# DETERMINATION OF OPTIMAL DESIGN OF NAVIGATION TEMPLATES FOR TRANSPEDICULAR IMPLANTATION IN THE CERVICAL AND THORACIC SPINE: RESULTS OF CADAVERIC STUDIES

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**Objective.** To perform comparative analysis of safety and accuracy of pedicle screw placement in the cervical and thoracic vertebrae using custom-made 3D-printed navigation templates of various designs.
**Material and Methods.** The study was performed on three cadaver preparations. A total of 60 pedicle screws were placed in C2–T4 using navigation templates of different designs. Three types of templates were used to install 20 screws in each group: monolateral templates in group A, bilateral templates in group B, and bilateral three-point templates supported by the spinous process in group C. The safety and accuracy of screw placement were evaluated by CT with following comparative evaluation.
**Results.** Three-point templates (group C) demonstrated the highest implantation safety, only one screw (5 %) perforated pedicle's wall with grade 1, 19 screws (95 %) were completely surrounded by bone tissue. In group A, three screws (15%) were placed with grade 1, two screws (10 %) with grade 2, and one screw (5 %) with grade 3. In group B, two screws (10 %) were placed with grade 1, and one screw (5 %) – with grade 2.The average deviation at the screw entry point was 5.0 ± 0.5 mm in group A, 1.7 ± 0.3 mm in group B, and 0.35 ± 0.05 mm in group C. The average deviation at the end point was 5.1 ± 0.7 mm in group A, 3.5 ± 0.6 mm in group B, and 0.53 ± 0.05 mm in group C. Differences between groups in terms of implantation safety and accuracy are statistically significant ($p < 0.05$).
**Conclusion.** Bilateral three-point navigation templates supported by spinous process are recommended for pedicle screw placement in the cervical and thoracic spine.
**Key Words:** navigation templates, spinal navigation, 3D printing, pedicle screwplacement
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Patient-specific navigation templates created by 3D printing are a novel method of spinal navigation that makes it possible to place screw-fixing systems in the spine with high degree of accuracy and safety. At the same time, some conditions should be observed in order to achieve the projected implantation results: the template placement in the very precise position, prevention of its displacement and deformation, when the screw trajectory is being formed [1–9]. The observation of these conditions is supposed to impact peculiar features of the template design (the choice of a contact zone, framework geometry, etc.).

The majority of publications considering this problem describe only the results achieved using a certain type of templates, without comparing their variants. Moreover, some important aspects of template designing are described insufficiently, that could complicate the method implementation in new medical institutions.

The objective of the study was to perform a comparative analysis of safety and accuracy of pedicle screw placement in the cervical and thoracic vertebrae using patient-specific 3D-printed navigation templates of different designs.

## Material and Methods

Three formalin-fixed cadaveric specimens of the cervical and thoracic spine were used in the study. The C2–T4 vertebrae were selected for implantation. Navigation templates were designed on the basis of the MSCT DICOM data acquired with a slice thickness of 1 mm. The files were preliminary processed, and the STL models were created using the Inobitec DICOM Viewer (version 1.9.0) software. The models were finally processed, and the implantation trajectory and contact zone were chosen, and auxiliary structures and tubular guides were created using the Blender 2.78 and Autodesk Netfabb Premium 2017 software. The Gcode printing files were created using the Cura 3.5.1 software.

Printing was performed by laying a molten PLA polymer thread (Infitary M508 printer). The implantation into lateral masses was planned for the C1 vertebrae, and transpedicular trajectory was planned for the rest vertebrae.

The following three types of templates were compared:

– monolateral (Group A) – the template framework has a tubular guide and a base pad resting upon the interarticular zone and vertebral arch on the one side (Fig. 1a);

– bilateral (Group B) – two monolateral guides on the both sides are connected with a linking element (Fig. 1b);

– bilateral templates with additional support by the spinous process (three-point support, Group C) – the basic element of the template is similar to that of the bilateral design, but the template construction has an additional support by the spinous process, and stiffening ribs (Fig. 1c).

Soft tissues of the dorsal structures of the vertebrae were dissected, then the templates were fitted tightly on the vertebral surface, and the screw trajectories were formed with a high-speed drill equipped with a 2-mm drill bit through the tubular guides. When the drill and guides were removed, monoaxial screws with the diameter of 3.5 mm (Fig. 2) were implanted, and the screw placements were assessed by MSCT.

The implantation accuracy and safety were assessed by the method proposed by Kaneyama et al. [10]. The safety was assessed by the following criteria. Grade 0: the screw was completely within the bone structures; Grade 1: the screw partially perforated the wall of the bone structure, but more than 50 % of the screw diameter remained within the bone; Grade 2: the screw perforated the bone structures and more than 50 % of the screw diameter was outside the bone; Grade 3 (penetration): the screw perforated completely outside the bone structure. The accuracy was assessed by the deviation (mm) of the actual trajectory from the planned trajectory of the screw at the vertebral entry point and at the intersection of the screw axis with the anterior cortical layer of the vertebral body (end point) by means of overlaying axial and sagittal MSCT slices with the use of the Mimics Research 20.0 software (Fig. 3).

The results were characterized by normality of distribution, and several parametric and nonparametric samplings were statistically analyzed using Kruskall–Wallis and Chi square tests, respectively, with the Statistica 10 software.

## Results

None of the templates ensured the necessary contact with the posterior C1 vertebral semi-ring because of a small contact surface, that is why this level was excluded from the analysis. Consequently, 20 screws (C2–T4) were inserted per each group. Group C demonstrated the highest degree of implantation safety, only one screw (5 %) perforated the pedicle wall with Grade 1, 19 screws (95 %) were completely surrounded by bone tissues. Groups A and B demonstrated Grades 2 and 3, the worst results was observed in Group A (Table 1). Differences between the Groups in terms of implantation safety and accuracy were statistically significant ($p < 0.05$).

The analysis of the deviation of the screw actual trajectories from the planned ones showed a similar tendency. Group A showed the greatest deviations at the entry and end points. When a linking element was added (bilateral template, Group B), a significant decrease in the deviation was observed at the entry point in two planes, and at the end point in the axial plane; it could be explained by the mobility retention of the template of this design in the sagittal plane. The addition of the third support point by the spinous process increased the fixation stability and ensured the minimum deviation in the compared Groups (Table 2). The comparative analysis performed both for all the samplings simultaneously and by pairs demonstrated statistically significant differences ($p < 0.05$).

## Discussion

According to the literature data, a Team from the Laboratory of Biomechanics and Engineering Design of the Catholic University of Leuven (Belgium) was the first to report on the use of navigation templates in spine surgery. During the cadaveric study, screws were successfully inserted in the L2, L3, and L4 vertebrae [11]. Since that time, researchers from different countries carried out dozens

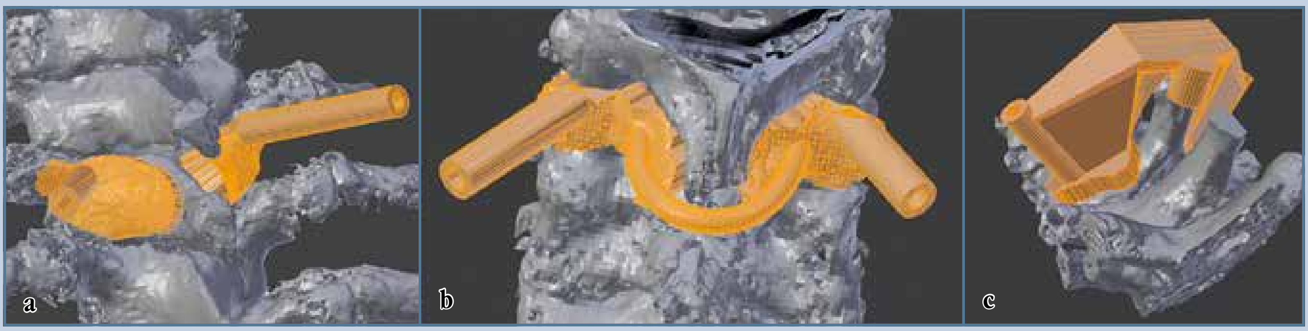


**Fig. 1**
Different types of navigation templates at the design stage (described in the text)

of studies to demonstrate a high degree of accuracy and safety of screw implantations in all regions of the spine with the use of patient-specific templates. At the same time, the introduction of novel technologies and materials for 3D printing, software for modeling, as well as gathered experience of the method implementation necessitated a search for optimal parameters of template creation to ensure best results of screw implantations.

In 2005, there were presented results of the cadaveric experiment with the insertion of 14 screws in the lumbar spine, four screws in the cervical spine, and 32 screws in the thoracic spine. In the lumbar spine, the template design proposed by van Brussel et al. [11] was used, with the support by the spinous and transverse processes. In the thoracic and cervical spine, a modified template design with additional support points was used. A total four different types of templates were used, three of them were designed for one vertebra, and the forth group contained multilevel templates. In all cases, the templates were fixed on a vertebra by means of contacts in several points, rather then by the inverse contact between the template and vertebra. The results demonstrated 44 % of the pedicle perforation, when multilevel templates were used, and 43 %, when any variant of a single-level template was used.

Kaneyama et al. [10] reported on 48 screws implanted in C2 with the mean deviation of 0.36 ± 0.62 mm in the axial, and 0.30 ± 0.24 mm in the sagittal planes. The safety of two screws implanted was ranked as Grades 2 and 3. No complications were reported. In 2015, the same team of researchers [13] published the results of 80 pedicle screws fixed in C3–C6 with the mean deviation from the planned trajectory of 0.29 ± 0.31 mm (0.0–1.6 mm); 78 screws were completely inside the bone (Safety Grade 0), 2 screws penetrated the bone structure by less than half of the diameter (Grade 1). The authors used three types of templates for each screw placement: for entry point marking, screw holes drilling, and screw insertion.

**Fig. 2**
The drill bit is being inserted through the tubular guides

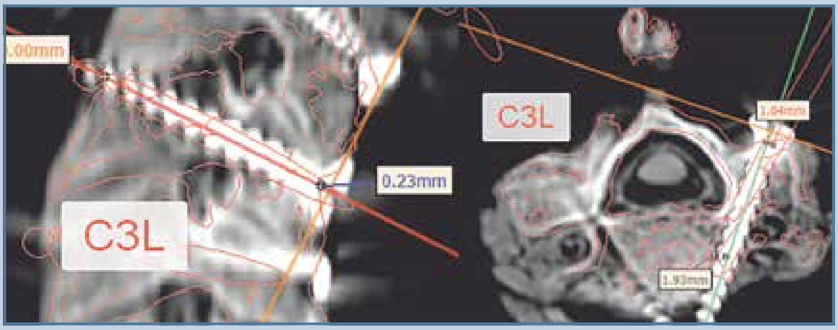


**Fig. 3**
Determining the deviation between the planned and actual trajectories

**Table 1**
Distribution of screws in terms of implantation safety, n (%)

| Safety grade | Types of templates | | |
|---|---|---|---|
| | monolateral (A) | bilateral (B) | three-point (C) |
| 0 | 14 (70) | 17 (85) | 19 (95) |
| 1 | 3 (15) | 2 (10) | 1 (5) |
| 2 | 2 (10) | 1 (5) | – |
| 3 | 1 (5) | – | – |

The greatest number of screws implanted during the cadaveric experiment was reported by Ma et al. [14]. They randomly divided 20 thoracic cadaveric specimens into two groups of 10. In Navigation Template Group, bilateral templates were used, and they were supported partially at the vertebral arches, intervertebral joints, and the spinous process. In Free-Hand Group, 156 screws (65 %) were completely surrounded by the bone. A total number of bone perforations was 84, including 58 (24.2 %), 16 (6.6 %), and 10 (4.2 %) cases classified as Grade 1 (4 mm of the screw diameter), respectively. When navigation templates were used, only 16 screws (6.6 %) perforated the bone wall with Grade 1.

Table 2

Deviations between the planned and actual trajectories, mm

| Types of templates | Entry point | | | End point | | |
|---|---|---|---|---|---|---|
| | axial | sagittal | среднее | axial | sagittal | среднее |
| Monolateral (A) | 5.00 ± 1.00 | 5.00 ± 0.90 | 5.00 ± 0.50 | 5.20 ± 0.80 | 4.80 ± 0.90 | 5.10 ± 0.70 |
| Bilateral (B) | 1.50 ± 0.50 | 1.80 ± 0.40 | 1.70 ± 0.30 | 4.00 ± 1.00 | 3.10 ± 0.70 | 3.50 ± 0.60 |
| Three-point (C) | 0.35 ± 0.10 | 0.35 ± 0.07 | 0.35 ± 0.07 | 0.52 ± 0.10 | 0.54 ± 0.20 | 0.53 ± 0.20 |

Takemoto et al. [15] reported that they used this method in the thoracic spine in 40 patients. The article paid special attention to peculiar features of the template designing, in particular, determining of the optimal localization of support areas. Thus, initially 14 support areas were determined, later seven of them were excluded on the basis of the segmentation reproducibility and stability analyses. The authors reported the optimal range (intensity window) to be 100–350 HU, because the value > 350 HU excluded some bone structures, and the value < 100 HU increased a number of artifacts. The changes in the surface profile of the vertebra in the region of the apex of transverse and spinous processes were revealed within the mentioned range, therefore, the points of this localization were excluded as support areas.

Cecchinato et al. [16] presented the results of their randomized clinical study. Twenty-nine patients undergoing surgical correction for spinal deformity were randomized to Group A (navigation templates) or Group B (free-hand implantation). A total of 540 screws were implanted. Group A consisted of 14 patients, who received 297 pedicle screws, including 224 screws (75.4 %) classified as Grade 0 (the screw was completely surrounded by the bone), 44 screws (14.8 %) classified as Grade A (protrusion of 4 mm). As a result, 268 screws (90.2 %) were implanted in the safe area of the pedicle and 29 screws (9.8 %) were malpositioned. In Group B (free hand), 243 screws were implanted, including 160 screws (65.8 %) with Grade 0, 42 screws (17.3 %) with Grade A, 19 screws (7.8 %) with Grade B, and 22 screws (9.1 %) with Grade C. In total, 202 screws (83.1 %) were in the safe area of the pedicle, and 41 screws (16.9 %) were malpositioned. In the study, a specific template design was used. The template consisted of two broad tubular guides with the support at the spinous process and vertebral arches. The inner diameter of the tubular guide was designed to fit the diameter of the screwdriver equipped with a special stylet with a narrow opening in order to form a channel inside the tubular guide. An interesting approach to the design of the support area should be mentioned: unusual support pillars were created instead of the inverse contact area corresponding to the tubular guide diameter.

Ferrari et al. [17] used a system of support cylinders and noted that hollow cylinder guides should not contact the bone, because a complete tissue dissection at the entry point could be complicated in case of implantation in the lumbar spine. The rest cylinders served as a support framework. Four cylinders (forming pairs) were supported at the articular processes and the vertebral arch root, the fifth cylinder (impair) was fixed on the spinous process. The cylinders were linked together by the outer framework and cross rods. The force vectors of pressure at the template were also taken into consideration; the axes of the cylinders were designed perpendicular to the support area. Surgeons mentioned that it was easy to properly place the template due to the support at the spinous process. The template placement did not require additional soft tissue dissection in comparison with the classical approach, and any false-positive position was easily determined by the absence of contact of all four cylinders with the bone.

Judging by the abovementioned sources, some researchers created the support area, which completely embraced the dorsal structures (in analogy with the inverted image of the vertebra). Another approach to design was aimed to create templates with point support (for example, templates with support cylinders). This method reduces the degree of necessary dissection, but can cause false-positive positioning of the template.

Three types of navigation templates were used in the experiment performed. In all cases, only a part of the dorsal structures was used as a support area. It is important to determine the golden mean, when choosing the support area. On the one side, the contact area must ensure a tight contact in a strongly defined position, on the other side, it is important to minimize the dissection of soft structures during the standard approach.

The support at the spinous process is an important element that simplifies the template placement in the proper position, makes it possible to control the midline, and reduces the possibility of its displacement when the channel is formed. The support point at the spinous process increases the template stability by reducing deviation risks, and stiffening ribs ensure the necessary framework stability, thus preventing the template deformation and breach. According to our opinion, this very design is the optimal one for screw implantation in the cervical and thoracic spine.

The study results demonstrate a high degree of safety and accuracy of the implantation, when navigation tem-

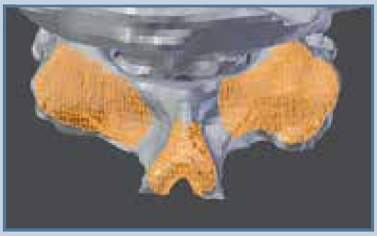

**Fig. 4**
The optimal support area of a patient-specific template in the cervical and thoracic spine (by the example of C2)

plates are used, that in general agrees with the earlier published works [10–17]. It should be mentioned that some studies demonstrate successful use of templates to implant screws in C1 [6]; at the same time we have found insufficient stability of templates at that very level because of a small surface area. The results of the implantation with monolateral templates are inconsistent with some experiments performed earlier [3–4], that can be explained by different reproducibility of technologies.

On the basis of the literature data and the results we have obtained, the following recommendations can be formulated for the navigation templates production:

1) It is necessary to use the interarticular area of the vertebral arch and the apex of the spinous process as a support area (Fig. 4);

2) The support area at the apex of the spinous process should be designed in such a way that the matching of the elements should ensure a lock-and-key fixation (Fig. 5);

3) The linking elements of the framework should be designed in the form of stiffening ribs in order to prevent the template deformation (Fig. 5).

*Limitations.* The study was carried out on a formalin-fixed cadaveric material, so some factors were absent that could impact the implantation results in clinical practice (pressure of paravertebral tissues on the template, density of the cortical layer, bleedings, etc.). Moreover, only three types of templates were compared, although 3D printing technologies make it possible to create a large variety of design variants.

## Conclusion

The use of bilateral navigation templates has demonstrated better results of safety and accuracy of implantation in comparison with monolateral ones. Bilateral three-point navigation templates supported by the spinous process are recommended for pedicle screw placement in the cervical and thoracic spine, because their usage has demonstrated the highest outcomes.

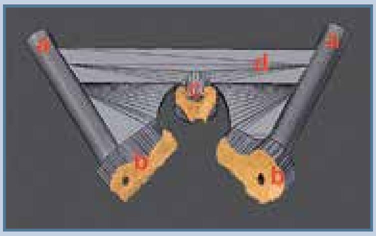


**Fig. 5**
The optimal design of the navigation template: *a* – tubular guides; *b* – support area; *c* – support at the spinous process with a fixing device; *d* – linking elements (stiffening ribs)

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