# Pedicle Screw Revision in Robot-Guided, Navigated, and Freehand Thoracolumbar Instrumentation: A Systematic Review and Meta-Analysis

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**Keywords**
- Computer assisted
- Freehand
- Neurovascular complication
- Pedicle screw
- Revision
- Robot
- Spinal fusion

**Abbreviations and Acronyms**
3DFL: Three-dimensional fluoroscopy
AR: Absolute risk
CI: Confidence interval
CT: Computed tomography
FH: Freehand
GRADE: Grading of Recommendations Assessment, Development and Evaluation
NV: Navigation
OR: Odds ratio
RCT: Randomized controlled trial
RD: Risk difference
RG: Robotic guidance

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OBJECTIVE: **Various computer-based guidance systems have been devised to reduce costly screw-related complications, yet their clinical effectiveness has never been comparatively assessed in a meta-analysis. We aimed to evaluate the incidence of clinically relevant pedicle screw revisions among robot-guided, navigated, and freehand spinal instrumentation.**

METHODS: **Controlled trials comparing robot-guided, navigated, or freehand spinal instrumentation for any indication and that specifically reported the proportion of patients who experienced pedicle screw revisions were included. Estimates were pooled using random-effects meta-analyses. Sensitivity analyses including zero-event trials and assessing per screw incidences were carried out.**

RESULTS: **Among 37 studies (7095 patients), intraoperative revisions in robot-guided (odds ratio [OR], 3.6; 95% confidence interval [CI], 0.7–19.4; $P = 0.14$) and navigated (OR, 1.5; 95% CI, 0.3–7.2; $P = 0.64$) procedures were comparable to freehand. Although postoperative revisions were reduced in robot-guided (OR, 0.3; 95% CI, 0.1–0.9; $P = 0.04$) and navigated (OR, 0.3; 95% CI, 0.2–0.5; $P < 0.001$) procedures, statistical significance was lost in sensitivity analyses for robotic guidance, but not for navigation. The pooled incidence of malpositioned screws requiring postoperative revision was 2.1%.**

CONCLUSIONS: **Based on the available data in the peer-reviewed literature, computer assistance in the form of robotic guidance or navigation has the potential to reduce the incidence of costly and clinically relevant postoperative revisions for screw malposition. It is essential to further investigate on a higher level of evidence if the clinical benefits of computer assistance warrant the high acquisition and maintenance costs inherent to these systems.**

## INTRODUCTION

An estimated 3.6 million spinal instrumentations were performed in the United States between 2001 and 2010, creating >$287 billion in total charges, with a steadily increasing trend.[1] Although computer-based navigation (NV) systems have long been established as standards in certain cranial procedures, adoption in spinal instrumentation has been slow.[2] To operate safely and efficiently in minimally invasive procedures, in which the line of sight is limited or even nonexistent, surgeons must rely on imaging, NV, and other methods of guidance. Therefore, an abundance of systems have been developed to assist in pedicle screw placement.

Conventionally, pedicle screws have been placed without guidance by relying on anatomic landmarks, with or without the use of fluoroscopic control.[3] In 1995, the concept of NV was introduced to spine surgery.[4] These NV systems can approximately be divided into 2 different principles: one principle is based on matching preoperative computed tomography (CT) images with real-time intraoperative fluoroscopy, which then allows visualization of screw trajectories in real time using reference arrays.[5-8] The other principle instead relies on intraoperative CT or three-dimensional fluoroscopic (3DFL) imaging with landmark-based registration. However, in these NV systems, establishment of the final trajectories for drilling and screw insertion has to be made by the surgeon on the spot. Robotic guidance (RG), first introduced in 2006, allows for preoperative planning of transpedicular trajectories.[9] This preoperative blueprint encompasses not only the ideal trajectory but also optimal screw angulation, length, and thickness. During surgery, an overlay of the preoperatively planned trajectories and intraoperative imaging is produced, and a stable working channel, through which screws are manually inserted, moves into position by use of a robotic arm.[9,10]

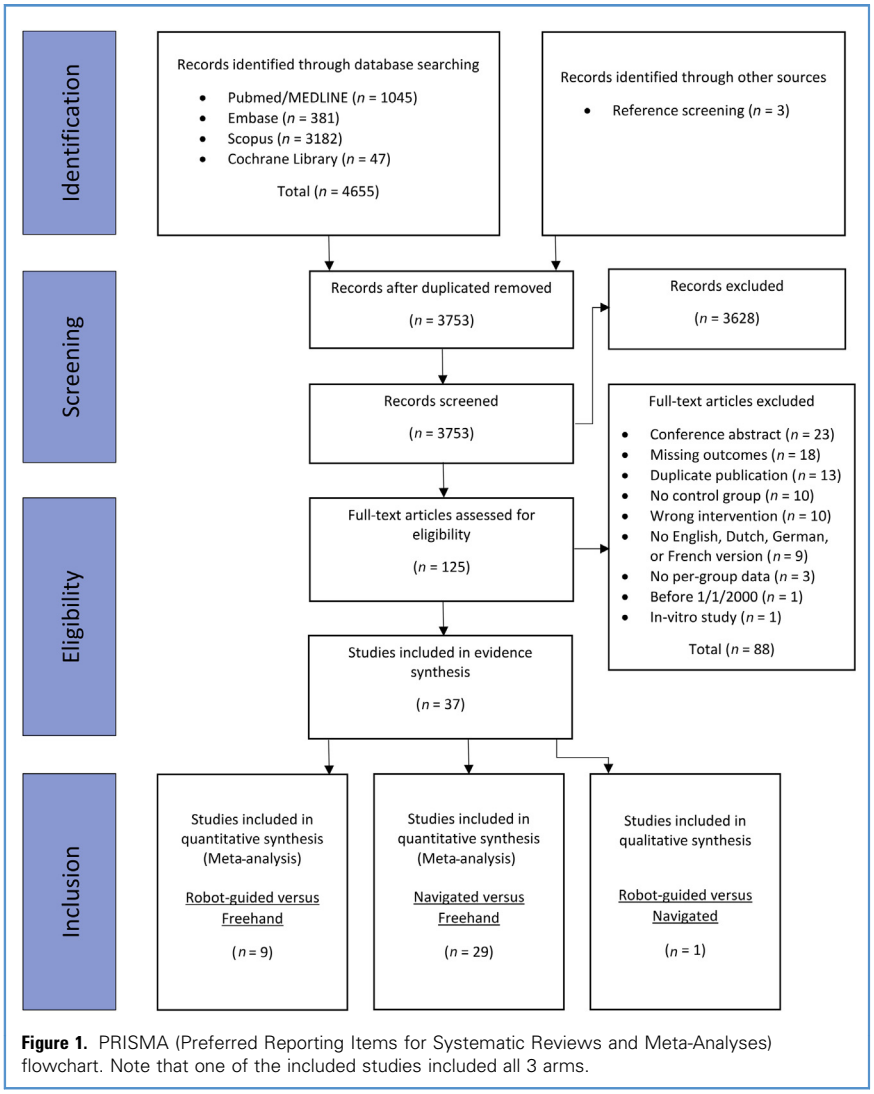


**Figure 1.** PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flowchart. Note that one of the included studies included all 3 arms.

Malpositioned pedicle screws cause significant added use of health resources.[11] Overt malposition is usually revised intraoperatively. This situation prolongs operative time, adds radiation and tissue trauma, and has been shown to reduce pullout strength.[10,12] Screws may require revision surgery if a patient presents with postoperative neurovascular complications, which produces additional costs and perioperative morbidity.[11] However, not all malpositioned pedicle screws require revision.[13-15]

There is some evidence that NV and RG improve the accuracy of screw placement as assessed by various radiologic grading scales.[16-18] However, data on the clinical impact of malpositioned pedicle screws causing neurologic complications and associated revision surgeries is sparse in the peer-reviewed literature, and no meta-analysis has been performed on this matter.[10,13,15] Although improved radiologic accuracy should be pursued, it is debatable that radiologic accuracy directly translates into an improved clinical outcome or a lower incidence of screw-related neurovascular complications requiring revision, especially when considering the substantial costs associated with these devices.

The aim of this meta-analysis was to evaluate all data on the incidence of pedicle screw revision using freehand (FH), NV, or RG techniques in the peer-reviewed literature.

## METHODS

### Overview

A systematic review and meta-analysis of all controlled studies that compare at least 2 techniques of pedicle screw insertion (RG, NV, or FH) was carried out. The outcomes of interest were 1) the occurrence of intraoperative revisions of pedicle screws and 2) the occurrence of revision surgery (postoperative revision) for 1 or more malpositioned screws. Title and abstract screening, full-text review, and data extraction were handled independently by 2 reviewers (V.E.S. and A.M.K.), and disagreements at any stage were resolved by discussion and consensus. We followed the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) protocol. This review was registered on PROSPERO (www.crd.york.ac.uk/prospero, record ID: 73108).

### Search Strategy

The MEDLINE (OVID), Embase (OVID), Cochrane Library, and Scopus (Elsevier) databases were searched to identify eligible articles. The search strategy included combinations of robot, robot-guided, robot-assisted, freehand, free-hand, conventional, navigation, navigated, bone screw, pedicle screw, and spinal fusion (see **Tables A1** and **A2**, **Supplementary Material 1**). Word variations and exploded MeSH (Medical Subject Headings) were searched for wherever feasible. In addition, hand-searched reference lists and literature databases of various device manufacturers were used to identify further studies of interest. The last comprehensive search was conducted on November 1, 2017.

### Study Selection

Only in vivo studies in English, Dutch, German, or French enrolling humans of all age groups were considered if published after January 1, 2000. Because few randomized controlled trials (RCTs) were anticipated, prospective and retrospective comparative studies of adult and pediatric individuals were included. To be considered, patients had to undergo posterior pedicle screw fixation of the thoracolumbar spine. Studies had to compare at least 2 techniques of pedicle screw insertion (RG, NV, or FH) and were included if they reported at least 1 of 1) the