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REVIEW ARTICLE

Robot-assisted and fluoroscopy-guided pedicle screw placement: a systematic review

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Abstract

Purpose At present, most spinal surgeons undertake pedicle screw implantation using either anatomical landmarks or C-arm fluoroscopy. Reported rates of screw malposition using these techniques vary considerably, though the evidence generally favors the use of image-guidance systems. A miniature spine-mounted robot has recently been developed to further improve the accuracy of pedicle screw placement. In this systematic review, we critically appraise the perceived benefits of robot-assisted pedicle screw placement compared to conventional fluoroscopy-guided technique.

Methods The Cochrane Central Register of Controlled Trials, PubMed, and EMBASE databases were searched between January 2006 and January 2013 to identify relevant publications that (1) featured placement of pedicle screws, (2) compared robot-assisted and fluoroscopy-guided surgery, (3) assessed outcome in terms of pedicle screw position, and (4) present sufficient data in each arm to enable meaningful comparison (>10 pedicle screws in each study group).

Results A total of 246 articles were retrieved, of which 5 articles met inclusion criteria, collectively reporting placement of 1,308 pedicle screws (729 robot-assisted, 579 fluoroscopy-guided). The findings of these studies are mixed, with limited higher level of evidence data favoring fluoroscopy-guided procedures, and remaining comparative studies supporting robot-assisted pedicle screw placement.

Conclusions There is insufficient evidence to unequivocally recommend one surgical technique over the other. Given the high cost of robotic systems, and the high risk of spinal surgery, further high quality studies are required to address unresolved clinical equipoise in this field.

Keywords Robotics · Robot assisted · SpineAssist · Fluoroscopy guided · Pedicle screw · Bone screw · Spine · Spinal surgery · Neurosurgery · Systematic review

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Introduction

Pedicle screw placement is a common surgical procedure to achieve fusion in the thoraco-lumbar spine. The anatomical proximity of the vertebral pedicles to associated neurovascular structures means that surgical misplacement of pedicle screws may result in serious morbidity. It has been estimated using a geometric model of spinal anatomy that a maximal translational error of less than 1 mm and rotational error of less than 5° are permissible to ensure satisfactory screw implantation [16]. The clinical corollary is that tools improving the accuracy and precision of pedicle screw placement can improve the outcome of patients undergoing spinal fusion.

At present, most spinal surgeons performing pedicle screw implantation do so using either anatomical landmarks or C-arm fluoroscopy [13]. The accuracy of pedicle screw implantation using these techniques varies considerably in the literature (from 28 to 94 %), though the evidence generally favors the use of image-guidance systems [5, 10, 25, 27]. A miniature spine-mounted robot has recently been developed to further improve the accuracy of pedicle screw placement [2, 4, 22]. Since 2006, a number of studies have individually supported its use [1, 9, 11, 12, 14, 20–22, 24, 26].

In this systematic review, we collect and critically appraise the evidence to evaluate whether, in patients undergoing pedicle screw implantation, robot-assisted surgery offers an advantage over conventional fluoroscopy-guided procedures in terms of pedicle screw position.

Materials and methods

The review protocol was registered on the PROSPERO international prospective register of systematic reviews. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement was used in the preparation of this manuscript.

Search methods

The Cochrane Central Register of Controlled Trials (CENTRAL), PubMed, and EMBASE databases were searched between January 2006 and January 2013. Relevant combinations of free-text search terms [(robot*) AND (pedicle OR screw)] and MeSH terms ["Robotics" AND ("Spine" OR "Bone Screws")] were used. An English language restriction was applied. References lists of selected papers were also reviewed, and expert opinion sought, to identify additional eligible manuscripts. Two authors (HM and TPC) independently identified articles using the above search criteria.

Inclusion and exclusion criteria

Titles and abstracts were screened to identify publications that met criteria of (1) featuring placement of pedicle screws, (2) comparing SpineAssist® (Mazor Surgical Technologies Ltd., Caesarea, Israel) and fluoroscopy-guided surgery, (3) assessing outcome in terms of pedicle screw position, and (4) presenting sufficient data in each arm to enable meaningful comparison (more than ten pedicle screws in each study group). Full articles were subsequently obtained and further assessed for eligibility. Discrepancies were resolved by discussion with a senior author.

Data extraction

The following data were extracted from eligible full articles: (1) study design, (2) study group characteristics including number of subjects and pedicle screws implanted in each arm, (3) outcome measures used to assess pedicle screw position, (4) key results, and (5) other results, such as radiation exposure and duration of operation.

Corresponding authors were contacted to provide supplemental data when required. In circumstances when this was not possible, data were extrapolated using the original results reported.

Appraisal of evidence

The Jadad and Methodological Index for Non-Randomized Studies (MINORS) scoring systems were used to guide evaluation of the quality of randomized and non-randomized studies, respectively, [8, 23]. Studies of greater quality were given appropriately greater weighting in the qualitative analysis.

Raw data on screw positions were used to determine the odds ratio in each study. The odds ratio for the key results was calculated using MedCalc version 12.3.0.0.

Results

A total of 246 retrieved articles were pooled from electronic library databases and other sources, of which 65 were duplicates (Fig. 1). We excluded 159 articles on the basis of their title and abstract because they did not present original data, did not feature pedicle screws, did not have both a robot-assisted and a control group, or had insufficient data in each arm to enable meaningful comparison. Full text screening of the remaining 22 articles led to the exclusion of a further 17 articles. In all, 5 articles were identified that satisfied our inclusion criteria, comprising two randomized controlled trials (of which one reported preliminary findings), one prospective cohort, one retrospective cohort, and one cadaveric study (Table 1) [9, 11, 17, 18, 20]. A total of 1,308 pedicle screws were reported—729 using robot-assistance, and 579 using fluoroscopy-guidance.

Pedicle screw placement

All included studies assessed pedicle screw position using post-operative fine-cut computed tomography (CT). In all, 94.1 % (686/729) of pedicle screws placed with robot-assistance were satisfactory, compared with 92.7 % (537/579) of pedicle screws placed with fluoroscopy-guidance. Ringel et al. [17] favored fluoroscopy-guidance ($p = 0.019$), and the remaining studies supported robot-assistance (albeit often not reaching statistical significance) [9, 11, 18, 20]. A forest plot summarizing the odds ratios of the included studies is illustrated in Fig. 2.

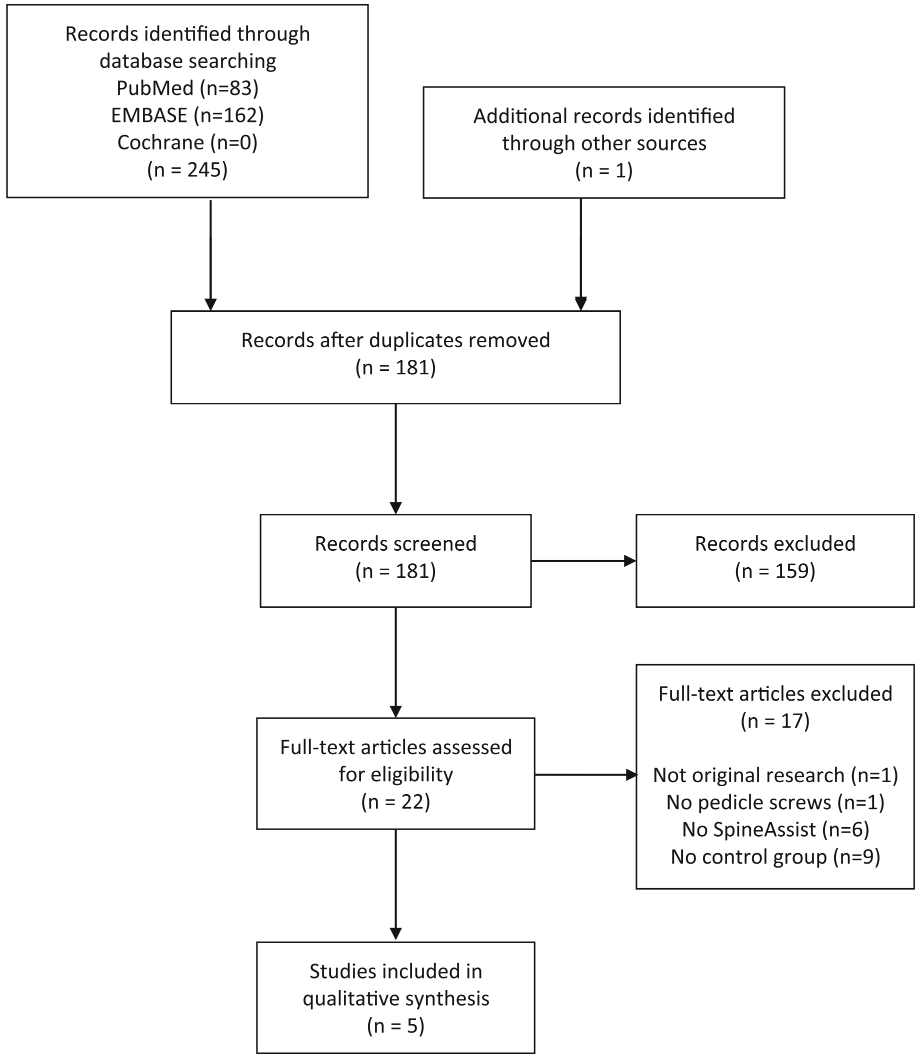

Fig. 1 Flow chart of search and selection process

Duration of surgery

The duration of surgery in the robot-assisted and fluoroscopy-guided groups was not reported as being significantly different in any of the three studies that analyzed this data [9, 11, 17].

Radiation exposure

All included studies commented on radiation exposure of patients and surgeons during pedicle screw implantation, though radiation doses during additional planning CT were not included in statistical significance testing. Kantelhardt et al. and Lieberman et al. [9, 11] reported radiation exposure to be significantly less during robot-assisted pedicle screw insertion compared to fluoroscopy-guided procedures, while Ringel et al. and Schizas et al. [17, 20] observed no significant difference in radiation exposure. Roser et al. [18] did not perform a statistical comparison on their preliminary findings, but a trend towards reduced radiation exposure in the robot-assisted group was observed.

Appraisal of quality of evidence

The Jadad system was used to evaluate the quality of the studies by Roser et al. and Ringel et al. [8, 17, 18]. Both studies were randomized but the methods to generate the sequence of randomization were not described. The Roser et al. study presents the preliminary results of 37 patients and the groups were therefore not balanced, with fewer patients undergoing fluoroscopy-guided ($n = 10$) than robot-assisted ($n = 18$) pedicle screw placement. Neither study fully addressed blinding. Although in the Ringel et al. study the position of pedicle screws was evaluated post-operatively by an independent neuroradiologist blinded to the technique used, it is unclear whether patients were also blinded. No participant withdrawal or loss to follow-up was reported.

Table 1 Summary of included studies

Reference	Level of evidence	Study group	Outcome	Key results	Other
Ringel et al. [17]	Single centre randomized controlled trial (Level 2)	60 pts undergoing lumbosacral pedicle screw implantation randomized into two equal groups: 30 pts FG ($n = 152$ screws), and 30 pts RA ($n = 146$ screws)	Pedicle screw position using Gertzbein and Robbins scale (positions A or B considered satisfactory)	FG: 142/152 (93 %) screws satisfactory RA: 124/146 (85 %) screws robot-assisted ($p = 0.019$)	Ten RA screws required intra-operative revision, one FG screw required post-operative revision. Duration of surgery and radiation exposure was not significantly different
Roser et al. [18]	Single centre randomized controlled trial (Level 2)	37 pts undergoing lumbosacral pedicle screw implantation randomized into three groups: 10 pts FG ($n = 40$ screws), 9 pts IG ($n = 36$ screws), and 18 pts RA ($n = 72$ screws)	Pedicle screw position using Gertzbein and Robbins scale (position A considered satisfactory)	FG: 39/40 (98 %) screws satisfactory IG: 33/36 (92 %) screws satisfactory RA: 71/72 (99 %) screws satisfactory	Study aims to recruit 30 pts per group. As preliminary results are reported here, statistical analysis was not performed
Schizas et al. [20]	Single centre prospective cohort study (Level 3)	34 consecutive pts undergoing thoraco-lumbar pedicle screw implantation divided into two groups: 23 pts FG ($n = 64$ screws) and 11 pts RA ($n = 64$ screws)	Pedicle screw position using the Rampersaud scale (positions A or B considered satisfactory)	FG: 59/64 (92 %) screws satisfactory RA: 61/64 (95 %) screws satisfactory ($p = 0.71$)	Radiation exposure was not significantly different
Kantelhardt et al. [9]	Single centre retrospective cohort study (Level 3)	112 consecutive pts undergoing thoraco-lumbar pedicle screw implantation divided into two groups: 57 pts FG ($n = 286$ screws), and 55 pts RA ($n = 250$ screws)	Pedicle screw position using Wiesner and Schizas scale (positions 0 or 1 considered satisfactory)	FG: 262/286[a] (92 %) screws satisfactory RA: 236/250[a] (95 %) screws satisfactory ($p < 0.05$)	Radiation exposure was significantly less in robot-assisted cases ($p = 0.0001$). Duration of surgery was not significantly different
Lieberman et al. [11]	Cadaveric study	12 cadavers underwent pedicle screw implantation divided into two groups: 2 cadavers FG ($n = 37$ screws), and 10 cadavers RA ($n = 197$ screws)	Pedicle screw position using the Rampersaud scale (position A considered satisfactory)	FG: 35/37[a] (95 %) screws satisfactory RA: 194/197[a] (99 %) screws satisfactory ($p = 0.082$)	Radiation exposure was significantly less in robot-assisted cases ($p < 0.001$). Duration of surgery was not significantly different

Pts patients, *FG* fluoroscopy-guided, *IG* image-guided (BrainLab VectorVision), *RA* robot-assisted (SpineAssist)

[a] Numbers calculated using percentages reported

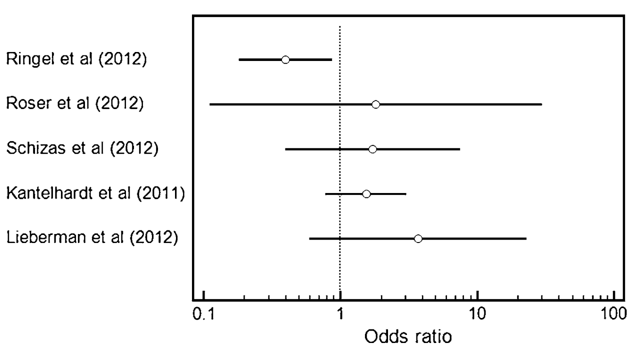

Fig. 2 Forest plot of pedicle screw accuracy comparing robot-assisted and fluoroscopy-guided insertion (>1 favors robot-assisted; <1 favors fluoroscopy-guided)

The quality of the studies by Schizas et al. and Kantelhardt et al. were evaluated using the MINORS system [9, 20, 23]. Neither study prospectively calculated the study size. The Schizas et al. [20] study did not report on the baseline equivalence of the control and intervention groups with respect to patient demographic factors such as age, sex and body mass index (BMI). The Kantelhardt et al. [9] study was retrospective.

Lieberman et al. [11] utilized human cadavers in a study that did not report pre-hoc power calculation, but otherwise was well designed.

Discussion

The evidence for robot-assisted pedicle screw placement is both limited and inconclusive. Five comparative studies were identified only. The findings of these studies are mixed, with the largest randomized controlled trial favoring fluoroscopy-guided procedures, and the other studies advocating robot-assisted pedicle screw placement. There is therefore insufficient evidence to unequivocally recommend one surgical technique over the other.

The randomized controlled trial by Ringel et al. [17] represents the highest level of evidence study identified in this review. Applying the Jadad criteria, the method of randomization was not described, and patients did not appear to have been blinded to the procedure they underwent, though this is unlikely to have influenced the primary outcome of pedicle screw position. Notwithstanding these limitations, the study was generally well constructed and demonstrated significantly poorer screw placement in the robot-assisted group compared to the fluoroscopy-guided group (85 vs. 93 %). Moreover, ten screws placed using robot-assistance required intra-operative revision compared to only one in the control group. Duration of surgery and radiation exposure was not significantly different in the two groups, though patients undergoing robot-assisted surgery did require an additional planning CT.

The other randomized controlled trial by Roser et al. [18] reported preliminary findings of a three-arm study comparing fluoroscopy-guided, image-guided (BrainLab Vector-Vision 2, Feldkirchen, Germany), and robot-assisted pedicle screw placement. The study aims to enroll 90 patients with 4 screws per patient, but has so far recruited 37 patients, with fewer patients undergoing fluoroscopy-guided ($n = 10$) or image-guided ($n = 9$) surgery than robot-assisted ($n = 18$) pedicle screw placement. Statistical evaluation was not performed on these interim findings, but image-guided and robot-assisted pedicle screw placement had a comparable accuracy to conventional fluoroscopy-guided surgery, with a trend towards reduced radiation time and dosage.

The studies by Schizas et al. and Kantelhardt et al. [9, 20] are prospective and retrospective non-randomized cohort studies, respectively. In both studies, pedicle screws implanted using robot-assistance were better positioned than those placed using fluoroscopy-guidance (95 vs. 92 % in both cohorts). The Kantelhardt et al. study also reported reduced radiation exposure in the robot-assisted group, though the length of surgery did not differ significantly. Schizas et al. did not report on the equivalence of confounding variables in the intervention and control groups. Neither study acknowledged a prospective power calculation.

Despite being a human cadaver study, the study by Lieberman et al. [11] satisfied our inclusion criteria and was incorporated in our analysis. Although the authors did not prospectively calculate the study size, it was otherwise of high quality. As with the aforementioned cohort studies, pedicle screws placed using robot-assistance were better positioned than those placed using fluoroscopy-guidance (99 vs. 95 %); however, this did not reach statistical significance ($p = 0.082$). Radiation exposure was significantly less in screws placed using robot-assistance, but the length of surgery did not differ significantly.

A number of potential sources of bias were identified. Firstly, it is possible that certain patients were more likely to undergo robot-assisted pedicle screw placement in the cohort studies. For example, it may be that following the introduction of the robot into surgical practice, fairly straightforward cases were selected in the first instance while the operating team was still becoming more familiar with the technique. This selection bias is an inherent limitation of these non-randomized studies.

Secondly, intra- and inter-study variation in patient groups was noted. Not all studies reported on potential confounders such as unbalanced age, sex and BMI. While the studies by Ringel et al. and Roser et al. limited their participants to patients undergoing lumbosacral pedicle screw implantation the remaining studies included those undergoing thoracic pedicle screw implantation too. The anatomical differences between the lumbar and thoracic vertebra result in different maximal tolerable translational and rotational errors in these regions [16]. Interestingly, none of the studies included patients with thoracic scoliosis, and it could be argued that these cases, which have a very high rate of screw malposition [7], have the most to gain from the use of robot-assistance.

Thirdly, the nature of the robot-assisted operative technique varied considerably, including percutaneous pedicle screw implantation via a paramedian Wiltse approach [11, 17, 18], open pedicle screw implantation [20], and a combination of the two techniques [9]. In one study that compared robot-assisted percutaneous and open pedicle screw implantation, the accuracy of screw placement did not appear to differ significantly [9]. The robot itself may be attached to the spine in various ways, which may also influence accuracy. Ringel et al. [17] describe a platform that was fixed to a cranial spinal process with a K-wire, and attached to the operating table by a bed mount. They speculate that this may have been an insufficient method of fixation because, as the robot was only attached to the patient via a single K-wire, relative slippage might have occurred. Alternative methods of attaching the robot to the spine, such as the use of a platform connected to a spinous process clamp, with additional K-wires to cranial and caudal spinous processes, or to the iliac crests, may have therefore improved accuracy. The fluoroscopy-guided (control group) surgical technique of the control group also differed between studies depending on the use of a 2-C-arm set up or a single rotating C-arm, and either percutaneous or open approach. Surgical proficiency in the robot-assisted and fluoroscopy groups is difficult to quantitatively assess. All studies reported that operating surgeons were familiar with both robot-assisted and fluoroscopy-guided techniques, though it is suspected that experience and learning curve progression would be more advanced with the latter.

Lastly, all included studies involved independent blinded investigators to assess pedicle screw position using post-operative fine-cut CT. Unfortunately the metric tools used to satisfactorily determine screw placement varied widely including the Gertzbein and Robbins scale, Rampersaud scale, and Wiesner and Schizas scale [6, 15, 19, 28]. In the instance when the same scale was shared, criteria for a satisfactory position varied; for example, while the Schizas et al. and Lieberman et al. studies both adopted the Rampersaud scale, the former considered positions A and B adequate (completely in pedicle, or <2 mm breach), while the latter considered only position A acceptable (completely in pedicle only). The requirement for a universally adopted method of gauging pedicle screw position is widely acknowledged in the literature.

In addition to pedicle screw position numerous other factors may influence the choice of surgical technique. The high cost of robotic systems may limit availability of this technology for widespread use. In addition, the use of such systems requires additional training to the surgeon and operating team. Surgeons performing spinal fusion may be attracted to the use of robot-assistance if in addition to improving the accuracy and precision of pedicle screw implantation, there is associated reduction in radiation exposure without significantly lengthened operating times. The safety of such systems is paramount, and surgeons must be reassured that in the event of malfunction or failure, patient risk is minimal. Large forces are exerted during pedicle screw placement that can lead to skidding of the implantation cannula, or shift of the vertebrae, resulting in malposition if not appreciated during surgery. An often ignored additional prerequisite to the diffusion of robotic systems is their acceptability to patient population. To this end, although most studies have found attitudes to be generally positive, female and elderly patients may be more cautious about accepting robot-assisted surgery over conventional techniques [3].

In conclusion, given the high risk of spinal surgery, and the high cost of robotic systems, further studies to justify the clinical benefit and healthcare economics are required.

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Conflict of interest None.

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