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A NEW SURGICAL POSITIONING SYSTEM FOR ROBOTIC ASSISTED MINIMALLY INVASIVE SPINE SURGERY AND TRANSPEDICULAR APPROACH TO THE DISC

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Minimally Invasive Spine Surgery (MISS) procedures for the treatment of spinal pathologies have experienced exponential growth due to improved techniques and decreased trauma to the patient. Several MISS procedures that require the use of a trans-pedicular cannula as a guiding tool for pedicle screw placement, delivery of biomaterials to the vertebral body or injection of biologics to the disc space have been described. Although these are clear advantages of MISS, the limited dissection and exposure may reduce the accuracy and stability of operation and make spine surgeons rely heavily on intraoperative fluoroscopy, raising concerns over the level of radiation exposure. Robot-assisted minimal invasive surgery has aroused more attention for its high precision and stability, minimizing risks of damage to neurovascular structures and diminishing harmful exposure to ionizing radiation. The aim of this paper is to describe and characterize a new surgical positioning system for for robotic assisted MISS. The system is conceived to be integrated in a surgical platform capable of supporting the surgeon in a new procedure to treat degenerative intervertebral disc disease. For this purpose, it is necessary to orientate a cannula in order to guide the bone drill along a planned route, to access the intervertebral disc through the pedicle and endplate. In particular, we describe a mechanism that percutaneously guides a cannula towards the intervertebral disc based on the acquisition of few fluoroscopic images. The design of the positioning system, with its features and constrains imposed by the presence of instrumentation and medical staff in the operating room, as well as the software for trajectory planning during surgery, are here described.

Back pain is one of the major source of chronic disability (1) and it has an important socioeconomic impact due to its treatment costs and related loss of work days (2). Although open techniques of surgical repair and augmentation of the spine are widely practiced with good success, the comorbidities of open back surgery are serious and well documented. First of all, extensive soft tissue dissection during open surgery has been shown to trigger short term damage and affect long term degenerative changes (3), which increase the patient's susceptibility to re-injury (4) determining long recovery time and extended loss of work days (2, 5).

With the evolution of modern spine surgery, the use of Minimally Invasive Spine Surgery (MISS) procedures for the treatment of spinal pathologies has experienced exponential growth due to improved techniques and decreased trauma to the patient (6). Indeed, these techniques are associated with decreased intraoperative blood loss, operative time and morbidity. Moreover, these procedures enable earlier mobilization, decreased hospital stay, decreased pain, and an earlier return to baseline function when compared with conventional open procedures. In the past decades, MISS has been widely used in

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deformity, trauma spinal tumor, degenerative disease and spondylolisthesis. Moreover, several MISS procedures that require the use of a trans-pedicular cannula as a guiding tool for pedicle screw placement, delivery of biomaterials to the vertebral body or injection of biologics to the disc space have been described. These procedures are performed in close contact to nervous structures and therefore need high precision.

Although there are clear advantages in MISS, the limited dissection and exposure may reduce the accuracy and stability of operation and make spine surgeons rely heavily on intraoperative fluoroscopy, raising concerns over the level of radiation exposure for all the people in the operating room. Therefore, during the last few decades, robot-assisted minimal invasive surgery has aroused increasing attention for high precision and high stability. Indeed, robotics may help minimize the risk of damage to neurovascular structures maintaining a high degree of accuracy and consistency; furthermore, it may facilitate surgeon access and operating room dynamics, diminishing harmful exposure to ionizing radiation in patients and the operative team. Several surgical robotic platforms have been developed to guarantee an effective surgical technique and assistance to surgeons (7, 8) and are being used to deal with different procedures such as minimally invasive and percutaneous repair and treat a wide variety of orthopedic disorders, such as degenerative disc disease or spinal fractures.

The aim of this paper is to describe and characterize a new surgical positioning system for robotic assisted MISS. This system is conceived for integration in a surgical platform able to support the surgeon in a new procedure to treat degenerative intervertebral disc disease. The surgical procedure involves a transpedicular approach to access the intervertebral disc, which can be performed percutaneously, overcoming the disadvantages of open surgery (9-12). However, this approach bring the risks of nerve root damage and dural tear (13). For this purpose, it is necessary to orientate a cannula to guide the bone drill along a planned route, in order to access the intervertebral disc through the pedicle and endplate. The design of the positioning system, with its features and constrains imposed by the presence of instrumentation and medical staff in the operating room, as well as the software for trajectory planning during surgery, are here described.

The surgical platform

In order to mitigate the risk of injuries during the execution of the transpedicular procedure, a surgical platform has been developed to support the surgeon in defining and following the proper route to the nucleus pulposus during the drilling of the vertebrae. The platform consists of a positioning system and a drilling-trajectory-planning software that work together. The positioning system is clamped to both sidebars of the operating table (Fig. 1) and it slides along them. The clamping mechanism is mounted below the operating table, while the positioning system is situated on one side of it. This allows the medical staff more freedom of movement around the operating table, as well as the use of the platform together with other instruments in the operating room, namely the C-arm.

The Positioning System

The positioning system supports the surgical tools used to drill the vertebras. Its mechanical architecture has 5 Degrees of Freedom (DoF) for freely positioning the surgical tool in the space. The missing degree of freedom corresponds to the rotation around the axis of the tool, which is indeed not necessary considering that most tools are axisymmetric (e.g, cannulae to create a percutaneous access). The 5 DoFs are manually actuated by the surgeon through knobs (Fig. 1). Rotational joints are equipped with an encoder (RLS, RM22) to measure the angular amplitude (Resolution 0.35°). Each joint is kinematically irreversible, so that it locks in the specific configuration defined by the surgeon.

An additional l-DoF allows the translation of the surgical tool along the direction of intervention. The kinematic architecture (Fig.. 2) can be divided into three sub-modules: i): a mechanical device for rough positioning of the surgical tools (joints d_0, j_0 and d_1); ii): a double planar parallelogram (joints $j_{1\text{-}8}$) that creates a remote center of motion (RCM) centered on the tip of the surgical tool; iii): a support for a linear guide (joint d_4) on which the surgical tool can slide.

Such architecture provides a large workspace (755x600x311 mm^3) outside the patient's body (13) and once all joints are locked, only the advancement of the surgical tool along the drilling direction must be taken care of by the surgeon. Materials used are aluminum (EN AW 6060), stainless steel (EN 1.4404) and carbon fiber (HS). The overall weight is 64.7 Kg.

Software for trajectory planning during surgery

The trajectory-planning algorithm relies on the possibility of reconstructing the three-dimensional orientation of a segment using its projections on two orthogonal planes. In the case of the described surgical procedure, such projections are provided by two perpendicular fluoroscopic images of the operating site [antero-posterior (AP) and medio-lateral (ML) views of the lumbar spine], acquired through a C-arm.

The software developed and implemented in MATLAB (Mathworks, Natick MA, USA) allows to: i): determine the current orientation of the cannula and the related configuration of the positioning system (14); ii): plan a safe route to reach the intervertebral space; iii): return the joint parameters j_1 and j_2 to update the configuration of the positioning system so that the driller can reach the IVD space following the planned route. A global reference frame, O-x-y-z, is adopted for the resolution of the problem (Fig. 3). The calculation of current of orientation and trajectory planning requires the following steps:

a) Identifying on both images the same detail (e.g. vertebra thickness, cannula length) and scaling the two views so that such detail has the same dimensions in ML and AP views. In this way, scale changes, due to accidental shifts of the rotation center of C-arm during the acquisition, are compensated.
b) Identifying two points of the cannula on ML and AP views (e.g. the tip and the distal point) in order to: i): operate a registration of the images (along the y-direction); ii): evaluate the current orientation of the cannula and the corresponding configuration of the positioning system (Fig. 3).
c) Choosing on both projections the desired entry point on the vertebra end plate. At this point the software draws a line representing the transpedicular route projected on the two views (Fig. 3).
d) Once the transpedicular trajectory is defined, the software returns the joint parameters according

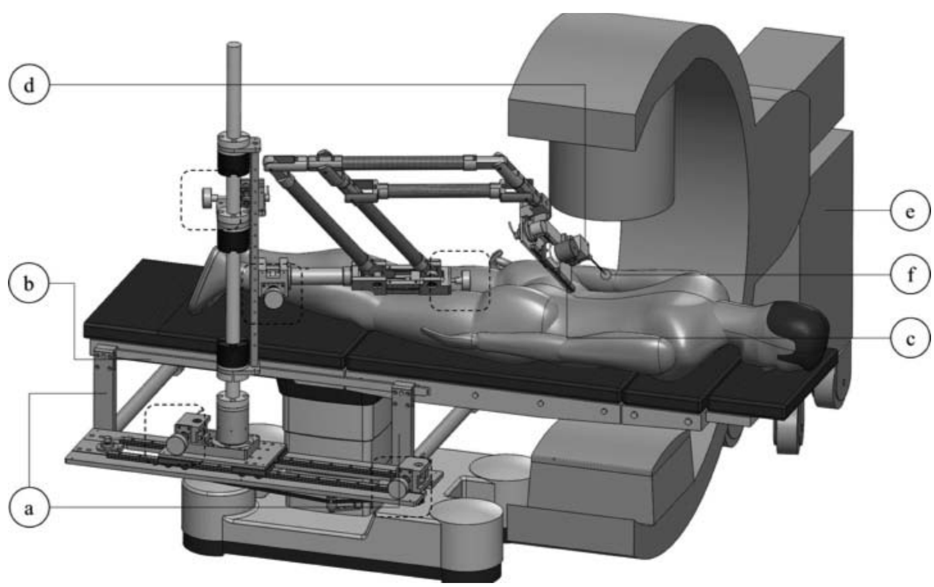

Fig. 1. *The surgeon can adjust the kinematic configuration of the positioning system by manually operating the knobs (highlighted with dashed square); **a**): clamping bars; **b**): side bar of the operating table; **c**): linear guide; **d**): surgical tool; **e**): C-arm; **f**): RCM of the double planar parallelogram.*

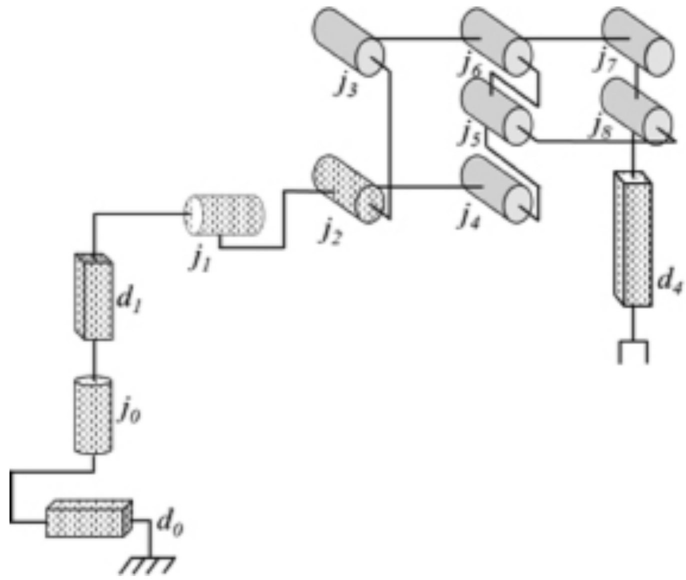

Fig. 2. *Kinematic architecture of the positioning system. Dash ed joints are manually actuated.*

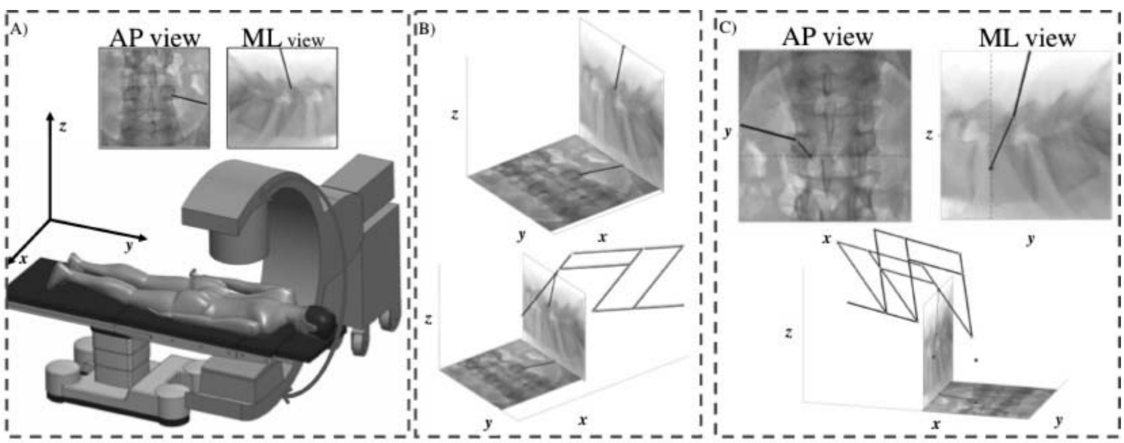

Fig. 3. *Software operating scheme: **A)**: acquisition of the medio-lateral (ML) and antero-posterior (AP) fluoroscopic projections; **B)**: the surgeon identifies the cannula ends on both images and the software reconstructs the current positioning system configuration; **C)**: the surgeon chooses the entry point on the end plate (blue dots) on both **AP** and **ML** views. The software evaluates the joints parameter to be set so that the positioning system can guide the drilling tool along the selected route.*

to which the operator can manually adjust the configuration of the positioning system (Fig. 3).

DISCUSSION

In this paper, a new device for MISS has been developed. We designed and described a surgical positioning system able to percutaneously guide the cannula orientation towards the intervertebral disc based on the acquisition of a few fluoroscopic images. Starting from the identification of the insertion point and trajectory to the intervertebral disc drawn on two perpendicular C-arm fluoroscopic images by the surgeon, the software can guide the insertion through the regulation of the system joints configuration.

Different robotic-assisted MISS procedures have been previously described and two different approaches can be identified in image-guided navigation. Indeed, a distinction can be made between systems that enable navigation on preoperatively acquired 3D MR- or CT- scans (15-20) and approaches based on intraoperatively fluoroscopic images (21-24). The first approach provides 3D insight and no further radiation during surgery.. However, the 3D image-guided navigation procedure can still be quite invasive and time consuming since the most commonly used image-to-patient registration technique in MR- or CT-guided navigation requires touching anatomic landmarks and therefore removal of soft tissue. The second approach, which is based on intraoperatively acquired fluoroscopic data, does not require an extra image-to-patient registration step, limits radiation and can guide in the procedure by displaying the instrument in multiple projection directions simultaneously. However, it does not provide true 3D information to the surgeon. In clinical practice, commercial systems for the preoperative planning in 3D virtual environment based on CT scan are used. The SpineAssist (MAZOR Surgical Technologies, Caesarea, Israel) is an image-based mechanical guidance system used for spinal fusion. During surgery, two fluoroscopic images are acquired and matched to the pre-operative CT information to guide a surgical robot.. (25, 26)

We propose a surgical positioning system for orienting the insertion of a surgical cannula during MISS that is characterized by a unique set of features, which is not exhibited by other solutions. Indeed, the new system is characterized by low invasiveness, as no mechanical fixtures onto the bones is necessary; low cost; ease of installation, since it can be used in any standard or hybrid surgical room equipped with a C-arm. Moreover, the system has been designed and dimensioned to be compatible with the size of C-arm workspace and interfere minimally with the surgical procedure and medical staff.

The designed system includes a software for the identification of the target cannula orientation, starting from the desired insertion point, and from the pre-planned insertion direction, and a mechanical support handling the cannula and orienting it as required. Starting from two perpendicular fluoroscopic images, the software can assist the surgeon to plan a safe route to reach the intervertebral space. Thus, the software developed for the transpedicular route planning aims to reduce the number of fluoroscopic images, considerably decreasing the absorbed dose for the patient. Furthermore, the SPS simplifies the cannula insertion procedure: the route planning does not require the use of an additional optoelectronic system, but it is only based on fluoroscopic images captured with a C-arm fluoroscope.

In the final prototype, a dedicated position sensor measures the advancement of the drill. In such configuration, the couple of initial images is theoretically sufficient to assure the correct positioning of the cannula. Nonetheless, we expect that a few additional images should be acquired for redundancy and safety reason.

CONCLUSION

This new surgical positioning system represents a promising robotic device for use in various minimally invasive interventional procedures of the spine such as vertebral biopsy, vertebroplasty, paraspinal abscess drainage, spinal fusion, discectomy and regenerative approaches decreasing the radiation exposure to the attending staff and increasing precision. However, further experiments, especially in vivo studies are needed to establish this application in the clinical routine.

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