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Accuracy and safety of three-dimensionally printed animal-specific drill guides for thoracolumbar vertebral column instrumentation in dogs: Bilateral and unilateral designs

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Abstract

Objective: To evaluate the safety and accuracy of a unilateral three-dimensionally printed animal-specific drill guide (3DASDG) design for unilateral stabilization in the thoracolumbar vertebral column of dogs compared to a bilateral design.

Study design: Cadaveric study.

Sample population: Fifty-two corridors in one canine cadaver.

Methods: Two 3DASDG designs with 2 drilling tubes each were created from T8 to L7 vertebrae. Fifty-two corridors were drilled on the right and the left sides by using unilateral and bilateral designs, respectively. Planned and postoperative trajectories (entry point, exit point, angle) were compared to establish the accuracy. Statistical analysis was used for accuracy comparison between designs. Safety was evaluated by using Zdichavsky classification.

Results: Unilateral and bilateral drill guide designs were not different for entry point and angle deviations; however, they were different for the exit point deviations. Two corridors breached outside the vertebra. For all guides, mean entry and exit point deviations were less than 1 and 2 mm, respectively. The maximum entry or exit point deviation in both groups was 4.7 mm. The mean angle deviation was <3.5°, and the maximum angle deviation was 9.3°.

Conclusion: No difference was detected in accuracy of entry points and angle deviations between drill guide designs tested in normal vertebrae. The technique was classified as highly safe.

Clinical significance: A unilateral drill guide design may be a safe alternative to bilateral guides for unilateral stabilization of the thoracolumbar vertebral column in dogs.

1 | INTRODUCTION

The standard of care for vertebral body stabilization of the canine thoracolumbar spine includes unilateral and bilateral instrumentation with vertebral body plating, pins, or screws and polymethylmethacrylate.[1-5] Placing vertebral implants within safe bone corridors can be technically challenging not only because of the vertebral anatomy itself (vertebral body size and shape, exiting nerve roots, surrounding soft tissues including blood vessels)[6] but also because of the possible concurrent disorder affecting the dog (instability or congenital malformation).[7-9] Whether intervention is unilateral or bilateral can depend on several considerations such as the implant used, the anatomy, and the required stiffness.[2,3] Although implants have been placed by using a free hand technique for decades, the accuracy and safety of the technique have never been studied.

Interest in the production of three-dimensional (3D) printing of drill guides to improve the safety of implant placement in veterinary neurosurgery has been growing.[10-16] These animal-specific drill guides are produced to target a safe drilling corridor, established preoperatively from computed tomography (CT) data. Technique benefits include not only accuracy and optimization of safe drilling corridors but also possible superior biomechanical properties of screws, reduced surgical time, and reduced morbidity.[11] A very attractive aspect of the technology, therefore, resides in the creation of animal-specific, rapidly created, inexpensive, safe drill guides. Limitations include 3D design software knowledge, the requirement for clean bone preparation, and the production of debris intraoperatively.[17] There can be great variability in the drill guides design, with each study having its own unique designs. The differences in accuracy between different 3D printed drill guide designs or specific design recommendations have not been reported. In human spinal surgery, drill guides can be designed for the intent of bilateral or unilateral stabilization,[18-21] whereas, in veterinary surgery, those reported in the thoracolumbar spine only have a bilateral design.

Because of the limited data available for unilateral 3D printed animal-specific drill guide (3DASDG) design and the possibility of unilateral instrumentation, the objective of this study was to compare the accuracy and safety of two drill guide designs for use in instrumentation of the thoracolumbar vertebral column of dogs. We hypothesized that a bilateral design would have superior accuracy compared with a unilateral design and that both designs would be safe.

2 | MATERIALS AND METHODS

2.1 | Study design

An ex vivo nonrandomized method-comparison study of the accuracy and safety between unilateral and bilateral 3DASDG designs in the canine thoracolumbar vertebral column was performed.

2.2 | Design and manufacture of the drill guides

Computed tomographic images of the thoracolumbar vertebral column of an adult beagle dog (13 kg) cadaver were acquired (1-mm slice thickness, bone algorithm; GE LightSpeed 8; GE Healthcare, Milwaukee, Wisconsin). The dog had been acquired through donation and euthanized for reasons unrelated to the present study. Resultant DICOM (Digital Imaging and Communications in Medicine) images were imported into 3D planning software (Mimics version 21; Materialise, Leuven, Belgium) for segmentation (3D volume creation). This software platform shows multiplanar reconstruction (MPR) orthogonal views (transverse, sagittal, frontal planes) and a 3D volume reconstruction. A bone algorithm preset (bone CT threshold [Mimics; Materialise]) was used to create a mask. The mask was trimmed to isolate the region of interest (vertebral column) and used to create a 3D mesh. A cylinder tool with a radius of 1.25 mm was used to create a desired drill guide trajectory. The trajectories were, therefore, created for a 2.5-mm drill guide for intended placement of a 3.5-mm cortical screw or 3.2-mm pin. Drill guides were created spanning from eighth thoracic (T8) to seventh lumbar (L7) vertebra. Two drill guide trajectories were created in the cranial and caudal aspects of each vertebral body, passing obliquely from dorsoabaxial to ventroaxial orientation and inspected in orthogonal planes to ensure no corridor breach. The 3D vertebral column mesh and trajectories were then exported into Materialise 3-Matic. The vertebral column mesh surface was optimized by using the uniform remesh tool (target triangles 0.5 mm) to reorganize the mesh with triangles of identical sizes, facilitating design for the software. The drill guides were created by incorporating the trajectories and creating a base matching the outer surface of the vertebra model (Figure 1). Briefly, an area on the outer vertebral surface was marked by using a brush marking tool delimiting the base. It was then given a 2-mm thickness, and its mesh was uniformly remeshed with 0.5-mm triangles (Figure 1A-G). Drill tubes were then created on the basis of the previously established trajectories. An outer tube was first designed with a radius of 3.3 mm; then, another tube (inner) with an internal radius of 0.1825 mm (to fit a Synthes 2.5-mm drill sleeve [Synthes drill sleeve 312.28; Synthes, Paoli, Pennsylvania]) was also designed and then subtracted from the outer one (bolean subtraction tool). The drill tube was united to the base (Boolean union tool). A second drill tube was created in the same manner (Figure 1 H-M). For the bilateral drill guide design, a connector (inverted U shape) going over the spinous process connected the drill guide to a contralateral base (designed as before). All drill guides were labeled according to their respective vertebra number and were printed by using a stereolithography printer (Form 2; Formlabs, Sommerville, Massachusetts) in methacrylate photopolymer resin (Dental

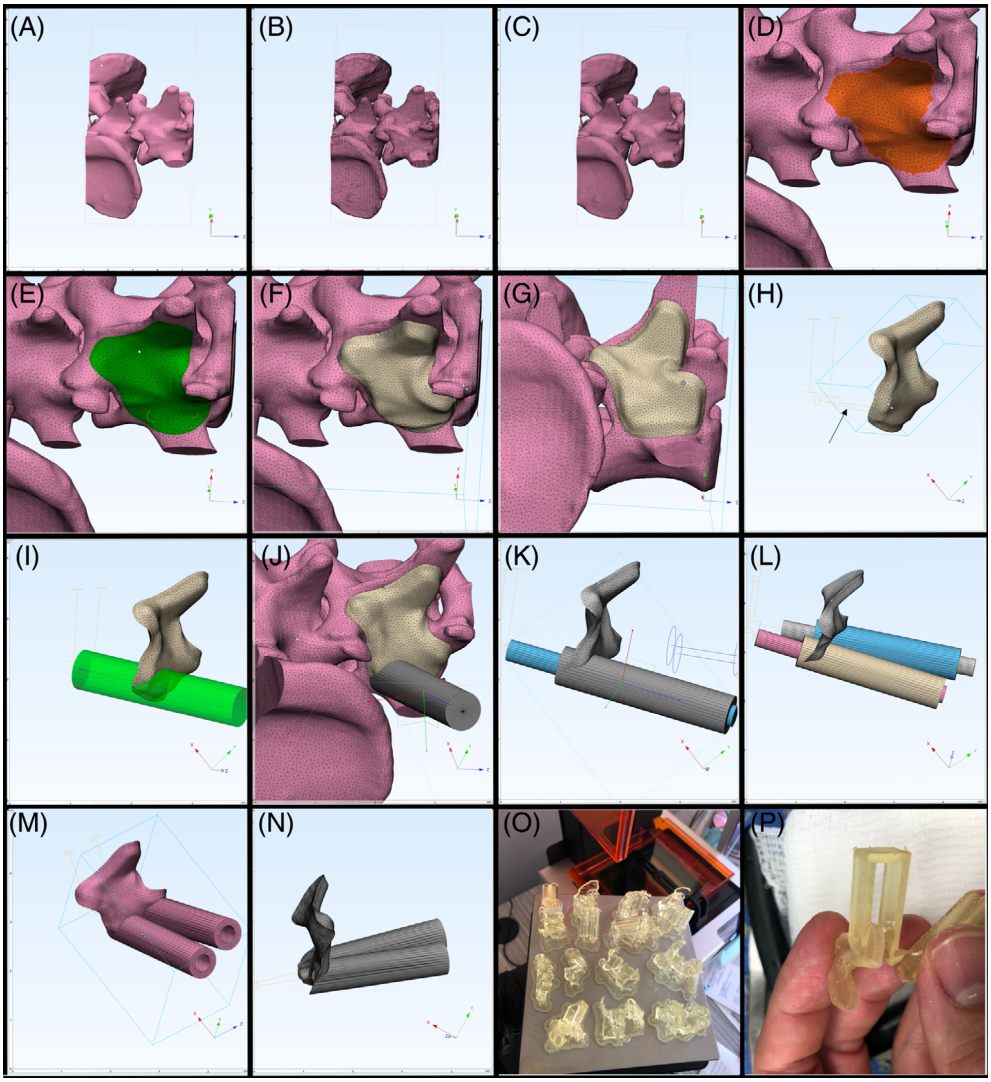

FIGURE 1 Production of three-dimensionally (3D) printed guides. A-C, After exportation of the 3D mesh and drill guide trajectories into Materialise 3-Matic, a part of the lumbar vertebral column was uniformly remeshed (with triangles of similar sizes). D-G, Creation of the base of the right drill guide of L6 vertebra. A surface was selected on the mesh to minimize future guide movements by expanding over bone surface with less soft tissue attachments (insertion of tendons, articular capsules) and to fit around surface reliefs. Therefore, the base footprint extended medially on the surface of the vertebral spinous process, cranially around the cranial articular process base, and caudally around the caudal articular process base and accessory process. It was given a thickness of 2 mm and then uniformly remeshed. H-N, Drill tube design. Primitive cylinders were then created centered on the trajectories (yellow lines seen under the base [H, arrow]). An inner cylinder was subtracted from an outer cylinder to give a hollow tube. Two tubes were designed per base (unilateral design). The 3D volume of the vertebra was then subtracted from the base and tubes, giving a perfect surface match for the drill guide, with the result that the drill guide was vertebra specific. O, Example of drill guides at the end of the printing process on the Form 2 build platform. P, Bilateral drill guide after removal of the supporting material

SG resin; Formlabs) and steam sterilized (Figure 1O,P). The orientation of the drill guide for printing is automatically set by the software of the 3D printer (PreForm, Formlabs), and it was adjusted only when the support material would interfere with the portion of the base in contact with the vertebra. Vertebral models were also 3D printed (Form 2; Formlabs) to assure correct fit of the drill guides postprocessing by using clear resin (Formlabs; Figure 2A). A 2.5-mm drill sleeve was introduced into each guide to ascertain appropriate fit and patency.

2.3 | Cadaveric surgical procedure

The dog cadaver was placed in sternal recumbency. Padding was placed underneath the pelvis to maintain the lumbar vertebral column in horizontal position. After skin and fascia incision, the epaxial musculature of the thoracolumbar region (from seventh thoracic vertebra to the sacrum) was reflected bilaterally and maintained in place with Gelpis retractors, and soft tissues were carefully elevated with a Freer periosteal elevator and gauze

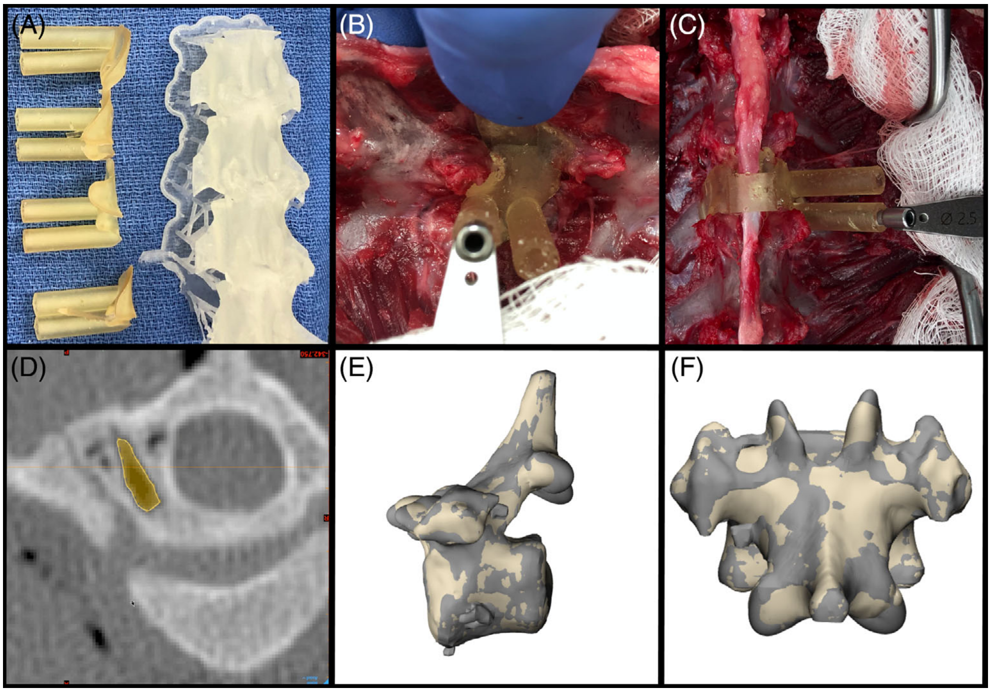

FIGURE 2 Evaluation of three-dimensionally (3D) printed guides and corridors A, Drill guides were tested for correct fit on 3D printed model of vertebra. B,C, Drill guides were fitted into place after dissection and cleaning of the bone where the base would lie. D, Transverse view of the postoperative computed tomography; note the trajectory (yellow area) left after drilling a thoracic vertebra. These voids were used to create the postsurgery data. E,F, Coregistration between 2 vertebrae (one gray and one beige) which have been superposed to compare planed trajectories to postsurgical drilling. These images illustrate the accuracy of the registration process between the 2 vertebrae (the gray and beige vertebrae uniformly overlay each other), which is important for accurate results

where the drill guide base would rest. The unilateral drill guides were placed on the right side, and a 2.5-mm drill sleeve was placed into the guide tubes (Figure 2 B,C). They were held in place manually, and the vertebrae were drilled by using a 2.5-mm drill bit (Synthes), perforating both cortices. The same technique was used for the bilateral drill guides on the left side. We elected to use the drill-sleeve-in-the tube technique to simulate limiting the potential risk of material contamination during drilling in a live animal. All drill corridors were flushed with saline (to improve trajectories identification in CT images).

2.4 | Postoperative evaluation: drill guide accuracy

Postoperative CT images were acquired with the same variables as preoperative CT images and were segmented to extract the vertebral column and voids left after drilling by one of the authors (T.C.) using Materialise Mimics (Figure 2D). Analytical cylinders were created on the basis of on the vertebral drilling void 3D objects, which yielded coordinates for a drill entry, drill exit, and central axis for angle deviation. The postoperative vertebral column and drilling voids were then coregistered to the preoperative vertebral column and planned drill locations by using automated alignment tools (combination of two registration methods in Materialise 3-matic; N-Points registration with >3 points and Global registration). This renders the postoperative 3D mesh superposed over the preoperative planning mesh (Figure 2E,F). Accuracy of the model's registration was reviewed by 2 of the authors (T.C. and J.G.). Entry and exit points were then recorded in all three planes (x, y, z) for both the preoperative and postoperative data as well as the angle deviation between them. Entry and exit deviation values were calculated by using the distance formula = SQRT($[X_2 - X_1]^2 + [Y_2 - Y_1]^2 + [Z_2 - Z_1]^2$) for each location, and then the average was calculated for each category. Angle differences between the cylinders for planned trajectories and postoperative drill void could be compared using the angle calculation tool (within 3-Matic).

2.5 | Postoperative evaluation: drill guide safety

All CT images were reviewed by one of the authors (J.G.) using MPR reconstructions in a bone window and 3D volume reconstruction (Horos, horosproject.com) to evaluate for any breaches along the length of the drill track. The latter were evaluated according to the Zdichavsky classification,[22] a validated scoring system for pedicle screw placement in the human spine by using defined criteria (location of the pedicle screw in regard to the vertebral pedicle or vertebral body) for the grading. Because the drilling corridors were for a 2.5-mm drill bit, the distances from the drilling corridor edge to the vertebral canal cortex and to the outer vertebral cortex were also evaluated to ensure that a 3.5-mm screw could be safely used (distance above 0.5 mm on each side of the corridor would represent a safe corridor). Safety was, therefore, defined as the absence of breach of either of these bone cortices.

2.6 | Statistical analysis

To estimate an appropriate sample size, Cohen's D sample size was used. For a Cohen's D effect size of 0.8, which is considered "large," it was calculated that 26 corridors per technique were required to detect this effect size with 80% power in a two-sided *t* test. Data are summarized with mean and SD. Examination of the distribution of deviation data revealed a skewed right distribution. After a log transformation, the distribution for each variable followed a normal distribution. Therefore, *P*-values were calculated on the basis of the log-transformed data, although the raw data are provided for estimates of mean (SD). Testing was conducted by (1) two-sample *t* tests for independent data and (2) a mixed-effects analysis of variance with covariates for region (lumbar vs thoracic) and type (caudal vs cranial) and with sample identification as a random effect. The two methods produced very similar test results. Therefore, we report the simpler statistical model results of two-sample *t* tests. All tests were conducted at a 5% significance level in R for statistical computing version 3.5 (R foundation for statistical Computing, Vienna, Austria); http://www.R-project.org/.

3 | RESULTS

3.1 | Design and manufacture of the drill guides

The workflow was developed in collaboration among coauthors (student, surgeons, and software engineers). Several prototypes of drill guides were designed to achieve a guide that was stable on the vertebra 3D printed models. The approximate time for design of a drill guide for a single vertebra was under 20 minutes. In total, 13 unilateral and 13 bilateral 3DASDG were created. Each guide consisted of 2 drill tubes, totaling 26 drill channels per side. Appropriate fit was found for the 2.5-mm drill sleeve in all guides.

3.2 | Cadaveric study

Two of the bilateral drill guides broke at the connector level (one during removal of the 3D printed supports, the other during the procedure). They were reprinted and breakage did not recur.

3.3 | Postoperative evaluation: drill guide accuracy

Two-tailed *P* values were calculated after log transformation for angle deviation ($P = .696$) and entry ($P = .492$) and exit points ($P = .030$) between unilateral and

TABLE 1 Deviations of the angle and entry and exit distances for unilateral and bilateral 3DASDG

Measurement	Unilateral	Bilateral	*P*-value[a]
Angle deviation, °	3.450 (1.739)	3.504 (2.034)	.696
Thoracic	2.912 (1.005)	3.454 (2.320)	.924
Lumbar	3.912 (2.113)	3.546 (1.842)	.539
Entry distance deviation, mm	0.934 (0.958)	0.960 (0.621)	.492
Thoracic	0.906 (1.233)	0.936 (0.556)	.326
Lumbar	0.957 (0.692)	0.981 (0.693)	.953
Exit distance deviation, mm	1.458 (0.910)	1.910 (0.821)	.03
Thoracic	1.333 (0.924)	2.081 (0.861)	.025
Lumbar	1.566 (0.918)	1.764 (0.788)	.464

Note: Data are mean (SD).
Abbreviation: 3DASDG, three-dimensionally printed animal-specific drill guide.
[a]*P*-value is based on log-transformed data.

bilateral drill guide designs. There was no difference between the 2 designs in angle and entry deviation. There was a decrease in exit distance deviation for the unilateral drill guide compared with the bilateral drill guide ($P = 0.025$) (Table 1).

When all drill guides were considered, the mean angle deviation of the trajectories was less than 3.5°, and the maximum angle deviation was 9.3°. There was only 1 outlier deviation in each design (9.3° at L7 on the right, caudal trajectory and 9.21° at T9 on the left, cranial trajectory). The mean entry and exit point deviations were less than 1 and 2 mm, respectively. The maximum entry or exit point deviation was 4.7 mm (Table 2A,B).

TABLE 2A Mean angle deviations for thoracic and lumbar vertebrae

Vertebrae	Mean angle deviation, °
Thoracic	
T8	2.80
T9	2.19
T10	5.15
T11	2.62
T12	2.53
T13	3.81
Lumbar	
L1	3.28
L2	4.44
L3	3.54
L4	3.59
L5	4.55
L6	2.45
L7	4.26

TABLE 2B Angle, entry, and exit deviations

Vertebrae	Thoracic	Lumbar
Minimum angle deviation, °	0.92	1.18
Maximum angle deviation, °	9.21	9.30
Mean entry distance deviation, mm	0.92	0.96
Mean exit distance deviation, mm	1.70	1.66

3.4 | Postoperative evaluation: drill guide safety

Vertebral bone cortex breach was identified for 2 of 52 trajectories. According to the Zdichavsky classification system, all drilled trajectories but 2 were classified as I (optimally placed pedicle screw fully contained within the pedicle and vertebral body). The trajectory of T10 cranial on the left was IIIa (partial penetration of the lateral pedicle wall) and was suspected to be related to the trajectory design being too close to the vertebral end plate. The trajectory of L7 caudal on the right was IIa (partial penetration of the medial pedicle wall). In addition, cranial and caudal trajectories of T12 on the left merged because entry points were likely too close, but there was no cortical breach (Figure 3). The findings were identical for the calculated 3.5-mm screw corridors. Overall, error incidence was 5.8% (3/52), with a breach incidence of 3.8% (2/52). Unilateral and bilateral drill guides had the same rate of breach (3.8% [1/26]).

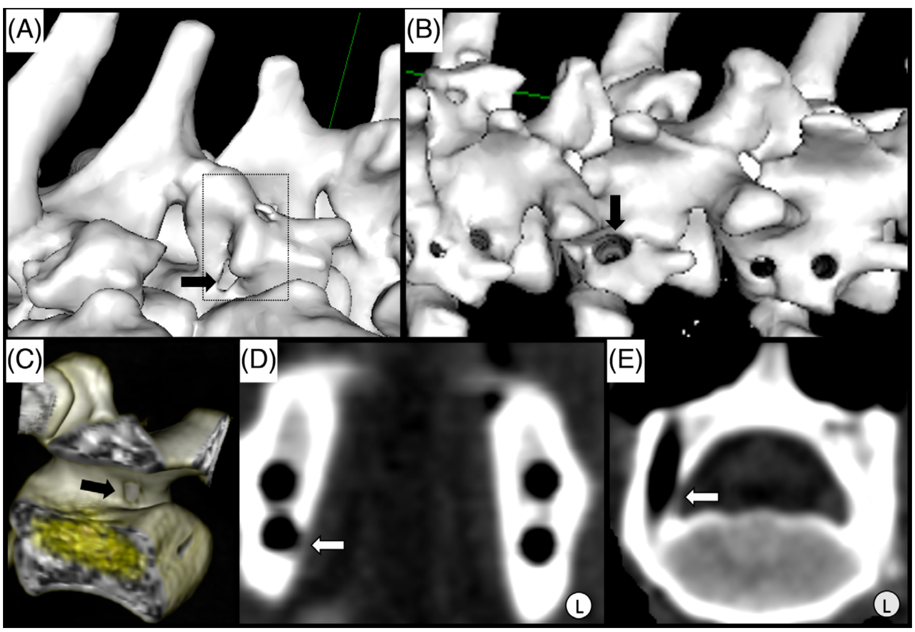

FIGURE 3 Computed tomographic appearance of vertebral breaches. A, Three-dimensional (3D) volume reconstruction, left lateral view. The dotted square encloses the T10 cranial corridor, and the focal breach of cortex is visible (arrow). B, 3D volume reconstruction, dorsal view. Fusion of the 2 corridors occurred at T12 vertebra (arrow). C, 3D volume reconstruction, medial view after image cropping of the L7 vertebra pedicle. A focal breach is observed (arrow). D,E, A focal loss of cortex has led to the breach (arrows); the trajectory, however, appears safe

4 | DISCUSSION

In this ex vivo method-comparison study, we evaluated the performance of two 3DASDG designs for thoracolumbar vertebral column implant placement in 13 vertebrae after 52 trajectories. The accuracy of 3 variables (entry point, exit point, angle deviation) was evaluated between 2 designs, and statistical difference was found only for exit point deviations. The incidence of breach into the vertebral canal or outside the vertebra was low (3.8%).

The accuracy of the drill guides in this study is in line with another previously reported 3DASDG design.[13] This research provides evidence that safety margins of 1 mm for entry points, 2 mm for exit points, and 4° for angle deviation should therefore be taken into consideration during trajectory planning of drill guides design. Proximity to the end plate should also be kept in mind as well as proximity between two entry points. The safety of the 3DASDG was established by the evaluation of vertebral bone breach by using a classification system previously described in veterinary medicine.[10] The incidence of breach in this study (3.8%) was similar to previously reported data[10,13] and indirectly sets the accuracy of the technique at 96.2%. We have refrained from the use of the term *pedicle breach* in this report because corridors did not always go through vertebral pedicles.

In this study, no statistical difference was found between designs, whether for the thoracic or lumbar vertebral column entry points or angle deviations. The exit point deviation was significantly different, however, with the unilateral thoracic drill guide design being more accurate. This information is clinically relevant because placement of thoracic implants is notoriously difficult and is associated with further risks because of its narrower bone corridors, steeper corridor angle, and proximity to the chest.[6] The unilateral design is also attractive for this anatomical region because a bilateral design use may be more complicated (longer spinous process, larger muscle mass to dissect).

In human spinal surgery, the complexity of thoracolumbar vertebral column instrumentation is similarly challenging compared with in dogs. When placement of thoracic pedicle screws was based solely on anatomical knowledge (free hand technique), pedicle violation varied from 15% to 41%.[22-24] Although additional intraoperative imaging was helpful, the accuracy was still highly variable (3%–43%).[25-27] The overall pedicle violation rate was 7.6% when drill guides were used, whereas it was between 1.4% and 19% when CT-based neuronavigation was used.[28,29] Methods other than the Zdichavsky classification exist to assess the accuracy of pedicle screw placement.[30] The most widely used system grades the pedicle breach by increments of 2 mm, with breaches up to 2 mm categorized as a safe/acceptable zone, while >2 mm is considered unsafe. The second most common technique is an "in-or-out" classification, in which trajectories or screws are either contained within the pedicle or they are not. There does not seem to be unanimity regarding which grading scheme is best to use. Research to develop and validate a grading scheme for implant safety in the canine thoracolumbar spine is warranted.

The current study has several limitations. First, the guide was designed by a single person. This limitation, however, brought consistency in the design. Second, all corridors were drilled by a single person. It is indeed possible that there was variability between and/or within operators using the same drill guides (interoperator and intraoperator variability). Third, the side of the surgery was not randomized, and the same design was used for both sides. Fourth, only one dog cadaver was used. The appropriate sample size for trajectories was, however, estimated by statistical analysis. Fifth, the exposure used in this study was far greater than that used during a conventional approach for vertebral stabilization, and this might have facilitated the placement of the drill guides. Finally, errors inherent to the technology might have been introduced during design or production of the drill guides. Stereolithographically printed surgical guides for dentistry can, for example, have errors up to 13% compared to their original design, with most of the inaccuracies coming from either the data manipulation by the operator or the inconsistent fit of the surgical guide.[31] The printing process (object build orientation, positioning) and postprocessing (curing, sterilization) can also alter the guide.[32] Steam heat sterilization, however, had no significant effect on the dimensional changes of surgical guides (printed with the same printer and resin type as this study).[33] The print orientation can influence the printing accuracy, with a 45° orientation recommended for the build. In addition, objects printed on the borders of the build platforms were more prone to inaccuracies than those printed in the center.[32] Additional research in the study of accuracy of drill guide design is required to minimize errors.

In conclusion, we demonstrate that both unilateral and bilateral 3DASDG designs are accurate and safe for instrumentation in the thoracic and lumbar vertebral column of dogs in an ex vivo model. Bilateral design does not seem to be required for accuracy and safety when only unilateral implants are used. Additional research is required to establish how to optimize 3DASDG design in veterinary neurosurgery.

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CONFLICT OF INTEREST

Thomas Cullum works for Materialise. All other authors declare no conflicts of interest related to this report.

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