Thoracolumbar Spinal Stabilization with Three Dimensional-Printed Drill Guides and Pre-Contoured Polyaxial Bone Plates

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Abstract

Objective The aim of this study was to report new preoperative and intraoperative techniques performed for canine thoracic or lumbar spine kyphosis stabilization using three-dimensional-printed patient-specific drill guides, polyaxial titanium bone plates and drill stops, and to determine the accuracy of screw placement using these techniques.

Study Design Retrospective study, five client-owned dogs.

Results Three-dimensional-printed patient-specific drill guides and drill stops allowed safe drilling and screw placement in all of the cases, with (i) 84% of the screws graded as I (ideal placement) and 16% as IIa, IIIa or IIIb according to the modified Zdichavsky classification (partial penetration of medial pedicle wall, partial penetration of lateral pedicle wall and full penetration of lateral pedicle wall respectively), (ii) mean medio-lateral deviation of ± 4.06 degrees (standard deviation: 8.21 degrees) compared to planned trajectories and (iii) variation in screw depth of ± 2.29mm (standard deviation: 3.07mm) compared to planned depth.

Conclusion We believe that the techniques presented here for thoracic spinal stabilization in dogs show promise; they allowed safe placement of screws along planned trajectories and depth; they also removed the need to use polymethylmethacrylate, while the use of titanium offers the possibility to repeat magnetic resonance imaging in these cases with chronic spinal conditions.

Keywords
- spine
- 3D-printed drill guide
- polyaxial titanium plate
- drill accuracy
- dogs

Introduction

Vertebral malformations have been previously reported in dogs, particularly in brachycephalic breeds, with the most frequently observed malformations being hemivertebrae (ventral, lateral or ventrolateral aplasia), wedge vertebrae (ventral or lateral hypoplasia) or butterfly vertebrae (ventral and median aplasia).[1,2] In some cases, excessive curvature of the spine may develop subsequent to these malformations, in particular kyphosis with or without scoliosis. This can then result in either static spinal cord compression or dynamic compression as a result of excessive mobility of the vertebrae relative to each other.[1,2] Each patient presents a unique challenge due to their individual malformation(s) and a bespoke surgical solution is required.

Previously described surgical treatments of thoracic spinal malformations, with a dorsal approach targeting the

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pedicles, include placement of pins and polymethylmethacrylate (PMMA), cortical screws and PMMA, cortical screws and cerclage wire and readily contourable bone plates such as the String of Pearls.[1,3–7] No differences in stiffness have been reported between the String of Pearls plate, titanium locking plate or pin and PMMA constructs when cadaveric studies have been performed.[8]

Given its comparable biomechanical properties, versatility in a wide variety of situations and that there is no requirement for pre- or intraoperative-contouring of implants, PMMA constructs are often the fixation method of choice for the veterinary neurosurgeon.[4,9] However, due to heat generated during polymerization with some surgical cements, their use is not recommended near the spinal cord.[10,11] Polymethylmethacrylate is also challenging and time consuming to remove if the position of the implant requires revision in the immediate postoperative phase or later due to implant failure or infection.

Implant placement is most commonly performed by freehand drilling, with a recent canine *ex vivo* study describing image-guided freehand drilling, where 100% safety was achieved; however, clinical application of this technique has not yet been reported.[12] The human spinal surgery literature describes freehand drilling *in vivo* and a relatively variable accuracy of screw placement, with only 69 to 94% of screws being recorded as completely intrapedicular.[13] The technical challenges associated with free-hand drilling are amplified in companion dogs, due to their small size and the variety of vertebral malformation morphologies observed.[1,2] This has prompted a search for techniques and strategies to facilitate the placement of a mechanically stiff construct in a way that allows consistent intrapedicular placement in patients with a variety of vertebral malformations. The advent of 3D printing has provided an opportunity to produce drill guides that are bespoke to the patient, theoretically providing the surgeon with ideal intrapedicular placement trajectories.[14] The Polyaxial Locking (PAX) plate system (Securos Surgical, Massachusetts, United States) allows some degree of flexibility in screw insertion, with angulation (up to 10 degrees away from perpendicular) used to place screws through the plate.[15]

In a retrospective assessment of a clinical case series, we report the development of a method for application of locking implants to companion dogs with vertebral malformations, where we aimed to avoid the challenges associated with both PMMA use and freehand drilling, by combining use of the PAX system with bespoke three-dimensional-printed patient-specific drill guides (3D-PSG). We followed a sequence of steps for each case: acquisition of a pre-operative computed tomography (CT), 3D printing of the thoracic spine anomaly, contouring of PAX plates using the 3D-printed spine, acquisition of a CT of the 3D-printed spine with the contoured plates laid on it to then determine the screw's trajectories of best fit using a computer-aided design (CAD) software, design of 3D-printed drill guides allowing to drill the pre-planned trajectories safely within the vertebral pedicles. To investigate the accuracy of screw placement with this novel method of application we used the screw length within bone, the mediolateral screw angle and the modified Zdichavsky classification to assess safety.[16]

Materials and Methods

Inclusion Criteria

Canine patients with vertebral malformations that were presented to Highcroft Veterinary Referrals between August 2018 and August 2021 that matched the following inclusion criteria were included in a retrospective evaluation: (i) dogs less than 20 kg of any breed, age or sex; (ii) cases with a clinical complaint of hindlimb ataxia with or without paresis caused by a T3-L3 myelopathy based on their neurological examination; (iii) cases that underwent magnetic resonance imaging (MRI) demonstrating presence of a thoracic spine deformity leading to spinal cord injury and therefore suspected to have a degree of spinal instability; (iv) cases that underwent surgical intervention for stabilization of the abnormally formed portion of the thoracic spine using pre-contoured polyaxial bone plates applied using 3D-PSG; (v) cases with a postoperative CT allowing assessment of implant positions.

Magnetic resonance imaging of the thoracolumbar spine was performed for each patient using a 1.5 Tesla machine; Philips Achieva (Rotterdam, the Netherlands) with the patient under general anaesthesia and positioned in dorsal recumbency. The following MRI images were acquired: sagittal and transverse planes in T1- and T2-weighted images (TR 550 ms, TE 12 ms, field of view [FOV] 140 $\times$ 250 mm, matrix 512, slice thickness 2mm), axial plane in T1- and T2-weighted images (TR 3650 ms, TE100ms, FOV 80 $\times$ 80mm, Matrix 400, slice thickness 2 mm) and 3D DRIVE (TR 1500ms, TE 250ms, FOV 120 $\times$ 250mm, matrix 512, slice thickness 2 mm). No contrast was used. Computed tomography images of the thoracolumbar spine were acquired using a 16-slice scanner (Siemens Somatom Scope, Erlangen, Germany) with dogs sedated or anaesthetized, positioned in sternal recumbency in the same position as they would be placed for surgery, the images were acquired using the following parameters: 130 kV, 120 to 150mAs (Care:Dose 4D was used) FOV 500mm, pitch 0.65 and a rotation time of 1s with a slice thickness of 0.6mm. The raw data were post-processed using a medium-sharp bone algorithm (B70s) with a slice thickness of 0.75 mm and the smallest FOV achievable. They were subsequently evaluated using multiplanar reconstruction and 3D volumetric reconstruction.

Magnetic resonance imaging and CT images were assessed using a free and open-source code DICOM viewer (Horos, Horos Project, Nimble Co LLC, Purview, Annapolis, Maryland, United States).

Preoperative Planning

Following CT imaging, DICOM images were sent to Vet3D, allowing production of a model of the spine 3D-printed in methacrylate photopolymer white resin (Formlabs, Somerville, Massachusetts, United States). Then PAX plates were contoured to match the region of kyphosis (►**Fig. 1A** and **B**) using PAX reconstruction plate bending pliers. The contoured PAX plates were then held onto the resin 3D-printed

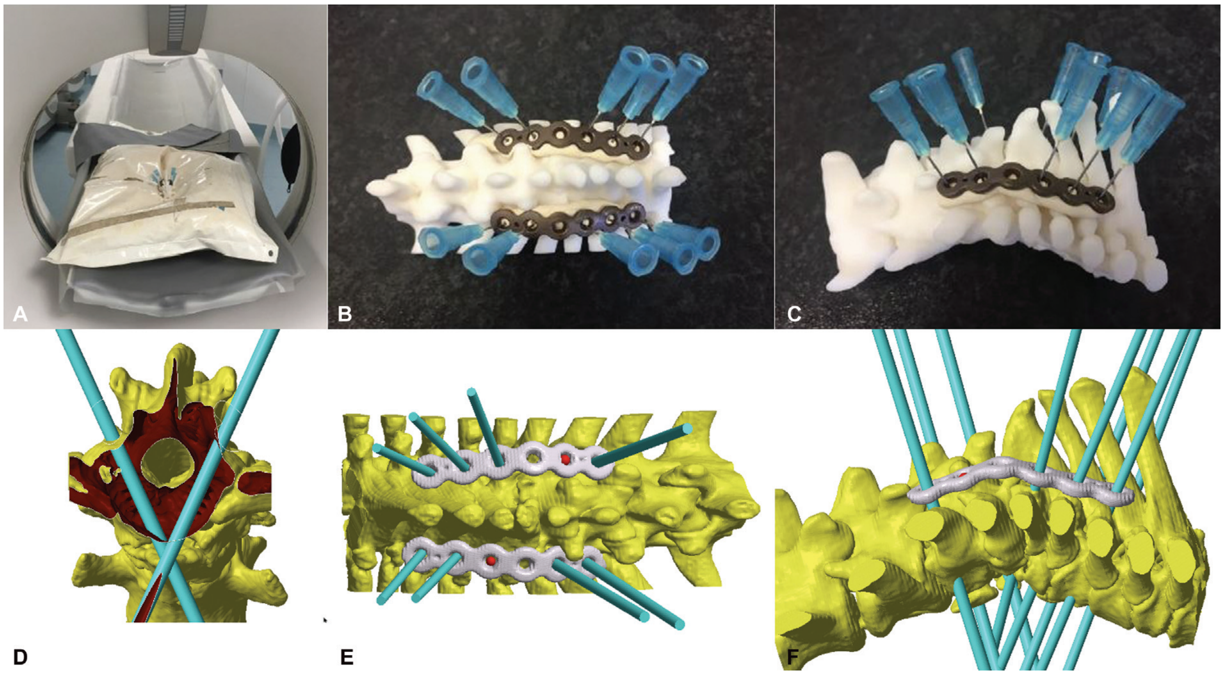

Fig. 1 **(A)** Performing computed tomography of three-dimensional (3D)-printed spinal model (methacrylate photopolymer white resin: Formlabs, Somerville, Massachusetts, United States) with contoured the Polyaxial Locking (PAX) plate, to allow for drill trajectory and drill-guide planning. **(B)** Dorsal aspect of 3D-printed spinal model, with contoured PAX plate in situ. **(C)** Lateral aspect of 3D-printed spinal model, with contoured PAX plate in situ. **(D)** Transverse planning imaging showing drill trajectories produced using computer-aided design. **(E)** Dorsal planning imaging showing pre-contoured plate and drill trajectories produced using computer-aided design. **(F)** Lateral planning imaging showing pre-contoured plate and drill trajectories produced using computer-aided design.

model using pressure-sensitive adhesive putty (UHU White Tack, Cowling & Wilcox Ltd, United Kingdom) placed between the model and the plates. Twenty-three-gauge hypodermic needles (►**Fig. C**) were placed through the holes of the PAX plates at 90 degrees to the plate, although these were not essential for future planning, but rather used to mimic best fit for the screws. A CT of the 3D-printed resin model, with the contoured plates and needles in place, was then performed and the resulting DICOM images were sent to Vet3D. We then used CAD software to plan drilling trajectories and produce custom 3D-PSG (►**Fig. 1D**) using a standard protocol. Firstly, DICOM data were used to create a surface-rendered representation of the spine using a medical image processing software (Osirix, Pixmeo, SARL; Geneva, Switzerland). This was exported as a Standard Triangle Language file to CAD software (Netfabb professional, Netfabb GmbH: Parsberg, Germany). Safe transpedicular screw trajectories were orientated in the 3D virtual spinal models, and drill guides designed to facilitate pilot hole drilling. The model of the spine with pilot holes was 3D-printed in methacrylate photopolymer high temperature resin (Formlabs, Somerville, Massachusetts, United States), whereas the drill guides were 3D-printed in methacrylate photopolymer BioMed Amber resin (Formlabs, Somerville, Massachusetts, United States), both using a Form 3 printer (Formlabs, Somerville, Massachusetts, United States). The BioMed Amber resin used to print the drill guide is certified as autoclavable and biocompatible (EN ISO 10993-1:2018; 10993-3:2014; 10993-5:2009). The high temperature resin is certified by the manufacturer to have a heat deflection temperature of 238°C 0.45 Mpa (ASTM D 648-16). The models were cleaned using tripropylene glycol monomethyl ether using a Form Wash, and ultraviolet- and heat-cured using a Form Cure (both Formlabs, Somerville, Massachusetts, United States) according to the manufacturer's instructions for each resin type. Prior to surgery, ethylene oxide sterilization (the 3D-PSG and spinal models printed in high temperature resin are also autoclavable) of the drill guides and spinal models was performed for 24 hours. Surgery was then performed, with the 3D-PSG used for application of the previously contoured PAX plate and 1.5 or 2 mm titanium self-tapping pedicle screws, in combination with drill stops made from ethylene oxide sterilized PVC tubing (Gemini Tackle Company Ltd, Lincolnshire, United Kingdom) to limit depth of the drill tracts.

Surgical Technique

All surgeries were performed at Highcroft Veterinary Referrals, with anaesthetic protocols and postoperative analgesia regimes tailored to each individual case as appropriate.

In all cases, bilateral dorsolateral approaches were performed to expose both sides of the spinal column. At this stage, in some cases, additional procedures were required, including a right hemilaminectomy alongside durotomy and marsupialization of the dura for a case with a subarachnoid diverticulum noted intraoperatively. Spinous processes were then burred flat as necessary to ensure good bone contact with the footprint of the 3D-PSG, before the overlying soft tissues were dissected off the bone to allow placement. Using the 3D-PSG (►**Fig. 2**) and drill stops set at the appropriate

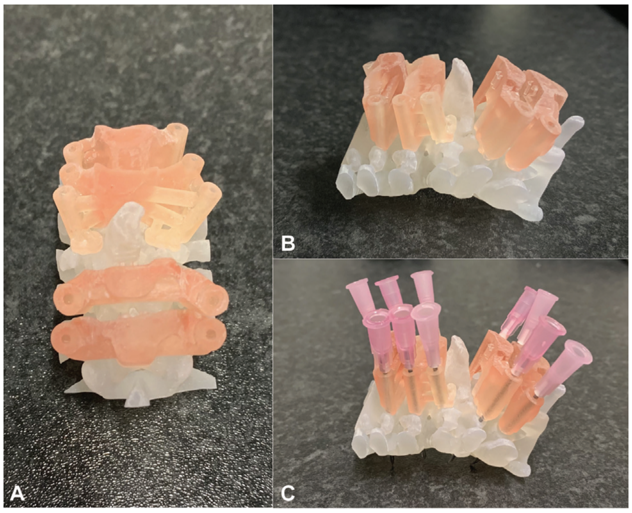

Fig. 2 **(A)** Three-dimensional (3D)-printed model (methacrylate photopolymer high temperature resin: Formlabs, Somerville, Massachusetts, United States) with 3D-printed patient-specific drill guides (3D-PSG) (methacrylate photopolymer BioMed Amber resin (Formlabs, Somerville, Massachusetts, United States) in place, dorsoventral view. **(B)** 3D-printed model with 3D-PSG in place, lateral view. **(C)** 3D-printed model with 3D-PSG in place and 16G needles filling the drill tracts, lateral view.

depth (►**Fig. 3**), screw tracts were drilled through the vertebral pedicles/vertebral bodies as appropriate for each case before placement of the pre-contoured PAX plates to achieve stabilization of the spine. Closure of the musculature, subcutaneous and skin layers was routine, with postoperative CT performed to confirm appropriate implant positioning (►**Fig. 4**) using the same CT scanner and protocols as preoperative imaging.

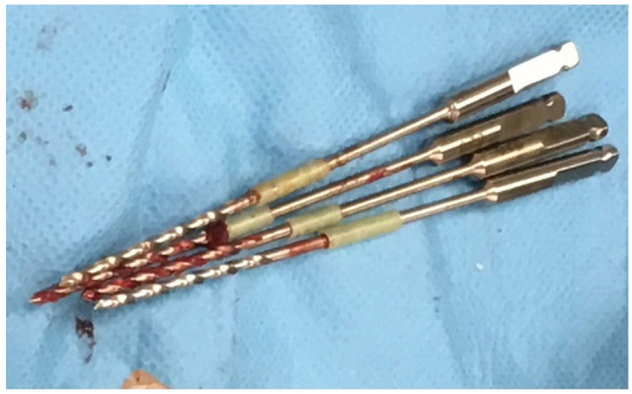

Fig. 3 Rubber tubing novel drill stops, ethylene oxide sterilized.

Antimicrobials

All cases received perioperative intravenous antibiotic medications (cephalexin 20mg/kg intravenously upon induction and this was repeated every 90 minutes whilst in theatre).

Postoperative Evaluation

One of the authors (OG) reviewed all CT images, utilizing CT multiplanar reformatting to allow assessment of each placed screw individually in its long axis, recording the mediolateral screw angle (►**Fig. 5A**), screw length within bone (►**Fig. 5B**) and the modified Zdichavsky classification for each implant.[16] The planned screw length within bone and planned mediolateral screw angle was determined using the same method, but using CT images of the 3D-printed spinal models, with 18G needles placed to fill the drill tracts and 3D-PSG. Any discrepancy in screw length or mediolateral deviation, compared to what was planned, was recorded. Postoperative neurological examination and follow-up results were recorded for each patient.

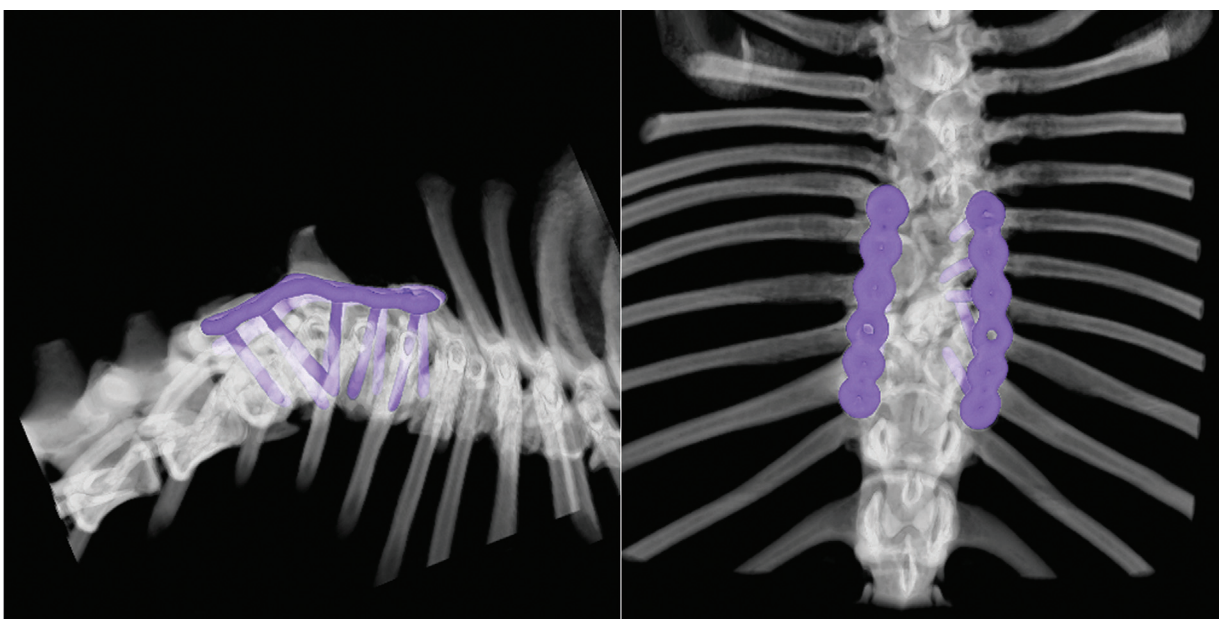

Fig. 4 Postoperative computed tomography reconstructions showing application of pre-contoured the Polyaxial Locking plates using 3D-printed patient-specific drill guides and novel drill stops.

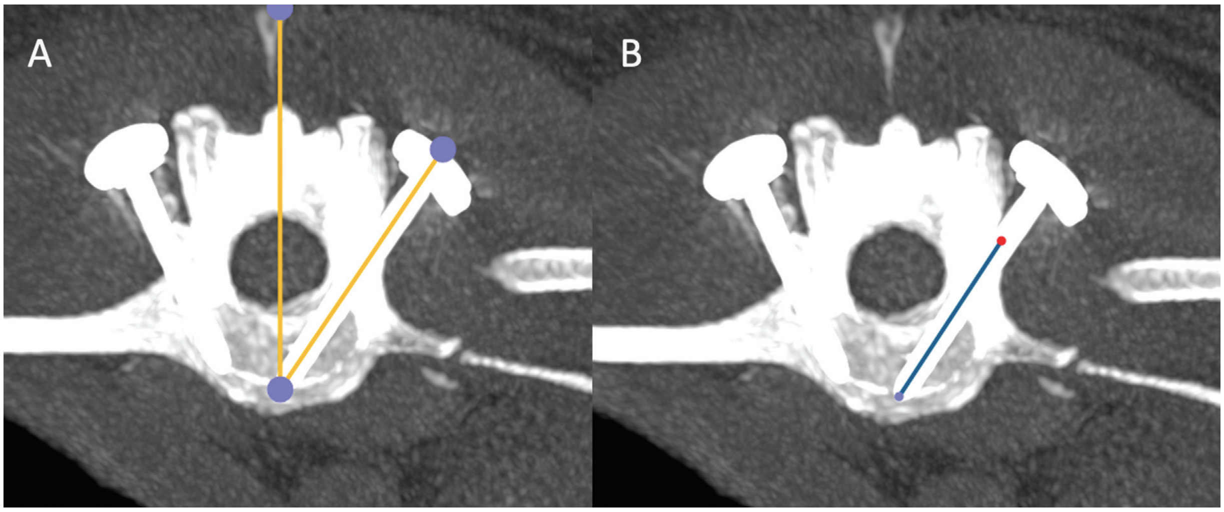

Fig. 5 Transverse computed tomography image allowing assessment of implant positioning. **(A)** Measurement of the mediolateral screw angle and **(B)** measurement of screw length within bone.

Results

Nine dogs met the inclusion criteria; however, four of these were excluded from the analysis because: (i) two had anomalies where pre-contouring of the plates was not required; (ii) in one case, it was not possible to match the plate holes with screw's trajectories allowing secure purchase within the bone; and (iv) one case lacked a postoperative CT.

Five mature dogs were included in the series: four French Bulldogs and one Pug (►**Supplementary Appendix Table 1**, available in the online version). The median age at the time of spinal stabilization was 3.13 years (range: 0.75–6). Three dogs were female and two were male. The median body weight was 8.78 kg (range: 5.30–12.60). There were five cases of spinal malformation: kyphosis secondary to a thoracic ventrodorsal wedge vertebrae, kyphosis and scoliosis secondary to a thoracic ventrodorsal wedge vertebrae, kyphosis secondary to thoracolumbar hemivertebrae, scoliosis secondary to a thoracolumbar hemivertebrae and thoracolumbar subarachnoid diverticulum alongside butterfly vertebrae. Before spinal stabilization, all the dogs had significant clinical impairment as a consequence of spinal instability, with five showing neurological deficits (ataxia and paraparesis).

Thirty-seven 1.5 or 2 mm screws were placed across these five cases, with one case having 5 screws, one case having 6 screws, one case having 7 screws, one case having 8 screws and one case having 10 screws (a median of 7 screws). Thirty-one of the screws were graded as I, three grade IIa (too medial), one grade IIIa (too lateral) and one grade IIIb (too lateral) according to the modified Zdichavsky classification.[16] Of the five screws that were not grade I, three were placed in the same dog (►**Supplementary Appendix Table 2**, available in the online version) and graded as IIa, IIIa and IIIb. A mean mediolateral deviation of $\pm$ 4.06 degrees (standard deviation: 8.21 degrees) when compared to planned trajectories was recorded and the mean variation in screw depth was $\pm$ 2.29mm (standard deviation: 3.07 mm) when compared to the planned screw depth. No patients required revision of implant positioning.

Two self-limiting postoperative complications were reported: (i) in one case, the postoperative CT scan revealed evidence of an iatrogenic moderate left caudal pneumothorax, though this remained clinically silent with no evidence of respiratory dysfunction; and (ii) in another instance, an acute flare of brachycephalic obstructive airway syndrome was observed and successfully managed conservatively.

All cases returned to Highcroft Veterinary Referrals for repeat consultation and CT at 6 to 8 weeks postoperatively, with implants remaining in the same position in all instances. In one case, repeat CT was obtained 2 years after the surgery when the dog returned for reassessment due to progressive ataxia and back pain, which showed that the implant had remained in place. The clinical signs were thought to be due to occurrence of a sub-arachnoid diverticulum. At the time of our study (mean follow-up of 21.4 months, range: 4–37 months), all patients are able to walk and other than the dog discussed above, with no evidence of ataxia. Good outcome and quality of life are reported by the owners in all cases and no complications have been documented.

Discussion

The use of 3D printing in veterinary surgery is a recent development and is a field that is currently undergoing much research. The use of 3D-PSG has been studied in several applications, including but not limited to transcondylar screw placement, atlanto-axial ventral stabilization, vertebral fracture stabilization, shoulder arthrodesis and minimally invasive plate osteosynthesis, where the technique has been proposed to be safe.[17–21] In our experience we have felt more comfortable with the use of 3D-PSG, compared to using free-hand drilling. The goal of our procedures was to achieve spinal stabilization by applying two dorsally-positioned PAX plates between two normal vertebrae, bridging the area of malformation and placing pedicle screws through the plates into both the normal vertebrae and the area of malformation. This was not always achievable due to the malformations encountered and our technique was adapted; however, it is beyond the scope of this paper to discuss the principles of locking constructs and suggest guidelines for screw numbers and positions. Our data suggest that this proof-of-concept technique is safe for the placement of bicortical pedicle screws in dogs with thoracic vertebral malformations and instability. Our results compare well with a similar recent canine study[14] with an intrapedicular placement rate of 96.7%, where bicortical pedicle screws were placed using patient-specific 3D-printed drill guides and screws were bonded with PMMA, rather than utilizing a locking plate. One dog was more challenging that the other because of its diminutive size (5.3kg), whereas the other dogs were all more than 10 kg. In this case, three screws out of the five placed were not graded I, therefore dropping the overall percentage of grade I screws. It is possible that the smaller size of that patient could have meant the same degree of deviation resulted in a change of Zdichavsky grade that may not have occurred in a larger patient. Additionally, challenging soft tissue elevation leading to poor guide-bone contact could have resulted in slipping of the guide. However, our data compares very favourable when compared to free-hand drilling in human patients.[13] The comparable study by Elford and colleagues[14] reported reports a similar number of cases (6 dogs) to us and therefore we believe our own cohort adds further useful data on the safety of 3D-printed guides.

We utilized the modified Zdichavsky classification to grade placement of the pedicle screws due to its reported high intra- and inter-observer reliability and the use of this classification system in recent and comparable veterinary studies.[12,14] To the knowledge of the authors, no grading system exists for pedicle screw placement in veterinary patients, with all classifications adapted from the human literature.[12,14,16]

As the implants used are titanium, this lends flexibility, should the patient require further MRI postoperatively and the lesser degree of beam-hardening artefact induced by the titanium implants, when compared to stainless steel, allows for more accurate assessment of implant positioning post-operatively with CT.

Limitations associated with our study include the small cohort of dogs; therefore, we are offering proof-of-concept, rather than firm evidence that this technique is superior or inferior to others. A major limit is that this technique is not applicable to all cases with a thoracic kyphosis; we encountered one case where it was not possible to match the holes of the PAX plates to the desired screw trajectories due to the internodal distance of the plates, so we abandoned this technique. However, we could have considered the use of other plates, such as the Evolox Locking System (N2 Ltd, Portsmouth, United Kingdom) which allows 10 degrees of screw angulation or the String of Pearls System (Orthomed UK, Huddersfield, United Kingdom) that can be contoured by medial to lateral bending, cranial to caudal bending and torsion. We have also experienced cases where the Cobb angle was too high to allow plates to be placed, even before we considered matching the plates holes to the pedicles. The lack of standardized timescales for follow-up, which is difficult to achieve in our referral setting is also a limitation, and it is difficult to ascertain the real clinical benefits of the proposed technique. Finally, a barrier to widespread use of this technique is the required expertise in the use of CAD software and the approximately 2 to 3 hours needed for each case to select the right trajectories and design the 3D-PSG. It is then necessary to CT the 3D-printed spinal model, with contoured plates in position, which is another moderately time-consuming step. A strategy to alleviate some of the time delay involved currently would be to have the 3D printer and CT scanner in the same location, allowing contouring to be undertaken immediately following production of the spinal model. Alternatively, having a 3D scanner next to the 3D printer could also allow to 3D scan the 3D-printed spinal model with contoured plates in position. The use of 3D-PSG also increases the cost of the surgery and may introduce a recruitment bias, with only the cases where the owners could afford surgery being able to be included in this study. However, the possibility to pre-contour commercially available titanium plates is an advantage and negates any requirement for the printing of bespoke implants.

In our hands, this proof-of-concept technique proved to be safe and reliable for these patients. The accuracy of screw placement shows promise and further research to assess the clinical outcome is required.

Authors' Contributions
O.G. contributed with conceptualization, study design, data acquisition, data interpretation and analysis, drafting and revising the manuscript. L.E. and D.O., H.V., D.R., and B.O. took part in data acquisition, and drafting and revising the manuscript. N.G. contributed with conceptualization, study design, data acquisition, data interpretation and analysis, drafting and revising the manuscript. All authors approve the submitted manuscript and are publicly accountable for relevant content.

Conflict of Interest
The 3D-PSGs are produced by B.O. of Vet 3D. The rest of the authors report no conflict of interest.

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