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Comparative Study of the Complications of Pedicular Screw Fixation Techniques in the Thoracolumbar Spine: A Systematic Review

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Abstract

Introduction: The use of pedicle screws increases postoperative stability and consolidation of arthrodesis. Pedicle arthrodesis is currently the standard treatment for the thoracolumbar spine, presenting the best fusion and stiffness rates, and among its main indications is the possibility of better correction of spine deformities in the thoracic and lumbar region. However, due to different definitions and the lack of a control group, many of these studies have limited comparative analysis, resulting in the scarcity of comparative studies with standardized methodology. **Objective:** It was to analyze, through a systematic review, the safety and efficacy of instrumentation with pedicle screws in the spine which have been questioned, despite its wide use for stabilization of the spine, comparing the complications present in the insertion techniques of pedicle screws. **Methods:** The rules of the Systematic Review-PRISMA were followed. The literary search process was carried out from January to March 2023. A bibliographic search was carried out in MEDLINE, PubMed, and Scielo for articles produced between 2001 and 2023. The quality of the studies was based on the GRADE instrument, and the risk of bias was analyzed according to the Cochrane instrument. The Cohen test (Funnel Plot) and The Heterogeneity Test (Chi-Square Test – X^2) were performed, with $p < 0.05$ with no statistically significant difference, at the 95% CI. **Results and Conclusion:** A total of 134 articles were found. A total of 67 articles were evaluated in full and 12 were selected to compose the results of this systematic review. According to the GRADE instrument, most studies (X^2 = 90.2% > 50%) followed a controlled clinical study model and had a good

methodological design, with $p < 0.05$. It was shown that poor positioning of pedicle screws is the most common cause of complications. The surgeon's skills and the length and diameter of the pedicle screw can also affect the different modes of placement. Robotic computer assistance has the potential to reduce the incidence of postoperative revisions. Minimally invasive techniques have contributed to the reduction of surgical trauma and complications, thus allowing patients who had restrictions on performing the surgical approach, such as the elderly and critically ill patients, to undergo surgical treatment.

Keywords

Pedicular Arthrodesis, Complications, Spinal Instrumentation

1. Introduction

The use of pedicle screws was initially described by Boucher in 1950, and used by Roy-Camille in 1960, with the main objective of increasing postoperative stability and consolidation of the arthrodesis [1] [2]. However, the technique became popular in 1980, with Cotrel-Dubousset, with pedicle screw fixation, gaining notoriety with the third generation of spinal instrumentation [3].

In this context, surgical treatment techniques have evolved due to the unsatisfactory results obtained after conventional discectomies. Thus, the stabilization of the degenerated lumbar segment through the placement of screws in arthrodesis as a therapeutic option has become a frequent procedure [4].

Also, pedicle arthrodesis is currently the standard treatment for the thoracolumbar spine. Due to the better fusion and rigidity rates, among its main indications is the possibility of a better correction of spine deformities in the thoracic and lumbar region, such as in cases of idiopathic scoliosis, congenital kyphoscoliosis, kyphosis, degenerations, infections, neoplasms, and lumbosciatic pain. Therefore, the reduction in movement caused by this technique allows bone fusion and permanent stabilization of the segments [5] [6].

Among the described techniques, the freehand technique consists of placing a screw inserted blindly, requiring the correct identification of anatomical reference points for screw insertion and the surgeon's experience. The use of intraoperative fluoroscopy, which is widely used due to its wide availability, however, is not very accurate, in addition to presenting the surgeon's exposure to radiation as a disadvantage [7] [8].

Such techniques are imprecise, not allowing a direct view of the screw entry point, thus, promoting the occurrence of several complications such as loss of fixation, neurological damage, and vascular injury. To improve accuracy, investment was made in navigation. However, it is a high-cost method, with restricted access. Thus, new technologies have been created in the search for better precision and reduction of complications. There are several studies on the use of pedicle screws, however, due to different definitions and the lack of a control

group, many of these studies have limited comparative analysis, resulting in the scarcity of comparative studies with standardized methodology [6] [7] [8] [9].

Therefore, the present study analyzed, through a systematic review, the safety and efficacy of instrumentation with pedicle screws in the spine that has been questioned, despite its wide use for spine stabilization, comparing the complications present in insertion techniques of pedicle screws. The secondary objective was to analyze the outcomes in the literature regarding fixation of the spine itself and its various methods such as image-guided surgery and robotic surgery, as well as complications and follow-up.

2. Methods

2.1. Study Design

The rules of the Systematic Review-PRISMA Platform (Transparent reporting of systematic reviews and meta-analysis (Available in: https://www.prisma-statement.org/) were followed.

2.2. Data Sources and Research Strategy

A bibliographic search was carried out and developed on Scopus, PubMed, Science Direct, Scielo, and Google Scholar with articles produced between 2001 and 2023 in relation to studies on the use of pedicle screws in thoracolumbar surgeries. Clinical studies were included that evaluated the results of pedicle screw placement techniques in different age groups, regardless of the cause of the surgery, with a statistically significant sample size, as well as studies that analyzed the use of freehand surgery, guided surgery by robotic imaging and surgery. Studies with consistent methodology and results, with minimal risk of bias, were also selected. Randomized clinical trials, case-control studies, case series, and meta-analyses of English, Portuguese, Spanish, and French literature were analyzed. The authors evaluated the type of study, the number of patients, the anatomical region, the number of pedicle screws, the type of placement of pedicle screws, the incidence of complications, and the type of complication, regardless of the technique used. Studies that compared complications in screws applied in different anatomical regions, case reports, studies with cadaveric parts and animals, models, abstracts, and presentations were excluded. Case-control, cross-sectional, meta-analysis/systematic reviews, systematic reviews, randomized controlled trials, case series, retrospective studies, and cohort studies were evaluated.

The search strategies for this systematic review were based on the MeSH Terms: *"Pedicular Arthrodesis, Complications, Spinal Instrumentation"*. The literary search process was carried out from January to March 2023. Also, the combination of the keywords with the booleans "OR", "AND", and the operator "NOT" were used to target the scientific articles of interest.

2.3. Study Quality and Bias Risk

The quality of the studies was based on the GRADE instrument, and the risk of

bias was analyzed according to the Cochrane instrument. Two independent reviewers (1 and 2) carried out research and study selection. Data extraction was performed by reviewer 1 and fully reviewed by reviewer 2. A third investigator decided on some conflicting points and made the final decision to choose the articles.

2.4. Statistical Analysis

For data analysis, a database was built in a Microsoft Excel spreadsheet, which was exported to the Minitab 18® statistical program (version 18. Minitab. LLC. State College. Pennsylvania, USA). The Cohen test was performed to calculate the effect size and the inverse of the standard error (precision or sample size) was determined to determine the risk of bias in the studies using the Funnel Plot. The Heterogeneity Test (Chi-Square Test - X^2) of the results between the studies was also determined, with $p < 0.05$ with no statistically significant difference, in the 95% CI.

3. Results

Summary of Findings

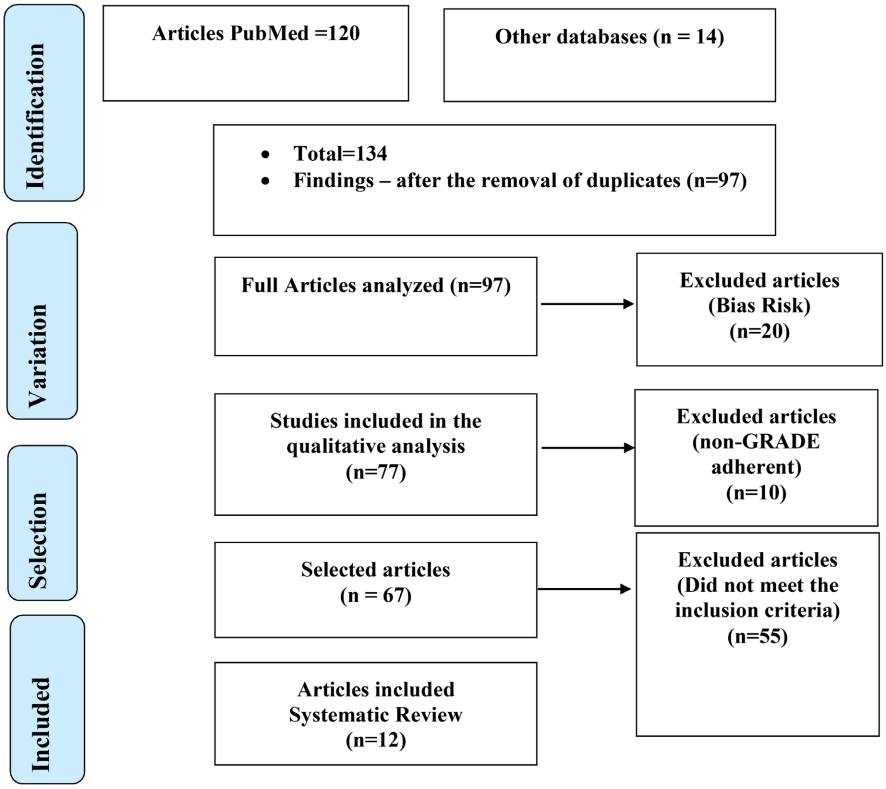
A total of 134 articles were found. Initially, duplication of articles was excluded. After this process, the abstracts were evaluated and a new exclusion was performed, removing articles that did not include the theme of this article. A total of 67 articles were evaluated in full and 12 foram selecionados para compor os resultados desta revisão sistemática. The 55 studies that were excluded in the last analysis did not meet most of the inclusion criteria that were mentioned in the methods. According to the GRADE instrument, most studies (X^2 = 90.2% > 50%) followed a controlled clinical study model and had a good methodological design, with $p < 0.05$. Considering the Cochrane tool for risk of bias, the overall assessment resulted in 20 studies with a high risk of bias to the small sample size (Figure 1 and Figure 2).

Figure 2 presents the results of the risk of bias of the studies through the Funnel Plot, showing the calculation of the Effect Size (Magnitude of the difference) using the Cohen Test (d). Precision (sample size) was determined indirectly by the inverse of the standard error (1/Standard Error). This graph had a symmetrical behavior, not suggesting a significant risk of bias, both between studies with a small sample size (lower precision) that are shown at the base of the graph and in studies with a large sample size that are presented in the upper region.

Of the twelve selected articles, a total of 7642 patients were analyzed, analyzing complications related to more than 45,287 screws mentioned in the studies. Table 1 presents the main information of each study that was selected, such as the number of patients, number of screws, and main results.

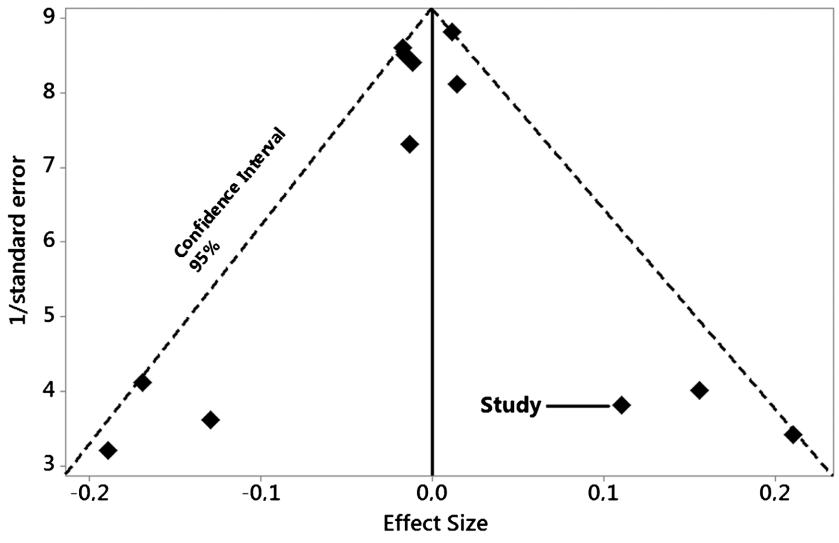
In studies that used the freehand pedicle placement technique, the main complication was poor positioning of the screws, however, with a low rate of reapproached (0.23% - 0.625% of patients). Other complications have been observed,

such as radicular symptoms, orthostatic headache, intraoperative pedicle fracture, infections and pneumothorax, transient neurological deficits, superior mesenteric artery syndrome, and massive intraoperative blood loss [10] [11] [12] [13].



Source: Own authorship.

Figure 1. Study Eligibility (Systematic Review, n = 12 studies).



Source: Own authorship.

Figure 2. The symmetrical Funnel Plot does not suggest a risk of bias between the small sample size studies that are shown at the bottom of the graph. High confidence and high recommendation studies are shown above the graph, with n_{total} = 12 studies.

Table 1. Main data and clinical outcomes of selected articles.

REFERENCES	PATIENTS	N° SCREWS	RESULTS
1. Suk, SE-II. *et al.* (Case-control) (2001)	432 (Freehand)	4604 (Thoracic pedicle screws)	• Inadequate positioning of 67 screws from 48 patients • 35 screw loosenings • 4 patients with neurological complications • 11 intraoperative pedicle fractures • 9 postoperative infections • 1 pneumothorax • There was no vascular or visceral injury • 1 re-approached
2. Vecina, E *et al.* (Cross-section study) (2008)	40	228 (116 thoracic and 112 lumbar)	• 8.63 of the thoracic and 5.36 of the lower back with poor positioning. • There was no neurological, vascular, visceral complication.
3. Verma, R. *et al.* (systematic review and meta-analysis) (2010)	719 Navigation 569 not Navigation	3555 Navigation 2437not Navigation	• 612 badly positioned screws. • In the unguided group (not Navigation) there were 13 cases of neurological complications. • There were no reports of other complications.
4. Hicks JM. *et al.* (Systematic review) (2010)	1666	4570	• Poor positioning of 717 of the thoracic screws. • 11 underwent reoperation for correction, and 10 cases with vascular complication. • 04 cases with neurological complication
5. Gelalis, I.D. *et al.* (Systematic review) (2012)	1105 patients	Freehand: 2412 screws in 362 patients CT navigation: 1902 screws in 313 patients Fluoroscopic navigation: 668 screws in 107 patients	• Freehand: 2 L5 root irritation, 1 headache, and paresis • Fluoroscopy: 8-degree neurological deficit • 3 resolved symptoms without surgery • 5 required surgery • Tc navigation: 6 transient sciatic pain, 2 dysesthesia – 5 resolved, 1 reoperation
6. Ringel F. *et al.* (Randomized prospective study) (2012)	60	Freehand: 67 Robot: 68	• Freehand: 1 with poor positioning requiring reapproach due to radicular pain • ROBOT: 10 converts
7. Dede O. *et al.* (Retrospective case series) (2014)	480	5923	• Poor positioning on 8 screws. • 3 cases were reoperated. • 3 neurological complications.
8. Sanchez JAS *et al.* (Retrospectivo Cohort) 2015	125 (57 bilateral and 68 unilateral instrumentation)	470	• 427.33 screws without breaks • 39.33: Rupture ≤ 2 mm • 3.33: Rupture ≥ 3 mm
9. Zhao Q, *et al.* (Retrospective Cohort) (2018)	781	3124	• **46 complications, including:** ✓ 7 intraoperative complications ✓ 3 guide wire break ✓ 1 abdominal aorta injury ✓ 3 extravasation of cerebrospinal fluid

Continued

10. Vardiman AB, *et al.* (Retrospective Cohort) (2020)	56	8 without robot 348 inserted by navigated robotic guidance	• 9 were repositioned • 339 successful screw • two complication: explatation of interbody and vacuum-assisted wound closure
11. Kwan MK *et al.* (Retrospective Study) (2021)	1057	The average number of screws used in each patient was 14.1 ± 2.4 screws	• 20 superficial infection • 2 deep wound infection • 1 transient neurological deficit • 2 superior mesenteric artery syndrome • 1 massive blood loss • 1 generalized tonic - clonic seizure • 1 lung atelectasis
12. Liang D *et al.* (meta -analysis) (2021)	272 minimally invasive percutaneous surgery 280 open surgery	Not mentioned	• Screw dislocation: 6 minimally invasive percutaneous surgery and 4 open surgery • Infection: 6 minimally invasive percutaneos surgery and 5 open surgery

Source: Own authorship.

Comparing the freehand techniques, with the aid of fluoroscopy, navigation with CT, and navigation with fluoroscopy. Only patients with fluoroscopy navigation did not have neurological complications. Among the patients approached with the aid of fluoroscopy, 5 needed re-approach (1.5%) and one (0.319%) among the patients by CT navigation [9].

In the study by Zhao Q *et al.* [8], percutaneous fixation with pedicle screws (PFPS) was performed in 781 patients, in which 46 patients (5.9%) evolved with complications, such as breakage of the intraoperative guidewire, injury to the abdominal artery, spinal dura mater injury, poor positioning of the postoperative pedicle screw, screw breakage, plug screw falling out, connecting rod loosening, poor reduction, and late infection. Fourteen underwent revision surgery (1.79%).

When comparing percutaneous fixation with open fixation, in studies with 176 cases of percutaneous and 178 open approaches, there were 6 and 4 displacements, respectively. Thus, it was verified lower numbers of infections, hospitalization, and infection in the percutaneous approach [14].

There was an attempt to combine the placement of pedicle screws guided by fluoroscopy associated with electrophysiological monitoring, through electromyography (EMG), and a minimally invasive approach. Where 125 patients, among them, 57 had a bilateral approach, and 68 unilateral. In this way, 470 transpedicular screws between T-12 and S-1 levels were examined. There were a total of 427.33 (90.92%) screws without rupture, 39.33 (8.37%) pedicles with rupture ≤ 2 mm, and 3.33 (0.71%) with rupture ≥ 3 mm. No complications were found, such as nerve root injury or surgical revision [15].

Comparing only the freehand technique and robot-assisted implantation, 60 patients were selected, where 298 screws were used, 152 by freehand and 146 by

robot-assisted. In 7 robot-assisted implants, they were converted to freehand because they did not have enough bone contact and 1 because of poor positioning that was causing radicular pain. Among patients approached using the freehand technique, only one (0.65%) needed to be re-approached due to radicular pain caused by poor screw positioning [16].

In the study by Vardiman AB *et al.* [17], when performing the robot-assisted minimally invasive approach in 56 patients, 356 pedicle screws were placed. Eight were without the robot and 348 were inserted by robotic guidance, of these, 9 needed to be repositioned (2.5%).

The main complication, according to the studies, is the incorrect positioning of the screws, as verified in the aforementioned studies, in addition, neurological symptoms and superficial and deep infections.

4. Discussion

In the present study, no comparison was made between the specificities of the fixation techniques, such as the anatomical area and variations in the approach planes. Prioritize the analysis between the fixation of the column itself and its various methods and subsequent complications.

Studies show that navigation promotes greater precision and safety in screw placement compared to other techniques. Due to the proximity of the spinal canal and adjacent vessels, poor positioning can lead to complications, thus proper placement is critical. However, the literature demonstrates that the use of navigation systems did not reduce the rate of neurological complications [6] [9].

The study by Ringel *et al.* [16] compared the precision of screw insertion using robots and the conventional freehand implant, showing a greater number of poorly positioned screws assisted by robots, however, most studies are accumulating evidence of greater precision with robotic surgery. The robotic technique does not reduce the surgeon's exposure to radiation, and no difference between surgical times has been demonstrated [2] [5] [14]. Also, when compared with the fluoroscopy-guided technique, robotic surgery had a lower rate of malpositioning and less intraoperative blood loss [17].

Traditional approaches involving open fixation result in major surgical trauma, excessive blood loss, and a longer recovery time, thus, percutaneous fixation techniques have emerged as an alternative, replacing open surgeries with minimally invasive approaches. Minimally invasive approaches, such as PPSF, are an alternative for reducing trauma, excessive blood loss, and reducing recovery time, but there are several complications related to the intra and postoperative period, and a complete and thorough preoperative evaluation is essential [18]. However, when comparing the open technique, it was confirmed the shorter surgical time, bleeding volume, pain, and postoperative infection, in addition, to the smaller number of screw displacements [8].

By combining fluoroscopy with electrophysiological monitoring, a high accuracy (90.2%) was verified, in which no clinical complications were recorded.

Evidence the importance of knowing the radiological anatomy of the spinal pedicle and the correct interpretation of the EMG. But the limitation of such an approach is the cost of the equipment, the inability to obtain the real-time location of the guide wires in the vertebral body, and the radiological exposure of the patient and the surgeon. In addition, the benefits of the clinical outcome have not been identified [15].

Studies have shown that the most observed neurological complications were: paresis, paresthesia, L5 root irritation, severe headache due to CSF fistula, transient sciatica, dysesthesia, leg pain, and dura mater injury [8] [9] [11]. Among the vascular complications were: injury to the abdominal aorta, laceration of the iliac vein, inferior vena cava, and superior mesenteric artery (SMA) syndrome [8] [13] [19].

The most common intra and postoperative complications related to the screw were guidewire rupture, screw breakage, connecting rod loosening, fracture of the medial wall of the pedicle, fracture of the lateral wall of the pedicle, inter-somatic explantation, superficial infection and deep tissue and vacuum-assisted wound closure [8] [13] [17] [18].

In this scenario, there is a wide variation in reported accuracy when it comes to anatomical landmarks, which will not be discussed in the present study due to the lack of a standardized assessment method and/or the lack of consensus on what, or at what interval the accuracy of pedicle screw placement is considered satisfactory. Given the above, it is necessary to increase the use of safer intraoperative methods that allow better positioning of the screws and further investigation for use at different levels of the spine. In addition to creating new techniques that seek to improve the accuracy of placement of the pedicle screw, reduce the surgeon's exposure to radiation and obtain low cost, such as the creation of a guide pin with the aid of 3D printers [20] [21]. More research in this area should include randomized clinical trials with well-established methodologies to reduce bias.

The limitations of the present study can be summarized a priori from the heterogeneity of different types of studies, indications for the surgical approach, demographic characteristics of the patients, surgeons' skills, and the varied complexity of the surgery, in addition to different levels of the spine. Likewise, there was no discussion about the characterization of good positioning, and the degrees/scales of positioning, since this is not the objective of the work.

5. Conclusion

Based on the data available in the reviewed literature, it was shown that poor positioning of the pedicle screws is the most common cause of complications. The surgeon's skills and the length and diameter of the pedicle screw can also affect the different modes of placement. Inaccuracy in the insertion of pedicle screws, in addition to reducing system stability, can cause neurological, vascular, and visceral damage. The most serious and most feared complication is the neuro-

logical complication, both during and after surgery. Robotic computer assistance has the potential to reduce the incidence of postoperative and clinically relevant revisions for screw misplacement. Assistive technologies and prostheses for spinal fusion are evolving rapidly. Minimally invasive techniques have contributed to the reduction of surgical trauma and complications, thus allowing patients who had restrictions on performing the surgical approach, such as the elderly and critically ill patients, to undergo surgical treatment. In this way, expand the indications of the approach. It is necessary to expand the number of randomized clinical trials on robotic and traditional surgery in different age groups to analyze the degree of complications, as well as increase patient follow-up.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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