

Biomechanical comparison of 2 veterinary locking plates to monocortical screw/polymethylmethacrylate fixation in the cadaveric canine cervical vertebral column

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Abstract

Objective: To assess biomechanical properties of 2 veterinary locking plates and compare fixation among these plates and monocortical screws/polymethylmethacrylate (PMMA) fixation in cadaveric canine cervical vertebral columns.

Study Design: Biomechanical cadaveric study.

Materials: Nineteen large breed cadaveric canine cervical vertebral columns (C2-C7) from skeletally mature dogs were used. A cortical ring was placed as disk spacer at C4-C5 in all specimens. Seven vertebral columns were implanted at C4-C5 with two 4-hole, 3.5mm string of pearls plates (SOP) and 6 were implanted with two 6-hole, 2.4mm titanium locking reconstruction plates (Ti recon plate). All screws were placed monocortically. Six specimens were implanted with monocortical titanium screws and PMMA (Ti screws/PMMA), tested as part of a prior study.

Methods: Stiffness testing in 3 directions was performed of the unaltered C4-C5 vertebral motion unit and repeated after placement of the disk spacer and implant fixation. Data were compared using a linear mixed model that incorporated data from previously tested spines (Ti screw/PMMA).

Results: The mean post-fixation stiffness (N/m) and 95% confidence intervals for SOP, Ti recon plate and Ti screws/PMMA respectively were 407 (330,503), 284 (198,407) and 365 (314,428) in extension; 250 (178,354), 147 (106,204) and 311 (235,416) in flexion; and 528 (441,633), 633 (545,735) and 327 (257,412) in lateral bending. There were no significant differences in stiffness increase among the 3 fixation methods within any evaluated measurement directions.

Conclusions: Monocortical fixation with two 3.5mm SOP and two 2.4mm Ti recon plates may offer an alternative fixation to monocortical screws and PMMA.

INTRODUCTION

Various distraction-stabilization methods for treatment of canine cervical spondylomyelopathy have been described clinically, with a few having been assessed biomechanically.¹⁻¹⁵ It has been sufficiently demonstrated that bicortical implants are not safe to use in the canine cervical spine^{7,8,16} and the focus has shifted to monocortical fixations using techniques such as monocortical screws/polymethylmethacrylate (PMMA) and locking plates.^{1,2,5,7,12-15} While monocortical screw/PMMA constructs offer great freedom in their application, locking plates offer a low profile implant without possible side-effects of PMMA application. The only veterinary locking plate biomechanically evaluated in the canine cervical spine has been the 3.5mm locking compression plate (LCP; DePuy Synthes Vet, West Chester, PA).¹ This study showed that ventral fixation with one LCP plate and 2 screws in each adjacent vertebral body increases stiffness at the implanted vertebral motion unit compared to the intact spine and ventral slot procedure. However, data comparison between this implant and others is not possible because other fixations were not tested in that study and other publications have different study designs and testing protocols.⁷ Schöllhorn et al compared a novel ventral cervical intervertebral anchored fusion device (C-LOX®) to the 3.5mm LCP and found no significant difference in stiffness between the 2 fixation methods.¹² The LCP fixation, however, did not include an intervertebral spacer unlike the integrated cage of the C-LOX. The addition of an intervertebral spacer has been shown to significantly increase

construct stiffness in a canine cervical cadaver model,⁶ therefore it is challenging to directly compare a fixation with an intervertebral spacer to one without. While the ideal stiffness required of fixation constructs to achieve bony union in the canine cervical spine is not known, it is beneficial to be able to directly compare various implants in regards to their construct stiffness. With the addition of long-term clinical results of such methods, this may help establish recommendations for types of fixation in the canine cervical vertebral column.

The objectives of this study were twofold: to evaluate changes in stiffness after application of 2 different veterinary locking plates, specifically the 3.5mm string of pearls (SOP) plate and the 2.4mm titanium locking reconstruction plate (Ti recon), applied with monocortical screws; and to compare stiffness data of the locking plate constructs to that of monocortical screw/PMMA constructs in cadaveric canine vertebral columns. The use of both locking plates in the canine cervical spine has been reported in clinical reports.^{13,14}

The statistical null hypothesis was that there would be no difference in the stiffness increase among the three fixation constructs.

MATERIALS AND METHODS

Vertebral specimens

The study was approved by the local Institutional Animal Care and Use Committee. Cervical vertebral columns (C2-C7) were harvested from 19 skeletally mature dogs (23-31 kg body weight) euthanized for reasons unrelated to this study. Orthogonal radiographs were performed to exclude dogs with evidence of open physes or

vertebral column conditions affecting vertebrae or disk spaces. To maintain groups with similar bone mineral density (BMD) and thereby reduce variations of screw fixation strength, cervical vertebral columns were sorted into balanced groups based on dual-energy x-ray absorptiometry (DEXA) measures of BMD at C4 and C5 (Lunar Prodigy; GE Healthcare, Milwaukee, WI).¹⁷ 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 0.9% sterile saline solution and frozen at -20°C until testing. Specimens were kept moist during processing and testing with 0.9% sterile saline solution. Cortical bone ring grafts harvested from cadaveric canine tibiae were cut using a linear precision saw (Isomet 4000, Buehler, Lake Bluff, IL) prior to vertebral column implant fixation and frozen at -20°C until testing. Bone rings varied in outer diameters between 9 and 12mm and thicknesses between 4.0 and 5.2mm (in approximately 0.1mm increments). These sizes were selected based on radiographic measurements of C4-C5 disk space dimensions and the ring most closely matching each subject was selected at the time of implantation.

Surgical fixation

All fixations were performed by one person and implants within groups were applied in a similar manner. The C4-C5 disk space was approached via a standard ventral approach. The longus colli musculature was separated and retracted. Partial discectomy was performed at C4-C5, leaving a thin rim of annulus fibrosus along the lateral and dorsal borders. The exposed vertebral endplates were freed of cartilage by curettage without removing any bone. Cortical rings were placed into all specimens under manual

distraction to serve as intervertebral spacers as previously described.⁶ The actual size of each bone ring was based on best fit and was influenced by the remaining annulus and space created during manual distraction.

In group 1 (n=7), C4-C5 was stabilized using two parallel 4-hole 3.5mm SOP plates (Orthomed, Halifax, West Yorkshire, UK) applied to the ventral vertebral body surfaces. Plates were placed just lateral to the ventral crest and staggered so that the screw holes of one plate were positioned between the cylindrical sections of the other and placed such that screw placement avoided the intervertebral disk space. The right plate was positioned more cranially and was fixed with 2 screws in C4 and 1 screw in C5, while the left plate was shifted more caudally with fixation of 1 screw in C4 and 2 screws in C5. One screw hole remained open in each plate (Figure 1A). Plates were not contoured and it was attempted to keep the distance between vertebral body and each end of the plate similar. A 2.5mm drill bit and a plate specific guide (Orthomed, Halifax, West Yorkshire, UK) were used to drill the cis-cortex only and 3.5mm self-tapping stainless steel screws were placed in monocortical fashion (DePuy Synthes Vet, West Chester, PA). A SOP plate holding lever was not used. Length of screws was estimated based on lateral radiographic measurements of the vertebral bodies as well as approximate distance between the screw hole and bone surface. Based on these values, only 16 and 18mm screws were used. Due to the ventrolateral SOP plate position on the vertebral body, the first screw was placed in a dorsomedial direction (toward midline of the vertebral body) at an estimated 20-30 degrees. Once the first screw was locked, placement of the other screws was determined by the plate.

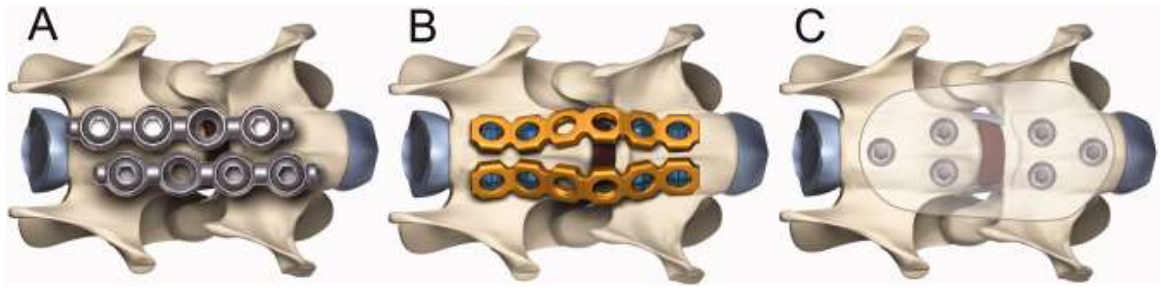


Figure 1. (A) Application of 2 non-contoured 4-hole 3.5 mm string of pearls plates to the ventral aspect of C4–C5. Plates are staggered with 1 plate fixed with 2 screws in C4 and 1 screw in C5, and the other plate fixed with 1 screw in C4 and 2 screws in C5. All 3.5 mm self-tapping cortical screws are placed monocortically. (B) Application of 2 contoured 6-hole cuttable 2.4 mm titanium locking reconstruction plates to the ventral aspect of C4–C5. Two 3 mm self-tapping titanium locking screws are placed monocortically cranially and caudally in each plate. (C) Application of self-tapping titanium cortical screws and polymethylmethacrylate (PMMA) to the ventral aspect of C4–C5. Three screws each are placed monocortically in C4 and C5 and fixed with 20 g PMMA.

For specimens undergoing Ti recon plate fixation (n=6), C4–C5 was stabilized using 2 cuttable 2.4 mm titanium locking reconstruction plates (DePuy Synthes Vet). Plates were cut to include 6 holes and were contoured to lie as close as possible on the ventrolateral aspect of the vertebral bodies. Plates in 5 specimens were applied so that the 2 most cranial and the 2 most caudal screw holes were filled, leaving 2 holes empty overlying the disk space (Figure 1B). One specimen with smaller vertebral bone dimensions had only 1 screw hole left open over the disk space to better accommodate the screws within the vertebral bodies but was subsequently excluded from statistical analysis. A 2.4 mm drill bit and threaded guide were used to drill the cis-cortex and 3.0 mm self-tapping titanium locking screws (DePuy Synthes Vet) were placed in monocortical fashion. Based on measurements on pre-fixation lateral radiographic, only 10 mm long screws were applied.

Specimens undergoing fixation with Ti screws/PMMA (n=6) had been tested as part of a previous study using the same inclusion criteria and procedural protocols. The specimens had a cortical ring disk spacer placed and C4–C5 stabilization with monocortical self-tapping titanium screws and PMMA (DePuy Synthes Vet and Simplex P Bone Cement, Stryker, Mahwah, NJ, respectively; Figure 1C).⁶

Orthogonal radiographs were obtained pre-testing to assess implant and cortical ring position and post-testing to assess implant failure, bony damage secondary to mechanical testing, and shift in cortical ring graft position (Figure 2).

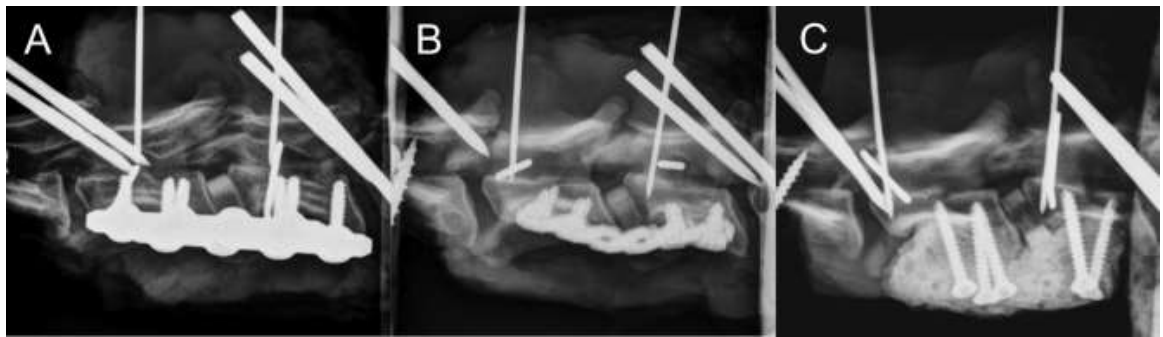


Figure 2. Lateral radiographs of stabilized canine cadaveric C4–C5 vertebral segments. A cortical ring graft has been placed as intervertebral spacer in all specimens. (A) Two 4-hole 3.5 mm string of pearls plates and six 3.5 mm monocortical self-tapping stainless steel screws. (B) Two 6-hole 2.4 mm cuttable titanium reconstruction plates and eight 3.0 mm monocortical self-tapping titanium locking screws. (C) Six 3.5 mm monocortical self-tapping titanium cortical screws fixed with polymethylmethacrylate. Note dorsally located end-threaded pins and small Kirschner wires are part of the potting and extensometer set up.

Biomechanical data collection

Potting of the cervical vertebral columns was performed as previously reported and allowed for isolated testing of the C4-C5 vertebral motion unit (VMU).^{6,7}

Extensometers measured localized deformation at the C4-C5 VMU during extension, flexion and right lateral bending using a custom made four-point bending fixture. Testing protocol was the same as in previous studies to allow for direct comparison of data. Briefly, specimens were tested intact and after fixation. They underwent 4 full cycles of extension, flexion and lateral bending with testing being load-controlled at 50 N/min to 150 N in flexion and extension and to 100 N in right lateral bending. Load and extensometer displacement data from the 4th cycle were used to calculate load-displacement curves for each bending moment of the unaltered and instrumented C4-C5 motion unit. Stiffness (N/mm) was calculated by selecting the linear portion of each load-displacement curve.

Statistical analysis

Categorical data were described using frequencies, proportions, and 95% mid-P exact confidence intervals (Epi Info, version 6.04, CDC, Atlanta, GA). Body weight and DEXA values were summarized as means (95% CI). The normality assumption was evaluated for body weight, DEXA measurements, and stiffness by plotting histograms, calculating descriptive statistics, and performing the Anderson-Darling test (MINITAB Statistical Software, Release 13.32, Minitab Inc, State College, PA). Stiffness data were transformed using the natural logarithm due to violation of the normality assumption. Geometric means (95% CI) were calculated on log-transformed stiffness and back-transformed for description. The frequency of male vs. female cadavers was compared between the SOP and other fixation methods combined using Fisher exact tests. Body weight and DEXA measurements were compared between the three fixation methods

using 1-way ANOVA. Mixed-effects linear models were used to estimate the effect of fixation method on the increase in stiffness obtained through fixation. Mixed-effects models were fit for each outcome (flexion, extension, right lateral bending) to compare the baseline (pre-fixation) stiffness (3 models) and the increase in stiffness due to fixation (fixated stiffness–baseline stiffness) (3 models). Body weight, DEXA measurements, and sex were included in all models as covariates. Post hoc pairwise comparisons between fixation methods, when necessary, were adjusted using Bonferroni correction of P values, maintaining type I error at .05. Statistical evaluation of stiffness was performed in commercially available software (IBM SPSS Statistics Version 22, International Business Machines Corp, Armonk, NY). All statistical tests were considered significant at $P \leq .05$.

RESULTS

Vertebral specimens

The dog population was comprised of 17 Pit Bulls or Pit Bull mix-breed dogs, 1 Rottweiler mix-breed and 1 Labrador mix-breed dog (14 intact males, 5 intact females) with a weight range from 23 kg to 31 kg (median of 26.4 kg). All dogs were mature based on radiographic physal closure, and there was no radiographic evidence of cervical vertebral column disease. One dog from group 2 was excluded from the statistical analysis because smaller vertebral dimensions did not allow similar plate application as in the other specimens. Sex, body weight, and bone mineral density were not significantly different among treatment groups (Table 1).

Biomechanical testing

There was no significant differences in stiffness increase between the 3 fixation methods for flexion ($P=.459$), extension ($P=.113$), or right lateral bending ($P=.292$, Table 2).

Table 2. Comparison of stiffness increase across fixation methods. Means and confidence intervals calculated on the natural logarithm scale and then back transformed into the natural scale.

| | SOP | Ti recon plate | Ti screw/PMMA | |
|------------------|----------------------|-----------------------|----------------------|------------------|
| Direction | Mean (95% CI) | Mean (95% CI) | Mean (95% CI) | P value * |
| Extension | | | | |
| Pre-fixation† | 7.6 (5.6, 10.4) | 7.8 (5.3, 11.5) | 6.1 (3.4, 10.9) | 0.545 |
| Post-fixation‡ | 513 (384, 685) | 245 (192, 311) | 478 (354, 652) | 0.113 |
| | | | | |
| Flexion | | | | |
| Pre-fixation† | 4.7 (2.8, 8.0) | 5.8 (2.2, 14.9) | 7.8 (5.3, 11.7) | 0.512 |
| Post-fixation‡ | 250 (178, 354) | 147 (106, 204) | 311 (235, 416) | 0.459 |
| | | | | |
| Lateral | | | | |
| Pre-fixation† | 5.6 (3.5, 9.1) | 6.0 (3.0, 11.9) | 4.8 (2.9, 7.7) | 0.814 |
| Post-fixation‡ | 528 (441, 633) | 633 (545, 735) | 327 (257, 412) | 0.292 |
| | | | | |
| | | | | |
| | | | | |

SOP= String of Pearls, Ti= titanium, PMMA= polymethylmethacrylate

*Based on mixed-effects linear regression adjusting for body weight, DEXA values, and cadaver sex.

†The dependent variable for these analyses was the natural logarithm transformed baseline (pre-fixation) stiffness values.

‡The dependent variable for these analyses was the difference in the natural logarithm transformed stiffness values (fixated – baseline values).

Radiographic implant assessment

Radiographs of the specimens pre-testing showed minimal canal penetration by a screw

tip in 3/42 screws for SOP (2 were <1 mm; 1 was <2 mm), 2/48 screws for Ti recon plates (both <1 mm), and 1/36 screws for Ti screws/PMMA (<2 mm).⁶ In one Ti recon specimen, 1 screw penetrated the caudal endplate of C4 by <1 mm. This specimen (excluded from statistical analysis) had smaller vertebral dimensions and only 1 set of screw holes was left empty over the disk space, resulting in closer proximity of the angle fixed screws to the slanted disk space. Cortical ring grafts were seated within the borders of the endplates in all specimens.

Radiographs post-testing showed no evidence of failure of the implants or bone. The cortical ring grafts had not shifted from their original position.

DISCUSSION

In these cadaveric, canine, cervical vertebral columns, we did not demonstrate a difference in the stiffness of 2 veterinary locking plates applied with monocortical screws and an intervertebral cortical ring spacer, from that of monocortical screws with PMMA and a cortical spacer.

Monocortical screw/PMMA constructs have been shown to be biomechanically equivalent to bicortical pin/PMMA constructs.⁷ Similarly, due to the increased strength and rigidity of the screw-plate interface, monocortical instead of bicortical screw fixation is acceptable for locking screw/plate constructs.¹⁸⁻²⁰ This makes their use for the canine cervical vertebral column ideal and should avoid complications related to injury to neurovascular structures. For this study, we chose 2 veterinary locking plate systems that are available for canine patients. Clinical reports describing the use of these two plates with the addition of disk spacers support their application in clinical patients.^{13,14} While a

benefit of the SOP plate may be lower cost of the implant through the use of standard cortical screws instead of locking screws, the Ti recon plate offers the advantage of MR-compatibility and improved post-implantation imaging.

PMMA is readily available and inexpensive, and provides a strong and versatile fixation construct when used with screws or pins. However, the thickness of PMMA necessary for appropriate construct stiffness makes it a large and bulky implant which can interfere with the trachea and esophagus, and soft tissue closure. The exothermic polymerization of the PMMA has potential health implications for the staff and can be damaging to tissues. Finally, adjusting or removing PMMA after curing is a challenge, particularly in the confines of exposure of the ventral cervical spine.²¹⁻²⁵

The use of plate and screws allows for fixation with a much lower profile and allows the removal the implant with relative ease. Locking plates offer the additional advantage of usage of monocortical screws and do not require perfect contouring to the undulating vertebral body surface. However, plate designs in regards to screw trajectory, screw hole distance, length and size of the plate may not be appropriate for the patient-specific vertebral body dimensions.

There were no significant differences within each measurement direction evaluated among the three fixation methods. However, there were descriptive differences in stiffness of extension, flexion, and lateral bending among the different fixation methods. Stiffness in extension was greater than in flexion with all construct types. This is likely due to the location of fixation on the ventral vertebral body surface, which is the tensile surface during extension.²⁶ This allows the fixation to counteract distraction forces on the ventral aspect of the VMU during extension and induce compression at the dorsal

vertebral endplate/disk spacer interface. Compression and subsequent load-sharing can occur due to the presence of the disk spacer, provided this has appropriate contact to and fit along the endplates. In flexion, the ventral fixation is on the compression side of the stabilized VMU, where it provides less resistance to bending stresses and may allow gapping on the dorsal aspect of the VMU.²⁷

An unexpected finding was the stiffness in lateral bending of the Ti recon plate constructs compared to the other implants. Due to the increased moment of inertia, stiffness in lateral bending was, as expected, substantially higher compared to extension and flexion within the same implant construct. It was, however; also higher compared to lateral bending of the SOP and Ti screw/PMMA constructs. While the lesser stiffness of reconstruction plates in extension and flexion compared to the other 2 implants may be explained by the smaller plate size (3.5 mm SOP and 2 cm PMMA cement mantle vs. 2.4 mm Ti recon plate), different implant design (lateral notches of a reconstruction plate) and different material properties (stainless steel and PMMA vs. titanium), the high stiffness values in lateral bending are difficult to explain. Due to the v-shaped notches between screw holes of reconstruction plates, they are considered less rigid than other plates of comparable size, and should be less stiff when tested in lateral bending. If plate size, design, and material are not the cause of this increase in stiffness, and data is assumed to be representative despite the small number of specimens, it is possible that the screw locking mechanism is the cause. All 3 implants (including the Ti screw/PMMA construct) could be considered locking since screws are rigidly connected to the fixation. While bonding with PMMA, especially with manual application, could feasibly allow for a small amount of movement of the screw head within the PMMA, the SOP and Ti recon

plate have a dedicated screw locking mechanism. It is possible that the stability of the SOP screw, which locks a standard cortical screw using a press-fit against a recessed chamfer, is less than the stability of the threaded screw in the threaded hole of the Ti recon plate. Another possible explanation may be the application of 4 screws per vertebral body using the Ti recon plates, compared to 3 screws in the other 2 fixations. Finally, these results could also have been influenced by the inherent variations in vertebral size and implant position in this study. Evaluation of these plates under standardized conditions would be helpful.

Biomechanical testing of the canine vertebral column is challenging due to its complex structure. Even within the same dog breed, vertebral dimensions vary, making standardization of procedures difficult. Implants were placed in a similar manner, but each was adjusted to the individual ventral vertebral body surface and size. While unavoidable, these differences in implant placement coincident with differences in individual bony anatomy likely affected results, evident by the large variability within fixation methods. Larger sample sizes to improve confidence in estimates may be required to avoid type II error and more definitely compare the fixation methods.

The order and number of cycles of testing were based on a previous test protocol which did not repeat testing after all directions were evaluated. Testing could weaken the construct and affect stiffness for subsequent measurements. Fatigue testing was not performed due to the difficulties of maintaining specimens in proper position during prolonged testing. While the current study cannot comment on the ideal stiffness of implants for clinical stabilization, it did make relative comparisons across fixation methods.

The study was restricted to use of a set inventory of screws with the lengths of locking screws used for both implants in this study ordered based on pilot data. Ideally, each screw length would have been determined individually during placement, according to depth gauge measurements. The availability of shorter screws may have obviated the screw penetration in 1 SOP and 1 Ti recon plate.

Radiographic accuracy of determining vertebral canal violation of monocortical screws in the canine cervical spine has been evaluated and found to be high for screws penetrating the cortex.⁷ Based on this, postoperative assessment of possible screw penetration into the canal was based on radiographs only. While not likely, it is possible that implant configurations with different screw orientations affect this accuracy and that screw violations may have been missed in our study.

Technical challenges during plate applications presented themselves during the study, which also hold clinical significance. Due to the short length and resulting deviation of screw direction, the SOP plates were not contoured. It was difficult holding the SOP plate during placement of the first screw since no reduction clamps were used to fix it in place. Often the plate would be pushed further away from the bone while the screw tried to purchase the cis cortex. When applying manual counterpressure, the plate would sometimes be closer to the bone than planned. This meant that despite the correct screw length based on depth gauge measurements this first screw could be too long or too short. For subsequent screws, this was not an issue since the SOP plate was now locked in position. Inadvertent tilting of the plate over the uneven vertebral bone could also bring the angle-stable screws into a less desirable trajectory (i.e. closer toward the endplate/disk space). While close contact with underlying bone is not a requirement of locking plates,

contouring appears to be a procedural feature in clinical reports describing the use of the 2.4mm Ti recon locking plate.^{14,28} Due to their different shape and smaller size, contouring was easily performed on the 2.4mm Ti recon locking plates and was aimed to be within 1mm to the vertebral body bone surface. Contouring therefore also changed the trajectory of the angle stable screws, which was taken into preoperative planning consideration as to where to position the plate. Disadvantageous screw trajectory led to penetration of the endplate of C4 in 1 specimen. In this case, the spine was smaller than the others and the decision was made to shorten the plate length to 5 holes rather than 6. This specimen was excluded in the statistical analysis for this reason. Better decision making in regards to plate length and position on the bone may have prevented this problem.

In conclusion, two 3.5mm SOP plates and two 2.4mm Ti recon locking plates in combination with a cortical bone disk spacer significantly increase stiffness of the cadaveric C4-C5 VMU. Our null hypothesis was not rejected in this group of specimens as stiffness of these plate constructs was not significantly different to fixation with screws/PMMA in any evaluated measurement direction. However, there were apparent differences between measurement directions, which could be inherent to the moment of inertia of the fixation methods or might have been caused by variations in anatomy and implant application. Compared to screw/PMMA fixation, these locking plates offer fixation with decreased bulk and improved ability for implant removal if required. Preoperative planning with determination of the appropriate plate length and screw positioning, and intraoperative attention to location of screw placement and trajectory are necessary to avoid screw penetration into the vertebral canal or adjacent disk spaces.

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DISCLOSURE

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

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