



COMPARISON OF PEDICLE SCREW PLACEMENT USING O-ARM NAVIGATION AND NAVIGATIONAL TEMPLATES IN AN ANIMAL MODEL EXPERIMENT

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Objective. To perform a comparative analysis of experimental pedicle screw placement using custom-made 3D-printed navigational templates and using O-arm (cone-beam computerized tomograph, CBCT) and navigation station.

Material and Methods. The experiment was performed on five fresh anatomical specimens of the lamb thoracic and lumbar spine. In Group 1, 44 screws were inserted using O-arm and Stealth Station S7 navigation system, and in Group 2, 72 screws were inserted using 3D-printed navigational templates. The main comparison criterion was the safety of implantation assessed based on a grade (0 to 3) of cortical bone perforation on postoperative CT. The extra comparing criteria were the time of implantation and summary radiation exposure required for screw placement. In Group 2, the accuracy of implantation was analyzed by assessing the deviation (mm) of the actual screw trajectory from the planned one at the point of entry into the vertebra and at the intersection of the screw axis with the anterior cortical layer of the vertebral body (end point), and by measuring the angles between the trajectories. The results were evaluated for normal distribution and subjected to statistical analysis for paired independent groups using the Kruskal-Wallis test and Chi-square in the Statistica 10 software.

Results. Analysis of the safety revealed significant difference between the groups ($p < 0.0001$). In Group 2 there were not any cases of cortical bone perforation, in Group 1 (O-arm) grade 0 was registered for 28 (64 %) screws, grade 1 for 7 (16 %) screws, grade 2 for 4 (9 %) screws, and grade 3 for 5 (11 %) screws. The average time of one screw placement was 81.00 (64.50; 94.00) sec in Group 1 and 40.75 (33.50; 52.25) sec in Group 2, $p < 0.001$. In Group 2, the mean deviation of the entry point was 0.50 (0.34; 0.87) mm, and of the end point – 1.10 (0.66; 1.93) mm. The mean angle between the planned and actual trajectories was 2.76 (0.80; 4.89) degrees in the axial plane and 2.62 (1.43; 4.35) degrees in the sagittal plane. The average design time for one template was 8.75 (8.00; 9.75) min, and 3D printing time – 60 (57; 69) min. The approximate material cost for one template printing was 45 rubles, for one anatomical specimen of lamb thoracic and lumbar spine – 390 rubles. The CT dose index (CTDI) for the O-arm was 8.99–9.01 mGy, and dose length product (DLP) for one model (3 scans) was 432 mGr × sm. In Group 2, there was no intraoperative X-ray control, the CTDI for preoperative CT was 10.37–10.67 mGy, and DLP was 459–477 mGr × sm.

Conclusion. The results of the experiment on a lamb spine biomodel showed that pedicle screw placement with 3D custom-made navigational templates is associated with better results of the safety and the speed of implantation as compared to that with intraoperative O-arm navigation. This justifies the 3D-printed template using in case of increased mobility of the spine during implantation, where the accuracy of CT navigation is significantly reduced. In clinical practice, these conditions correspond to transpedicular fixation of the cervical spine and screw fixation of the C1–C2 vertebrae.

Key Words: navigation, 3D printing, template, guide, spine, O-arm, transpedicular fixation.

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The use of spinal navigation has been increasingly used and is likely to become an integral part of spinal surgeries in the future. Numerous studies have demonstrated a higher accuracy of implantation performed using navigation equipment compared to the free hand technique [1–6]. Minimization of potential complications has always been a priority in any field of surgery, and the currently emerging social relationships between

various participants in the treatment process create an increasing demand for higher safety of medical manipulations. On the other hand, the growing financial costs of high-tech operations dictate the need to search for less costly alternatives.

Spinal navigation techniques are based on intraoperative comparison of the anatomical structures of the spine with the data of previous radiation examination. This is achieved by using either

navigation equipment with a reference frame mounted on one of the vertebrae, followed by integration of surgical instrumentation, or custom-made templates fabricated using a 3D printer [7–11]. Both navigation principles have been investigated in numerous studies demonstrating a comparable high accuracy of insertion performed using navigation templates and intraoperative CT navigation. However, there are no publications

directly comparing these techniques within a single prospective study.

The aim of this study is a comparative analysis of transpedicular insertion in an experiment using custom-made 3D templates and cone-beam computerized tomography (CBCT) combined with a navigation station.

Material and Methods

The experiment was performed on five fresh anatomical specimens of the sheep thoracic and lumbar spine. The anatomical features included pronounced spinous processes of different shape in the thoracic and lumbar regions, short oval-shaped pedicles, and pointed vertebral bodies. The mean axial angle between pedicular axes was 32.73° (27.47° ; 47.08°) in the thoracic spine and 67.16° (65.10° ; 70.72°) in the lumbar spine. The geometrical parameters of pedicles derived from cross-sectional morphometry (Fig. 1) are presented in Table 1.

In Group 1, 44 screws were placed using the O-arm CBCT and Stealth Station S7 (Medtronic) navigation station. The specimens were placed on the operating table; an approach to the posterior spinal structures was performed using an electric knife and standard surgical tools (Fig. 2). A reference frame was mounted on the spinous process, and a standard mode scan was performed. After registration, a transpedicular hole was made using a guided awl, and then a mono-axial screw of 3.5 mm in diameter was inserted. Repeated scans were performed only for implantation of new screws after remounting of the frame; no screw reposition was performed if malposition was detected.

In Group 2, 72 screws were implanted. The specimens were subjected to preliminary CT scans with a slice thickness of 1 mm. Navigational templates were designed on the basis of DICOM data. File processing and STL model generation were performed using the Mimics Innovation Suite 21.0 (Materialize) software. Final processing of the spine model and design of navigation templates were performed using the Blender 2.78 soft-

ware. A single-level bilateral templates with two contact points in the lamina and articular process area and with an additional contact area on the top of the spinous process (Fig. 3) was designed for each vertebrae; this design provided high accuracy rates in previous studies [11]. A Gcode print file was generated using the Cura 4.2 software. The spine model and navigational templates were 3D-printed from polylactide (PLA) using FDM technology on an Infinitary M508 printer.

The posterior vertebral structures were exposed; the templates were tightly fitted; screw holes were formed through the guide tubes using a 2 mm high-speed drill, followed by screw insertion (Fig. 4). The main criterion for comparison was the safety of insertion, which was assessed using CT-based data on pedicle cortical perforation. A four-point grading scale was used: 0 – the screw is completely contained within the bone; 1 – the screw partially perforates the bone, but more than 50 % of the screw diameter is inside the bone; 2 – the screw perforates the bone, while more than 50 % of the screw diameter is outside the bone; 3 (penetration) – the screw is completely outside the bone [12].

Additional comparison criteria were the time of implantation and the total radiation exposure required for screw placement. Also, the accuracy of implantation was analyzed in Group 2. The criterion was based on an assessment of the deviation (mm) between the planned and actual screw trajectories at the point of entry into the vertebra (entry point) and at the intersection of the screw axis with the anterior cortical layer of the vertebral body (end point), which was achieved by superimposition of axial and sagittal CT slices in the Mimics Innovation Suite 21.0 software (Materialize). In addition, the planned and actual angles between the screw axes in two planes were measured (Fig. 5).

The results were evaluated for a normal distribution and subjected to statistical analysis for paired independent groups using the Kruskal-Wallis test and the Chi-square test in the Statistica 10 software. The distribution of data in groups is presented as a median and

25–75 % quartiles in the Me (25 %; 75 %) format in the case of an abnormal data distribution and as a mean and standard deviation in the $M \pm SD$ format in the case of a normal distribution.

Results

Safety analysis revealed statistically significant differences ($p < 0.01$) between the groups. No cases of cortical perforation were detected with navigational templates; all safety grades were present in the O-arm group (Table 2). Initially, placement of screws in six biomodels (3 in each group) was planned. After insertion of 72 screws in three biomodels in Group 2 and 44 screws in two biomodels in Group 1 and staged processing of the obtained data, mathematical modeling revealed that even the subsequent 100% accuracy of insertion in Group 1 would result in statistically significant differences; therefore, the experiment was discontinued. The mean time for inserting a single screw was 81.00 (64.50; 94.00) s in Group 1 and 40.75 (33.50; 52.25) s in Group 2; $p < 0.001$.

In Group 2, the mean deviation was 0.50 (0.34; 0.87) mm for the entry point and 1.10 (0.66; 1.93) mm for the end point. The angle between the actual and planned trajectories was 2.76° (0.80° ; 4.89°) in the axial plane and 2.62° (1.43° ; 4.35°) in the sagittal plane. The deviation and trajectory angle divergence parameters are presented in Table 3.

The mean time for designing a single template was 8.75 (8.00; 9.75) min; the time for printing a single template was 60.00 (57.00; 69.00) min. The cost of material for producing a single template was 45 rubles; the cost of a single model of the sheep thoracic and lumbar spine was 390 rubles.

The computed tomography dose index (CTDI) for the O-arm was 8.99–9.01 mGy; the dose-length product (DLP) was 432 mGy $\times$ cm for a single specimen; during screw insertion, each specimen underwent 3 scans. Insertion of screws using navigational templates was performed without X-ray control; the computed tomographic dose index during



Fig. 1

Cross-sectional morphometry of the sheep vertebral pedicles: D1 – larger diameter; D2 – smaller diameter; E – ellipticity; Perimeter – cross-sectional perimeter; Area – cross-sectional area

preoperative CT was within 10.37–10.67 mGy, and DLP was 459–477 mGy × cm.

Therefore, the use of navigational templates was accompanied a statistically significant increase in the safety and speed of implantation, with the radiation exposure being the same. An analysis of the planned and actual trajectories revealed minimal and clinically insignificant differences that may be designated as method error.

Discussion

The experiment demonstrated superior insertion parameters for navigational templates compared to O-arm navigation. Then, the question arises as to the cause for the outcomes observed in Group 1 and their difference from the published data on the use of O-arm navigation in clinical practice [1–6, 13–16]. In our opinion, the main factor is mobility of

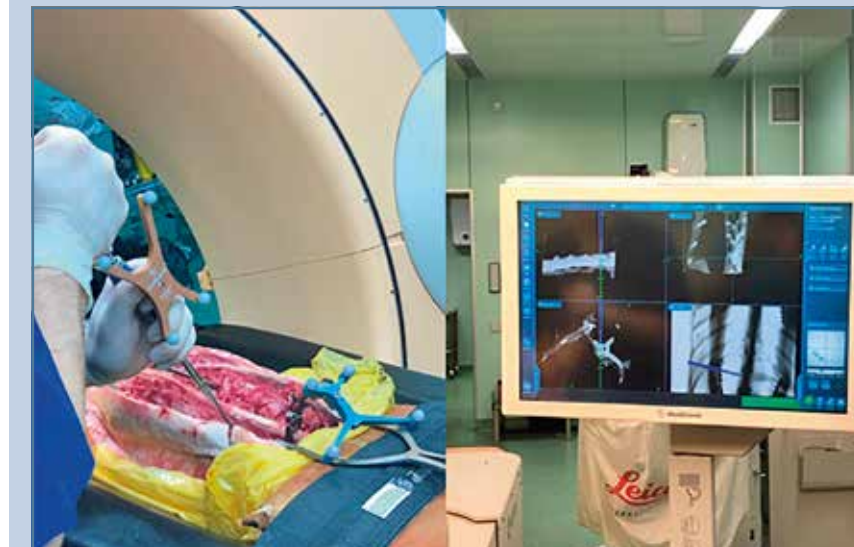


Fig. 2

Placement of transpedicular screws using intraoperative O-arm navigation

the used biomodel on the operating table due to difficulty of its rigid fixation in a desired position and remaining mobility between the vertebrae.

The main factor for unsatisfactory implantation when using navigation equipment is believed to be a displacement of the landmarks relative to the reference. In spinal surgery, this is associated with mobility of the vertebrae relative to the vertebra bearing the frame. External fixation of the patient does not guarantee immobility of the adjacent vertebrae [1–6]. In cases where the pedicle diameter is much larger than that of the navigated instrument (e.g., the lumbar spine), there is a certain distance margin that enables safe insertion, even in the

case of landmark displacement [13–16]. The thoracic spine with a smaller diameter of the pedicles is also less mobile. The most technically difficult implantation in humans is transpedicular fixation in the cervical spine at the subaxial levels due to a small diameter of the pedicles, a large insertion angle requiring wide opening of the wound, and mobility of the cervical spine [17–21]. In this experiment, mobility of the spine remained, which probably affected the results of implantation. We suppose that the accuracy of implantation might be improved by more frequent CT scans, but in a clinical setting, this would increase radiation exposure to the patient.

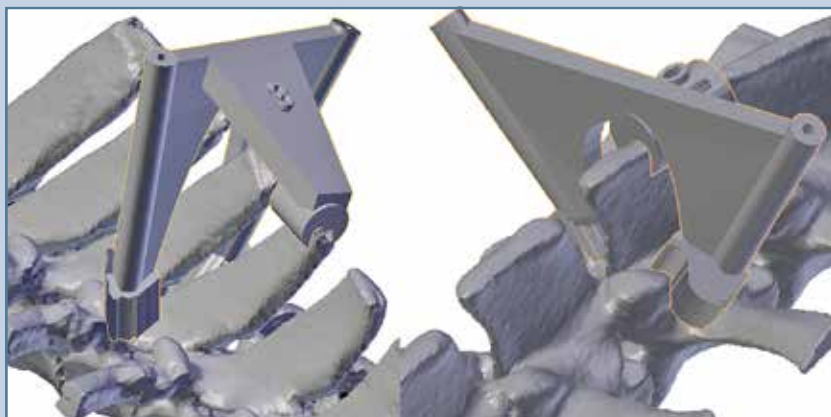
An analysis of the clinical outcomes reported in the literature should take into account the fact that if intraoperative CT is used, screw insertion is followed by a control scan with screw reposition in the case of incorrect insertion [1–6, 13–16]. In our experiment, screw reposition was intentionally avoided, and control was based on the postoperative CT data, which enabled comparison of the primary insertion characteristics.

The use of custom-made navigational templates resting on a single vertebra

Table 1

Averaged parameters of the sheep vertebral pedicles

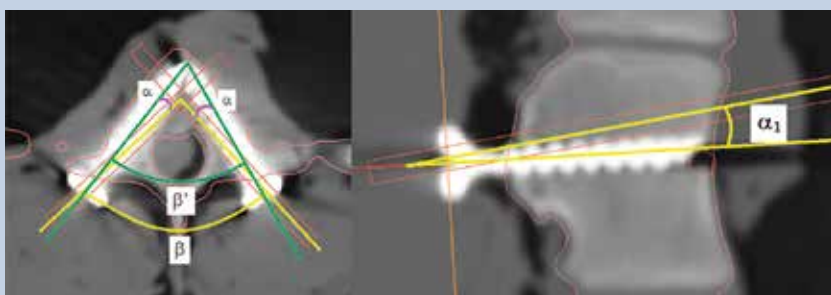
Parameter	Value
Transverse diameter, mm	5.41 (4.55; 7.60)
Longitudinal diameter, mm	20.64 (18.02; 26.28)
Ellipticity	0.95 ± 0.04
Perimeter, mm	44.28 (39.89; 57.97)
Cross-sectional area, mm ²	91.16 (76.80; 146.75)

**Fig. 3**

Design of navigational templates in the thoracic and lumbar spine

**Fig. 4**

3D-model of the spine and transpedicular screw insertion using navigational templates

**Fig. 5**

Assessment of the deviation of angles of the planned and actual trajectories in the axial and sagittal planes: α – angle between the planned and actual axes of insertion of a single screw in the axial plane; β – angle between the planned axes of insertion in the axial plane, β' – angle between the actual axes of insertion in the axial plane, α_1 – angle between the planned and actual axes of insertion of a single screw in the sagittal plane

eliminates the mobility factor as a negative predictor of implantation. As indicated in previous studies, the main factors for correct navigation in the case of templates are placing them in the correct position and preventing displacement and deformation. This is largely achieved due to the template design features: the use of a three-point contact, stiffeners, and fixing elements. Of great importance is also the adequacy of preparation of the spine for the use of this technique: careful exposure of the contact area and sufficient dissection to minimize possible displacement of the template due to pressure of the paravertebral muscles [7–12, 22]. The results in Group 2 have shown that, if the prerequisites are met, the navigational template technique enables insertion of screws with a high accuracy in a short time and without the use of X-ray control.

The two navigation techniques can be compared using the literature data, but it is associated with a number of limitations due to differences in the methodology and evaluation criteria. We did not find publications comparing intraoperative CT navigation and navigational templates within a single study. In the case of transpedicular fixation in the cervical spine, both techniques demonstrate a high accuracy. For example, Ishikawa et al. [23] report the results of insertion of 108 screws, of which 96 (88.9 %) screws are classified as grade 0, 9 (8.3 %) screws as grade 1 (perforation is less than 2 mm or less than half the screw diameter), and 3 (2.8 %) screws as grade 2. Despite the absence of insertion-associated complications, the authors indicate that grade 2 or higher malposition can lead to catastrophic consequences. Chachan et al. [24] reported an analysis of transpedicular insertion in the cervical spine using O-arm navigation. Patients who underwent revision surgery were excluded from the study. Out of 241 screws inserted at the C2–C7 level (197 at C3–C6), screw breach was detected in 17 (7.05 %) cases: 10 grade 1 screws and 7 grade 2 screws. All breaches were lateral; there were no neurovascular complications. According to the article, after repeated scans, screws with sig-

Table 2

Safety of implantation in groups

Safety of implantation	O-arm navigation (Group 1)	Navigational templates (Group 2)
Grade 0	28 (64 %)	72 (100 %)
Grade 1	7 (16 %)	—
Grade 2	4 (9 %)	—
Grade 3	5 (11 %)	—

nificant malposition were repositioned. Theologis and Burch [25] reported the results of 121 pedicle screw placement at the C2–C7 level using O-arm navigation. The authors indicate that 99.2 % of screws were inserted without injury to the neurovascular structures; in one case, there was medial malposition at the C5 level due to acute radiculopathy. In this case, the degree of bone perforation was not assessed; postoperative CT scans in patients without newly identified neurological deficit were also not performed, which prevents full assessment of the quality of implantation.

If navigation guides are used, grade 0 safety of transpedicular screw insertion in the cervical spine is within a range of 80.6–97.5 % in various studies [26–30]. The largest series was reported by Sugawara et al. [31] who inserted 538 transpedicular screws in the cervical spine during a multicenter prospective study; there were no signs of cortical violation in 98.9 % of cases; the other cases were grade 1 without complications.

Of course, our findings cannot be fully extrapolated to humans because no bio-model can fully reproduce surgical conditions. However, laboratory conditions enable obtaining specific data, reproduction of which in a clinical study is impossible or difficult, e.g., the safety of insertion at a small diameter of the pedicles in the case of atypical anatomy and without screw reposition.

Investigation of radiation exposure has showed that preoperative CT performed for design and 3D printing is similar to three scans performed on an O-arm. It should be understood that the experimental data are somewhat arbitrary because the number of scans depends on many factors and can vary significantly during surgery. The principle itself is important: navigational templates can be used without intraoperative radiological control. If patients undergo a preoperative CT scan for diagnostic and planning purposes, then the use of an O-arm, in any case, is accompanied by increased radiation exposure compared to navigational templates. If there is no

preoperative CT, the difference in radiation exposure is determined by the difference in doses of preoperative (using templates) and intraoperative (using O-arm navigation) CT.

It is worth noting that the two techniques are not completely interchangeable. The use of navigational templates can be difficult if the contact area is insufficient, e.g., in revision surgery or destructive processes. O-arm navigation also allows percutaneous procedures, but the cost of this equipment is disproportionately higher than that of 3D printing and requires special equipment in the operating room, which limits the availability of this technique. Due to the experimental nature of the study, the obtained results should not be considered as an unambiguous superiority of one of the navigation techniques. According to the literature data, the accuracy in a clinical setting is comparable. In our opinion, the use of navigational templates makes implantation more standardized and less dependent on the factor of the surgeon's experience, knowledge of the individual anatomy, and segmental mobility of the spine; therefore, in practice, this technique may be considered primary in the case of complex fixation trajectories, in particular for surgeons with little experience.

Conclusion

According to the experimental results in sheep spine biomodels, placement of transpedicular screws using individualized navigational templates is accompanied by better results in the rate and safety of insertion in comparison with O-arm navigation. On the basis of the obtained results, it may be concluded that 3D templates are especially relevant in increased mobility of the spine during insertion when the accuracy of CT navigation is significantly reduced. In clinical practice, these conditions occur in transpedicular fixation of the cervical spine and screw fixation of the C1–C2 vertebrae.

Table 3

Assessed trajectory deviation parameters in Group 2

Parameters in the template group	Value
Entry point mean, mm	0.50 (0.34; 0.87)
End point mean, mm	1.10 (0.66; 1.93)
$\angle\alpha$, deg	1.64 (0.78; 3.50)
$\angle\alpha_1$, deg	2.76 (0.80; 4.89)
$ \angle\beta - \beta $, deg	2.62 (1.43; 4.35)
Axial entry point, mm	0.27 (0.19; 0.66)
Axial end point, mm	0.80 (0.24; 1.52)
Sagittal entry point, mm	0.64 (0.20; 1.27)
Sagittal end point, mm	1.20 (0.36; 2.38)

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