Computer-assisted fluoroscopic navigation of pedicle screw insertion

An in vivo feasibility study

Tsai-Sheng Fu, Li-Huei Chen, Chak-Bor Wong, Po-Liang Lai, Tsung-Ting Tsai, Chi-Chieh Niu and Wen-Jer Chen

Department of Orthopaedic Surgery, Chang Gung Memorial Hospital
Correspondence W-JC: chenwenj@adm.cgmh.org.tw
Submitted 03-09-05. Accepted 04-03-11

Background Accurate placement of pedicle screws is difficult.

Patients and methods We evaluated the feasibility and accuracy of pedicle screw insertion assisted by a real-time, 2-dimensional (2D) image-guided navigation system in 12 patients who underwent thoraco-lumbar and/or lumbar stabilization. 66 pedicle screws were inserted either by senior spine surgeons or residents. The accuracy of positioning of the screws was evaluated using postoperative plain radiographs and thin-cut CT.

Results 61 of the 66 screws were inserted successfully. 5 screw insertions showed structural violations: 4 on the medial and 1 on the lateral pedicle wall. The accuracy was higher in the sagittal plane than in the axial plain. There was no difference between the surgical error rates caused by the senior surgeons and the residents.

Interpretation Using computer-assisted 2D fluoroscopic image navigation, it is possible to achieve reliable and accurate pedicle screw insertion during low thoracic and lumbar spinal surgery.

Although the clinical and mechanical benefits of pedicle screw fixation have been well documented, accurate placement continues to be a source of concern with normal fluoroscopy-assisted screw insertion. High rates of pedicle screw misplacement, up to 40%, have been reported (Gertzbein and Robbins 1990, Castro et al. 1996, Pihlajamaki et al. 1997, Schwarzenbach et al. 1997). Also, using standard fluoroscopy, the patient and surgical team are all at risk of high radiation exposure during the operation (Hynes et al. 1992, Fuchs et al. 1998, Rampersaud et al. 2000).

Image-guided systems (IGS) have been documented to improve the accuracy of pedicle screw insertion and reduce exposure to radiation (Schwarzenbach et al. 1997, Merloz et al. 1998, Amiot et al. 2000, Kothe et al. 2001, Youkilis et al. 2001). Such methods have not been widely accepted due to the steep learning curve, the cost of preoperative computed tomography (CT), and the extra surgical time required for patient registration, data acquisition, and transfer. Recent reports from preclinical studies have claimed that the CT-free computer-assisted fluoroscopy-guided system (FGS) could potentially eliminate these disadvantages (Choi et al. 2000, Foley et al. 2001).

In this clinical trial we investigated the feasibility and safety of computer-assisted fluoroscopy-guided techniques for surgeons with varying degrees of experience in posterior spinal fixation.

Patients and methods

This prospective study included 12 consecutive adult patients (10 women), who underwent thoracic and lumbar fusion and instrumentation using transpedicular screw (TPS) fixation. The mean age of the patients was 59 (39–77) years. Since the computer-assisted FGS is a novel technique and was first used in this clinical trial, all the patients

DOI 10.1080/00016470410004102

included were informed preoperatively and gave written consent before participation. The study was approved by the hospital ethics committee.

The indications for surgery were degenerative spondylolisthesis for 5, spondylolytic spondylolisthesis for 3, tuberculous spondylitis for 2, and failed earlier back surgery for 2. These 12 surgical procedures were conducted with the assistance of a VectorVision2 Fluoro (BrainLAB, Inc., Munich, Germany) fluoroscopy-guided system. All screws were inserted by a senior surgeon on one side of the patient and by a resident on the contralateral side with the same navigation procedures.

System overview

The VectorVision2 Fluoro consisted of a fixation ring, the X-ray cone, the dynamic reference clamp (DRC), reflective marker spheres for use with surgical instruments, and the VectorVision2 central workstation with a computer and a monitor. The X-ray registration kit is attached to the C-arm image intensifier and remains in place throughout the procedure. The DRC is attached directly to the vertebra of the patient at the level of interest. Image registration is completed automatically by the software. A video cable from the C-Arm to the workstation allows images to be captured, thereby directly eliminating the need for data transfer.

The X-ray registration kit contains a number of spherical tungsten markers of different diameters, arranged in a unique geometric pattern on two parallel disks. A number of disk-shaped reflective markers are distributed around the device, which can be tracked by the cameras. Many factors such as variations in the position of the C-arm relative to the earth's magnetic field, the effect of external electromagnetic fields in the vicinity of the C-arm generated by other electrical devices in the operation room, and the mechanical non-rigidity of the C-arm structure will cause a certain amount of image distortion of acquired images. The position of the tungsten marker shadow is automatically used to correct image distortion by the software of system and is used to compute the projection vector of the images (Figure 1). Shadows of the tungsten marker grid on the captured images are detected automatically and removed by artificial intelligence algorithms.

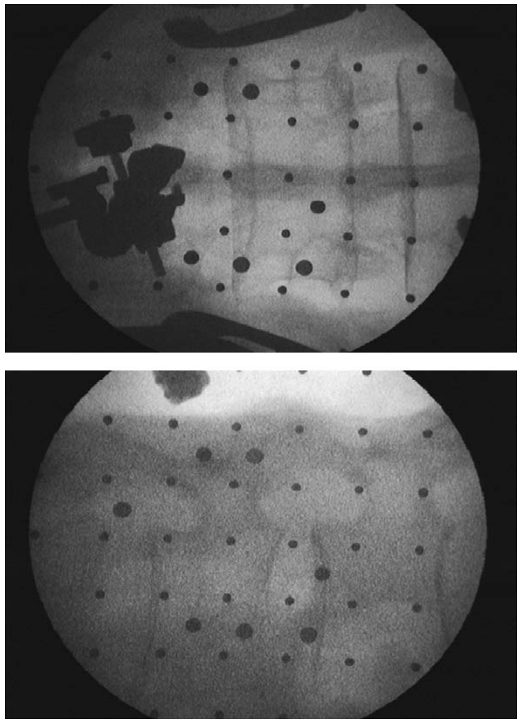

Figure 1. A number of spherical tungsten marker shadows of different diameters are arranged in a unique geometric pattern on the fluoroscopic images. The position of the tungsten marker shadows is automatically used to correct image distortion.

By tracking the position of the C-arm (X-ray registration kit) and the patient (DRC), this system can locate the surgery-specific regional anatomy of the captured images. Any surgical instrument can be tracked by attaching an adapter with reflective markers. The relative position of the instrument is then displayed simultaneously on all of the pre-acquired images.

Surgical technique

The patient was placed in the prone position. The C-arm was draped into the operative field in sterile fashion. The surgical exposure followed conventional principles. The DRC was attached securely to the spinal process of the vertebra to be detailed and the X-ray registration kit was mounted onto the image intensifier of the fluoroscope for registration. Antero-posterior (AP) and lateral fluoroscopic images were acquired for virtual navigation of each vertebra. The vertebral level of interest was centered in the fluoroscopic beam to reduce paral-

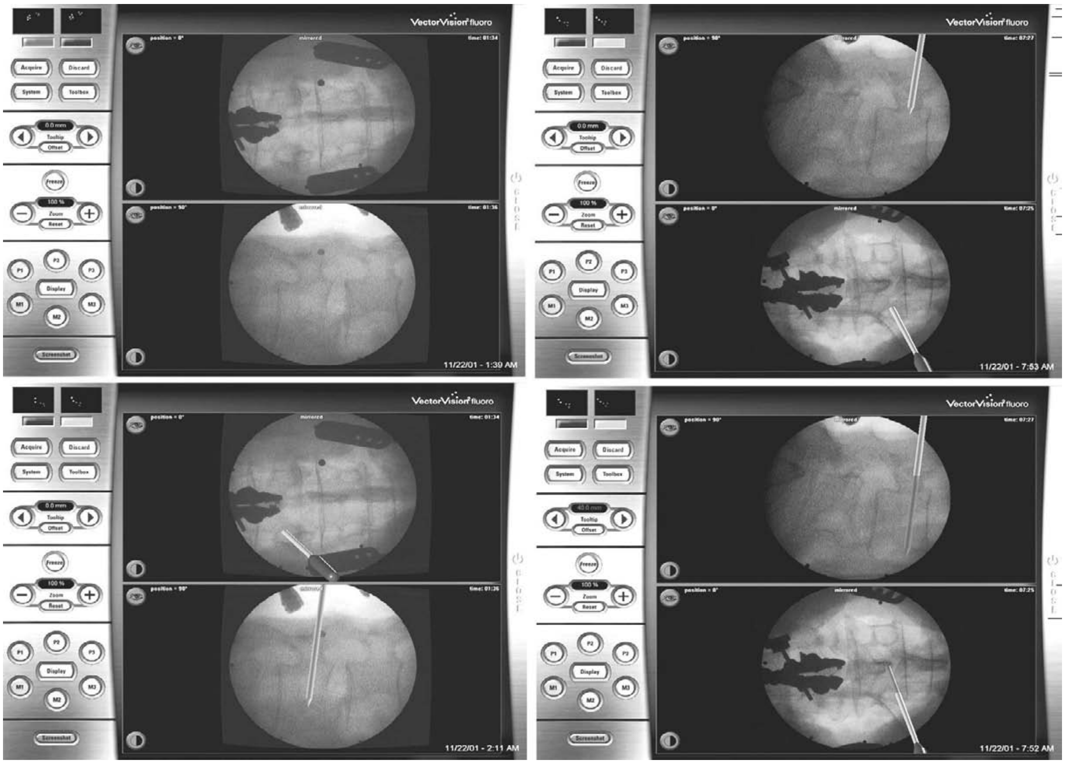

Figure 2. The trajectory lines corresponding to the tracked tools were overlaid onto the saved fluoroscopic images in real time, for surgical planning and navigation.

lax. It is important to ensure that the fluoroscopic beam is parallel to the pedicle of interest in the coronal and sagittal planes. In the true AP image, the spinal process was centered between the pedicles and these appeared to have round and sharp cortical margins. In the true lateral image, the superior and inferior end-plates were made parallel and the bilateral pedicles were made to overlap.

After acquiring satisfactory fluoroscopic images of the site and verifying the images for accuracy by the software until the system showed an inaccuracy of below 2 mm, the images acquired were saved for navigation and the C-arm was moved out of the operating field. The surgical instruments, such as the pedicle awl, probe, and screwdriver, were tracked by attaching an adapter with reflective markers. The relative positions of these instruments were then displayed simultaneously on all of the pre-acquired images. The trajectory corresponding to the tracking tool was overlaid onto the saved fluoroscopic images in real-time mode (Figure 2).

After the matching procedures had been done, the surgeon located the surgical entry point with the awl. The screw channel was prepared with a pedicle probe guided by the real-time trajectory line. The walls of the screw channel were checked for perforation using a flexible sounding-probe. A pedicle screw of adequate length and diameter was inserted under the real-time guiding trajectory. During surgery, the pedicle screws were inserted by a senior surgeon on one side of the patient, and by a resident on the contralateral side. Typically, 5.5-mm diameter screws were used for the lower thoracic vertebra and 6.5-mm diameter screws were used for the lumbar vertebra. The time required for the matching procedure and for the implantation of each spinal unit was recorded (4 screws for 2 vertebrae).

Evaluation of screws

The final placement of each pedicle screw was evaluated on AP and lateral plain radiographs. A postoperative thin-cut CT scan (2-mm contiguous

Figure 3. Axial computed tomography images showing lateral and medial pedicle wall violations by transpedicle screws.

non-overlapping images) of the surgical region was obtained for each instrumented vertebra. Transverse and sagittal sections were generated in order to assess the positioning of the screw in all planes of the pedicle shaft. The distance between the edge of the screw and the pedicle walls was measured. The location and degree of any pedicle wall violation was recorded by means of a modified grading system for wall violation (Youkilis et al. 2001). Screws that replaced the cortex without extending beyond the cortical margin were considered to be grade I. A grade II violation was defined as a screw that extended less than 2 mm beyond the cortex. Screws that extended more than 2 mm beyond the cortex were considered to be grade III violations. Grade II and III screws were considered to represent true cortical violations. The surgical error rate attributable to either the senior surgeon or the resident was determined for each.

To evaluate the relative intraoperative accuracy provided by the navigation system, the intraoperatively planned virtual images were compared with the postoperative radiographs. The difference in sagittal screw angle (SSA) between the planned virtual images and the postoperative lateral plain radiographs was determined. The SSA was determined between a line parallel to the inferior vertebral end-plate and a line through the center of the screw (Kothe et al. 2001).

Results

66 pedicle screws were inserted. There were 2 T9 surgeries, 6 T10, 4 T11, 6 L2, 10 L3, 18 L4, 18 L5, and 2 S1 surgical procedures. The average time for registration and screw insertion (1 segment including 4 screws) was 48 (24–90) min. There were no intraoperative or postoperative complications such as the occurrence of neurological symptoms, vascular injuries, or wound infections. The mean distance between the edge of the screw and the superior and inferior pedicle walls was 3.3 (SD 2.1) mm and 4.4 (SD 1.9) mm, respectively. The mean postoperative SSA was 5.6° (SD 4.2°). The mean difference in SSA between the planned virtual images and the postoperative plain radiograph was 2.1° (SD 1.8°).

3 of the 66 screws inserted exhibited grade I medial cortical replacement without extending beyond the cortical margin. 5 demonstrated true cortical violation, and this involved 3 grade II and 2 grade III screws (Figure 3). Of these 5 violations, 2 had been performed by senior staff and 3 by residents. The most common trajectory for these violations was towards the medial pedicle wall. 4 violations were located in the medial cortex and 1 in the lateral pedicle cortex (Tables 1 and 2). No cortical

Table 1. Review of cortical violations

Case	Side/Level	Direction	Grade	Surgeon
1	Right / L3	Lateral	III	Resident
2	Left / L4	Medial	II	ST [a]
2	Left / L5	Medial	II	ST
4	Left / L4	Medial	III	Resident
5	Right / L5	Medial	II	Resident

[a] Senior staff.

Table 2. Subset analysis of grade II and III cortical violations

Site	Total no. of screws	No. of violations
T9	2	0
T10	6	0
T11	4	0
L2	6	0
L3	10	1
L4	18	2
L5	18	2
S1	2	0

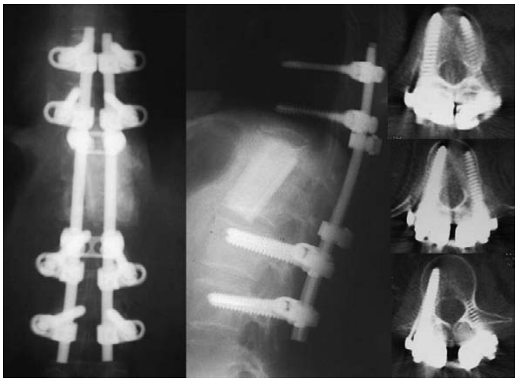

Figure 4. Postoperative plain radiographs and axial computed tomography images through the pedicle regions, demonstrating good location of the screws.

perforations occurred in the lower thoracic spine. Of the 66 screws evaluated, 61 were considered to have been inserted accurately (Figure 4).

Discussion

We found good accuracy of screw insertion using a virtual fluoroscopy system as compared to the overall accuracy reported for 3-D image-guided systems (Schwarzenbach et al. 1997, Merloz et al. 1998, Amiot et al. 2000, Kothe et al. 2001, Youkilis et al. 2001).

In the current study, 5 of 66 pedicle screws were considered to be malpositioned when using computer-assisted 2-D fluoroscopic navigation. We have reviewed the rate of malpositioning of posterior transpedicle Zielke instrumentation in our department when using the conventional technique: it was 3.6% (33 of 922 screws), i.e. lower (Chen et al. 1997). The reason for this lower rate with the conventional technique was that we used only plain radiographs to evaluate the positioning of the screws. All 33 screws with misplacement were found to violate the pedicle cortex on the sagittal plane, including superior and inferior cortical wall. We believe that the frequency of cortical violation would have been higher if we had used postoperative CT scan to evaluate the medial and lateral cortical wall in the axial plane. On the other hand, no cortical violation was found in the sagittal plane in the current study. The results were really superior to the conventional procedure in the prevention of cortical violation in the sagittal plane.

Our results show the limitation of the computer-assisted fluoroscopy-guided system; it only offers real-time two-dimensional images. The most common trajectory for pedicle violations was on the axial plane. In the first few cases, we simply acquired AP and lateral fluoroscopic images for navigation. The choice of insertion angle in the axial direction has always been determined by the judgment of the surgeon and is heavily influenced by the surgeon's experience. It would most likely lead to perforation of the medial or the lateral pedicle wall, as with conventional fluoroscope-guided procedures (Castro et al. 1996). Following the completion of several cases, we acquired satisfactory images in several different planes for navigation; thus, no perforation of the pedicle wall occurred subsequently.

The accuracy of the image-guided system is clearly clinically important for computer-assisted spinal surgery. In the present study, the results pertaining to the mean difference in sagittal screw angle between virtual and postoperative images demonstrated the rather good accuracy of this system. The equipment itself did not result in the incorrect positioning of the screw in the vertebra. Since the machine cannot compensate for the poor quality of the pre-acquired fluoroscopic images used for surgical guidance, a clear high-quality image is very important (Choi et al. 2000, Foley et al. 2001). The use of a good fluoroscope system and a proper fluoroscopic technique will provide the necessary clear surgical landmarks on the pre-acquired images. This should help to avoid the possible misinterpretation of images and intraoperative errors that could arise during the insertion of pedicle screws.

The average time of registration and pedicle screw insertion for one segment (four screws) was 48 (24–90) min. The longer surgical duration than was perhaps necessary can have several contributory factors. Firstly, the surgical duration included a learning stage for using this novel technique. Secondly, in order to prevent inaccuracies caused by movement of the motion segment during the insertion of the pedicle screws, repeated registration for each adjacent vertebra was deemed necessary and thus conducted. These procedures were the most time-consuming. Finally, we also used this system as a teaching aid for residents, in order to clearly demonstrate the correct and incorrect points for screw insertion, and also the trajectory lines to be followed during the surgical procedure. However, most of these factors can be taken into account and thus compensated for in subsequent use of the surgical equipment.

The error rate resulting from the senior staff with experience and that resulting from the residents did not appear to be different. The learning curve is not steep. Novice surgeons can be more confident since the real-time image-interactive navigation function allows selection of the optimal trajectory and point of entry for pedicle screw insertion. Although the use of computer-assisted technique is not really indispensable for experienced surgeons (and for the lumbosacral area), the equipment offers surgeons clear advantages—especially for the appropriate simulation of screw positioning and for teaching.

In conclusion, computer-assisted 2-D fluoroscopic navigation for pedicle screw fixation is a safe and reliable procedure for lower thoracic and lumbar surgery. Based upon the results obtained to date, and further experience with this surgical modality, we believe that it will be possible to apply this new technique successfully to more-difficult fields, especially for cases of spinal deformity, for upper thoracic surgery, and/or surgical revision procedures.

No competing interests declared.

Amiot L P, Lang K, Putzier M, Zippel H, Labelle H. Comparative results between conventional and computer-assisted pedicle screw installation in the thoracic, lumbar, and sacral spine. Spine 2000; 25: 606-14.

Castro W H M, Halm H, Jerosch J, Malms J, Steinbeck J, Blasius S. Accuracy of pedicle screw placement in lumbar vertebrae. Spine 1996; 21: 1320-4.

Chen W J, Niu C C, Chen L H, Shih C H. Survivorship analysis of DKS instrumentation in the treatment of spondylolisthesis. Clin Orthop 1997; (339): 113-20.

Choi W W, Green B A, Levi A D O. Computer-assisted fluoroscopic targeting system for pedicle screw insertion. Neurosurgery 2000; 47: 872-8.

Foley K T, Simon D A, Rampersaud Y R. Virtual fluoroscopy: computer-assisted fluoroscopic navigation. Spine 2001; 26: 347-51.

Fuch M, Schmid A, Eiteljorge T, Modler M, Sturmer K M. Exposure of the surgeon to radiation during surgery. Int Orthop 1998; 22: 153-6.

Gertzbein S D, Robbins S E. Accuracy of pedicular screw placement in vivo. Spine 1990; 15: 11-4.

Hynes D E, Conere T, Mee M B, Cashman W F. Ionising radiation and the orthopaedic surgeon. J Bone Joint Surg (Br) 1992; 74: 332-4.

Kothe R, Strauss J M, Deuretzbacher G, Hemmi T, Lorenzen M, Wiesner L. Computer navigation of parapedicular screw fixation in the thoracic spine. A cadaver study. Spine 2001; 26: E496-E501.

Merloz P, Tonetti J, Pittet L, Coulomb M, Lavallee' S, Sautot P. Pedicle screw placement using image guided techniques. Clin Orthop 1998; (354): 39-48.

Pihlajamaki H, Myllynen P, Bostman O. Complications of transpedicular lumbosacral fixation for non-traumatic disorders. J Bone Joint Surg (Br) 1997; 79: 183-9.

Rampersaud Y R, Foley K T, Shen A C, Williams S, Solomito M. Radiation exposure to the spine surgeon during fluoroscopically assisted pedicle screw insertion. Spine 2000; 25: 2637-45.

Schwarzenbach O, Berlemann U, Jost B, Visarius H, Arm E, Langlotz F, et al. Accuracy of computer-assisted pedicle screw placement. An in vivo computed tomography analysis. Spine 1997; 22: 452-8.

Youkilis A S, Quint D J, McGillicuddy J E, Papadopoulos S M. Stereotactic navigation for placement of pedicle screws in the thoracic spine. Neurosurgery 2001; 48: 771-9.