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Computerised and technical navigation in total knee-arthroplasty

Received: 15 October 2004
Accepted: 20 January 2005

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Abstract The objective of the study was to evaluate the precision, concordance, practicability and the early clinical outcome of the use of a computerised navigation system in a comparative study with a group of 100 patients. Two groups of 50 patients each underwent implantation of a bicondylar knee prosthesis either by means of the freehand navigation system or by means of technical instrumentation. We found that the computerised navigation system provided a higher precision than the technically instrumented implantation: 94% of the prostheses implanted with the navigation system have an alignment within a range of -3° to 3° on of the Mikulicz line. Only 46% of the patients operated by means of the technical instrumentation reached this aspired result. Furthermore, the navigation system showed smaller ranges in the deviation of the aspired alignment. The radiological and computer-modeled alignment

values differed both pre- and post-operatively, but to a larger extent before surgery. The varus or valgus deviations of the axis were more distinct radiologically under the weight of the patient's body than in the computer model. The clinical outcome examined by the use of the HSS score after a mean follow-up of 7 months is good in both groups, and without significant differences. On average, the duration of surgery was 13 minutes longer in the computerised navigation group. We conclude that the benefit of the computerised navigation system is represented by the high improvement of precision. Achieving early clinical results identical to those in the technical instrumentation group, we expect a reduction of aseptic loosening in the computerised navigation group.

Key words Computer assisted surgery • Total knee arthroplasty • Osteoarthritis

Introduction

Different computerised navigation systems have been developed in the field of knee arthroplasty [1–4]. The advantage in using such systems is achieving a higher precision in the implantation of knee prostheses compared

with technical instrumented implantation. The benefit of higher precision is reduction of aseptic loosening [5]. Looking for such an improvement, we introduced a computerised navigation system in our clinical practise. We compared the new system to the technical instrumented procedure, in a prospective study of 100 patients undergoing total knee arthroplasty.

Materials and methods

In the period between August 2002 and February 2003, 100 patients underwent primary implantation of a bicondylar knee prosthesis; 50 patients each were treated with the computerised navigation system or with technical instrumentation. The groups were randomised by strictly alternating the use of either the technical instrumentation or the computerised navigation. All surgeries were performed by two experienced surgeons. All patients gave informed consent prior to inclusion in the study. Usage of the computerised navigation system was performed in accordance with ethical standards of the 1964 Declaration of Helsinki.

The computerised navigation system used in this study is the Surgetics System. This system is an open platform which in this case was used as an application to implant a modular knee system with a rotational platform (ESKA Implants, Lübeck, Germany).

The navigation system is used in a 5-step procedure:

1. After a standard approach to the knee joint is established, two infrared reflectors (rigid bodies) are applied to the femur and tibia.
2. Second, the anatomical landmarks are measured with a pointer to determine the alignment: the middle of the upper ankle joint, the intercondylar eminence, and the notch are measured; the rotational centre of the hip joint is determined by kinematic measurements; and scanning and digitalisation of the tibial and femoral surfaces (bone-morphing) conclude the process of data acquisition (Fig. 1).
3. Step 3, the size of the implant and its position are planned (Fig. 2).
4. The navigated surgical procedure consists of the freehand navigated insertion of the guide pins to place the resection blocks for the tibial and femoral cutting planes by means of a

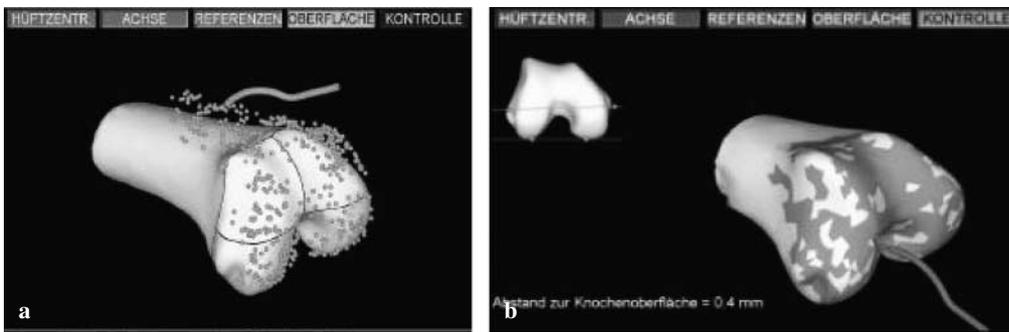


Fig. 1a, b Measurement of anatomical landmarks. **a** Digitalisation of the surface is done in quadrants. The generated virtual model is based on the areas marked in grey. **b** To determine the rotation of the femoral component, the reference plane is oriented at the posterior condyles

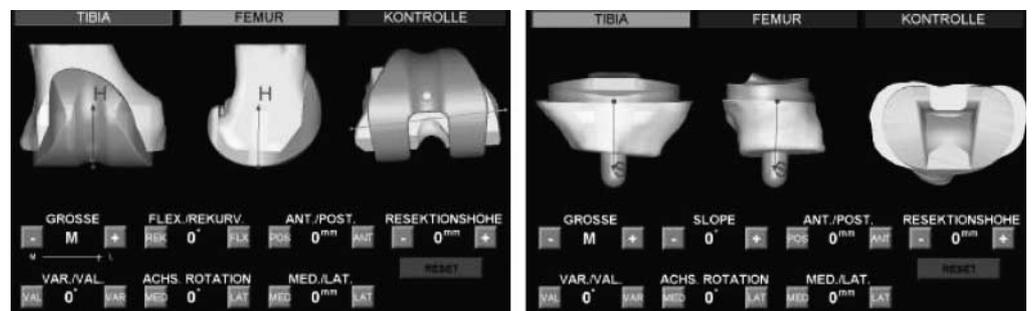


Fig. 2 All positions of the implants can be varied three-dimensionally for the femur (left) and tibia (right)

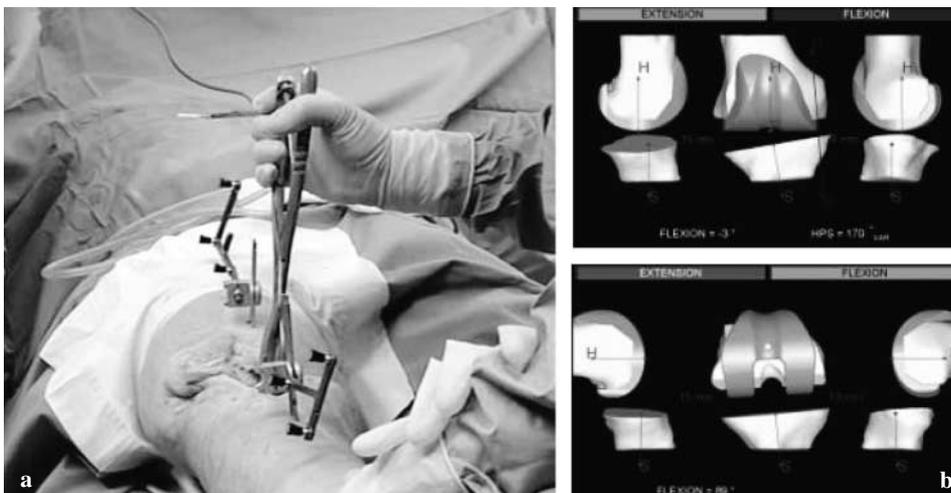


Fig. 3a, b Computer-navigated surgical procedure. **a** The flexible spreader tongue creates an isometric tension of the collateral ligaments shown here for the extension gap. **b** The numerical values in millimetres reflect the pathological conditions and enable exact balancing



Fig. 4 Intramedullary tibial and femoral orientation of the sawing block for the tibial cut (*right*) and the rotational femoral cut (*left*)

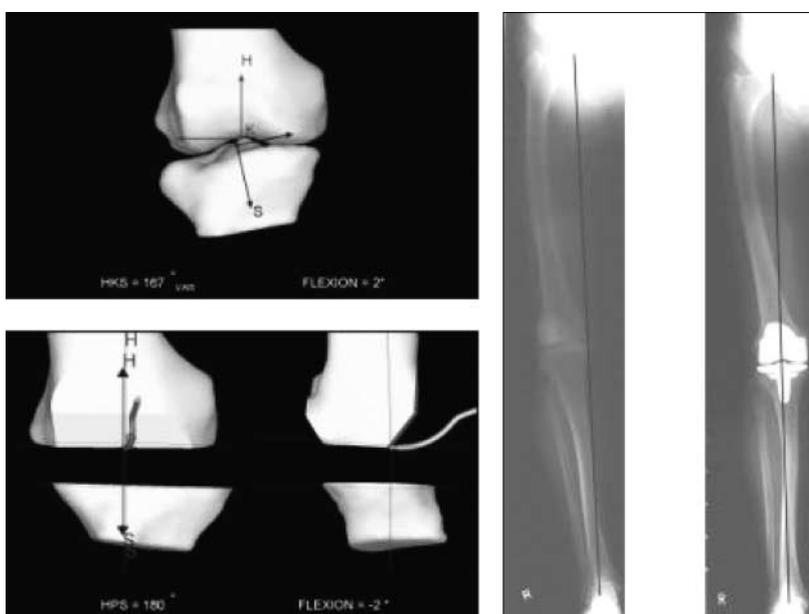


Fig. 5 The result of the navigated final documentation (*left*) was compared with the radiological result of leg alignment in standing position (*right*)

universal guiding device. When resection is completed, the ligament balancing of the flexion and extension gap is examined by means of a flexible spreader tong (Fig. 3).

5. Finally, the surgical result is re-examined and documentation is stored on CD-ROM.

Technical instrumentation consists in the intramedullary femoral and tibial orientation of the sawblocks (Fig. 4). It is also developed to implant the same prosthesis as in the navigated group. This procedure also includes five steps. Using the same approach to the knee joint initially, an intramedullary tibial rod is inserted (step 1). This rod guarantees a perpendicular cutting plane in reference to the tibial axis. The second step includes the insertion of a femoral intramedullary rod to assemble the horizontal cutting plane of the distal femur which can be changed according to the preoperative planning from 3° to 6° of valgus. The third and fourth steps include the ligament balancing of the extension and flexion gap by using different spacers to achieve an appropriate ligament balancing. In the fifth step, the femoral

intramedullary orientated rotational sawing block is assembled with an external rotation of 3°. Finally the implantation is completed by using drilling guides to prepare the cemented or uncemented fixation of the implant.

Radiographs of the entire leg with patients in a standing position were taken pre-operatively and on postoperative day 14. The leg axis (Mikulicz line) was determined by our radiological department. Leg alignment calculated for creation of the model before implantation was compared with radiological findings after implantation (Fig. 5).

Clinical examinations were performed pre- and postoperatively, at a mean follow-up of 7 months (range, 5–14 months) using the Hospital for Special Surgery Score, HSS score [6]. Maximum HSS score is 100; scores of 85–100 are considered to be excellent, 70–84 as good, 60–69 as fair and <60 as a poor result.

Duration of surgery corresponding to the “incision-suture time” noted in the anaesthesiological report was evaluated.

Statistical methods

To compare the pre- and postoperative radiological results for the technical and the navigated groups, chi-square test was used. To compare improvements in clinical outcomes in both groups, the Mann-Whitney test was used. The 95% confidence interval was calculated to test the concordance of the radiological and navigated virtual findings of the alignment before and after surgery.

Results

A total of 100 patients underwent primary knee arthroplasty guided by technical instrumentation or computerised navigation. The 2 groups were similar for age and gender (Table 1). Patients received cementless or cemented bicondylar prostheses or, in some cases, a hybrid prosthesis.

Table 1 Characteristics of 100 patients who underwent primary total knee arthroplasty, by type of surgical guidance. Values are number (percentage) of patients unless otherwise indicated

	Technical instrumentation (n=50)	Computerised navigation (n=50)
Age, years ^a	72 (49–91)	69 (40–83)
Male	11 (22)	14 (28)
Operated knee		
Left	23 (46)	21 (42)
Right	27 (54)	29 (58)
Technique		
Cementless	17 (34)	29 (58)
Cemented	32 (64)	19 (38)
Hybrid	1 (1)	2 (4)

^a Values are mean (range)

Radiological outcome

Radiographic evaluation of the entire leg in standing position first distinguished patients on whether the deviation from a straight line was $>3^\circ$ or $\leq 3^\circ$ (Fig. 6). Preoperatively, the number of patients with a deviation $\leq 3^\circ$ was the same in each group (n=6; 12%). Postoperatively, in the technical instrumentation group, 46% of all patients (n=23) achieved the aspired range; in the computerised navigation group, 94% of the patients (n=47) achieved a surgical result corresponding to the targeted leg axis (Fig. 6). This difference was statistically significant at the 0.01 level ($p=0.001$; chi-square test).

Preoperatively, 35 patients in the technical instrumentation group and 37 in the computerised navigation group had a leg axis angle $<180^\circ$ (Fig. 7). In the technical instrumentation group, the interquartile range (IQR) was from 2° varus to 10° valgus; IQR for the computerised navigation group was from 1° varus and 12° valgus. Postoperatively, the IQR in the technical group ranged from 2° and 5° valgus, while that in the computerised navigation group was from 1° varus to 2° valgus (Fig. 7).

Clinical outcome

The preoperative median HSS score of the technical instrumentation group was 62.9 (range, 38–79) while that of the computerised navigation group was 62.0 (range, 37–93). Clinical evaluation performed at a mean of 7 months revealed improvements in median HSS score in both groups, to 83.0 (range, 62–97) for the technical instrumentation group and to 82.0 (range, 39–64) in the computerised navigation group. There was no significant difference in postoperative HSS scores (Fig. 8) between

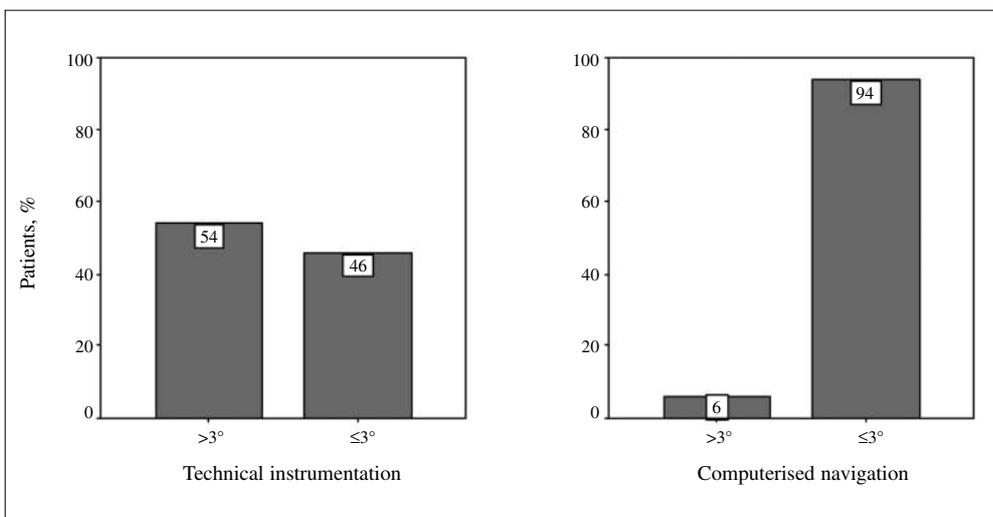


Fig. 6 Deviation of leg axis from a straight line at postoperative day 14, by treatment group

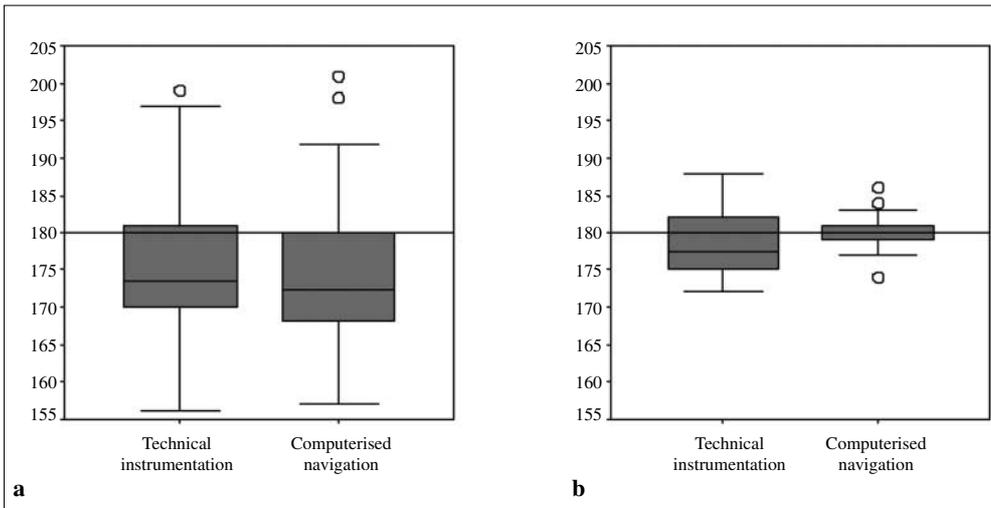


Fig. 7a, b Valgus and varus deviation of leg axis, by treatment group. **a** Preoperative values. **b** Postoperative values

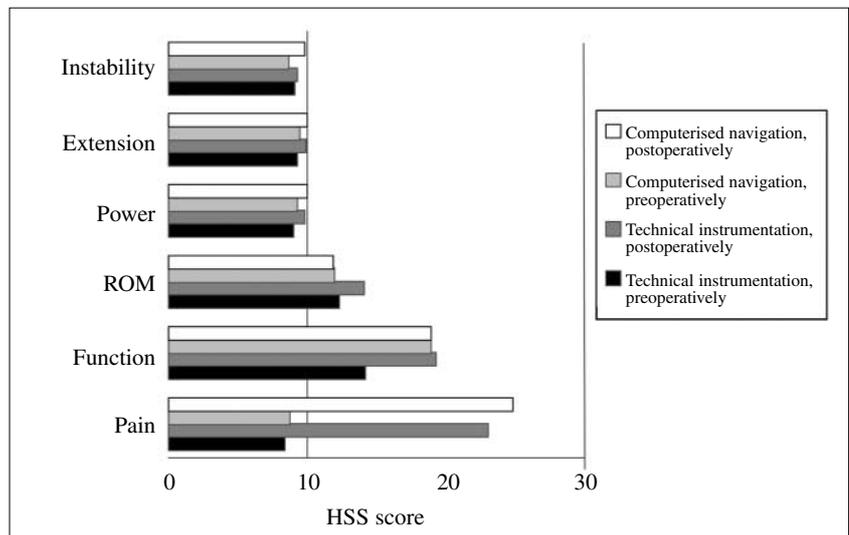


Fig. 8 Clinical outcome (HSS score) at follow-up after a mean of 7 months, and comparison to preoperative values, by treatment group. ROM, range of motion

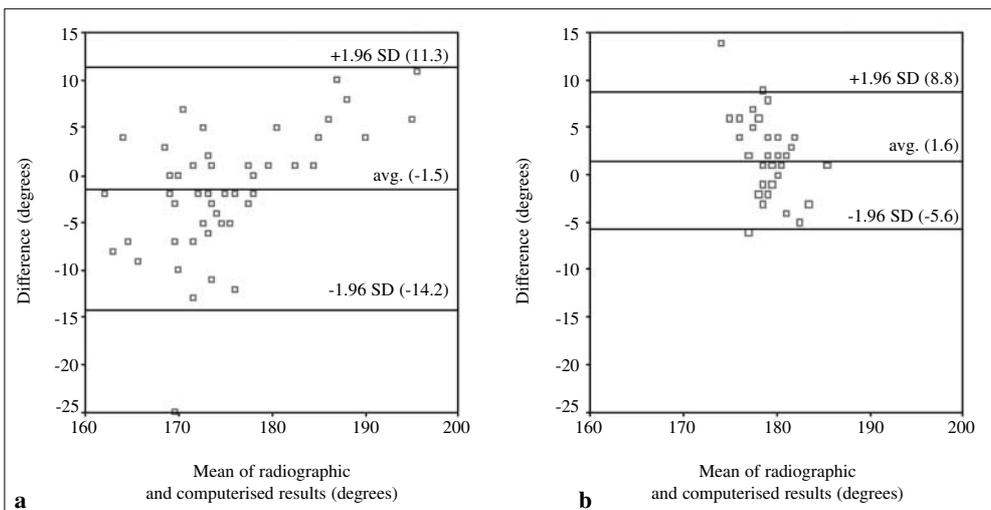


Fig. 9a, b Bland-Altman plots for agreement between radiographic findings and computerised measurements. **a** Preoperative analysis. **b** Postoperative analysis

the technical instrumentation and the computerised navigation groups ($p=0.883$; Mann-Whitney test).

To understand the concordance of both diagnostic methods (radiography vs. computerised methods) we used the Bland-Altman analysis to compare both preoperative and postoperative findings (Fig. 9). Preoperatively, the correlation between the two methods was low and the 95% CI ranged from -14.2° to 11.3° degrees. The Bland-Altman plot shows systematic deviations between the methods: the radiographic values are much lower than computer-determined values for valgus patients and much higher than computer-determined values for varus patients. These differences are due to the fact that the radiographic measurements were made when patients were standing; the weight of the body accentuates the degree of varus or valgus deviation. The computerised measurement was with the patient lying down. Although, on the Bland-Altman plot, postoperatively the range of difference was reduced, 95% of patients were still in a range from -5.6° to 8.8° . There is no systematic deviation between the two methods, due to the fact that the ranges are smaller than before surgery.

The mean duration of surgery for the technical instrumentation group was 80 minutes (range, 40–135 minutes). In the computerised navigation group, it was 93 minutes (range, 55–145 minutes).

Discussion

The computerised navigation system achieves superior precision and simultaneously a considerable reduction of the range of alignment in comparison to the technically instrumented implantation. We consider a possible variation of the kinematically determined rotation centre of the hip joint to be a possible cause for the remaining 6% beyond the aspired range. The reason for this may be a limited rotatory capacity of the hip joint. In obese patients, tilting of the pelvis during kinematic measurements is also conceivable.

The fact that it was possible to achieve the aspired surgical objective with regard to leg alignment in only 46% of the cases in the technically instrumented group, might, as we see it, be caused by the circumstance that intramedullary alignments of the sawing guides showed a high level of ranges due to the individual differences in the anatomy of the tubular bones of tibia and femur despite thorough pre-operative planning [7, 8].

With regard to concordance, we found that the difference between the results of the radiological evaluation and the computer-determined navigated model, in the computerised navigation group consisted in an equidirectional

deviation of the varus and valgus values preoperatively as well as postoperatively. Clearly more distinct pathological values were found pre-operatively in the radiological measurement. We believe this is caused by the body weight increasing the axis deviation of varus and valgus. This is expressed in the preoperative Bland-Altman plot: the more distant the mean range is from the median, the more extreme are the radiographic results, whether valgus or varus. This impression disappears when the deviation of the leg alignment is lower. This is why we think that there is such a low level of concordance between the postoperative results in the Bland-Altman plot. The methods of leg alignment determination, radiographic and computerised, are based on different technical and physical systems and are applied under different conditions. Therefore, it is not possible, in our opinion, to replace one method by the other.

The duration of surgery in the computerised navigation group was, on average, 93 minutes, i.e. 13 minutes longer than in the technical instrumentation group. In the process of the study it decreased consistently, which leads us to believe that it was subject to a learning curve (data not shown).

The clinical outcomes at the short-term follow-up are almost identical between groups. This is important evidence showing that surgical needs like fixation of tibial and femoral markers and a slightly prolonged time of surgery do not deteriorate the clinical outcome. We have seen this problem in the use of surgical robots for the implantation of the stem in hip arthroplasty, obtaining excellent radiological results but worsening the clinical outcome due to the surgical needs of the technique [9].

The main improvement of the high precision computer-navigated knee arthroplasty can be seen in the biomechanical aspects. Several studies pointed out the importance of the postoperative alignment and possible complications of a sharp increase of loosening rates in cases of severe postoperative deviation of the leg axis from the aspired surgical result [10–12]. We hope to minimize the rate of aseptic loosening and unequal wear of polyethylene due to the much better alignment.

This is why, in our clinic, if possible, we always carry out primary prosthetic knee replacement with a bicondylar knee prosthesis with the computerised navigation system. We observed that the additional amount of time involved is declining and believe that the considerably improved surgical results justify the extra time. The costs of purchasing the system and the intraoperative items (rigid bodies) can be considered moderate. This increase in quality gives rise to the expectation of less revision surgeries, which represent a benefit for the patient and an economic advantage for each treatment [13–15].

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