



# Effect of a titanium cage as a stand-alone device on biomechanical stability in the lumbosacral spine of canine cadavers

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## ABSTRACT

Degenerative lumbosacral stenosis is a common disease in dogs characterised by intervertebral disc herniation, loss of disc height and stenosis. Decompressive dorsal laminectomy and partial discectomy can cause spinal instability and worsen foraminal stenosis. Pedicle screw and rod fixation (PSRF) with an intervertebral body cage allows for distraction and restoration of disc height and restores foraminal apertures. The aim of this study was to evaluate the ex vivo biomechanical properties of a titanium intervertebral cage alone and in combination with PSRF in the lumbosacral spine of dogs. The range of motion, neutral zone, neutral zone stiffness and elastic zone stiffness of the lumbosacral joint (L7–S1) of nine canine cadavers were determined in flexion/extension, lateral bending and axial rotation for four conditions: (1) native (unmodified) spine; (2) dorsal laminectomy and discectomy; (3) stand-alone cage; and (4) cage in combination with PSRF. The intervertebral disc height decreased after dorsal laminectomy, but increased after insertion of the cage. Insertion of the stand-alone cage decreased the range of motion and neutral zone compared to the laminectomy–discectomy and increased neutral zone stiffness in all directions. The range of motion further decreased after PSRF. From a biomechanical point of view, the use of a stand-alone intervertebral cage is a potential alternative to dorsal fixation of the lumbosacral junction, since it increases spinal stability and restores disc height.

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## Introduction

Degenerative lumbosacral stenosis is a common disease in large breed dogs. It is characterised by intervertebral disc degeneration, disc herniation, loss of disc height, proliferation of soft tissue and bone, and foraminal stenosis. Lumbosacral stenosis and compression of the cauda equina cause low back pain and lameness. Dorsal laminectomy and partial discectomy result in clinical improvement in 66.7–96.5% of treated dogs (Meij and Bergknut, 2010), but propulsive forces are not restored after decompressive surgery in dogs with degenerative lumbosacral stenosis compared with healthy control dogs (Suwankong et al., 2007). Recurrence of clinical signs has been reported in 18% of dogs after dorsal laminectomy (Danielsson and Sjöström, 1999). Laminectomy and discectomy cause further loss of disc height and stenosis of foraminal apertures, and decrease the stability of the lumbosacral junction (Smolders et al., 2012; Early et al., 2013), thereby accelerating the development of degenerative changes (Meij et al., 2007; Tobias and Johnston, 2012). Additionally, the continued mobility and increased instability

contribute to a higher risk for clinical complications related to the nerve roots (Jones et al., 2008; Tobias and Johnston, 2012; Jeffery et al., 2014).

Dorsal fixation–fusion of the lumbosacral junction provides stability and may prevent subsequent degenerative changes. Distraction restores the disc height and opens the foraminal apertures, thereby relieving the pressure on neural tissues. Biomechanical evaluation in canine lumbosacral spines has shown increased stability of the lumbosacral joint after pedicle screw–rod fixation (PSRF) following dorsal laminectomy (Meij et al., 2007). In vivo evaluation of PSRF in a pilot study of three dogs (Smolders et al., 2012) and in a study including 12 dogs with severe degenerative lumbosacral stenosis (Tellegen et al., 2015) demonstrated improvement of clinical signs and improved pelvic limb function relative to the preoperative function, as revealed by force plate analysis, owner questionnaires and clinical examination. However, disadvantages of PSRF are increased surgical time and risk of complications, the possibility of implant failure and the risk of fracturing the articular process, especially when prior distraction is used. This might in part be due to the lack of a ventral stabilising construct, such as an intervertebral spacer.

Fixation via intervertebral fusion can be achieved after implantation of an intervertebral cage. This technique has been used in dogs

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to treat disc-associated cervical spondylomyelopathy (da Silva et al., 2010; Steffen et al., 2011). Increased stability of cervical spinal segments C4–C7 was demonstrated in canine cadavers following implantation of a titanium cage (Schöllhorn et al., 2013). Clinical studies showed neurological improvement after cervical spine distraction/fusion using an intervertebral cage (da Silva et al., 2010; Steffen et al., 2011). However, no studies exist examining the use of intervertebral titanium cages in lumbosacral disease. Therefore, we sought to evaluate the biomechanical properties of a titanium cage as a stand-alone device and in combination with PSRF in lumbosacral junction of canine cadaveric spines.

## Materials and methods

### Specimens

Nine spinal segments were collected from the cadavers of healthy mixed breed dogs, euthanased in unrelated experiments approved by the Ethics Committee on Animal Experimentation of Utrecht University (DEC: 2014.II.08.064; 2013.III.08.054). The range of ages of the dogs was 1.7–3.2 years (median 2.8 years) and range of weights was 22–33 kg (median 27.2 kg). The segments showed no sign of degenerative disc disease on macroscopic and radiographic examination. All surgical procedures were performed by an experienced neurosurgeon (B.P. Meij), ensuring uniform circumstances for comparison of the different lumbosacral spine conditions.

### Preparation and testing of the specimens

Specimens were prepared and tested as described by Meij et al. (2007). Before testing, specimens were thawed to 4 °C and the spinal segment from lumbar vertebrae L4–L5 to caudal vertebrae Cd1–Cd2 was prepared by removing the soft tissues unrelated to the biomechanical stability of the lumbosacral junction, leaving axial spinal muscles and ligaments in place. In order to achieve optimal fixation, iron screws were inserted in the vertebral bodies of L5 and sacral vertebrae S3–Cd1. L5 and S3–Cd1 were fixed in neutral position in the metal cups, which were subsequently filled with heated alloy (Cerro-low147; Cerro Metal Products Company), consisting of bismuth (48%), lead (25.6%), tin (12.8%), cadmium (9.5%) and indium (4%). During preparation and testing, specimens were sprayed regularly with saline (0.9% NaCl) in order to keep them moist.

The spinal segments were placed in a four-point bending device. Load was applied to this device by a hydraulic materials-testing machine (Instron Model 8872, Instron Corporation IST) attached to the bending device. The loading protocol was displacement-controlled with a maximum bending moment of 3 Nm. A cyclic bending moment from 3 to –3 Nm was repeated three times in order to complete one series of recordings (Fig. 1). The data of the third cycle of each recording were used for further analysis.

The range of motion (ROM), neutral zone (NZ), neutral zone stiffness (NZS) and elastic zone stiffness (EZS) of the spinal segments were determined in three directions (flexion/extension, lateral bending and axial rotation) for each of the four groups. The conditions of the spine were tested in the following sequence: (1) native (unmodified) spine; (2) surgical dorsal laminectomy and partial discectomy; (3) insertion of the cage; and (4) stabilisation using dorsal pedicle screw-rod fixation.

Firstly, the native spine was tested, measuring the displacement of both loading directions in flexion–extension, lateral bending and axial rotation. These data were subsequently used as baseline values. Therefore, each spine served as its own control.

Secondly, surgical dorsal laminectomy and partial discectomy were performed as described by Meij et al. (2007). The interspinous ligament and the spinous processes of L7 and S1 were removed with a rongeur, two thirds of the caudal lamina of L7 and the lamina of S1 were removed using an electrical burr, after which the ligamentum flavum was resected. The cauda equina was retracted laterally and, using a scalpel number 11, a rectangular window was removed from the dorsal annulus fibrosus, followed by complete removal of the nucleus pulposus with a ball-tipped probe and grasping forceps.

Thirdly, to allow insertion of the cage, the spinal segment L7–S1 was distracted with a Gelpi retractor and the cauda equina was retracted laterally. The cartilaginous layers of endplates were removed using a curette preserving the cortical bone of the endplate. A trial cage (Curved trial implant, 396.610, DePuy Synthes) was inserted using an implant holder (396.891, DePuy Synthes) to determine if the implant would fit accurately between the end plates. When necessary, the annulus fibrosus window was enlarged. After reaching the correct fit, a titanium cage with a height of 4.5 mm (SynCage-C short implant, curved cage, 495.221S, DePuy Synthes) was inserted in the disc space.

Fourthly, the spine was further stabilised using PSRF. Four 25 mm long, 4.2 mm wide titanium pedicle screws (USS Small Stature, DePuy Synthes) were inserted as described by Meij et al. (2007) and were connected using two titanium rods with a diameter of 6 mm and a length of 50 mm.

### Assessment of the intervertebral disc height and the width of the foraminal aperture

After each testing step, digital dorsoventral and lateral radiographs were obtained (Fig. 1). The radiographs were examined using a RadiAnt DICOM Viewer (Version 2.2.3, Medixant). Intervertebral disc heights were measured on the lateral radiographic views and the average disc height, obtained from the dorsal, middle and ventral portions of the intervertebral disc, was divided by the average L7 length, resulting in a disc height index (DHI) (Willemis et al., 2015). The width of the foraminal aperture was measured similarly and divided by the average L7 length, resulting in a foraminal width index (FWI).

### Data and statistical analysis

For each condition of the spinal segments, the total ROM of flexion/extension, lateral bending and axial rotation was calculated. In addition, for the flexion/extension direction, the respective ROMs were determined. The total ROM was defined by the range of angular displacement between the minimum (–3 Nm) and the maximum (3 Nm) loads. This total ROM was additionally divided in the ROM between –3 Nm and 0 (the ROM during extension) and the ROM between 0 and 3 Nm (the ROM during flexion) for the flexion/extension direction.

Measurement of the neutral zone of the spine segment provides information about the range over which a motion segment moves freely with minimal resistance. Therefore, we considered the neutral zone (NZ) as the region with low bending stiffness and determined by calculating the angular displacement between –0.1 Nm and +0.1 Nm. The stiffness of this zone (NZS) was calculated from the upward slope of the load–displacement curve. The elastic zone stiffness (EZS) provides information about the relative elastic deformation of the spinal segment and is defined as the slope of the elastic zone. The total ROM, NZ, NZS and EZS were calculated for the directions flexion/extension, lateral bending and axial rotation.

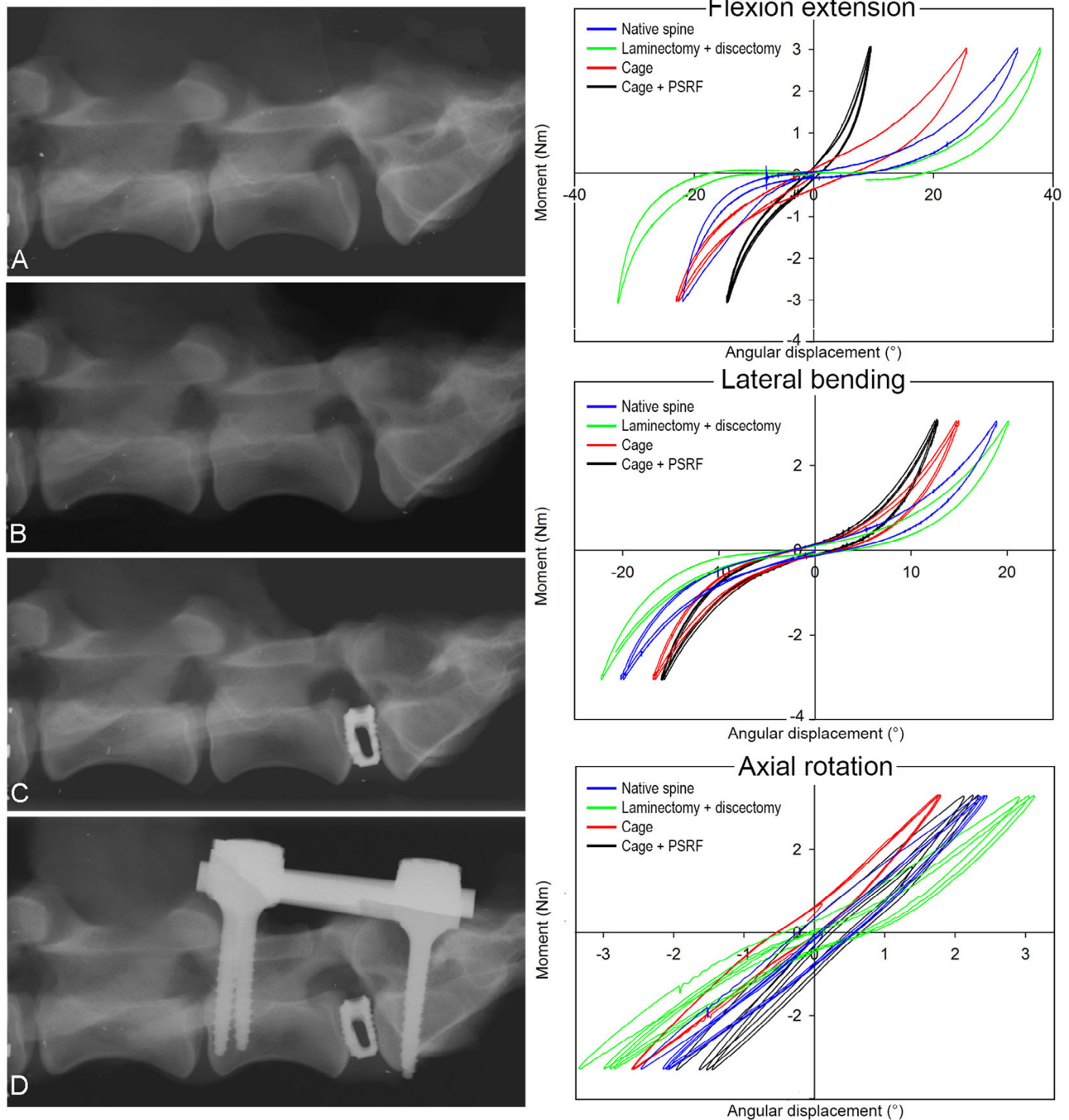
Statistical analysis was performed using R statistical software version 3.0.2. A linear mixed model was used to analyse DHI, FWI, ROM, NZ, NZS and EZS, containing both fixed and random effects. The condition of the spine (native, laminectomy-discectomy, cage alone and cage with PSRF), and the interaction between these groups were taken as a fixed effect, while the canine donor was taken into account as a random effect. The optimal model was chosen based on the Akaike Information Criterion. The normal distribution of the data was assessed with a QQ plot and Shapiro–Wilk normality test of the residuals. In order to correct for multiple comparisons, a Benjamini–Hochberg correction was applied. A *P* value of <0.05 was considered to be significant. The corresponding Cohen's *d* effect size (ES) and confidence interval (CI) were calculated.

## Results

The laminar defect after surgical dorsal laminectomy had a median length of 29.2 mm (range 20–35 mm), a median width of 12.1 mm at the level of L7 (range 9–20 mm) and a median width of 15.8 mm at the level of S1 (range 11–20 mm). The median width of the dorsal fenestration of the annulus fibrosus was 9.6 mm (range 9.1–13.7 mm) and the median length was 3.1 mm (range 2.2–4.0). Insertion of the cage was possible in all nine spinal segments and no implant failure or migration was observed during testing of the segments. All pedicle screws were inserted adequately and completely as assessed by visual inspection, palpation and radiography. During insertion, no fractures of the articular facets of L7 occurred and no failure or loosening of the pedicle screws was found during testing. At removal of the implants, the pedicle screws and the cage were found to have a proper engagement with bone.

DHI decreased after dorsal laminectomy and discectomy compared to the native spine segment (ES 0.33, CI 0.25–0.42, *P* = 0.14; Fig. 2A). Subsequently, DHI increased after insertion of the cage compared to the laminectomy-discectomy spinal segments (ES 1.08, CI 1.02–1.17, *P* < 0.01). The FWI increased after insertion of the cage compared to the native spine (ES 0.69, CI 0.64–0.76, *P* < 0.01) and the laminectomy-discectomy spinal segments (ES 0.76, CI 0.71–0.80, *P* = 0.01; Fig. 2B). There was an additional increase of the FWI after further stabilisation with PSRF (ES 0.13, CI 0.07–0.18, *P* = 0.32).

The total ROM during flexion/extension increased after dorsal laminectomy (ES 1.39, CI 3.14–5.58, *P* = 0.001) and significantly decreased after insertion of the cage (ES 2.53, CI –1.99 to 6.31, *P* < 0.001; Fig. 3A). After PSRF, the total ROM decreased further (ES 0.33, CI 2.55–8.20, *P* < 0.001) (Fig. 3A). After laminectomy-discectomy, ROM increased in extension (ES 1.54, CI –1.24 to 4.64, *P* < 0.001), but not



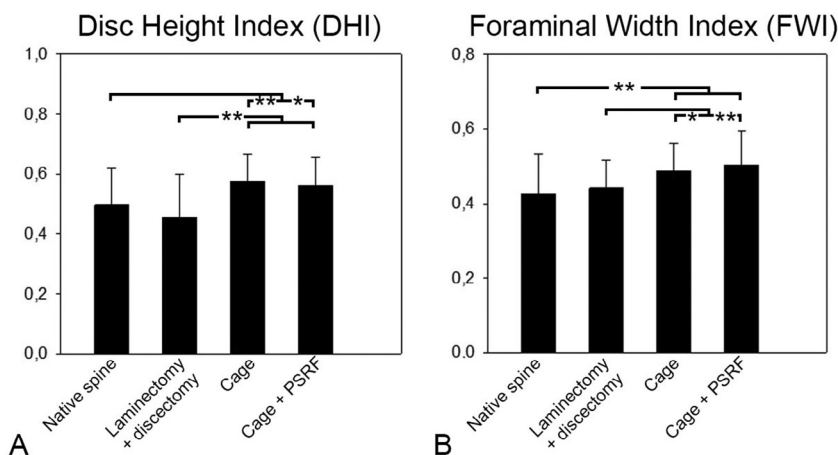
**Fig. 1.** Representative lateral radiographs of the spinal segments of the four different conditions of one canine donor: (A) native spine; (B) laminectomy and discectomy; (C) stand-alone cage; and (D) the cage with additional pedicle screw-rod fixation. Representative examples of the angular displacement (°) of the spinal segments plotted against the moment (Nm) for the four tested conditions for flexion extension, lateral bending and axial rotation. Each plot shows one loading cycle, consisting of a cyclic bending moment from 3 to -3 Nm, which was repeated three times in order to complete one series of recordings.

flexion. The ROM did not differ during extension of the native spine and the spine with the stand-alone cage. The total ROM during lateral bending did not differ after dorsal laminectomy, but decreased during lateral bending after insertion of the stand-alone cage (ES 1.02, CI -3.04 to 4.16,  $P < 0.001$ ) and again after additional PSRF (ES 1.08, CI -2.1 to 3.8,  $P < 0.001$ ; Fig. 3B). The ROM increased after dorsal laminectomy during axial rotation (ES 2.22, CI 1.73–2.58,  $P < 0.001$ ), but then decreased after insertion of the cage (ES 1.23, CI 0.74–1.90,  $P < 0.001$ ; Fig. 3C). A further decrease in ROM was noted after fixation with PSRF (ES 1.13, CI 0.46–1.48,  $P < 0.001$ ). The total ROM did

not differ between the native spine and the spine with the stand-alone cage in axial rotation.

After dorsal laminectomy, NZ increased in flexion/extension (ES 2.06, CI -4.19 to 6.38,  $P < 0.001$ ) and axial rotation (ES 2.24, CI 2.20–2.26,  $P < 0.001$ ; Figs. 3A, C), whereas NZS decreased in axial rotation (ES 2.39, CI 2.18–2.59,  $P < 0.001$ ; Fig. 4C). NZ decreased and NZS increased after insertion of the cage for all directions (Figs. 3, 4). NZ decreased further in lateral bending after PSRF (ES 1.09, CI 0.46–1.53,  $P = 0.02$ ; Fig. 3B), whereas NZS increased in flexion and extension (ES 1.77, CI 1.70–1.79,  $P < 0.01$ ) and axial rotation after PSRF





**Fig. 2.** (A) Disc height index (DHI), consisting of the disc height corrected for the length of the seventh lumbar vertebra, displayed as the mean DHI for the four conditions with standard deviations. (B) Foraminal width index (FWI), consisting of the foraminal width corrected for the length of the seventh lumbar vertebra, displayed as the mean FWI for the four conditions with standard deviations. \* $P < 0.05$ ; \*\* $P < 0.01$ .

(ES 0.68, CI 0.33–1.05,  $P = 0.02$ ; Fig. 4). NZ and NZS did not differ in terms of axial rotation between the native spine and the stand-alone cage condition.

EZS increased after laminectomy-discectomy (ES 0.55, CI 0.40–0.61,  $P = 0.005$ ) and decreased after insertion of the cage during flexion and extension (ES 0.79, CI 0.73–0.81,  $P < 0.001$ ; Fig. 4A). Subsequently, EZS increased further during flexion and extension after stabilisation with PSRF (ES 4.28, CI 4.24–4.31,  $P < 0.001$ ; Fig. 4A). In lateral bending, EZS increased after stabilisation with PSRF (ES 1.32, CI 1.26–1.36,  $P < 0.001$ ; Fig. 4B). During axial rotation, EZS decreased after decompressive surgery (ES 1.17, CI 1.04–1.26,  $P = 0.004$ ) and increased after insertion of the cage (ES 0.70, CI 0.55–0.79,  $P = 0.033$ ) and after additional fixation with PSRF (ES 1.31, CI 1.14–1.47,  $P < 0.001$ ; Fig. 4C).

## Discussion

The aim of this study was to evaluate the biomechanical behaviour of a titanium stand-alone intervertebral cage in a cadaveric lumbosacral spine mimicking a surgical treatment scenario for degenerative lumbosacral stenosis. Our study demonstrated that insertion of the intervertebral titanium cage restored or increased disc height, opened intervertebral foramina and stabilised the intervertebral space when compared to dorsal laminectomy-discectomy. Additional pedicle screw-rod fixation did not improve these biomechanical variables beyond insertion of the cage alone.

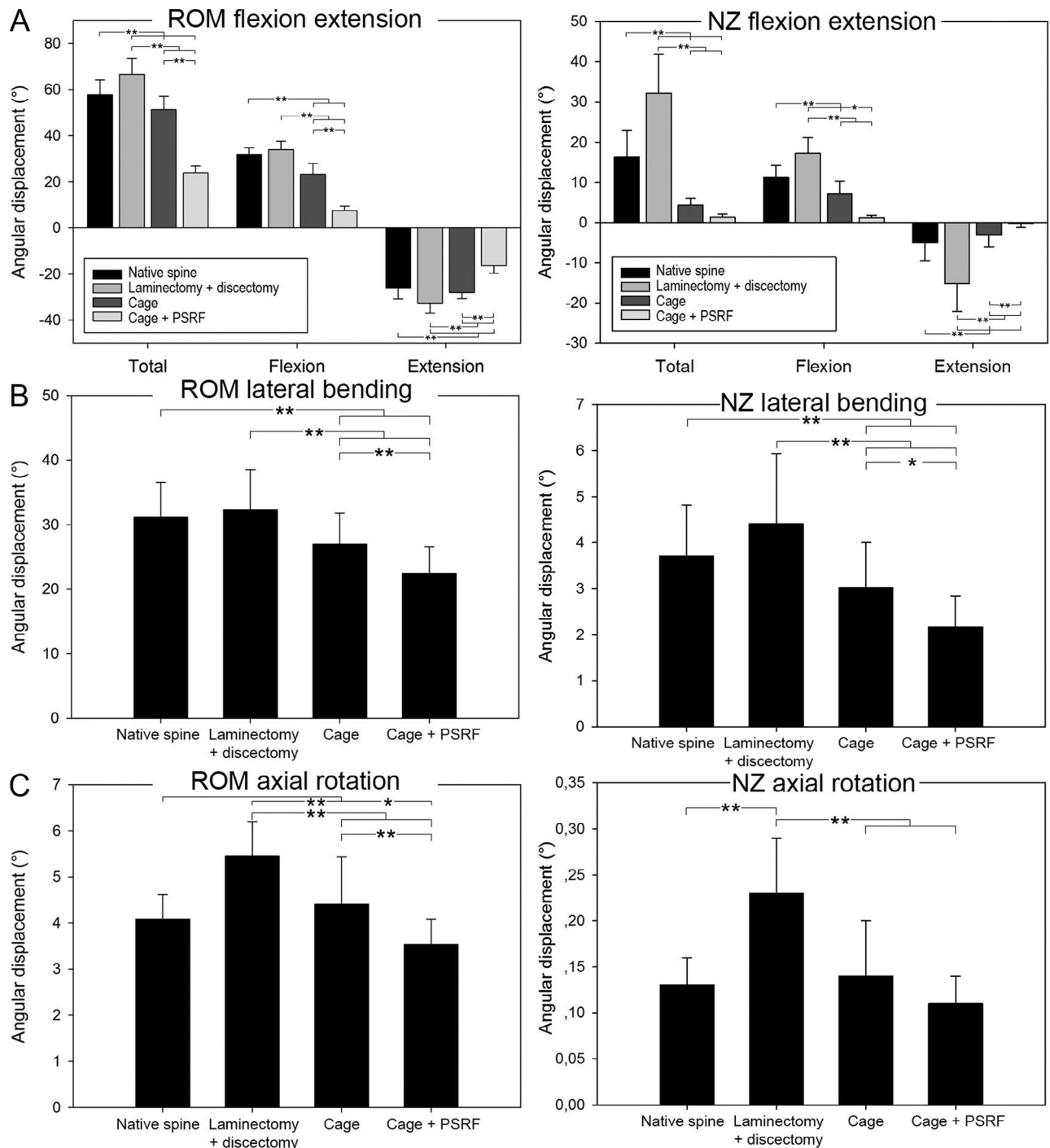
After dorsal laminectomy and discectomy, DHI decreased, as could be expected after removal of the intervertebral disc, mimicking the clinical situation in intervertebral disc disease, which is marked by loss of disc height. This decrease of DHI was reversed after insertion of the stand-alone cage, resulting in a significantly larger DHI compared to DHI in spines following laminectomy-discectomy and compared to the native (unmodified) spines. The increase in DHI compared to the unmodified spines indicates that a certain level of distraction is achieved in the lumbosacral joint after cage insertion. Given that insufficient relief of nerve compression contributes to absent or reduced clinical improvement after dorsal laminectomy (Jeffery et al., 2014), implantation of an intervertebral cage distracts and opens the foramina, thereby potentially relieving the compression of the nerves. This was underscored by our measurements of the intervertebral L7-S1 foraminal apertures, which showed a significant increase of FWI after insertion of the stand-alone cage.

After implantation of the stand-alone cage, ROM and NZ decreased, and NZS increased, in all directions compared to the laminectomy-discectomy spine. This suggests that insertion of the stand-alone cage improves stabilisation of the lumbosacral joint after decompressive surgery. In line with this, no significant difference was observed between the native spine and the spine with the stand-alone cage with respect to ROM during extension and axial rotation. In addition, NZ did not differ between the native spine and stand-alone cage in flexion/extension, as well as in the lateral bending and axial rotation. Altogether, this indicates that the stand-alone cage has the potential to provide similar stability to the intact intervertebral disc in the native spine immediately after surgery. It is predicted that, in vivo in the long term, the titanium cage, especially if loaded with bone graft material, will promote ingrowth of bone and fuse the vertebrae together, resulting in a more rigid spinal segment.

Fusion of the vertebrae was observed in two in vivo studies employing different models of a stand-alone cage in goats (van Dijk et al., 2002; Kroeze et al., 2013). In a clinical study with a cervical cage implant and additional fixation with cervical locking plates, bridging of new bone through the cage was present at 6 months after surgery (Steffen et al., 2011). It remains to be determined whether cage subsidence occurs, how fast the stand-alone cage might fuse the vertebrae at the lumbosacral junction and what effect this fusion might have on LS stability and on adjacent spinal segments.

Implantation of an intervertebral stand-alone cage seems to be less technically demanding compared to PSRF. Insertion of the stand-alone cage required less consideration of the key landmarks compared to the insertion of the pedicle screws, which is regarded as a relatively demanding surgical technique with a clear learning curve (Yahiro, 1994). In addition, the insertion of screws into the pedicles carries potential risks such as fracturing of articular processes (Tobias and Johnston, 2012). However, additional protection of the cage with PSRF might reduce the risk of cage migration into the vertebrae.

The intervertebral cage used in this study (4.5 mm SynCage-C) is the smallest cage available in this series and was especially developed for smaller specimens of the human cervical spine. This cage had a good fit for the lumbosacral spine of large breed dogs, although small differences were noted between different spinal segments during insertion of the cage. In slightly larger lumbosacral segments, the cage was inserted with more ease than in smaller lumbosacral segments. This emphasises the importance of the



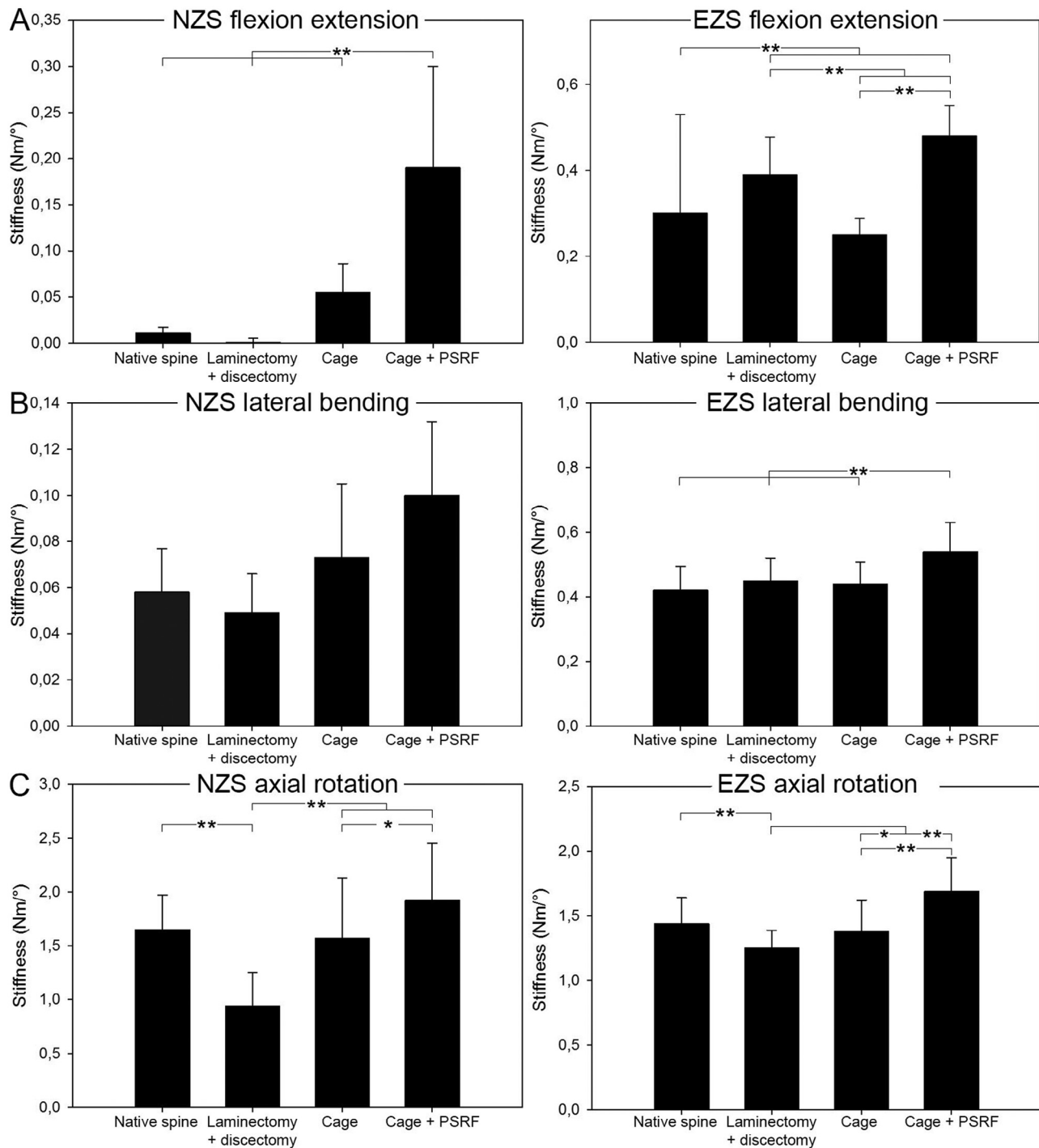
**Fig. 3.** (A) Range of motion (ROM) and neutral zone (NZ) for flexion and extension, displayed as the mean angular displacement (°) with standard deviation for each of the tested conditions. The ROM and NZ were divided in the ROM during flexion, the ROM during extension and the total ROM (flexion and extension combined). \* $P < 0.05$ ; \*\* $P < 0.01$ . (B) ROM and NZ for lateral bending displayed as the mean angular displacement (°) with standard deviation for each of the conditions. \* $P < 0.05$ ; \*\* $P < 0.01$ . (C) ROM and NZ for axial rotation displayed as the mean angular displacement (°) with standard deviation for each of the conditions. \* $P < 0.05$ ; \*\* $P < 0.01$ .

development of canine specific intervertebral cages for future use in a clinical setting.

## Conclusions

Implantation of a stand-alone, intervertebral, titanium cage increases the stability of the lumbosacral joint in canine cadavers after ex vivo dorsal laminectomy and discectomy. The insertion of a stand-alone intervertebral cage restores spinal stability to a state similar

to the native (unmodified) spine and restores the disc height and intervertebral foraminal apertures, thereby potentially decompressing more neural tissues than after dorsal laminectomy alone. Therefore, the use of a stand-alone intervertebral cage as an intervertebral fusion device could offer a promising alternative for posterior distraction and fixation/fusion of the lumbosacral spine after decompressive surgery. However, clinical studies with a long term follow-up are necessary to study the progression of the intervertebral fusion in vivo and the development of possible



**Fig. 4.** (A) Neutral zone stiffness (NZS) and elastic zone stiffness (EZS) for flexion and extension displayed as the mean stiffness (Nm/°) with standard deviation for each of the tested conditions. \* $P < 0.05$ ; \*\* $P < 0.01$ . (B) NZS and EZS for lateral bending displayed as the mean stiffness (Nm/°) with standard deviation for each of the conditions. \* $P < 0.05$ ; \* $P < 0.01$ . (C) NZS and EZS for axial rotation displayed as the mean stiffness (Nm/°) with standard deviation for each of the conditions. \* $P < 0.05$ ; \*\* $P < 0.01$ .

complications with a stand-alone intervertebral cage in patients with degenerative lumbosacral stenosis.

#### Conflict of interest statement

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The funding bodies and DePuy Synthes had no influence on the study design, data analysis and data interpretation.

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