Alignment in total knee arthroplasty
A COMPARISON OF COMPUTER-ASSISTED SURGERY WITH THE CONVENTIONAL TECHNIQUE

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Restoration of neutral alignment of the leg is an important factor affecting the long-term results of total knee arthroplasty (TKA). Recent developments in computer-assisted surgery have focused on systems for improving TKA.

In a prospective study two groups of 80 patients undergoing TKA had operations using either a computer-assisted navigation system or a conventional technique. Alignment of the leg and the orientation of components were determined on post-operative long-leg coronal and lateral films.

The mechanical axis of the leg was significantly better in the computer-assisted group (96%, within ±3˚ varus/valgus) compared with the conventional group (78%, within ±3˚ varus/valgus). The coronal alignment of the femoral component was also more accurate in the computer-assisted group.

Computer-assisted TKA gives a better correction of alignment of the leg and orientation of the components compared with the conventional technique. Potential benefits in the long-term outcome and functional improvement require further investigation.

Total knee arthroplasty (TKA) has been established as reliable treatment for the osteoarthritis of the knee. In the Swedish Knee Arthroplasty Register a satisfactory outcome has been reported in 82% of patients after TKA with aseptic loosening and instability as the most common indications for revision TKA, and an overall rate of revision of 15% at ten years.

Axial alignment of the limb with restoration of the mechanical axis is a determinant of the outcome. A mechanical axis within a range of ±3˚ varus/valgus is thought to be associated with a better outcome. However, in previous studies post-operative alignment of the limb exceeded a range of ±3˚ in up to 30% of cases.

Petersen and Engh reported the radiological results of 50 primary TKAs performed using the conventional technique. In their study, 26% of TKAs failed to achieve an alignment within ±3˚ varus/valgus. Mahaluxmivala et al analysed 673 TKAs. They found an alignment of more than ±3˚ varus/valgus in 25% of cases, independent of the surgeon’s experience.

Although various guides for alignment have been designed to improve accuracy, several limitations of these instruments are reported. Errors may be due to variations in the bony anatomy, visual misjudgement by the surgeon or limitations of technique.

Recently, navigation systems have been developed to improve the accuracy of alignment of the components in TKA. So far, only a few studies have been published, reporting the results of computer-assisted TKA. In a prospective study by Mielke et al, the radiological results after computer-assisted versus conventional insertion of the components were analysed. These authors found a clear tendency for a better alignment of the limb in computer-assisted TKA. However, in another study Jenny and Boeri found no significant differences when using computer-assisted techniques.

Our aim in this prospective study was to analyse the accuracy of orientation of the components and post-operative alignment of the leg in computer-assisted TKA and to compare this with the conventional surgical technique. Our hypothesis was that the computer-assisted procedure would lead to better orientation and alignment of the leg and might improve the outcome.

Patients and Methods
In a prospective study, two unselected groups of 80 patients each underwent primary TKA using either a computer-assisted CT-free navigation system or a conventional technique. Between August 2002 and February 2003, 160 consecutive patients were allocated into two
groups according to the day of the week when the operation was undertaken. This was arranged independently of the orthopaedic surgeons by a hospital secretary. No exclusions were defined with regard to age, gender, the degree of deviation of the axis of the leg or previous surgery.

The same implants (PFC Sigma; DePuy Inc, Warsaw, Indiana) were used in both groups. All the operations were performed by one team (LP, HB), who had performed several hundred conventional PFC Sigma TKAs and more than 120 computer-assisted procedures before starting this study.

In the computer-assisted group there were 59 women and 21 men with a mean age of 68.7 ± 9.3 years (31 to 88) and a mean pre-operative deviation of the axis of the leg of 8.4 ± 5.1° (26° varus to 21° valgus).

In the conventional group (control group) there were 53 women and 27 men with a mean age of 70.9 ± 9.1 years (47 to 88) and a pre-operative deviation of 8.6 ± 4.3° (23° varus to 12° valgus). The operations were performed by one team (LP, HB), who had performed several hundred conventional PFC Sigma TKAs and more than 120 computer-assisted procedures before starting this study.

Before resection of the bone the surgeon can check and document the axes of the leg and examine the ligamentous laxity throughout the range of movement. Depending on the surgeon’s preferences, resection can start on the femoral or tibial side. The orientation of the cutting blocks and definition of the cutting planes are determined using the navigation system (Fig. 2). After the resections have been performed, cutting planes are checked and documented by the verification function of the system. At each step of the operation, the surgeon can check the ligamentous tension (Fig. 3). Moreover, the axis of the leg, the range of movement, and the stability of the joint can be examined and documented with the trial implants or after cementing.

**Radiological measurement.** The axial alignment of the limb and the orientation of the components were evaluated on standardised pre- and post-operative full-length weight-bearing radiographs by two independent observers (MT and CL) three times on different days. Sagittal alignment was measured on lateral radiographs 20 x 40 cm in size. For the mechanical axis of the leg and frontal alignment the following angles were measured: the hip-knee-ankle (HKA) angle (= mechanical axis of the leg), the frontal femoral component (FFC) angle and the frontal tibial component (FTC) angle (Fig. 4a). For the sagittal plane the following angles were measured: the lateral femoral component (LFC) angle and the lateral tibial component (LTC) angle.
The LFC angle was measured between the anterior cortex of the distal femur and the shield of the femoral component. The LTC angle was measured in relation to the posterior tibial cortex.

**Statistical analysis.** The Kolmogorov-Smirnov test was used to evaluate if axial alignment followed a normal (Gaussian-shaped) distribution and Levene’s test was used to assess the homogeneity of variance (constant variance).

Gender was compared between groups using Fisher’s exact test. The alignment of the limb and duration of the operation were compared between the two groups using unpaired Student’s t-tests with the assumption of homogeneity of variance used as appropriate. The chance-corrected kappa coefficient was calculated to determine intra- and inter-observer agreement with kappa values interpreted according to the recommendations of Landis and Koch as follows: slight, 0.00 to 0.20; fair, 0.21 to 0.40; good, 0.41 to 0.60; excellent, 0.61 to 0.80; almost perfect, 0.81 to 1.00.

For comparing post-operative alignment of the leg between the two groups, box-and-whisker plots were used and deviations compared using the Mann-Whitney U-test. The box limits represent the lower quartile (25th percentile) and upper quartile (75th percentile) and the box height is the interquartile range (IQR). The upper and the lower whiskers are 1.5 x IQR distance from the box limits and the median is displayed as a horizontal line across each box. For continuous variables and differences between two means, 95% confidence intervals (CI) were calculated. Two-tailed values of $p < 0.05$ were considered to be statistically significant. Analysis of the data was performed using the SPSS statistical package version 11.5 (SPSS Inc, Chicago, Illinois).
Results

Intra- and inter-observer reliability. Intra-observer reliability was almost perfect for both the computer-assisted technique and the conventional technique (p < 0.001 in each case). In the computer-assisted group, kappa = 0.97 for observer A and 0.97 for observer B. In the conventional group, kappa = 0.95 for observer A and 0.97 for observer B. The inter-observer reliability was excellent for the computer-assisted (kappa = 0.96) and conventional (kappa = 0.97) techniques. The reliability was thus very high with both techniques.

Mechanical axis of the leg. Based on absolute deviations, the mean pre-operative mechanical axis was 1.4° (95% CI 1.2 to 1.7) in the computer-assisted group and 2.4° (95% CI 2.0 to 2.8). The mean difference between the two groups was 1° (95% CI 0.4 to 1.3). These results were nearly identical for both observers.

Regarding the post-operative mechanical axis of the leg, the median raw deviation was 0° in the computer-assisted group (IQR, -1 to +1) and 1° (IQR, -2 to +2) in the conventional group (Mann-Whitney U-test, p = 0.016; Fig. 5). Thus, the computer-assisted technique was associated with significantly less variability. Of TKAs 77 (96%) had an axis within a range of ±3° in the computer-assisted group compared with 62 (78%) in the conventional group. In the computer-assisted group, axes exceeding ±3° of varus/valgus were seen in three cases (maximum 5°) compared with 18 in the conventional group (maximum 8°) (Fig. 6).

Alignment of the components

Frontal plane alignment. The mean deviation of the FFC angle from the neutral axis was 1.5° (95% CI 1.2 to 1.7) in the computer-assisted group and 2.1° (95% CI 1.7 to 2.4) in the conventional group (t-test p < 0.01). The mean difference between the two groups was 0.6° (95% CI 0.1 to 1.0). In the computer-assisted group 74 (92%) patients had a varus/valgus alignment within a range of ±3° compared...
with 69 (86%) in the conventional group. The maximum deviation in the computer-assisted group was 4° and in the conventional group 8°.

The mean deviation for the FCT angle was 1.2° (95% CI 1.0 to 1.5) in the computer-assisted group and 1.5° (95% CI 1.2 to 1.7) in the conventional group and this difference did not reach statistical significance (t-test, p = 0.20). For the tibial component, 78 (98%) patients in the computer-assisted group had a varus/valgus alignment within a range of ±3° compared with 75 (94%) in the conventional group.

Sagittal plane alignment. The mean LFC angle was 7.3° (95% CI 6.6 to 8.1) in the computer-assisted group and 9.5° (95% CI 8.5 to 10.4) in the conventional group (t-test, p < 0.001). The mean difference between the two groups was 2.2° (95% CI 1.1 to 3.3).

The mean LTC angle was 2.5° (95% CI 1.9 to 3.1) in the computer-assisted group and 4.5° (95% CI 4.0 to 5.2) in the conventional group (t-test, p < 0.001). The mean difference between the two groups was 2° (95% CI 1.3 to 2.8).

No conversion from computer-assisted surgery to the conventional technique was required in the study. The mean duration of the operation (skin to skin) was 78 ± 12 minutes for the computer-assisted and 64 ± 11 minutes for the conventional group (t-test, p < 0.001). The 95% CI for this mean difference is 11 to 18 minutes longer for the computer-assisted technique.

Discussion

In previous studies, an increased incidence of aseptic loosening has been seen in patients with post-operative malalignment of the mechanical axis of the leg. Several authors have reported superior results if 3° of varus/valgus deviation in the frontal plane were not exceeded.6-11 Rand and Coventry10 found a rate of survival of 90% at ten years for patients with less than 4° of deviation from the neutral axis. By contrast, it decreased to 73% (varus) and 71% (valgus) when the axis of the limb exceeded 4°. Hvid and Nielsen7 investigated the overall post-operative alignment of the limb in 138 consecutive TKAs. They reported superior long-term results for a femorotibial angle of between 5 and 7°. In a study by Ritter et al,11 421 TKAs were analysed with regard to the femorotibial angle (normal, 5 to 8°; varus ≤4°; valgus ≥9°). In this study, the highest rate of aseptic loosening was found in patients with a varus malalignment. Jeffrey et al8 analysed the outcome after TKA in 115 patients. They found a rate of 24% of prosthetic loosening when the mechanical axis exceeded ±3° varus/valgus deviation, while it was only 3% in those patients with an axis within a range of ±3°.

In our study, the post-operative axis of the limb exceeded 3° of varus/valgus deviation in 22% of the patients operated on with the conventional technique. These results were in agreement with those of Petersen and Engh12 who reported a post-operative varus/valgus deviation of the axis of the limb of >3° in 26% of patients. Similar results were reported by Mahaluxmivala et al13 on 673 TKAs. They found a varus/valgus deviation of the axis of more than ±3° varus/valgus in 25% of patients.

In our study, the post-operative axis of the limb was significantly better in the computer-assisted group. These findings were in agreement with the results of Mielke et al,14 who reported a tendency for a better femorotibial axis when using a navigation system (Orthopilot; Aesculap, Tuttingen, Germany). This did not however reach statistical significance. Similar results were obtained by Jenny and Boeri,19 who found no significant difference post-operatively between computer-assisted TKA and the conventional technique. In their study, a mechanical axis of ±3° varus/valgus was achieved in 83% of patients using a navigation system and in 78% using a conventional technique.

In a multicentre study21 involving 555 TKAs, a significantly better post-operative axis was achieved with computer-assisted surgery (Orthopilot-System). In this study 88% of patients attained an axis of ±3° varus/valgus alignment, while only 72% in the conventional group had a comparable result.

In the same study, a significantly better orientation was reported in the computer-assisted group for the tibial component in the frontal and sagittal planes, and for the femoral component in the frontal plane.

These findings are comparable with our results. We also found a better orientation of the femoral component in the frontal plane. By contrast, we could not determine any significant differences for the tibial component in the frontal plane, which may have been due to different limits for the range of acceptable orientation between these studies.

In the conventional technique extramedullary alignment guides or intramedullary rods are used for orientation. Intrinsic to this technique are potential errors for malalignment.17-20 However, even if using a navigation system, there may be reasons for variation of the mechanical axis of the leg due to a deviation of the saw blade in dense bone. Plaskos et al22 reported cutting errors of 0.6° to 1.1° in varus/valgus alignment and 1.8° in flexion/extension. Other factors are variations in the cementing of the prosthetic components or inaccuracies in determining the axis on post-operative weight-bearing long-leg radiographs.23 However, the computer-assisted technique does offer the advantage that some of these errors can be identified and corrected intra-operatively.

Additional operating time is needed when using navigation systems in TKA. However, after an initial learning curve, the computer-assisted surgical procedure took only 14 minutes longer to perform. This additional time is acceptable in clinical practice. In future, it may be reduced by an improvement of the computer-assisted workflow and by the development of specific navigation-adapted instruments.

The navigation system used in this study was provided by Brain LAB, Heimstetten, Germany.

No other benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.
References