Fluoroscopy-Based Navigation in Genesis II Total Knee Arthroplasty with the *Medtronic »Viking« System*

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Introduction
Mal-alignment reduces the survival of total knee replacements. The imbalance of the soft-tissue results in instability of the replaced knee joint. This leads to functional deficits and increased wear.
Computer-assisted technology has been introduced into orthopaedic surgery based on the knowledge that it can improve the precision of surgical procedures. Computerized three-dimensional imaging has been the prerequisite to adapt these techniques. In total knee replacement an optimized alignment to the mechanical axes of the lower limb in comparison to the traditional instrumentation is required. The additional aim is to achieve a correct soft-tissue balancing.
Computer-assisted surgical procedures are based on CT-scan analysis and kinematic evaluation of the anatomy of the lower limb. The acquisition of fluoroscopic imaging for navigation has been described in traumatological procedures [3] Fluoroscopic navigation with the Medtronic system has been widely used in spine surgery [2].
The advantages are a minimum of radiation exposure and the exact and reproducible fixation of pedicle screws. Fluoroscopic-assisted navigation offers a high level of precision and surgical safety [3].
These advantages of minimal radiation and of reproducible accuracy are adapted for the development of a stable software and new instruments for fluoroscopic-assisted navigation in total knee arthroplasty.
The goal is to plan preoperatively and to adjust intra-operatively to the individual anatomy, and to navigate the surgical tools and cutting guides to reduce the human errors. After evaluation of medical images (CT, MRI, fluoroscopy) and correlation to anatomical landmarks, determined by sensors mounted on surgical instruments the physician can be guided during performance [2, 3]. At any time the surgeon is able to simulate and to control the precision of each single step of the procedure. This technology leads to a new approach to documenting the individual procedure and performing follow-up studies in the future.

Requirements

Data related to the individual patient's anatomy are required for computer-assisted surgery. Function of the extremity is a prerequisite for the kinematic acquisition of these data. In case of an ankylosis of the adjacent joints (i.e. the hip or ankle joints) the necessary mobility can not be expected. The ankylosing osteoarthritis of the knee also may be an exclusion for kinematic evaluation of the extremity.

For the CT-based navigation preoperative imaging and evaluation has to be performed. This technique needs very sophistically logistic planning. Even more the radiation exposition for the patients is critical in the routine of total knee replacement. Additionally, the amount of costs have to be considered in relation to the achieved improvement of accuracy on a regular base.

Navigation is »only« a supplementary instrument for the implantation of the knee arthroplasty. For optimal use a learning curve is necessary. Failures may be expected if navigation is only used in »special« cases. Navigation integrated in the routine surgical procedure has to follow these principles: availability, reproducibility, cost-effectiveness and safety. To correspond with these criteria the effort and the costs have to correlate with efficacy. The equipment has to be appropriate to the integration into the routine. Under these postulations the CT-based navigation is at least controversial for the routine of total knee arthroplasty.

In fluoroscopy-assisted navigation of TKA the individual lower limb is evaluated radiographically including all joints: the hip, the knee and the ankle joint. After acquisition of these images in two planes the mechanical axis of the limb is calculated in 3 dimensions.

The availability of these data is not restricted in any way. This information is stored and is available for controls and quality management. The time for fluoroscopic investigation and image acquisition is 8 min and less than 1 min of fluoroscopic radiation.

The surgeon estimates the individual quality of the images and is able to include this information into the further decisive steps of the surgical procedure. The additional time of data acquisition in the operation theatre does not increase the overall time considerably.

Having registered the axes of the limb the surgeon outlines the anatomic landmarks of the femoral condyles and of the tibia plateau with a mobile diode which is mounted to a probe. After complete data evaluation a 3D model of the extremity is calculated. The discrimination of the data is of less than 2 mm and smaller than 2° within the acceptable limits.

Surgical Procedure

The patient is in supine position. A tourniquet is put on the thigh. It may be inflated at any time during the procedure.

A pre-patellar longitudinal skin incision is carried out. To mount the femoral navigation frame this incision is proximally extended about 4 cm longer. Mediopatellar opening of the joint. Proximal and distal of the joint line the navigation frames are mounted to transosseous fixed pins.

Two fluoroscopic images are taken of the joints: the femoral head in 45° angle and in a.p. and lateral view of the knee and ankle joint. The center of the femoral head is identified on the monitor. After registration of the mechanical axes the intra-articular landmarks of the femoral condyles and of the proximal tibia are determined with a free diode. The mechanical femoral axis is defined by the relation of the intercondylar center, the epicondylar axis and the »Whiteside line« at the distal femur to the center of the femoral head. The tibial axis is determined by the a.p. alignment perpendicular to the center of the tibial head and to the center of the distal tibia. The rotational alignment is depending on the midtransversal axis at the tibial head diverging 10° of the posterior corticalis axis and at the center of the joint surface of the distal tibia.

The resection guides are registered and the osteotomies of the joint surfaces are performed with the navigated instruments. During each step it is possible to adjust the cutting guides within the limits of less than 2 degrees of deviation to the navigated axes.

At any time an intraoperative clinical control and revision is possible. The program and the controls have to be coordinated.

The system offers the control of the alignment of the trial implants. Dynamic testing during continuous motion and at 0°, 30° and 90° flexion enables the test of the soft tissue balancing. All these tests are documented automatically.

Experience with Fluoroscopic Navigation

Experimental data of fluoroscopic navigation had been presented after cadaver surgery [1]. After further clinical testing the technology of fluoroscopy-assisted navigation had been introduced for clinical studies. At each stage of development a very sophisticated documentation of all data had been collected. The documentation of each step of the surgical procedure is an excellent contribution to quality control and quality improvement. This is a very important advantage of navigation.

During the phase of development of fluoroscopy-assisted navigation an integration of the system into the routine program was not possible. The testing of new instruments has been time consuming. With up to 4 total knee replacements the same day it is not possible to use the navigation system at each procedure because there has been only one set of instruments for navigation available. After some experience and the development of adequate equipment, we are now able to state that the application of the system is now stable, safe and reproducible.

Results

We had the opportunity to start with the clinical application of the fluoroscopic navigation »Viking« in our clinic in May 2001. Out of a total of 240 TKA within the last year, we were able to use the fluoroscopic-assisted navigation system in 50 of the Genesis II TKA. During the early phase of this study we were not able to increase the frequency of application considerably. It is our goal to use the navigation system in each case to achieve optimal results for all patients.

To evaluate the accuracy of the new fluoroscopic navigation system all these patients are introduced into a prospective study design in comparison to traditional implantation techniques. The results of this study is not yet available.

Alignment

The advantage of this system is a control of accuracy at any time of the procedure and it allows an online documentation. Surgical time is slightly increased by the acquisition of the fluoroscopic images (Fig. 33.1). We have to admit that it is still a more time-consuming procedure in comparison to the traditional instrumentation with alignment rods.

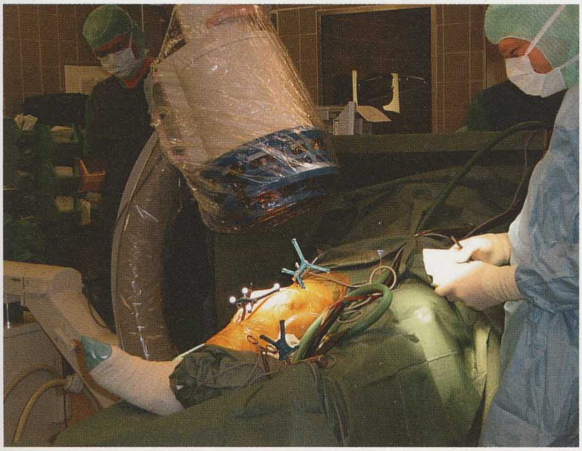


Fig. 33.1. Acquisition of the center of the femoral head with mounted navigation frames at the knee

We check the alignment of the resection planes regularly during the surgical procedure. The real presentation of the fluoroscopic images on the touch-screen facilitates the imagination of the surgeon during the procedure. A virtual line representing the anatomical structures and the position of the limb may have a negative influence on the surgeons' compliance. The intraoperative control shows a very high accuracy of less than 2° degrees deviation (Fig. 33.2).

It is essential that there are no contraindications for the application of the fluoroscopic-assisted navigation. In contrast, kinematic-based navigation may be limited in case of ankylosing disease of the hip and of the knee which is going to be operated.

Control of the Results Intraoperatively

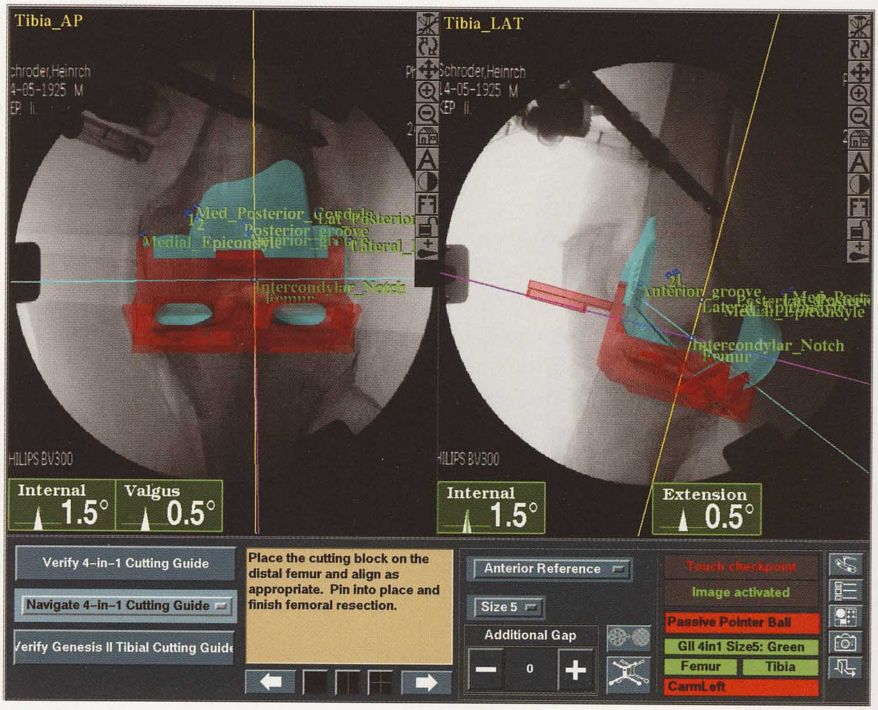
It is possible to control the results of alignment. The control studies did not show any failure that was related to the navigation system. Even in cases of very severe deformities of the femur or of the tibia (i.e. posttraumatic deformities) the intraoperative control with alignment rods did confirm the exact alignment and the correct implantation of the arthroplasty (Fig. 33.3).

Testing of Soft-Tissue Balancing

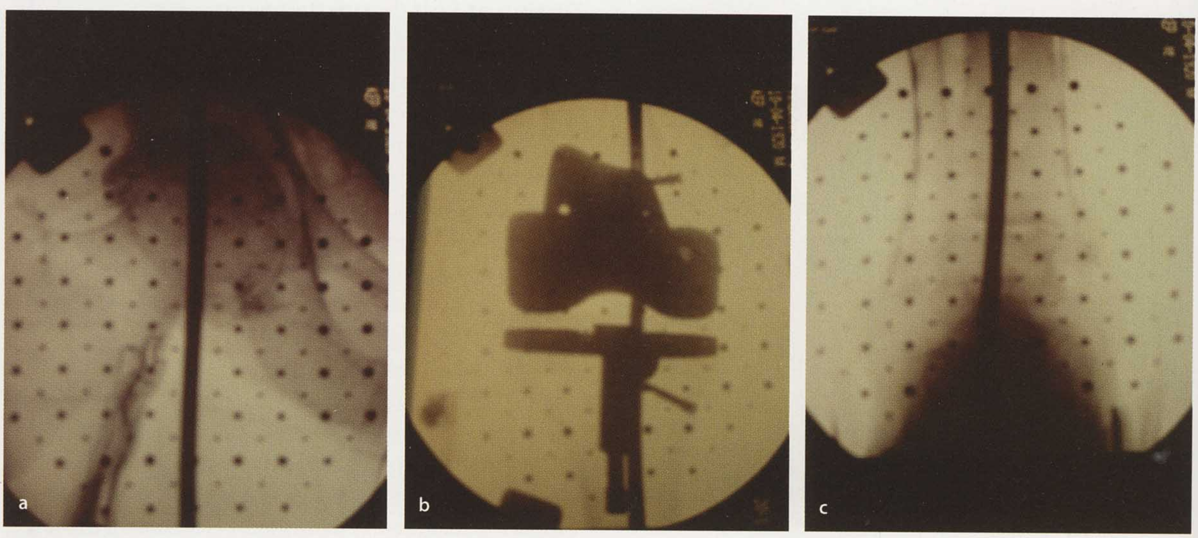
Fluoroscopic-assisted navigation with the »Viking« system (Medtronic) offers a great advantage after implantation of the trial implants. It is now possible to check the soft-tissue balancing dynamically and in various degrees of flexion. The tests are documented in neutral 0° and in 90° of flexion. The tests are performed for the following parameters:

- a.p. translation (anterior drawer sign),
- varus- and valgus stress,
- rotational stability.

After these dynamic tests it is still possible to improve soft-tissue balancing by adequate procedures. It is interesting to note that using the »Viking« navigation system we can see that there is hardly any correction of the resection necessary because of the accuracy of implantation of the TKA.



■ **Fig. 33.2.** The real fluoroscopic image of the knee in combination with the virtual image of the implant on the screen and the results after resection



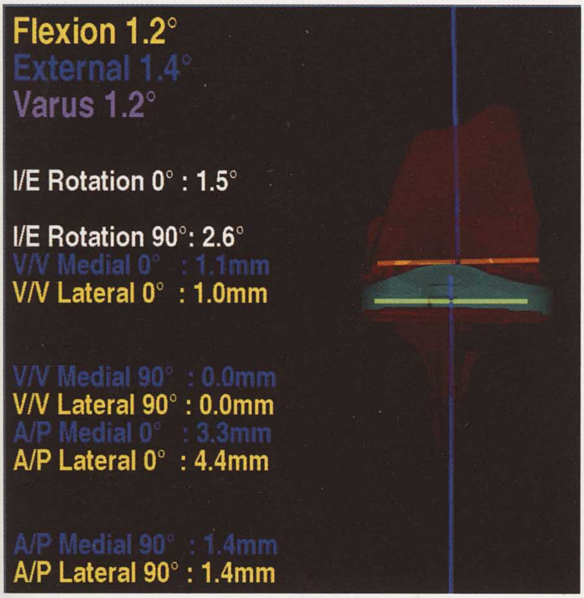
■ **Fig. 33.3a-c.** Intraoperative fluoroscopic control after insertion of the trial-implants with the alignment rod. **a** Center of the femoral head, **b** the knee, **c** center of the ankle

The mean values show excellent results. The tests before the closure of the capsule cause an increased laxity at 90° flexion. The rotating platform of the Genesis II TKA provides a high degree of rotational capacity (◘ Fig. 33.4). After finishing the knee replacement the manual controls did not give any sign of pathologic laxities (◘ Table 33.1).

◘ **Table 33.1.** Fluoroscopic-assisted navigation: Genesis II/ rotating platform (n=50)

Level of evaluation	Results (median)	Standard deviations
V/V lateral 0°	2,3 mm	0,1 – 5,8 mm
V/V lateral 90°	2,9 mm	–2,7 – 14,3 mm
a.p. lateral 0°	1,9 mm	–5,4 – 6 mm
a.p. lateral 90°	2,9 mm	–8,0 – 6,4 mm
I/E rotation 0°	3,6°	0 – 7,0°
I/E rotation 90°	9°	2,0 – 16,9°

V/V Varus/Valgus, *a.p.* Translation, *I/E* internal/external rotation.



◘ **Fig. 33.4.** Visualization and documentation of the soft-tissue balancing at 0° and 90° of flexion

Limitations of Alignment

The improvements of the designs of knee arthroplasties include the development of better instrumentation techniques to achieve a reproducible alignment to the mechanical axis of the lower limb.

There are still some controversial publications in terms of the navigation-guided instruments. Some of the critical cuts and positions of the implants are depending on the visual analysis by the surgeon.

Variables for alignment in TKA

- Intercondylar femoral center
- Transepicondylar axis of the femur
- Rotation of the tibia
- Center of the distal tibia
- Position of the patella implant

It is well accepted that it is not possible to define the epicondyles as a point at the distal femur. Using the fluoroscopic-assisted navigation system it is possible to exactly define the center of the femoral head and of the distal tibial joint surface. But still it is difficult to accurately describe the rotation of the tibia.

Time of Surgical Procedures

A continuous reduction of the total time of the surgical procedures have been registered for the fluoroscopic-assisted navigation during the experience of more than 12 months. With a total time of 90 min cut to finish of surgery a reasonable time has been achieved. This is not only true for the senior author but also for 3 senior surgeons at our hospital. This could be demonstrated during various visits of other colleagues. We are now going to include the online documentation of the timing into our software program.

The testing of soft-tissue balancing is a new part of the surgical procedure which justifies additional time. The graph demonstrates the »learning curve« during the first applications of the navigation system (◘ Fig. 33.5). The black line »trial alignment« of this graph shows the time of laxity tests that are about 10 minutes unchanged. It is expected that this time will be reduced in the future also.

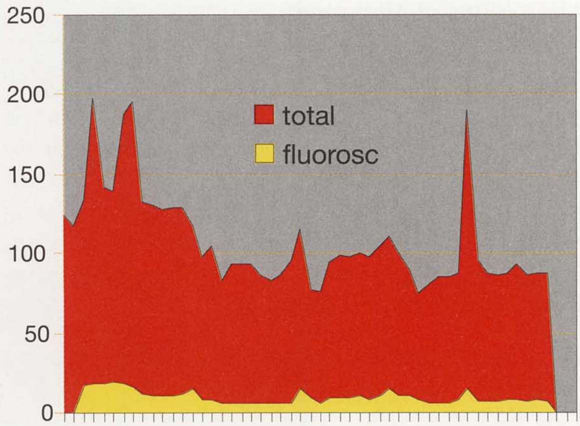


Fig. 33.5. Additional time for navigation

Additional Efforts for Navigation

Navigation in total knee arthroplasty is in a stage of development. At the phase of application it is not only time-consuming. During the first 20 navigated TKA one more nurse has been needed to adjust the camera during the navigation. The use of fluoroscopic investigation and registration took more time during the first cases than it was necessary later. The exact positioning and the stable fixation of the navigation frames has been established after our experience. The development of special instruments for navigated total knee arthroplasty will help to reduce the time of surgery even more.

Discussion

Various systems to navigate the total knee arthroplasties are already available. Kinematic-based navigation shows the advantage that it is applied independently of any imaging. The disadvantage seems to be the limitation in case of severe joint contracture and ankylosis of the knee and of the adjacent hip joint. Also patients with greater masses of soft tissues surrounding the knee are excluded of this method. The results do not confirm a higher degree of reproducibility. As limiting factors for kinematic based-navigation

- the variability of the surgeons,
- the value of surface registrations and
- movements of the navigation frames

had been identified as problems [4].

The CT-based navigation may give the highest degree of accuracy. The fact that this method is depending on CT scan preoperatively is restricting its application. This technology is not available in all hospitals and it needs more time and more radiation exposure for the image acquisition and it is very expensive in the routine.

Fluoroscopic navigation seems to give the best solution. It offers a very high degree of accuracy and the best way of reproducibility. The reduction of radiation using the fluoroscopy is an advantage for the surgeon [5]. At any time the update of the imaging is available. It is less time-consuming than the CT-based navigation. The online imaging on the screen offers an excellent compliance for the surgeon. The time for surgery used for documentation and laxity tests seems in good relation to the improved quality.

Prospective studies are planned to verify the significance of this system.

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