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CLINICAL ARTICLE - SPINE

Unskilled unawareness and the learning curve in robotic spine surgery

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Abstract
Background Robotic assistance for the placement of pedicle screws has been established as a safe technique. Nonetheless rare instances of screw misplacement have been reported.The aim of the present retrospective study is to assess whether experience and time affect the accuracy of screws placed with the help of the SpineAssist™ robot system.
Methods Postoperative computed tomography (CT) scans of 258 patients requiring thoracolumbar pedicle screw instrumentation from 2008 to 2013 were reviewed. Overall, 13 surgeons performed the surgeries. A pedicle breach of >3 mm was graded as a misplacement. Surgeons were dichotomised into an early and experienced period in increments of five surgeries.
Results In 258 surgeries, 1,265 pedicle screws were placed with the aid of the robot system. Overall, 1,217 screws (96.2 %) were graded as acceptable. When displayed by surgeon, the development of percent misplacement rates peaked between 5 and 25 surgeries in 12 of 13 surgeons. The overall misplacement rate in the first five surgeries was 2.4 % (6/245). The misplacement rate rose to 6.3 % between 11 and 15 surgeries (10/158; p=0.20), and reached a significant peak between 16 and 20 surgeries with a rate of 7.1 % (8/112; p=0.03). Afterwards, misplacement rates declined.
Conclusions A major peak in screw inaccuracies occurred between cases 10 and 20, and a second, smaller one at about 40 surgeries. One potential explanation could be a transition from decreased supervision (unskilled but aware) to increased confidence of a surgeon (unskilled but unaware) who adopts this new technique prior to mastering it (skilled). We therefore advocate ensuring competent supervision for new surgeons at least during the first 25 procedures of robotic spine surgery to optimise the accuracy of robot-assisted pedicle screws.

Keywords Spine instrumentation · Pedicle screw · Robotic surgery · Spinal fusion · Computer-assisted surgery · Learning curve

Introduction

Pedicle screws are the main component of thoracolumbar instrumentation [3]. Several methods have been introduced to improve the accuracy and, therefore, the safety of pedicle-screw placement [7]. One of many techniques employed by spine surgeons is a miniature robotic spine surgery system named SpineAssist™ (Mazor, Caesarea, Israel) [14, 19]. This semi-active robotic system is employed worldwide. It was designed to assist the surgeon by pointing out the direction of the previously planned entry point and trajectory for pedicle screws. Although it may provide an overall increase in the rate of accurately placed pedicle screws, the system has certain pitfalls [18]. Hu and Lieberman [8] reported recently that when used by a single experienced surgeon, the rate of misplaced screws with this robot system decreases after about 30 surgeries. However, there are no data from institutions with multiple surgeons. As is the case with all surgical techniques,

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it is intuitive to assume that a certain degree of experience is required to become proficient in its use. The present analysis was conducted to assess if experience has an influence on accuracy and, if so, to provide a recommendation for the number of supervised surgeries required to achieve the optimal level of pedicle screw accuracy.

Materials and methods

For this retrospective study, we reviewed the charts of 258 consecutive patients requiring thoracic and/or lumbar spine surgery with posterior instrumentation from 2008 until 2013. The date of surgery and the operating surgeon were recorded.

Surgical technique

Entry points and trajectories of pedicle screws were planned on the SpineAssist system image-processing unit prior to surgery. Using a fluoroscope equipped with an add-on and a spinous process anchored clamp, we performed intraoperative dataset matching and the robot was attached to a specific bridge, which is additionally pin-fixed percutaneously to spinous processes cranially and caudally. Screws were then inserted guided by the robot arm as described elsewhere [14]. We performed lateral fluoroscopy before drilling of the pedicle and during screw placement.

Accuracy

The primary outcome measure was screw accuracy. Postoperative computed tomography (CT) scans with axial, coronal and sagittal reconstructions were obtained for all patients, and the accuracy of screw placement was evaluated by measuring the amount of pedicle cortical wall breach. Based on the common assumption that Gertzbein and Robbins' grade A and B screws [5] (i.e. screws with a pedicle breach of 2 mm or less in any direction) are acceptable [17], screws with a cortical breach of 3 mm or more were considered significant misplacements. Surgeon experience was denominated by number surgeries in steps of five for group comparisons. Nonparametric testing (Mann-Whitney *U*) was used to compare the rate of misplaced screws at each experience level to the baseline (surgeries 1–5) with a significance level of $p<0.05$.

Results

Accuracy

Thirteen surgeons operated on 258 patients during the observation period and placed 1,265 screws. Out of these 1,265 screws, 48 surpassed the pedicle by ≥3 mm, leading to a misplacement rate of 3.8 %.

When displayed by surgeon (Fig. 1), the development of percent misplacement rates peaked between 5 and 25 surgeries in 12 of 13 surgeons. The overall misplacement rate in the first five surgeries was 2.4 % (6/245). The misplacement rate rose to 6.3 % between 11 to 15 surgeries was 6.3 % (10/158; p= 0.20) and reached significance between 16 to 20 surgeries with a rate of 7.1 % (8/112; p=0.03) only to decline steadily afterwards. The rate of surgeries with at least one misplaced screw stratified by surgeon experience is displayed in Fig. 2.

Discussion

Effect of a surgeon's case load on accuracy of robotic spine surgery

Our data support the notion that robot-assisted screw placement is a safe technique with a low overall rate of screw malposition of 3.8 %. The figure of 9 % [11] misplacement rate found in freehand pedicle screw placement (albeit with

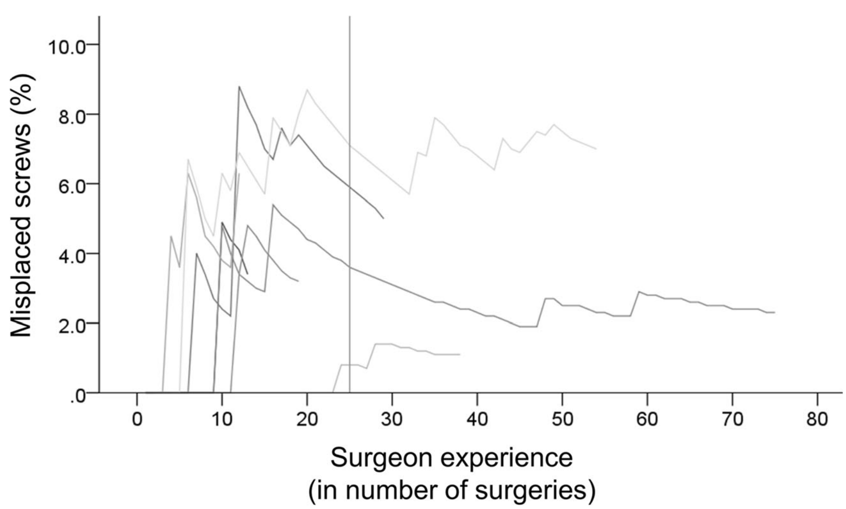

Fig. 1 Individual misplacement rate per surgeon. The *y*-axis shows the proportion of misplaced screws by individual surgeon (*each line* one surgeon). On the *x*-axis, the surgeon experience is shown in steps of five. Note that the percent rate of surgeries with malposition decreases with experience. The peak misplacement rate was passed at 25 surgeries (marked by the *vertical red line*) in all but the surgeon

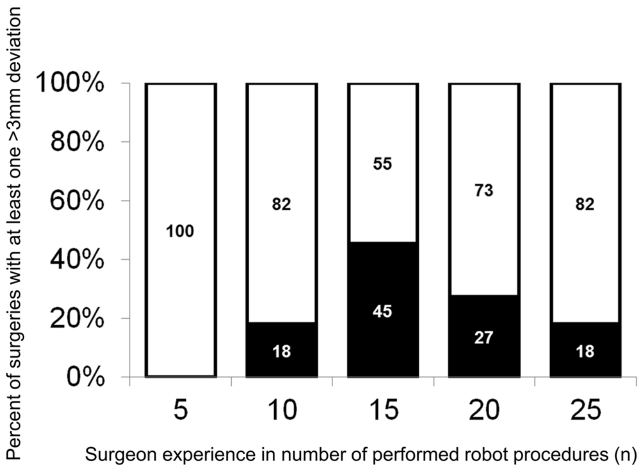

Fig. 2 Overall misplacement rate versus surgeon experience. The *y*-axis represents the misplacement rates (in percent of surgeries with at least one misplaced screw, i.e. >3 mm of pedicle breach). The *x*-axis displays the number of surgeries performed by a surgeon. The *black section of the bar* describes the number of surgeries with a misplacement. Misplacement rates reach a peak in surgeons after 10–20 surgeries and decline afterwards

rare neurological sequelae [4]) was not surpassed at any time of the learning curve in our study. The peak misplacement rate of 7 % was reached between 16 and 20 surgeries.

We found that screw placement with robot-assistance is safe even in the early phase of training with the system, since we found no indication that lower case numbers were associated with tangibly higher misplacement rates. Second, trends towards very low rates of misplacement were found as soon as surgeons crossed the 25-case mark.

Our data have to be interpreted in the context of a large teaching hospital with a high rate of surgeon fluctuation. Surgeons in the early phase of exposure to the robot are routinely assisted by more experienced colleagues, which may explain the low misplacement rate in the first five cases. This is one of the explanations why we found no tangible effect of the case load on screw accuracy and that screw accuracy remained low throughout the study. We observed a very low misplacement rate in the first five robot-assisted cases. A peak in screw inaccuracies occurred between cases 10 and 20. Whether this is due to a precocious leap in one's self-awareness after a favourable experience in the first 5–10 cases remains speculative. However, one potential explanation can be found in psychological terms [12]. There is a critical step in all learning processes, which is the transition from decreased supervision (unskilled but aware) to increased confidence of a surgeon (unskilled but unaware) who adopts this new technique prior to mastering it (skilled) [12]. We, therefore, advocate ensuring competent supervision for new surgeons at least during the first 25 procedures of robotic spine surgery to optimise the accuracy of robot-assisted pedicle screws. This is in keeping with Hu and Lieberman [8] who proposed 30 surgeries to define the crucial phase of the learning curve. Kim et al. [10] employed cumulative summation to assess the quality of pedicle screws throughout the learning curve for 80 consecutive screws using the new generation of robot system (Renaissance). Their results suggest a non-inferiority of robotics compared with freehand placement in a study where overall accuracy was high even in the early period of robot guidance.

Accuracy reported from other studies

Using the robot arm, a multicentre study found a 98 % rate of clinically acceptable screw placements. No permanent nerve damage occurred using the robot. In the 139 patients who underwent postoperative CT scans, 89.3 % of screws were intrapedicular and 9 % of screws showed a minor pedicle cortical breach [2]. The first series of 31 patients undergoing posterior instrumentation with SpineAssist showed that up to 98.3 % of screws were within 2 mm of the preoperative planning [15]. This indicates that screws were well positioned, but does not necessarily reflect pedicle breach such as indicated in the Gertzbein and Robbins grading.

A retrospective comparison of conventional, open robot-guided and percutaneous robot-guided techniques found an accuracy rate of 94.5 % in the robot-group compared with 91.4 % in conventionally placed screws [9]. Another study found no superiority of accuracy and emphasised that surgeons should use caution and constant fluoroscopic control when using robot assistance [17]. Of note, only one prospective robot study exists [16] where the authors found that the use of the robot led to a higher rate of laterally misplaced screws, which is in keeping with our observation that the majority of misplaced screws are lateral. As the authors acknowledged readily, the low accuracy may in part be due to the fact that for their study, the robotic system was attached to the operating table as opposed to the spinous process [16]. Another explanation may be an unconscious tendency to plan trajectories more laterally than necessary while trying to avoid the spinal canal. This is discussed as a potential source of "false lateralisation" due to erroneous or overly cautious planning, which should not be interpreted to the detriment of the robot system but is rather attributable to wrong planning.

Technology and the learning curve

It is safe to state that most spine surgeons have learned to place pedicle screws based on anatomical landmarks with fluoroscopic guidance. Later, the availability of minimally invasive instrumentation techniques has shifted the focus of the surgeon's attention from exposed anatomical features towards radiographic identification of the pedicle. The past decade saw the introduction of intraoperative imaging, navigation and robot systems. Nowadays in many centres, surgeons in training acquire their first knowledge of pedicle screw placement in vivo with those auxiliary techniques. When using neuronavigation, both duration of surgery and pedicle perforation rates have been shown to decrease over time with surgeon experience [1].

To assess the accuracy of pedicle screw placement, objective measures can be applied, i.e. millimetres of pedicle breach. This allows us to draw conclusions based on a relatively small set of data. Other surgical techniques, however, are usually indirectly compared via clinical outcome obtained using the "gold standard" in order to define the learning curve. A satisfactory plateau where a surgeon achieves a constant rate of desirable results with the Da Vinci system was quantified variably at about 30 for hysterectomy compared with open surgery [13] and at over 150 for prostatectomy [6].

Pitfalls in the use of the robotic system

One of the possible sources of inaccuracy, despite good registration, is the phenomenon of a cannula sliding off the facet joint as mentioned by several groups [16, 17]. This sliding leads to lateral misplacement in the lumbar spine. Therefore, we observe a higher frequency of lateral inaccuracy of robot-assisted screws, which constitutes about 70 % of all misplacements when using the robot system [16]. When placing freehand screws, lateral misplacements only represent 30 % of misplacements [16]. In the thoracic spine, the costotransverse process is inclined towards the midline, leading to the potential for medial displacement in the thoracic spine in case of medial skidding. In our experience, surgeons with a higher caseload tend to pay more attention to haptic feedback, even when inserting the working cannula, as well as including the thoracolumbar fascia in the stab incision to minimise deviation of the trajectory due to pressure from surrounding tissues.

We suggest the use of fluoroscopic control throughout the learning curve in order to maintain control over the proposed trajectory.

Although adequate technical assistance in the initial phase is provided by the manufacturer, it is our opinion that surgeons should be prepared to switch from robotic to conventional screw placement at any time of the procedure. The Tessitore spine surgery group in Geneva, Switzerland, proposed a hybrid technique for the first 20 robot surgeries to become acquainted with the Mazor system: After a midline opening, the anatomic entry points are identified and prepared. Only then is the robot system installed and the registration performed. This technique allows the surgeon to visually control the plausibility of entry point and trajectory for each pedicle screw. Lateral fluoroscopy can be added as is deemed necessary [17]. Percutaneous screw placement where no visual control is possible can then be initiated after satisfactory results were obtained during this transitional period.

Conclusions

The learning curve for robotic spine surgeries is limited by a rise in misplacement rates between 10 and 20 surgeries. We therefore suggest a skilled supervision during the first 25 cases for surgeons new to the technique.

Conflicts of interest None.

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Comment

The authors report the quality of screw placement using a robotic device. This article is well written and timely. Quality of provided healthcare should be shown to patients, insurance companies and healthcare-controlling instances. One of the issues to support quality is the number of patients who have been treated annually. This report shows that even for this technique a learning curve is present and a minimum number of patients should have been treated to gain experience. After that experience will not greatly improve (expressed as breaches of the pedicle).

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