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DEFORMITY

A Comparison of Drill Guiding and Screw Guiding 3D-Printing Techniques for Intra- and Extrapedicular Screw Insertion

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Study Design. Screw randomized cadaveric study.
Objective. To compare the accuracy of three-dimensional (3D)-printed drill guides *versus* additional screw guiding techniques for challenging intra- and extrapedicular screw trajectories.
Summary of Background Data. Pedicle screw placement can be technically demanding, especially in syndromic scoliosis with limited bone stock. Recently, 3D-printing and virtual planning technology have become available as new tools to improve pedicle screw insertion. Differences in techniques exist, while some focus on guiding the drill, others also actively guide subsequent screws insertion. The accuracy of various 3D-printing-assisted techniques has been studied; however, direct comparative studies have yet to determine whether there is a benefit of additional screw guidance.
Methods. Two cadaveric experiments were conducted to compare drill guides with two techniques that introduce additional screw guiding. The screw guiding consisted of either k-wire cannulated screws or modular guides, which were designed to guide the screw in addition to the drill bit. Screws were inserted intra- or extrapedicular using one of each methods according to a randomization scheme. Postoperative computed tomography scanning was performed and fused with the preoperative planning for detailed 3D screw deviation analysis.
Results. For *intrapedicular* screw trajectories malpositioning was low (2%) and the modular guides revealed a statistically significant increase of accuracy ($P = 0.05$) compared with drill guides. All techniques showed accurate cervical screw insertion without breach. For the *extrapedicular* screw trajectories both additional screw guiding methods did not significantly ($P = 0.09$) improve accuracy and malpositioning rates remained high (24%).
Conclusions. In this cadaveric study it was found that the additional screw-guiding techniques are not superior to the regular 3D-printed drill guides for the technically demanding *extrapedicular* screw technique. For *intrapedicular* screw insertion, modular guides can improve insertion; however, at cervical levels regular 3D-printed drill guides already demonstrated very high accuracy and therefore there is no benefit from additional screw guiding techniques.
Key words: 3D virtual surgical planning (VSP), 3D-printing, dysplastic pedicle, extrapedicular screws, guides, pedicle screw, templates.
Level of Evidence. 3
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Since the introduction of the transpedicular screw technique, it has gradually become accepted as the gold standard for correction and fusion in spinal deformity surgery. Pedicle screw insertion remains, however, a technically demanding procedure and is considered risky because of the proximity of vital structures such as the spinal cord, the vertebral arteries or aorta, and the nerve roots.[1] There are numerous studies reporting high rates of screw malpositioning by freehand screw insertion, some peaking up to 30%.[2–5] Pedicle screw placement can be especially challenging in syndromic scoliosis such as neurofibromatosis typel or in revision cases in which there is limited bone stock. Pedicles can be dysplastic or even absent, sometimes requiring alternative extrapedicular screw trajectories.

Computer navigation techniques based on intraoperatively acquired computed tomography (CT) images were developed to minimize pedicle screw malpositioning.[6,7]

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More recently, three-dimensional (3D)-printing and virtual planning technology have become available as new tools to improve transpedicular spine fixation. Patient-specific 3D-printed drill guides, also referred to as drill templates, were introduced to facilitate pedicle screw insertion. In contrast to computer navigation, guides are independent of vertebral motion, eliminate the repetitive look-away to check imaging screens, are not affected by the surgeon's hand motion, and do not require intraoperative fluoroscopy. Several authors reported the advantage of patientspecific guides for accurate pedicle screw positioning in spinal deformity surgery.[8–11] Optimized designs have been proposed for guided unilateral approaches,[12] for multilevel application,[13] and for use in revision surgery.[14] Most described techniques focus on guiding the drill or pedicle probe; the subsequent screw insertion is often being done free-hand.

The pedicle cortex integrity can intraoperatively be monitored using pedicle wall sounders, electrical stimulation techniques, or radiographic imaging.[15–18] However, a correct position of a pilot hole does not guarantee that a screw will follow the intended trajectory during insertion. In fact, our 3D accuracy studies into patient-specific guides revealed a mean screw deviation of 1.40 mm and 6.7° for the entry point and angular deviation, while drilling of the pilot hole itself has shown lower deviations of respectively 0.76 mm and 3.2.[19,20] These results indicate potential improvement, just by improved alignment of screws with 3D-guided pilot holes. To achieve improved alignment, some authors advocated to also guide the actual screw after drill bit guidance, by using an additional guide or a removable inlay in a modular designed guide.[21] Another potential solution to reduce misrouting of screws with respect to the pilot hole might be the use of cannulated screws, while the K-wires hypothetically force the screw to follow the pilot hole.[22]

The accuracy of various 3D-printing navigation techniques has been studied; however, differences have not been well defined due to the lack of adequate comparative data. To the best of our knowledge, no study has been conducted to directly compare the two suggested screw-guiding methods with regular 3D-printed drill guides, which at present is the most commonly used method for 3D-printing-assisted pedicle screw insertion. Therefore, the purpose of this study was to evaluate whether a different guide design (modular guides) or the additional use of cannulated screws can enhance the accuracy of the screw insertion with the aid of 3D-printed drill guides. Emphasis was placed on alternative extrapedicular screw trajectories for dysplastic or absent pedicles because these cases could potentially benefit the most from improved precision.

MATERIALS AND METHODS

Specimen

Two full-body Thiel-embalmed human cadavers (female age 91 and male age 83) were used for this study. The entire spine was imaged prior to the experiment, using a SOMATOM Force CT scanner (Siemens, Forchheim, Germany). Images were acquired with 0.6 mm slice thickness and reconstructed using a bone imaging (i70 h) kernel, in accordance with the clinical scanning protocol.

Study Design

The study was divided into two subexperiments evaluating three groups, namely, 1) regular drill guides (control group), compared with the two experimental groups, 2) drill guides combined with cannulated screws, and 3) modular guides. In groups 1 and 3 regular solid core pedicle screws were used. The first specimen was subject to a randomized controlled experiment, by comparing group 1 (regular drill guides) with group 2 (drill guides combined with cannulated screws). The second specimen was used to compare the accuracy of regular drill guides (group 1) *versus* modular guides (group 3). The experiments are schematized in Figure 1. Screw randomization was performed using a randomization generator that uses balanced permutations. The generator creates balanced permutations of treatments for situations in which each vertebrae (left/right pedicle) is to receive both the experimental as well as the control treatment at random. This resulted in an equal distribution of spinal segments in the groups. Blocks were used to obtain an even distribution (experimental/control) per spinal region.

Virtual Surgical Planning

CT image data of the specimen was loaded into Mimics v22 (Materialise, Leuven, Belgium) to perform bone segmentation using an appropriate Hounsfield Unit threshold. The 3D volumetric image masks were converted into 3D surface models and exported to 3-matic v14 (Materialise, Leuven, Belgium). The pedicle screw trajectories were pre-planned in close collaboration with the surgeons (J.M.K., C.F.). The 3D plans included full-length spine instrumentation of cervical (C3–C7), thoracic, and lumbar pedicle trajectories. Where possible, thoracic screws were planned extrapedicular, simulating salvage procedures for dysplastic or absent pedicles.

Guide Design

The regular drill guides were produced according to the design blueprints as previously reported by the authors.[19,20] This design was developed for use in the cervical and thoracic spine, and requires removal of the interspinous ligament. For the lumbar region a modified lumbar ligament sparing guide design was developed. To avoid direct contact between drill bit and print material, a metal inlay was used. Figure 2 displays an example of a cervical, thoracic, and lumbar guide design.

The modular guides were designed in a way that both drilling and screwing was integrated into one device. Therefore, the regular guide design was modified in several ways. First, cylinders that fit around the pedicle screws (Polaris deformity system, Zimmer Biomet Spine Inc, CO) were positioned bilaterally. Subsequently, to insert the same metal inlay into the larger cylinders, a 3D-printed removable

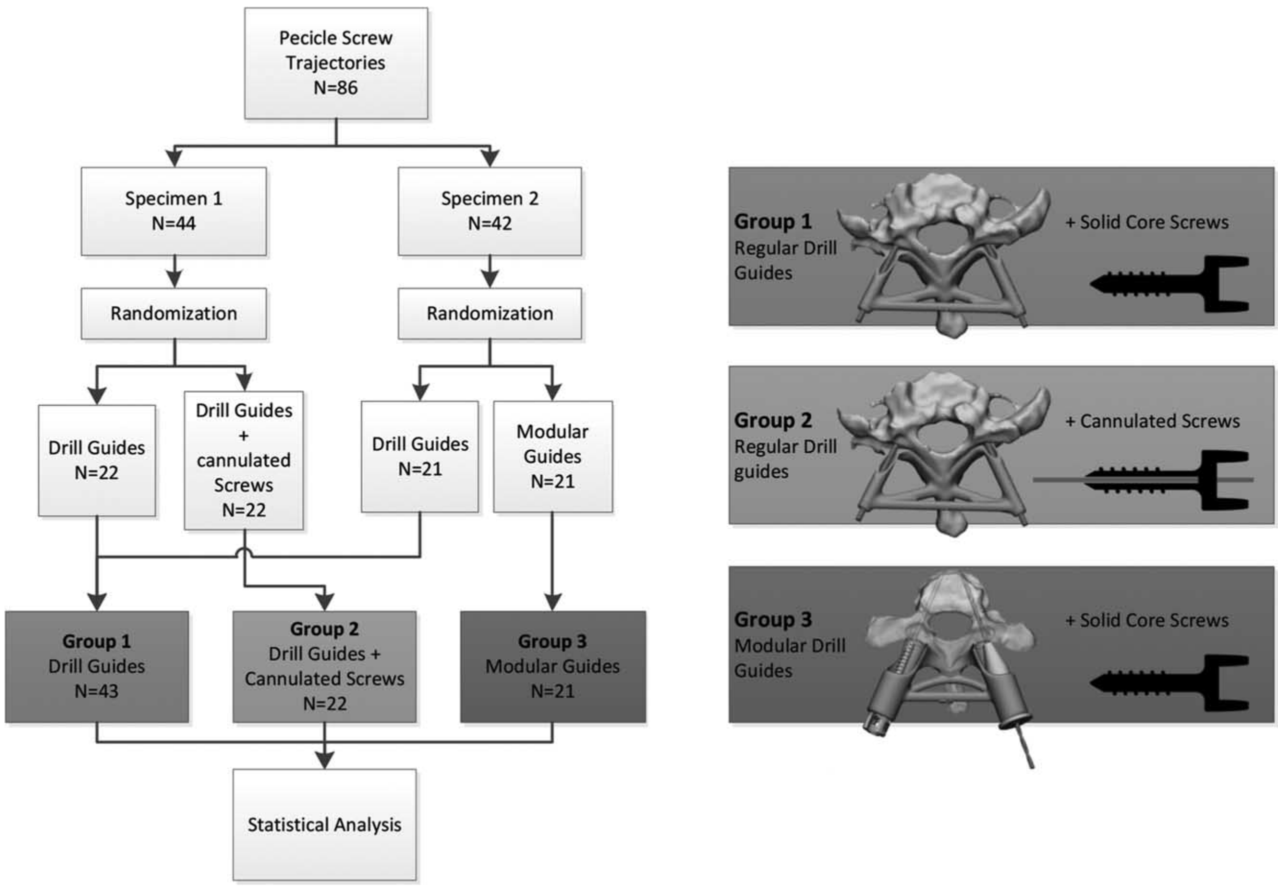

Figure 1. Flowchart of the study design. Regular solid core screws were used in group 1 and group 3, cannulated screws were inserted in group 2.

spacer with a tapered distal tip was made. Lastly, an opening was created near the bone entry points to facilitate movement of the polyaxial screw head and subsequent release of the guide (Figure 3A and B).

Study Procedures

During the experiments, the specimen was placed in the prone position with the head in a Mayfield Cranial Clamp. The spine was exposed as in surgical routine, through a

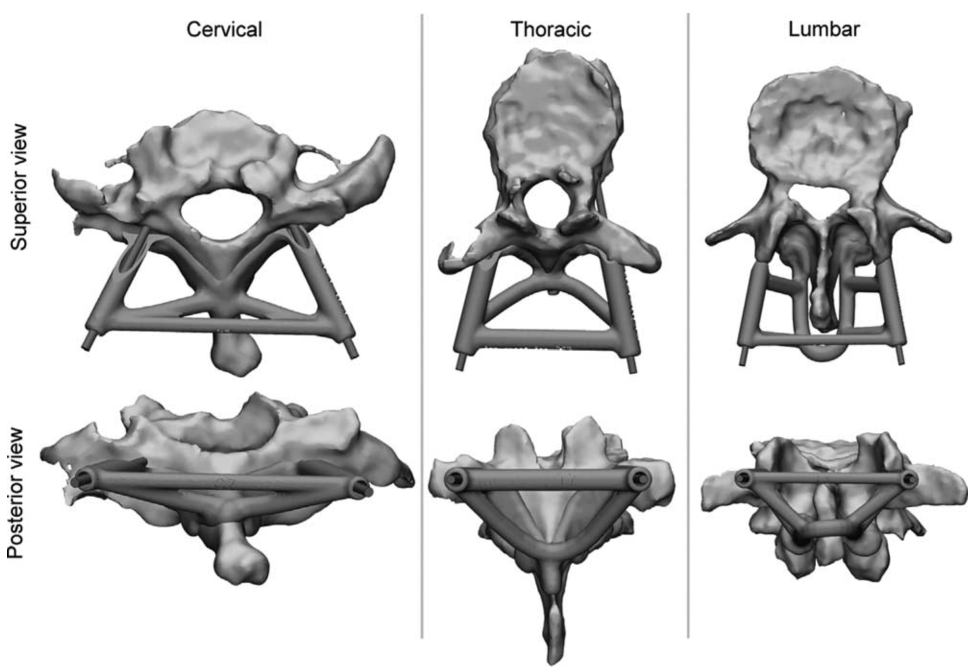

Figure 2. Individualized drilling guides, visualized in blue, for the cervical, extrapedicular thoracic, and lumbar spine. The lumbar spine guide bridges over the spinous process so that the interspinous ligament can be preserved. Visualized in superior view (upper row) and in posterior view (lower row).

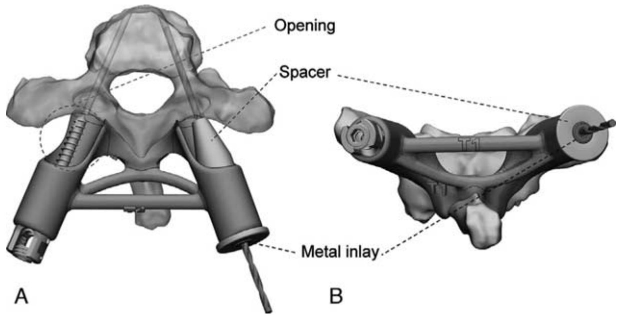

Figure 3. Modular guide design (for drill bit as well as screws), visualized in superior view (A) and posterior view (B). The cylinders' diameter was designed to match with the screw head size. The base of the guide was kept open so that the screw heads can move freely after screw insertion and the guide can be removed.

posterior midline approach. Soft tissue was stripped from the vertebrae's posterior aspects. To ensure a tight fit of the guides, meticulous care was taken to dispose the laminae and spinous processes from soft tissue. The guides were then positioned level by level, and held in place manually. After inserting the metal inlay, drilling was performed using a Ø 2.2 mm drill bit and tapped afterward. Screw type (core or cannulated) was selected according to the randomization. Screws allocated to the drill guide group (group 1) where inserted "unguided" into the pilot hole, after the removal of the guide. For the cannulated screw group (group 2), screws were advanced across a Ø 1.6 mm guide-wire after the removal of the 3D guide (Figure 4 A and B). The guide-wire was secured by hand and just before completion, the wire was retracted to prevent anterior migration and penetration. For screws in the modular guide group (group 3), the spacer was removed after drilling, clearing the path for the screw to be inserted through the guide (Figure 5 A and B). In line with common clinical practice, the screw diameter increased depending on the spinal segment involved: 4 mm for cervical, 4.5 to 5.5 mm for thoracic, and 5.5 and 6.5 mm for lumbar spine. Post procedural CTs were performed after the experiments, including iterative metal artifact reduction postprocessing.

Outcome Measurements

The postprocedural CT was used for evaluating the 3D screw deviation as primary outcome, which is a quantitative measurement for accuracy with respect to the virtual surgical plan.[19] Separate models for the individual vertebrae and pedicle screws were reconstructed, so that subsequent registrations were unaffected by vertebral realignment after surgery. After coarse digital alignment, the postoperative vertebrae models were registered level by level to the

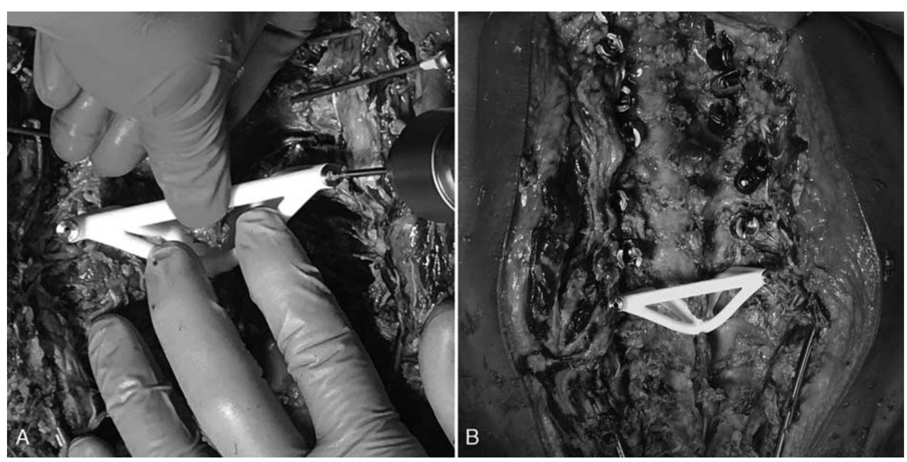

Figure 4. Intraoperative, posterior view during the first experiment showing (A) drilling of the pilot hole trajectories by the use of the regular drill guides, (B) inserted screws, k-wire assisted cannulated screws (group 2), and regular solid core screws (group 1) according to the randomization.

Figure 5. Superior view photographs taken during the second experiment involving the modular guide. A, For all screws, pilot holes were drilled using drill guides. B, Screws allocated to the modular guide group were inserted through the guide, after the drill inlay was removed (group 3). The remaining screws were inserted without guide assistance (group 1).

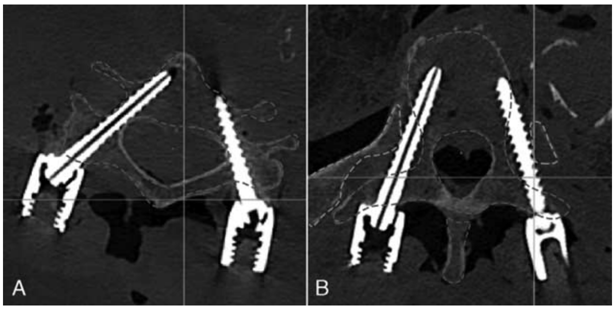

Figure 6. Example slices of the postprocedural CT in experiment 1, showing (A) a pair of cervical pedicle screws, cannulated and solid core, and (B) a pair of thoracic extrapedicular screws, cannulated and solid core. For enhanced visualization the vertebra is outlined in red and rib is outlined in green.

preoperative models using surface-based registration. As secondary outcome, all screws were also assessed using the "in" or "out" classification system.[23] For the extrapedicular trajectories the screw tip had to be located inside the vertebral body to be classified as "in."

Statistics

Statistical analysis was performed using SPSS version 23.0 (IBM Corp, Armonk, NY) and a *P* value of less than 0.05 was considered to be statistically significant. The distribution of continuous accuracy data was described using mean and standard deviation. The data demonstrated a non-normal right-skewed distribution and therefore, a square-root transformation was performed to meet model assumptions for analyses. The difference in screw placement accuracy between the techniques was analyzed using one-way analysis of variance, after testing for homogeneity. Tukey comparison test was used for *post hoc* analysis. Box plots were used for visualizing the distribution of accuracy data in the spinal subregions. Inferential statistics were not performed between the subregions due to the small sample sizes in these subgroups.

RESULTS

3D Deviation Analysis

In all, 86 screw trajectories were subject to the 3D deviation analysis based on the postoperative CT images (Figure 6 A and B). The accuracy of the control group (group 1, regular drill guides) was in the same range for both experiments. The accuracy with respect to the virtual plan is listed in Table 1. For the extrapedicular screw trajectories the results were similar for both screw guiding methods. The best angular accuracy for these in-out-in screw trajectories was achieved with the cannulated screw-method (group 2), but the difference with regular drill guides (group 1) was not statistically significant ($P = 0.09$). For intrapedicular screw trajectories, the modular guides (group 3) revealed a statistically significant increase of accuracy ($P = 0.05$) in comparison with regular drill guides. Figure 7 provides a detailed overview of intra-pedicular screw accuracy, clustered per spinal region. The graph shows that the use of cannulated screws (group 2) or modular guides (group 3) in the cervical region does not add up to the high levels of accuracy that are already reached with regular drill guides (group 1).

Secondary Outcome Measurements

Intrapedicular Screws

Based on the in-out classification, 98% (43 of 44 screws) of intrapedicular screws was positioned successful. All 20 cervical pedicle screws were inside the pedicle without signs of cortical breach and with fully intact vertebral foramen. The six thoracic screws that were planned intrapedicular were all in correct position. For the lumbar region, 17 of 18 screws were situated inside the pedicle, 1 screw was malpositioned and located laterally of the pedicle.

Extrapedicular Screws

For the extrapedicular screws in the thoracic spine, 10 of a total of 42 screws (24%) were malpositioned, with the

TABLE 1. Accuracy of the Control Group 1 (Regular Drill Guides) Compared With the Two Experimental Groups 2 and 3 (Cannulated Screws and Modular Guides)

	N	Entry Point Deviation (mm)			Angular Deviation (°)		
		Mean	Std. Dev.	*P*	Mean	Std. Dev.	*P*
Intrapedicular							
Group 1 drill guides	21	2.09	1.40		4.90	3.21	
Group 2 cannulated screws	10	2.36	2.03	**0.99**	5.16	2.82	**0.89**
Group 3 modular guides	11	0.97	0.57	**0.05***	2.30	1.09	**0.05***
Total	42	1.86	1.50		4.29	2.91	
Extrapedicular							
Group 1 drill guides	22	2.08	1.23		7.33	4.12	
Group 2 cannulated screws	12	1.57	0.98	**0.49**	4.34	3.01	**0.09**
Group 3 modular guides	10	1.76	0.79	**0.88**	5.57	4.73	**0.37**
Total	44	1.87	1.08		6.11	4.12	

*Tukey with $P \leq 0.05$.

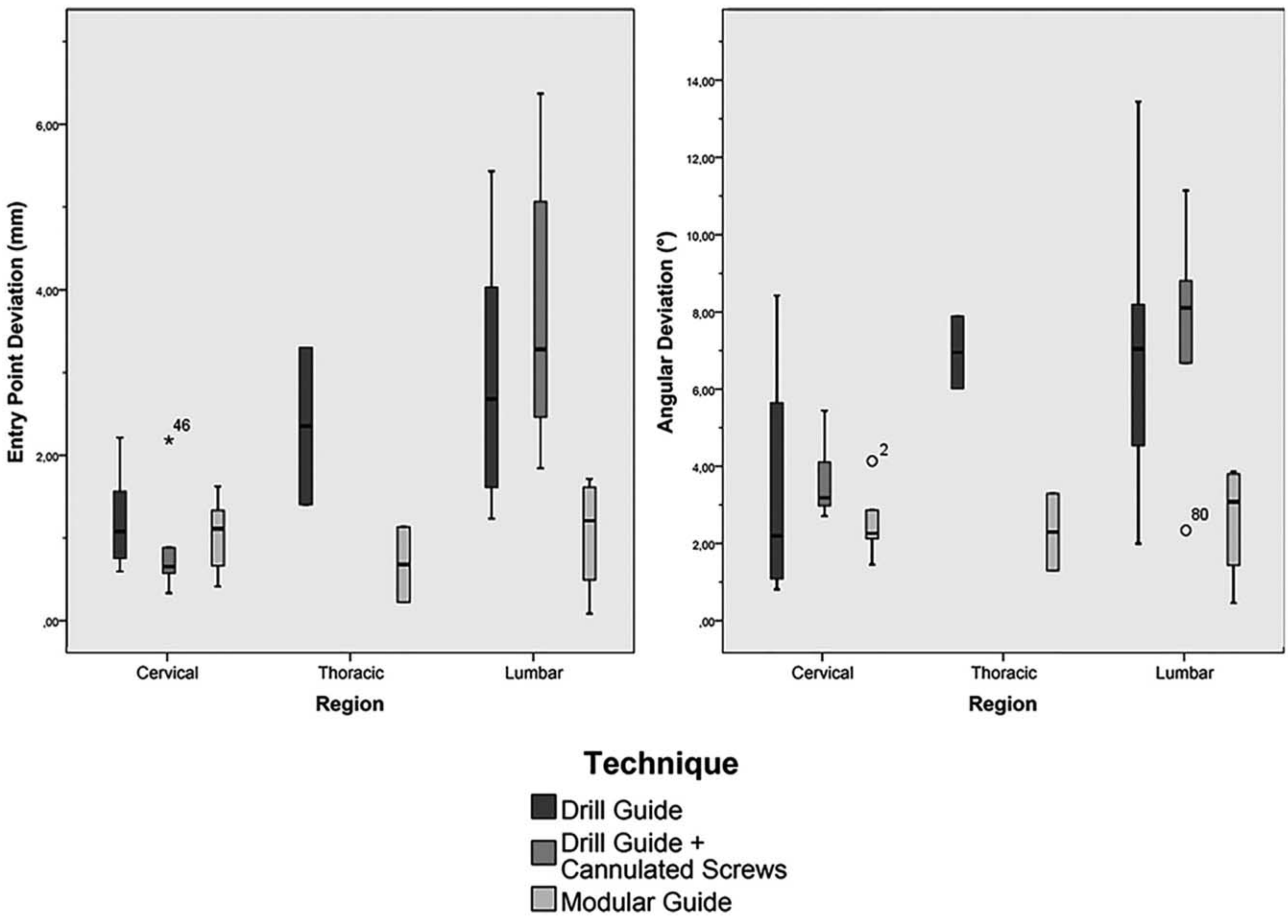

Figure 7. Deviation from plan for all Intrapedicular screws grouped per technique and clustered per spinal segment. 3D deviations divided into entry point deviation (mm) and angular deviation (°). Outliers are displayed with stars or circles. Note that the thoracic levels only consist of very limited data (six screws), this is because most thoracic screws were placed extrapedicular.

screw-tip outside the vertebral body (Figure 8). Of those 10 malpositions, 2 were cannulated screws (group 2), 3 screws were placed using a modular guide (group 3), and 5 screws were inserted by means of a regular drill-guides (group 1).

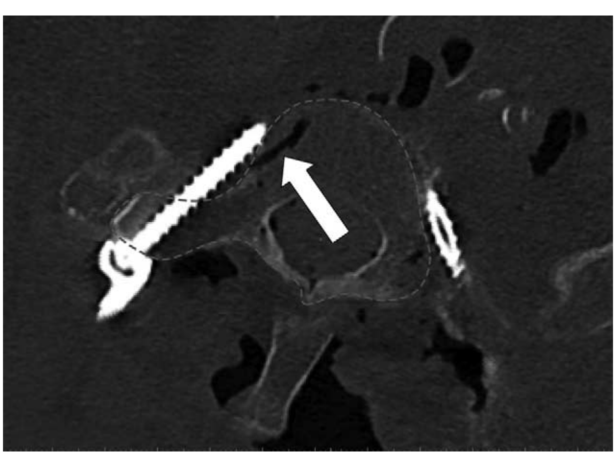

Figure 8. Extrapedicular planned screw positioned using the regular drill guide technique (group 1) not entering the second entry and skidding of the lateral cortex of the vertebral body. The still clearly visible pilot trajectory is pointed out by a white arrow.

DISCUSSION

In this study, we evaluated two techniques aiming to enhance the accuracy of screw insertion with the aid of 3D-printed guides. The results demonstrate that modular guides can significantly improve the accuracy of pedicle screw insertion in the lumbar spine compared with regular drill guides. Both screw guiding techniques did, however, not improve the accuracy for extrapedicular screw trajectories. Especially these in-out-in screw trajectories are often malpositioned, but additional screw guiding did not provide a definitive solution for these technically demanding trajectories.

Over the past decades, new technologies have come available to support the surgeon during the crucial steps of screw insertion in spinal deformity surgery. In recent years, patient-specific drill guides have emerged as a novel promising tool for pedicle screw placement. Custom-made guides fit onto the individual vertebrae. As such, intraoperative movements of the spine do not affect screw placement accuracy, in contrary to computer navigation. A shift of the real-time structures relative to the planned trajectory, however, is one of the major flaws of computer navigation.[24]

The accuracy of 3D-printed guides for pedicle screw insertion has been subject of various studies. Until now, no studies specifically evaluated and compared the mutual 3D printing techniques. This study evaluated the benefit of two 3D-printing navigation techniques that focus on screw guidance in addition to drill-bit guidance. Emphasis was placed on alternative extrapedicular screw trajectories, which show comparable biomechanical strength in case of correct positioning.[25] This technique, regularly used in syndromic scoliosis, is technically demanding and could potentially benefit most from improved precision.

In the present study, we found that the modular guide technique (group 3) resulted in a significant higher accuracy compared with regular drill guides (group 1). The greatest accuracy gain with modular guides was achieved in the lumbar region. For the cervical region, modular guides merely seem to add up to the high levels of accuracy already achieved with the regular drill guides. The improvement for lumbar region might be best explained by the lumbar screw thickness and associated wider thread, allowing the screws to easily deviate from pilot trajectory, which seems to be prevented by the actively screw steering mechanism of modular guides. The entry point deviations of regular drill guides in the lumbar region diverge considerably from our earlier study.[20] Though previous results were limited to the upper-thoracic spine, this may be related to the interspinous ligament sparing design that was specifically used in the current study. The current study design does not allow us to directly examine the possible negative accuracy effect of the ligament sparing design, but examining this issue should be the focus of future research.

Extrapedicular screw placement remains a high-risk procedure, showing a misplacement rate (in-out classification) of 24% in this series. Although 3D angular accuracy improved with cannulated screws (group 2), the difference with the regular drill guides (group 1) was not significant. Small divergence just before second entrance may have induced sliding of the screw tip along the slanted cortex of the vertebral body. Although this phenomenon was observed for regular drill guides (Figure 8), it was not observed for modular guides, but metal artifacts may have hindered clear visualization. Nevertheless, the modular guide failed to adequately direct the screw into the planned trajectory. Also, the cannulated screws could not prevent malpositioning, which may be due to multiple reasons; *e.g.*, k-wire misrouting, the premature withdrawal of the k-wires, or initial pilot hole malpositioning.

One limitation of the current study is the use of only two cadaveric specimen. Although screws were randomized, the difference in bone quality might influence the accuracy. Another limitation is that cadaveric specimen typically present with low bone mineral density, consequently screws might more easily deviate from plan in contrast to a clinical situation. Therefore, the current study might slightly underestimate the actual accuracy. For thoracic levels, the results are largely limited to extrapedicular trajectories and no final conclusions can be drawn from intrapedicular thoracic screw trajectories.

The results of this study implicate that regular drill guides (group 1) are safe and accurate for the cervical region, and screw guiding techniques are of no benefit. Modular guides may be superior for lumbar pedicle screws, these guides should be considered for narrow lumbar pedicles that need most accurate screw insertion. In case of using regular drill guides for the lumbar screw insertion, results suggest that the ligament avoiding design may be less accurate and therefore should be avoided until direct comparative studies are available. For *extrapedicular thoracic* screws none of the evaluated 3D-printing navigation techniques provide a solution to the high malposition rates. It should be noted that the absence of pathological pedicles in the current cadaveric simulated setting might have induced a discordance with the actual clinical setting. In general clinicians should consider the optimal technique for each case, taken into account whether the size of the pedicle is safe for 3D-guided screw insertion, the provided accuracy data can help with such decision making.

In conclusion, in this study it was found that for *extrapedicular* screw insertion, the screw-guiding 3D-printing techniques are not superior to the regular 3D-printed drill guides. For *intra pedicular* screw insertion, modular guides can improve accuracy of particularly lumbar pedicle screws. The placement of cervical pedicle screws using the 3D-printed drill guides appears to be an accurate without additional screw guidance.

➢Key Points

- ❑ 3D-printing and virtual planning technology are promising new tools for improving intra- and extrapedicular screw insertion for spinal deformity surgery.
- ❑ Some techniques focus on guiding the drill while others also guide subsequent screw insertion, a direct cadaveric comparison between mutual techniques was made.
- ❑ Screw-guiding techniques are not superior to the regular 3D-printed drill guides for the technically demanding extrapedicular screw technique.
- ❑ For intrapedicular screw insertion, modular guides can improve insertion; however, at cervical levels regular 3D-printed drill guides already demonstrated very high accuracy and therefore there is no benefit from additional screw guiding techniques.

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