Research Square

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Accuracy of Navigated Pedicle Screw Placement in the Cervical Spine: A comparative Evaluation of a Novel Orthogonal View Evaluation Method (OVEM) Versus other Classification Systems (Neo/Modified Gertzbein-Robbins/Wiesner)

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Abstract

Study design: A retrospective, comparison study.

Purpose: This study compares different computed tomography (CT)-based methods for evaluating the postoperative position of cervical pedicle screws (CPS). Specifically, our novel Orthogonal View Evaluation Method (OVEM) alongside the Neo, modified Gerzbein-Robbins, and Wiesner classifications to validate a standardized system for postoperative assessment of screw placement in the cervical spine

Methods

All enrolled patients underwent navigated, posterior stabilization using CPS in the subaxial spine (C3-C6). The intra- and inter-observer assessment was carried out using two statistical methods: the Fleiss Kappa and the Gwet´s agreement coefficient (Gwet´s AC1).

Results

A total of 90 (60 men and 30 women) patients with total number of screws 275 (median 2, IQR 2 to 4) were enrolled in the study. The OVEM classification demonstrated a statistically significant lower number of screws categorized as correctly placed compared to the other classification across all reviewers ($p < 0.001$).

The reliability analysis showed the highest agreement for OVEM 2 and Neo 2 for Reviewer 1, with Gwet's AC1 (95% CI) of 0.83 (0.77, 0.888) and OVEM for Reviewers 2 and 3 with Gwet's AC1 (95% CI) of 0.87 (0.818, 0.917).

Intra-observer agreement was highest for Reviewer 1 in OVEM 2 with Gwet's AC1 (95% CI) of 0.97 (0.943, 1.0), for Reviewer 2 in Neo with 0.97 (0.941, 1.0), and for Reviewer 3 in OVEM with 0.90 (0.829, 0.970). Inter-observer agreement was highest for Neo, with Gwet's AC1 (95% CI) of 0.89 (0.855, 0.927) among Reviewers 1, 2, and 3.

Conclusions

OVEM evaluation method appears to be more sensitive to detect misplaced screws, has similar reliability and reproducibility in comparison to Neo/modified Gerzbein-Robbins/Wiesner classifications.

Introduction

Posterior instrumentation is well-established method of stabilizing a wide range of cervical spine pathologies. Cervical pedicle screws (CPS) fixation has gained increasing popularity due to its superior biomechanical properties[1, 2]. However, CPS placement technically demanding and controversial, largely because of the small pedicle dimensions, complex angulation, intraoperative cervical mobility,

and close proximity of critical neurovascular structures including the vertebral artery, spinal cord, and nerve roots.

Postoperative radiological assessment is routinely performed to evaluate screw placement accuracy and ensure patient safety. Plain radiographs are unreliable for this purpose and are inferior to computer tomography (CT)[3]. Nevertheless, conventional CT assessments relies on two-dimensional (2D), biplanar imaging of a geometrically complex three-dimensional (3D) structure, which may limit the accuracy of CPS evaluation[4]. Despite several classification systems have been proposed, systemic comparison among them remains challenging[5–8]. The only validated pedicle screw classification system to date is Gertzbein-Robbins classification, originally developed for thoracolumbar instrumentation[9]. However, it does not differentiate between medial and lateral breaches, accounts for superior and inferior perforations, and lacks the precision required for cervical spine assessment[10].

A modified version of the Gertzbein-Robbins classification, also referred to as the Wiesner classification, was adopted for evaluation of CPS instrumentations. This system categorizes CPS placement into four grades based on 2 mm incremental pedicle perforations[11–17]. A similar grading framework is employed in another widely recognized and commonly used system, the Neo classification[18].

The aim of this study is to introduce and validate the OVEM classification, a novel 3D volumetric system for evaluating CPS placement. By assessing screw position within the narrowest portion of the cervical pedicle in three dimensions, this approach may provide greater sensitivity, accuracy and reliability.

To our knowledge, no prior validation study has established a gold-standard classification system for CPS placement.

Material and methods:

This retrospective, single-center study was conducted in accordance with the Declaration of Helsinki and approved by the Ethical Board Authority (Dnr 2023-01288-02). Ninety consecutive patients who underwent posterior stabilization of the subaxial cervical spine between 2015 and 2022 were included. CPS fixation methods included standalone CPS constructs but also hybrid configurations involving CPS with lateral mass screws (LMS) and/or pedicle screws in upper thoracic spine.

All procedures used 3D image-guided navigation (O arm^{TM} and Stealth Station, Medtronic Inc., Memphis, TN, USA), and postoperative CT scans (1.25 mm slice thickness) to enable high-quality multiplanar reconstruction and screw assessment. Radiological evaluation and classification of CPS placement were performed using archived digital records (Sectra IDS7) by three reviewers with varying spine experience: reviewer 1 (orthopedic resident, more than three years of experience in spine surgery), reviewer 2 (orthopedics spine surgeon with more than five years post-residency experience in spine surgery), reviewer 3 (fellowship trained, senior consultant neuro-spine surgeon with more than 10 years of post-residency experience). Assessments were performed independently, separated by several weeks

to minimize recall bias, with results collected by fourth with results collected by fourth author not involved in evaluation.

Orthogonal view evaluation method (OVEM)

CT multiplanar reconstruction (CT-MPR) generated images orthogonal to each pedicle´s long axis, allowing detailed 3D assessment of screw placement (Figure 1.). Screws were classified as follows:

- Grade 1: screw fully contained within pedicle with visible surrounding bone
- Grade 2: minor cortical engagement, limited to screw thread
- Grade 3: cortical perforation of the pedicle wall in any direction engaging the internal diameter of the screw without neuro-vascular injury
- Grade 4: cortical perforation (grade 3 screw) with vertebral artery and/or neural injury

Neo/Modified Gerzbein-Robbins /Wiesner classifications

Assessed on axial CT images and divided into four grades:

- Grade 0: screw fully contained
- Grade 1: breach of the pedicle with less than 2 mm penetration
- Grade 2: breach of the pedicle with more than 2 mm and less than 4 mm penetration
- Grade 3: breach of the pedicle with more than 4 mm penetration (i.e., complete misplacement)

As these three classifications share methodology and design, only the Neo system was used for statistical comparison. Table 1 summarizes OVEM and Neo classifications. Correct placement was defined as follows:

- OVEM/Neo: grades 1-2 and 0-1, respectively
- OVEM 2/Neo 2 modification: only grade 1 and 0, respectively

Statistical analysis

Descriptive statistics summarized screw placement ratings for all reviewers. McNemar’s test compared the number of correctly placed screws between Neo and OVEM. Accuracy was calculated in three distinctive and consecutive steps: first, based on initial grades for OVEM and Neo classifications assessed by reviewer 1, 2 and 3. Thereafter, both classifications were dichotomized and assigned as OVEM and Neo with two initial grades in both classifications were assessed as “non-misplaced screws” and grade 3 and 4 for OVEM and grade 2 and 3 for Neo as “misplaced screws”. Following this, both OVEM and Neo classification were dichotomized into second model and assigned as OVEM 2 and NEO 2 in which only first grade in each classification was regarded as “non-misplaced” with following grades as

“misplaced screws”. Accuracy comparisons between OVEM and Neo, as well as OVEM 2 and Neo 2, were performed using cross-tabulations for reviewers 1, 2, and 3 to determine sensitivity and specificity.

Intraobserver reliability was evaluated via repeated assessment of three separated batches of 30 patients per reviewer. Interobserver agreement was analyzed first across all three reviewers, then between senior reviewers 2 and 3 using the Fleiss Kappa as well as the Gwet´s agreement coefficient (Gwet´s AC1), the latter preferred for symmetrical data imbalance. All analyses were performed using R version 4.2.1.

Results

A total of 90 patients (60 men and 30 women) were enrolled in this study. The total number of analyzed CPS was 275 with median of 2 (IQR 2 to 4) and range 7. C6 was the most common instrumented vertebra (36%) followed by C5 (28%), C4 (19%) and C3 (17%).

The number of correctly placed screws was statistically significantly higher with the Neo classification compared to OVEM for all reviewers ($p < 0.001$). See Figure 2.

Sensitivity and Specificity of OVEM, OVEM 2, Neo, and Neo 2 classification models:

Reviewer 1:
The highest sensitivity was observed in the OVEM 2 compared to Neo model, while the highest specificity was noted in the OVEM compared to Neo 2 model.

Reviewers 2 and 3:
The highest sensitivities were found in the OVEM compared to Neo and OVEM 2 compared to Neo models. The highest specificity was again observed in the OVEM compared Neo 2 model.

The results are summarized in **Table 2**.

Reliability testing:

Reviewer 1:
The highest reliability was observed in the OVEM 2 compared to Neo 2, with Gwet’s AC1 (95% CI) of 0.83 (0.775, 0.888).

Reviewers 2 and 3:
The highest reliability were observed in the OVEM compared to Neo, with Gwet’s AC1 (95% CI) of 0.87 (0.818, 0.917) for reviewer 2 and 0.62 (0.528, 0.714) for reviewer 3.

The results are summarized in **Table 3**.

Intra-observer agreement:

Reviewer 1:

Highest Fleiss' Kappa (95% CI) value for Neo classification: 0.73 (0.529, 0.921)

Highest Gwet's AC1 (95% CI) value for OVEM 2: 0.93 (0.868, 0.983)

Reviewer 2:

Highest Fleiss' Kappa (95% CI) value for OVEM: 0.88 (0.748, 1)

Highest Gwet's AC1 (95% CI) value for OVEM and Neo: both 0.97 (0.927, 1) and 0.97 (0.941, 1), respectively

Reviewer 3:

Highest values for both Fleiss' Kappa and Gwet's AC1 (95% CI) for OVEM: 0.86 (0.762, 0.955) and 0.90 (0.829, 0.97)

The results are summarized in **Table 4**.

Inter-rater agreement (all reviewers):

Highest values for Neo classification with Fleiss' Kappa (95% CI): 0.40 (0.26, 0.538) and Gwet's AC1 (95% CI): 0.89 (0.855, 0.927) respectively.

The results are summarized in **Table 5**.

Inter-rater agreement (senior reviewers 2 and 3):

Highest values for Neo classification with Fleiss' Kappa (95% CI): 0.37 (0.154, 0.592) and Gwet's AC1 (95% CI): 0.92 (0.88, 0.955) respectively

The results are summarized in **Table 6**.

Analysis of misplaced screw trajectories:

An additional review of trajectories of screws classified as misplaced according to OVEM (grades 3 and 4), revealed that the most common trajectory was in the lateral-upper direction, accounting for 33% of all misplaced screws. See figure 3.

Discussion

We found that the OVEM classification identified a higher number of misplaced CPS compared to the Neo classification, indicating greater sensitivity but lower specificity.

The introduction and implementation of intraoperative image navigation have enhanced the accuracy and precision of CPS placement, which has translated into improved clinical outcomes[19]. Optimal screw placement is defined as complete containment within the cancellous bone of the pedicle, without any cortical breaches or protrusions of the screw.

The absence of a consensus about a gold-standard classification is underscored by the fact that three systems: Neo, modified Gertzbein-Robbins and Wiesner classification, share the evaluation methodology, yet none have been formally validated. The OVEM classification was developed to provide a 3D based model for CPS position assessment. The findings of our current study corroborate OVEM's superior sensitivity in detecting even minor deviations of the screw within the pedicle's bony corridor along its axis, thereby enhancing its clinical utility and lying the foundation for future advancements, such as artificial intelligence (AI)-driven automated radiological assessment. Moreover, it incorporates clinical outcomes by introducing a specific grade (G.4) to describe neurovascular complication. 2D evaluation, although traditionally utilized, can fail to detect screw misplacements, particularly when the screw follows pedicle's anatomical axis, which is more likely to occur due to its smaller bone volume in the cervical spine.

Medial, superior and inferior screw perforations are well described in the literature[5, 7, 20, 21]. However, the most common type, accounting for up to 84%, is lateral perforation[5, 7, 18, 22]. This is postulated to occur due to diminished cortical bone thickness of the pedicle contiguous with the vertebral artery [23, 24]. Our findings corroborate this observation, revealing that lateral-high and lateral-low misplacements constituted for more than 60% of all recorded displacements, underscoring their predominance in the overall misplacement pattern. Thus, reliance on the Neo classification, which permits a certain degree of misplacement (e.g., up to 2mm), may foster a false sense of security. To put it in the perspective, given that the most common diameter of CPS is 3.5 mm, a 2 mm misplacement translates to over half of the screw being outside the intended bony corridor.

It is crucial to interpret these findings from clinical perspective. Misplaced screws may lead to devastating consequences, including permanent neurological deficit, chronic neuropathic pain, vascular and/or visceral injury. Nonetheless, several studies showed that the CPS placement is generally safe, with vertebral artery injury being rare (0.2 to 0.4%), and nerve root and spinal cord injury occurring in 0.9% and 0.3% of cases, respectively[25, 26]. However, s construct incorporating misplaced screws, may exhibit significantly compromised biomechanical integrity, predisposing development of pseudarthrosis and screw dislodgment. This can precipitate development of cervical deformity, and theoretically, neurological deterioration.

We strongly believe that this leniency may hinder the advancement of accurate and reliable CPS planning and insertion techniques. Postoperative assessment and classification of CPS placement are essential, as they indirectly evaluate the screw placement method employed during surgery. The adoption, of 2 mm threshold (Neo grade 1 or modified Gertzbein-Robbins/Wiesner grade 2) as a margin of acceptable error likely accounts for the discrepancies between accuracy of CPS in the current study and the literature[10,

17, 19]. We encountered a statistically significant lower number of correctly placed screws in the OVEM classification compared to the Neo system across all reviewers. OVEM's rigorous criteria enhance sensitivity but reduce specificity. CPS deemed by OVEM would often be considered acceptable by Neo or other similar 2D-based systems. This indicates that most misplacements detected by OVEM were minor and clinically insignificant. Inter-observer agreement was highest for the Neo classification, likely due to its tolerance for minor errors. In contrast, eliminating the margin of error (e.g., Neo vs Neo 2) resulted in a five- to seven-fold increase in identified misplacements and a corresponding drop in inter-observer agreement. Interestingly, applying of stricter criteria in OVEM (e.g., OVEM vs OVEM 2) resulted in much higher inter-observer agreement, suggesting that the model's robustness improves with greater rigor.

When comparing only senior reviewers (reviewers 2 and 3), the inter-observer agreement dropped by nearly a half for OVEM 2, while for the Neo 2 classification demonstrated a threefold decrease. That reaffirms that eliminating accepted error margin increases the sensitivity in Neo classification but consequently reduces apparent sensitivity of the OVEM in comparison. In contrast, the OVEM 2 model demonstrated the highest sensitivity among all of the reviewers compared to Neo model. We postulate that the differences between the junior and both senior reviewers can be attributed to two key factors: first, the OVEM's classification unique learnings curve, which initially seems demanding and time-consuming for less experienced reviewers, and second, discrepancy in clinical experience with planning of CPS instrumentation utilizing CT-MPR.

Our findings indicate that, despite its lower specificity, the OVEM classification provides superior sensitivity, rendering it a more reliable and robust tool for assessment and classification of CPS placement. This explains the consistently higher misplacement rates identified by the OVEM across all reviewers. Furthermore, the OVEM exhibited greater intra-observer reproducibility among experienced clinicians, irrespective of the error tolerance specified in the Neo models.

This study has important limitations. Its retrospective design resulted in screw assessment performed on non-anonymized images, which might be a source of confirmation bias. Secondary, we did not included assessment of neuro-radiologist due to local routines in which 2D assessment is performed on post-operative images (similar to Neo/modified Gertzbein-Robbins/Wisener classifications) and therefore we wanted to avoid evaluation bias with skewed results caused by this practice. The study did not consider pedicle screws intentionally placed with a violation of the pedicle i.e. due to small size of the pedicles pre-operatively. The present study does not investigate the clinical significance of implant placement or its impact on neurological outcome and complication rates in patients treated with navigated CPS fixation. These aspects were investigated in separate study that has been submitted to a different peer-reviewed international spine journal.

Conclusions

The OVEM classification system demonstrates greater robustness and sensitivity, providing more reliable information about screw displacement and potential risk for neurovascular injury. In contrast, the

inherent margin of error in the Neo classification and its modified variants, limits their reliability and reproducibility, regardless of the evaluator's experience.

Although OVEM classification may require greater clinical experience and a steeper learning curve, it offers improved accuracy. We conclude that a robust, reproducible classification system is essential for accurate evaluation of the cervical pedicle screw placement. Such system ca enhance assessment of clinical and radiological outcomes, improve surgical technique, and support higher-quality research in cervical spine surgery.

Declarations

Competing Interests

The first author has received teaching honoraria and a research grand from industry in connection with a separate, published study. These relationships however are unrelated to the present work.

Declaration of Conflict of Interest

The first author of this manuscript has received teaching honoraria and a research grand from industry in connection with a separate study. These relationships are unrelated to the present work. The remaining authors declare no potential conflicts of interest related the research, authorship, and/or publication of this article.

Contribution

All listed authors have actively contributed to the preparation of the manuscript.

Author Contribution

All listed authors have actively contributed to the preparation of the manuscript. All listed authors made substantial contributions to the preparation of this manuscript. L.B. and J.M.D. conceived and designed the study. J.A., H.L., and L.B. collected data from available medical records. A.B. provided consultation on the selection of appropriate statistical analyses, performed all statistical calculations, and prepared Figure 1. J.A. drafted the initial version of the manuscript under the supervision of L.B. Tables 1 and 2–6 were prepared by L.B. Figure 2 was designed and prepared by J.W. Interpretation of the results was undertaken through collaborative discussions among L.B., J.W., J.M.D., and L.-O.K. All authors contributed to the writing of the manuscript. The final manuscript was critically reviewed and revised by J.W., J.M.D., L.-O.K., and L.B

Data Availability

The data is only available internally by the authors due to ethical reasons. For external researchers, ethical approval may be obtained via formal application to the Ethical Board Authority.

Founding

The study has received no founding.

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27. Founding
28. The study has received no founding

Tables

Tables 1 to 6 are available in the Supplementary Files section.

Figures

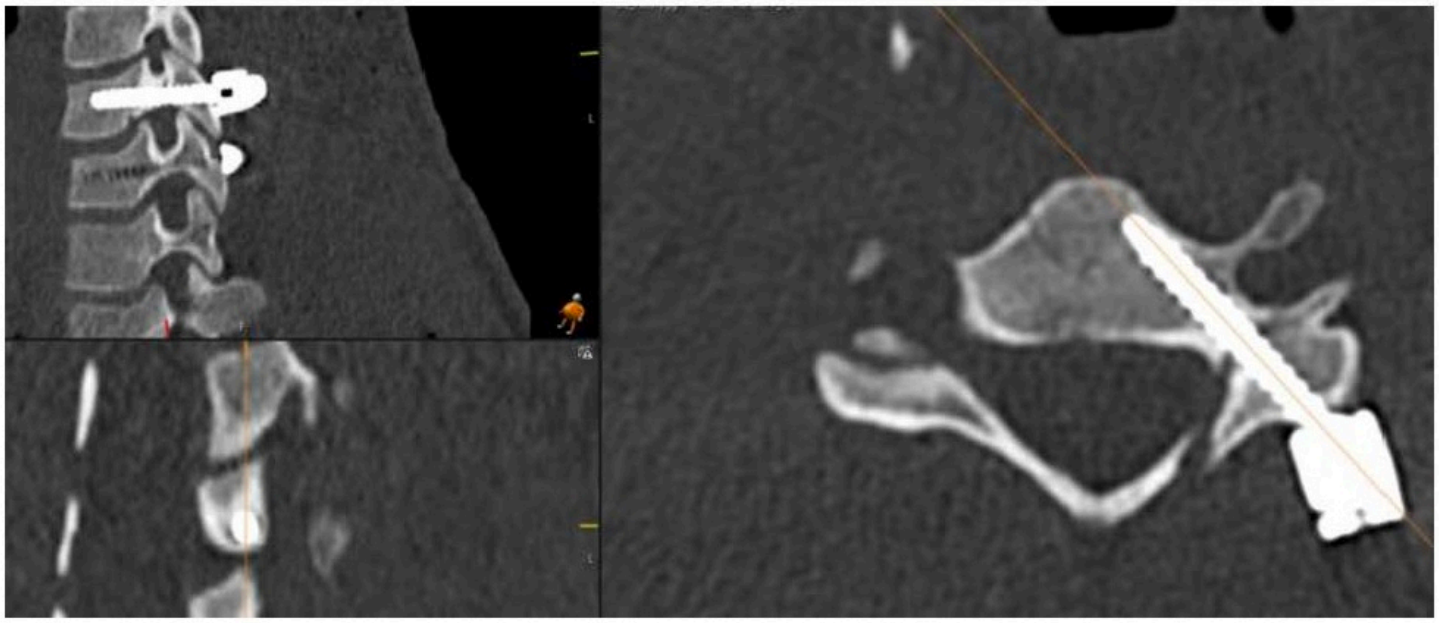


Figure 1

Demonstration of multiplanar reconstruction (MPR) on computer tomography images (CT)

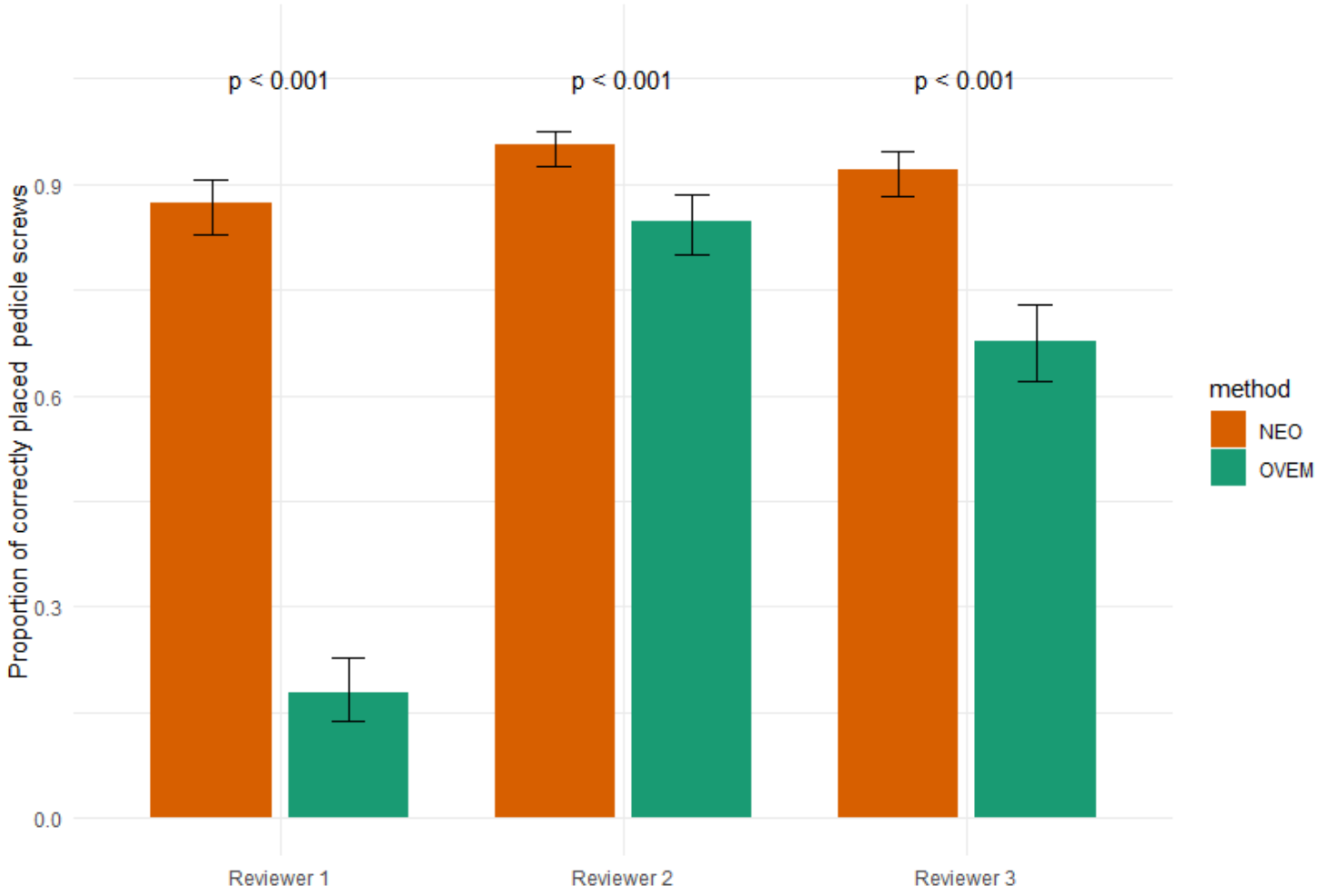


Figure 2

Direct comparison of correctly placed screws between OVEM and Neo classification among the reviewers 1, 2 and 3.

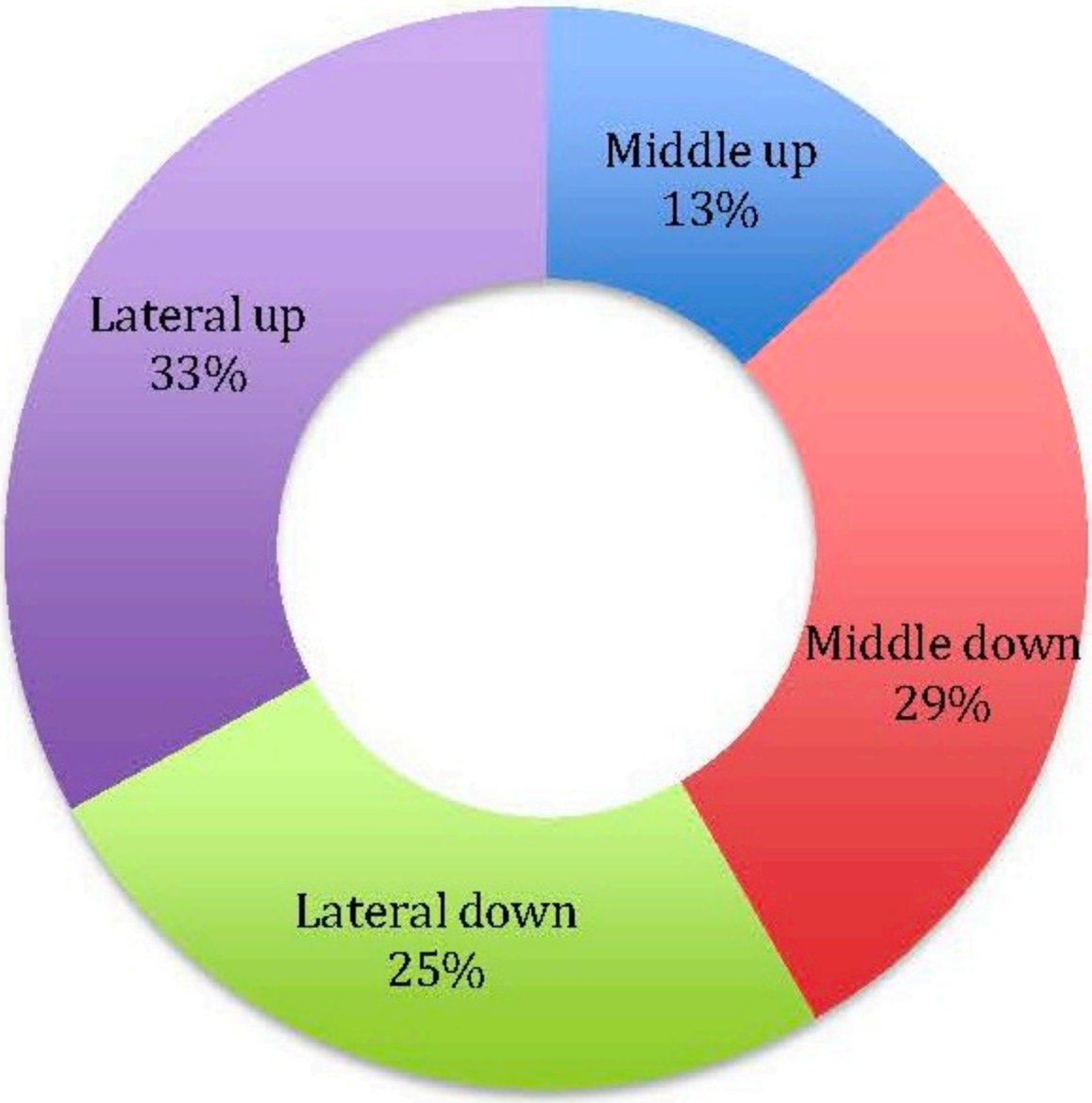


Figure 3

Type and percentage of CPS misplacement trajectories

Supplementary Files

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- Table4final.docx
- Table5final.docx

- Table2final.docx
- Table3final.docx
- Table6final.docx
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