RUNNING HEAD: Effect of a Cervical Intervertebral Spacer on Construct Stiffness

Effect of an Intervertebral Disk Spacer on Stiffness after Monocortical Screw/Polymethylmethacrylate Fixation in Simulated and Cadaveric Canine Cervical Vertebral Columns

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ABSTRACT

Objective: To determine the biomechanical effect of an intervertebral spacer on construct stiffness in a PVC model and cadaveric canine cervical vertebral columns stabilized with monocortical screws/polymethylmethacrylate (PMMA).

Study Design: Biomechanical study.

Sample population: PVC pipe; cadaveric canine vertebral columns

Methods: PVC model – PVC pipe was used to create a gap model mimicking vertebral endplate orientation and disk space width of large-breed canine cervical vertebrae; 6 models had a 4-mm gap with no spacer (PVC group 1); 6 had a PVC pipe ring spacer filling the gap (PCV group 2). Animals – large breed cadaveric canine cervical vertebral columns (C2-C7) from skeletally mature dogs without (cadaveric group 1, n=6, historical data) and with an intervertebral disk spacer (cadaveric group 2, n=6) were used. All PVC models and cadaver specimens were instrumented with monocortical titanium screws/PMMA. Stiffness of the 2 PVC groups was compared in extension, flexion, and lateral bending using non-destructive 4-point bend testing. Stiffness testing in all 3 directions was performed of the unaltered C4-C5 vertebral motion unit in cadaveric spines and repeated after placement of an intervertebral cortical allograft ring and instrumentation. Data were compared using a linear mixed model approach that also incorporated data from previously tested spines with the same screw/PMMA construct but without disk spacer (cadaveric group 1).

Results: Addition of a spacer increased construct stiffness in both the PVC model ($P < .001$) and cadaveric vertebral columns ($P<.001$) compared to fixation without a spacer.

Conclusions: Addition of an intervertebral spacer significantly increased construct stiffness of monocortical screw/PMMA fixation.

INTRODUCTION

Canine cervical vertebral column stabilization is an emerging treatment option for dogs with traumatic injuries and cervical spondylomyelopathy (CSM).[1-5] Few surgical techniques for stabilization of the CSM vertebral column few have been assessed biomechanically.[6-8] In addition to stabilization, the goal of several canine surgical procedures is to create distraction between 2 vertebrae and ultimately achieve bony fusion across the intervertebral space.[1,4,9] Bony fusion of the instrumented vertebrae should improve long-term stability and allow load-sharing with spinal implants, without which fatigue failure of the hardware is likely.[10] Bicortical pins and polymethylmethacrylate constructs (PMMA) have been a landmark technique for cervical vertebral column stabilization in dogs; however, there is a high risk of implant violation into the vertebral canal and some recommend avoiding bicortical implants in the cervical vertebral column.[1,11,12]

A recent study documented the biomechanical equivalence of mono- and bicortical screw and PMMA constructs in the cadaveric canine cervical vertebral column.[6] In that study 3.5mm cortical stainless steel and titanium screws inserted monocortically performed similarly to bicortical 1/8 inch positive profile Steinman pins. Locking plates further enable the use of monocortical screw fixation. Whereas few comparative biomechanical studies have been performed, clinical reports support use of this approach for the canine cervical vertebral column.[2,5,7,9,13] Treatment options for the intervertebral disk include leaving it intact, performing a ventral slot or partial diskectomy with bone grafting, or adding something structurally stronger such as washers, cement plugs or cortical grafts.[4,14-16] Intervertebral spacers have been promoted as a method to improve construct biomechanics and maintain distraction after spinal fusion in people.[17-21] Intervertebral spacers of various designs have been used in conjunction with vertebral column stabilization in animals but have not been biomechanically evaluated in dogs.[2,9,13,15,16,22]

Our purpose was to determine the biomechanical effects of an intervertebral spacer in cadaveric canine cervical vertebrae stabilized with monocortical screws and PMMA. A synthetic bone substitute model (polyvinyl chloride pipe) was developed and tested before evaluation in cadavers. We hypothesized that the addition of an intervertebral disk spacer would significantly increase construct stiffness compared with specimens instrumented without a spacer in a synthetic and cadaveric model.

MATERIALS AND METHODS

PVC models

A cervical intervertebral space was simulated using two 20 cm long segments of 12.5 mm diameter PVC pipe (12.7 mm outer diameter, 2 mm wall thickness) separated by a gap. The PVC pipe was cut at a 30° angle to create a gap model mimicking vertebral endplate orientation and cervical disk space width similar to that of a large-breed dog. Twelve models were created using screw and PMMA fixation: 6 with a 4-mm gap with no spacer (PVC group 1) and 6 with a spacer filling the gap (PVC group 2). Spacers were created from 4-mm thick rings cut perpendicularly from PVC pipes to simulate a cortical ring allograft used in clinical patients with cervical distraction/fusion.[2] All models were instrumented with 6 self-tapping titanium alloy cortical screws (Synthes Vet, West Chester, PA) inserted monocortically and PMMA (Simplex P Bone Cement, Stryker, Mahwah, NJ) for fixation of the simulated disk space. Three screws were inserted in a triangular fashion adjacent and parallel to the angled cut surface simulating the disk space. Holes were drilled with a 2.5mm drill bit through 1 wall of the PVC pipe and screws were advanced until they contacted the opposite inner surface of the ring. Screws protruded 12-15 mm from the PCV pipe and 20g PMMA were applied to form a uniform cement mantle (Fig. 1).

Mechanical Data Collection – PVC models

Small K-wires were placed in the dorsal and lateral plane to connect an extensometer which was used to measure motion at the interface. Construct stiffness in extension, flexion and lateral bending for both PVC groups was determined using a custom 4-point bend fixture. (Fig. 2 A) The testing protocol was similar to an earlier study using canine cervical vertebral specimens wherein testing was load-controlled at 50 N/min to 150 N in flexion and extension and to 100 N in right lateral bending.[6] Each PVC model underwent only 2 full cycles of extension, flexion, and lateral bending because data were very similar during pilot PVC model testing. Actuator displacement (mm), applied load (N), and extensometer displacement (mm) data were collected continuously and recorded at 0.5 N intervals using the data acquisition system integral with the servohydraulic test frame (MTS Bionix 858 Test System, MTS, Eden Prairie, Minnesota). Load and extensometer displacement data from the 2nd cycle of each loading direction were used to calculate load-displacement curves for bending moment of the PVC model with gap and with the PVC spacer. Stiffness (Nm/m) was determined by calculating the slope of the linear portion of each load-displacement curve. One PVC model from either group (without and with spacer) was subjected to fatigue testing to 200,000 cycles without evidence of failure.

Vertebral Specimens

The study was approved by the Institutional Animal Care and Use Committee. Cervical vertebral columns (C2-C7) were collected from 12 skeletally mature dogs (21-30 kg body weight) euthanized for reasons unrelated to this study. Lateral and dorsoventral radiographic projections were made to exclude dogs with radiographic evidence of open physes or evidence of vertebral column deformities and other conditions affecting vertebrae or disk spaces. Six specimens were tested as part of another study under the same inclusion criteria and procedural protocols; these 6 spines had monocortical titanium screw and PMMA fixation without a spacer (cadaveric group 1).[6] The other 6 spines represented specimens with an intervertebral spacer and fixation (group 2). Cervical vertebral columns were sorted into balanced groups based on dual-energy x-ray absorptiometry (DEXA) measures of bone mineral density at C4 and C5 (Lunar Prodigy; GE Healthcare, Milwaukee, WI). Surrounding soft tissues were removed except for paravertebral musculature, joint capsules and ligaments associated with the C3-C6 vertebrae. Specimens were wrapped in moist towels soaked in sterile saline (0.9% NaCl) solution and frozen at -20ºC until testing. Specimens were kept moist during processing and testing with sterile saline solution. Cortical ring allografts from cadaveric canine tibiae were collected before vertebral column instrumentation and frozen at -20ºC until testing. Ring dimensions (height and width) were adjusted to disk space dimensions of each specimen measured on radiographs. Ring depths varied between 4.0 and 5.2mm as determined with digital calipers.

Mechanical Data Collection – Cadaveric Specimens

Potting of the cervical vertebral columns was performed and allowed for isolated testing of the C4-C5 vertebral motion unit (VMU).[6] Briefly, after removal of soft tissues (sparing C4-C5), the VMUs of C2-C4 and C5-C7 were stabilized and potted. K-wires were placed on midline in the dorsal and lateral plane in C4 and C5 to connect an extensometer to measure localized deformation at the C4-C5 VMU. Each specimen was allowed to thaw to room temperature and tested in extension, flexion and right lateral bending using a custom made four-point bending fixture (Fig. 2 B). A preload of 5 Newtons (N) was applied to stabilize the specimen and to assure that all specimen tests were initiated under the same conditions. Testing was load-controlled at 50 N/min to 150 N in flexion and extension and to 100 N in right lateral bending. Each specimen underwent 4 full cycles of extension, flexion and lateral bending and was allowed to rest in neutral for 30 seconds between each cycle to allow for tissue recovery. Actuator displacement (mm), applied load (N), and extensometer displacement (mm) data were collected as with the PCV model. Load and extensometer displacement data from the 4th cycle of each loading direction were used to calculate load-displacement curves for each bending moment of the unaltered and instrumented C4-C5 motion unit. Stiffness (Nm/m) was calculated by selecting the linear portion of each load-displacement curve. The same loading and data collection protocol was used in both groups (spacer, no spacer) after instrumentation with monocortical screws/PMMA.

Surgical Fixation – Cadaveric Specimens

The longus colli musculature was resected in an ~5cm long by 3.5cm wide area centered over the C4-C5 intervertebral disk. In group 1, the intervertebral disk remained unaltered. In group 2, a partial diskectomy was performed by removing the ventral annulus fibrosus, the nucleus pulposus and part of the remaining annulus, leaving only a thin rim of annulus intact along the lateral and dorsal borders. Manual distraction was applied to facilitate placement of a cortical ring allograft previously harvested from the tibial diaphysis of 2 of the study dogs. The C4-C5 VMUs of both groups were stabilized with 6 monocortical self-tapping titanium alloy cortical screws (Synthes Vet, West Chester, PA**)** and PMMA as previously described[6] (Fig. 3). Briefly, after predrilling the ciscortex, 3 screws each were inserted into C4 and C5 and advanced until they contacted the inner cortex of the vertebral canal. Screw orientation was parallel to the vertebral endplate for all but the most caudal screw, which was oriented in a cranioventral to caudodorsal direction toward the caudal endplate of C5 because of physical obstruction by the potting construct. Screws protruded 12-15 mm from the ventral vertebral body surface to allow incorporation into 20 g PMMA to create a uniform cement mantle. Cement was allowed to harden for a minimum of 20 minutes before testing.

Postoperative Implant Assessment – Cadaveric Specimens

Post-testing, orthogonal radiographs were obtained to assess monocortical screw and cortical ring allograft position as well as potential bony damage from mechanical testing (Fig. 4) Specimens were then cleared of remaining soft tissues using a dermestid beetle colony and evaluated for potential screw violation of the vertebral canal and position of the cortical ring allograft.

Statistical Analysis

Data were assessed for normality by calculating descriptive statistics, plotting histograms, and performing the Anderson-Darling test for normality. Dog weight and DEXA scan values were compared between cadaveric groups using t-tests. Linear mixed models were used to estimate the spacer effect on stiffness values independently for PVC and cadaveric models. Dependency among observations within the PVC model/spine was controlled through the addition of a random effect and assuming a first order autoregressive correlation structure. Additionally, a linear mixed model was used to compare the post-instrumented stiffness of PVC and cadaver models. Statistical analysis was performed using software (IBM SPSS Statistics Version 21, International Business Machines Corp., Armonk, NY) and significance was set at $P < .05$.

RESULTS

PVC Models

Addition of a PVC ring as a simulated intervertebral disk spacer significantly increased stiffness in the PVC model (P< .001) and the increase in stiffness varied by directional measures (P=.003). Mean increases in stiffness by the spacer were 2819 N/mm, 1757 N/mm, and 1586 N/mm for extension, flexion, and lateral bending, respectively. The post-instrumented stiffness of the PVC model in general was greater than the cadaveric (P<.001) and the improvement in stiffness by the addition of the spacer was greater for the PVC model (P<.001).

Vertebral Specimens

The dog population was comprised of 11 Pit Bulls or Pit Bull mix-breed dogs and 1 Rottweiler mix-breed dog (9 intact and 1 neutered male, 2 intact females) with a weight range from 21 - 30 kg (median, 26.5 kg). All dogs were mature based on dentition and radiographic physeal closure, and had no radiographic evidence of vertebral column disease. Body weight and bone mineral density were not significantly different among treatment groups (P=.55 and P=.65, respectively).

Mechanical Testing – Cadaveric Specimens

Mean (±SD) difference in stiffness from pre- to post-fixation in extension was 263 ±67 N/mm and 491 ± 144 N/mm for the monocortical titanium screw/PMMA construct without a spacer (cadaveric group 1) and the monocortical titanium screw/PMMA construct with a spacer (cadaveric group 2), respectively. Mean difference in stiffness from pre- to post-fixation in flexion was 180 ± 53 N/mm and 314 ± 87 N/mm for groups 1 and 2, respectively. Mean difference in stiffness from pre- to post-fixation in lateral bending was 185 ± 47 N/mm and 328 ± 69 N/mm for groups 1 and 2, respectively. Instrumentation increased stiffness over the unaltered spine ($P<.001$).

The addition of a cortical ring allograft as intervertebral disk spacer increased overall construct stiffness in cadaveric cervical vertebral columns compared to specimens stabilized without a spacer ($P< .001$) and the benefit was not different over measured directions ($P=.316$; Fig. 5).

Postoperative Implant Assessment

There was no radiographically or visually apparent evidence of failure of the implants or bone after mechanical testing. Upon visual examination, 1 of the 36 monocortical screws in group 2 (spacer) penetrated the transcortex by <2mm. As previously reported, 9 of 36 titanium screws in group 1 (no spacer) had violation of the transcortex (4 caused cortical lift, 3 penetrated <1 mm, and 2 penetrated <2 mm into the vertebral canal).[6] Cortical ring allografts were seated within the borders of the endplates and all were below the level of the ventral aspect of the vertebral canal. None of the spacers could be dislodged with gentle probing.

DISCUSSION

Addition of an intervertebral spacer significantly increased construct stiffness in all directional measures in both the PVC as well as the cadaveric cervical vertebral model compared to specimens stabilized without a spacer in all directions measured.

Based on principles of osteosynthesis, implants across an intact disk space would function in bridging mode. Bridging implants (formerly described as buttress implants) are subjected to full weight bearing forces without load-sharing by the stabilized bone.[23] Concerns of bridging implants relate to cyclic stress on the implant and premature failure because of fatigue. Solid fixation of both plate ends with at least 3 bicortical screws is recommended for long bone fractures stabilized in bridging mode without adjunct fixation such as an intramedullary pin.[23] The anatomy of the canine cervical vertebral column creates challenges for safe application of bicortical implants and the extremely high incidence of vertebral canal violation has given preference to monocortical implant fixation in dogs requiring cervical vertebral stabilization.[6,8,11] In a cadaveric biomechanical study, mono- and bicortical fixation of a vertebral motion unit with an intact intervertebral disk produced equivalent stiffness; however, the effects of cyclic loading on such vertebral bridging implants have not been studied in vitro.[6]

The increase in construct stiffness after placement of an intervertebral spacer is likely because of load sharing between 2 adjacent segments through the spacer. In the cadaveric specimens, cortical ring allografts were placed while the intervertebral space was distracted, subsequently placing them under compression upon release of traction. Using a spacer to achieve axial compression across the disk provides load sharing between adjacent vertebral endplates, leading to increased construct stiffness. Such load sharing should in theory decrease the load on fixation implants, reduce the risk of component failure and improve implant longevity. The ultimate goal of spinal stabilization with an intervertebral spacer is bony fusion.[20] It is generally accepted that without longterm fusion of bone, implants will be subjected to cyclic loading with eventual fatigue failure.[24]

Interbody fusion incorporating an intervertebral spacer is considered the standard of care in human cervical vertebral column stabilization.[25] Common biological materials include auto- and allografts of tricortical iliac crest or cortical ring grafts.[26,27] We used cortical ring allografts because this is the current spacer material used clinically by the 1st author. When using a cortical ring allograft as an intervertebral spacer, the solid bone ring structure maintains disk space height while allowing bony fusion to occur through the center of the ring (commonly filled with cancellous autograft). A cortical allograft may undergo resorption and replacement by autogenous bone over time or be incorporated into the fusion bone directly. Reported complications with the use of cortical bone grafts as an intervertebral spacer in people include spacer expulsion, intervertebral non-union, subsidence of spacer, and collapse of bone graft. [28-32] Additionally, patient morbidity can be an issue when an autograft is used.[33] Another complicating issue with using allografts for spinal fusion is availability of graft bone. While canine allograft is commercially available within the United States, many countries do not have veterinary bone banks, which then requires harvesting and processing grafts locally to be used for a clinical patient.

Interbody fusion cages were designed for human distraction/fusion procedures to help eliminate possible complications from autogenous and allogeneic bone grafts. Their goal is to provide immediate stability of the affected VMU, maintain disk height and alignment and achieve a high fusion rate.[20] Materials such as titanium, carbon fiber, polyetheretherketone (PEEK), and PMMA have been biomechanically evaluated and clinically applied as interbody cages for cervical fusion in people.[19,20] The reported use of human interbody fusion cages in clinical veterinary neurosurgery is limited to 2 reports.[9,34] We are unaware of canine-specific interbody fusion cages.

Before evaluating cadaveric specimens, proof of concept testing was performed on PVC pipe models. There was a concern that the difference in stiffness between specimens with and without a spacer would be difficult to detect because the monocortical screw/ PMMA construct by itself already provided a high degree of stiffness. Bone models made of PVC pipe have been used for simulation of canine and human long bone fractures and biomechanical testing of various fixation devices.[35-37] Whereas PVC pipe as a model for vertebrae has not been reported, the gap model we used was able to document the biomechanical effects of a spacer. Despite using the same biomechanical testing set-up, overall stiffness values were much greater in the PVC model compared with the cadaveric group, challenging the value of the PVC model as an appropriate way to test devices in the spine. Possible reasons for this difference in stiffness may be the absence of secondary means of deformation in PCVs models through interfaces other than the one being tested (perfect cylinder versus geometrically complex vertebral structure), the lack of tissue relaxation in

PVC pipes, and excellent gap bridging in PCV model (straight cut surfaces contacting straight spacer).

A weakness of our study was that none of the vertebral constructs were fatigue tested. In a clinical setting, long-term cyclic loading of implants is likely to be an important determinant of implant loosening and/or failure. If an intact disk or a VMU after ventral slot with fixation is comparable to a fracture gap model, then the addition of a spacer should have a protective effect on implant longevity because of improved load sharing between affected vertebrae. Technical difficulties with maintaining proper position of the specimen during long testing periods and failure of the potting connection before failure of the surgically fixed VMU make fatigue testing with this model challenging. Pilot data of 2 PVC models (1 with and 1 without a spacer) was conducted to 200,000 cycles without evidence of failure of either construct. This highlights both the stability of the constructs and the difficulty in designing and conducting a test protocol to differentiate between the fatigue behavior of the two means of fixation.

Summarily, we showed that addition of an intervertebral spacer significantly increased construct stiffness; however, data were obtained in an in vitro model which may differ from that of a living patient. Whether the addition of such a spacer decreases construct failure or influences the incidence or rate of bony fusion across the disk space needs to be determined in long-term clinical studies.

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DISCLOSURE

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

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FIGURE LEGENDS

Figure 1 Photographs of 2 PVC simulating adjacent vertebrae and an intervertebral disk space with applied monocortical screw/polymethylmethacrylate fixation. Top – PVC model without a spacer (PVC group 1), bottom – PVC model with a spacer. The K-wires have been placed to connect the extensometer used to measure displacement across the simulated disk space.

Figure 2 Photographs of the 4 point bending set-up for a PVC model testing after fixation without a spacer (A) and a canine cadaveric cervical vertebral column before surgical fixation (B). Both models are being tested in extension. The extensometer is attached to dorsally placed k-wires.

Figure 3 Photographs of a cadaveric canine vertebral specimen after diskectomy (A) with a cortical ring allograft (small photo insert), monocortical fixation with titanium screws (B), and after polymethylmethacrylate application (C).

Figure 4 Lateral radiographic projection of C4-C5 vertebrae stabilized ventrally with monocortical titanium screws and PMMA. The white arrow indicates the cortical ring allograft placed within the intervertebral disk space.

Figure 5 Stiffness of intact and surgically fixed cervical vertebral specimens in extension, flexion and lateral bending. The intact spines are depicted in black; Group 1 (no intervertebral spacer) is depicted in gray; and Group 2 (intervertebral spacer) is depicted in gray stripes.

Stiffness was significantly different between the intact and surgically fixed specimens, and between the 2 experimental groups (*P*=.002).

FIGURES

Figure 1 Photographs of 2 PVC simulating adjacent vertebrae and an intervertebral disk space with applied monocortical screw/polymethylmethacrylate fixation. Top – PVC model without a spacer (PVC group 1), bottom – PVC model with a spacer. The K-wires have been placed to connect the extensometer.

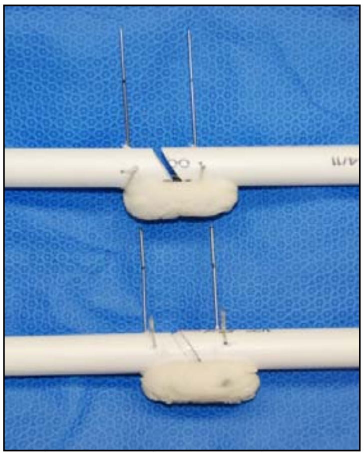


Figure 2 Photographs of a cadaveric canine vertebral specimen after diskectomy (A) with a cortical ring allograft (small photo insert), monocortical fixation with titanium screws (B), and polymethylmethacrylate application (C).

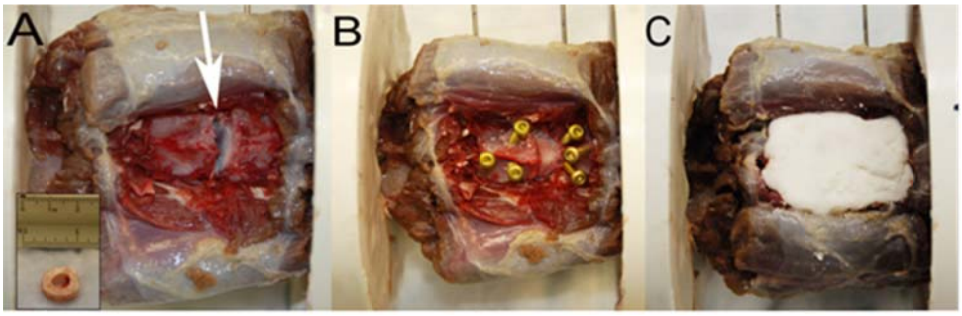
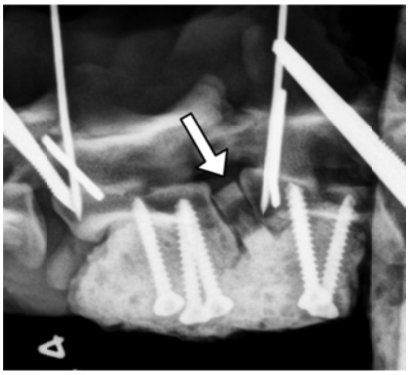
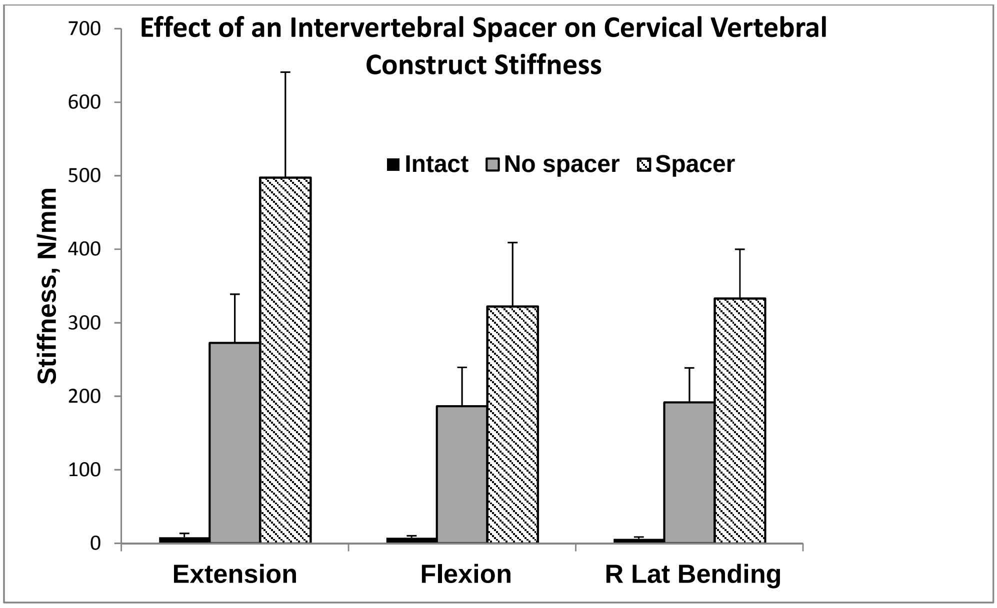


Figure Lateral radiographic projection of C4-C5 vertebrae stabilized ventrally with monocortical titanium screws and PMMA. The white arrow indicates the cortical ring allograft placed within the intervertebral disk space.



Graph 1 Stiffness comparison of intact and surgically fixed cervical vertebral specimens in extension, flexion and lateral bending – the intact spines are depicted in black, group 1 (no intervertebral spacer) is depicted in gray and group 2 (intervertebral spacer) is depicted in striated gray. Overall stiffness was significantly different between the intact and surgically fixed specimens, and between the two groups (p=0.002).


Effect of an Intervertebral Spacer on Cervical Vertebral Construct Stiffness
Stiffness, N/mm
700
600
500
400
300
200
100
0
Intact
No spacer
Spacer
Extension
Flexion
R Lat Bending