

Comparison of accuracy and safety between robot-assisted and conventional fluoroscope assisted placement of pedicle screws in thoracolumbar spine

A meta-analysis

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Abstract

Objective: The purpose of this systematic review and meta-analysis is to explore the screw positioning accuracy, complications related to pedicle screw implantation, revision rate and radiation exposure between robot screw placement and traditional fluoroscopic screw placement.

Methods: We searched several databases, including CNKI, Wanfang database, cqvip database, PubMed, Cochrane library and EMBASE, to identify articles that might meet the criteria. Meta-analysis was performed using Revman 5.3 software.

Results: A total of 13 randomized controlled trial were included. The results showed that the pedicle screw accuracy of the robot assisted group was significantly better than that of the conventional freehand (FH) group (OR=3.5, 95% confidence interval [CI] [2.75,4.45], $P < .0001$). There was no significant difference in the complications caused by pedicle screw implantation between the robot-assisted group and the conventional FH group [OR=0.39, 95%CI (0.10,1.48), $P = .17$]. The rate of facet joint invasion in the robot-assisted group was significantly lower than that in the conventional FH group (OR=0.06, 95%CI [0.01,0.29], $P = .0006$). The revision rate in the robot-assisted group was significantly lower than that in the conventional FH group (OR=0.19, 95%CI [0.05,0.71], $P = 0.0.01$). There was no significant difference in the average radiation of pedicle screws implantation between the robot-assisted group and the conventional FH (mean difference = -7.94, 95%CI [-20.18,4.30], $P = .20$).

Conclusion: The robot-assisted group was significantly better than the conventional FH in the accuracy of pedicle screw placement and facet joint invasion rate and revision rate. There was no significant difference in the complication and fluoroscopy time between the two groups.

Abbreviations: CI = confidence interval, FH = freehand.

Keywords: fluoroscopy, meta-analysis, pedicle screws, placement of pedicle screws, robot-assisted

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All data generated or analyzed during this study are included in this published article [and its supplementary information files].

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1. Introduction

Pedicle screw fixation is a common method to restore spinal stability. The pedicle of thoracic vertebra is small, the average diameter is about 8 mm, and there are many important nerves and blood vessels adjacent to the pedicle. The failure of screw placement often leads to serious complications. At present, the technique of freehand pedicle screws placement under fluoroscopy guidance is most commonly used in clinic. However, the accuracy of pedicle screws placement under fluoroscopy is affected in many aspects, the lack of experience of the operator or the morphological variation of pedicle may lead to the failure of pedicle screws placement.^[1] With the development of orthopaedic robot technology, spinal internal fixation technology ushered in a new way. However, some scholars hold a different point of view, they believe that the current evidence cannot prove that robot-assisted are more accurate than conventional fluoroscopy assisted placement of pedicle screws.^[2,3] The lateral slip of the casing at the entrance and even the software used by the robot are all possible reasons for the decrease in the accuracy of robot-assisted placement of pedicle screws.^[3,4] Some scholars support that robot-assisted placement of pedicle screws can achieve higher accuracy.^[5] These published meta analyses have some

limitations, such as the number of pedicle screw placement is still small,^[6] or the included studies are non-randomized controlled trials.^[5,7] Therefore we conduct a meta-analysis to systematically evaluate the accuracy and safety of robot navigation and traditional fluoroscope assisted placement of pedicle screws.

2. Materials and methods

Randomized controlled trials of pedicle screw implantation guided by robot-assisted and fluoroscopy was searched in CNKI, Wanfang database, PubMed, Cochrane collaboration network, Web of science, EMBase and CBM database from the establishment of the database to December 2020. The search words include: robot, robotic, robotic-assisted, pedicle screw, freehand technique.

2.1. Inclusion and exclusion criteria

The inclusion criteria were established as follows: patients with lumbar degenerative diseases; this study must be a randomized controlled trial comparing robot-assisted pedicle screws placement with fluoroscopic guideline placement; at least one outcome must be included. The exclusion criteria are established as follows: Repeat publication; Unable to get full text; The result report is incomplete;

2.2. Statistical analysis

Meta-analysis was performed with Revman 5.3 software. The continuous outcomes are presented as mean difference and 95% confidence interval (CI), and odds ratio (OR) and 95% CIs are presented for counting outcomes. Chi-square test and I^2 were used to evaluate the heterogeneity. When $P > .1$ and $I^2 \leq 50\%$, the heterogeneity was small, and the fixed effect model was selected. If $P < .1$ and $I^2 > 50\%$ indicate greater heterogeneity, the subgroup analysis is carried out according to different conditions, and the random effect model is selected. Publication bias was evaluated by funnel plots.

2.3. Ethics approval statement

This study does not need to be approved by moral and ethical clerks.

3. Results

3.1. Search results

A total of 351 studies were retrieved in all databases. After removing repetition and screening, the articles that did not conform to the inclusion criteria were removed, and the final number of articles included was 13 (Fig. 1)

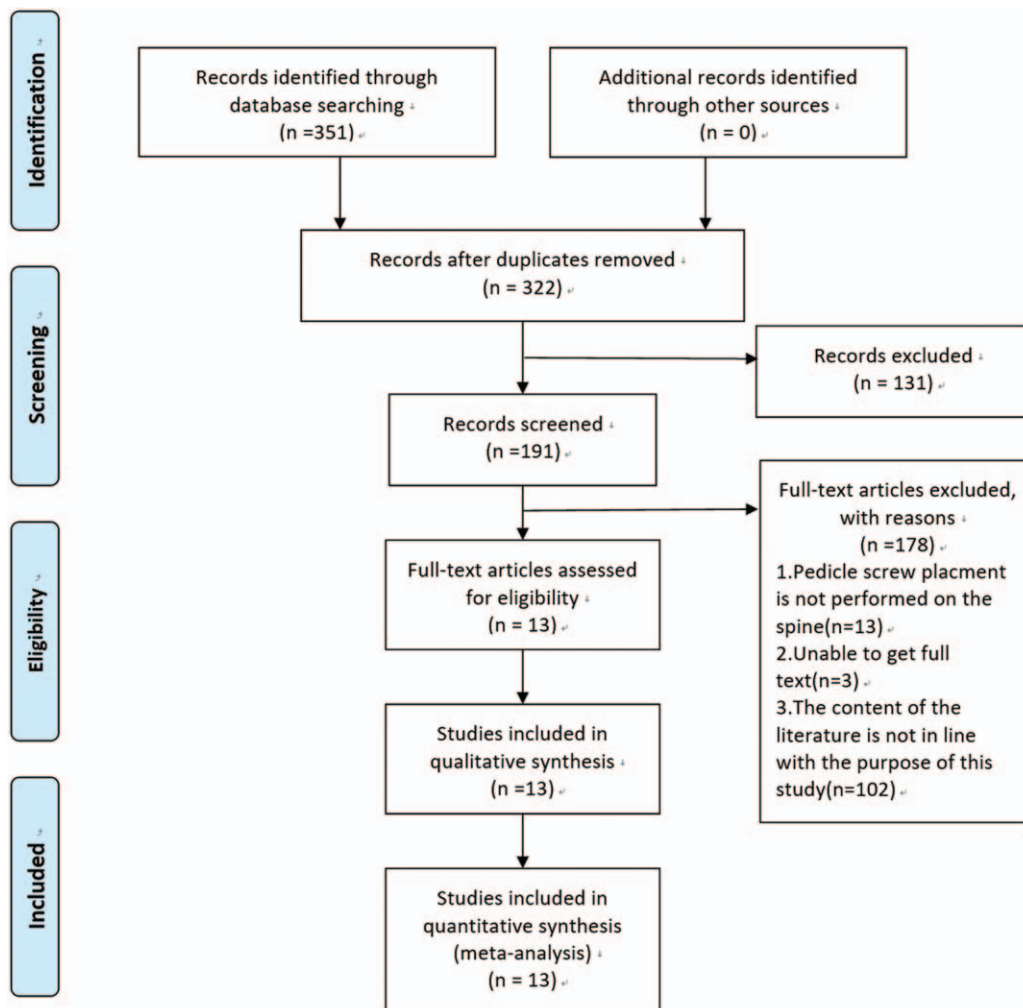


Figure 1. The flow chart of the literature screening process.

Table 1**Baseline characteristics of included studies.**

Author	Year	Country	Robot type	Disease	Number of robot-assisted pedicle screws	Number of pedicle screws under fluoroscopy	Outcome
ZHA ^[11]	2019	China	Mazor	Lumbar degenerative disease	276	255	①②
Yang ^[13]	2019	China	TiRobot	Lumbar degenerative disease	208	202	①
Xu ^[14]	2018	China	TiRobot	Lumbar degenerative disease	132	106	①②
Tian ^[15]	2016	China	TiRobot	Lumbar degenerative disease	102	88	①②
Huang ^[8]	2020	China	TiRobot	Lumbar degenerative disease	112	128	①②
Ringel ^[3]	2013	Germany	Mazor	Lumbar degenerative disease	146	152	①②④
Li ^[9]	2020	China	Mazor	Lumbar degenerative disease	32	50	①②⑤
Kim ^[18]	2017	South Korea	Mazor	Lumbar degenerative disease	156	172	①②③④
Hyun ^[17]	2017	South Korea	Mazor	Lumbar degenerative disease	130	140	①②③④⑤
Han ^[12]	2019	China	Mazor	Lumbar degenerative disease	532	584	①②③④
Feng ^[10]	2019	China	TiRobot	Lumbar degenerative disease	202	225	①④
Roser ^[16]	2013	Germany	Mazor	Lumbar degenerative disease	40	72	①⑤
Jamshidi ^[19]	2020	America	Mazor	Lumbar degenerative disease	374	111	⑤

①Accuracy of pedicle screw placement (pedicle screw is completely located in the cortex); ②Complications caused by pedicle screw implantation; ③Facet joint invasion rate; ④Revision rate. ⑤Fluoroscopy time (per pedicle screw).

3.2. General characteristics and risk of bias of the included study

The characteristics of the inclusion trial are shown in Table 1. Eight of the studies^[8–15] were from China, two^[3,16] from Germany, two^[17,18] from South Korea and one^[19] from the United States. Risk of bias of the included study is shown in Figure 2 and Figure 3.

4. Results of meta-analysis

4.1. Accuracy of pedicle screw placement (pedicle screw is completely located in the cortex)

A total of 12 articles^[2–13] reported the accuracy of pedicle screw placement. The heterogeneity test was carried out on all the included literatures, and the results showed that there was heterogeneity among the studies ($I^2 = 76\%$), so the random effect model was used to merge. The results of meta-analysis showed that the accuracy of pedicle screw placement under robot-assisted was higher than that of traditional fluoroscopy guidance (OR = 2.91, 95%CI [1.77,4.80], $P < .0001$) (Fig. 4).

4.2. Complications caused by pedicle screw implantation

A total of 9 articles reported the complications associated with pedicle screw placement. The heterogeneity of all the included literatures was tested, and the results showed that the heterogeneity between the studies was small ($I^2 = 0\%$), so the fixed effect model was used to merge. The results of meta-analysis showed that there was no significant difference in complications between robot-assisted pedicle screw placement and traditional fluoroscopy. (OR = 0.39, 95%CI [0.10, 1.48], $P = 0.17$) (Fig. 5).

4.3. Facet joint invasion rate

A total of 3 articles reported the rate of facet joint invasion. The heterogeneity of all the included literatures was tested, and the results showed that the heterogeneity between the studies was small ($I^2 = 0\%$), so the fixed effect model was used to merge. The results of meta-analysis showed that the invasion rate of pedicle screw implantation assisted by robot on facet joint was lower

than that of traditional fluoroscopy. (OR = 0.06, 95%CI [0.01, 0.0006]) (Fig. 6).

4.4. Revision rate

A total of 5 articles reported the revision rate. The heterogeneity of all the included literatures was tested, and the results showed that the heterogeneity between the studies was small ($I^2 = 0\%$), so the fixed effect model was used to merge. The results of meta-analysis showed that the revision rate of pedicle screws assisted by robot was lower than that of traditional fluoroscopy. (OR = 0.19, 95%CI [0.05, 0.71], $P = 0.01$) (Fig. 7).

4.5. Fluoroscopy time (per pedicle screw)

A total of 2 articles reported the fluoroscopy time of each pedicle screw. The heterogeneity of all the included literatures was tested, and the results showed that the heterogeneity among the studies was large ($I^2 = 99\%$), so the random effect model was used to merge. The results of Meta-analysis showed that there was no significant difference in fluoroscopy time of each pedicle screw between robot-assisted and traditional fluoroscopy. (mean difference = -7.94, 95%CI [-20.18pr. 4.30], $P = 0.20$) (Fig. 8).

4.6. Publication bias

The accuracy of pedicle screw placement was used to make inverted funnel chart for publication bias analysis. The results showed that the funnel chart was basically symmetrical, suggesting that there was no publication bias (Fig. 9).

5. Discussion

Pedicle screw is the most commonly used internal fixation in spinal surgery.^[20] The lumbar pedicle is larger and more suitable for pedicle screw implantation. The pedicle of thoracic vertebrae is small, and pedicle screw placement under fluoroscopy is easy to fail.^[21] Based on the three-column theory of the spine, pedicle screws can stabilize the three-column structure of the spine at the same time.^[22] At present, fluoroscopy-guided pedicle screw placement is the most widely used technique in clinic. However,

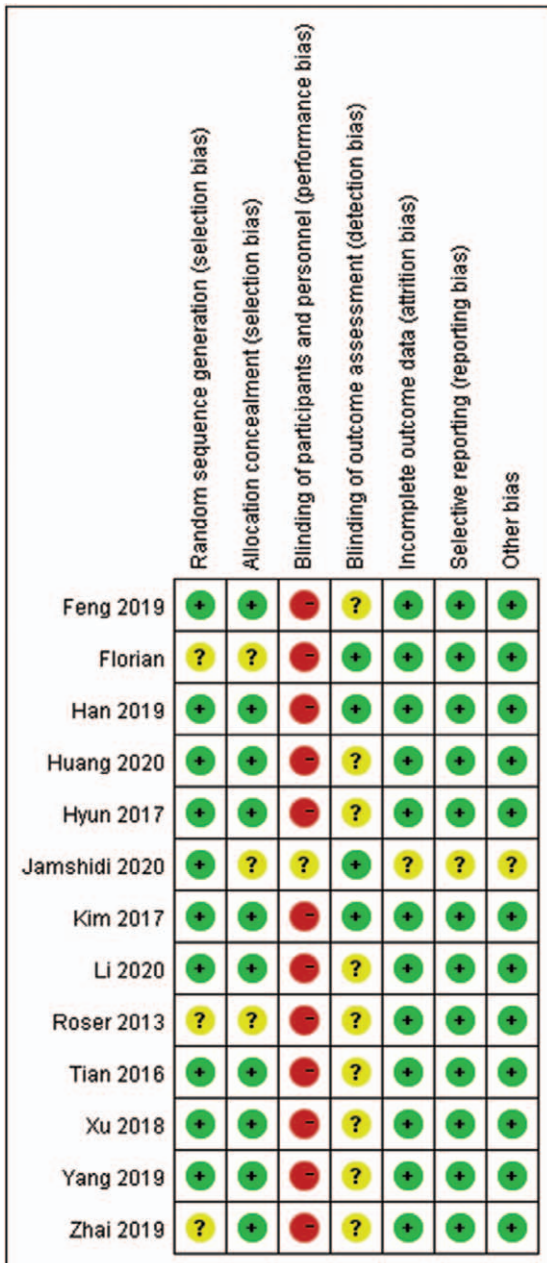


Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

the variation of anatomical morphology of pedicle is often seen in clinic.^[23] In addition, the unclear anatomical signs and the operator's lack of experience may lead to the failure of nail placement.

Under the available evidence, the incidence of misplacement of pedicle screws is in the range of 3% to 55%.^[24] Even if senior physicians perform pedicle screw implantation, there is a screw adjustment rate of about 10%.^[25] Among the various navigation technologies currently carried out, robot-assisted pedicle screw placement has attracted a lot of attention from spinal surgeons.^[26] The robot has significant advantages in fine movement, reducing operator fatigue or physiological tremor, reducing radiation exposure, shortening pedicle screw placement

time and so on. At present, the Israeli SpineAssist/Renaissance system is widely used in clinic.^[27] SpineAssist / Renaissance system applies "Hover-T" technology. During the operation, the Hover-T frame was fixed on the spinous process of the patient, and then the fluoroscopy was carried out during the operation, and the images obtained were compared with the CT of the patients before operation, so as to complete the registration of each vertebral body.^[28] Finally, the position of pedicle screw was designed, and then the operation of pedicle screw placement was completed. Because the bridge track is fixed to the spinous process of the patient's spine, the Renaissance system reduces the risk of misplacement of pedicle screws due to respiratory movement. The advantage of Chinese TIROBOT is that real-time navigation can be obtained according to the three-dimensional images during the operation.^[29] However, some scholars have pointed out that in the process of 3D image reconstruction and registration, distortion will occur due to electromagnetic field deflection, which will affect the system error of the robot.^[30] The accuracy of pedicle screw placement assisted by robot is more than 90%.^[2,31-36] However, the existing meta analysis of robot-assisted pedicle screw placement is not rigorous, and different evaluation criteria of screw placement accuracy are often mixed and unified, and there is some controversy about the accuracy of robot-assisted screw placement. The meta-analysis of Liu et al^[37] and Gao et al^[38] pointed out that there was no difference in the accuracy of pedicle screw placement between robot navigation and fluoroscopy guidance. Some scholars have also pointed out that robot-assisted pedicle screw placement is more accurate.^[5] Therefore, in our meta-analysis, we included the number of pedicle screws without cortical invasion in each literature. meta-analysis showed that the accuracy of pedicle screw placement assisted by robot was higher than that under traditional fluoroscopy. In terms of radiation results, Kantelhardt et al^[32] pointed out that the radiation time of robot-assisted screw placement is shorter than that of pedicle screw implantation under fluoroscopy. Roser et al^[16] also pointed out that robot-assisted pedicle screw implantation reduced the fluoroscopy time by about half compared with traditional fluoroscopy. At the same time, it was reported that in the initial learning process, although there was no significant difference in fluoroscopy time between robot-assisted pedicle screw implantation and traditional fluoroscopy, the fluoroscopy time during operation could be reduced with familiarity with the robot. However, different number of pedicle screws, surgical experience and surgical methods will affect the change of radiation dose. Therefore, in this meta-analysis, we make a statistical analysis of the radiation index of each screw, and the results show that there is no statistical difference in the fluoroscopy time between robot-assisted pedicle screw implantation and traditional fluoroscopy. The accurate implantation of pedicle screws for the first time is very important to avoid the decrease of screw pullout force caused by adjusting the screw path. The evidence from our meta-analysis showed that robot-assisted pedicle screw placement was lower than fluoroscopic guidance in terms of screw adjustment rate. Kim et al^[39] pointed out that the entry point of pedicle screw assisted by robot is more lateral, which can obtain a larger internal inclination angle and help to protect the joint capsule. Wang et al conducted Logistic regression analysis on the data of 237 cases, pointing out that the invasion of the articular process of the adjacent vertebral body during the operation was one of the important factors leading to adjacent spondylosis. This Meta shows that robot-assisted pedicle screw implantation is superior

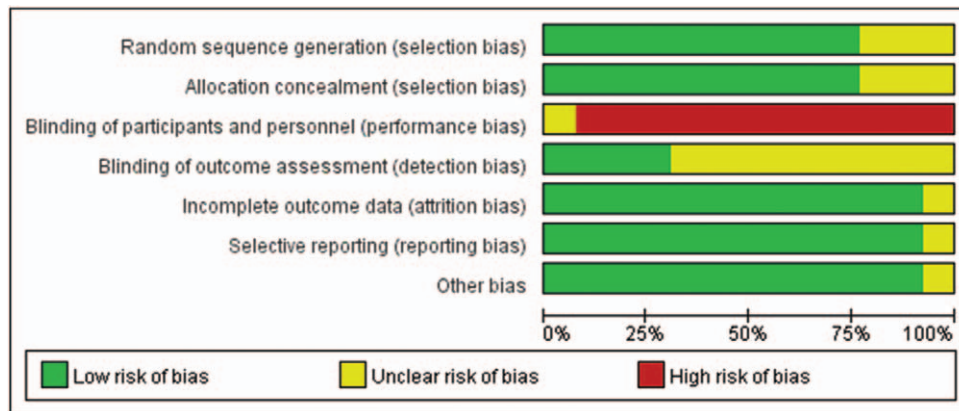


Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

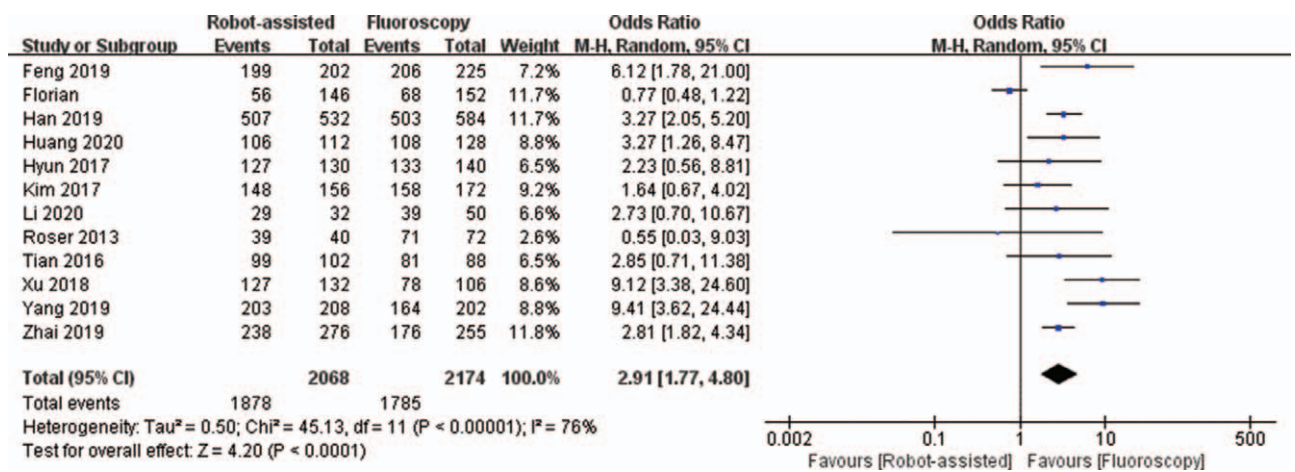


Figure 4. Forest plot of the comparison of the accuracy of pedicle screw placement between Robot-assisted and fluoroscopy.

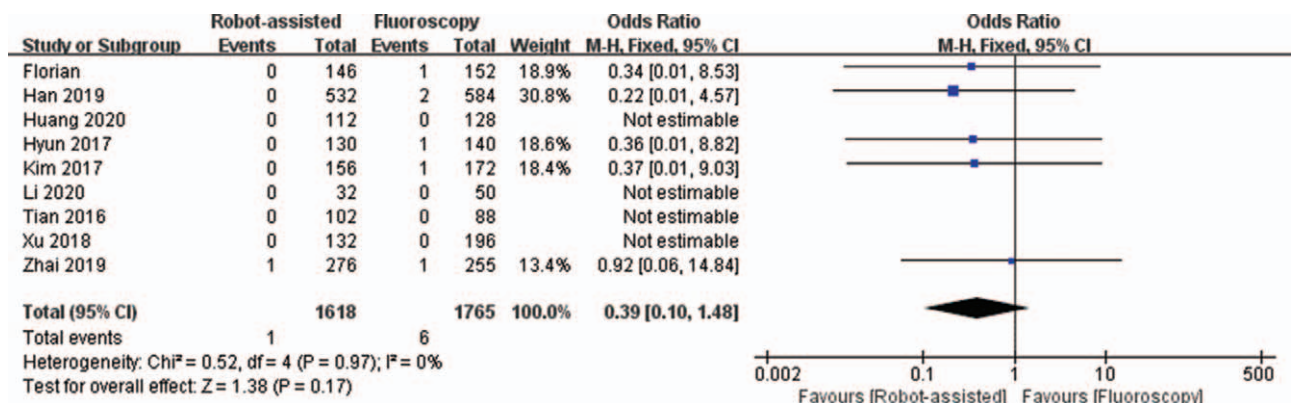


Figure 5. Forest plot of the comparison of complications caused by pedicle screw implantation between Robot-assisted and fluoroscopy.

to traditional fluoroscopy in the protection of facet joints. In terms of neurovascular injury caused by pedicle screw implantation, there was no statistical difference between robot-assisted and traditional fluoroscopic pedicle screw placement.

In this meta-analysis, we have some shortcomings. First of all, we did not consider the impact of minimally invasive or open on the accuracy of nail placement. Secondly, because of the different experience and methods of operation, there are no statistics on

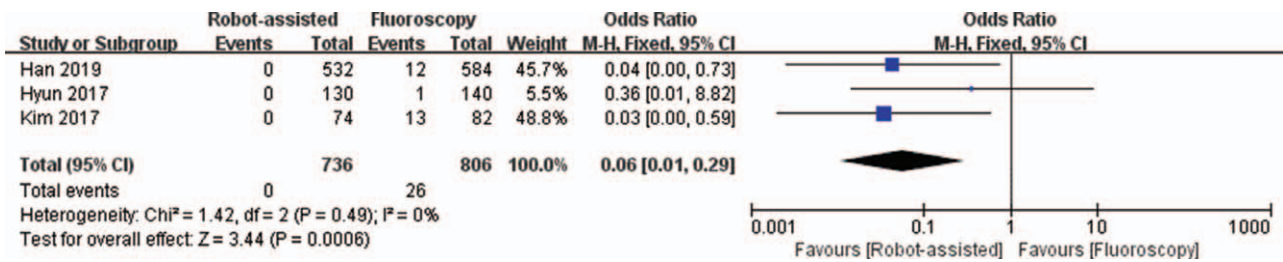


Figure 6. Forest plot of the comparison of facet joint invasion rate caused by pedicle screw implantation between Robot-assisted and fluoroscopy.

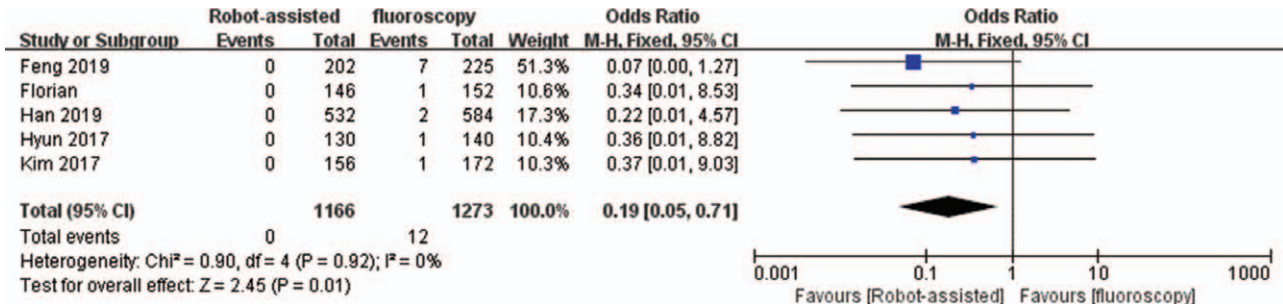


Figure 7. Forest plot of revision rate caused by pedicle screw implantation between Robot-assisted and fluoroscopy.

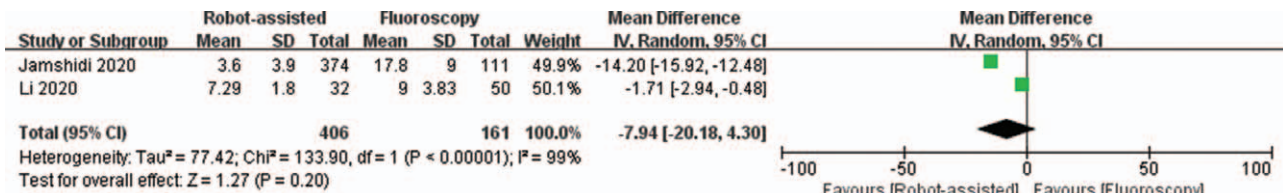


Figure 8. Forest plot of fluoroscopy time caused by pedicle screw implantation between Robot-assisted and fluoroscopy.

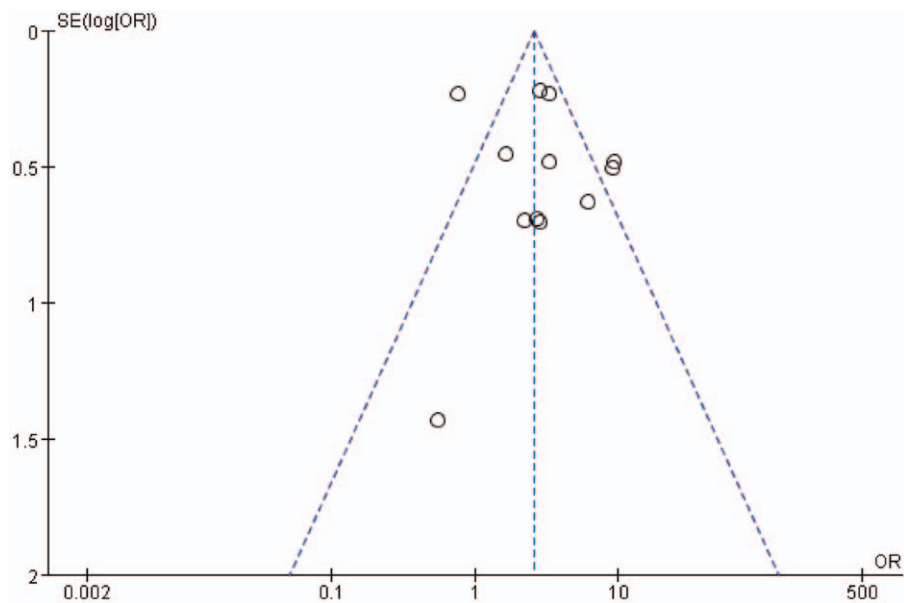


Figure 9. Funnel chart.

the time of operation, the amount of blood loss and so on. Finally, the risk of publication bias is widespread in meta-analysis, but we believe that our results are convincing and hope to get more high-quality randomized controlled trial in our future work.

6. Conclusion

This systematic review and meta-analysis provide evidence based on 13 randomized controlled trials comparing robot-assisted and conventional fluoroscope assisted placement of pedicle screws. The results showed that the accuracy of robot-assisted pedicle screw placement is higher than conventional fluoroscope assisted. In addition, the rate of facet joint invasion and revision rates by robot-assisted pedicle screw implantation was also significantly lower than fluoroscope assisted. However, there was no significant difference in the average radiation of pedicle screws and related complications between robot-assisted and fluoroscopy assisted in pedicle screw placement.

Author contributions

Data curation: Shangju Gao, Can Cao, Changren Li, Liang He, Xu Ma, Meng Li.

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Supervision: Wenyi Li.

Validation: Wenyi Li.

Writing – original draft: chuntao li.

Writing – review & editing: Wenyi Li.

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