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A new approach to computer-aided spine surgery: fluoroscopy-based surgical navigation

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Abstract A new computer-based navigation system for spinal surgery has been designed. This was achieved by combining intraoperative fluoroscopy-based imaging using conventional C-arm technology with free-hand surgical navigation principles. Modules were developed to automate digital X-ray image registration. This is in contrast to existing computed tomography- (CT) based spinal navigation systems, which require a vertebra-based registration procedure. Cross-referencing of the image intensifier with the surgical object allows the real-time image-interactive navigation of surgical tools based on one single registered X-ray image, with no further image updates. Furthermore, the system allows the acquisition and real-time use of multiple registered images, which provides an advanced multi-directional control (pseudo 3D) during surgical action. Stereotactic instruments and graphical user interfaces for image-interactive transpedicular screw insertion

have been developed. A detailed validation of the system was performed in the laboratory setting and throughout an early clinical trial including eight patients in two spine centers. Based on the resulting data, the new technique promises improved accuracy and safety in open and percutaneous spinal surgery.

Key words Spine · Implant · Pedicle screws · Navigation · Fluoroscopy

Introduction

The technique of spinal fixation relying on transpedicular screws was introduced into clinical practice by Roy-Camille et al. [31, 32]. Since then, transpedicular implant systems have been the focus of increased attention and are widely used for rigid segmental fixation for a wide variety of indications. Despite the many advantages of this technique, the placement of pedicle screws is a difficult pro-

cedure and remains a surgical challenge, in particular for the less experienced surgeon.

To insert a transpedicular screw, an entry point is identified and a spatial orientation is assumed in both the sagittal and transverse plane. In addition, the depth of insertion has to be controlled. A variety of different landmark-based surgical techniques supported by special spinal instruments have been suggested [17, 20, 30]. However, previous studies have shown a continuously significant rate of incorrect placement of transpedicular screws

in vitro and in vivo for thoracic, thoracolumbar, and lumbar procedures, ranging from 10 to 41% [7, 10, 16, 34, 38, 40].

Mechanical drill guides have been suggested by a few authors to reduce the risk of pedicle and vertebral cortex perforation [15, 41]. However, doubts regarding their application accuracy and reliability have prevented wide clinical application of these devices.

Due to the limitations of landmark-based techniques, intensive use is made of digital X-ray fluoroscopy, using so-called C-arm systems. Steinmann et al. [37] found a significantly reduced misplacement rate when combining image intensification with the use of a new translucent drill. However, there are a variety of disadvantages of this technique:

1. X-ray fluoroscopy involves considerable radiation exposure to the patient as well as the surgical staff [29, 35].
2. It cannot be applied during the entire screw insertion procedure due to possible spatial conflicts between the C-arm frame, the surgeon, and the surgical instruments.
3. The image-interactive tool guidance may be misleading due to distortions of the digital X-ray images [2], and
4. Using a single fluoroscopy unit in constant mode, only one surgical view can be controlled.

In the past few years, CT-based computer-aided spinal navigation systems have been introduced [19, 24–26]. These techniques require preoperative acquisition of a CT data set, providing for the first time a direct link between the preoperative plan and its intraoperative surgical execution. As a result, significantly improved misplacement rates have been reported in the literature [1, 8, 18, 22, 33]. Despite these convincing early results, there has been lack of widespread enthusiasm for CT-based spinal navigation systems. Current criticism focuses on the limited medical benefit for lumbar cases with relatively normal morphology, the costs of additional tomographic image data, and the additional time spent intraoperatively for the vertebra-based registration procedure.

Based on our experience with standard CT-based navigation systems for orthopedic applications (see [23] and the literature cited therein) we propose a new computer-based technique for spinal surgery. It combines intraoperative fluoroscopy-based imaging using widely available C-arm technology with modern surgical freehand navigation. The goals set for this new computer-based technique are:

1. Integration of digital X-ray fluoroscopy into an existing navigation concept
2. Automatic image registration and distortion correction of the images
3. Development of surgical tools and appropriate graphical user interfaces for image-interactive transpedicular screw insertion
4. Development of referencing techniques to significantly reduce radiation exposure

5. Evaluation of the system's performance in a laboratory setting, and
6. Introduction of the system into the operating theatre

Materials and methods

Surgical system and procedures

Stereotactic concept

The concept of the proposed new surgical system follows the stereotactic principles originally established by Clarke and Horsley [6] early in the last century, which have recently been adapted to the needs of modern image-guided surgery by an expert group [36]. It involves three basic components:

1. The therapeutic or surgical object, here the vertebral anatomy to be operated on.
2. An associated virtual object, usually provided by medical imaging, and
3. A navigator to image-interactively approach the surgical object and perform surgical interventions on it. Mathematically, this requires real-time transformation of the components' rigid coordinate spaces [19, 25].

In the present work, the virtual object is represented by so-called registered digital X-ray images provided by the integration of standard fluoroscopy units into the surgical navigation. This allows the real-time visualization of a surgical tool in one or more separately acquired C-arm images, which is equivalent to the representation of the tool in fluoroscopic images when using constant C-arm control.

Fig. 1 Instrumentation for X-ray fluoroscopy-based surgical navigation (from left to right): (1) Strober box with sockets to connect up to 12 instruments equipped with light emitting diodes (LEDs) to the optoelectronic camera. (2) Virtual keyboard (for use with CT-based system only) allowing remote control of the software without a system engineer in place. (3) Accuracy checking instrument. (4) Gravity base to detect spatial orientation of the C-arm. (5) Calibration unit used in conjunction with the following three instruments: (6) pointer for manual digitization of points and checking of matching accuracy, (7) pedicle probe, and (8) pedicle awl. Both pedicle instruments are modifications of the standard USS tools (Stratec Medical, Oberdorf, Switzerland). (9) Dynamic reference base to establish a local coordinate system on the vertebra to be operated on

Fig. 2 System setup with the main components and their associated local coordinate systems (COSs). *Top left*: The C-arm and the Image Intensifier COS (II-COS). *Top right*: Example of one surgical instrument and its local Tool-COS (T-COS). *Bottom left*: The patient, representing the Surgical Object (SO-COS). Those three local COSs are three dimensional and are defined by four LEDs each. *Bottom right*: The C-arm Image as displayed on the monitor (CI-COS). Note, that this is a two-dimensional coordinate system

System components

An optoelectronic navigator (Optotrak 3020, Northern Digital, Waterloo, Ontario, Canada) mounted onto a movable camera stand was used to track the 6D positions, i.e., translations and rotations of (1) the surgical object, (2) all surgical tools (see Fig. 1), and (3) the image intensifier of the C-arm (see Fig. 4). For this purpose, marker carriers holding four or more infrared-light-emitting diodes (LEDs) were attached to these components. Every set of LEDs defines a local coordinate system (COS). Coordinate transformations between these systems can be performed by using rigid body transformation data provided by the position sensor. A Sun ULTRA 1 workstation (Sun Microsystems, Schwerzenbach, Switzerland) was connected to the standard video output of the C-arm using an off-the-shelf video framegrabber board, SLIC Video (Osprey Systems, Cary, N.C., USA). The workstation communicates with the navigator through custom software and associated client/server architecture. The system setup is schematically shown in Fig. 2.

Image registration

For standard CT-based surgical navigation systems, an intraoperative procedure, termed registration, is required [5, 19, 25]. It involves the identification of associated points or clouds of points on both the surgical and the virtual object, followed by a mathematical transformation between their 3D coordinate spaces (3D to 3D). In contrast, for fluoroscopy-based surgical navigation, images are acquired intraoperatively and are registered by simultaneously tracking the surgical object and the image intensifier with the optoelectronic camera. This requires in addition a transformation between the 3D Image Intensifier coordinate system II-COS and the 2D C-arm Image coordinate system CI-COS (3D to 2D).

For this, an extrinsic calibration of the fluoroscope had to be performed to determine the X-ray projection parameters. Let V represent the tip of a surgical tool (see Figs. 2, 3). Since the tool is assumed to be a rigid body, the coordinates of V with respect to the Tool coordinate system T-COS remain constant. To represent the

Fig. 3 Linear cone beam projection model as used for C-arm calibration. The X-ray initiates at location R and projects a point V representing a tool tip onto the C-arm image plane as V' . The point where the 'X-ray axis' pierces the image plane is defined by Φ

tip with respect to the CI-COS, V has to be transformed from the T-COS into the CI-COS. Using transformation data provided by the optical navigator, V can first be transformed into the Surgical Object coordinate system SO-COS and then into II-COS.

C-arm calibration

The final 3D to 2D transformation from the II-COS to the CI-COS involves simulation of the actual X-ray projection. It is based on a linear cone beam projection model, as shown in Fig. 3. Here, R represents the center of the X-ray source with respect to the II-COS, and the orientation of the image plane is described by two vectors η and ξ , which point along increasing row (x -) and column (y -) coordinates of the digital C-arm image.

The projection parameters R , η , ξ , and ϕ , which are assumed to be constant for a specific C-arm, have to be acquired in a preoperational calibration procedure [14]. In this study, a calibration plate was used, which holds 37 spherical metal markers placed copla-

Fig. 4 Ring with eight LEDs mounted onto the image intensifier to establish the II-COS. The LEDs are arranged in such a way that at least four of them are visible to the camera for any orientation of the C-arm. *On top*: Calibration plate with 37 spherical metal markers

Fig. 5 In vitro image-interactive navigation. In two previously acquired C-arm images, the current location of one pedicle instrument is displayed. *Left:* right oblique view with the tool's axis shown as a black circle in the center of a cross-hair. *Right:* Lateral view. The instrument is represented as a black line with a cross-hair identifying the tool's tip. A dotted line indicates the trajectory that the instrument is about to follow

Fig. 6 In vitro pedicle canal preparation. A human specimen with the dorsolateral musculature intact is mounted into the testing setup. The pedicle awl is about to penetrate the left pedicle of L4. The dynamic reference base is attached to the L4 spinous process

narly in a regular grid (see Fig. 4). It was imaged at two different distances from the image intensifier. The calibration plate was additionally equipped with LEDs to track its location in space. From this, the 3D location of the center of each marker in the II-COS can be computed. The 2D positions of the projections of the markers in the CI-COS are obtained automatically by custom image analysis

software. Then the projection parameters can be calculated using an error minimizing algorithm [9, 13, 14, 21].

Initial experience with the instrumented fluoroscope indicated that the overall accuracy was affected when the C-arm was moved into certain positions after the external calibration. This was particularly noted when the arm was turned from one position to the opposite one. Careful analysis revealed that these errors were caused by deformations of the C-shaped frame of the fluoroscope, resulting in motion of the X-ray source relative to the image intensifier. The range of deformation, which was measured to be up to several millimeters, was found to be significantly different for different types of fluoroscopes. Two solutions were proposed and applied throughout this work:

1. Real-time control of the deformation by mounting another set of LEDs on the X-ray source of the C-arm, and
2. Compensation of the deformation using a correction function determined by means of a complex spatial calibration of the fluoroscope

The first solution was used during laboratory evaluation and in vitro testing of the system, while the second one was applied in the operating room (OR) setting. In addition, to provide redundant safety in the OR setting, a special accuracy checking instrument (see Fig. 1) was designed to verify every image acquired. A detailed description of both correction methods will be presented in a separate paper.

It is known from daily surgical routine that today's fluoroscopes show prominent distortions in their digital images. The main source is the spherical shape of the input phosphor of the image intensifier, which results in stationary pincushion distortions. A smaller amount is caused by external magnetic fields in the operating room, and can vary within every image [12]. While these effects may be acceptable for the standard use of the fluoroscope, they will significantly influence the application accuracy during the real-time C-arm image-interactive guidance of a surgical tool, and have to be compensated. For this intrinsic calibration, the aforementioned regular, coplanar grid of spherical markers was imaged once preoperatively in a position nearly parallel to the image plane of the image intensifier. Projections of the markers represent local values of the distortion. Nominal values for an undistorted image were calculated by transforming the 3D positions of the spheres into the CI-COS. A vector field that contains the correction information for each pixel of the C-arm image was determined using a bilinear interpolation algorithm [13, 14]. It was then applied to every image acquired, to compensate for its distortions.

Surgical procedure

For the placement of transpedicular screws, several views of the vertebra, e.g., one lateral and two oblique fluoroscopic images, are obtained and automatically loaded into the workstation. Custom graphical user interfaces allow for further image manipulations

Table 1 Clinical data of the three patients who were operated during clinical evaluation

Pa- tient	Sex	Age	Diagnosis	Level	No. of screws
1	Male	38	Spinal stenosis L1–L3	L1–L2	4
2	Female	17	Idiopathic thoracic scoliosis	T11–L1	3
3	Male	57	Spinal stenosis	L1–L2	4

such as pan, rotate, flip, and zoom, as well as image-interactive navigation of the surgical tools (see Fig. 5). The tip of the pedicle awl, which is used to make the indent hole, must be positioned in the middle of the pedicle oval seen on the corresponding oblique image and have its axis aligned with the pedicle axis. For proper

alignment, the linear graphical tool representation on screen must point towards the center of the pedicle oval. The cranio-caudal angulation of the tool is controlled on the lateral image of the vertebra and should be parallel to the end plate. After the indentation of the screw trajectory, the screw canal is prepared using the pedicle probe under real-time computer guidance on the basis of the previously acquired images. No further radiation is needed. Finally, the pedicle screw may be delivered with a standard screwdriver or a special stereotactic screwdriver (Medivision, Oberdorf, Switzerland).

System evaluation

Laboratory evaluation

The technical feasibility of the newly designed fluoroscopy-based navigation system was first checked in the laboratory environment.

Fig. 7 A, B Intraoperative acquisition of registered X-ray images. **A** Oblique image with LEDs on the image intensifier, dynamic reference base, and gravity base (*in front*) in view. **B** Lateral image

Fig. 8 Clinical evaluation: fluoroscopy-based navigation with the instrument's tip at the pedicle isthmus

Fig.9 Clinical evaluation (note that the instrument position is the same as in Fig. 8). Display of the CT-based system used for checking and correction. The first seven images show CT sections reconstructed perpendicularly to the tool's axis. Images 8 and 9 are reconstructions along its axis

For this, four complete plastic lumbar spine models L1-L5 (Synbone AG, Malans, Switzerland) were used. Forty pedicle screws were inserted, 20 simulating an open and 20 a percutaneous surgical approach. Modeling of the percutaneous technique was achieved by wrapping the plastic spines in a non-translucent foam material. For the acquisition of the registered digital X-ray images, a fluoroscopy unit, BV 21 (Philips, Hamburg, Germany), was used. The final result of the screw navigation was assessed by gross visual inspection of the instrumented pedicles and the vertebral body at each spinal level.

In vitro testing

Three human lumbar spines L1-L5 were removed within 24 h of death. Lateral and anteroposterior (AP) plain radiographs were obtained to rule out extreme bony abnormalities. The specimens were frozen at -20°C and thawed before testing. As shown in Fig. 6, the dorsolateral soft tissues were kept, to avoid direct visual control of the posterior elements, thus simulating a percutaneous surgical approach. The same fluoroscopy unit, BV 21, was used as for the laboratory evaluation. In each specimen, ten pilot holes were drilled under image guidance using the stereotactic pedicle instruments, totaling 30 screw preparations. After canal preparation with the stereotactic pedicle probe, all pedicles had a 4.0-mm aluminum cylinder inserted to increase their visibility on the radiographs. The vertebrae were surgically separated from each other and any soft tissue cleaned off. Using a diamond band saw (EXACT, Hamburg, Germany), each pedicle was carefully sectioned perpendicular to the screw axis, with a slice thickness of about 2.0 mm. All histological sections were X-rayed and classified [1]. To simulate a standard pedicle screw, a circle with a diameter of 6.0 mm was concentrically projected onto the shape of the metal cylinder in each histological section imaged.

Fig.10 Result of in vitro testing. Pedicles of one specimen, L1-L5, are cut into four to five histological sections each. The inserted aluminum cylinder demonstrates the accuracy of the prepared pedicle canals

Table 2 Results from in vitro testing. Assessment of histological sections was based on a 6.0-mm screw template

Level	Slices	Ideal	Cortex touched	Cortex engaged	Cortex perforated
L1	26	18	6	2	0
L2	24	18	5	1	0
L3	24	20	3	1	0
L4	24	22	2	0	0
L5	24	23	1	0	0
Σ	122	101 (82.8%)	17 (14%)	4 (3.2%)	0

Clinical evaluation

The system was initially clinically evaluated at the ORTON Orthopedic Hospital in Helsinki (three patients) where a fluoroscopy unit, BV 25 Gold (Philips, Hamburg, Germany), is available. The unit was equipped with two rings holding LEDs, and underwent the calibration procedure described earlier. A special software module allowed the new fluoroscopy-based technique and the CT-based SurgiGATE Spine system (Medivision, Oberdorf, Switzerland) to run on the same workstation simultaneously. Three patients, two male and one female, were chosen for this study, diagnosed with lumbar spinal stenosis and idiopathic thoraco-lumbar scoliosis. Diagnostic CT scans were available on film and digitally on tape. Open insertion of 11 pedicle screws (6.0 mm in diameter) was planned at levels ranging from T11 to L2. Patient data are summarized in Table 1.

After midline approach, the dynamic reference base was attached to the spinal process of the respective vertebrae. Next, a matching procedure was performed, which was needed in order to navigate with the CT-based system. The fluoroscope was positioned over the spine level to be operated on, and registered X-ray images were acquired (see Fig. 7) as described earlier. This procedure was repeated for each spine level.

With the help of the graphical user interface of the fluoroscopy-based system, the entry point of the screw canal was adjusted with the stereotactic pedicle awl. Its validity was then checked, switching to the real-time mode of the CT-based system. Error values in medio-lateral and supero-inferior directions were measured. If the

malpositioning of the pedicle awl in the CT slices was found to be 2.0 mm or greater in any direction, the instrument was corrected accordingly. The screw canal orientation was then adjusted with the fluoroscopy-based system using the stereotactic pedicle probe. Again, the position of the probe was verified and corrected with the CT-based system if necessary. During canal preparation, this procedure was repeated at the location of the pedicle isthmus and near the anterior border of the vertebral body (see Figs. 8,9). Post-operatively, CT scans were acquired as reference.

Before the second part of the clinical evaluation, which was performed at the University Hospital in Bern, the system was systematically improved with special focus on an easy to use man-machine interface. Placement of pedicle screws in five patients undergoing lumbo-sacral stabilization for degenerative disease was done using the new technique in combination with the available Ziehm fluoroscope (Ziehm GmbH, Nuremberg, Germany). Intraoperative procedures were similar to the technique described above; however, as preoperative CT data were not available in these cases, a CT-based intraoperative navigation control was not performed.

Results

Laboratory evaluation

A first prototype of the fluoroscopy-based navigation system was used during the early laboratory evaluation. Special attention was devoted to the handling of the system and the functionality of the graphical user interface. The optimal position for the optoelectronic camera was found to be at the foot of the patient, about 2.2 m away from the image intensifier. Acquisition of registered fluoroscopic images had to be performed with the C-arm facing the camera laterally. However, the circumferential design of the marker carrier provided sufficient cross-referencing, with at least four markers visible for the camera at any required C-arm position. The dynamic reference base was fixed to the spinal process, with its LEDs facing caudally. User interface of the fluoroscopy-based system proved to

Table 3 Overall results from clinical evaluation, summarizing the insertion of 11 pedicle screws under fluoroscopy-based image-interactive navigation

Patient	Level/ side	Entry point acceptance		Error direction				Screw channel acceptance		Error direction			
		Yes	No	Med.	Lat.	Sup.	Inf.	Yes	No	Med.	Lat.	Sup.	Inf.
1	L2/R	x	—	—	—	—	—	x	—	—	—	—	—
1	L2/L	—	x	2 mm	—	2 mm	—	—	x	x	—	—	—
1	L1/R	x	—	—	—	—	—	x	—	—	—	—	—
1	L1/L	x	—	—	—	—	—	x	—	—	—	—	—
2	T11/L	x	—	—	—	—	—	x	—	—	—	—	—
2	L1/R	x	—	—	—	—	—	x	—	—	—	—	—
2	L1/L	—	x	2 mm	—	—	—	x	—	—	—	—	—
3	L1/R	x	—	—	—	—	—	x	—	—	—	—	—
3	L1/L	x	—	—	—	—	—	x	—	—	—	—	—
3	L2/R	x	—	—	—	—	—	x	—	—	—	—	—
3	L2/L	x	—	—	—	—	—	x	—	—	—	—	—

be self-explanatory and easy to use, even for relatively inexperienced spinal surgeons. Only minor changes had to be made to it before application of the system for insertion of pedicle screws into plastic vertebrae.

Gross visual inspection of the plastic spines from both groups, i.e., those operated on using an open as well as a simulated percutaneous approach, revealed all pedicle screws placed within the pedicles. Neither pedicles nor vertebral body cortices had been perforated. It should, however, be noted that the overall quality of the fluoroscopic images, particularly available resolution and contrast, were found to be much better than for the *in vitro* setting and those observed beforehand in the operating theatre.

In vitro testing

A total of 122 histological sections from 30 pedicles were analyzed. A typical X-ray image data set for a complete lumbar spine, L1-L5, is shown in Fig. 10. With the help of the 6.0-mm screw template, accuracy data were determined and classified [25]. Positioning of the aluminum cylinder geometrically centered within the pedicle was considered as ideal. This was found in 101 pedicles (82.8%). A simulated screw that touched the pedicle cortex at one or more locations without cortex engagement was classified as “cortex touched”. Seventeen (14%) of the insertions fell into this category. Histological analysis of the sectioned pedicle slices revealed no cortex perforation. Cortex engagement, which was defined as engagement of the pedicle cortex by up to one half of its thickness at the engagement location, was registered on four slices (3.2%). A tendency for higher incidence of cortex involvement at higher lumbar levels was observed. Experimental data of the *in vitro* testing are summarized in Table 2.

Clinical evaluation

C-arm positioning in the OR setting was performed with extreme care, to avoid situations in which the chosen global correction technique would have failed to compensate for C-arm deformation. The accuracy checking instrument was used for further safety. By this, a clinical application accuracy of the system for each acquired X-ray fluoroscopic image was found to be better than 1.5 mm (max. error). The graphical user interface, which had been optimized during the laboratory evaluation, seemed to be convenient for the surgeons, who had extensive experience with the CT-based SurgiGATE system. They critically remarked on the need for a technician to run the system, and virtual keyboard control by the surgeon was suggested [24–26].

In the early clinical trial (Helsinki), the location of the entry points as suggested by the fluoroscopy-based sys-

Fig. 11 A–C Results from the clinical evaluation. **A** Postoperative CT scan showing well-centered pedicle screws. The reconstructed sections on the bottom represent orthogonal cuts along the screw axes: **B** left pedicles, **C** right pedicles)

tem was accepted in 9 out of 11 cases. The screw trajectories were found to be correct in 10 out of 11 cases. The entry point of one screw at level L2 had to be shifted 2.0 mm cranio-medially. Due to the limited quality of one of the registered images, the screw canal was prepared using the CT-based system. The entry point of the second screw at level L1 had to be shifted 2.0 mm medially. In this case, the final trajectory was established using the fluoroscopy-based technique after correction of the entry point. The overall results are summarized in Table 3.

The postoperative CT scans showed full agreement with data from the CT-based system regarding the position of all pedicle screws. No cortex perforations were detected. Due to the metal artefacts, a refined classification according to the *in vitro* results was not feasible.

In the second clinical trial (Bern), the system worked in all cases and was used to navigate the placement of 25 screws. Initially, the image quality provided by the C-arm, especially following data transfer into the workstation, was found to be insufficient for accurate navigation, particularly in AP and oblique views. For security reasons, conventional additional C-arm shots were performed during pedicle canal preparation. Obese patients were particularly difficult to image at the lumbo-sacral junction. During the trial, image quality was improved by adjusting contrasts and use of a different computer video board. An advanced graphical user interface and virtual keyboard control implemented after the Helsinki trial allowed easy handling of the system.

Discussion

This is the first comprehensive investigation of the use of registered X-ray fluoroscopy in spinal surgery. The presented solution is based on a combination of widely available C-arm technology with modern freehand surgical navigation. Since surgeons are familiar with these kind of images, the interpretation of anatomical features is straightforward.

Continuing early stereotaxy work from the pre-CT era, the concept of registered digital X-ray images was reintroduced within the framework of modern medical robotics and computer-assisted surgery. Pioneering work has been done by Lavallée and co-workers, in using registered images for different surgical areas (see [5] and literature cited therein). For spinal surgery and spinal kinematic analysis, they developed a fluoroscopy-based 3D/2D matching technique via edge detection in digital X-rays [11, 12]. Weese et al. compared pseudo projections from CT data to fluoroscopic images for surgical registration [39]. Potamianos et al. described in two successive papers [27, 28] basic concepts of intraoperative image guidance for key-hole surgery, such as percutaneous renal procedures, involving intrinsic and external calibration of video-fluoroscopy. However, with their passive articulated arm sys-

tem, dynamic referencing of the patient was not possible. A similar approach to X-ray camera calibration incorporating advanced computer vision techniques was suggested by Brack et al. [3]. Brandt et al. proposed a C-arm based planning and robotic execution system for total hip replacement [4]. However, no clinical data can be gained from any of those studies, as the systems have not been transferred to the operating theatre, nor have they been used for the image-interactive control of surgical instruments.

The proposed system allows automatic registration of the acquired fluoroscopic images by means of internal and external calibration, and should have provided submillimeter accuracy, as has been found by other authors [27, 39]. However, stress-dependent C-arm deformations were found to play a crucial role. As a solution, simultaneous tracking of the X-ray source and the amplifier was successfully applied during the laboratory work. Intraoperatively, however, the line of sight for the amplifier and the X-ray source LEDs cannot be assured during the complete procedure. Therefore, a method for global correction was developed and used clinically in combination with an accuracy checking instrument. Current work is devoted to the optimization of this technique.

As in existing CT-based spinal navigation systems [8, 18, 25, 26, 33], cross-referencing including the image intensifier was introduced. In this way, the use of the new computer-based system with only one registered image is equivalent to the standard use of an image intensifier in constant mode. Moreover, acquiring n registered images from different directions and navigating in these images interactively would be equivalent to the simultaneous use of n C-arms in constant mode. A further advantage of the new system is that the C-arm can be removed from the surgical situs after image acquisition. Consequently, radiation exposure to the patient and the surgical staff can be reduced significantly for the majority of spinal interventions.

We found that the results of the *in vitro* study achieved with the fluoroscopy-based system compare well with our former data derived from CT-based systems [33]. The overall application accuracy allowed the positioning of all 30 pedicle screws without cortex perforation. The pedicle cortex was touched or engaged in 17.2% of the slices, whereas in the CT-based system 9% of the slices were affected. An ideal positioning of the transpedicular screw was achieved in 82.8% as compared to 91% with the CT system. These differences do not seem to have any clinical relevance, since most of the cortex engagements were found in smaller pedicles at higher lumbar levels, where screws with a 6.0 mm diameter are not advocated.

The reported clinical trials were the first use of the prototype system in an OR setting and the concept could be proofed. However, due to the relatively small number of patients, a final assessment and comprehensive comparison with CT-based systems is not yet possible. Therefore,

additional randomized prospective studies are required. A further improvement should concern the time used intra-operatively for proper C-arm positioning over the spinal segments. The goal would be to outperform existing CT-based systems significantly regarding the duration of surgery. This should be achieved soon by further technical changes and the usually steep learning curve experienced during the hospital integration of new computer-based surgical instruments.

Inherent limitations of the new technology may arise from current limitations of fluoroscopic imaging, such as brightness and contrast of the images, as well as the fact that axial cuts cannot be provided to the surgeon. However, recent trends in C-arm technology are quite promising and may further close the gap with plain radiographs on the one hand and CT scans on the other.

As with every new surgical device, fluoroscopy-based computerized navigation has its specific indications. Based on our early experience, we would advocate its use

for open and percutaneous thoraco-lumbar approaches in cases with relatively normal spinal morphology. For patients diagnosed with structural scoliosis, spinal tumors, anatomical spinal abnormalities as well as spinal revisions, where there is critical need for the axial projections, CT-based navigation systems would be preferable.

The proposed technology is not limited to spinal applications. It will provide added value to existing medical equipment in general. With appropriate stereotactic surgical instruments and graphical user interfaces, it could give significant medical benefit to other areas of orthopedic surgery as well.

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