Comparison of the Biomechanical Properties of a Ventral Cervical Intervertebral Anchored Fusion Device With Locking Plate Fixation Applied to Cadaveric Canine Cervical Spines

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Objective: To evaluate fixation properties of a new intervertebral anchored fusion device and compare these with ventral locking plate fixation.

Study Design: In vitro biomechanical evaluation.

Animals: Cadaveric canine C4–C7 cervical spines (n = 9).

Methods: Cervical spines were nondestructively loaded with pure moments in a nonconstraining testing apparatus to induce flexion/extension while angular motion was measured. Range of motion (ROM) and neutral zone (NZ) were calculated for (1) intact specimens, (2) specimens after discectomy and fixation with a purpose-built intervertebral fusion cage with integrated ventral fixation, and (3) after removal of the device and fixation with a ventral locking plate.

Results: Both fixation techniques resulted in a decrease in ROM and NZ (P < .001) compared with the intact segments. There were no significant differences between the anchored spacer and locking plate fixation.

Conclusion: An anchored spacer appears to provide similar biomechanical stability to that of locking plate fixation.

Canine disc-associated cervical spondylomyelopathy (DACSM) is characterized by dynamic and static compression of the cervical spinal cord, nerve roots, or both, leading to varying neurologic deficits.\textsuperscript{1,2} Various surgical procedures have been used for treatment of DACSM, although most can be classified as either decompressive or distraction/fusion techniques.\textsuperscript{1} The latter are commonly used in dogs with lesions that appear markedly improved with manual traction on advanced imaging.\textsuperscript{3}

Distraction/fusion techniques typically involve discectomy followed by manual or mechanical distraction of the affected segment.\textsuperscript{3} Recent data have shown that additional long-term increase in spinal canal diameter occurs beyond initial distraction because of remodeling with regression of both ligamentous and bony structures, and progression of segmental degeneration may be halted.\textsuperscript{4} Reported distraction techniques include use of Steinmann pins with polymethylmethacrylate (PMMA),\textsuperscript{5} PMMA interbody plugs,\textsuperscript{6} and locking plates.\textsuperscript{7} Other common fixation methods include implantation of an interbody cage (cortical ring allografts,\textsuperscript{8} carbon cage,\textsuperscript{8} distractable titanium cage,\textsuperscript{9,10} acrylic cage,\textsuperscript{11} or cervical disc arthroplasty\textsuperscript{12}) to restore disc and foraminal dimensions and to stabilize the segment until bony fusion has occurred. Interbody cages provide stability only through tensioning of the remaining intact ligaments and thus offer little stabilization during extension because the ventral ligamentous structures are absent after discectomy. Because the caudal area of the cervical spine is lordotic in dogs, there is a high risk of extrusion of intervertebral implants from shearing forces.\textsuperscript{8} In contrast to people and horses, where the intervertebral cage can be used as a stand-alone device, additional ventral stabilization (usually ventral vertebral body plating) against ventral dislodging is usually necessary in dogs.

With the aim of combining the benefits of an intervertebral spacer and monocortical screw fixation, a stand-alone ventral cervical intervertebral fusion device was developed. Our purpose was to compare the stabilizing properties of this anchored spacer with those of ventral plating using a locking plate after ventral cervical discectomy in canine cadaveric spine specimens. We hypothesized that the anchored spacer would provide stability approaching that of the plate construct.

MATERIALS AND METHODS

Specimens

The cervical spine region C4–C7 was harvested from 9 mature beagles euthanatized for reasons unrelated to this study. The
medical history of each dog was reviewed to exclude trauma, malignancy, or metabolic disease that might otherwise compromise the mechanical properties of the cervical spine. Computed tomography (Philips Brilliance 16-slice spiral CT, Philips Medical Systems, Cleveland, OH) was performed before dissection in all specimens to rule out evidence of spinal disease before study inclusion. CT images were evaluated by a boarded radiologist (CS).

Careful dissection was performed to preserve all ligaments, joint capsules, discs, and osseous structures. The cervical column was wrapped in a cotton towel soaked in saline (0.9% NaCl) solution and stored at -20°C. Specimens were thawed at room temperature for 12 hours before testing. During the entire preparation phase, specimens were regularly sprayed with saline and were wrapped in saline-soaked towels throughout the testing phase to prevent dehydration of the disc and adnexal structures. Segments cranial (C4–C5) and caudal (C6–C7) to the implant were made rigid with screws inserted from the middle of the disc after the longitudinal axis of the spine (Fig 1). Lengths of each vertebra were measured with a ruler. Dimension of screws were chosen to permit solid fixation of both motion units C4–C5 and C6–C7 with penetration of almost 2/3 of the C5 and C6 vertebral bodies, respectively and embedding of screw heads within PMMA. The C4 and C7 vertebral bodies were each potted into square stainless steel tubes (50 mm × 50 mm × 2 mm) using PMMA, which was allowed to dry in air for ~30 min before testing. The C5–C6 segment was freely mobile for testing.

Implants

All specimens were tested under 3 conditions in the following order: (1) intact spine segments, (2) after discectomy, and implantation of the new stand-alone anchored spacer, and (3) after removal of the spacer and application of a stainless steel locking plate (5 hole, 2.4-mm LCP, Synthes, Switzerland). The anchored spacer was a custom-made titanium device (C-Fix, Rita Leibinger GmbH & Co. KG, Neuhausen, Germany), which combines an intervertebral spacer with a conventional screw fixation mechanism that is contained within the excised disc space (Fig 2). Dimensions of the cage were based on previous MRI studies of Beagle dogs of similar size and weight scanned at our institution.

Surgical Procedures

After intact stability testing, specimens were positioned ventrodorsally and a single-level discectomy of C5–C6 was performed with an 11 scalpel blade and a rongeur, leaving the lateral and dorsal part of the annulus fibrosus and the endplates of both vertebrae intact. The dorsal longitudinal ligament was preserved in each specimen. Distraction was achieved using a modified Gelpi retractor with the tips placed in holes drilled in the cranioventral part of C5 and the caudoventral part of C6, respectively. During anchored spacer insertion or plate insertion, pre-testing CT examination was used to assess the size of the specimen and determined screw length to avoid

Figure 1 Schematic representation of the biomechanical testing system for fixation of canine vertebral specimens (C4 through C7) with a screw inserted axially in the C4–C5 and C6–C7 vertebral bodies. PMMA filled the space between each vertebra and the stainless steel tubes. The PMMA embedding partially touches the C5 and C6 vertebrae, respectively. The load was applied with 4 wheels to minimize friction. In this configuration, extension was applied and the apparatus was turned to apply flexion.

Figure 2 Photograph and schematic representation of a cervical stand-alone ventral intervertebral fusion device. The transverse view (lower left) shows the thin struts of the intervertebral part of the device. The broader ventral aspect supports the 4 screw inserting devices. The sagittal view (lower right) shows the slight convex shape matching the shape of the vertebral body.
spinal canal penetration. The intervertebral spacer was secured with 4 monocortical conventional 2.4-mm self-tapping screws angled slightly away from the intervertebral space. After completing stability tests, the anchored spacer was removed from the specimens under slight distraction, without causing further injury to the intervertebral disc space and adjacent structures. A vertebral distractor was placed to allow the same amount of distraction created by the spacer. Degree of distraction was controlled with a ruler and testing was repeated after fixation with a ventrally applied locking plate. The plate was secured with 2 monocortical locking screws in each vertebral body. The central hole of the plate, lying over the intervertebral space, was left free of screws.

**Mechanical Testing**

Construct were loaded by 4-point bending performed on a servo hydraulic testing machine (MTS Mini Bionix 858, MTS Systems Corporation, Eden Prairie, MN; Fig 1). Three load/unload cycles (displacement controlled mode) from 0 to 50 N total force with a constant velocity of 0.2 mm/s (0.40°/second) were applied. Crosshead displacement and total force were recorded at a sampling frequency of 25 Hz. Considering the change of lever arm and effective force depending on the bending angle, the maximum loading moment was between 1.1 and 1.4 N m (initial lever arm of 60 mm). The load limit was set to 50 N based on a pilot study (results not shown) reaching a plateau of the sigmoidal displacement curve. The pilot testing was continued until failure, revealing embedding failure at >250 N.

The primary stiffness afforded by implants was measured in terms of the range of motion (ROM) and neutral zone (NZ) of the vertebral specimen instrumented with the implant of interest. NZ describes the range over which the specimen moves essentially free of an applied load. ROM is the sum of motion in flexion and extension under maximal loading (including neutral and elastic zone).13

**Data Analysis**

Bending angle and moment were calculated by crosshead displacement, force, and 4-point bending device geometry (Matlab 7.6.0, The MathWorks, Inc., Natick, MA). ROM for each direction was defined as the angular deflection during the 3rd loading cycle at 1 N m. NZ was defined as the remaining angle at the position where the applied moment reached zero during the 3rd unloading cycle (Fig. 3).

Differences in absolute ROM (Fig 4) and NZ (Fig 5) values were evaluated using paired t-tests with Bonferroni correction (1-tailed tests were performed to investigate a reduction of motion because of treatments against the intact spine segment and 2-tailed tests for comparison between treated segments). Significance level was set at $P < .01$. The relative ROM and NZ (% of intact specimen) of the treated specimens were calculated setting the values of the intact specimens to 100%.

![Figure 3](image_url) The hysteresis curve (angular displacement [°] over the applied moment [Nm]) for the C5–C6 canine vertebral segment of a specimen before and after stabilization with cage and locking plate, respectively. Compared with the intact spine specimen, cage and plate stabilization resulted in a reduction in ROM and in NZ. The NZ describes the range over which the specimen moves essentially free of an applied load (analogous the vertical part of the curve) and ROM is the sum of motion in flexion and extension under maximal loading (including neutral and elastic zone). The NZ and ROM of the intact specimen are identified.
Compared to the intact spine specimens, plate stabilization resulted in a significant reduction in ROM (mean reduction 41.8% ± SD 12.1, P < .001) and NZ (mean reduction 48.4% ± SD 20.4, P < .001). There was no significant difference in ROM (P = .15) or NZ (P = .81) between the 2 stabilization techniques (Figs 3–5). It was not possible to calculate NZ stiffness because of the lack of crossing the zero loading point since each direction was tested separately.

During all tests, the 1st cycle was slightly different because of preconditioning. The change of lever arm was ~20% for the intact case. The plated and caged cases were stiffer, thus the change of lever arm was ~10%. These changes were consistent among all tested specimens.

One sample was removed from statistical analysis because of loosening of the plate fixation leading to interruption of the test. Otherwise, no bone fractures were found in any of the specimens and none of the screws or plates showed signs of fracture, loosening, or breakage after testing.

**DISCUSSION**

We evaluated the stability provided by a cervical intervertebral device incorporating integrated ventral fixation and compared the biomechanical characteristics of this implant to locking plate fixation. We found that both surgical constructs resulted in a significant reduction in motion compared with intact cervical specimens and that the stability of this new implant is, at least, equivalent to that provided by ventral plating.

Stepwise loading leads to a continuous change in angulation (creep effect) during constant application of a defined load. In contrast, continuous loading is considered more physiologic than stepwise loading and limits the creep effect whilst producing smaller ROM and NZ values. Based on these findings, we applied continuous loads. To compare stability between the 2 stabilization techniques, the same specimens were used, so that differences in ROM and NZ could be evaluated as paired samples.

The biomechanical advantages of restoring intervertebral disc width in the treatment of DACSM has been discussed extensively. Results of most studies in people support an increase in stability with interbody cage stabilization. Because stability is related to the distribution of load at the cage–bone interface, it is dependent on the shape of the cage. In people, it is also related to bone density and the extent of surgical endplate damage with possible subsidence or cage migration into the adjacent vertebral body. The amount of endplate cartilage and bony removal varies between spacer techniques used in dogs and might be associated with subsidence.

Indeed, cage subsidence may result in partial loss of distraction in dogs although it was not found to consistently elicit clinical signs. In people, excessive subsidence has however been described to cause adverse effects, such as segmental kyphosis, foraminal stenosis with recurrent radiculopathy, and neck pain. The optimal cage design should offer a contact area that ensures sufficient resistance against subsidence together with sufficient space for bone ingrowth and prevention of stress protection. The spacer designed for this
study was therefore of slim dimension to allow preservation of the integrity of the endplates during placement. In addition, its ovoid shape fits with the anatomic form of the endplates and may allow a larger contact area between the vertebra and the implant, which could enhance load transmission between the bone and the implant. This might be an explanation for the lesser variability for ROM and NZ of the new implant compared to plate fixation. In vivo studies using this construct are necessary to confirm this hypothesis.

In people and horses, intervertebral cages can be used as stand-alone devices. A distractible fusion cage was used as a stand-alone device in a Doberman with DACSM with successful outcome 40 months after surgery. However, additional stabilization against ventral dislodging is usually considered necessary in dogs because extrusion of the implant with nonanchored devices may occur. This is frequently provided by ventral plating, which has been shown to increase stiffness and decrease ROM in the treated segment. Additional plating has also been used in people treated with cylindrical cages with the aim of minimizing the risk of subsidence and spinal kyphosis. In horses, the intervertebral cage is used in the kyphotic upper cervical area and is therefore protected from ventral extrusion. The anchored spacer with integrated plate system we used was developed to overcome plate-related complications while averting the risk of implant extrusion. It preserves the natural anatomic profile of spine and is seated completely within the disc. The spacer combines the features of spacers and rigid titanium plates in a single piece and appears to provide similar stability under flexion-extension to ventral locking plate osteosynthesis based on our results.

Cages developed at our institution were manufactured for both conventional screws (C-Fix) and locking screws (C-Lox, Rita Leibinger GmbH & Co. KG, Neuhausen, Germany). In both cages, screws can be placed in an angled position directed toward the caudal and cranial margins of the adjacent vertebrae, respectively. This should partially replace the ventral stabilization lost after resection of the ventral longitudinal ligament and annulus fibrosus. We used conventional screws, assuming this construct affords less rigidity than with locking screws. Given that this system resulted in ROM and NZ similar to a locking plate, use of the cage with locking screws may afford even greater stability.

Complications, such as hardware failure and the development of pseudarthrosis, have been described in dogs treated with mechanical stabilization when bony fusion is absent. Indeed, in the absence of spinal fusion, hardware failure might be merely a time-dependent certainty. The thin strut of the titanium anchored spacer we used could theoretically permit new bone ingrowth as a first step toward bony intervertebral fusion. However, leaving the endplates intact may prevent bony proliferation within the intervertebral space and only permit fusion by ventral and lateral bridging of the treated vertebrae (spondylosis). Nonetheless, previous reports suggest that bony fusion in the canine cervical spine may mostly result from external bony bridging complete spondylosis with bony filling of the intervertebral gap has only very sparsely been described. Indeed, spinal bony fusion of the endplates was not evident on histologic examination in three dogs stabilized with pedicle screw-rod fixation of the L7-S1 disc space, despite curettage of the endplates and insertion of cancellous bone grafts.

There were several limitations to our study. One limitation of using cadaveric specimens is that the biomechanical limits of the canine cervical vertebral column are largely unknown. In 2 previous biomechanical studies, specimens were loaded under displacement control, leading to bending moments of up to 18 Nm. In contrast to our testing, these studies included 3 vertebral motion units and loading the specimens to failure was found impossible because angular deformation exceeded the physical limits of the bending machine. In other biomechanical studies of the canine cervical spine, bending moments were limited to 1 and 1.5 N m, respectively. In 1 study, the physiologic limit of the passive moment exerted at the C4-C5 intervertebral space for a standing dog with the head and neck positioned horizontally was estimated to be 4 N m based on canine cadavers. However, in anesthetized dogs, applied pure moments of >1.1 N m were found to compromise breathing. Higher bending moments may not therefore be necessary to simulate physiologic conditions. Similar to these findings, we found that the ROM within a bending moment of 1 N m reached a plateau level. Furthermore, pilot testing at the beginning of this study without limitation of the bending moment lead to a longer plateau and breakage of the PMMA embedding at a bending moment of ~5 N m. Moreover, assessment of ROM may not be necessary as measurement of the NZ may be sufficient to evaluate biomechanical improvement in stability.

Specimens were not randomized after testing of the intact spine. This could have influenced the biomechanical characteristics of the ventral locking plate fixation. The decision to start the testing with the new device was initially taken because we thought that the screw holes for fixation of the new device because of their lateral position would not interfere with the subsequent median plate fixation. Additionally it would have been more difficult to estimate and create the same amount of distraction when starting testing with plate fixation. Inserting the new device first allowed us to measure the width of the intervertebral space and to reproduce a similar distraction before plate fixation. However, illustrating the potential drawback of performing a nonrandomized study, 1 specimen had to be excluded from data analysis because of plate loosening during the last phase of testing. The small volume of the vertebra and the narrow positioning of the 2nd plate screw in the holes created by the anchoring spacer screws may have caused microfracture and subsequent screw loosening in this case. In the remaining tested constructs, stable plate fixation was achieved and the results of biomechanical testing seem to confirm the good anchorage of the plates to the bone. Unfortunately the constructs were not radiographed or dissected after testing, but macroscopic examination did not reveal any signs of loosening or instability after the last testing cycle.

We used spines of Beagle dogs although they are not the typical breed affected by DACSM because cadavers were readily available at our institution. In consequence, the dimensions of the cage were specifically adapted to the vertebral size of Beagles for this study. An advantage to using these Beagles was that dogs were all of similar age and
conformation and had been kept under the same conditions, providing a more standardized subject. We used the C5–C6 intervertebral disc space, which is the second most commonly affected intervertebral disc in DACSM in large-breed dogs. C6–C7 was not used because of difficulties in the embedding procedure. In this in vitro investigation, isolated cadaveric spines with removed muscular tissue were studied. In vivo, muscle forces and the complex integration of neural feedback provide some additional control of segmental spinal motion and similarly contribute to the load that must be withstood by any instrumentation construct. Therefore, our study did not include forces representing muscular interactions; however, muscular interaction should provide even more stability in vivo than we observed.

A further limitation is that the specimens were only tested in flexion and extension; however, ROM is greater in flexion and extension than with lateral bending and clinical spinal cord compression, which may justify testing under these conditions. Nonetheless, lateral bending and axial rotation are coupled motion patterns that could be biologically relevant to the stability of the construct.

We concluded that the ease of placing and fixing the cage combined with the stability achieved makes it an attractive alternative for distraction/fusion techniques. Because of the absence of fatigue testing for this fixation method the level of stiffness required for long-term stability and fusion remains unclear and further investigations are necessary before the anchored spacer can be recommended for routine use; however, we believe that there is sufficient supportive evidence to begin clinical trials and to evaluate the efficacy of this implant in prospective clinical studies.

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DISCLOSURE

The authors declare no financial or other conflicts of interest related to this report.

REFERENCES


