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# Accuracy Assessment of Pedicle and Lateral Mass Screw Insertion Assisted by Customized 3D-Printed Drill Guides: A Human Cadaver Study


## Abstract

### Background

Accurate cervical screw insertion is of paramount importance considering the risk of damage to adjacent vital structures. Recent research in 3D technology describe the advantage of patient specific drill guides for accurate screw positioning, but consensus about the optimal guide design and the accuracy is lacking.

### Objective

To find the optimal design and to evaluate the accuracy of individualized 3D-printed drill guides for lateral mass and pedicle screw placement in the cervical and upper-thoracic spine.

### Methods

Five Thiel-embalmed human cadavers were used for individualized drill-guide planning of 86 screw trajectories in the cervical and upper-thoracic spine. Using 3D bone models reconstructed from acquired CT scans, the drill guides were produced for both pedicle and lateral mass screw trajectories. During the study, the initial minimalistic design was refined, resulting in the advanced guide design. Screw trajectories were drilled and the realized trajectories were compared to the planned trajectories using 3D deviation analysis.

### Results

The overall entry point and 3D angular accuracy were 0.76±0.52mm and 3.22±2.34°, respectively. Average measurements for the minimalistic guides were 1.20mm for entry points, 5.61° for the 3D angulation, 2.38° for the 2D axial angulation, and 4.80° for the 2D sagittal angulation. For the advanced guides, the respective measurements were 0.66mm, 2.72°, 1.26°, and 2.12°.

**Conclusion**

The study ultimately resulted in an advanced guide design including caudally positioned hooks, crosslink support structure, and metal inlays. The novel advanced drill guide design yields excellent drilling accuracy.

**Keywords**

3D-printing; 3D surgery; Lateral Mass Screw; Pedicle Screw; Template; Drill Guide; Rapid Prototyping;

**Short title**

Drill guides for mass lateral and pedicle screws.

# Introduction

Posterior cervical fixation has become a routine procedure for the treatment of unstable cervical spine due to trauma, congenital malformations, degenerative diseases and tumors. The accurate placement of screws in the cervical region is challenging, given the risk of damage to adjacent vital structures (i.e., arteries, nerve roots, and spinal cord). [1]

Computer-assisted surgery (CAS) has been adopted as a safe and accurate guiding system for the placement of lateral mass and pedicle screws. Current CAS navigation systems rely on optical infrared camera tracking linked to a computed tomography (CT) dataset. The CAS navigation system nevertheless lacks adequate registration of the supine-acquired preoperative CT data to the intraoperative prone-positioned spinal column, due to substantial cervical spinal mobility. [2,3] The use of intraoperative CT is therefore required in order to provide optimal registration of the cervical spine to the navigational instruments, [4] thereby resulting in increased radiation exposure compared to a preoperative acquired dataset.

Although cranial-clamp immobilization maintains the prone position of the spinal column, it does not completely prevent the individual cervical vertebrae from rotational movement during surgical exploration. In particular, the atlas and axis remain relatively mobile, which can cause segmental shift during intraoperative manipulation. Each surgical manipulation after obtaining the intraoperative CT may cause CAS registration errors, which can result in screw malposition. Even with modern O-arm intraoperative CT technology, this cannot be completely ruled out. [5]

In recent years, 3D virtual planning in spine surgery has been gaining increased attention. [6] The use of individualized 3D-printed drill-guiding templates for spinal screw placement has been reported as one of recent innovations. [7–11] The safety of screw placement is reported by measuring the margin from screw to pedicle wall on postoperative CT. Cases of pedicle wall violation are classified by the severity of the pedicle breach. Few studies report advanced deviation analysis by superimposing the surgical preoperative plan over the postoperative result. [12–14] To date, no systematic metric data about the entry point and angular accuracy have been published. During the surgical virtual-planning process, this information can be of essential value when deciding whether the placement of pedicle screws would be safe within specific pedicle dimensions.

In recent years, various guide designs have been presented in the literature, varying in printing material, bone-contact areas, and applicability for vertebrae levels. To date, no consensus seems to exist about the best guide design, probably due to the lack of a universal method for assessing accuracy. This study concerns the development of a new optimal guide design through a series of cadaveric tests. The results are analyzed by reproducible deviation analysis involving the superimposition of outcome over planning.

# Materials and Methods

## Specimens

Five randomly selected full-body Thiel-embalmed human cadavers were obtained from the anatomy department, University Medical Center Groningen.[15] Computed Tomography (CT) scans were performed two weeks before the procedure. CT scans (Siemens AG Somatom Force, Forchheim, Germany) were made with a 0.6mm slice thickness and a Br65h kernel, in accordance with the clinical scanning protocol. Images were stored in uncompressed DICOM format. The postoperative CT was performed immediately after the procedure with identical scan parameters.

## Trajectory planning and guide design

The scope of this study was limited to the cervical spine and the first two thoracic vertebrae. Using Mimics v19 (Materialise, Leuven, Belgium), each individual vertebra was segmented and reconstructed into a 3D model (Figure 1). For precise screw positioning, the screw trajectory feature in iPlan (Brainlab, Munich, Germany) was used, which includes multiplanar CT reconstruction along screw direction. Entry points and target points were defined by an experienced spine surgeon, using both the axial and sagittal planes. The definite position was established by sliding through the probe view. In the cervical region, screws were planned bilaterally for each level. The majority of cervical screws were planned into the lateral mass, except for the C7 vertebra, where the pedicle size and angle allowed for pedicle screw insertion. For the thoracic spine, pedicle screw trajectories were planned, according to the clinical standard.

The screw trajectories and bone-segmented models were exported to stereolithography (STL) files and subsequently imported into 3-matic v11 medical design software (Materialise, Leuven, Belgium), in order to create the final surgical drilling guides. All guides were optimized for the available drill bits. For each guide, bone-contact areas were defined within the multi-disciplinary team of technical physicians and spine surgeons. The contact areas selected were extruded to create the base plates for the guides, using a 0.2mm bone offset to correct for any left-over soft tissue. The first cadaver experiment was intended to explore the functionality of a bare minimal guide design, using a base part with tubes and hooks around the superior edge of the lamina, highly similar to most guide designs presented in the field so

far. (Figure 2A) The guides proved flexible in the first cadaveric test, and the initial design was therefore improved with crosslink support to obtain a more rigid construction. In addition, the hooks were shifted to the inferior edge of the lamina in order to prevent slipping during drilling. The base thickness was also increased, and the tubes were extended. (Figure 2B,C) The C1 guide slightly differs from the other levels, with the tubes floating just below the posterior arch, connected to the base contact area of the guide. All guides were produced in medical certified polyamide using selective laser sintering (SLS) 3D-printing. Metal drill sleeves were manufactured to fit into the templates' tubes, thus protecting the inner surface of the tube, preventing polyamide particles to come off, reinforcing the design, and serving as a guide for the drill bit. Adding these drill sleeves to the design is new, compared to what has already been published in this field.

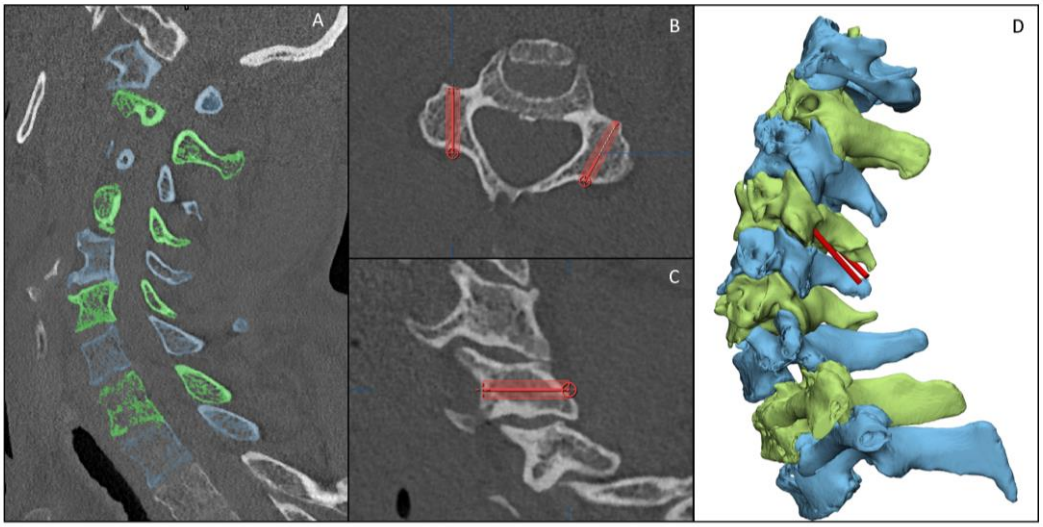


***Figure 1.*** *A, Individual vertebra-level segmentation. B, Example of C4 screw planning, axial and sagittal view. C, 3D reconstructed model of segmentation, including C4 screw-trajectory planning*

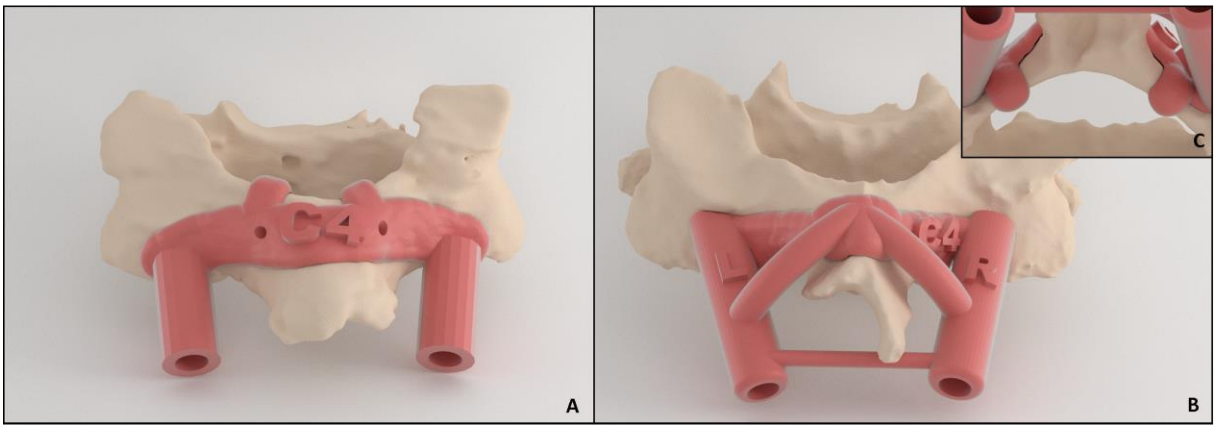


***Figure 2.*** *A, Minimalistic drill guides design of first cadaveric series, base thickness 1.2mm and 15mm tubes. B, Advanced drill guides design with crosslink support structure, base thickness 1.8mm and 20mm tubes, and C, caudally positioned hooks*

**Surgical approach**

The simulated surgical procedures were performed by senior surgeons, in accordance with standard protocol and using standard neurosurgical equipment, in the skills laboratory of the University Medical Center Groningen (Figure 3). It was deliberately chosen not to use radiography during the procedure, as this may introduce bias when measuring the accuracy of guides as a solitary navigational tool. Specimens were positioned in prone position using a Mayfield 3-point cranial-clamp system. A posterior midline incision was created to approach the cervical and upper thoracic spine, as in the routine procedure, with exposure of the posterior aspects of the cervical and upper thoracic vertebrae. Meticulous removal of the soft tissues from the spinous processes, laminae, and lateral mass was performed, in order to ensure tight bone contact for the guides. After the optimal fit was achieved the guides were hold in place manually, allowing both for control of the guide position, and to prevent leverage of the drill within the tubes. Given that metal screws might cause image artifact during post-procedural CT scanning, custom-manufactured cylindrical radiopaque markers that precisely fit the drilled trajectories were inserted. The high radio intensity enables threshold segmentation for separating the markers from the bony cortex (Figure 4).

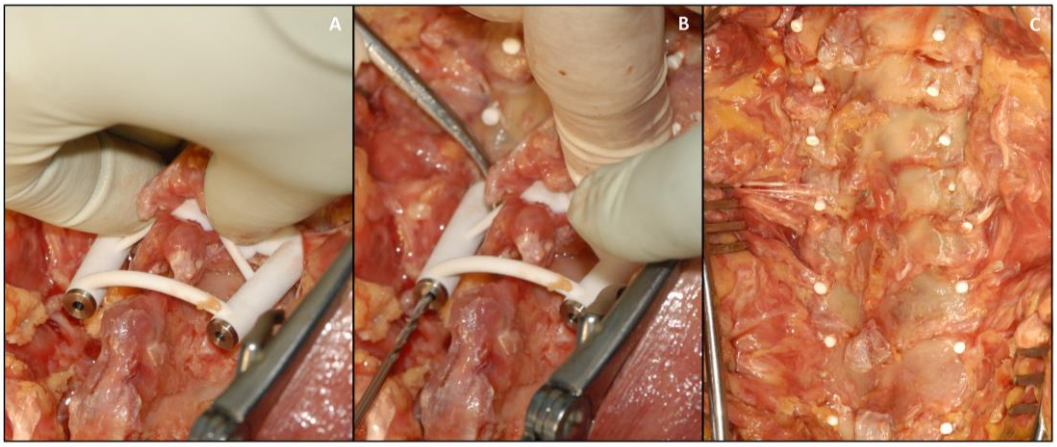


***Figure 3.*** *A, Positioning of the drill guide on the 4$^{th}$ cervical vertebra. B, Drilling the left trajectory through the guide. C, Markers inserted in the drilled trajectories (image orientation: cranial structures shown in the upper part of the images)*

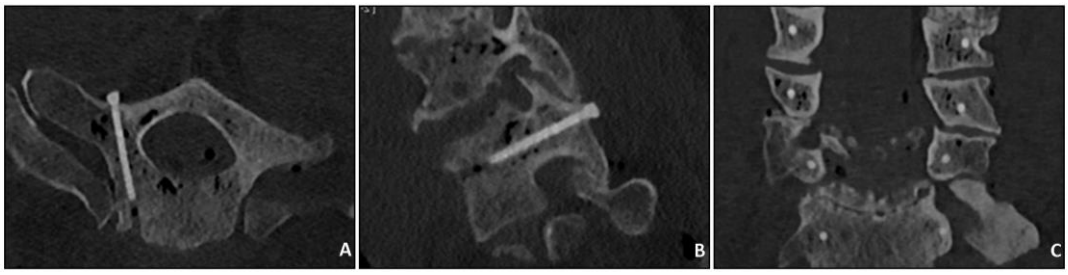


***Figure 4.*** *Results of the postoperative CT scan in A, Axial, B, Sagittal, and C, Coronal view.*

**Deviation analysis**

By performing a 3D deviation analysis the realized screw trajectories were evaluated (Figure 5). Using the post-procedural CT, the individual vertebrae and markers were segmented and reconstructed into 3D models. The postoperative vertebrae were roughly repositioned over the preoperative 3D plan using global point matching of several anatomical landmarks. Further precision alignment was achieved by the iterative closest point registration function. The registration process was performed for each individual vertebra, given the possibility of vertebra levels shifting between pre-procedural and post-procedural scans. To perform the accuracy measurements, the software auto-generated virtual fitted cylinders around the markers. This allowed the central axis of the planned cylindrical trajectories and the fit

cylinders to be obtained without any manual user interference so as not to introduce inter-observer and intra-observer errors.

The 3D angle between the two axes was measured in order to determine the angular deviation of the surgical outcome from the planned screw trajectory. In addition, 2D angle deviation measurements were performed, given that, in clinical practice, lateral or medial pedicle wall breaches are more likely to cause vital injuries. It was necessary to create projection planes for these sagittal and axial angle deviation measurements. Since a plane in the 3D coordinate space can be determined from 3 individual points, the choice was made to define the axial plane by the entry and target point of the planned trajectory, and additionally, the contra-lateral entry point. The sagittal plane is defined in screw direction, perpendicular to the axial plane. The entry point deviation is measured from the planned entry point to the realized trajectory, perpendicular to the planned trajectory.

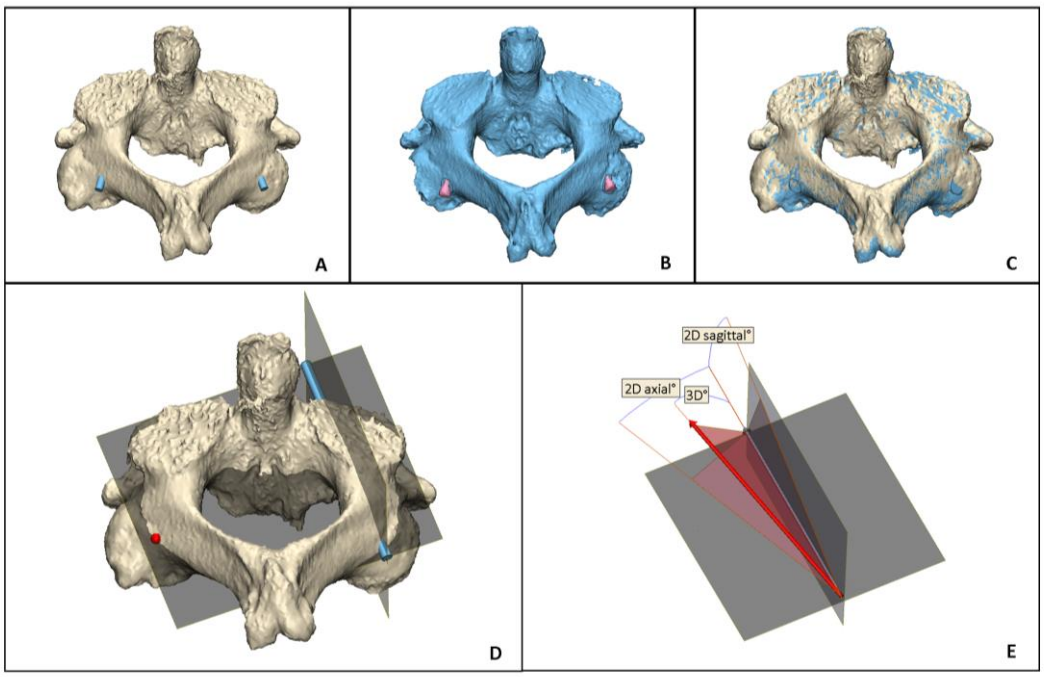


***Figure 5.*** *A, PreOp segmented model, including the planned trajectories. B, PostOp segmented model with realized trajectories. C, Per-level Iterative Closest Point registration of the PreOp and PostOp models. D, Axial planes defined by entry point, target point and the contralateral entry point. The sagittal planes are defined in screw direction, perpendicular to the axial plane. E, Visualization of angular measurements between planned (blue arrow) and realized (red arrow) trajectories.*

## Statistics

Students' t-tests were used to compare results of the minimalistic design and the advanced guide design, assuming $P<.05$ as the level of statistical significance. All statistical analysis was performed in SPSS version 23.0 software (IBM Corp., Armonk, USA).

# Results

In all, 86 drill trajectories over 5 human cadavers were analyzed. The deviation analysis results for each specimen and the overall trajectory accuracy are listed in Table 1. The entry point and 3D angular accuracy over all specimens were 0.76±0.52mm and 3.22±2.34°, respectively. With regard to 2D angular accuracy, deviation was significantly higher in the sagittal plane, as compared to the axial plane (2.59±2.31° vs 1.45±1.31°, $P<0.01$). In Table 2, the mean measurements are compared between different groups. Average measurements for the minimalistic guides were 1.20mm for entry points, 5.61° for the 3D angulation, 2.38° for the 2D axial angulation, and 4.80° for the 2D sagittal angulation. For the advanced guides, all of these measurements were significantly lower ($P<0.01$), at 0.66mm, 2.72°, 1.26°, and 2.12°, respectively. The comparison between accuracy of pedicle and lateral mass guides revealed no significant differences in entry point or 3D angular deviation. However, when comparing the angular deviation in the axial plane (2D), pedicle guides appeared to be more accurate ($P=0.04$).

# Discussion

Our findings suggest that it is feasible to use individualized 3D-printed drill guides for drilling screw trajectories in the cervical and thoracic spine. The promising advanced guide design consists of polyamide with metal inlays, caudally positioned hooks, and a crosslink support structure. The analysis revealed a low mean entry-point deviation of 0.76mm from the preoperative plan. The results of the quantitative deviation analysis provide valuable information concerning the accuracy of this navigation method, which can be used for future screw planning. To our knowledge, the accuracy data presented here are novel.

The use of navigational drill guides for the human vertebrae was first described by Van Brussel et al. in 1996. [16] Improvements in imaging and rapid prototyping techniques have since given rise to more comprehensive drill-guide studies in both cadaveric and clinical settings. [7–12,17,18] To date, however, no consensus has been reached about the safest and most accurate guide design. Some studies report very high levels of accuracy verified by post-operative CT evaluation, suggesting an almost perfect match with the planned trajectories. [7,9] The analysis was performed by measuring the screw position with respect to the pedicle wall or mid-pedicle. It is nevertheless possible for screw positions to deviate from the plan but still be classified as accurate, if no violation of the pedicle wall is observed. The objective comparison of the mutual results call for quantitative deviation analysis by superimposing the postoperative result over the preoperative plan. Three studies have been based on 3D deviation analysis, using point registration of several anatomical landmarks. [12–14] In these studies, however, the analysis is limited for atlantoaxial or thoracic pedicle screw placement, such that the applicability for remainder vertebrae levels is not yet known. Jiang et al. describe guides that lack drill-guiding tubes, using only entry-point holes. [13] Probing the inner cortical wall is however not always successful, especially in most challenging cases with severe osteoporosis, the direction-guiding tubes can be highly beneficial. Tubes can also be used as drill-stop by tailoring the length needed. This even may in future allow for screw-placement without the use of any radiography in the OR. Instead of removing the tubes we therefore chose to further optimize the guide. In the subsequent deviation analysis, we measured the direct entry and angular errors between the planned and realized trajectories.

The significant improvement in entry point between the minimal and advanced designs proves that the additional features make drilling more accurate (1.22 vs 0.66mm, $P<0.01$). We developed a new guide design with novel features that prevent the guide from bending and

slipping. Although the caudally positioned hooks aim to prevent slipping of the guides, surgeons should always ensure tight contact between bone and guide. Trajectories deviate less in the axial plane than they do in the sagittal plane (1.45° vs 2.59°, P<0.01). This is probably due to the crosslink support structure, which mainly inhibits bending of the guide in the axial plane. It may improve safety, given that lateral or medial pedicle wall breaches are more likely to cause serious vascular damage or spinal-cord injuries. While the crosslink support structure tends to increase the stiffness of the guides, it remains important to prevent leveraging of the drill in the tubes, due to the flexibility of polyamide. Takemoto et al. was the first to describe the use of titanium-sintered drill guides with good results.[19] The titanium is stiffer and will cost five times more than polyamide, however, the improvement in accuracy remains unclear. We therefore chose to stabilize the low-cost polyamide guides with metal inlays. Our 3D-printed guides for the cervical and thoracic spine (C1–T2) costs 200 US$ per case. It should however be noted that this does not include the personnel costs of a technical physician, which currently requires a half-day work in case of long-segment spondylodesis.

Despite the excellent drilling accuracy that was ultimately achieved, the extensive steps of development also have contributed to the final results. Clinicians should therefore be aware that similar accuracy cannot be assumed from the outset. Our multi-disciplinary team of technical physicians and spine surgeons passed through the inevitable learning curve by completing the cadaveric series before introducing the technique into clinical practice. Another current limitation is the potential presence of osteoporotic bone, osteophyte, or a previously performed laminectomy, which can pose challenges for guide design. The use of current guide-design is restricted to cases in which the lamina is still present. Patient specific modeling however enables us to treat the most severe cases. Otsuki et al. described a design that uses several small contact points connected by cylindrical primitives to deal with iatrogenic bone damage during revision surgery.[20] For our guide design, additional contact areas should be introduced to achieve a good fit after laminectomy (e.g., lateral mass border, osteotomy surfaces, transverse processes). Another challenge for the clinical adoption of drill-guides is the lead time for spine fixation procedures. Currently the technique will only be suitable for elective-cases due to the external production, shipment and sterilization process, requiring at least one week. We do however expect this production time can in future be greatly reduced, when in-house 3D-printing facilities come available.

## Conclusion

The cadaveric series ultimately resulted in an advanced guide design including caudally positioned hooks, crosslink support structure, and metal inlays. Surgical application of the design resulted in excellent drilling accuracy. The results of this study are in the range of accuracy we deem suitable for the next step in research, involving the assessment of guides in a patient pilot for cervical and thoracic spine procedures. Future studies should attempt to provide a mutual comparison with CAS, including accuracy, safety, costs, operation time, complications, and radiation exposure.

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