Strategic Considerations

Cooperation with industrial navigation developers should be made dependent upon whether these companies are prepared to fulfill medical demands on navigation surgery:

- Navigation systems should not only be regarded as aids for positioning endoprostheses (electronic spirit levels), but should also provide for intraoperative kinematic analysis. Particularly in the case of frictional joints such as the shoulder or knee, the analysis of intraoperative kinematics is of far-reaching importance for postoperative function. A reduction of the navigational measurements solely to an alignment of the prosthesis at the same time means a reduction of quality management to the postoperative X-ray image.

- The development of navigation systems should be organized in such a way that the systems are available to the user as open systems, i.e. the user must be free to choose the design of prosthesis during the operation. A reduction of the software to individual products - possibly those of the developing company - leads to a restriction of the physician's freedom of action and thus to a disadvantage for the patient. Open systems not only make it possible to freely choose the implant design, but also to check the kinematic qualities of different endoprostheses, to use kinematic navigation systems in prosthesis development and, above all, to determine mal-positioning of the in-situ prosthesis and its abnormal kinematics in revision cases.

- The development of modern navigation systems should include the possibility of allowing interactive processes between the senders and the central hardware. This will make it possible to rapidly build up modules for further joint regions and to change software in quick development steps, in order to make it even more user-friendly. This will minimize the secondary costs, and interactive processes between the LED and the central computer system will thus enable industrial development work that will rapidly encompass the different regions of the body.

Development Steps

The Stryker-Leibinger navigation system has been jointly developed in our department since the autumn of 1999, initially in cadaver experiments, and since March 2000 in a pilot project. Over this period and up to today, the navigation has been repeatedly modified and the software repeatedly coordinated, in order to translate the understanding of the generated data more clearly for the operating team. Further development of the tools for implantation also represented a major development step, especially the development of thin fixation pins for closing the soft-tissue coat at any time. The system is now available in a wireless design. Navigation of the section blocks without additional intra-medullary anchorage is possible; further development steps are envisaged in the use of mini-robots that will perform the osseous sections in the future.

Description of the System

The Stryker knee navigation system is a module for analysis of the leg axes, the alignment of the resection surfaces...
and thus of the prosthesis components, as well as the kinematics of the knee. The system is a so-called imageless navigation system, i.e. a preoperative three-dimensional reconstruction of the knee based on CT scans is not necessary. Two hardware platforms are available: a laptop and a workstation version. Both platforms are for mobile application and, in addition to the computer, include an infrared camera system, a flat screen and all entry aids. The working area of the system comprises a spherical space with a diameter of 1 m. The system should be set up around 1.5 m from the area of surgery. Communication between the navigation instruments and the camera is wireless via active, light emitting diodes (LEDs). The process is controlled by the operator himself using a specially developed pointer. Foot pedals and similar aids are not necessary. This means that the method does not require people who are familiar with computer systems. No additional persons are necessary in the operating theatre.

To begin with, the first tracker is fixed in place via a small incision in the iliac crest. A further fixation pin is attached to the distal femur and to the proximal tibia within the surgical incision. For this purpose, special rotationally stable fixation pins were developed, which are available both as monocortical and as bicortical. Particular importance was attached to a slim form of the pins in order to avoid soft-tissue compression and to be able to follow joint kinematics both with an opened and a closed joint capsule. After entry of the individual patient data, the system set-up and initialization of the pointer and trackers takes place. The anatomical landmarks are then defined and the center of the femoral head is ascertained by determination of rotation. The epicondylar axis, the Whiteside line, the femur and the tibial center, the malleolae and the center of the ankle are also determined via single-point digitalization. Defects in the femoral condyles and on the tibial plateau are recorded by means of surface digitalization, in order to exactly define the level of resection and to prevent displacement of the joint line.

The actual pathological situation is calculated from the data and the deformities present preoperatively are shown. The calculation is made using mathematical algorithms. From the relative distances between the individual landmarks during different movements, such as varus/valgus, rotational stress or a.p. shifting, a calculation of the kinematic curve is made.

Navigation of the individual resection blocks is done in part with specially developed instruments or using universal gauges. The advantage of this is not only that the Stryker prosthesis families are supported, but also that the system can be used with other prosthesis types (Figs. 45-1 to 45-4).

The navigation system analyzes the original pathology, not only in relation to the axis, but also in relation to the kinematics at the initial measurement. Intraoperatively, the bone sections can be measured in all freedoms of movement, the surfaces of the bone can be examined after the bone has been prepared, and the intraoperative kinematics after bone resection and soft-tissue balancing are visualized, along with the result after insertion of the original prosthesis and closure of the capsule.

Fig. 45-1. Hardware of the Stryker-Leibinger navigation system (three infrared cameras, localizer, laptop and monitor)