Navigation in total-knee arthroplasty

CT-based implantation compared with the conventional technique

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Background **Exact axial limb alignment in total-knee arthroplasty (TKA) is important for a successful outcome. We evaluated the efficiency of computer-assisted implantation in TKA and compared it with the classical surgeon-controlled technique.**

Patients and methods **We implanted 100 TKA using either the computer-assisted technique (50) or the conventional approach (50). There were no significant differences between the groups regarding the preoperative leg deformity. Accuracy of implantation was determined in postoperative long-leg coronal and lateral radiographs.**

Results **A postoperative leg axis between 3° varus and 3° valgus was achieved in 46 patients in the group with computer-assisted implantation and 36 patients in the control group (p = 0.01). A significant difference was also seen for the femoral component alignment in frontal plane. No complications influencing the clinical outcome were observed.**

Interpretation **A CT-based navigation system improves the accuracy of TKA, but higher costs and time-consuming planning will mean that its usage is limited to special cases. Additional tools such as ligament balancing, which are presently only available with the CT-free software module, require to be added to the CT-based system.**

In total-knee arthroplasty (TKA), exact axial limb alignment and restoration of the mechanical axis is one important factor affecting outcome (Jeffery et al. 1991, Ritter et al. 1994). In previous studies, there have been attempts to define a range of tolerable limb alignment. Rand and Coventry (1988) found a 10-year survival rate of 90% for patients with less than 4° deviation from the neutral leg axis. In contrast, the survival rate decreased to 73% (varus) and 71% (valgus) when the limb axis exceeded 4° degrees. Hvid and Nielsen (1984) investigated the overall postoperative alignment in 138 consecutive TKAs. They reported superior long-term results for a femorotibial angle of 5–7°. Ritter et al. (1994) analyzed 421 TKAs regarding the femorotibial angle (normal: 5°–8°, varus: ≤ 4°, valgus: ≥ 9°) and found the highest rate of loosening in patients with a varus malalignment. Jeffery et al. (1991) analyzed the outcome after TKA in 115 patients and found a 24% rate of loosening when the mechanical axis exceeded ± 3° varus/valgus, while it was only 3% in the other cases.

Although mechanical alignment guides have been designed to improve alignment accuracy, there are several fundamental limitations to this technology, e.g. entry point, saw blade deviation (Delp et al. 1998). Therefore, navigation systems have been developed recently to increase the accuracy of prosthesis implantation in TKA.

To date, only a few studies reporting the results of computer-assisted TKA have been published. In a prospective study, Mielke et al. (2001) analyzed and compared radiographical results after navigation-based and conventional prosthesis implantation. They found a clear tendency for a better alignment of the mechanical limb axis in navigation-assisted TKA. In the group with navigation-assisted TKA, 43% of cases showed an ideal alignment (0° varus/valgus), while only

23% of cases had an optimal leg axis in the control group. In contrast, Jenny and Boeri (2001) found no differences in the postoperative mechanical leg axis between navigation-assisted TKAs and those implanted using a conventional technique.

In this prospective study, we analyzed postoperative leg alignment in navigation-assisted TKA and compared it with that of a conventional ("surgeon-controlled") implantation technique. In the group undergoing computer-assisted TKA, prostheses were implanted using a CT-based navigation system.

Patients and methods

Study design and patients

In this prospective study, TKA was performed in two groups of 50 patients each using either a CT-based navigation system (the "navigated" group) or a conventional technique (the "conventional" group). The patients were designated to the groups by the weekday of operation. No exclusions were defined regarding age, sex, degree of leg axis deviation or previous operations.

The "navigated" group consisted of 40 female and 10 male patients with a mean age of 66 (30–80) years. The mean preoperative deviation of leg axis was 7.1° SD 5.1° (range: 18° varus to 22° valgus).

In the "conventional" group, 42 female and 8 male patients were included with an average age of 72 (50–85) years and a preoperative deviation of leg axis of 9.1° SD 4.0° (range: 17° varus to 15° valgus).

In the "navigated" group, TKA was performed using the CT-based version of BrainLAB's VectorVision Knee 1.1 in combination with the DePuy PFC Sigma™ implants. In the "conventional" group, the same type of prosthesis was implanted in a conventional surgeon-controlled technique using the Spezialist-2 instrumentation. All of the operations were performed by two senior surgeons (LP and JG) experienced in both computer-assisted and conventional TKA. In the "navigated" group, TKA was done for osteoarthrosis in 36 knees and for rheumatoid arthritis in 14 knees. The corresponding figures for the "conventional" group were 38 and 12, respectively.

Preoperative CT scans and planning procedure

According to a standard protocol, CT scans of the leg were performed the day before surgery, including slices from the femoral head, knee and ankle. Once computer models of the bones had been created, tibial and femoral components were orientated within an automatically created treatment plan for neutral leg alignment and bone resection planes were determined by the navigation system. If necessary, a fine tuning of resection planes and component orientation can be performed using either the 3D surface images or the original CT scans (Figure 1). On average, the planning procedure and data transfer took 23 (14–47) min.

Operative technique in the study group

At the start of the operation, a reference frame has to be attached to the distal femur or the proximal tibia with a bicortical pin (Figure 2). This is followed by a surface matching process in which the surgeon has to digitize up to 20 points of free choice on the bone surface of both the femur and the tibia. Femoral and tibial cutting blocks are orientated in real time visualization on the display of the navigation system. The epicondylar axis was used for rotational adjustment of the femoral component. For the proximal tibial resection plane, the resection level was set to 8 mm from the deepest point of the higher tibia plateau level. Rotational alignment of the tibial tray was orientated to the medial third of the tuberosity of the tibia. After resection, all planes were checked by the verification tool of the navigation system (Figure 3).

Postoperative evaluation of radiographs

The axial limb alignment was evaluated on standardized pre- and postoperative full- length weight-bearing radiographs (Figure 4) by two independent observers, three times on different days. The Kolmogorov-Smirnov test was used to evaluate whether axial limb alignment followed a normal (Gaussian) distribution and no significant deviations were identified. Limb alignment between the groups was compared using unpaired t-tests. A two-tailed $p \leq 0.05$ was required for a statistically significant result. The coefficient of variation was calculated to determine intra-observer and inter-observer variability. The intra-observer variability for limb axis determination was less than 3% and

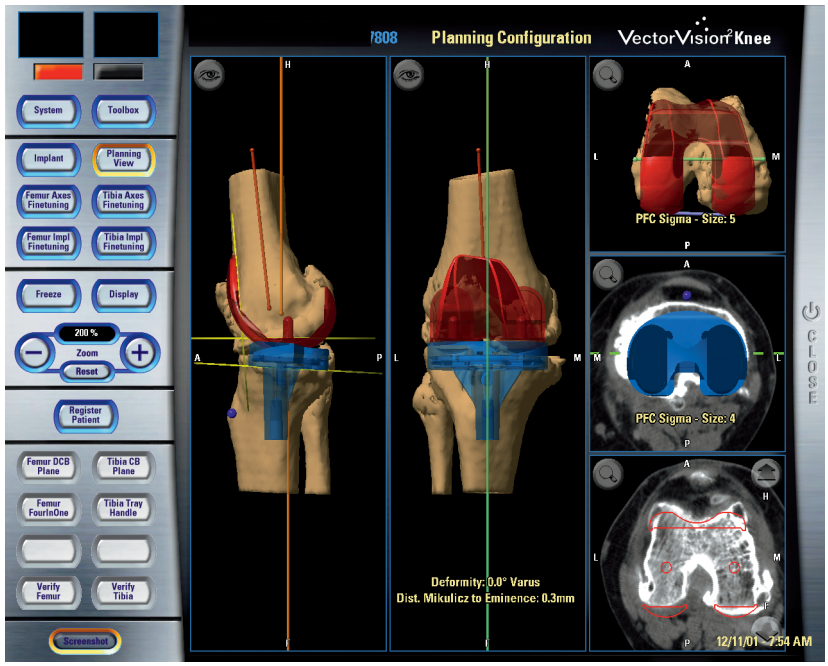

Figure 1. The preoperative planning can be performed either in the original CT data or in a 3-D model. It provides further information about the rotation of the components and necessary bone resections.

the inter-observer variation was less than 4%.

Results

Postoperative leg axis

In the navigated group the mean postoperative leg axis was 0.4° valgus (SD 1.8°, range: 5° valgus to 4° varus), while in the conventional group it was 1.2° varus (SD 2.9°, range: 11° varus to 4° valgus) ($p = 0.01$).

46 patients in the "navigated" group and 36 patients in the "conventional" group had a leg axis within a range of ± 3°.

The 4 outliners in the "navigated" group were within a range of ± 5° of leg alignment, while in the "conventional" group 4 of the 14 outliners exceeded a range of ± 5°. A tendency for valgus adjustment was found in the "navigated" group, while a trend towards varus implantation was seen in the "conventional" group (Figure 5).

Component alignment

Frontal alignment. In the "navigated" group, the frontal alignment of the femoral component was significantly better than in the "conventional" group ($p = 0.5$). 21 of the femoral components had a perfect alignment of 0°, as compared to 13 in the "conventional" group. 48 patients in the "navigated" group had a varus-valgus alignment of the femoral component to the mechanical axis within a range of ± 3°, as compared to 44 in the "conventional" group (Figure 6).

In both the navigated and the conventional

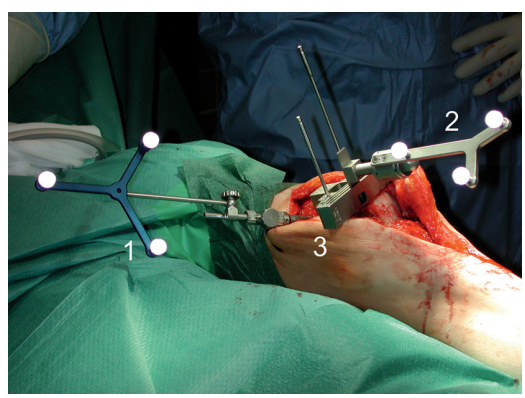

Figure 2. A reference frame (1) is attached to the distal femur. The plane control tool (2) has been fixed to the standard cutting block (3) of the Specialist II instruments.

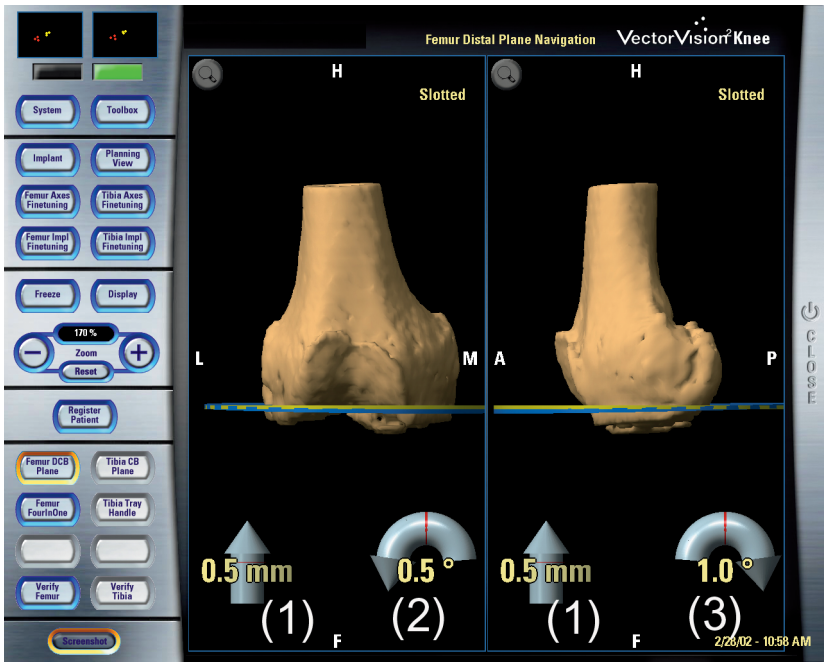

Figure 3. After a bone resection, the navigation system offers information about the cutting errors and deviations in each separate plane (resection high (1), varus/valgus (2) and flexion/extension (3)).

group, one third of tibial components had a perfect alignment of 0°. 48 patients in the navigated group had a varus-valgus alignment of the tibial component within a range of ± 3°, as compared to 47 in the conventional group (Figure 7).

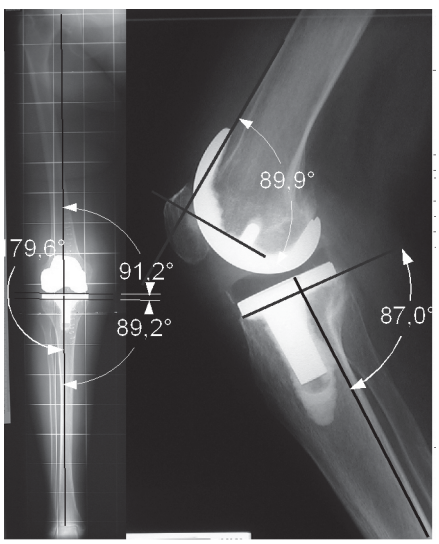

Figure 4a and b. Axial alignment of the prosthesis was evaluated using standardized pre- and postoperative full-length weight-bearing radiographs.

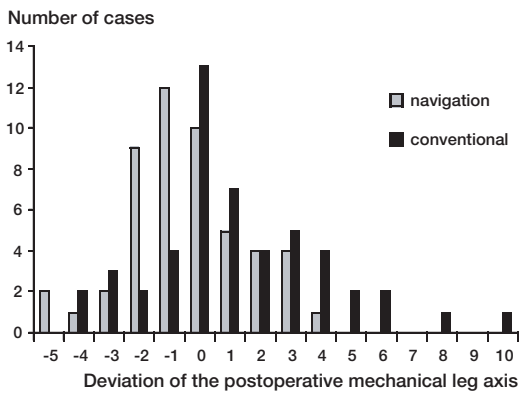

Figure 5. Distribution of the postoperative mechanical leg axis.

Sagittal alignment. The femoral component was planned in a slight flexion of 2° to the anterior femoral cortex to avoid notching. In the "navigated" group, the flexion-extension alignment was 3.3° (SD 2.3), while in the "conventional" group it was 6.8° (SD 3.6). The position of the tibia component was planned with 3° posterior slope, as recommended by the manufacturer. In the "navigated" group, the tibial slope was 3.9° (SD 2.2), while it was 4.6° (SD 2.7) in the "conventional" group.

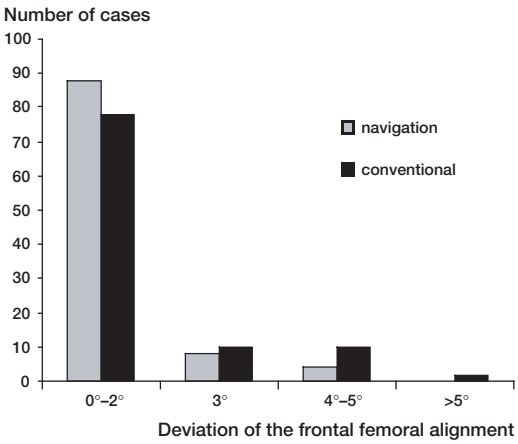

Figure 6. Distribution of the frontal femoral alignment.

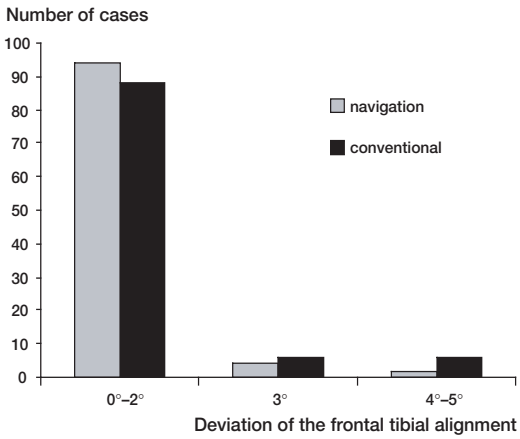

Figure 7. Distribution of the frontal tibial alignment.

Surgical procedure

No conversion from computer-assisted surgery to the conventional technique was required. The mean time for surgery (skin to skin) was 81 (66–115) min for the "navigated" group and 62 (44–90) min for the "conventional" group. There were no complications such as infections or fractures due to the insertion of the Schanz's screws.

Discussion

Aseptic loosening is still the main reason for failure of total-knee arthroplasty. As early as 1977, Lotke and Ecker drew attention to the correlation between limb axis alignment and loosening. The precise limits of acceptable alignment relative to the mechanical axis have not been defined, but many authors suggest a 3° window in the frontal plane for the highest success rate (Jeffery et al. 1991, Ritter et al. 1994).

In the conventional technique, intramedullary or extramedullary rods are used for orientation of prosthesis components. However, the use of these instruments may be associated with errors resulting from variations in anatomical shape or visual misjudgement (Teter et al. 1995, Novotny et al. 2001).

In our study, one quarter of the patients in the "conventional" group had a postoperative limb axis exceeding 3° varus/valgus of the mechanical axis. Similar results were reported by Petersen and Engh (1988) and by Mahaluxmivala and co-workers (2001), who also showed that the deviations in limb axis were independent of the surgeon's experience.

We found a significantly better postoperative limb axis in the "navigated" group. These findings are in agreement with the results of Mielke and co-workers (2001), who reported a mechanical axis of ± 3° in 51 of their 60 patients when using the Orthopilot-System. The same CT-free navigation system was used in a multicenter study. In this study the mechanical leg axis was ± 3°, while only 72% (191/266) of patients reached a comparable leg axis when using the conventional technique (Clemens et al. 2003).

In a study by Jenny and Boeri (2001), a mechanical axis of ± 3° varus/valgus was achieved in 25/30 of the "navigated" cases, while 21/30 patients operated on in a conventional technique showed a comparable axis of limb alignment.

These findings are similar the results of Saragaglia and co-workers (2001) who reported a mechanical leg axis of ± 3° in 21/25 patients using the Orthopilot System. In our study, the number of outliners with a postoperative leg axis of ≥ 4° was significantly lower in the "navigated" group. The maximal deviation of leg axis was 5°.

We found a tendency towards a valgus orientation in the navigated group. This may result from saw blade deviation in dense bone stock when cutting the medial tibial plateau. These errors are difficult to correct when using the conventional cutting blocks. Nevertheless, the protective effect of valgus alignment has been shown in a large

clinical series (Ritter et al. 1994). These results were confirmed by Ryd et al. (1995) when assessing micromotion using radiostereometry.

Different reasons may be relevant to explain deviation of the mechanical leg axis, even if using a navigation system. In all image-based systems (e.g. CT-based), the accuracy of navigation depends on the quality of the data and the intraoperative acquisition of reference points, which are necessary for correlation of the image set to the patient's real anatomy. However, some factors contributing to deviation of the leg axis may relate to the navigation system itself.

Other reasons for variations of the leg axis may be the cementing technique of the prosthesis components and also inaccuracies in determining the leg axis on postoperative weight-bearing long leg radiographs. On the other hand, an important advantage of navigation systems is that some of the errors discussed above can be verified and corrected intraoperatively.

The CT-based system can be easily adjusted to the surgeon's own preferences concerning the method of femoral rotational alignment and level of bone resection. Balancing the knee involves correct component positioning and correct ligament balancing to achieve a good alignment. However, to date, this version of the software does not offer a tool for determination of ligament tension, since the femoral and tibial navigation cannot be performed simultaneously. At this time, this is a limitation of the CT-based version compared to the CT-free VectorVision software module.

Additional operating time is required when using navigation systems in total-knee arthroplasty. In our study, however, this took only 20 min after an initial learning curve. In the future, the additional time needed might be reduced even further by improvement of the navigation workflow and the development of navigation-adapted instruments.

The use of a navigation system is associated with additional costs. The system itself costs 169 000 € or has a monthly leasing rate of 4 990 €.

The navigation system we used in this study led to a significant improvement in prosthesis alignment in total-knee arthroplasty when compared with the conventional technique. For most surgeons, however, the required preoperative CT scans and the time-consuming planning are disadvantages of CT-based navigation. In contrast, in special cases these CT scans and the opportunity of preoperative planning might be helpful. Nevertheless, navigation systems afford the opportunity of detailed data acquisition and documentation of results.

In our department, the use of the CT-based software module has dramatically decreased since the CT-free module was implemented. In the clinical routine, the acquisition of surface information for the CT-free system is no more time- consuming than gathering the registration points for the CT-based module, without the time-consuming organization of the CT scan and data transfer.

Today, indications for a CT-based module are given in less than 1% of our patients. We still prefer the CT-based module in cases with severe bony deformities. On the other hand, the ligament balancing tools and the additional information about the gap size are especially important advantages of the CT-free module which we no longer wish to do without. Thus, we believe that the future of navigated TKA will involve CT-free navigation.

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No competing interests declared.

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