The objective of this prospective study was to assess this possible loss of accuracy and to suggest possible solutions to minimize this risk.

Material and methods: A consecutive series of 50 total knee arthroplasties was studied using an imageless computer navigation system. This study compared the spatial orientation of the prosthesis components determined using software (frontal positioning for the femoral component, frontal and sagittal positioning for the tibial component) with the recorded orientation of the corresponding bone cuts, which allowed us to quantify the loss of accuracy of these predefined positions after cutting. Trial and final implant orientation was taken into account. Moreover, the mechanical axes of the lower limb, the trial and then the final prosthesis in place were compared. Two procedures were abandoned in the study and two patient files were incomplete, which left a series of 46 cases (29 females and 17 males; mean age at surgery, 67 years; mean BMI, 31.27).

Results: Bone cut orientation was consistently found to be satisfactory. Frontal orientation of the final femoral component (0.2° valgus) did not differ statistically significantly from the distal femoral cut (0.3° valgus) and from the orientation of the trial femoral component, as was true of the slope of the tibial component (4.8°) versus the tibial cut (6.3°) and the mechanical axis of the lower limb with the trial prostesis and the final implant. The frontal plane orientation of the tibial component (0.6° varus) differed statistically significantly from the bone cut (0.1° valgus).
Discussion: Several studies have demonstrated the value of computer-assisted surgery, notably in the accuracy of the bone cuts, confirming the work reported herein. The loss of accuracy observed between the bone cut and the final implantation can only be explained by soft tissues between the prosthesis and the bone cut, unequal cement thickness, an orientation error in the impaction handle when placing the final implant, or a conflict between the prosthetic keel and cortical bone. Better exposure of the tibial plateaus, discontinuation of cement use, and navigated impaction ancillary tools could reduce these errors.

Level of evidence: Level IV. Prospective study.

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Introduction

The development of computer-assisted surgery [1—4] in total knee arthroplasty is motivated by the search for improved accuracy in implant positioning and improved ligament balance, while minimizing the constraints of this technology (learning curve, material costs). This improvement in accuracy provided by a computer navigation system, guarantee of prosthesis longevity, has been demonstrated in several studies [1,5—15].

To increase this implantation accuracy, several lines of research are possible:

1) better definition of the fundamental anatomic landmarks, particularly during adjustment of femoral component rotation, which is always problematic [7,11,16];
2) reduction of imperfections during bone cutting (use of unbendable saw blades, more stable anchoring of the cutting blocks, or even computer-navigated saw blades);
3) reduction of the loss of accuracy when implanting prosthetic components (cemented or cementless) [12];
4) better intraoperative stability of rigid bodies [11].

A review of the literature reveals that the results demonstrate some residual variation in implant positioning, less in computer-navigated arthroplasties than when conventional ancillary instrumentation is used [2,3], but nevertheless real, despite the increased precision in the orientation obtained with navigation.

The objective of this prospective study was to assess the loss of accuracy in implant orientation during the final positioning of prostheses, in particular searching for the spatial planes where this loss is greatest so as to design solutions that could minimize these losses.

Material and methods

From May 2008 to June 2009, 50 primary total knee arthroplasties were performed in the author’s orthopaedics department.

In all cases, the primary implant was the ProfixTM implant (Smith & Nephew, Memphis, TN, USA) (Fig. 1), a classic sliding prosthesis with seven femoral component sizes and five tibial component sizes, the latter equipped with a standard keel 60 mm in length and 14 mm in diameter (Fig. 2). The intrinsic posterior tibial slope was 0°, the implant’s sagittal orientation was induced using a specific cutting block 0°, 4°, and 7° in posterior tibial slope.

The prosthesis orientation was navigated using the VectorVision Kolibri system (Brainlab, Munich, Germany) (Fig. 3), an imageless navigation system that does not require preoperative CT images, using a stereoscopic infrared camera. The reflecting antenna were fixed to the femur and the tibia (rigid bodies), a mobile reflecting diamond-shaped antenna with four bearings was used to control the positioning of the cutting blocks (Fig. 4).

The Bone Morphing™ technique was used. Images were acquired using a stylet based on a number of computerized landmarks (epicondyles, tibial plateaus, malleoli, supratrochlear bone surface, Whiteside line, etc.) to determine the mechanical axis of the lower limb nearly instantaneously and to choose the nearest knee in the database.

Measurement accuracy was on the order of 0.5°, sufficiently acceptable given the imprecision of the spatial determinations, notably regarding the anatomic landmarks.

Navigation was used systematically during all the primary arthroplasties. We abandoned two navigated procedures, one because of intraoperative femoral rigid body movement and the other because of computer failure.

Figure 1 Profix™ knee prosthesis (Smith and Nephew, Memphis, Tennessee, USA).
Two cases could not be used because of incomplete data registration. The series therefore comprised 46 cases: 29 females and 17 males, with a mean age of 67 years at surgery (range, 38—88 years), 26 right knees, 20 left knees, and a mean BMI of 31.27 (range, 18.82—41.93).

The mean preoperative deviation determined by computer (unloading) was 1.3° varus (range, 17.5° varus to 14.2° valgus; 13 valgus, 31 varus).

The bone cuts were made independently, the distal femoral cut first. The desired tibial slope was 7°.

The cement was set with the knee in extension, with the femoral component cemented in only three cases (6.5%) and the tibial component cemented systematically.

To meet the study’s objectives, three steps were added to the classical navigation procedure (which systematically included computer verification of the bone cuts after completion):

1) computer verification of frontal orientation of the trial femoral component with the reflecting antenna used for the bone cut verification;
2) computer verification of the frontal and sagittal orientation of the trial tibial component, always with the mobile antenna positioned on the trial implant;
3) repetition of these two steps with the final implant in place, using the same instrument (Fig. 5).

The flexion of the femoral component and the rotation of the two components were not studied [12].

The different data were registered on successive screen captures, for later statistical analysis, comprising the statistical significance of the loss in accuracy of the frontal
orientation of the trial and final femoral components in relation to the orientation of the femoral bone cut, then the loss of accuracy in the tibia orientation (frontal and sagittal), and finally on the loss of accuracy of the overall mechanical axis of the lower limb with the trial prosthesis and then the final prosthesis in place. This required calculation of the Chi², the reference value $\pm 2°$.

The beta risk was evaluated to determine the power of the study: 4% for the tibial measurements.

Comparing the successive positioning over the 50 procedures of the bone cuts, the trial components, and then the final prosthetic components allowed us to study the hypothesis that implant orientation was less accurate as the different steps proceeded.

Results

Frontal orientation of the distal femur

Frontal orientation of the distal femoral bone cut, evaluated 46 times (100%), was a mean 0.3° valgus (range, 1.5° varus to 1.7° valgus; SD, 0.71), of the trial femoral component, also evaluated 46 times (100%), 0.2° valgus (range, 1.9° varus to 2.1° valgus; SD, 0.90), and of the final prosthesis in place, evaluated 43 times (93%), 0.2° valgus (range, 2.0° varus to 2.5° valgus; SD, 0.99). The loss of accuracy during impaction of the final femoral component was not statistically significant ($p = 0.068$) (Fig. 6).

Frontal orientation of the proximal tibia

Frontal orientation of the tibial cut, evaluated 44 times (96%), was 0.1° valgus (range, 1.8° varus to 1.5° valgus; SD, 0.72), of the trial prosthesis, evaluated 43 times (93%), 0° varus (range, 3.7° varus to 2.0° varus; SD, 0.98), and of the final tibial component, evaluated 42 times (91%), 0.6° varus (range, 3.4° varus to 2.2° varus; SD, 1.45) (Fig. 7): respectively, 90.9%, 86.0%, and 50.0% within the ideal range. The difference between the bone cut and the final implant was statistically significant ($p = 0.001$).

The side and the BMI had no influence on the error.
The posterior tibial slope

The posterior tibial slope of the bone cut, evaluated 44 times (96%), was a mean 6.3° (range, 3.3°–9.0°; SD, 1.47°) of the trial tibial component, evaluated 43 times (93%), 5.9° (range, 1.0°–8.5°; SD, 1.56°), and finally of the final tibial component, evaluated 42 times (91%), 4.8° (−1.9°) for an anterior slope at 9.5° ± 2° (Fig. 8). The loss of accuracy during implantation of the final tibial component in the sagittal plane was not statistically significant (p = 0.168).

The overall mechanical axis of the lower limb

The overall mechanical axis of the lower limb (Fig. 9), with the trial prosthesis in place (41 cases; 89%) was 0.3° valgus (range, 2.9° varus to 2.6° valgus; SD, 1.45°) and 0.2° valgus (range, 2.9° varus to 3.5° valgus; SD, 1.67°) after implantation of the final components (evaluated 46 times [100%]) (nonsignificant difference, p = 0.467).

Discussion

Several studies [1–15] have proven the value of computer-assisted surgery, notably in terms of increased accuracy in bone cutting, which confirms our work. The distal femoral bone cut is located a mean 0.3° valgus (range, 1.5° varus to 1.7° valgus), which corresponds to the data reported in the literature [8,13]. Similarly, the frontal and sagittal tibial cuts (respectively, 0.1° valgus [range 1.8° varus to 1.5° valgus] and 6.3° [range, 3.3°–9.0°]), as expected (using the 7° posterior slope tibial cutting block). The only residual imperfections were found in the orientation in rotation of the femoral component [16].

Jeffrey et al. [17] showed that more accurate orientation of the prosthetic components is the guarantee of longevity in arthroplasty.

It remains to be proved that bone cut accuracy will provide ideal orientation of the final implants, i.e., without loss of accuracy between the actual cutting and implanting the prosthesis (cemented or cementless). Yet for Catani et al. [12], there is a loss of accuracy between these two steps. In this study, the loss of accuracy between the bone cuts and implant positioning exceeds 1° in the frontal plane for the femur and in the frontal and sagittal planes for the tibia in, respectively, 20%, 11%, and 33% of the cases and 2° in 4%, 3%, and 9% of patients. Loss of accuracy greater than 3° was observed but only for tibial slope. The author stresses the importance of regular intraoperative verification of cutting and prosthetic component orientation during the procedure, notably before the cement sets. Contrary to our study, no significant difference was found in terms of how much accuracy is lost in the orientation of the tibial component compared to the femoral component.

The present study emphasizes the positioning error of the tibial component. The mean frontal tibial orientation changes from 0.1° valgus for the bone cuts to 0° varus for the trial implant and then to 0.6° varus for the final implant (90.9%, 86.0%, and 50.0%, respectively, within the ideal range). This loss of accuracy is statistically significant (p = 0.001).

The use of cement as well as the existence of a sufficiently long and voluminous tibial keel can explain this loss of accuracy, notably in the final implant. Given the asymmetry of the proximal tibial metaphysis, a conflict between the prosthetic keel and the cortical bone may exist but not be detectable on standard X-rays. It would be interesting to attempt to visualize this on CT.

Tibial slope, undoubtedly for the same reasons, is subject to great variability, but this was not statistically significant.

The cumulative errors result in the modification of the overall mechanical axis of the lower limb between the trial and final implants (from a mean 0.3° valgus to 0.2° valgus), but this difference was not, however, statistically significant.

Reducing these positioning imperfections in the final implants should consequently increase the percentage of mechanical axes situated within the ideal range (±3°, or even better, ±2°).

In view of the results from our series, the divergence of femoral frontal orientation, most particularly tibial frontal and sagittal orientation between bone cuts and implants, deserves to be taken into account and corrected during TKA with repeated measurement of the orientation of the cuts and components.

This study of a single-center, prospective, and continuous series presents several limitations:

First of all, the small size of the series could induce insufficient statistical power. Nevertheless, the beta risk in a tibial comparative series was evaluated at 4%, according satisfactory reliability to the study’s conclusions.

Next, the series only studied one type of implant and a single type of navigation system, limiting the study’s interpretation.
Finally, this study does not distinguish the respective responsibility of the computer system (measurement errors) and the implant itself (positioning errors, prosthetic component—bone conflict) in the measurement errors detected.

Computer measurement errors have been studied [20,21]. The conclusions are in agreement with ours. The accuracy of the computer measurements ensures reliability and reproducibility of navigation procedures in orthopaedic surgery, whether in arthroplasties or in realignment osteotomies [18,19]. In a series of 20 TKAs, Jenny found an inter- and intraobserver difference of 0.1° in the determination of the overall mechanical axis of the lower limb and concluded that the intraoperative measurements of this mechanical axis were reliable during a navigation-assisted procedure [18]. Hüfner e al. assessed the accuracy of navigation systems to be ±1 mm and ±1° [19]. It is therefore highly probable that the errors found in our study were implant-positioning errors.

Possible solutions

First of all, intraoperative immobilization of the rigid bodies must be respected. Movement can easily be detected; in this case, the procedure should be either converted to conventional arthroplasty or the computerized procedure should be reset, which lengthens the operative time.

1) Sealing can be eliminated (mainly the tibial component in our practice), but this raises the problem of anchoring quality [20] (screws, modification of the tibial keel).

2) Any keel—cortical bone conflict should be prevented. The prosthetic design must absolutely take this into account.

3) The anatomic exposure should be sufficient so that no soft tissue intervenes between the bone and the implant.

4) The ancillary impaction instrumentation could be designed so that the tibial component can be placed with a fin punch handle [12]. It would be interesting to conduct the same study comparing the respective loss of accuracy during tibial component impaction.

Only in this condition will the frequency of knee prosthetic revisions be reduced and thus compensate the added cost to the healthcare system of the acquisition of the navigation system, which today remains a costly investment [21].

Conclusion

This prospective study of 50 total knee computer-navigated arthroplasties confirms the value of computer-assisted surgery, notably in terms of bone cutting accuracy, guaranteeing satisfactory positioning of the prosthetic components and the longevity of the implant. This advantage is nevertheless minimized by positioning errors committed during implantation of the final prosthesis, particularly in the tibia.

More rigorous implantation of the final tibial component should be attempted, perhaps with the assistance of a fin punch handle and clearing the tibial plateaus of any soft tissue that may be found between bone and implant and preventing any tibial keel—cortical bone impingement (small knees, external tibial close wedge osteotomy revisions), even by using cementless implants.

Conflict of interest statement

None.

References


