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Computer-assisted screw insertion into the first sacral vertebra using a three-dimensional image intensifier: results of a controlled experimental investigation

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Abstract Currently there are few data available regarding the application and efficacy of computer-assisted procedures in the sacral spine. In order to optimize and standardize this procedure, a controlled experimental investigation has been performed. The aim of the study is to systematically assess the efficacy of a novel three-dimensional image intensifier used for navigated transiliac screw insertion into the first sacral vertebra. Screws were inserted iliosacrally into the first sacral vertebra of preserved human cadaver specimens. The instrument navigated procedure was performed with the “Siremobil Iso-C^{3D}” (Siemens Medical Solutions) and the “Navigation System” by Stryker. The accuracy and quality of the imaging procedure as well as the fluoroscopic exposure times were measured. These results were compared to three control groups (CT-based navigation, C-arm navigation, and fluoroscopic guidance). In each group a total amount of 20 screws was implanted. Screw position was post-operatively assessed by Iso-C^{3D} or CT-scan. The navigated procedure

using the Iso-C^{3D} provided good feasibility characteristics without requiring a specific matching process. It revealed the shortest procedure time of all navigated procedures and significantly decreased fluoroscopic time compared to C-arm navigation and fluoroscopic guidance. Furthermore, Iso-C^{3D} navigation showed no screw malposition and was in this regard superior to C-arm navigated and fluoroscopic guided procedures. The quality of imaging was sufficient for accurate placement, but did not share the high-resolution level of CT-based navigation. These findings indicate that application of the Iso-C^{3D} for navigated transiliac screw insertion into S1 can be recommended as a feasible and safe technique, enabling the surgeon to reduce procedure and fluoroscopic time. Further progress in improving the quality of the Iso-C^{3D} image should be attempted.

Keywords Computer-assisted surgery · Three-dimensional image intensifier · Spine · Sacral vertebra · Transiliac screw insertion

Introduction

Computer-assisted procedures are widely established in spinal surgery and predominantly utilized for transpedicle screw insertion into the thoracolumbar spine [14, 22]. Most

procedures are based upon optoelectronic navigation systems that enable surgeons to perform real-time instrument guidance on a computer generated anatomical map [20]. Using this method, radiation exposure is decreased while procedural precision is optimized [13].

All navigated procedures require imaging of the patient's anatomy, which can be received preoperatively from MRI or CT-scan or intraoperatively from image converting systems [15]. Using both procedures, good clinical and radiological results regarding feasibility and precision of transpedicle screw insertion into the thoracolumbar spine can be achieved [4, 7, 21].

In contrast, there have been few studies comparing the efficacy of different navigation and insertion procedures in the sacral spine and posterior pelvic girdle [1, 27]. A procedure of special interest to our group is the transiliac screw insertion for traumatic or degenerative disorders of the sacroiliac joint [8, 18, 25]. The procedure is technically demanding and is at present either fluoroscopic guided or computer assisted using C-arm or CT-based navigation [12, 17, 28, 31].

Currently there are no data available indicating which procedure provides best conditions regarding minimizing procedure duration, optimizing procedure precision, or minimizing radiation exposure. In order to address these parameters, a controlled experimental investigation was conducted. The aim of this study is to systematically evaluate the feasibility and results of a novel three-dimensional image intensifier system used for navigated transiliac screw insertion into the first sacral vertebra.

Methods

The study was performed on 20 human cadaver specimen previously preserved by Jores' solution. About 80 screws were bilaterally inserted into the first sacral vertebra (S1) using either 3D-fluoroscopic navigation (group I), CT-navigation (group II), 2D-fluoroscopic navigation (group III) or fluoroscopic

guidance only (group IV). Ten trials each, including two screws inserted into S1 were performed in each group.

Procedures were performed on a radiolucent operating table consisting of carbon fibre reinforced plastic (Maquet, Rastatt, Germany). 6.5 mm short-threaded (20 mm) cannulated cancellous screws were percutaneously inserted iliosacrally with the cadaver in a supine position, guided by 3.2 mm threaded wires (AsnisIII, Stryker, Duisburg, Germany). All screws were inserted by the same surgeon. The operative procedure followed that recently described by Tile [29].

The navigated procedure was performed with the 'Navigation System' by Stryker and the "Siremobil Iso-C^{3D}" (Siemens Medical Solutions, Erlangen, Germany). Prior to the procedure, the C-arm was calibrated, provided with a tracker, and connected to the navigation system. Subsequently, the dynamic reference base was attached to the contralateral spina iliaca and 100 single images from a cubic area of 12 cm³ were acquired during 120 s automated orbital scan.

Single C-arm images were obtained prior to the scanning to assure that the scanned volume was correctly centred over the iliosacral area. By this procedure, any repetition of the scanning procedure could be avoided. Images were automatically converted to a multiplanar reformatted series, which was immediately available for navigation without registration.

After completing preoperative planning (Fig. 1a) the navigation procedure was begun (Fig. 1b). The navigation system was used to pilot the guide wire placement, which was fluoroscopically assessed for every trial group. Time (min) per screw placement was measured for subsequent radiation exposure as well as for the total time elapsed for every trial of each method, which included all work steps from image acquisition to final fluoroscopic assessment of guide wire position.

Fig. 1 Screenshots taken from Iso-C^{3D}-navigated procedure: preoperative labelling (planning) of a correct screw position (a) and intraoperative guidance of the navigated drill sleeve (b) on the preoperatively received fluoroscopic 3D-scan

Fluoroscopic time involved every C-arm shot performed during the procedure but did not include 3D-scans preoperatively or postoperatively acquired by CT or Iso-C^{3D}.

The planning workflow of the CT procedure retained the same protocol as in group I. For registration surface matching of the equilateral iliac crest was performed via a short skin incision. Prior to this procedure the threshold for an optimal visualization of the bone was identified and set (Fig. 2a). Precision of the registration was verified before the navigated procedure was begun (Fig. 2b). The C-arm navigation and fluoroscopic guidance were performed with the Iso-C^{3D}, utilizing the regular 2D-modus. The same modus was used in each group to validate proper guide wire position.

Screw position was postoperatively assessed by multiplanar reformatted Iso-C^{3D} images (groups I and IV) and CT-scan (groups II and III), respectively. The CT-scans were performed as thin slice procedures (140 kV, 40 m As, collimation 3 mm, pitch 0.7) with a 16-slice spiral CT (XM 8000, Philips). Cross-sectional, sagittal and coronal views were obtained from each specimen. Procedure blind evaluation of screw position was performed by two radiologists. Any screw penetration of bony cortices was valued as malposition.

Sample size was calculated by performing a power analysis. A total of $n=9$ trials was identified as being sufficient to verify statistical differences between the trial groups concerning procedure and fluoroscopic time. The difference in mean values between the test groups was calculated as being at least 1.5 times the standard deviation in group I. According to this sample size estimation, a total of $n=10$ experiments each consisting of two screw insertion trials was carried out on each group.

All data were given as mean value $\pm$ SD. Differences between the trial groups were evaluated by a standard t -test. If the sample data were not normally distributed, the Mann-Whitney rank sum test was used instead.

Fisher's exact test was used to detect differences between the groups regarding the precision of screw position. All tests were calculated with a desired power of $\beta=0.8$ and a significance level of $\alpha=0.05$. Statistical analysis was performed with SigmaStat (Version 2.03) by SPSS.

Results

The navigation procedure using the Iso-C^{3D} revealed superior placement accuracy and reduced radiation exposure time relative to the standard methods. Relevant technical problems did not occur. In one case the procedure had to be aborted and repeated due to system declination probably caused by accidental contact with the reference base (Fig. 3). Procedure time was 26.3 ± 8.5 min. per screw, and thus significantly shorter than in the other navigation groups, but significantly increased compared to fluoroscopic guidance (Table 1, Fig. 4).

Delayed procedure times in CT-based navigation were associated to time consuming registration. As surface matching of the equilateral iliac crest via stab incision did not allow for precisely navigating the posterior parts of the pelvis point-to-point matching of defined landmarks (both spina iliaca ant. sup., equilateral tuberculum pubicum, fixed greater trochanter) was applied in order to create a coordinate system that includes the whole pelvis. However, this procedure also failed to provide a sufficient matching accuracy. Successful registration was obtained from surface matching of the rigidly preserved skin of the specimen only which was subsequently used for registration in the course of the study.

Fluoroscopic time was 0.25 ± 0.09 min per screw in the Iso-C^{3D} navigated group. Thus, fluoroscopic time was significantly decreased compared to C-arm navigation and fluoroscopic guidance (Table 1, Fig. 5). Further, the Iso-C^{3D} navigation experienced no screw

Fig. 2 Workflow of the CT procedure: identification of the threshold allowing for a proper identification of the bony surface (a) and verification of the matching procedure by screening prominent landmarks with a large calibrated pointer (b)

Fig. 3 Screenshots intraoperatively taken from Iso-C^{3D} navigated procedure: orientation of the navigated drill sleeve along the corridor of safe screw positioning on the preoperatively received fluoroscopic 3D-scan (a) and corresponding C-arm shot (inlet view) showing the true position of the drill sleeve which reveals a significant system declination (b)

malposition and was in this regard superior to C-arm navigated and fluoroscopic guided procedures (Table 2). However, these differences were not statistically significant.

Quality of imaging allowed for a safe performance of navigation and a reliable postoperative detection of screw position (Fig. 6). Compared to CT-scan a significant impairment of quality of image became obvious mainly caused by anchoring pins out of stainless steel, which were used for fixation of the reference base. A further impairment of quality of image occurred in obese specimen.

Discussion

The Iso-C^{3D} has been successfully validated for the operative treatment of articular long bone fractures and fractures of the thoracolumbar spine [5, 6, 10, 11, 16, 23, 32]. Recently, Iso-C^{3D} guidance was approved for use on the pelvis and sacral spine. Until now however, quantitative methodological investigations of the Iso-C^{3D}-assisted navigation for orthopaedic procedures in the pelvis and the sacral spine were not available.

In our study we demonstrate that Iso-C^{3D}-assisted surgical guidance significantly shortens procedure time relative to CT-based or fluoroscopic guided navigation. We further demonstrate that intraoperative fluoroscopic time and thus radiation exposure duration was significantly reduced compared to C-arm navigation and fluoroscopic guidance.

These results are confirmed by the findings of other study groups [24, 26, 28]. However, further investigations are mandatory to identify the procedure, which requires the lowest overall per-case radiation, including total preoperative and postoperative radiation exposures.

In addition to time reduction, the Iso-C^{3D} procedure also revealed a high level of placement precision without screw malpositions. In contrast, fluoroscopic guidance [24, 30] and C-arm navigation [9, 28, 30] malposition rates of 24 and 14%, respectively, are not unusual.

We found comparable prevalence of screw malposition in both procedures, which can be explained by limited quality of image and lack of three-dimensionality. Further, the problem of bent drill bits or guide wires has to be recognized [2].

Table 1 Averaged procedure and fluoroscopic time per screw and incidence of screw malposition observed in the different treatment groups

Procedure	Procedure time (min)	Fluoroscopic time (min)	Malposition (%)
Conventional	15.4 ± 4.0	0.77 ± 0.2	20
Fluoroscopic navigated (2D)	31.5 ± 4.9 ^{*,**}	0.30 ± 0.1 [*]	20
CT-Navigation	58.3 ± 12.9 [*]	0.21 ± 0.1 ^{*,***}	0
Fluoroscopic navigated (3D)	26.3 ± 8.5 ^{*,**,*}	0.25 ± 0.1 ^{*,***}	0

Fluoroscopic time involves every C-arm shot taken intraoperatively but does not include pre- and postoperatively acquired 3D-scans by CT or Iso-C^{3D} * $p < 0.001$ versus conventional; ** $p < 0.001$ versus CT-navigation; *** $p < 0.05$ versus Fluoroscopic navigated (2D)

Fig. 4 Procedure time per screw measured in the different procedure groups (F.n. 2D-Fluoroscopic navigated, F.g. Fluoroscopic guided)

The quality of imaging using the Iso-C^{3D} was significantly reduced compared to CT. The impaired quality of image was mainly caused by anchoring pins

Fig. 5 Fluoroscopic time per screw measured in the different procedure groups (F.g. Fluoroscopic guided, F.n. 2D-Fluoroscopic navigated)

Table 2 Occurrence of screw malposition in the different groups

Malposition	Iso-C	CT	F.n.	F.g.
Neuroforamen	–	–	–	1
Spinal canal	–	–	–	1
Anterior penetration ala	–	–	3	2
Anterior penetration S1	–	–	1	–
Total (n)	–	–	4	4

F.n. 2D-Fluoroscopic navigated, F.g. Fluoroscopic guided

made of stainless steel, which were used to fixate the reference base. Further impairment might occur as a result of obesity and/or eccentric patient position during the scan, which can influence the quality of imaging as well.

Although CT-navigation provides the surgeon with relatively high-resolution images, it does not provide the surgeon with live images. This is an especially necessary characteristic when intraoperative reduction or rearrangement of the patient's position is necessary.

In contrast to the CT-based procedure, using the Iso-C^{3D} for navigated screw insertion into S1 enables the surgeon to verify the screw position immediately in the OR. An additional benefit of utilizing the Iso-C^{3D} for navigated procedures results from the fact that the staff might leave the theatre during the scanning procedure.

Moreover CT-navigation requires the execution of a complementary procedure, which is technically challenging and time demanding. Arand et al. [3] found an average procedure time of 42 min per screw, indicating a substantial loss of time using the CT procedure.

In our study, the registration of osseous landmarks was not a satisfactory method of navigation initiation. Unfavourable results by this procedure were also described for the thoracolumbar spine [14]. We demonstrate that the skin of preserved specimens can be successfully used for surface matching. However, this procedure is not applicable in vivo.

The percutaneous application of fiducials seems helpful towards increasing procedure precision [3, 33], but the implantation has to be carried out prior to CT-scan and requires several additional skin incisions. Fiducials percutaneously implanted into bone may cause markedly increased clinical complaints as previously described [19].

Overall, application of the Iso-C^{3D} can be recommended as a feasible and safe procedure for navigated transiliac screw insertion into the first sacral vertebra, offering major advantages compared to competing navigation procedures.

Remaining problems that have to be kept in mind concerning a limited display window and the quality of images, as well as relatively high acquisition costs. Application of the Iso-C^{3D} further requires radiolucent tables as well as an update of the navigation system, which could potentially lead to significant cost increases.

Fig. 6 Quality of image using CT-Scan (a) versus Iso-C^{3D} - Scan (b) after transiliac screw insertion into S1

Conclusion

Optoelectronic navigation systems are commonly used for computer-assisted iliosacral screw insertion. Images needed to perform the navigated procedure can be acquired preoperatively by CT-scan or intraoperatively by C-arm. While imaging by CT-scan delivers three-dimensional data records of high resolution, C-arm imaging features the possibility to obtain more current images, which can be intraoperatively updated at any time.

Application of the Iso-C^{3D} simultaneously provides the surgeon with both three-dimensional mapping of the anatomical substrate and virtually real-time imaging.

Navigation with the Iso-C^{3D} shows good feasibility without requiring a registration resulting in acceptable procedure time and minor radiation exposure. Further, the procedure allows for precise and safe iliosacral screw insertion. And, although problems with the Iso-C^{3D} system remain, including a relatively high acquisition cost and relatively low level of image resolution, this technology represents a feasible and in several ways superior alternative to current methods.

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