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GUIDELINE

Guidelines for navigation-assisted spine surgery

Wei Tian (✉)[1,2], Bo Liu[1], Da He[1,2], Yajun Liu[1,2], Xiaoguang Han[1,2], Jingwei Zhao[1,2], Mingxing Fan[1,2]; International Society for Computer Assisted Orthopaedic Surgery

[1]*Department of Spine Surgery, Beijing Jishuitan Hospital, Beijing 100035, China;* [2]*Beijing Key Laboratory of Robotic Orthopaedics, Beijing 100035, China*

Abstract Spinal surgery is a technically demanding and challenging procedure because of the complicated anatomical structures of the spine and its proximity to several important tissues. Surgical landmarks and fluoroscopy have been used for pedicle screw insertion but are found to produce inaccuracies in placement. Improving the safety and accuracy of spinal surgery has increasingly become a clinical concern. Computer-assisted navigation is an extension and application of precision medicine in orthopaedic surgery and has significantly improved the accuracy of spinal surgery. However, no clinical guidelines have been published for this relatively new and fast-growing technique, thus potentially limiting its adoption. In accordance with the consensus of consultant specialists, literature reviews, and our local experience, these guidelines include the basic concepts of the navigation system, workflow of navigation-assisted spinal surgery, some common pitfalls, and recommended solutions. This work helps to standardize navigation-assisted spinal surgery, improve its clinical efficiency and precision, and shorten the clinical learning curve.

Keywords guidelines; spine surgery; computer-assisted navigation

Introduction

Owing to the complex morphology of the spine and its proximity to several significant tissues (such as the spinal cord and nerve roots), pedicle screw misplacement might lead to decreased stability and neurological, vascular, and visceral injuries [1–3]. Improving the safety and accuracy of spinal surgery has increasingly become a clinical concern. Since 1995, computer-assisted navigation has been used in spinal surgery [1] and has significantly improved its accuracy [2–7], reduced intraoperative radiation exposure [8–16], and improved the safety of minimally invasive spinal surgery [12,17–22].

Computer-assisted navigation is an extension and application of precision medicine in orthopaedic surgery. However, no clinical guidelines have been published for this new and fast-growing technique, thus potentially limiting its adoption. The International Society for Computer Assisted Orthopaedic Surgery has invited experts to create appropriate guidelines based on recently published related studies.

The guidelines presented in this document should be interpreted as academic recommendations and are intended to help further discussions and guide field practices. Clinical decisions must be based on the specific situation of each patient.

1. Target group

The target group for these guidelines comprises surgeons, technicians, and nurses involved in navigation-assisted spinal surgery.

2. Epidemiology

Table 1 lists the accuracies of traditional and computer-assisted spinal surgery techniques [2–7]. The results show that the computer-assisted method significantly improves the accuracy and safety of spinal surgery [12,17–22].

3. Terminology

3.1 Computer-assisted navigation technique

This technique uses computer and medical images to aid

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Correspondence: Wei Tian, jstspine@126.com

Table 1 Clinical accuracy of conventional surgery and different types of navigated spinal surgeries

Types of surgery	Clinical accuracy (%)
Conventional surgery	49.7–1.7
2D fluoroscopy-based navigation	73.7–95.0
3D fluoroscopy-based navigation	81.9–100
Preoperative CT-based navigation	90.8–94.4

CT, computed tomography; 2D, two-dimensional; 3D, three-dimensional.

surgeons for a precise operation. The surgical instruments are tracked in 3D space, and the positional information is then interpreted by the software and overlaid onto the recorded images of the spine, thus producing a visual display that can be interpreted by the surgeon. The recorded spinal images can be pre-obtained by the software using reference points to intraoperatively locate the images and instrumentation. Alternatively, the device itself creates either an X-ray or computed tomographic (CT) image sequence in the operating theater, calibrates these images, and references them to the instrumentation.

3.2 Infrared optical navigation system

This navigation system uses infrared light to track devices. Depending on how the infrared light is emitted and received, these systems can either be active or passive. In active infrared navigation systems, infrared light-emitting diodes are attached to a tracker and a smart surgical tool. The camera tracks the infrared light beam and transmits the signal to the navigation workstation. In passive infrared navigation systems, reflective bodies are attached to a tracker and a smart surgical tool. Infrared light-emitting diodes are attached to the camera, and their light is reflected to the camera by the reflective bodies and is then transmitted to the navigation workstation.

3.3 Tracker

Trackers are instruments used to track coordinate information by intraoperatively emitting or reflecting infrared information to a position sensor. (1) Patient trackers are attached to a specific anatomical structure and then transmit or reflect infrared information to the camera. (2) C-arm trackers are calibrated by the engineer and placed on the C-arm to automatically register C-arm images. (3) Universal trackers are attached to surgical tools and transmit or reflect infrared information to the camera.

3.4 Pointer

Pointers are intraoperative devices used to register the patient's world coordinate system with the imaging virtual coordinate system and to track the patient's spatial position during the navigation.

3.5 Smart tool

Smart tools are surgical instruments with an installed tracker that displays the corresponding coordinates in the navigation image.

3.6 Camera

A camera tracks the emitted or reflected infrared light beam and transmits the signals to the navigation workstation to determine the corresponding coordinate information.

3.7 Match

Match is the process of corresponding and superimposing the patient's intraoperative anatomical structures on the acquired images. (1) Point-to-point matching: the pointer is used to intraoperatively touch the reference points on the surface of the vertebrae and match the corresponding positions with the virtual images. (2) Surface matching: the pointer is employed to touch several random points covering the surface of laminar structures and match the corresponding positions with the 3D image model.

3.8 Registration

Registration is the process of using a specific algorithm to find the corresponding points between the anatomical structures identified in the world coordinate system (space-absolute coordinate system) and the navigation images of the virtual coordinate system.

3.9 Track

With the use of the pointer and smart tool trackers, the track reflects the real-time coordinates provided by the virtual coordinate system to guide the surgical procedure.

3.10 2D C-arm fluoroscopy-based navigation

Intraoperative X-ray images are taken by the C-arm system and transmitted to the navigation system to guide the operation.

3.11 Preoperative 3D CT-based navigation

Preoperative CT images are taken according to specific requirements and transmitted to the navigation system to guide the operation.

3.12 Intraoperative real-time 3D fluoroscopy-based navigation

Intraoperative 3D images are taken by the C-arm or O-arm or by using intraoperative CT systems and are then transmitted to the navigation system to guide the operation.

3.13 Image drift

Image drift occurs when the image position does not match the actual position due to intraoperative displacement, deformation of patient's structures, or long-distance transmission of the infrared light beam.

3.14 Computer-assisted minimally invasive spinal surgery

This approach combines minimally invasive spinal surgery with computer-assisted navigation to improve its precision and safety.

4. Indications for navigation-assisted spine surgery

Computer-assisted navigation can be used in most spinal surgeries. This technique focuses mainly on improving the accuracy of internal fixation and tracing lesion boundaries. Navigation-assisted spinal surgery techniques are advantageous in patients with anatomical variations and malformations or unclear bony anatomical landmarks and can be applied in minimally invasive spinal surgery [22–24] and spinal revision surgery [25].

(1) Spinal trauma: indications include odontoid fracture [26], unstable Hangman's fracture [27], lower cervical spinal fracture [28], and thoracic and lumbar spinal fracture [21].

(2) Degenerative spinal disease: indications include cervical disc herniation [29], cervical spinal stenosis [29], cervical ossification of the posterior longitudinal ligament [30], thoracic ossification of the ligamentum flavum [31], lumbar disc herniation [32], lumbar spinal stenosis [33], and lumbar spondylolisthesis [34].

(3) Spinal malformation: indications include upper cervical spinal malformation [34], severe congenital spondylolisthesis [35], scoliosis [36], and kyphosis [37].

(4) Spinal tumors: indications include primary or secondary spinal tumors [38] and intraspinal tumors [39].

(5) Spinal infections: indications include, but not limited to, spinal tuberculosis infection [40].

5. Contraindications for navigation-assisted spine surgery

(1) Systemic diseases or medical comorbidities, namely, severe hemorrhagic, cardiovascular, and respiratory diseases and other ailments that contraindicate surgery and prevent patients from tolerating general anesthesia or surgery.

(2) Excessive mobility or instability of the planned spinal segments in which significant intraoperative changes in the position of the spine cause significant navigational errors.

(3) Concerns about radiation exposure.

(4) Inability to place a tracker that is stable and rigid throughout the procedure.

(5) Failure of the system to calibrate or correctly acquire the images.

6. Learning curve

Computer-assisted navigation is a surgical-assistive technique that requires training and mastery. Operation time, radiation exposure, and accuracy of pedicle screw placement are influenced by the duration of learning but improve with surgeons' experience and training [41–43].

7. Placement of navigation instruments and patient positioning

Fig. 1 shows the placement of the navigation equipment and the patient position. The camera is placed on one side of the operation bed, above and toward the operation field, to ensure that the pathway between the camera and the trackers is not blocked. The operating light must be considered for potential obstruction of the camera during surgery, because the light itself may interfere with the camera while detecting the tracker points. The C-arm is placed on the other side of the operation bed. The computer system can be placed far from the operation area. Other tools such as electrophysiological monitors and autologous blood transfusion equipment can be arranged as appropriate.

8. Navigation-assisted spine surgery

The proposed guidelines aim to apply to different types of navigation systems, standardize clinical practice (Fig. 2), improve the clinical efficiency and precision of the navigation system, and shorten the clinical learning curve.

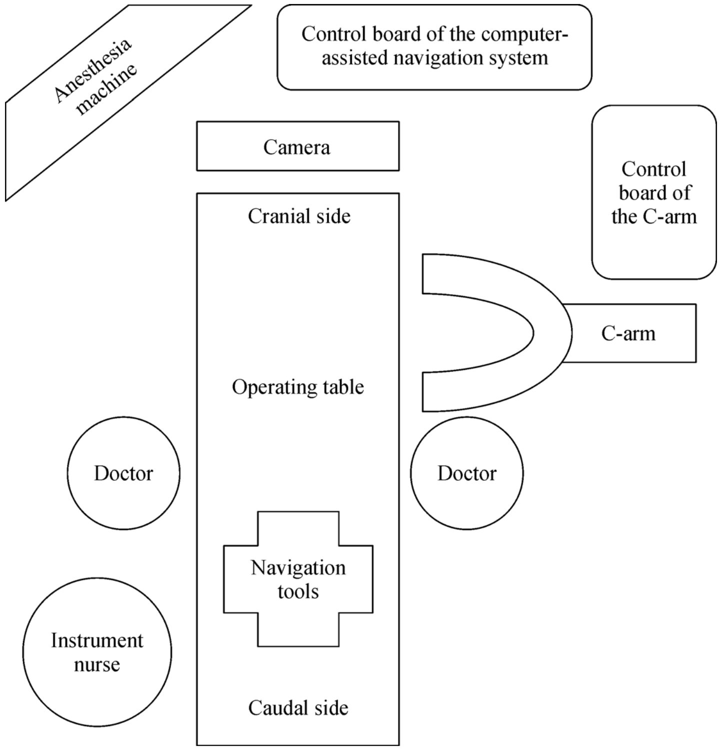

Fig. 1 Position sketch for the positions of the participant and navigation equipment.

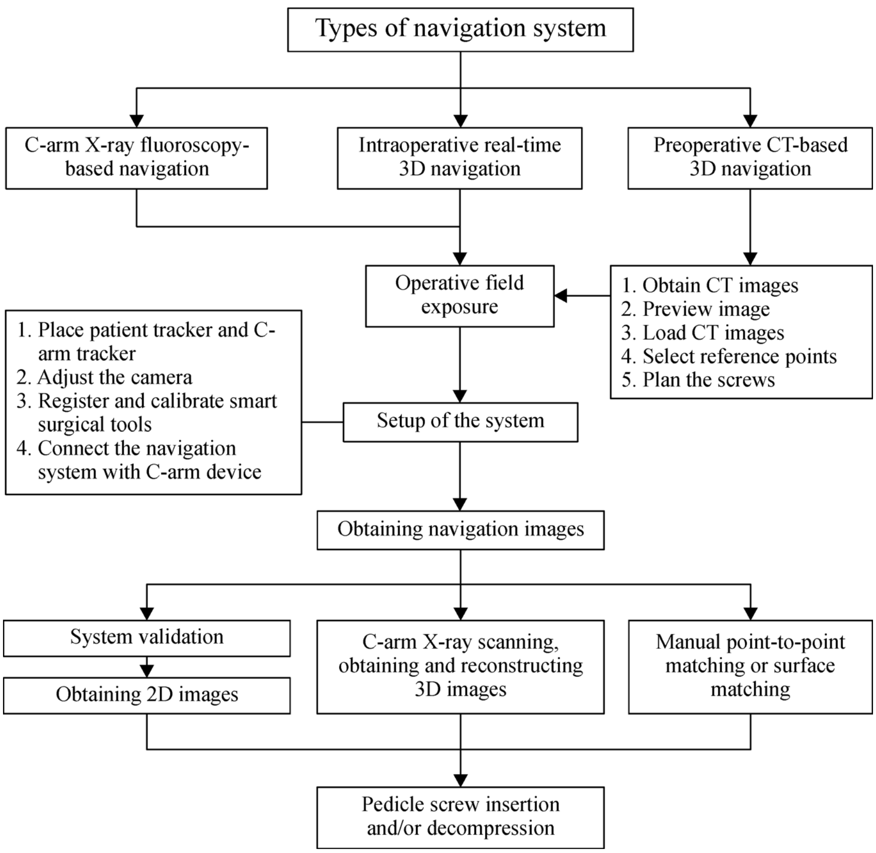

Fig. 2 Representative flow diagram of computer-assisted navigated spine surgery.

8.1 Preoperative design

Preoperative design is essential for CT-based navigation and must be completed prior to the surgery.

8.1.1 CT image acquisition

Obtain the CT images of the surgical site under specific parameters and transmit them to the computer navigation system. Recommended scanning parameters are as follows: no-tilt scan, minimize the scope of the scan while complying with the surgical requirements to reduce interference from surrounding soft tissues, and layer thickness ⩽ 1 mm.

8.1.2 Image preview

Click “image preview” in the navigation software to confirm that the marking sequence of the image coincides with the patient’s position and orientation.

8.1.3 Image loading

Once selected and arranged in sequence, load the images into the patient’s record and automatically complete image reconstruction in 3D planes.

8.1.4 Reference point selection

Once 3D images are obtained, select at least three prominent and distinct anatomical landmarks on the vertebral laminae of the operated segment to complete point-to-point matching.

The following must be considered during reference point selection: (1) reference points should be easy to expose, (2) soft tissues must be completely removed, (3) reference points should be confirmed by the surgeon, and (4) reference points should be selected separately for each surgical vertebral segment for multi-segment operations.

8.1.5 Surgical design

Osteotomy site, decompression extent, and the position, length, and diameter of the pedicle screw all can be planned and designed in the software.

8.2 Surgical procedures

8.2.1 Patient positioning

The patient’s position is similar to that in conventional surgery and can be prone, supine, or lateral positions in accordance with the surgical requirements.

8.2.2 System installation

(1) Install the patient tracker: select the appropriate patient tracker and fix it to the spinous process. In upper cervical surgery, the tracker can be placed *in vitro*. The tracker should not interfere with surgery nor be blocked, and the tracker and spinal segments are intraoperatively stabilized as much as possible to avoid navigation errors.

(2) Adjust the location of the cameras and sensors toward the surgical field and patient tracker.

(3) Register and calibrate the smart surgical tools as follows. First, turn on the smart surgical tool and calibration tool. Point the tip of the tool at the target center of the calibration tool and start registration and calibration. Use a universal tracker and a universal registration desk to register and calibrate tools that are not specially designed for navigation.

(4) Register the C-arm fluoroscopy device tracker by connecting the navigation system with the C-arm fluoroscopy system.

(5) Adjust the relative position of the C-arm tracker, patient tracker, and smart surgical tools to ensure their visibility and position in the center of the monitor screen without any obstacles. The distance between the patient tracker and sensor should be approximately 1.5 m.

8.3 Image acquisition

8.3.1 Accuracy validation (applies only to 2D C-arm fluoroscopy-based navigation)

Initiate system accuracy validation by obtaining a fluoroscopic image and determining whether the image of the trackers and smart surgical tools covers the contour of the calibrated image.

8.3.2 Point-to-point matching (applies only to preoperative 3D computed tomography-based navigation)

Select the preoperatively designed reference points for intraoperative point-to-point matching.

8.3.3 Surface matching (applies only to preoperative 3D computed tomography-based navigation)

Touch at least 35 points on the surface of the anatomical structures using the pointer. Ensure that the pointer is immobile while clicking the button. Reference point distribution must cover the entire bony structure of the posterior laminar surface.

8.3.4 Image acquisition and automatic registration (applies to 2D C-arm fluoroscopy-based navigation or preoperative 3D computed tomography-based navigation)

(1) 2D C-arm fluoroscopy-based navigation: obtain several views of the vertebra, such as one anterior–posterior, one lateral, and two oblique fluoroscopic images, by the C-arm and load them into the workstation. The registration is automatic; thus, manual point-to-point or surface matching is unnecessary.

(2) Intraoperative real-time 3D navigation: choose the scanning area, patient position, and location of the C-arm on the computer user interface. Manually move the C-arm to the end-point of scanning and then to the start-point of scanning. Continue to hold the switch and start 3D scanning until the C-arm automatically rotates 190°. Continuously obtain 100 digital images, and reconstruct the 3D images. The entire scanning process takes 1–2 min. Load the images to the workstation, and the registration is automatic.

8.4 Pedicle screw insertion and decompression

8.4.1 2D C-arm fluoroscopy-based navigation

Choose the entrance point and sagittal angle of the screw by using the pointer under real-time computer guidance based on previously acquired 2D images.

8.4.2 Intraoperative real-time 3D navigation

(1) Move the registered and calibrated surgical tools in the navigated surgical field to ensure that the surgical tools are visible on the navigation image. This process can be repeated.

(2) Identify the estimated entrance point based on bony anatomical landmarks. Place the tip of the registered surgical tool next to the estimated entrance point. The exact entrance point can be determined using the navigation image. Drill through the cortical bone at the entrance point using the registered cone. If the angle is sharp between the cone and bone surface, then the surgeon can use a high-speed drill or rongeur to prepare the entrance point before drilling through the cortical bone.

(3) Place the drill tip on the entrance point. Choose the longest screw pathway on the sagittal and axial plane and ensure that the screw pathway goes through the center of the vertebral pedicle. Drill at the planned angle and stop at any time to verify the proper screw pathway on the reconstructed image. The diameter and length of the pedicle screw can be designed in the navigation software.

(4) Ensure the pedicle wall is intact before driving in the screw of the appropriate size. Tapping can be performed when necessary.

(5) Use intraoperative fluoroscopy to verify proper pedicle screw placement when necessary, and proceed with laminar decompression or fusion as preplanned. Navigation can also be used to track a drill bit and guide a saw or other devices, such as an ultrasonic bone scalpel.

8.4.3 Preoperative 3D CT-based navigation

The navigation system automatically calculates the systemic accuracy. If the error is acceptable (< 0.5 mm), then the procedure continues. The best entrance point and screw direction are chosen under CT-reconstructed 3D image guidance.

8.4.4 Combined preoperative CT/magnetic resonance imaging and intraoperative imaging (combined navigation)

For special surgical needs such as musculoskeletal tumor resection, navigation can be guided by preoperative CT/magnetic resonance imaging combined with intraoperative imaging.

9. Advantages of navigation-assisted spine surgery

Compared with traditional surgical techniques, computer-assisted navigation improves the placement accuracy of pedicle screw and other types of hardware [44–47] and decreases radiation exposure for medical practitioners [48]. When performed by experienced surgeons, this method does not increase the intraoperative blood loss and surgical time [49]. Computer-assisted navigation is more advantageous over minimally invasive spinal surgery, spinal revision surgery, correcting spinal malformation, and thoracic spinal surgery [50].

10. Pitfalls and recommended solutions

10.1 Fundamental requirements of surgeons

Surgeons must be familiar with traditional spinal surgeries and able to convert to traditional surgery when the navigation system fails.

10.2 Requirements for the operating table

The operating table must be radiolucent, and a carbon fiber operating table containing no metal is recommended. The base of the operating table should not interfere with intraoperative image collection.

10.3 Regular maintenance of the navigation system

10.3.1 Data line

Carefully check whether the interface of each transmission data line is loose or has fallen off and replace aged data lines.

10.3.2 Battery

Check for a fully-charged battery prior to operation to ensure that the navigation system functions normally.

10.3.3 Navigation tools

Carefully check for metal fatigue in the navigation tools to avoid intraoperative breakage.

10.3.4 C-arm tracker

Check and ensure that the screws and nuts on the tracker are tightly fastened. Unstable tracker fixation may cause coordinate errors during image acquisition and seriously affect the navigation accuracy.

10.3.5 Accuracy of the system

Regularly calibrate the system's precision.

10.4 Image drift

Navigation imaging is modeled on rigid bodies; therefore, the object's position must be relatively immobile during 3D coordination and image acquisition. The ability to detect image drift is a basic requirement for surgeons. When image drift is suspected, anatomical markers, such as spinous process, facet joints, or the root of the transverse processes, can be selected to verify navigation accuracy. If image drift cannot be corrected intraoperatively, then imaging scanning and other related procedures must be repeated [47,48].

Common causes of image drift include the following.

10.4.1 Relative displacement of the surgical objects to the patient's tracker

(1) When flexible parts of the spine (such as the cervical spine) are operated, forces applied to the spine or excessive stretching of surrounding soft tissues cause relative displacement between bony structures. Thus, surgeons must operate gently and minimize displacement of the spine and the patient under this circumstance. Force application must be halted to verify if the surgical tool is in the right position in the navigation image.

(2) Decompression or osteotomy can damage spinal column stability, resulting in the relative displacement of the anatomical structures. Temporary fixation is recommended to avoid image drift in this situation. If the system's accuracy remains uncertain, then use anatomical markers for verification.

(3) During long-segment fixation, the relative displacement of anatomical structures can occur when operating on distal vertebral bodies. The recommendation is to proceed operatively from the distal side of the tracker to the proximal side.

(4) If a patient intraoperatively changes position because of movement under anesthesia or disturbance on the table, then the stereotactic anatomical positions may be altered. Accuracy verification of the entire system is then necessary using anatomical landmarks after the patient is sedated and anesthetized.

(5) Displacement of the patient tracker: the patient tracker must be immobile relative to the patient. If the tracker is touched and moved intraoperatively, then navigation accuracy decreases, and the navigated operation may fail. This phenomenon is the most common reason for navigation failure [46]. Surgeons must restart navigation registration in this situation.

(6) Loosening or shifting of universal trackers: some navigation systems allow universal trackers to be connected to other tools, such as grinders and sleeves, which can then be registered and identified by the navigation system. Surgical instruments connected to a universal tracker must be rigid and solid; deformed or bent surgical instruments cause inaccurate navigation. Image drift occurs when the universal tracker is not firmly connected to the surgical tool. Therefore, surgeons should carefully check whether the tracker is tightly fixed and its position interferes with the operation prior to using tools connected to a universal tracker. Surgeons should also avoid touching the universal tracker intraoperatively. If touched by accident, then the tracker must be checked to ensure that it is not loose, and an anatomical landmark must be chosen for navigation accuracy validation.

10.4.2 Patient position changes

Changes in the relative position of anatomical structures may lead to inaccurate navigation when the patient lies supine for preoperative and intraoperative image capture. The recommendation is to perform intraoperative single-vertebra registration as close to the operative region as possible and frequent accuracy checks to ensure navigation accuracy.

10.4.3 Inaccuracy related to infrared light

An accurate navigation system requires good emission, reflection, and reception of infrared light. Navigation system inaccuracies may be caused by the out-of-range distance and angle, interference by stray light, or movement of relative positions [51]. The recommendation is to adjust the position of the sensor to ensure that the operating field is in the center of the detection range and to avoid bright-light irradiation of navigation tools and position sensors. When contaminated with blood, the infrared generator or reflective ball should be cleaned. Instrumentation that is currently not being used and lies outside the operative field, for example, on a Mayo stand, may still be visualized by the camera system, thus leading to errors in recognizing active instruments. Therefore, all instrumentations currently not in use must be placed in an area outside the camera field or behind an opaque cover/screen.

10.4.4 Navigation system hardware or software failure

If the navigation system shuts down, then contact the professional engineer first to ensure that preliminary investigation is performed under the engineer's guidance. If the problem cannot be solved, then the navigation equipment should be turned off, and the operation must be converted to conventional operating technique. Common arising problems are as follows:

(1) The image cannot be transmitted. Check whether the data wire is completely connected.

(2) The C-arm failed. Check whether the initial and end position of the C-arm can be detected by the position sensor.

(3) The system refused to scan again. Check whether the C-arm memory is full.

Precision medicine is a future trend, and computer-assisted navigation is one of its important components. These proposed guidelines aim to introduce different techniques to surgeons and encourage them to develop a wide interest in the area. These guidelines are broad based and for guidance purpose. The user interphase of different systems may vary. The guidelines were adapted by CAOS International in June 2018 in Beijing. With major developments in "intelligent" spinal surgery, the combination of computer-assisted navigation and surgical robotic techniques can be expected in the future. Revision of these guidelines is recommended every 2 years to incorporate newly published evidence.

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Compliance with ethic guidelines

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