VETERINARY SURGERY

Kinematic Behaviour of a Novel Pedicle Screw-Rod Fixation System for the Canine Lumbosacral Joint

Journal:	*Veterinary Surgery*
Manuscript ID	VSU-16-053.R5
Manuscript Type:	Original Article - Research
Keywords:	4-point bending, biomechanical testing, orthopedic biomechanics, orthopedic implant, spinal surgery

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ABSTRACT

Objective: To determine the biomechanical behaviour of a novel distraction-stabilization system, consisting of an intervertebral distraction bolt, polyaxial screws and connecting rods, in the canine lumbosacral spine.

Study design: Biomechanical study.

Sample population: Cadaveric canine lumbosacral spines (L4-Cd3) (N=8)

Methods: Cadaveric lumbosacral spines were harvested, stripped of musculature, mounted on a 4-point bending jig, and tested in extension, flexion and lateral bending using non-destructive compressive axial loads (0-150N). Angular displacement was recorded from reflective optical trackers rigidly secured to L6, L7 and S1. Data for primary and coupled motion were collected from intact spines; after destabilization at L7-S1, and following surgical stabilisation with the new implant system.

Results: As compared with the intact spine, laminectomy resulted in a modest increase in angular displacement at L6-L7 and a marked increase at L7-S1. Instrumentation significantly reduced motion at the operated level (L7-S1) with a concomitant increase at the adjacent level (L6-L7).

Conclusion: The combination of a polyaxial pedicle screw-rod system and intervertebral spacer provides a versatile solution of surgical stabilisation of the lumbosacral joint following surgical decompression in the canine lumbosacral spine. The increase in motion at L6-L7 may suggest the potential for adjacent level effects and clinical trials should be designed to address this question.

Clinical relevance: These results support the feasibility of using this new implant system for the management of degenerative lumbosacral disease in dogs. The increase in motion at L6-L7 may suggest the potential for adjacent level effects and clinical trials should be designed to address this question.

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INTRODUCTION

Surgical treatment of degenerative lumbosacral disease has been recommended for dogs with severe pain.[1] Decompressive surgery is considered an appropriate technique to relieve compression of the cauda equina and nerve roots in dogs with degenerative lumbosacral stenosis (DLSS)[2], and dorsal laminectomy with or without annulectomy and partial discectomy is currently the most commonly performed surgery.[3-6] Clinical results with this technique have shown to have overall success rates between 79% and 93.2%.[4,7] But recent studies have reported deterioration several weeks postoperatively[5] with inferior force plate parameters 6 months postoperatively compared to normal dogs.[8]

Several lumbosacral fixation techniques have been evaluated in dogs, with variable results.[3,9,10-15] Trans-articular facet screw fixation has been plagued with a high incidence of technical failure without effective stabilisation.[16] Pedicle screw fixation systems are widely used in human medicine and it has been shown that paired pedicle screws inserted in lumbar vertebrae at 30° offered more resistance to axial pull-out than paired pedicle screws placed parallel.[17] In a biomechanical study in canine spines the ideal pin insertion angle in the last lumbar vertebra was found to be 30°, providing the greatest amount of bone purchase with a wide margin of safety.[18] Biomechanical studies have shown that pedicle screw and rod fixation effectively stabilizes the lumbosacral spine in extension and flexion *in vitro*.[19] Clinically, pedicle screw-rod constructs applied after decompressive surgery have been associated with excellent stability, function and pain relief[12], with increased propulsive forces on force plate analysis during a 6-month postoperative period, albeit without confirmation of successful fusion on histopathology.[15,20]

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In a biomechanical study using a bovine calf spine model it was shown that stand-alone interbody fusion cages are effective in restoring neuroforaminal height and stabilize the spine to withstand foraminal deformation during daily loading[21], which has been confirmed in humans to have optimal clinical outcomes preventing subsequent collapse of the intervertebral space and compression of cauda equina and nerve roots.[22] Interbody cage combined with pedicle screw fixation provided sufficient stability and stiffness in a finite element study[23] and met the criteria for lumbo-sacral fusion in a clinical study.[24]

We have recently developed a spinal implant system that consists of a threaded intervertebral bolt to distract the neuroforamina, and polyaxial pedicle-vertebral body screws with connecting rods to increase holding strength of the construct and promote interbody fusion. The objective of this cadaveric study was to determine the efficacy of the new fixation system in restoring stability to the lumbosacral spine after decompressive surgery. The hypotheses were that (1) the new instrumentation would lead to a significant reduction in primary and coupled motion at the operated L7-S1 level after decompressive surgery and (2) that application of the new fixation system would not have a significant effect on the mobility of the adjacent L6-L7 disc space.

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MATERIALS AND METHODS

Specimens

The pelvis and lumbar spine (L4 to the third caudal vertebra) were harvested *en bloc* from eight skeletally mature large dogs (median 29.7kg, range 25.0 to 39.5 kg) that were euthanized for reasons unrelated to this study. The specimens were collected under an approved Institutional Care and Use Committee (IACUC) protocol. Breeds represented were Pitbull (N=1), Rottweiler (N=2), Pitbull cross (N=3) and German Shepherd Dog (N=2). The age of the dogs was estimated by dentition to be 1-2 years (N=5) and 2-3 years old (N=3). Radiographs confirmed closure of the vertebral growth plates and ruled out pre-existing spinal pathology within the lumbar spine and L-S junction.

Implants

The instrumentation consists of a tapered intervertebral distraction bolt, polyaxial screws, clamps, connecting rods, washers and nuts ([redacted]) (Figs 1, 2), all machined from medical grade titanium alloy (Ti6Al4V). The intervertebral bolt (19mm long, tapering from a diameter of 7.5mm proximally to 4.4mm distally) is coated with hydroxyapatite (HA) and has external positive profile threads (pitch of 2.125 mm and height of 1.49 mm above the surface of the spacer). The self-tapping cortical pedicle screws (4.5 mm, with a core diameter of 3.2mm) are available in lengths of 30, 35 and 40 mm. The rods with a diameter of 4mm have dumbbell ends, making it possible to lock the rods (between the washer and the nut) in any position within the polyaxial clamps. The rods, available in lengths of 32mm, 37 mm and 42 mm, can be bent as needed to allow for placement around the articular facets of L7 and S1.

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Specimen preparation

Muscle and soft tissue were removed from the specimens, taking care to leave ligamentous tissue (supraspinous ligament, interspinous ligament, capsules and ligaments of the articular facets) intact. The functional spinal units were disarticulated at the L4-L5 junction cranially and at the Cd3-Cd4 junction caudally, so that the final specimen included L5, L6, L7, the sacrum, the pelvis and Cd1-3. Immobilisation of L5-L6 and S3-Cd1 joints was achieved by placing wood screws bilaterally through the articulation between the adjacent vertebrae and perpendicular to the sacroiliac joints on each side. The accuracy of screw positioning was verified by radiography prior to testing (Fig 3). The cranial and caudal ends of the specimen, including the acetabulae, were embedded in 4” diameter PVC tubes filled with polyester resin (Bondo Body Filler; 3M, St Paul, MN) (Fig 3). After hardening, care was taken to ensure that the L6-L7 and L7-S1 articulations were freely mobile in flexion-extension and lateral bending. Specimens were wrapped in saline-soaked towels and frozen at -20C°. Before testing, the specimens were thawed for 24 hours at 4°C.

Dorsal Laminectomy, Annulectomy and Discectomy.

The supra- and interspinous ligaments were resected between L7 and S1 and the caudal one-quarter of the spinous process of L7 and the entire spinal process at S1-S2 were removed with rongeurs. A dorsal midline laminectomy, including the caudal quarter of the lamina of L7 and a larger portion of the S1-S2 lamina, was performed with the aid of a surgical burr. The articular facet joints were left intact. The interarcuate ligament was resected and the epidural fat and cauda equina removed. Dorsal annulectomy was performed, creating a rectangular window in the central

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dorsal annulus fibrosus, and nucleus pulposus material was removed with a Freer elevator from the central region of the disc (Fig 4A). The motion of the destabilized spine was then tested.

Specimen preparation - Instrumented spine

Using a dorsal approach (through the laminectomy), the tapered distraction bolt was driven into the center of the intervertebral space using a special applicator (Fig 4B), taking care to ensure that the top of the bolt came to rest flush with the ventral surface of the spinal canal (Fig 2). After drilling a hole with a 2mm drill, a 2.4-mm TTA screw was inserted from the floor of the vertebral canal (S1) through the central slots of the spacer into the caudal third of the L7 vertebra (Fig 2). For pedicle screw insertion in the L7 vertebra, the drill hole was made immediately subjacent to the mammillary process of the cranial articular process at the junction of the arch and the vertebral body. The screws were angled with the tip of the screw emerging in the mid-sagittal plane of the vertebral body (Figs 2A, 2B). For pedicle screw insertion in the sacrum, the entry point was cranial to the S1 neuroforamen and caudal to the caudal articular process of L7. The screw trajectory was directed into the alar wing of the sacrum, parallel to the sacroiliac joint but without encroaching on the joint (Figs 2A, 2C). As the screws in L7 do not enter the pedicle from dorsal to ventral but enter the base of the pedicle where it joins the vertebral body, all drill holes were made with a 3.2mm drill and an awl was not used. The *cis*-cortex was drilled and pedicle screws were inserted through the clamp, then screwed into the drill hole until their self-tapping tips just penetrated the *trans*-cortex. A washer was then placed on top of the pedicle screw head, the connecting rods were inserted (connecting the screws at L7

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and S1) and then locked into the polyaxial clamp with a threaded nut screwed down onto the dumbbell head of the rod (Figs 2, 4C).

Motion Capture

Relative angular displacements across the L6-L7 and L-S articulations were determined by measuring the relative movements of optical trackers with a dual-camera motion capture system (Polaris Vicra, Northern Digital Instruments, Waterloo, Ontario, Canada). For this purpose, three optical trackers (Polaris Vicra, Northern Digital Instruments, Waterloo, Ontario, Canada) were rigidly attached to L6, L7 and S1 using 3.2-mm Ellis pins. The dual-camera motion tracking system monitored the position of the motion trackers during the loading cycle. Each tracker consisted of four reflective marker balls arranged in a non-collinear fashion. For each applied moment, the motion of the vertebra was measured in 6 degrees of freedom (rotations and translations around the x-, y- and z- axes). Motions were described in relation to a coordinate system placed into the body.[25] Relative vertebral motions were calculated in terms of Euler angles by use of the angle sequence ZYX. In order to define the position of L6 and L7 in the testing volume and to define their zero position, a standardized series of anatomic landmarks on L6 and L7 was digitized. A total of four landmarks on each vertebra (L6 and L7) were marked with a drill hole and tissue marking dye (Fig 5) to ensure consistent identification. With the digitisation, Euler angle and translation of the specimen's motion trackers at L6, L7 and S1 were recorded simultaneously. S1 is considered fixed in the testing volume. The transformations gave the fixed coordinates of the four anatomical landmarks of L6 and L7 relative to the tracker, making it possible to calculate relative positions of the vertebrae during testing. Before starting the first loading cycle, the positions of all of

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the trackers was captured to document the neutral position of the spine. Subsequent changes in spinal angle and translation were then calculated. The same loading and data collection protocol was used for intact, destabilized and instrumented vertebral columns. Testing cycles for each spine were completed within four hours within a single day.

Biomechanical Testing

Mechanical testing was performed using a custom 4-point bending fixture.[26] The specimen was subjected to non-destructive compressive axial loads through a servohydraulic materials testing machine (Model 858, MTS Systems Corporation, Eden Prairie, MN) operating under load-control (Fig 6). Loads were applied from 0 to 150N at the L6-L7 and L7-S1 junctions in the dorso-ventral (DV) direction to induce extension, ventro-dorsal (VD) direction to induce flexion, and the mediolateral (ML) direction to induce (left) lateral bending. Motions resulting from applying the load were measured and calculated by the motion tracking system and differentiated into the primary (intended) motions (e.g. extension with DV loading) and secondary (coupled) motions (e.g. axial rotation). After being placed in the testing machine, and after each change of position, the specimen was pre-loaded to minimize the effects of specimen viscoelasticity and to verify the optimal orientation of the tracking tools (Fig 6). L7 and L6 vertebrae were then digitized using four anatomic landmarks per vertebra (Fig 5). The specimen then underwent ramp loading in 25N increments to a maximum of 150N, with the load held for 5 seconds at each increment to allow time for motion tracking. The resulting motions of the FSU (functional spinal unit) were described in relation to the previously mentioned anatomical coordinate system.[25]

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Testing Steps and Instrumentation

The specimens were tested sequentially in flexion, extension and left lateral bending as an intact spine, after decompressive surgery and after instrumentation with the new fixation system (Fig 7).

Post-operative Evaluation

Helical computed tomography scans (0.625 mm slice thickness) were obtained for every specimen to document the location and orientation of the spinal instrumentation used to stabilize the L-S junction. The screw trajectories were evaluated on transverse CT slices and analysed descriptively with a modified classification system reported in an earlier study (Fig 8).[15] Placement was considered optimal when the screw was positioned in the centre of the pedicle; acceptable placement was characterized by cortical encroachment of the medial pedicle wall; unacceptable placement was characterized by overt penetration of the medial pedicle wall and encroachment into the vertebral canal. The position of the stabilising wood screws in adjacent joints was also evaluated on CT.

Data Analysis and Statistics

Descriptive statistics of the data confirmed that they were normally distributed. Comparisons between intact, destabilised and stabilised groups were made using a one-way repeated measures analysis of variance (ANOVA) procedure with Bonferroni adjustment for post-hoc comparisons. The ANOVA model included factors related to the three treatment groups (intact, destabilised, instrumented) and the three loading protocols (i.e., extension, flexion, and left lateral bending). Statistical testing was performed using commercially available software (IBM SPSS

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Statistics Version 20, International Business Machines Corp., Armonk, NY) and significance was set at $p<0.05$. Each specimen served as its own control.

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RESULTS

Diagnostic Imaging

Screening radiographs from this series of dogs were unremarkable, with no evidence of spinal pathology. Radiographs of the potted prepared specimens showed that the wood screws were positioned appropriately across the L5-L6, S3-Cd1 and sacroiliac articulations, and no interference with the implants was detected on computed tomography post-operatively.

Destabilisation with Laminectomy, Annulectomy and Discectomy

The dimensions of the annulectomy and laminectomy defects in this study were based on those reported in previous studies.[15,19,20] The laminectomy defect had a mean (± standard deviation, SD) width of 12.8 ± 0.9 mm and length of 31.1 ± 2.9 mm. The rectangular annulectomy defect measured 4.8 ± 0.9 mm in length and 9.8 ± 0.7 mm in width.

Implants and Instrumentation

The connecting rods used were 32 mm (4 of 16 specimens), 37 mm (9 of 16) or 42 mm (3 of 16) in length and 4mm in diameter. The rods had to be bent to be able to place them over the facet joints in one specimen. The interbody bolts were generally positioned centrally within the intervertebral space (Fig 8D), with two bolts marginally deviated to the left and three spacers slightly tilted to the right in the sagittal plane. One bolt was seated incompletely and sat slightly above the ventral surface of the vertebral canal. All but one of the TTA screws were successfully placed through the slot in the bolt; in one specimen the drill bit broke but this was left in

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place since it effectively served the same function as the screw in preventing rotation and back-out of the bolt. Screws implanted into L7 and S1 respectively had a length of 35mm (n=3 and n=13 respectively) and 40mm (n=13 and n=3 respectively). Post-operative CT scans revealed that all L7 and S1 pedicle screws engaged the *trans*-cortex. All L7 pedicle screws were placed through the pedicle and vertebral body and all S1 screws were placed in the alar wing. Accuracy of pedicle screw placement is shown in Fig 8 and Table 1.

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Kinematics of the Lumbosacral Spine

Data collected at 25N were considered unreliable as they demonstrated significant early settling of the construct within the test frame, so only data from subsequent cycles were evaluated. Within each of the test constructs (intact, destabilised, instrumented) the patterns in angular displacement over load were consistent, so for reasons of clarity only the data from the highest load (150N) underwent statistical analysis.

Primary motions: Results for primary motion of L6-L7 and L7-S1 are summarized in Table 2 and graphically illustrated in Fig 9.

Range of motion in the L7-S1 joint in the intact and destabilised spine was higher than in the adjacent L6-L7 segment for flexion **(Fig 9A, $p<0.05$)** and extension (**Fig 9B,** $p<0.05$) but showed similar values for lateral bending **(Fig 9C**). Destabilization resulted in increased extension at L7-S1 **($p=0.049$)** but motions in flexion ($p=0.20$) and lateral bending ($p=0.73$) were not increased. Destabilisation at L7-S1 was not associated with changes in motion at L6-L7. Following instrumentation, there was near-complete elimination of primary motions at the instrumented L7-S1 level but no effect on motion at L6-L7, compared to the destabilised specimen. Motion at L7-S1 following instrumentation was significantly lower than in the destabilized specimen in **flexion (Fig 9A, p=0.001), extension (Fig 9B, p=0.002) and lateral bending (Fig 9C, p<0.001). Motion at the instrumented site was also lower than in the intact specimen for lateral bending (Fig 9C, p=0.015) but not flexion (Fig 9A, p=0.09) or extension (Fig 9B, p=0.09). Motion at L6-L7 was unaffected by instrumentation at L7-S1.**

Secondary (coupled) motions: Destabilization at L7-S1 was not associated with alterations in coupled motions as compared with intact specimens (Table 3). Instrumentation of L7-S1 resulted in statistically significant decreases in axial rotation during flexion, extension and lateral bending. Lateral bending during flexion and extension was also significantly reduced following instrumentation at L7-S1.

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DISCUSSION

The key finding from this study was that instrumentation significantly reduced primary and coupled motion at L7-S1 following surgical decompression, lending support to our first hypothesis. Although there was a trend towards altered motion at the adjacent (L6-L7) level following destabilisation and instrumentation, these differences were not statistically significant, supporting our second hypothesis.

In the intact specimen, L7-S1 demonstrated high mobility in flexion and extension, and moderate mobility in lateral bending. The adjacent L6-L7 joint was significantly less mobile than L7-S1, confirming what has been shown in previous studies.[27-29] The L6-L7 segment showed a slightly higher mobility in lateral bending compared to extension and flexion, in contrary to a previous study.[29] These small differences (of a few degrees) between the current study and previous reports are likely explained by variations in test conditions. Coupled motion values in lateral bending and axial rotation in the present study might have shown higher values compared to a previous study[29] due to suboptimal technique of potting and/or digitization.

Decompressive surgery, with annulectomy and discectomy, **increased L7-S1 motion in extension but not in flexion or lateral bending**, as compared with the intact specimen. Results from human cadaveric studies have shown that annulus injury with discectomy alters the mechanical properties of the lumbar spinal unit, however without any significance[30] Similar observations were made in our study, in accordance with results of an earlier study in dogs[19].

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Kinematics at L7-S1: The significant decrease in primary motion of the L7-S1 joint following instrumentation was anticipated and is consistent with earlier work evaluating a more traditional pedicle screw-rod system.[19] However, the design of that earlier study was such that the authors could not discriminate between motions at L6-L7 versus L7-S1.[19] In our experiment, it was possible to evaluate motions at the two levels independently, providing greater insight into spinal kinematics after stabilisation. Our results are consistent with prior biomechanical studies in humans that have shown that pedicle screw fixation, alone or in combination with an intervertebral spacer, is a very effective method for stabilizing the lumbar spine.[31,32]

Kinematics at L6-L7: Instrumentation of the L7-S1 joint resulted in alterations in motion at the adjacent segment (L6-L7), but none of these changes was statistically significant. Although a previous paper has reported that immobilization of the canine lumbar spine with a pin and clamp construct increased segmental motion at the adjacent segment[33], our results did not support this for the lumbosacral spine. Given the inherent variance in spinal motions in the intact and destabilised spines, and the potential confounding influence of differences in specimen size, it is perhaps not surprising that we were unable to identify a significant change at L6-L7. It is very possible that the limited sample size resulted in an increased risk of a type II (false negative) error. As a result, we remain cautious in interpreting the data relating to L6-L7 and would not exclude the possibility of adjacent level pathology ("domino lesion") following rigid spinal fixation of the L-S junction.[33]

Use of polyaxial clamps: Although we describe the screws in this system as being pedicle screws, this is not correct in the purest sense. True pedicle screws are inserted

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so that they run between the lateral and the medial walls of the pedicle.[12,15,19,20] In this system, the screws enter the pedicle but then deviate into the vertebral body. Cadaveric studies have shown that angulation of screws can increase screw pull-out strength in the lumbar spine.[17] Angling screws also makes it possible to achieve purchase in better quality bone and to avoid encroachment into critical anatomical structures such as the L6-L7 intervertebral space[13] and the sacro-iliac joint.[34] The novel implants used in this study and in clinical cases are made of titanium. Titanium spinal implants have been shown to have greater flexion stiffness in one-level instability compared to stainless steel constructs[35], and people treated with titanium spinal implants were presented less often with late postoperative infections than those treated with stainless steel spinal implants.[35] Titanium alloy has found to be an appropriate material for dorsal spinal instrumentation rods because of its low weight, high biocompatibility and high tensile strength.[36]

Distraction bolt: Interbody cages have improved the fusion rates for spine surgery in humans[37] by allowing bone to grow from one vertebral endplate to the adjacent endplate via fenestrations in the cage. A threaded cage augmented with pedicle screw fixation is considered safe and effective for the treatment of lumbar and lumbosacral instability in humans, with a 96% fusion rate after 2 years.[22] The titanium distraction bolt used in the present study is tapered and cone-shaped, with fenestrations opposite each vertebral endplate and covered with hydroxyapatite. Hydroxyapatite (HA) has been shown to have excellent osteoconductive properties making it a useful scaffold where bone regeneration is needed.[38] This device has previously been used in conjunction with String-of-Pearl plates to achieve cervical distraction-stabilization in dogs.[39] The rationale for using it in combination with the screw-rod system was that

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in addition to facilitating fusion, it will provide effective load sharing and decrease the risk of fatigue and subsequent implant failure.[26] To introduce the distraction bolt into the L7-S1 intervertebral space in-vivo, the cauda equina is retracted using a long, narrow instrument.[40]

Limitations: As with any cadaveric experiment, this study has a number of limitations that should be considered when interpreting the data. The potential impact of the relatively small sample size on statistical power has been mentioned. The absence of active muscle control means that the results from this study likely best reflect passive range of motion across L6-L7 and L7-S1. Every effort was made to eliminate motions outside of L6-L7 and L7-S1, but some residual instability may still have remained. We made a decision to limit testing to a maximum of 150N as this limit had been reported previously[26] and produced visible movements without any sign of impingement between the vertebrae. Testing was also limited to left lateral bending, although we felt that this was justifiable in terms of the symmetrical arrangement of the instrumentation around the spine. Finally, the new instrumentation was not tested against any other technique for lumbosacral instrumentation; comparative testing of this sort might have given valuable information about the performance of the different systems, especially with regard to discriminating the effects of instrumentation in general from those specific to a given implant system.

Conclusion

Application of a polyaxial screw-clamp fixation system in combination with an intervertebral distraction bolt has not been reported previously in the veterinary literature. The results from this cadaveric study demonstrate that the new implant

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system restores stability to the lumbosacral junction following destabilisation, and supports application of this technique for the management of DLSS in dogs.[40,41] Clinical studies will be needed to determine the safety and long-term efficacy of the new fixation system, especially with regard to potential domino lesions at adjacent spinal levels.

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FIGURE LEGENDS

Fig 1. Photographs of the intervertebral distraction bolt (top: side view, bottom: view from on top) and the components of the pedicle-screw rod fixation system: clamp, 3.5mm polyaxial screw, washer (bottom, notice the dipped inner circle and the indentation of the rim to accommodate the dumbbell-shaped rod), nut (top) and dumbbell-shaped connecting rod (from left to right).

Fig 2. Illustrations of the instrumented spine in the lateral (A) and transverse (B, C) planes, demonstrating the positioning and the trajectories of the pedicle screws, intervertebral distraction bolt, TTA screw, clamps and connecting rods.

Fig 3. Dorsoventral radiograph of canine specimen with the cranial (L5) and caudal (S3-Cd1) ends of the specimen potted in polyester resin and with the L-S junction centred between the potted ends. The L5-L6, S3-Cd1 and sacroiliac joints were immobilized with wood screws. For additional holding power, wood screws were inserted through the acetabulum into the ilial body, protruding 1cm within the potting medium. The cranial parts of the ilial wings have been removed. Drill holes, used as digitization points for the motion capture system, are visible bilaterally in the transverse processes of L6 and L7 and the base of the spinous processes of L6 and L7.

Fig 4. Photographs of the cadaveric specimen (A) in dorsal view after dorsal laminectomy and annulectomy, (B) in dorsolateral view with the intervertebral spacer connected to the applicator instrument while the spacer is screwed into the intervertebral space (note the Ellis pin for the motion tracker cranial to the applicator

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and the spacer), (C) in dorsolaterocaudal view showing the polyaxial screws, clamps on both sides and a connecting rod applied on the right side.

Fig 5. Ventral (A) and right lateral (B) view of the stripped specimen (L6-S1) with digitization landmarks in two planes, marked with a drill hole and tissue marking dye. The sagittal plane was defined by two digitization points cranial and caudal at the endplates in the ventral median plane (A, arrows) or cranial and caudal at the base of the spinous process (B, arrows). The transverse plane was defined by symmetric digitization points on the transverse processes (A, B –arrow heads).

Fig 6. Illustration of the biomechanical test set-up showing a representative lumbosacral specimen with ends potted in PVC cylinders. Retro-reflective optical trackers are rigidly attached to the vertebrae. The specimen is mounted on a 4-point bending jig and aligned with a servo-hydraulic materials testing machine.

Fig 7. Study design, illustrating the sequential testing as intact, destabilized and finally instrumented specimens.

Fig 8. Transverse computed tomography images of instrumented specimens. A, B: Images through the L7 vertebra demonstrating optimal (left screw in 8A, right screw in 8B), acceptable (right screw, 8A) and unacceptable (left screw, 8B) placement of pedicle screws. C: Image through S1 shows optimal (right screw) and acceptable placement (left screw) of pedicle screws and the TTA screw just ventral to the spinal canal. D: The transverse image through the L7-S1 intervertebral space depicts the

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intervertebral distraction bolt positioned vertically within the intervertebral disc space, with its base lying flush with the ventral surface of the vertebral canal.

Fig 9. Bar graphs comparing the angular displacement of the L6-L7 (grey) and L7-S1 (black) segments in intact, destabilized and instrumented spines under 150N of axial loading, resulting in flexion (A), extension (B) and left lateral bending (C) as primary motion. **Lines indicate significant differences (and associated p-values) between treatments or levels, as appropriate.**

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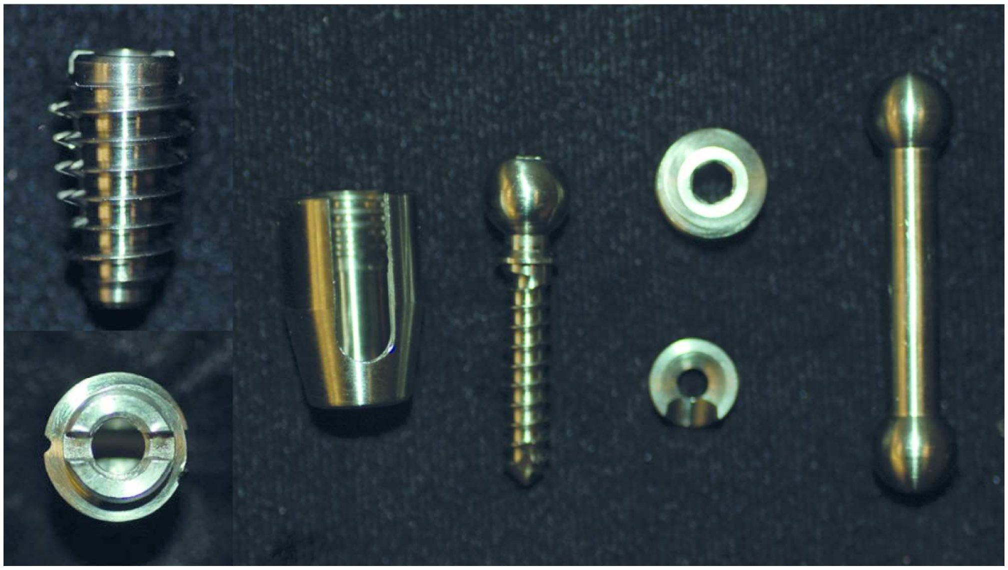

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195x110mm (300 x 300 DPI)

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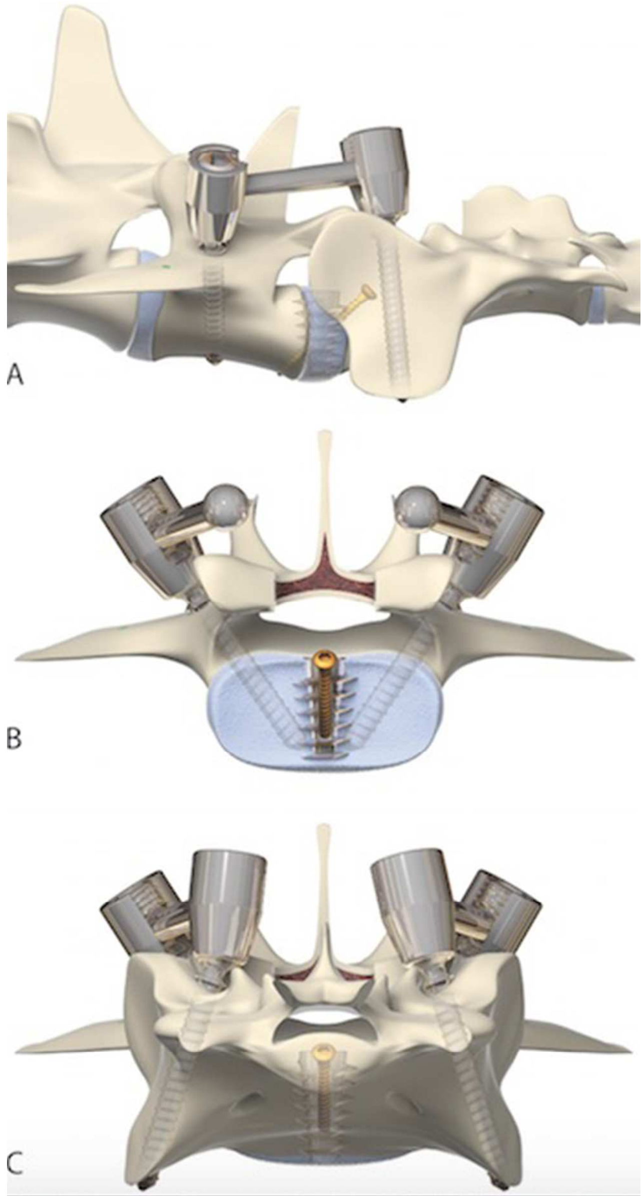
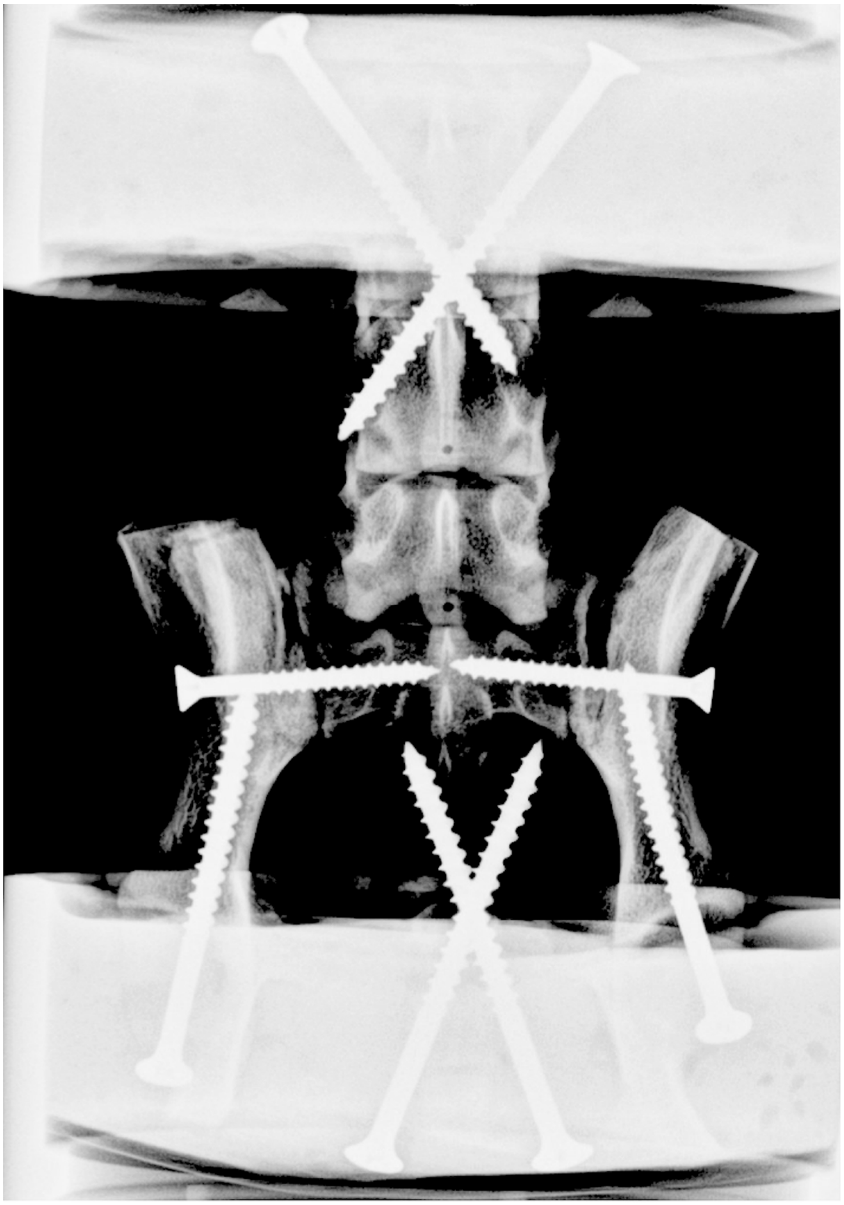


Fig 2. Illustrations of the instrumented spine in the lateral (A) and transverse (B, C) planes, demonstrating the positioning and the trajectories of the pedicle screws, intervertebral distraction bolt, TTA screw, clamps and connecting rods.

80x151mm (300 x 300 DPI)



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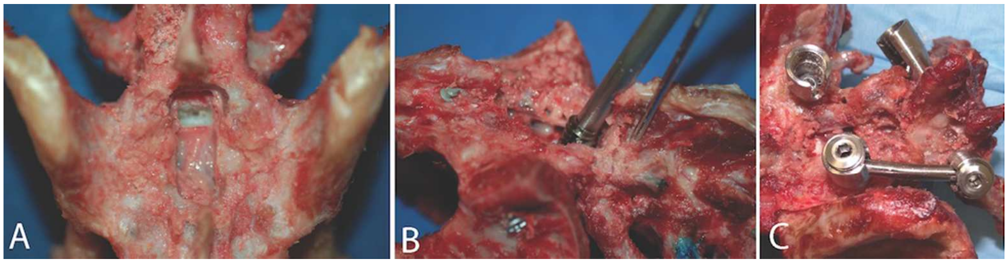
91x130mm (300 x 300 DPI)



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150x38mm (300 x 300 DPI)

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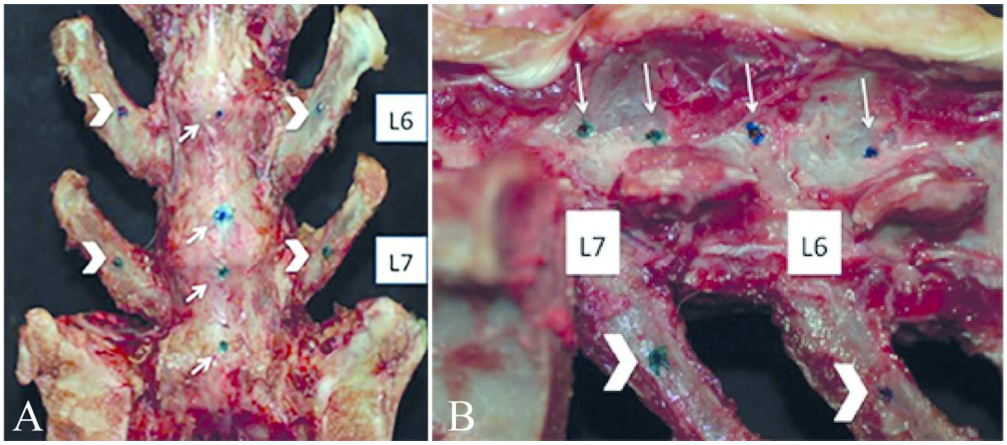

Fig 5. Ventral (A) and right lateral (B) view of the stripped specimen (L6-S1) with digitization landmarks in two planes, marked with a drill hole and tissue marking dye. The sagittal plane was defined by two digitization points cranial and caudal at the endplates in the ventral median plane (A, arrows) or cranial and caudal at the base of the spinous process (B, arrows). The transverse plane was defined by symmetric digitization points on the transverse processes (A, B –arrow heads).

144x62mm (300 x 300 DPI)

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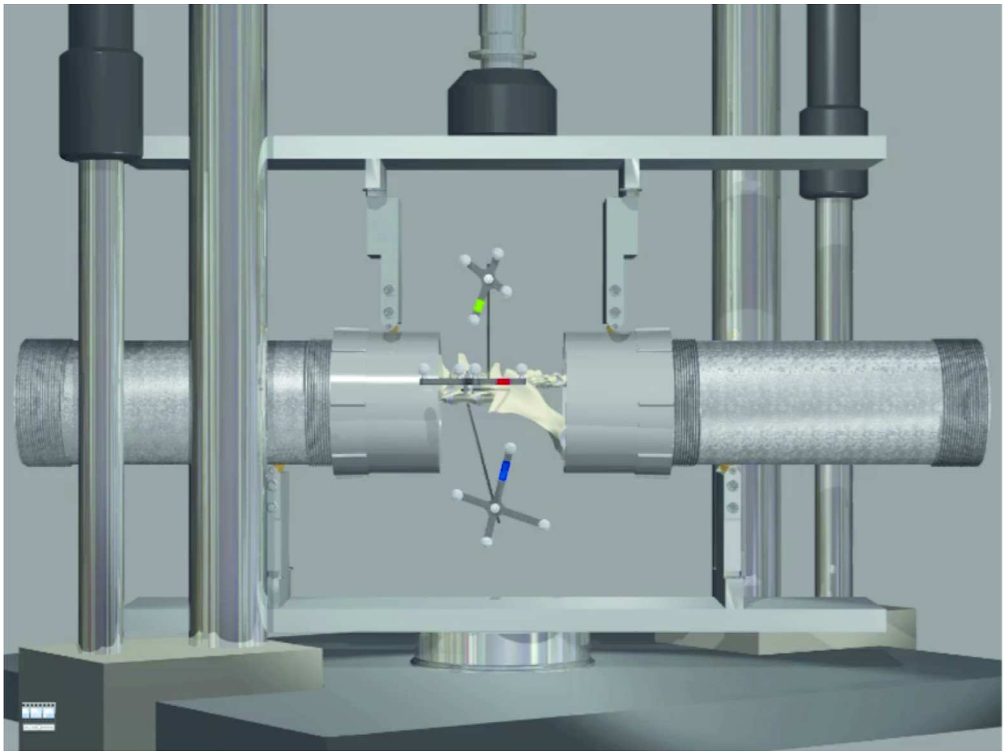
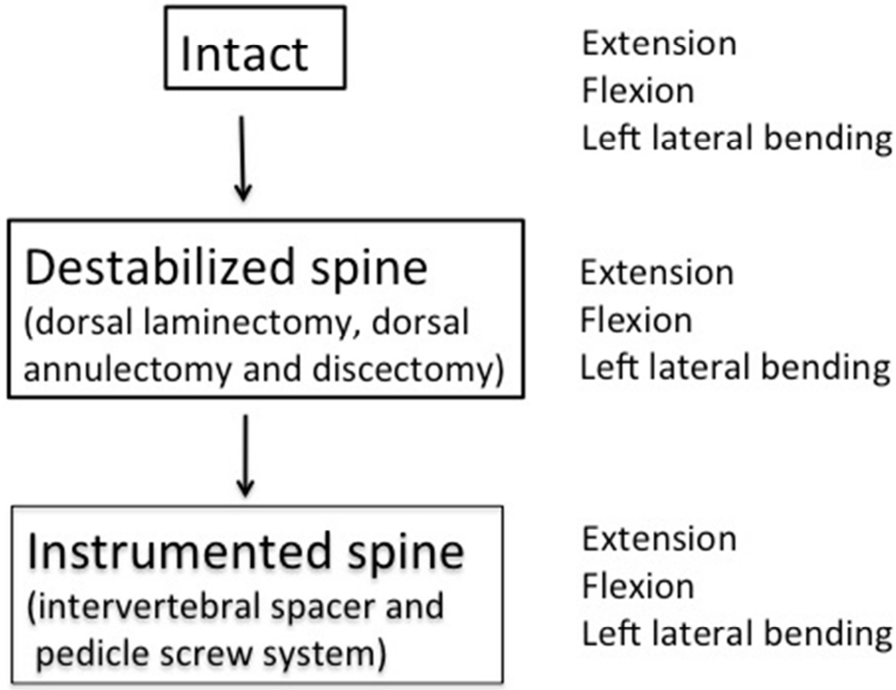


Fig 6. Illustration of the biomechanical test set-up showing a representative lumbosacral specimen with ends potted in PVC cylinders. Retro-reflective optical trackers are rigidly attached to the vertebrae. The specimen is mounted on a 4-point bending jig and aligned with a servo-hydraulic materials testing machine.

146x109mm (300 x 300 DPI)

view



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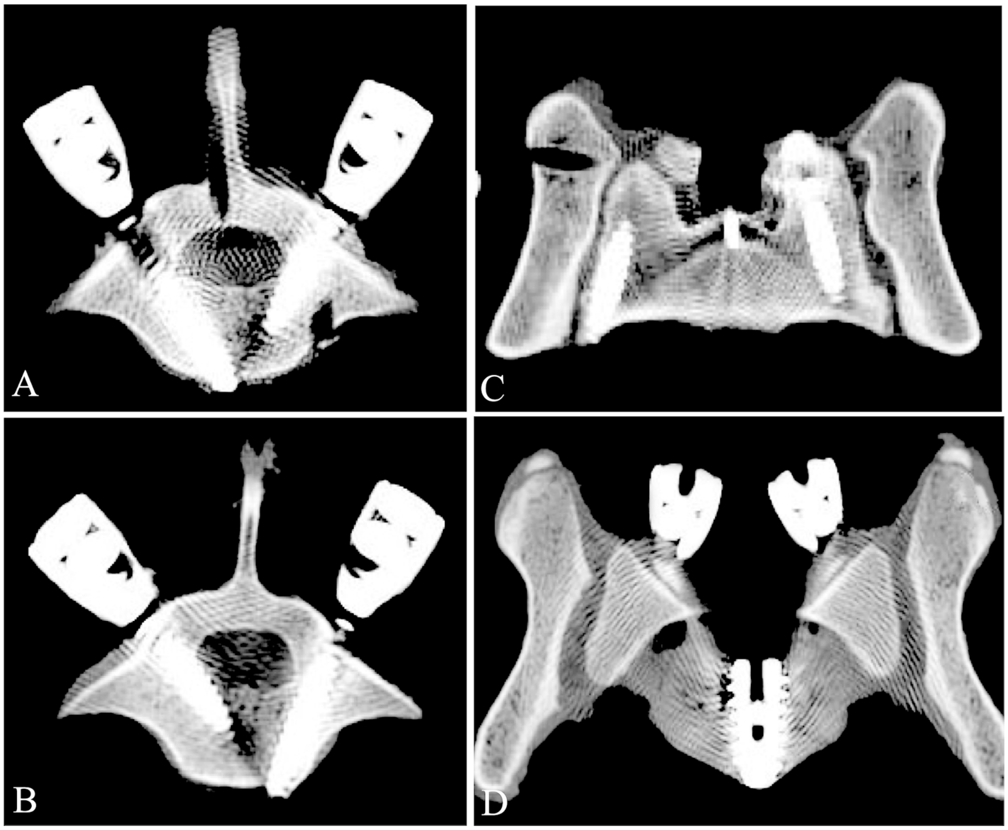
119x92mm (300 x 300 DPI)

view



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168x138mm (300 x 300 DPI)

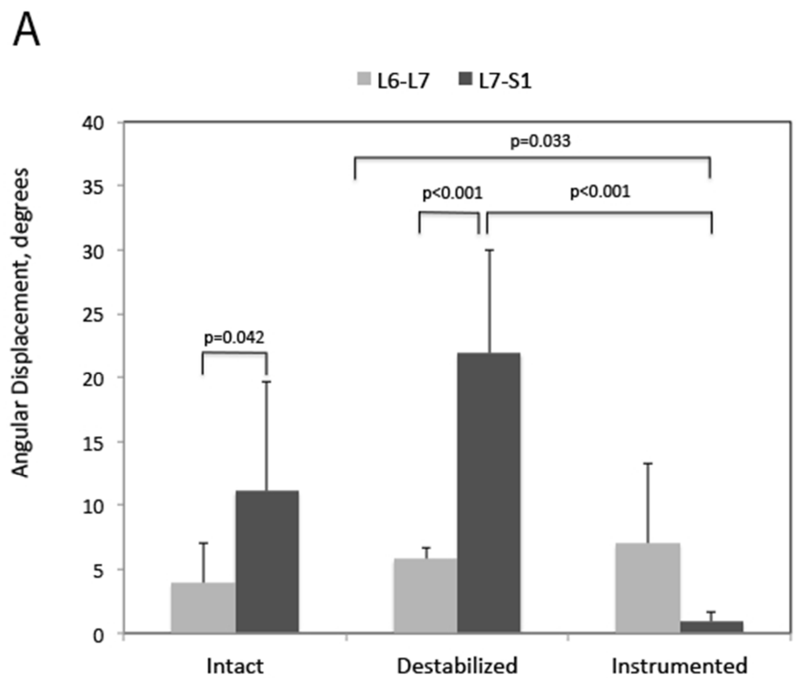
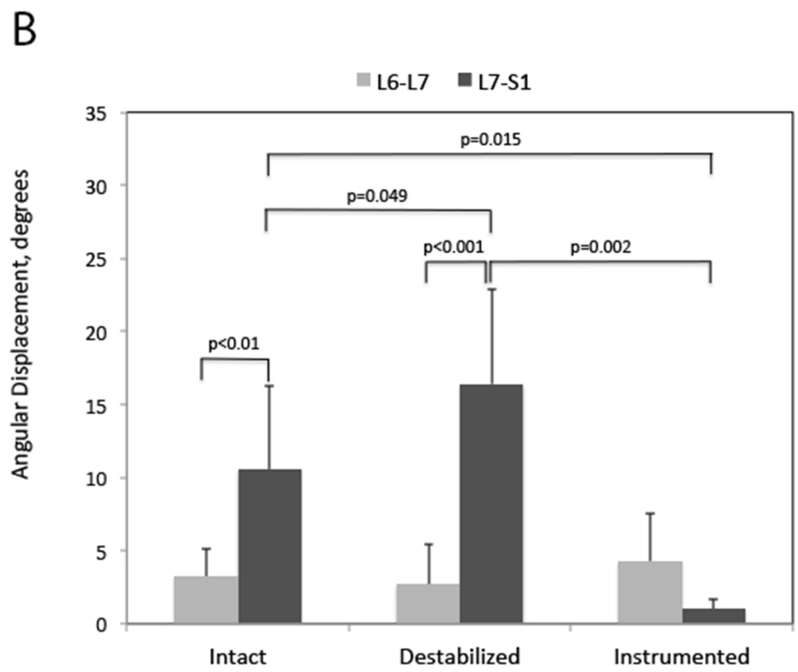


Fig 9. Bar graphs comparing the angular displacement of the L6-L7 (grey) and L7-S1 (black) segments in intact, destabilized and instrumented spines under 150N of axial loading, resulting in flexion (A), extension (B) and left lateral bending (C) as primary motion. Lines indicate significant differences (and associated p-values) between treatments or levels, as appropriate.

229x184mm (72 x 72 DPI)



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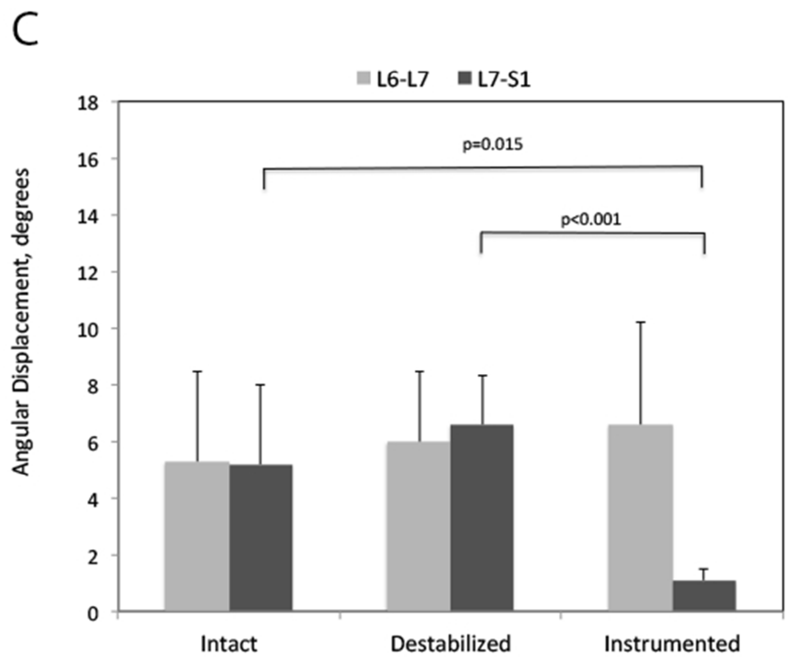
229x184mm (72 x 72 DPI)



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229x184mm (72 x 72 DPI)

Table 1. Number of pedicle screws (L7 and S1) with optimal, acceptable or unacceptable placement, evaluated post-operatively on computed tomography using a modified classification system.

Placement	L7 screws	S1 screws
Optimal	9/16	15/16
Acceptable	5/16	1/16
Unacceptable	2/16	0/16

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Table 2. Primary motions at L6-7 and L7-S1 in the cadaveric canine lumbosacral spine in the intact state, following destabilization (dorsal laminectomy and partial discectomy at L7-S1) and after instrumentation at L7-S1 segment with the novel fixation system. Primary motions, in degrees, are reported as mean ± SD (range) for flexion, extension and lateral bending tests performed under 150N loading.

			L6-L7			L7-S1	
	Primary Motion	Intact	Destabilized	Instrumented	Intact	Destabilized	Instrumented
VD	Flexion	3.9 ± 3.2	5.8 ± 0.9	7.0 ± 6.3	11.1 ± 8.5[c]	20.0± 9.3[c]	0.9 ± 0.7[ab]
DV	Extension	3.2 ± 1.9	2.7 ± 2.7	4.3 ± 3.2	9.8 ± 5.7[bc]	16.4 ± 6.5[ac]	1.0 ± 0.7[ab]
ML	Lateral bending	5.3 ± 3.2	6.0 ± 2.5	6.6 ± 3.6	5.2 ± 2.8[c]	6.6 ± 1.7[c]	1.1 ± 0.4[ab]

Superscript letters denote significant differences ($p<0.05$) from intact[a], destabilized[b] or instrumented[c] specimens.

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Table 3. Coupled motions (axial rotation or lateral bending) at the L7-S1 segment in the intact spine, following destabilization (dorsal laminectomy-partial discectomy at L7-S1) and after instrumentation with the novel fixation system. Data, in degrees, are reported as mean ± SD for flexion, extension and lateral bending tests performed under 150N loading.

Loading Direction	Secondary Motions	Intact	Destabilized	Instrumented
Flexion	Axial rotation	9.4 ± 8.3	11.5 ± 8.2^{c}	0.9 ± 0.7^{b}
	Lateral bending	10.6 ± 11.1	4.2 ± 6.8	0.7 ± 0.5
Extension	Axial rotation	12.5 ± 8.8^{c}	10.2 ± 7.0^{c}	0.5 ± 0.4^{ab}
	Lateral bending	12.4 ± 5.7^{c}	8.5 ± 4.7^{c}	0.6 ± 0.6^{ab}
Lateral bending	Axial rotation	4.7 ± 2.5^{c}	4.4 ± 2.9^{c}	0.4 ± 0.3^{ab}

Superscript letters denote significant differences ($p<0.05$) from intact[a], destabilized[b] or instrumented[c] specimens.

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