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Clinical Study for Registration-Free 3D-Navigation with the SIREMOBIL Iso-C^{3D} Mobile C-Arm

P. A. Grützner¹, A. Hebecker³, H. Waelti², B. Vock¹, L.-P. Nolte², A. Wentzensen¹

¹*Berufsgenossenschaftliche Unfallklinik Ludwigshafen*

Unfallchirurgische Klinik an der Universität Heidelberg, Ludwigshafen, Germany

²*M.E. Müller Institut für Biomechanik, Universität Bern, Bern, Switzerland*

³*Siemens AG, Medical Solutions, Erlangen, Germany*

Keywords

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 - SIREMOBIL[®] Iso-C^{3D} • C-arm
 - navigation • pedicle screw • registration-free
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Introduction

Imaging with a mobile C-arm is standard procedure in orthopedic emergency OR's and indispensable for performing osteosyntheses and other reconstructive surgical interventions on the locomotorium. Limitations to intra-operative two-dimensional imaging with such C-arms are often encountered, because complex, three-dimensional bone structures can only be inadequately imaged. In these cases, there remains uncertainty with regard to the correct reconstruction of bone structures and correct position of the osteosynthesis material.

CT-based surgical navigation made it possible to achieve a link between the preoperatively obtained three-dimensional image data and the intra-operative instrument position. The surgeon sees his instrument in a virtual medical image in real time. This is achieved by fitting the instrument with infrared light-emitting diodes (active markers) or reflective spheres (passive markers) and by capturing it with a camera. Transferring the instrument coordinates to the data set, and thus to the patient anatomy, requires a so-called registration process, frequently performed manually by approaching landmarks on the patient with the instrument. Since changes in the anatomy cannot be detected intra-operatively, applications for CT-based navigation are limited [1-4].

During navigation in 2D C-arm data, the so-called virtual fluoroscopy, both the surgical instrument and the C-arm are fitted with markers and tracked by the

navigation system camera. Up to four image converter planes can be made available simultaneously in the OR using a kind of virtual continuous fluoroscopy. The C-arm calibration necessary to this end takes place either while recording the image (online calibration) or once only in an offline process for all C-arm positions, to ensure automatic intra-operative registration in both cases. If there are changes in the anatomy, new images can easily be recorded regardless of the C-arm or patient position, and transferred into the navigation system. Imaging is initially limited to the two-dimensional information from the C-arm. For this reason, there are limitations with respect to complex anatomical structures, such as the spine, pelvis or joints [5-7]. For example, the vertebral canal cannot be reliably imaged using conventional methods. Image quality in C-arm-based 2D navigation is diminished especially at the thoracic spine. In addition, correctly adjusting the C-arm may become a challenge for the surgeon and nursing personnel.

Navigation while using large systems under OR conditions (CT, MRI) has thus far been the province of only a few hospitals and is associated with an enormous expenditure of financial and personnel resources. In light of these limitations, area-wide use would not appear to be a realistic option, even at centers that perform spinal operations. Logistical and technical preconditions here also limit use for emergency indications and additional ventral surgery on the spine.

The mobile SIREMOBIL Iso-C^{3D} 3D C-arm (Siemens AG, Medical Solutions, Erlangen) is one of the first devices that permits the intra-operative three-dimensional representation of bone structures without any additional expenditure. This enables direct process and result control of reconstructive surgery, so that conclusions from imaging can already be drawn intra-operatively [3-6, 12, 13, 19].

Intra-operative 3D imaging with the SIREMOBIL Iso-C^{3D} based on the SIREMOBIL Iso-C, the first mobile C-arm with true isocentricity and 190° orbital movement. In addition to conventional 2D imaging, a defined number of fluoroscopic images can be recorded at fixed angular steps in the 3D mode during motorized, continuous 190° orbital rotation. The 3D workstation in the C-arm monitor trolley simultaneously calculates a high-resolution, isotropic 3D data cube in the isocenter with an edge length of approximately 12 cm. Immediately after the data have been recorded, the surgeon can use this data to allocate any desired MPR slice planes in real time. In addition, the two-dimensional sequential radiographic projections are available as a film sequence.

Linking the SIREMOBIL Iso-C^{3D} to navigation with the integrated NaviLink™ interface (Siemens AG, Medical Solutions, Erlangen) makes it possible to transfer the generated 3D data directly to the linked navigation system in DICOM format, including the spatial coordinates. The advantages of CT-based navigation with three-dimensional representation of bone structures are therefore combined with the advantages of registration-free navigation with intra-operative imaging. The surgical instrument is immediately displayed in the image, i.e., without any complex manual registration procedure. Potential error sources resulting from poor registration are avoided, and new radiographic images can be generated intra-operatively, i.e., proximate in time to the surgical intervention.

During installation of the navigation system, the correlation between the 3D image volume and a special reference point on the C-arm is determined in an offline calibration process. The navigation system camera can localize this reference point, since it is permanently correlated with the active or passive markers of a marker

ring attached to the C-arm. The navigation system camera now intra-operatively detects the reference point position via the marker ring. The navigation system computer therefore immediately recognizes the position and orientation of the 3D data set in the OR from the offline calibration measurements. The position of the surgical instrument also detected by the camera can thus be virtually displayed in a 3D image, automatically and without manual registration [15] (Fig. 1). As a result, the clinical workflow in registration-free 3D navigation can be described as follows:

- 1) The marker ring is attached or already permanently affixed to the image intensifier of the SIREMOBIL Iso-C^{3D}.
- 2) A reference marker, a so-called DRB, is positioned on the patient to compensate for possible relative movements of the patient and navigation camera.
- 3) The navigation system camera is set up in such a way that it captures both the marker ring on the C-arm and the DRB on the patient.
- 4) The SIREMOBIL Iso-C^{3D} is moved to the start position where the coordinates of the marker ring are acquired. The automatic 3D scan is performed.
- 5) After the scan, the 3D image data can be viewed directly on the C-arm monitor trolley.
- 6) The image data and coordinates are transferred directly to the navigation system via the NaviLink interface.
- 7) The C-arm can be removed from the operating table to enable unrestricted patient access.
- 8) The surgeon begins the navigated surgical procedure. As an option, trajectories that provide valuable assistance in complex anatomical situations can be planned in the navigation system.



Fig. 1 Basic diagram of registration-free 3D navigation with the SIREMOBIL Iso-C^{3D}: The C-arm is provided with a marker ring.

The navigation system camera detects the positions of the surgical instrument and C-arm.

In the navigation computer, the instrument is displayed immediately after 3D image acquisition in the 3 MPR plane sections and the SSD of the object.

The reproducibility of the automatic registration and the precision of the overall system were demonstrated in preclinical studies [15]. Using the SurgiGATE® navigation system (Medivision, Oberdorf, Switzerland), we were able to show a system precision of ≤ 1.2 mm at a constant reproducibility. The studies were performed on a calibration phantom and on plastic models of the spine and pelvis that were provided with markers (Synbone, Switzerland).

Since Iso-C^{3D} navigation constitutes a new surgical procedure, the objective of this study was to evaluate the clinical benefit of this technique with respect to precision of screw placement, duration of surgical procedure and surgical fluoroscopy times, in comparison to conventional and other computer-assisted procedures (CT-based navigation and C-arm-based 2D navigation).

Patients and Methods

In January 2002, the Berufsgenossenschaftliche Unfallklinik Ludwigshafen acquired registration-free 3D navigation capability by linking the SIREMOBIL Iso-C^{3D} to the SurgiGATE navigation system. A total of 39 patients who had undergone intra-operative navigation using Iso-C^{3D} data were included in a prospective study from January 2002 until January 2003. Candidates for the study included patients with injuries or degenerative changes to the spine, pelvis and joints. These patients required intra-operative linear surgical action, which in most cases involved screw placement. However, the study also included patients who had undergone drilling procedures to fill cysts in the talus or axial elbow joint determinations.

A complete neurological status, conventional X-ray diagnosis and computed tomography were available preoperatively for all patients. This information was used to classify the injury and determine the surgical indication.

In addition to clinical baseline parameters such as age, sex, weight, fracture classification, OR duration and intra-operative blood loss, the duration of the surgical intervention, fluoroscopy duration and times required for navigation were intra-operatively documented as well. A team instructed and trained in operating the system had to be available. Under this condition, emergency indications involving spinal cord injuries and neurological disorders or those involving high-grade, unstable injuries were included as well. The patients were positioned on a non-metallic carbon table. Registration-free navigation without the need to manually define landmarks made a tissue-sparing preparation possible.

The set of pedicle instrumentations for the spine made up the largest percentage of the entire group, both in terms of patient numbers (24 of 39, or 61.5%) and individual actions (114 of 143, or 79.7%). Our hospital

has the most experience with spinal navigation as compared to other emergency surgery, e. g., on the pelvis or tubular bones. In addition, dorsal instrumentation is a standardized surgical procedure that is readily comparable in varying patient groups. A patient group from our hospital from the period between January 2000 and December 2001 served as comparison group. All patients with dorsal instrumentation on the thoracic and lumbar spine were included. The study protocol was identical to the protocol for patients with Iso-C^{3D} navigation. During this period, 28 patients underwent surgery with C-arm-based 2D navigation, 27 with CT-based navigation and 34 patients in a conventional manner, i. e., assisted by a 2D C-arm.

Navigation then took place according to a scheme derived from the limited scan volume of approx. 12³ cm³ and relative mobility between the individual vertebral bodies, especially in the case of instable spinal injuries. During mono- or bi-segmental instrumentation of the spine, all respective vertebral bodies to be instrumented could be imaged in a scan volume. At least 3 vertebral bodies of the thoracic spine could each be displayed completely in a scan volume. In the case of fusions involving more than two segments, it therefore became necessary to generate a second Iso-C^{3D} scan.

The DRB was secured to the vertebra to be instrumented before the 3D scan for navigation purposes. If another vertebra was to be navigated within the scan volume, the possible relative movement between this referenced vertebra and the vertebra to be instrumented had to be taken into account. In the case of immediately adjacent vertebral bodies without pathological mobility in this segment, the DRB did not have to be converted. If in doubt, the surgeon could check system precision at any time in a so-called verification mode. In this mode, the surgeon checked the instrument position by holding it against a clearly identifiable anatomical structure and evaluating the instrument visualization in the navigation system. Given a significant relative movement between the referenced and non-referenced vertebral body, registration took place with an intermediate step, without recording a new 3D data set. In these cases, previously inserted marker screws, so-called fiducials, or intra-operatively planned anatomical landmarks were used for manual registration, thereby eliminating additional radiation exposure from a second 3D scan of the same vertebral region. In most patients, dorsal instrumentation was followed by either a unilateral or bilateral ventral fusion. The OR and fluoroscopy times for these additional measures were not included in the study to improve the comparability of results.

The neurological status was determined and computed tomography performed postoperatively in all patients. The postoperative course was monitored for complications, such as postoperative bleeding and infection.



Fig. 2
 Vertebral fracture during Bekhterev's spondylitis (spondylitis ankylopoietica).
 The entire spine is completely ankylosed. The pedicles are difficult to delineate with conventional x-rays.



Fig. 3
 Intra-operative positioning of the SIREMOBIL Iso-C^{3D} for recording the 3D data set.
 The DRB is applied to the processus spinosus of a vertebra.

The implant position was postoperatively evaluated by an independent radiologist. On the spine, cases where the pedicle wall was exceeded by more than the pedicle screw thread were interpreted as a false position. Screw threads that just cut into the pedicle wall still counted as correct position. This corresponds to a perforation by the pedicle screw by more than 2 mm. This classification is used in most reference studies, since, given a very narrow pedicle diameter, the thread routinely cuts into the pedicle wall, even with an ideal screw position [16, 17].

Results

Overall Group

39 patients (22 male, 17 female) who intra-operatively underwent successful navigation in Iso-C^{3D} images were included in the study. A total of 143 drilling procedures were performed in the 39 patients. Pedicle instrumentations took place in 24 of the 39 patients (Fig. 2-6). 8 patients underwent screw placements on the pelvic ring (IS joint bolting (Fig. 7), bolting of anterior column, acetabulumosteosynthesis). 4 patients underwent a retrograde perforation of an osteochondritis dissecans on the talus and filling with autologous spongiosa (Fig. 8-10), while 1 patient underwent screw osteosynthesis on the neck of the femur, and 2 patients underwent placement of an immobilizer on the elbow joint.

7 hospital surgeons were involved in the study. The SIREMOBIL Iso-C^{3D} and SurgiGATE navigation system were always operated by the same person. Altogether 48 data sets were intra-operatively generated with the SIREMOBIL Iso-C^{3D} (maximum 2 per operation) and loaded into the navigation system. Only one 3D scan was recorded for navigation on the extremities (talus, elbow and hip joint). Two 3D data sets were generated in two cases for the pelvis, and seven cases for the spine. Another 18 scans (4 talus, 4 pelvis, 10 spine) were recorded for a direct, postoperative control of the implant position in the OR. A postoperative CT was performed in patients with spinal instrumentations or pelvic osteosyntheses who underwent no direct, postoperative control scan with the SIREMOBIL Iso-C^{3D}. All screws were correctly positioned in the postoperative controls of the pelvic group. The extremities revealed no incorrectly positioned screws, drilled canals or axes of motion. One pedicle screw was found to be 2 mm out of position in the spinal group. All other screws were either precisely centered in the pedicle, or the pedicle wall was at most touched by the screw thread. None of the pedicle screws perforated the ventral vertebral boundary. No infections or neurological complications were found postoperatively.

The average fluoroscopy time for recording the 3D scans and performing the 2D control measures 0.98 min for patients who underwent cyst drilling on the talus, 1.25 min for the spinal instrumentations, and 1.38 min

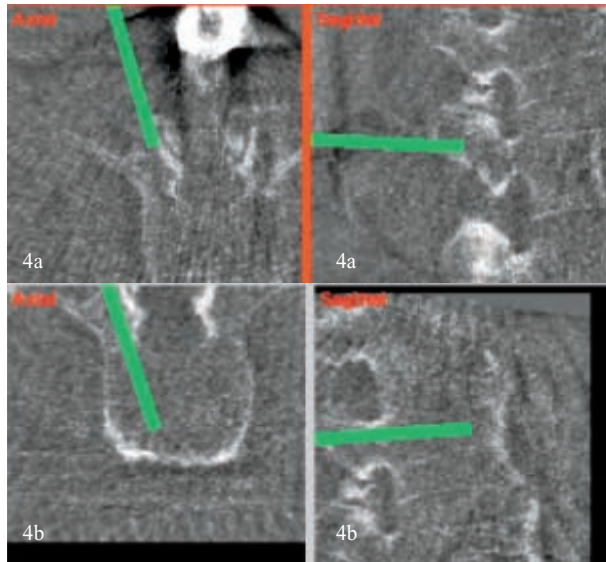


Fig. 4a , b
 Display of image data on the navigation system monitor with the current position of pedicle screw
 a) during insertion into the pedicle and
 b) after placement.

for the pelvic group (Table 1). The wide range in the spinal group is striking. This can be explained by the necessity of occasionally performing several more scans, and by the frequently difficult C-arm adjustment for the 2D position control of the pedicles. This contrasts with the narrow range for cyst drillings. All operations were here performed according to the same protocol.

Spinal Study

In the Iso-C^{3D} group, navigation was used to insert 114 pedicle screws (2 HWS, 60 BWS, 52 LWS) in 24 patients. Intra-operatively inserted marker screws (fiducials) were used for registration in 16 screws (8 vertebrae), while registration was automatic for the remaining screws.

Spinal instrumentations took place over 5 segments in one case, 4 segments in 2 cases, each with 8 pedicle screws, over 3 segments in 6 cases, 2 segments in 6 cases and monosegmentally in 2 cases. In patients with mono- and bi-segmental fusion, the entire instrumentation could be performed in the same 3D data set. To this end, the non-referenced vertebral body was provided with three marker screws and manually registered while recording the data set. In the other patients, the vertebral bodies were recorded proximal and distal to the



Fig. 5
 Complete instrumentation of 2 respective vertebrae, above and below the fracture.
 Instrumentation took place in two separately recorded SIREMOBIL Iso-C^{3D} data sets. The spondylitis made anatomical landmarks that are important for conventional instrumentation difficult to identify.

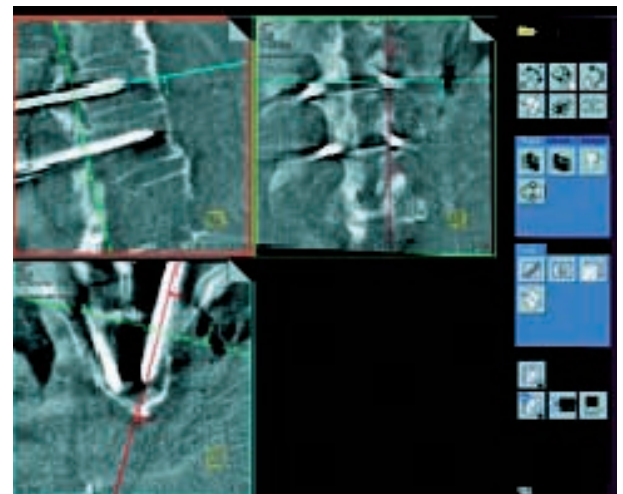


Fig. 6
 The correct position of pedicle screws and the fracture position could be evaluated in the post-operative Iso-C^{3D} scan.
 A postoperative CT was therefore no longer necessary for evaluation.



Fig. 7
 Depiction of the bolting of the sacroiliac joint on the pelvis. The screw position intra-operatively planned in the navigation system is shown in red, the actual position of the drill in green.

The length of the drilling procedure is concurrently shown. The quality of the Iso-C^{3D} data is excellent for reposition evaluation and navigation.

instability in two separate 3D data sets, which were used in conjunction with automatic registration for navigation purposes.

A comparison of operating times in the different vertebral groups reveals virtually no difference in average operating time, which measures 102 min during the Iso-C^{3D} navigation (Table 2). The differences in operating time variability are conspicuous, however. Iso-C^{3D} navigation here exhibits the narrowest range. This indicates a highly standardized OR process and an ability to find the correct screw placement without any additional fluoroscopy time.

Major differences in the individual groups are encountered for the intra-operative fluoroscopy times (Table 3). The fluoroscopy time has the lowest average (1.25 min) in the Iso-C^{3D} group, followed by C-arm-based navigation (3.0 min), and ending with the conventional method (4.18 min). Iso-C^{3D} navigation here also exhibits the narrowest range, which again allows us to conclude that the procedure is highly standardized.

No postoperative infection and no deterioration in the initial neurological situation were discovered in the spinal group. Pedicle instrumentation resulted in no neurological complications. No injured or irritated nerve roots were ever observed. In comparison to the control groups, Iso-C^{3D} navigation made it possible to

distinctly improve precision (Table 4). While the rate of incorrect placements in conventional technology still measured 10.3%, it was reduced to 4.5% in CT-based navigation, and 2.8% in C-arm-based 2D navigation. Iso-C^{3D} navigation cut the rate of incorrect placements to 0.9%.

Discussion

This prospective study is the first to show the clinical application of navigation in three-dimensional data sets from the SIREMOBIL Iso-C^{3D} with automatic registration for the spine, pelvis and extremities.

At 24 of 39 patients (61.5%) and 114 of 143 drilling procedures (79.7%), spinal instrumentation patients represent the largest study group. The literature describes a relatively high rate of incorrect placements (up to 40%) in the conventional technique [18, 19]. It is precisely in the case of the spine that an incorrect placement of implants can result in significant, long-term complications with regard to the stability and injury of vascular and neural structures. Therefore, the conventional technique requires that the surgeon possess a great deal of experience, since the screw must be positioned without any direct visual control. The objective of the navigation system is to improve the precision with which screws are positioned and to reduce intra-operative false drillings and corrections. Just as important is the

reduction of intra-operative radiation exposure, which is generally high during spinal operations, for both the patients and medical personnel.

CT-based and C-arm-based navigation systems made it possible to improve screw placement quality in anatomically complex regions of the locomotorium and to reduce the intra-operative fluoroscopy time [20-23]. However, both procedures are subject to system-immanent limitations. Registration of the CT data set first requires a data set that is suitable for navigation, and hence to be

custom made. The preoperative processing with segmentation, the transfer to the navigation system, and the intra-operative registration of these data are time-consuming steps and are subject to a considerable learning curve and potential errors that prevent the routine use of a navigation system at many hospitals. While registration is automatic in C-arm-based 2D navigation, there are significant limitations with respect to image quality and the display of complex, three-dimensional structures in 2D.



Fig. 8 Preoperative setup with SIREMOBIL Iso-C^{3D} navigation system and arthroscopy unit for the navigated drilling of a talus cyst.



Fig. 9 Intra-operative situation. A dynamic reference basis (DRB) is attached to the talus; the image data from the SIREMOBIL Iso-C^{3D} have been transferred to the navigation system.

The drilling procedure is performed with a navigated drilling machine and a navigated drill socket.

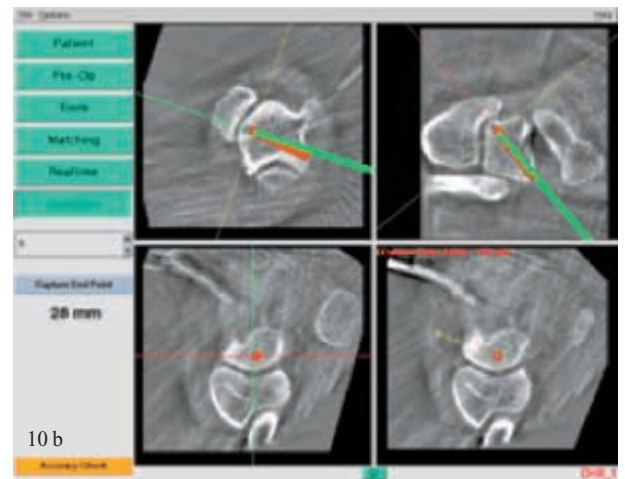
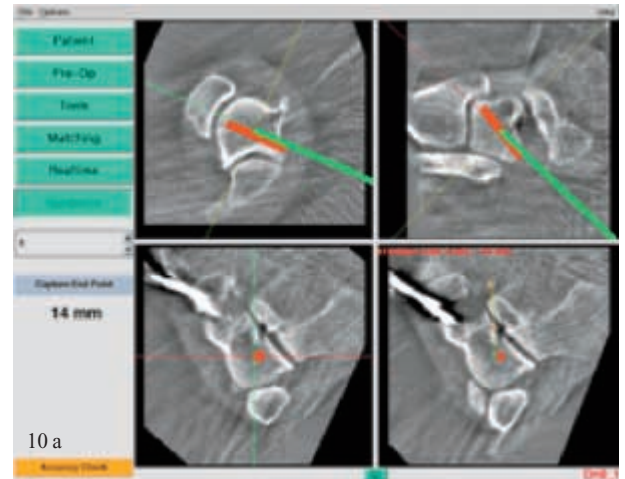


Fig. 10a, b Display of intra-operative image data on the navigation system monitor with the planned drilling direction (red) and current instrument position (green).

At 4.18 min, the fluoroscopy time during conventionally performed spinal operations at our hospital is clearly longer than for navigated operations, due to the axial pedicle adjustment we usually perform to check preparation and definitive screw position (Table 3). However, the relatively long average fluoroscopy time of 3.0 min during C-arm-based 2D navigation is also conspicuous in our results. In this procedure as well, the focus is placed on a correct axial adjustment of the pedicle, both for the registered images and for the screw

position control, wherein the pedicles are sometimes difficult to display in the 2D radiographic image, especially on the thoracic spine. In addition, the fluoroscopy times depend greatly on the individual abilities of the C-arm operator both during 2D navigation and during the conventional approach. In Iso-C^{3D} navigation, the fluoroscopy times are subject to far less fluctuation due to the highly standardized procedure, with the average being 2-3 times lower (1.25 min). Of particular note is that all OR personnel can be located outside the control

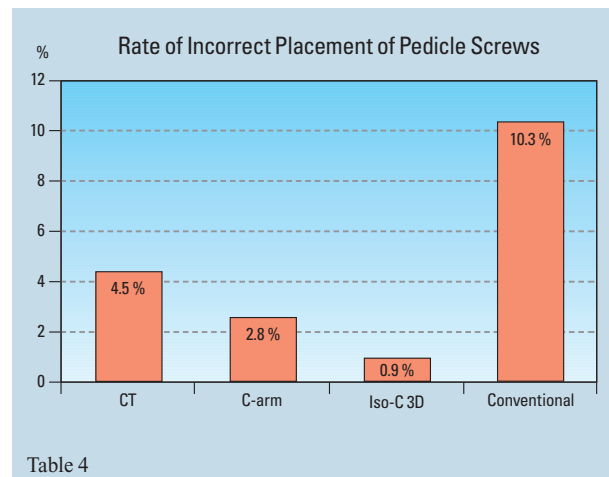
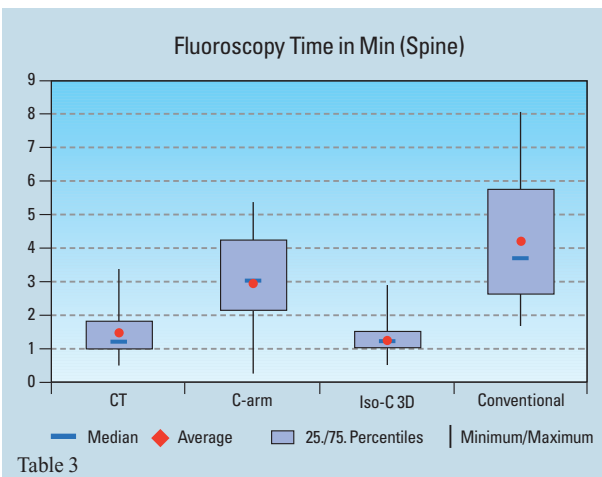
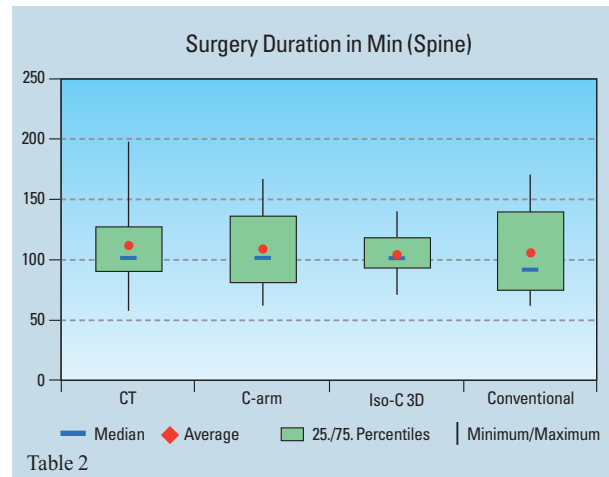
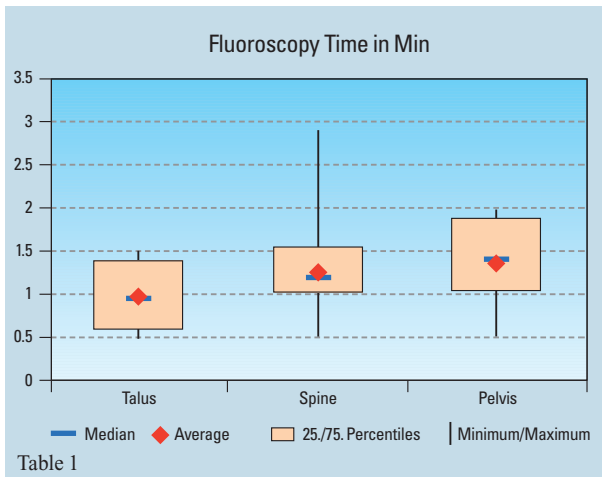


Table 1
Fluoroscopy times during Iso-C^{3D} navigation on various body regions in min:
Averages:
Talus 0.98 min (n = 4),
Spine 1.25 min (n = 24),
Pelvis 1.38 min (n = 8).

Table 2
Surgery duration of spinal operations in min:
Averages:
CT navigation:
111 min (n = 27);
C-arm navigation:
108 min (n = 28);
Iso-C^{3D} navigation:
102 min (n = 24);
conventional:
105 min (n = 34).

Table 3
Fluoroscopy time during spinal operations in min:
Averages:
CT navigation:
1.51 min (n = 27);
C-arm navigation:
3.0 min (n = 28);
Iso-C^{3D} navigation:
1.25 min (n = 24);
conventional:
4.18 min (n = 34).

Table 4
Rate of incorrect placement of pedicle screws with an incorrect placement of ≥ 2 mm in %:
CT navigation:
27 patients with 112 pedicle screws,
C-arm navigation:
28 patients with 108 screws.
Iso-C^{3D} navigation:
24 patients with 114 screws,
conventional: 34 patients with 136 screws.

area when recording the 3D data set, while the surgeon must most often stand right next to the radiation source in the conventional method.

In CT-based navigation, the fluoroscopy times are found by intra-operatively localizing the height of the vertebral bodies and documenting the correct screw positions after instrumentation is complete.

While a comparison of fluoroscopy times during Iso-C^{3D} navigation on the various regions does reveal slight differences for the pelvis, spine and extremities, the narrow range of averages between 0.98 and 1.38 min here also reflects a standardized OR process (Table 1).

This highly standardized OR process is also manifested in the surgery times. Even though shorter times are possible in isolated cases in the conventional approach, C-arm-based 2D navigation and CT-based navigation, they often exceed those for Iso-C^{3D} navigation owing to difficulties encountered while recording images, necessary corrections of screws, or difficulties in registration during CT-based navigation (Table 2).

The most important aspect is certainly the precision of the navigated actions. In the entire Iso-C^{3D} group, we found only one incorrect screw position, defined as a deviation exceeding 2 mm (Table 4). In this respect, Iso-C^{3D} navigation is not only superior to the conventional approach, but also yields better results than the C-arm-based 2D navigation and CT-based navigation procedures that have become established in our facility. As a result, Iso-C^{3D} navigation of the spine and pelvis has completely supplanted the other procedures, however, use is still hampered by the high training overhead. The results of our study reflect the trend described in the literature: Computer-assisted procedures yield an additional increase in intra-operative precision, wherein the greatest precision, as demonstrated here, is achieved with the new Iso-C^{3D} navigation.

Summary

Registration-free navigation in three-dimensional images from the SIREMOBIL Iso-C^{3D} was successfully used for the first time in this study in a larger group of patients. The results herein for the extremities, spine, and pelvis are very encouraging and portend a significant advance in safety and quality in the OR. As compared to the conventional approach and other computer-assisted procedures (CT-based navigation, C-arm-based 2D navigation), the lowest rate of incorrect placements and the lowest average fluoroscopy time was achieved during the placement of pedicle screws on the spine with Iso-C^{3D} navigation at a comparable average OR duration. Iso-C^{3D} navigation supports highly standardized work procedures in the OR. This is reflected in the narrow ranges of fluoroscopy times and OR duration.

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Abbreviations

| | |
|-----|-------------------------------|
| CT | = Computed Tomography |
| DRB | = Dynamic Reference Basis |
| MPR | = Multi-Planar Reconstruction |
| MRI | = Magnetic Resonance Imaging |
| OR | = Operating Room |
| SSD | = Surface Shaded Display |

Author's address

Dr. Paul Alfred Grützner
BG Unfallklinik Ludwigshafen
Unfallchirurgische Klinik an der Universität Heidelberg
Ludwig Guttman Str. 13
D-67071 Ludwigshafen
Germany

Tel.: +49-(0) 621-68 100
Fax: +49-(0) 621-68 2986
e-mail: pa.gruetzner@urz.uni-hd.de

Publishers:
Siemens AG
Medical Solutions
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Germany

Editorial board:
Dr. Karl-Jürgen Schmitt
Dr. Arnulf Oppelt
Elke Hinzmann
all at: Henkestrasse 127
D-91052 Erlangen
Phone: ++49-9131-84-6460
Fax: ++49-9131-84-5323
e-mail: elke.hinzmann@siemens.com

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