Computer-assisted fluoroscopic navigation of percutaneous spinal interventions

Jörg A. K. Ohnsorge · Khaled H. Salem ·
Andreas Ladenburger · Uwe M. Maus ·
Markus Weißkopf

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Abstract

Purpose Percutaneous spine procedures may occasionally be difficult and subject to complications. Navigation using a dynamic reference base (DRB) may ease the procedure. Yet, besides other shortcomings, its fixation demands additional incisions and thereby defies the percutaneous character of the procedure.

Methods A new concept of atraumatic referencing was invented including a special epiDRB. The accuracy of navigated needle placement in soft tissue and bone was experimentally scrutinised. Axial and pin-point deviations from the planned trajectory were investigated with a CT-based 3D computer system. Clinical evaluation in a series of ten patients was also done.

Results The new epiDRB proved convenient and reliable. Its fixation to the skin with adhesive foil provided a stable reference for navigation that improves the workflow of percutaneous interventions, reduces radiation exposure and helps avoid complications.

Conclusions Percutaneous spine interventions can be safely and accurately navigated using epiDRB with minimal trauma or radiation exposure and without additional skin incisions.

Keywords Spine navigation · Computer assisted surgery · DRB · epiDRB

J. A. K. Ohnsorge and K. H. Salem contributed equally as first authors to this work.

J. A. K. Ohnsorge · A. Ladenburger
Helmholtz-Institute of Biomedical Technologies,
RWTH Aachen University, Aachen, Germany

J. A. K. Ohnsorge · U. M. Maus
Department of Orthopaedic Surgery, St. Antonius Hospital
Emstek, Antoniusstr. 28, 49685 Emstek, Germany
e-mail: joerg.ohnsorge@kk-om.de

K. H. Salem (✉)
Department of Orthopaedic Surgery, RWTH Aachen University,
Aachen, Germany
e-mail: khaled_hamedsalem@hotmail.com

K. H. Salem
Department of Orthopaedic Surgery, Faculty of Medicine,
Cairo University, Cairo, Egypt

M. Weißkopf
Department of Spine Surgery, Wertingen General Hospital,
Wertingen, Germany

Introduction

The immediate proximity of neural structures, blood vessels and visceral organs is characteristic for the spine as an operative field. The various spine pathologies therefore demand a pin-point accuracy of diagnostic and therapeutic interventions, which may be difficult in cases with altered anatomy [1–7]. This particularly applies for percutaneous procedures which are based on accurate needle placement in the pedicles or the disc space [2–6]. Intraoperative orientation here is usually based on two-dimensional fluoroscopic imaging [2–8]. As the needle can only be visualised in one plane, the C-arm position must be changed repeatedly hence, the procedure is prolonged, being more incriminatory for the patient and bearing a higher risk for infection and collateral damage due to repetitive needle correction with higher radiation exposure [7, 9–12].

Computer assistance allows multiplanar visualisation and virtual navigation. Fluoroscopic navigation can display multiple X-ray images at the same time reducing radiation exposure while tracing the moving instrument in real time

[12]. The success of CT-guidance for percutaneous interventions has been shown in perineural injections [7], pulsed radiofrequency stimulation [9], spinal biopsy [13], percutaneous discectomy [14], kyphoplasty [15], aspiration of spinal cysts [16], and the implantation of pedicle screws [8,11,12,17–20]. Foley et al. [18] pointed out not only advantages, but also limitations of fluoroscopic navigation and urgently invited to engage in research for other solutions. Commercially available dynamic reference bases are designed for attachment with a screw or a clamp which demands a small incision [20, 21]. This is not only invasive but may also destroy the relatively thin spinous process [22]. Moreover, computer-assisted surgery requires an individual referencing process for every vertebral body because of the segmental spine mobility [23]. Simultaneous referencing of two or more adjacent spinous processes is technically not feasible. Even if navigation would allow their opto-electronic discrimination, there is not enough room for concurrent DRB fixation [9]. The tree-like design of conventional DRB constrains the surgeon's movement and puts its own stability at risk, as the surgeon may accidentally dislocate it [22].

To overcome these shortcomings, we developed a new flat epicutaneous DRB (epiDRB) and a new concept for computer-assisted fluoroscopic navigation of percutaneous interventions at the spine. Prior to clinical investigation, it was necessary to experimentally prove the reliability of the new “epiDRB” in comparison to a conventional DRB *ex vivo*. Likewise, evidence had to be gained that the new method of computer-assisted fluoroscopic navigation of percutaneous spinal interventions is applicable and that it improves accuracy, safety and results in comparison with conventional fluoroscopic-assisted procedures.

Materials and methods

A new concept for fluoroscopic navigation was developed, tested, evaluated and finally established for percutaneous spine applications. An infrared transmitter-sensor system (Polaris®, Northern Digital Inc., Waterloo, Canada), an opto-electronic navigation system (Stealth Station®, Medtronic SNT, Louisville, CO) with appropriate software (FluoroNav™, Medtronic SNT, Louisville, CO) and a C-arm fluoroscope (OEC Compact®, GE Medical Systems, Waukesha, WI) were used. A ‘Jamshidi’ type biptic needle (Baxter-Allegiance Healthcare Corp. IL) was supplemented with a passive tracking unit (Medtronic SNT, Louisville, CO) for navigation (Fig. 1). A DRB (Medtronic SNT, Louisville, CO) was used to evaluate a new epicutaneous dynamic reference base (epiDRB), designed to be placed directly onto the skin and into the area of interest with its centre of gravity as close to bone as possible.

Fig. 1 Jamshidi needle with passive tracking unit

Fig. 2 EpiDRB fixed to the spinous processes leaves room for unhindered instrumentation on both sides and works as an external fixation providing segmental stability

Fig. 3 EpiDRB atraumatically fixed in epicutaneous position with adhesive foil

A tight sequence of pilot holes equipped with set screws allows percutaneous multi-level pin fixation to adjacent spinous processes ($\varnothing$ 1.5, 2.0 or 3.0 mm) as a more resistant alternative (Fig. 2) to atraumatic skin fixation (Fig. 3) with a sterile adhesive film (OpSite, Smith & Nephew Inc., Memphis, TE). Thus, multi-level referencing is possible and segmental stability is provided. To decrease weight and allow radiolucency, the “epiDRB” was made of carbon fibre and carry adapters for spheric reflectors for wireless electro-optical navigation (3 M Health Care, Tustin, CA).

Ex vivo analysis

The applicability of the new epiDRB as a tracking unit and its fixation capacity regarding sufficient stability of the captured vertebrae for registration purposes was assessed in a cadaver study. With the “epiDRB” implanted into two spinal processes, slight flexion and extension of the human trunk was imposed manually upon the spine specimen for simulation of intraoperative unidirectional motion due to respiration. Motion was fluoroscopically monitored and iterative screen-shots were evaluated for measurable segmental mobility.

Using the immanent plausibility control function of the navigation system the 3D information gained from the “epiDRB” during extreme flexion and extension was verified by means of a navigated pointer and predefined anatomical landmarks. Thereby any diversification of the spatial relationship between the individual vertebra and the “epiDRB” indicating either segmental instability within the connection or dislocation of the “epiDRB” was traceable.

To assess the reliability of the “epiDRB”, it was tested in comparison to a classic DRB. Navigated drilling in bone was performed utilising both DRBs, while verifying the validity of the tracking. To assess the accuracy of computer-assisted navigation of a hand-held needle in soft tissue and bone, the experimental setup was designed to simulate the approach for IDETTM and kyphoplastyTM. For the former, the exact 3D centre of the intervertebral disc was defined as the optimal position of the needle tip at the end of procedure. For the latter, standardised globules of BaSO₄-augmented gypsum (Ø 7 mm) were implanted into the ventral wall of the vertebral bodies of a cadaver spine as spherical targets. The exact centre of this target was defined as the optimal end point of the transpedicular puncture. The respective approach for IDETTM and for kyphoplastyTM was performed bilaterally with a rigid cannula (Ø 3 mm) at five thoracic (T6–10) and five lumbar levels (L1–5) each ($N_{\text{total}} = 40$). In the trial group ($N_{\text{CAS}} = 20$), both approaches were navigated with computer assistance on one side of the spine ($N_{\text{A(CAS/IDET)}} = 10$, $N_{\text{B(CAS/Kypho)}} = 10$). In the control group ($N_{\text{Conv}} = 20$), the needle was placed on the other side by the conventional technique using 2D fluoroscopic imaging ($N_{\alpha(\text{Conv/IDET})} = 10$, $N_{\beta(\text{Conv/Kypho})} = 10$). A wire was implanted through the cannula marking both the trajectory and the end-point of the needle in situ.

The total operating time for the individual procedure was assessed from the first needle–skin contact until the surgeon declared reaching the definite position. This included implantation of the “epiDRB” as well as the acquisition of X-ray images for initial orientation and navigation. As multisegmental referencing is possible with

the epiDRB, the time for positioning the device was counted for a navigated procedure even if navigation was executed with the image information gained in the preceding trial. Fluoroscopy time was taken as a measure of radiation exposure to compensate for the automated dose accommodation of the C-arm fluoroscope. After each series, a densely collimated CT scan was obtained. The prevailing accuracy of both techniques was controlled by comparative calculations with DISOS[®] (Desktop Image-processing System for Orthopaedic Surgery, Institute for Biomedical Technology, Aachen, Germany) based on a CT-generated 3D-model followed by macroscopic measurements after histological cross sections.

In vivo analysis

To assess the clinical applicability of computer assistance in kyphoplasty, 10 patients with an indication for monovertebral augmentation were randomly chosen. An informed consent was obtained from every patient. Five lumbar (1 × L1, 2 × L3, 2 × L4) and five thoracic vertebrae (1 × T5, 1 × T6, 2 × T7, 1 × T8) were operated with our computer assistance concept with simultaneous fluoroscopic monitoring for safety reasons and to discover potential navigation errors. Postoperative CT scans were obtained. Results were compared to those of a control series of 10 patients operated using the conventional fluoroscopic-assisted technique including monovertebral augmentation of 5 lumbar (2 × L1, 2 × L3, 1 × L4) and 5 thoracic vertebrae (1 × T6, 2 × T7, 2 × T8).

To evaluate our new computer-assisted concept of injection therapy, 10 patients scheduled for a lumbar nerve root block (L5) were randomly selected after obtaining an informed consent. The epiDRB was fixed to the skin with an adhesive sterile foil (Fig. 4). As a thin injection needle

Fig. 4 Intraoperative set-up: epiDRB atraumatically fixed, C-arm with tracking unit for optoelectronic fluoroscopic navigation

cannot easily be navigated for its tendency to bend at the skin level, a tracked Jamshidi cannula was used as a guiding sleeve. A thin long needle was passed through for puncture. Its position was navigated and, if required, corrected according to patient's feedback. Once the patient confirmed pain from touching the nerve root, X-ray control was done. The resulting image with the needle in place was then compared to the virtual navigation image to detect any divergence.

Results

The atraumatic percutaneous fixation of the “epiDRB” proved stable enough for the respective application in soft tissue and bone throughout the entire experimental cadaver trial and the subsequent clinical study. In the experimental setting, fluoroscopic monitoring, measurements and computed verification did not reveal a profound tracking discrepancy during navigation, even when moderate manual flexion and extension stresses were applied to the spine specimen. The connection of two or three vertebrae via the “epiDRB” proved equally stable under all investigated conditions. Regarding reliability, the epiDRB proved comparable to conventional DRBs as there was no difference in the information obtained from either of the two devices during navigation.

Virtual planning of the insertion trajectory was easily feasible using two perpendicular X-ray planes. Post hoc mathematic and macroscopic evaluation of the cadaver study showed that the result of virtual planning could effectively be realised with an optoelectronically tracked hand-held needle through computer-assistance. Image-guided navigation of the needle was performed without difficulty and could be executed without any differences in soft tissue and in bone.

The results regarding accuracy, operation time and radiation time were encouraging for computer-assisted surgery (CAS) (Table 1). The mean pin-point aberration

Fig. 5 Accuracy analysis. The target is missed if the distance between the tip of the needle and the center of the target exceeds 5 mm

was 2 mm (range 1–5 mm) for both CAS applications. The mean aberration of conventional IDET™ (group α) was 4 mm (range 2–7 mm). The error of conventional kyphoplasty™ (group β) was 6 mm (range 3–9 mm). The mean axial deviation was 2° in the CAS group B (range 1°–4°), but was 4° in the conventional group β (range 2°–8°). With CAS, nerves were safely circumnavigated and the tip of the needle reached the target in all specimens. In contrast, the conventional technique often led to a peripheral or a parapedicular course of the needle. A marginal perforation of the medial cortical wall of the pedicle occurred in two cases and the needle ($\varnothing 3$ mm) missed the target ($\varnothing 7$ mm) in 50 % of the cases, which implies a minimum pin-point error of 5 mm (Fig. 5).

The radiation time was 75 % less in the experimental set-up with computer-assisted navigation (2–23 s) than with conventional fluoroscopy (28–130 s). There was no significant difference regarding the total time of the intervention.

In the clinical kyphoplasty trial, radiation time was similarly reduced in the navigation group compared to conventional fluoroscopy (18 vs. 75 s). Two perpendicular X-ray images were needed to find the optimal position for the “epiDRB”. Two more images were sufficient to navigate accurately. Continued fluoroscopy was not needed. However, the clinical application of this new method indicated that the total operation time is still slightly prolonged due to the installation of the system and a certain learning curve. The puncture itself can be performed in seconds as planning and alignment of the needle precedes skin perforation, hence, the actual net operation time is only minimal. Postoperative X-rays and CT scans showed satisfying results for both groups. There was no cortical perforation or cement leak, which was also realised in the conventional group. The clinical outcome was similar, with

Table 1 Results of the experimental analysis

Group	Deviation		Time (s)	
	Pin-point (mm)	Axial	Operation	Radiation
CAS				
A (IDET)	2	–	198	15
B (Kypho)	2	2°	250	18
Conv				
α (IDET)	4	–	286	59
β (Kypho)	6	4°	416	75

CAS computer assisted surgery, Conv conventional, IDET intradiscal electrothermal treatment, Kypho Kyphoplasty

no complications in either group and all patients being satisfied with their procedure.

In the clinical soft tissue intervention trial, radiographic control of the needle position during navigated nerve root therapy showed no gross difference compared to the virtual image generated by the computer. The overall accuracy of the procedure was high as the patient's feedback was the primary end-point for the definite needle position. Using the navigation system in addition to the C-arm caused more logistic effort, but was not exceedingly time-consuming (5–10 min). Fixing the epiDRB by adhesive films did not cause any gross disturbance of the navigation nor did it lead to any traceable dislocation of the device itself during the relatively short injection process (5–10 min). There was no difference between the virtual and the fluoroscopic reality during expiration and inspiration. Hence, atraumatic fixation of the epiDRB proved reliable as a stable reference in computer-assisted navigation of soft tissue injections.

Discussion

The new “epiDRB” proved reliable, no matter if fixed percutaneously to the bone or atraumatically to the skin. It delivered accurate 3D information for navigation in an experimental, as well as in a twofold clinical setup. It does not reduce the precision of the obtained 3D information. Its application was easy and convenient regarding unobstructed referencing and unhindered instrumentation. Its alternative attachment to bone by K-wires provides segmental stability, which may be important for long procedures like segmental spinal fusion using pedicle screws. In contrast to conventional DRB, no incisions are necessary and the integrity of bone and periosteum of the spinous process must no longer be impaired [22]. The risk of pain, structural damage and infection is hence reduced.

A similar reference frame unit has been promoted by Yang et al. [9] for CT-based navigation. Fixation was only obtained by Velcro strips wrapped around the body. The authors report no deterioration of the reference even though the device was carrying an “outboard” tracking unit representing a lever-arm with a weight of 130 g which unavoidably must lead to some tilt. Moreover, with the “epiDRB” referencing of several adjacent vertebrae at one time is possible. Two perpendicular X-ray images proved sufficient even for multi-level interventions using the navigated “epiDRB”. The percutaneously fixed “epiDRB” also provides sufficient stabilisation of 2–3 vertebrae to resist minor respiratory motion. In contrast, other authors reported deterioration of the navigation in adjacent levels when a conventional DRB is fixed at one single vertebra. To overcome this problem they suggested stopping respiration during image acquisition [23, 24].

Compared to the accuracy Yang et al. [9] lately reported for CT-based navigation using a similar, yet differently fixed DRB (4.6 mm, 3.6°), the results obtained for fluoroscopy-based computer-assisted navigation in this study using the epiDRB are significantly better (2.0 mm, 2°). The results of conventional fluoroscopically assisted proceeding in the control group of this study are not significantly worse than the reported results of the CT-based navigation (4–6 mm, 4°).

As Yang et al. did not deliver results of a control group it remains unclear if the reference unit they used is actually stable and reliable or if other systematic issues apply. At least the deductive reasoning may be suitable that the outcome of CT-based procedures is not significantly better than fluoroscopy-based procedures. This again is in line with the findings of Nourbakhsh et al. [25] from a meta-analysis regarding percutaneous spine biopsy.

Based on our experience, it is sufficient to acquire only two X-ray images of perpendicular planes for initial orientation and two more to serve as the definite navigation environment once the “epiDRB” is installed. However, final imaging with the needle in place may be recommended. It is undisputable that radiation exposure can thus be significantly reduced, if the surgeon actually relies on the navigation system and does not double-check with fluoroscopy. This reduces intraoperative radiation exposure, which is irrationally high in conventional interventions [26].

As for the study limitations, the numbers presented in the different groups are relatively small, hence, the power of this study remains low and the better navigation results are not of statistical significance. Nevertheless, the results do underline the initially stated hypothesis that computer assistance improves rather than impairs accuracy and safety in comparison to conventional methods. This was the ultimate requirement to justify its clinical application. It is unquestionable that the experimental set up insufficiently reflects the actual surgery. Accordingly, it was necessary to assess a preliminary clinical series to substantiate the results obtained in the experimental setting. It must also be mentioned that the requirements regarding accuracy defined for the experimental set up are much higher than those necessary for a successful operation. A deviation of few millimetres or degrees is generally tolerable [8, 11, 19, 20]. Correspondingly, the clinical results do prove the positive impact of computer-assisted navigation on accuracy, but do not necessarily prove a positive impact on clinical results. Yet, the elimination of outliers in this series justifies its future application in greater cohorts of patients with altered anatomy at least. For obese patients with a higher risk of gliding skin motions and in multisegmental referencing, percutaneous K-wire fixation is preferred to adhesive skin fixation.

It must be noted that with fluoroscopic navigation, the soft tissues can only be referenced indirectly taking for granted a stable relation to the bone that carries the DRB. In selected cases where a detailed visualisation is necessary, the opportunity to merge intraoperatively obtained 3D information with preoperatively or intraoperatively acquired CT or MRI scans may be considered [27]. A necessity of computer assistance for injections to the nerve roots or the facet joints is probably rare. Still, the presented method can be a valid alternative in complicated cases where extensive X-ray imaging must be expected and which otherwise would demand CT-guidance.

It should also be noted that opto-electronic navigation only indirectly traces the tip of a needle based on the assumption of a stable geometry. Bending of the object leads to incorrect localisation and erroneous navigation. It can therefore be recommended to use a navigated cannula as a guiding sleeve for a long needle fitting the inner diameter of the cannula. A needle with a sharp-edged triangular tip is unlikely to bend within the soft tissues if unidirectional force is applied [28].

The new “epiDRB” referencing concept reliably improves workflow, accuracy and safety of percutaneous spine interventions. Careful evaluation proved technical feasibility and clinical applicability together with a minimal radiation exposure. Under certain conditions, it therefore may be recommendable to use computer-assistance for percutaneous spinal procedures as the risk of complications can be reduced and side-effects do not occur with the presented technique. Further controlled clinical studies are required to substantiate the findings of this pilot study.

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Conflict of interest None.

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