Positioning of total knee arthroplasty with and without navigation support

A PROSPECTIVE, RANDOMISED STUDY

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We conducted this prospective randomised and externally evaluated study to investigate whether the use of a navigation system during total knee arthroplasty leads to significantly better results than the hand-guided technique. A total of 240 patients was included in the study. All patients received a condylar knee prosthesis. Two surgeons performed all the operations using the Stryker knee navigation system. Exclusion criteria included the necessity for the primary use of constrained implants.

The results revealed a highly significant difference between the two groups in favour of navigation with regard to the mechanical axis, the frontal and sagittal femoral axis and the frontal tibial axis (p < 0.0001). The use of a navigation system was therefore shown to improve the alignment of the implant.

Received 31 July 2002; Accepted 14 February 2003

Total knee arthroplasty (TKA) is a well-proven procedure. Although it usually produces excellent results, complications occur in 5% to 8% of cases because of loosening, instability, dislocation, infection or fracture.1-3 In 20% to 40% of patients, there may be less serious complications, such as anterior knee pain or limited movement.4-6 The success of joint replacement depends on many factors, including patient selection, prosthetic design, soft-tissue balancing, the alignment of the leg and the restoration of the joint line.7

Proper axial alignment is of paramount importance for the longevity of the implant. Minor malpositioning can lead to early loosening, increased polyethylene wear and poor function.8,9 Malalignment of the components in any anatomical plane can cause major complications. Malrotation of either the femoral or tibial component will critically affect patellar tracking and can lead to patellar subluxation or dislocation.10 Varus or valgus malalignment has been described as the commonest cause of early loosening.11 Alterations in the joint line usually lead to limited movement.5

Anteroposterior (AP) malpositioning of the femoral component by as little as 2.5 mm can reduce the range of movement of the knee by up to 20°.11 Changes in the tibial slope have a major effect on soft-tissue balancing and on the range of movement.12-14 In principle, either malalignment of any of the components or incorrect soft-tissue balancing can lead to failure of the implant.15 There is a general consensus in the literature that a normal physiological tibiofemoral angle of between 5° and 7° should be the aim of a TKA.15 The mechanical axis of the leg runs through the midpoint of the knee. There are different, traditional and anatomical concepts with regard to the proper alignment of the transverse joint line. It has not yet been established which of these approaches extends the longevity of the arthroplasty.16

The development of extramedullary and intramedullary guidance systems has greatly improved the accuracy of the alignment of implants, although cases of malalignment have nevertheless been reported. For example, when an extramedullary navigation system was used, malalignment by more than 4° in the coronary plane was reported in 8% of cases.17 Another study found that malignment occurred in more than 10% of cases.18 Computer-assisted systems have been recently developed in order to improve the alignment of components.19 However, some studies have indicated that navigational assistance did not always improve alignment.20-22

In this randomised study, we aimed to compare the radiological outcome of 120 TKAs which were implanted using a navigation system with that of 120, which were implanted using a conventional technique. The main variable which
was studied was alignment of the implant in the frontal and sagittal planes.

Patients and Methods

We used a knee navigation system which we developed in collaboration with Stryker Howmedica Osteonics, Allendale, New Jersey. It comprises a module for analysing the alignment of the leg, the resection planes and the prosthetic components. The module also quantifies the kinematics of the knee. The system is based on an image-less navigation method; thus a preoperative three-dimensional CT reconstruction of the knee is not necessary. Two hardware platforms are available, a laptop and a workstation version. Both are portable units consisting of a PC, an infrared camera system, a flat-screen monitor and menu prompts. The operational aspect of the system occupies a spherical area with a radius of about 50 cm. The system should be placed about 1.5 m away from the operating field. The navigation instruments and the camera communicate via active light-emitting diodes (LEDs). The surgeon guides the procedure himself using a specially developed pointer. Foot pedals are unnecessary, and the technology does not need a computer specialist at hand.

The procedure is initiated by positioning the first tracker through a tiny incision on the iliac crest. Additional fixation pins are attached to the distal femur and the proximal tibia within the operative field. Antiotational fixation pins were developed specifically for this purpose to be suitable for monocortical and bicortical anchorage. They were intentionally given a slender design to prevent damage to the soft tissue. The joint kinematics can be monitored regardless of whether the joint capsule is opened or not.

To set up the system, the patient’s data are entered and the pointer and tracker are initialised. The anatomical landmarks are then defined. The exact centre of the femoral head is pinpointed by rotational calculation. Single-point digitisation is then used to identify the epicondylar axis, Whitse’s line, the femoral and tibial centres, the malleoli and the centre of the ankle. Surface digitisation is carried out to identify defects of the femoral condyles or tibial plateaux. This allows the level of the resection to be determined exactly and prevents alteration of the joint line.

The data collected are used to calculate the current clinical status by means of mathematical algorithms and preoperative deformities are imaged. Kinematic curves are generated based on the distances between the landmarks in relation to each other during various manoeuvres such as varus/valgus, rotational stress or AP movement.

Navigation of the different cutting blocks can be performed optionally with specially designed instruments or with universal gauges. One advantage of this method is that it can easily be used with other knee replacement systems, not only those manufactured by Stryker.

Details of intervention. Two orthopaedic surgeons (MS and BW) performed all the procedures, each having previously performed more than 750 primary TKAs. None of the navigation-guided procedures needed to be interrupted. This method allows accurate trial assessment for proximal, distal, rotational, varus/valgus and anterior/posterior positioning and complete intraoperative kinematic analysis of the joint space. One primary aim of the study was to achieve accurate insertion of the implants in relation to the measurable angles.

All patients received a Duracon condylar TKA (Stryker Howmedica Osteonics) with a fixed A/P lipped polyethylene component. The patella was replaced in all cases and all components were cemented. The procedure was performed with a thigh tourniquet except in 11 patients who had a history of thrombosis. The perioperative treatment regimen involved the placement of an indwelling epidural catheter for pain control and included routine physiotherapy and rehabilitation.

Study period and sample size. The aim was to compare 120 patients treated with and 120 without navigation guidance and to determine the intra-group variability. The study started in November 2000 and its objective was achieved 13 months later. During this time, 373 TKAs were performed. The study excluded 133 cases because a primary, hinged arthroplasty was required to treat 63 patients with severe deformity or instability, or revisions were undertaken because of septic (23) or aseptic (43) loosening. Four patients who were originally allocated to the hand-guided group requested a navigated operation and were therefore also excluded.

All patients who were scheduled for a primary TKA, and for whom a condylar prosthesis was suitable, were included in the study. No exclusion criteria were specified as the aim was to determine whether navigation systems can be used successfully in any situation.

The purpose of the study and both surgical techniques were explained to all patients who gave their consent to receive either and to a short-term assessment and a further follow-up within three months. The study had ethical approval.

The patients were randomised according to the availability of the navigation equipment. As sterilisation of the navigation tracker was undertaken off-site, it could only be used on alternate days. At the time of being scheduled for surgery, between three and six months before admission, it was not known whether the operation would be carried out with the navigation system or not. This method generated groups of equal sizes.

The characteristics of the patients are shown in Table I. The two groups were comparable. Preoperative radiological studies revealed marked axial deviations in both groups (Table II). At follow-up at two months, the clinical parameters were recorded and standardised lateral and AP radiographs were taken in single-leg stance. The femoral and tibial angles and the mechanical axis of the leg were determined on a large Negatoscope table at a horizontal adjustment. The centres of the hip, the knee and the talus were
also recorded as described by Duparc and Massare.\textsuperscript{23} The mechanical axis of the leg on the postoperative radiographs was measured with digitisation and the position of the implant was analysed\textsuperscript{23,24}.

Statistical analysis. Pearson’s chi-squared test and SPSS statistics software (SPSS Inc, Chicago, Illinois) were used for testing significance. The differences in the measurements which were obtained with the two surgical techniques were compared with regard to deviations in the mechanical axis and the frontal and sagittal femoral and tibial axes.\textsuperscript{25} Incremental deviations to the left or right were summed and compared according to the following categories: no deviation (0˚), a deviation of 1˚ to 3˚ and a deviation of ≥4˚ from the 0 axis.

### Results

#### Mechanical axis

In the navigated group, a mechanical axis of 0˚ was achieved intraoperatively in 83 patients and seen in 69 on the single-stance radiograph postoperatively. An intraoperative deviation in the mechanical axis of 1˚ was achieved in 24 patients and seen postoperatively in 31. An intraoperative deviation of 2˚ was achieved in 13 and seen postoperatively in 17.

Axial deviations of greater than 3˚ were not detectable intraoperatively. If such were noticed, an intraoperative correction of the implant was undertaken. Postoperatively, two knees had a varus deviation of 3˚ and one had a 3˚ valgus deviation.

In the hand-guided group, a mechanical axis of 0˚ was seen postoperatively in 65 knees, an axis of 1˚ in 15, of 2˚ in 13 and 3˚ in 11 cases. Thus, with regard to alignment, more than 80% of patients had a good or very good outcome. In 16 others, however, there was major malalignment, up to 6˚ and 7˚ (Fig. 1). The difference between the two groups was statistically significant (chi-squared test = 26.8, \(p < 0.0001\)).

#### Femoral axis in the frontal plane

There was a postoperative axial deviation of the femoral component in the frontal plane of 0˚ in 82 knees in the navigated group and in 63 in the hand-guided group. This was statistically significant (chi-squared test = 26.8, \(p < 0.0001\)). Valgus deviations occurred more often in the navigated group. None of the navigated prostheses had a deviation of more than 3˚ varus or valgus. By contrast, 12 femoral components in the hand-guided group had a deviation of 6˚ or more in both varus and valgus (Fig. 2).

#### Femoral axis in the sagittal plane

Despite the use of a grid cassette for the single-leg stance radiographs instead of
a rotating compensating mask, it was not possible to obtain a sagittal radiograph of the whole leg in all cases. Obtaining lateral views of the femoral head is particularly difficult in obese patients, and postoperative measurements in the sagittal plane were only possible for 73 of the navigated and 86 of the hand-guided group.

Sixty-one implants (80%) in the navigated group were in the correct position and three were in 5˚ of flexion. Nineteen implants (22%) in the hand-guided group were in the correct position. In the remainder, there was extension or flexion malalignment of up to 6˚. The difference between the groups is highly significant (chi-squared test = 62.8, p < 0.0001) (Fig. 3).

**Tibial axis in the sagittal plane.** A dorsal inclination (slope) of 3˚ is advised when implanting the Duracon TKA. In 79 knees (66%) in the navigated group, a slope of 3˚ was achieved and presented as a 0˚ deviation in the graph (Fig. 5). In 25 (20%), the slope was extended by 1˚ and in 16 (13%) by 2˚. In the hand-guided group, a slope of 3˚ was achieved in 77 knees (64%). There were minor errors, but they did not exceed the 3˚ limit. With a tolerance of 2˚, there was no significant difference between the groups.

**Complications.** The complications, including delays in wound healing, are shown in Table III. One case of calf-vein thrombosis was detected by sonography in each group but did not cause delayed mobilisation. In early functional follow-up, knees which had not regained 90˚ flexion within 12 days of surgery underwent a manipulation under anaesthesia. This was necessary four times in the hand-guided group, and once in the navigated group.

**Discussion**

Initially, most orthopaedic surgeons viewed the development of navigation systems for total joint arthroplasty with great scepticism. However, a large variety of systems has been introduced into clinical practice. Isolated studies with
small results have been published which document the early results of navigated TKAs.\textsuperscript{20} Thus far, although some advantages have been reported with their use, the place of navigated systems remains controversial. The ability to carry out intraoperative implant kinematic measurements is important in the development of new implants and the assessment of fixed and mobile polyethylene.

The specific problem for the clinician is that navigation systems depend on mathematical algorithms. The exact charting of landmarks is not possible with complete certainty,\textsuperscript{26} which raises the question as to whether slight errors which occur intraoperatively due to the subjective perceptions of the surgeon, can lead to major errors in measurement when using the navigational system. It has not been possible to answer these questions with purely mathematical models and there is some uncertainty among users. The algorithm which was developed for the present navigation system takes into account the fact that although some landmarks can be identified very accurately by the surgeon, some can only be identified approximately. It is therefore possible to calculate very accurately the individual data with a mathematical matching procedure.

The 240 patients presented here who were treated within the scope of a prospective, randomised study are particularly interesting because no specific selection criteria were applied. The study design took the surgeons' routine technique into consideration.

The rate of wound healing and early infection suggests that the navigation-guided procedures cause more trauma to the soft tissues because the incision required for fixation of the rigid bodies is 4 cm longer than that used for access in conventional TKAs; no significance, however, could be established. The reduction in the use of manipulation during aftercare suggests improved kinematic alignment of the implant. The proof of this observation can only be given by conducting separate studies that also examine the results based on the American Knee Society Score.\textsuperscript{27} We had no patellar complications, probably because of appropriate rotational alignment of the femoral component and the asymmetrical Duracon Patella.

It is difficult to assess the postoperative outcome by measuring radiographs of the patient in a one-legged stance. It is well known that rotational alignment and particularly flexion of the knee both have a major effect on the radiological measurement of the femorotibial angle. In extremely unfavourable cases, such as those with contractures combined with rotational malalignment, measurements which are inaccurate by values up to 6° can be encountered.\textsuperscript{28,29} Even if strictly standardised one-legged stance radiographs are taken, the spatial alignment of the implant is imprecise. Positioning errors of 2° to 3° have to be acknowledged in both groups. Significant differences were, however, distinguishable between positioning with and without navigation.

We have not analysed the rotation of the femoral and tibial components. It would only have been possible to determine the angles of rotation using CT analysis of the limb. However, such analyses are done without definitive landmarks, which limits the interpretation of the results. From our point of view, rotation of the tibia and femur can only be defined by kinematic alignments. Such investigations have been confirmed by revision arthroplasties and in experiments on cadavers and will be the subject of a separate publication.

An important finding in our study is that occasionally major axial malalignments and errors of positioning were noted in the hand-guided groups, despite the fact that very experienced surgeons were performing the operations. These cases involved difficult clinical situations, mostly obese patients and sometimes those with dysplasia of the knee or axial deformities secondary to trauma or metabolic disorders. It is also difficult to determine the extension/flexion alignment of the implant using the manual technique. Anterior bowing of the femur can cause malalignment of the femoral component which has led to a tendency to implant it in flexion. A surgeon using the hand-guided technique will rarely be able to determine the position of the femoral head which usually lies anterior to the axis of the femur. Our study has clearly shown that the use of this navigation system leads to a significantly better outcome with regard to alignment of the implant (p < 0.001).

The difference in the axis of alignment of the tibial component in the sagittal plane between the two groups was not significant, which suggests that the slope of the implant can be adjusted correctly by eye. The navigation system provides the surgeon with data on rotation of the tibial osteotomy. A pathological kinematic curve is generated for malrotated components, and deviations of the varus/valgus angle at the various degrees of freedom in flexion can be identified during the analysis.

In previous publications, we have emphasised the importance of rigid bodies for reproducibly measuring the axes and kinematic relationships.\textsuperscript{30,31} Safety features (verification points) enable the surgeon to see whether movements of the navigation system or poor planning on the part of the surgeon are the cause of incorrect measurements.

Since the knee navigation system is used in real-time, there are no additional costs incurred by additional imaging procedures or preoperative trial measurements of the implant. The criticism that a kinematic system reproduces the individual failures of the surgeon has been refuted by the findings of our study. Another positive feature of the navigation system is that it can be used to implant all types of devices and also for revision surgery; this gives surgeons even greater freedom regarding their choice of implant.

This study was supported by Stryker, Howmedica, Osteonics Germany. No 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
