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ORIGINAL STUDY

Pedicle screw insertion : robotic assistance versus conventional C-arm fluoroscopy

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Bone-mounted robotic guidance for pedicle screw placement has been recently introduced, aiming at increasing accuracy. The aim of this prospective study was to compare this novel approach with the conventional fluoroscopy assisted freehand technique (not the two- or threedimensional fluoroscopy-based navigation). Two groups were compared : 11 patients, constituting the robotical group, were instrumented with 64 pedicle screws ; 23 other patients, constituting the fluoroscopic group, were also instrumented with 64 pedicle screws. Screw position was assessed by two independent observers on postoperative CT-scans using the Rampersaud A to D classification. No neurological complications were noted. Grade A (totally within pedicle margins) accounted for 79% of the screws in the robotically assisted and for 83% of the screws in the fluoroscopic group respectively (p = 0.8). Grade C and D screws, considered as misplacements, accounted for 4.7% of all robotically inserted screws and 7.8% of the fluoroscopically inserted screws (p = 0.71). The current study did not allow to state that robotically assisted screw placement supersedes the conventional fluoroscopy assisted technique, although the literature is more optimistic about the former.

Keywords : pedicle screw ; spine ; computer-assisted surgery ; image-guided techniques ; robotic surgery ; navigation ; freehand ; fluoroscopy.

INTRODUCTION

Indications for instrumentation of the thoracic and lumbar spine with pedicle screws have been expanding, and an increasing number of spinal conditions can benefit from this widespread use. However, pedicle screw insertion represents a potential risk to neurological and vascular structures. Accuracy of pedicle screw placement in *in vivo* studies varies widely (2). Several techniques have been developed, in particular CT-based navigation, in order to cope with this problem. A meta-analysis concluded that CT-navigation improves accuracy of pedicle insertion in the lumbar spine, but – interestingly – not in the thoracic spine (2). More recently robotically assisted pedicle screw insertion has been introduced, also aiming at increasing accuracy, as shown in a cadaveric study (*10*). Even though encouraging results have been published, in particular in a percutaneous

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setting involving mainly instrumentation of the fifth lumbar vertebra (*5*), no study comparing accuracy of this novel technique to other insertion methods is available, in particular in a more varied range of anatomical regions of the spine. A recent multicenter retrospective review performed by the developers of the robotic device included the majority of screws implanted worldwide using this novel technique (*1*). They reported on what was described as 'clinical acceptance', that is subjective evaluation by each operating surgeon of whether the position of the implant was judged being acceptable using intraoperative fluoroscopy. A proportion only of the screws inserted were evaluated by postoperative CT-scans. Moreover, this study did not have a control group. The authors wanted to independently compare the accuracy of this new robotical technique with the usual insertion technique in their unit, namely freehand insertion assisted by fluoroscopy and preoperative CT-scans.

MATERIALS AND METHODS

Patients

A total of 34 consecutive adult patients underwent implantation of 128 pedicle screws : 8 upper thoracic screws (T1-T6), 12 lower thoracic screws (T7-T12), 24 upper lumbar screws (L1-L3), 68 lower lumbar screws (L4-L5) and finally 16 sacral screws (S1). The robotic group consisted of 11 patients with 64 screws ; the fluoroscopic group consisted of 23 patients, also with 64 screws. Both groups were matched for spinal level, diagnosis (straight or scoliotic spines), side (right or left) and age : 65 and 66 years. The groups were less well matched as far as the male/female ratio was concerned : respectively 6/5 and 1/2. The underlying pathology was vertebral fracture, spinal stenosis, degenerative disc disease or lumbar scoliosis. No thoracic scoliosis patients were included.

The robotic device was obtained on loan for a specific trial period. The study was approved by the institutional review board.

Surgical technique

All patients were operated upon by a single surgeon. All operations were open, and no percutaneous techniques were employed. Two techniques were compared.

A. The conventional fluoroscopy assisted free hand insertion based on preoperative CT-scans

Lateral fluoroscopy only was used as a means of verifying the trajectory of pedicle preparation with the help of a probe. Integrity of the pedicle was also verified for each screw with the help of a ball-tipped probe.

B. Robotic screw insertion

The detailed technique having been reported in the literature (*5,10*), it will be briefly summarized. A preoperative spiral CT-scan of the spine was imported into a workstation commanding a miniature robotic system (MAZOR Surgical technologies Ltd). The software provided allowed for placement of virtual implants on the CT-images as well as three-dimensional verification of the prospected insertion path (Fig. 1). After exposure of the spine, a special clamp was attached to the spinous process of one of the vertebrae in the centre of the region to be instrumented. An antero-posterior and a 60° oblique view were obtained with an image intensifier, linked to the workstation. These two images were used by the system in order to compensate for any distortion. The motorized robotic device was attached to the previously described clamp (Fig. 2), and it placed a cannulated arm in the desired direction as defined in the preoperative plan for each individual screw to be inserted. Several levels could be instrumented without the need to alter the fixation of the device to the spine or to repeat the registration process. Following drilling of the path through the cannulated arm, K-wires were left in place and cannulated pedicle screws were inserted (DePuy Spine, Raynham, Il, USA). Additionally, lateral fluoroscopy was used to verify the trajectory and the screw position. No screw position was altered or abandoned as a result of the image intensifier verification. All screws intended to be inserted robotically were implanted without the need to abandon the robotic guidance. In both groups, screw insertion preceded any spinal decompression. Radiation dose (mGy/m2) and duration (seconds) were directly recorded from the image intensifier for the total length of the procedure and were divided by the total number of pedicle screws inserted.

Radiological evaluation at follow-up

Screw position was judged on DICOM images of a postoperative CT-scan by two independent observers, blinded to the method of screw insertion, twice within a two months interval. The Rampersaud scale (*6*) was used. It evaluates screw position in three different planes. CT-

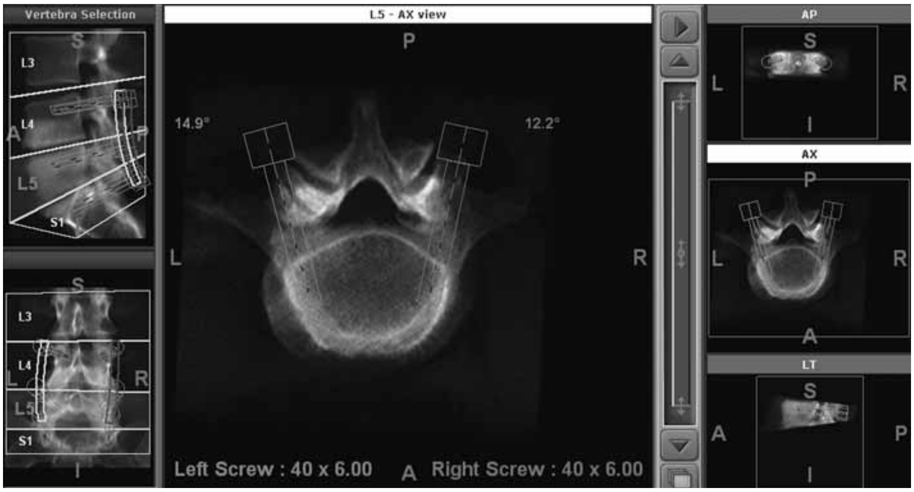

Fig. 1. — Screen capture from the planning software illustrating the visualization of the planned trajectories in three planes

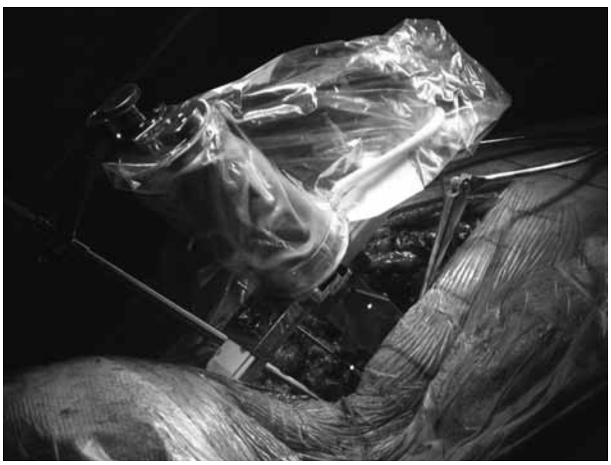

Fig. 2. — The miniature robot mounted posteriorly for instrumentation of the upper thoracic vertebrae during a cervico-thoracic fusion procedure.

images were therefore analyzed in axial, sagittal and coronal planes. The scale describes the relative position of the screw to the pedicle (Grade A = completely in ; Grade B = < 2 mm breach ; Grade C = 2-4 mm breach ; Grade D = > 4 mm breach). The scale also describes the direction of the breach. In the current study, grades C and D were considered as misplacements.

Statistical analysis

Fisher's exact test, Student's t-test and Cohen's kappa statistics were used, as appropriate.

RESULTS

Intra- and inter-observer reliability of the Rampersaud classification was moderate (0.35 and 0.45 respectively), being least good in the axial plane. No patients suffered neurological injury related to implant position.

Seventy-nine percent of the screws in the robotically assisted group and 83% of the screws in the fluoroscopic group were completely located within the pedicle (Rampersaud grade A). This difference was not statistically significant (p = 0.8). No more was there a statistically significant difference as to grades B, C and D (21% in the robotic group and 17% in the fluoroscopic group respectively) (p = 0.8).

In the robotically assisted group three screws were misplaced in the axial planes (grades C and D). Two were lumbar and one thoracic. Only one of the three (at the L2 level) was medially misplaced and of grade C (Fig. 3). One screw only was judged as grade D and was laterally placed (at the L4 level). The overall misplacement rate of the robotically inserted screws (C and D grades) was 4.7%.

In the fluoroscopic group 5 screws were misplaced in the axial plane. From those only one was thoracic ; it was laterally misplaced. There were two medially misplaced screws, each in a case of lumbar scoliosis (L5 right and left). Two screws were judged as grade D (at levels L2 and L5 level).

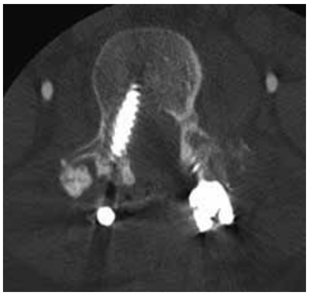

Fig. 3. — Axial postoperative CT image of the only grade C medially misplaced screw from the robotic group.

The overall misplacement rate (C and D grades) for the fluoroscopic group was 7.8% ($p = 0.71$).

In both groups no grade C or D pedicle breach was noted in the sagittal plane.

No statistical difference was observed between the two groups, neither as far as C and D grades were concerned, nor with respect to D grades alone ($p = 0.71$ and 0.62 respectively). Even though the number of thoracic screws was small (20 in total) no difference could be observed in misplacement rates between groups (one misplacement in each). No difference in peroperative radiation duration or dose received per screw implanted was observed between the two groups (Table I).

Table I. — Peroperative radiation : dose and duration

	Radiation dose/implant (mGy/m2)	Radiation duration/implant (sec)
Robotic group	0.18 (SD 0.18)	16.7 (SD 7.8)
Fluoroscopic group	0.11 (SD 0.11)	14.2 (SD 8.9)
t-test	p = 0.2 (not significant)	p = 0.5 (not significant)

DISCUSSION

Originality of the new technique

This novel robotically assisted screw insertion technique is different from the navigation techniques currently available. The main difference lies in the fact that the surgeon plans the direction and entry point of the placement of the screws on CT-images and relies on the system for the replication of the planned insertion path. It is therefore of paramount importance that the robotic device is rigidly fixed to the spine and that the cannulated arm, which is placed by the robot in the desired position, is not subjected to undue pressure by the soft tissues or by the surgeon himself during the drilling process. Furthermore the experienced surgeon may not always be able to verify the entry point. This verification is obviously not applicable to percutaneous screw placement where this device might also be used. Another major difference is that once the registration and matching process are completed, several levels can be instrumented at once without the need to acquire further images, providing of course that no movement between the vertebrae to be instrumented has taken place after the registration process.

Comparison with other studies

The accuracy of the robotically inserted screws was lower in the current study (79%) than in the study published by Devito *et al* (*1*), the originators of this technique (89.3% completely within the pedicle) (*1*), which as mentioned above had no control group and included 14 different surgical units. Noteworthy : this result was based on postoperative CT-scans, which were available in only 20% of their patients. The difference between both studies can be due to several factors such as a smaller number of screws in the current study but also to inclusion of percutaneous procedures in the Devito study (*1*), cases which as explained below could result in less soft tissue pressure and less trajectory deviation as compared to open procedures. It is worth noting nevertheless that percutaneous robotic insertion in the aforementioned study resulted in a smaller proportion of cortical breaches superior to 2mm, namely 2.4%, as opposed to 8.3% published in other studies (*7*).

The accuracy of screw placement using this novel miniature robotic device (79%) was close to the results of computer-assisted fluoroscopy (fluoro-navigation) using the same Rampersaud scale : 85% (*6*). But also the Rampersaud study mentioned that this accuracy was lower in the thoracic region ; it did not include a control group.

Intra- and inter-observer agreement

The intra- and interobserver agreement was fair to moderate, questioning the utility of the Rampersaud scale. This is, unfortunately, true for numerous other scales used in spinal surgery. For instance, agreement in using the AO classification of spinal fractures was found to be moderate (kappa = 0.475) (*11*).

Navigation systems still questionable

There is no agreement on the efficacy of navigated pedicle screw insertion in the literature (*9*). Even though a meta-analysis (*2*) concluded that navigation improved overall accuracy of pedicle screw insertion, this did not seem to apply to the thoracic spine . When examining the two main navigation techniques separately, namely CT-based and 2D fluoroscopy-based navigation, the former seemed to perform better than the latter, exception made for the lumbar spine where the two techniques were equivalent (*8*). A common problem in the various available studies on accuracy of screw placement is the difference in the methodology of screw position evaluation. This probably accounts for the extreme variability of screw placement accuracy, with some studies stating misplacement rates as high as 40% (*3*) rendering comparison between various studies inaccurate.

The misplacement rate in the current study was slightly lower in the robotic group when C and D grades were taken into account even though this did not reach statistical significance. It is noteworthy that the current study included only 15% of thoracic screws and in particular no thoracic scoliosis cases.

How to improve the robotic system ?

In the absence of software or hardware malfunctioning, the misplacement of pedicle screws using the robotic device can be explained through two different mechanisms. Firstly the drill can skid on bony surfaces inflicting a wrong trajectory to the drill bit compared to the one planned. Secondly pressure application during drilling can displace the vertebra to be instrumented, with again a different trajectory obtained from the planned one. Those possible errors could be minimized through usage of a high speed sharp trephine instead of the usual drill bit, and also through supplementary stabilization of the vertebra to be instrumented with the clamp supporting the robotic device. In theory, solving the above two issues could result in an even better accuracy compared to other navigation techniques, since the trajectory will be defined before surgery and carried out in accordance with the preoperative plan. On the contrary, in CT-based non-robotical navigation the surgeon will always have to hold the drill bit or pedicle finder in the best possible direction introducing a possible error during trajectory execution, which is independent of the accuracy of the matching process or the definition of the preoperative CT-scan.

Robotical system almost as good as an experienced spinal surgeon

The fact that the robotical system was no better than the conventional fluoroscopy technique was disappointing at first sight. It was nevertheless reassuring to observe that a robotic device still under development can insert pedicle screws – a delicate surgical task – with an accuracy almost equivalent to that of an experienced spine surgeon.

Strengths and flaws of this study

The strength of this study was that all operations were done by a single surgeon, and that both groups were matched for diagnosis and anatomical region. The different male/female ratios and the small groups constituted a weakness. Another weakness was the fact that the study included only a small proportion of thoracic screws (15%) and no thoracic scoliosis cases at all, precisely the areas which can be challenging even to experienced spinal surgeons. Larger studies including scoliotic thoracic spines with a control group for comparison are needed in order to verify the efficacy of this robotic technique.

Exposure to X-rays

Peroperative exposure to radiation in this series was equivalent for the two techniques. This could be due to the fact that the authors verified under image intensifier each robotically defined trajectory prior to definitive drilling, exactly like in the fluoroscopic group. As experience with this new system grows it might be possible to skip this verification step. Moreover, since the robotic arm is held in position in a stable way prior to drilling, the operating surgeon and operating room staff can withdraw at a safe distance from the radiation source during fluoroscopic verification (but not the patient). This might not be possible in some of the other navigation techniques or during non-navigated surgery. Of course, if the preoperative CT-scan was taken into account, the dose received by the patients was superior in the robotic group.

Robotic assistance useful for trainees

Finally the planning of the surgery using CT-scans in three different planes might enhance anatomy understanding and anticipate difficulties, not only for experienced surgeons but, more importantly, also for surgeons in training. Robotic assistance could play a role in a training setting by improving understanding of anatomy and allowing trainees to replicate placement accuracies of more experienced colleagues. Experienced surgeons using this technology for open lumbar cases might benefit less than younger colleagues.

Robotic assistance : time consuming ?

In this study we were unable to compare operative times between groups since a variety of different procedures was carried out, including decompression of neurological structures. Nevertheless, it does require some extra time (usually 10-15 minutes) to set up the targeting device and to acquire the first two fluoroscopic images necessary to the registration process similar to other navigation techniques.

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