Running head: Accuracy and safety of lateral vertebral stabilization

Title: Accuracy and Safety of Pin Placement During Lateral versus Dorsal Stabilization of Lumbar Spinal Fracture-Luxation in Dogs.

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ABSTRACT

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Objective:

To determine the accuracy and safety of pin placement for lateral vertebral stabilization to the reference dorsal stabilization.

Study Design: A randomized non-inferiority trial

Sample population: 20 Greyhound cadaveric lumbar spines (L1-L6)

Methods: 159 lumbar vertebral pins placed in 80 vertebrae were assessed; these pins were distributed approximately equally between the dorsal and lateral approaches, and between two surgeons. Pin angle accuracy, bone purchase distance, and distances from pin to the spinal canal and the aorta were measured for each pin.

Results: The lateral approach was superior for pin angle accuracy and bone purchase. The mean angle of deviation was 15.3 degrees with the dorsal approach, and 7.0 degrees with the lateral approach. The mean bone purchase was 16.7mm with the dorsal approach and 22.2mm with the lateral approach. Pins were placed at a mean of 2.3 mm from the spinal canal with the dorsal approach and 1.7mm with the lateral approach. Pins were placed at a mean of 3.8mm from the aorta with the dorsal approach, and 8.0mm with the lateral approach. The percentage of pins breaching the spinal canal was 14% with the dorsal approach and 19% with the lateral approach. 14% of pins breached the aorta with the dorsal approach, whereas none did with the lateral approach.

Conclusions: Relative to the dorsal approach, the lateral approach improves angle accuracy, bone purchase and distance between pins and the aorta, and is non-inferior with regards to the distance between pins and the spinal canal.

Introduction:

Lumbar vertebral fractures and luxations commonly follow motor vehicular accidents and falls from height.¹ Prognosis is based on presence of nociception. Methods to stabilize vertebral bodies include the use of pins and polymethyl methacrylate (PMMA), vertebral body plating, dorsal spinous process plating, facet joint plating and external skeletal fixation.²⁻⁹

Safe corridors for lumbar vertebral pin placement have been described for use in combination with PMMA.¹⁰ A closed fluoroscopic approach has been shown to increase accuracy of pin placement into the vertebral body compared to an open approach.⁹ Complications described for lumbar vertebral pin placement include breaching of the spinal canal, subsequent spinal cord damage and fatal vascular trauma.¹

A previous study by Hall et al. investigated the strength of lateral and dorsal pin stabilization and found that the novel lateral approach was non-inferior to the dorsal approach.⁵ No studies have tested the accuracy of lateral pin placement and its proposed clinical benefit. The lateral approach is theoretically advantageous due to a decreased risk of complications. This approach also minimizes intra-operative tissue dissection, facilitate wound closure and eliminate the bending of pins for PMMA fixation. Combined, these advantages should improve the safety of the approach.

The primary objectives of this study were to compare lateral versus dorsal approaches in terms of pin angle deviation from target angle, bone purchase, and safety based on distances from pin to the spinal canal and aorta. Secondary objectives were to assess whether any effects of approach on these measures differ between two surgeons, and

whether frequency of spinal canal and aorta breach, and penetration distances where breaches occur differ between approaches. We hypothesized that the lateral approach would provide similar or superior accuracy and safety than the standard dorsal approach.

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Materials & Methods:

Study Overview

The study design was a randomised non-inferiority trial that compared the lateral and dorsal approaches to spinal fixation. Both approaches were performed as previously

described by Hall⁵ in the L1, L2, L5 and L6 vertebrae from canine cadavers. The lateral approach was made from the left-sided approach and the dorsal approach was made from the dorsal midline. In this context, a non-inferiority trial aims to establish whether a new technique is not unacceptably worse than a reference standard for given measured variables. In the current study, the dorsal approach group served as the reference standard as it has been long accepted as a suitable approach for fixation of lumbar spinal fractures and luxations.^{3,6-8} As the novel lateral approach offers several advantages over dorsal approach, our primary interest was in whether the novel lateral approach with a recommended insertion angle of 75 degrees resulted in pin angle deviations from target angle, bone purchase distances, distances from pin tip to the spinal canal, and nearest distances between the pin tip and the aorta that are not unacceptably worse in comparison to the dorsal approach. Thus the reference standard dorsal approach with a recommended insertion angle of 60 degrees was used as the comparison or 'control' group.

Definition of Non-inferiority and Sample Size Calculations

Non-inferiority margins were specified *a priori*, as recommended.¹¹ For those measures where higher outcome values were favorable (length of bone purchase, distance from pin to the spinal canal and the aorta), if the lateral approach mean was shown to be probably no less than (i.e. no worse than) this margin below the dorsal approach mean, the lateral approach was to be declared non-inferior to the dorsal approach. For the absolute values of pin angle deviation from target, where lower outcome values were favorable, if the lateral approach mean was shown to be probably no greater than (i.e. no worse than) this margin above the dorsal approach

mean, the lateral approach was to be declared to be non-inferior to the dorsal approach.

There were no data to describe clinical consequences for patients of various pin angle deviations from target and bone purchase distances after repair, and while probabilities of spinal canal and aorta breach would be expected to decrease with increasing mean distances from pin to the spinal canal and the aorta, respectively, these relationships have not been described. Accordingly, non-inferiority margins were defined solely based on statistical considerations. We calculated non-inferiority margins using the `-ssi-` command in Stata (version 14.1, StataCorp, College Station, TX). The one-sided type 1 error probability was set at 0.05 and power was set at 80%. We assumed the within-approach standard deviation was the same as the largest of the standard deviations for the dorsal and lateral approaches from Hall⁵. As we were to place 2 pins per vertebrae and would use 4 vertebrae per cadaver and the individual pin was to be the unit of analysis, to account for any clustering (i.e. correlation of measures between pins in the same vertebra), we estimated intra-class correlation coefficients using the data from Hall⁵. These data consisted of 2 pins per vertebrae and 4 vertebrae per cadaver so multilevel mixed-effects linear regression was used with pin clustered within vertebrae and vertebrae clustered within cadaver. These models were fitted with Stata's `-mixed-` command using restricted maximum likelihood (REML) estimation. Approach (lateral or dorsal) was fitted as a fixed effect. Intra-class correlation coefficients for the correlation between pins in the same vertebra were calculated as previously described.¹² Sample sizes were calculated adjusted for the intra-class correlation coefficients and the consequent design effect¹²

given that there were to be 2 pins per vertebra; adjusted sample size was the unadjusted sample size (80 or 120 pins per approach) divided by the design effect.

(Table 1)

Non-inferiority margins are shown in Table 1. For example, for absolute value of pin angle deviations from target, if the within-approach standard deviation is 7.7 degrees, the intra-class correlation is 0.56, and 80 pins were enrolled in each group, the study would have 80% power (i.e. probability of 0.80) of detecting non-inferiority defined as a margin of +3.8 degrees. Based on these calculations and after consideration of available resources, we elected to enrol 80 pins in each group and used the corresponding non-inferiority margins.

Study Subjects

Cadavers were selected from those acquired for a previous study⁵. For that study, cadavers of active or recently retired racing Greyhounds of unknown age had been used. Spinal radiographs had been taken before dissecting out the specimens for the previous study and any cadaver with evidence of spinal disease had been excluded. Cadavers were eligible for the current study if they showed no evidence on computed tomography of iatrogenic damage to the vertebral bodies that would affect this study. In total, cadavers of 11 male and 9 female dogs weighing 26-37kg were selected for the current study. The lumbar vertebrae (L1-L6) and surrounding muscle had been harvested and L3 and L4 had been used for the previous study. Specimens had been wrapped in saline (0.9% NaCl) solution soaked paper towels and frozen at -9°C to -13°C for 12-14 months. For the current study, specimens were defrosted to room

temperature, all external implants from the previous study from L1, L2, L5 and L6 vertebrae removed and used in the current study. Each cadaver was identified by a computer-generated random number from 1 to 20. Pin placement was performed 12-24 hours after defrosting cadavers.

Allocation of Treatments

A factorial design was used with 2 surgeons each performing 20 lateral and 20 dorsal approach treatments with a total of 40 lateral pins and 40 dorsal pins to be placed by each surgeon. Each of the 20 lumbar vertebral columns contributed 4 vertebrae (L1, L2, L5 and L6). Within each column, all vertebrae received the lateral approach or all received the dorsal approach. Within each vertebra, 2 pins were placed in immediate succession by the same surgeon, with the cranial pin placed first. The treatments were implemented on 2 days 1 month apart, with 64 pins to be placed on day 1 by each surgeon, and 96 pins on day 2 by each surgeon. The study was performed over 2 separate days to reduce effects of any increases in accuracy with practice. Each surgeon treated two vertebrae in each column, with treatments allocated so that each surgeon treated equal numbers of L1, L2, L5 and L6 vertebrae within each. Within surgeon, both approach and column were alternated (i.e. dorsal then lateral in a different column then dorsal in a third column and so on). After completing one vertebra, the surgeon completed at least 5 treatments all in different vertebral columns before returning to a different vertebra in that original vertebral column. This was to minimize any benefits for accuracy associated with practice when using the same approach repeatedly, and any increases in accuracy when pinning the second vertebra from perceptions during surgery when pinning a previous vertebra of the same column.

Treatment Details

Treatments were performed by 2 specialist surgeons (S.S. & K.D) who were both right handed. Lateral and dorsal spinal fixation approaches were performed as previously described by Hall⁵. The lateral approach was made from the left side as the left-to-right pin trajectory was less likely to inadvertently penetrate the aorta than if the trajectory was right-to-left. The dorsal approach was made from the dorsal midline. The vertebral instability was assumed to be cranial to where pin placement occurred. Pin placement was angled caudally within the vertebral body, as would be the case for stabilizing a fracture cranial to the vertebral body. The starting point for the cranial pin was at the base of the lateral spinous process where the curve of the process ends as it becomes flat. The starting point for the caudal pin was at the caudal margin of the base of the lateral spinous process. Pin holes of 3.1mm diameter were pre-drilled. Positive-profile half pins (3.2mm; item 15180NP, Imex, Longview, TX) were placed in pre-drilled holes. The target pin angles (angle between the pin and the vertical axis in the transverse plane) were 60 degrees for the dorsal approach and 75 degrees for the lateral approach as previously described^{1,5,10}. The aim for pin penetration was to engage the trans cortex for bicortical pin placement and to avoid penetration of the aorta. Surgeons placed pins by feel and were not able to visualize the trans cortical surface. After each pin was placed, it was cut as close to the bone as possible so that placement of subsequent pins would not be biased by the presence of the previously placed pin. No PMMA was utilized as strength was not being assessed in this study.

Outcome Measures

The cadavers were scanned with computed tomographic imaging using a CT machine (Siemens SOMATOM Emotion 16-slice helical scanner, 100mAs, 130kV) after each treatment day. The order of scanning of cadavers from each day was allocated using computer-generated random numbers. The scans were performed by a technician blinded to the surgeon allocation. Measurements were obtained using the OsiriX program (v.3.9.4, Geneva) by the first-named author, who was also blinded to the surgeon allocation. The slice in which the greatest length of pin could be visualized within the vertebral body defined the transverse plane. Pin angle was measured in the transverse plane from the dorsal spinous process of each vertebra and expressed as deviation from the target angle for that approach. A negative deviation indicated that the pin was placed steeper (i.e. closer to vertical) than target and a positive deviation indicated that the pin was placed flatter (i.e. closer to horizontal) than target. Bone purchase length was the measured length of pin engaged in vertebral bone as viewed in the transverse plane. The distance from the pin to the spinal canal was the length measured from the nearest edge of the pin to the nearest edge of the spinal canal. The estimated distance from the pin to the aorta was calculated as the shortest distance from the pin to the estimated location of the closest aorta wall. Pin breach of the spinal canal was assessed in the transverse plane. Aorta breach was defined as occurring when the distance between the pin and the aorta was negative as described below. The pin starting point was not taken into consideration in regards to measurements

Distance between Pin and Aorta

A trigonometric method was developed to calculate the distance between the pin and the aorta. Aortic measurements were obtained at the level of L1 from 3 live non-study

Greyhounds ranging from 36 to 38.5kg that had computed tomography in the clinical setting unrelated to the study. Data from a fourth non-study Greyhound selected for this purpose were disregarded as the dorsal wall of the aorta was 16.7 mm below to the ventral surface of vertebra, compared to 3.7 to 4.7 mm for the other three Greyhounds. Distances between the pin and the aorta were calculated for each pin assuming the aorta was centered in the mid-sagittal plane directly ventral to the vertebra, its dorsal wall was 3.7 mm below to the ventral surface of vertebra, and that it was circular in cross-section with a diameter of 17.9 mm. These values were the smallest and largest, respectively, for 3 non-study Greyhounds.

(Figure 1)

As the smallest and largest values were used, our estimated nearest distances between the pin and the aorta were conservative (i.e. likely to result in underestimation of the nearest distances compared to if average values had been used). For pins whose tips extended beyond the nearest distance between the pin and the aorta, the distance from the point on the pin closest to the aorta was used (rather than the distance from the pin tip to aorta). The same methods were used where the pin tip did not extend beyond the trans cortex. Negative distances indicated that the aorta would have been penetrated under the assumptions described above. The same method was applied to data from Hall⁵ for sample size and non-inferiority margin calculations. For 2 pins in those data, the ventral exit was ipsilateral to the center of the aorta. The distances from pin to aorta were not calculated for these 2 pins. This did not occur for any study pins; the trajectories for all study pins were towards the contralateral side of the aorta center. Full details of the trigonometric method are available from the authors.

Statistical methods

All statistical analyses were performed using Stata (version 14.1, StataCorp, TX). Non-inferiority of lateral spinal fixation approach relative to dorsal spinal fixation approach were assessed for each of the absolute value of pin angle deviation from target (absolute difference between pin angle and target angle), bone purchase distance, and distances from pin to the spinal canal and the aorta. For assessment of non-inferiority, the null hypotheses are the reverse of those for usual comparative studies, and are one-sided.¹¹ Non-inferiority was assessed by performing linear regression and assessing the lower limits of the two-sided 95% confidence intervals (CIs) for the differences between means (lateral minus dorsal approach). For example, for pin angle (where lower outcome values were favorable), if the upper limit of the 95% CI was less than (i.e. more negative than) +3.8 degrees (the non-inferiority margin if 80 pins were used per approach), non-inferiority was to be declared, and we would then assess for non-superiority. If the upper limit was below (i.e. more negative than) 0 degrees, the lateral approach was to be considered superior.

Differences between means were assessed using the individual pin as the unit of analysis, using multilevel mixed-effects linear regression with pin clustered within vertebrae and vertebra clustered within cadaver. Models were fitted using Stata's `mixed` command with maximum likelihood estimation. Along with approach (dorsal or lateral), day of surgery (1 or 2), surgeon (1 or 2), vertebra (L1, L2, L5 or L6) and pin location within vertebra (cranial or caudal) were also fitted as fixed effects, all as categorical variables. For absolute values of pin angle deviation from target, the data were right skewed (as no values could be negative) but residuals from the model were

approximately normally distributed. No interim analyses or sub-group analyses were specified *a priori* and none were performed. The only interactions tested were approach by surgeon. These interactions were assessed using the same models; likelihood ratio p-values for the interaction term were used. Proportions of pins that breached the spinal canal were compared between approaches in the same way but using multilevel mixed-effects logistic regression with models fitted using Stata's -melogit- command. Proportions of pins that breached the aorta were compared using exact logistic regression with a model fitted using Stata's -exlogistic- command. Only approach was fitted as a fixed effect and this model did not account for clustering. However, more complex models were not possible as no lateral pins breached the aorta. Sufficient statistics and the mid-p-value rule were used, except for the lower limit of the 95% CI where median unbiased estimates without the mid-p-value rule were used.

Results:

Numbers of Pins and Reasons for Exclusion

A total number of 159 pins were placed over 2 days. Surgeon 1 placed a total of 80 pins; 40 in the dorsal approach and 40 in the lateral approach. Surgeon 2 placed a total of 79 pins, 40 in the dorsal approach and 39 in the lateral approach. One pin (a lateral approach pin by surgeon 2) could not be placed due to damage to the vertebrae from its use in the previous study and thus this pin was excluded from the study. The associated vertebral body had not been excluded from the study as no vertebral fractures or fissures were visible on initial computed tomography. In the previous study, holding pins had been utilized in the cadaver vertebral bodies. The holes for these holding pins only affected this one pin.

(Figure 2)

(Figure 3)

Pin Angle

The measure used was the absolute deviation in degrees from the intended or target angle for each approach. Surgeon 1 had a mean absolute angle deviation from the target of 8.2 degrees with the dorsal approach (range 0.3-32.1) and 7.0 degrees with the lateral approach (range 0.1-25.5). Surgeon 2 had a mean absolute angle deviation from the target of 22.5 degrees with the dorsal approach (range 0.2-40.3) and 6.9 degrees with the lateral approach (range 0.2-31.2). The P-value for interaction between approach and surgeon was <0.001 . For the pooled data, the mean absolute angle deviation was 15.3 degrees with the dorsal approach (range 0.2-40.3) and 7.0 degrees with the lateral approach (range 0.1-31.2). The estimated difference between means (lateral minus dorsal) from the pooled data was -8.5 degrees (95% CI -11.7 to -5.2). As the upper limit of the 95% CI (-5.2 degrees) was less than (i.e. more negative than) +3.1 degrees, we declare the lateral approach to be non-inferior. Further, as that limit was less than (i.e. more negative than) zero, we declare the lateral approach to be superior.

Length of Bone Purchase

Surgeon 1 had a mean bone purchase of 18.4mm with the dorsal approach (range 2.7-25.9) and 22.1mm with the lateral approach (range 17.3-26.8). Surgeon 2 had a mean bone purchase of 15.1mm (range 4.5-24.2) with the dorsal approach and 22.2mm with the lateral approach (range 16.2-27.2). The P-value for interaction between approach

and surgeon was 0.009. For the pooled data, the mean bone purchase was 16.7mm with the dorsal approach (range 2.7-25.9) and 22.2mm with the lateral approach (range 16.2-27.2).

The estimated difference in means (lateral minus dorsal) from the pooled data was 5.4mm (95% CI 4.1 to 6.8). As the lower limit of the 95% CI (4.1mm) was above -0.23mm (the non-inferiority margin), we declare the lateral approach to be non-inferior. Further, as that limit was above zero, we declare the lateral approach to be superior.

Distance from Pin to the Spinal Canal

Surgeon 1 had a mean distance of 2.0mm with the dorsal approach (range -5.4-9.2) and 1.4mm with the lateral approach (range -3.1-5.7). Surgeon 2 had a mean distance of 2.6mm with the dorsal approach (range -4.2-8.9) and 2.0mm with the lateral approach (range -1.7-5.6). The P-value for interaction between approach and surgeon was 0.932. For the pooled data, the mean distance from the spinal canal was 2.3mm with the dorsal approach (range -5.4-9.2) and 1.7mm with the lateral approach (range -3.1-5.7).

The estimated difference in means (lateral minus dorsal) from the pooled data was -0.6mm (95% CI -1.5 to 0.2). As the lower limit of the 95% CI (-1.5mm) was above -1.68 (the non-inferiority margin), we declare the lateral approach to be non-inferior. As that limit was below zero, we do not declare the lateral approach to be superior.

Distance from Pin to the Aorta

Surgeon 1 had a mean distance of 5.5mm with the dorsal approach (range -1.7-12.4) and 8.4mm with the lateral approach (range 1.5-15.0). Surgeon 2 had a mean distance of 2.1mm with the dorsal approach (range -5.7-8.8) and 7.6mm with the lateral approach (range 3.9-12.4). The P-value for interaction between approach and surgeon was 0.009. For the pooled data, the mean distance was 3.8mm with the dorsal approach (range -5.7-12.4) and 8.0mm with the lateral approach (range 1.4-15.0).

The estimated difference in means (lateral minus dorsal) from the pooled data was 4.2mm (95% CI 3.1 to 5.3). As the lower limit of the 95% CI (3.1mm) was above -2.5mm (the non-inferiority margin), we declare the lateral approach to be non-inferior. Further, as that limit was above zero, we declare the lateral approach to be superior.

Percentage of pins with spinal canal breach

Surgeon 1 experienced 20% (8/40) spinal canal breaches with the dorsal approach and 25% (10/40) spinal canal breaches with the lateral approach. Surgeon 2 experienced 8% (3/40) spinal canal breaches with the dorsal approach and 13% (5/39) spinal canal breaches with the lateral approach. The P-value for interaction between approach and surgeon was 0.762. For the pooled data, a total of 14% (11/80) spinal canal breaches occurred with the dorsal approach and 19% (15/79) spinal canal breaches with the lateral approach. The odds of breaching the spinal canal did not differ significantly between the lateral and dorsal approaches ($P=0.762$) but the estimated effect was very imprecise (odds ratio 1.5, 95% CI 0.4 to 5.8).

Percentage of pins with aorta breach

Surgeon 1 experienced 3% (1/40) aorta breaches with the dorsal approach and 0% (0/40) with the lateral approach. Surgeon 2 experienced 25% (10/40) with the dorsal approach and 0% (0/39) with the lateral approach. For the pooled data, 14% (11/80) of aortas were breached with the dorsal approach and 0% (0/79) with the lateral approach. The odds of breaching the aorta were significantly less for the lateral approach (odds ratio 0.1; 95% CI 0.0 to 0.3; $P < 0.001$).

Magnitude of spinal canal breach

The magnitude of the spinal canal breach was the measure of the pin width within the spinal canal. These data were from the pins that experienced spinal canal breach. The dorsal approach resulted in 11/80 pins with spinal canal breach with a mean distance of 2.8mm (range 1.5mm-5.4mm). The lateral approach resulted in 15/79 pins with spinal canal breach with a mean distance of 1.9mm (range 0.1mm – 3.1mm). The mean distance was significantly less for the lateral approach. The estimated difference in means (lateral minus dorsal and adjusted for covariates) was -1.9mm (95% CI -3.3 to -0.5mm; $P = 0.007$).

Magnitude of aorta breach

The magnitude of the aorta breach was measured as the length of pin penetration into the aorta. This data was taken from the 11 pins that experienced aorta breach. These were all from the dorsal approach. The range of pin penetration into the aorta was 0.3mm to 5.7mm, with a mean of 1.7mm.

Discussion:

Based on our results, the lateral approach for spinal fracture repair, as described by Hall,⁵ is superior to the dorsal approach in terms of pin angle, bone purchase, and distance from the pin to the aorta. In addition, the greater deviation from the intended trajectory of pin placement, spinal canal encroachment when the spinal canal was breached, and more frequent aorta breach observed with dorsal pin placement further support the safety of the lateral approach. The study demonstrated that the lateral approach was statistically not inferior to the dorsal approach in terms of pin proximity to the spinal canal, despite a higher percentage of spinal canal breaches associated with the lateral approach.

The degree of deviation from the recommended pin angle of insertion for the lateral approach⁵ (recommended pin angle 75°) was less than that of the dorsal approach (recommended pin angle 60°). For both approaches, a positive deviation would lead to decreased bone purchase and increased risk of aorta breach while a negative deviation would lead to less bone purchase and increased risk of spinal canal breach. Surgeon 1 had similar mean angle deviations for the dorsal and lateral approach whereas surgeon 2 was more accurate with the lateral approach than the dorsal approach. Surgeon 1 had performed more spinal fracture/luxation repairs than surgeon 2, which may have impacted the angle accuracy, possibly because the desired angle is easier to obtain with the lateral approach. Absolute values of angle deviation were used for statistical analysis as, for an individual pin, both positive and negative deviations can have adverse consequences. In a previous study⁹ assessing pin angle accuracy in thoracic and lumbar vertebrae, accuracy was improved with a fluoroscopic closed approach rather than an open approach. Fracture location can also affect pin accuracy as L6 and L7 are adjacent to the ilial wings laterally, complicating a lateral approach.

The starting point of pins was not assessed here as the authors felt its minimal variability would not impact the accuracy and safety of the approaches. The pin starting point would be similar for all cadavers as this anatomic recommendation was visualized for each pin placement by the surgeon. The surgeons involved were given the same instructions for approaches and variation would be more likely due to incorrect identification of anatomic landmarks rather than decreased accuracy.

Increased pin bone purchase length is likely to increase the strength of the fracture repair¹. The bone purchase length was superior in the lateral approach to the dorsal approach in our study. On average, the lateral approach had 5.4mm more bone purchase than the dorsal approach. In a previous study⁹, bone purchase was found to be greater in pins driven with fluoroscopic guidance rather than without fluoroscopic guidance, and in lumbar vertebrae in comparison with thoracic vertebrae.

The frequency of spinal canal breach was 19% (15/79) for the lateral approach and 14% (11/80) for the dorsal approach. There was a difference between surgeons with a higher frequency of spinal canal breach with surgeon 1 (23% or 18/80) than surgeon 2 (10% or 8/79). This may have been due to the fact that most of surgeon 2's pins had positive deviations in pin angle from target. Depending on the breach distance, spinal canal breach can result in a range of outcomes including no clinical effect, hemorrhage if the basivertebral veins are damaged, worsening neurological disease, and instability of surgical repair. Studies in human patients have documented spinal canal breaches up to 4mm with no clinical consequence.^{13,14} In the current study, the range of spinal canal breach distances was 1.5mm to 5.4mm with the dorsal approach

(mean 2.8 mm) and 0.1mm to 3.1mm with the lateral approach (mean 1.9mm).

Although human spinal canals are generally larger than canine spinal canals, the smaller spinal canal breach distances with the lateral approach may mean that clinically important consequences of breach are less common with this approach. We could reach no conclusion about whether the risk of spinal canal breach differs by approach as the confidence interval for the odds ratio for spinal canal breach was extremely wide.

Distance from the pin to the aorta in the lumbar region was measured to assess safety of approach. It is important that the pin engages the ventral vertebral body cortex to maximize bending strength and to minimize pin pull out strength.¹ There is a high risk of death after penetration of the aorta and this has been previously reported with vertebral fracture repair.² Both surgeons had increased distances from pin to aorta with the lateral approach, and the lateral approach was found to be superior to the dorsal approach. These results suggest that the lateral approach is safer than the dorsal approach in this respect, a conclusion consistent with the absence of aortic breaches with the lateral approach, compared to 14% (11 of 80 pins) with the dorsal approach. The lateral approach may be safer because the pin trajectory is not directed towards the aorta and major vessels.

The increased safety of the lateral approach supported in the present study, combined with the decreased tissue dissection involved with the lateral approach improve surgical outcomes for dogs. However, the lateral approach prevents observation of the articular facets, which may render it unsuitable in patients with zygoapophyseal joint subluxation, and fractures of the dorsal compartment where reduction cannot be

visualized. The authors have successfully used the unilateral pin and PMMA spinal fracture stabilization via a single lateral approach in the clinical setting for several years. Alignment of these cases was assessed with either radiography or CT post operatively and clinical outcomes appear similarly successful across dogs of varying breeds and sizes. This study and the results of Hall⁵ support the use of a lateral spinal approach and fixation method for lumbar vertebral fractures.

Limitations of this study include the limited number of cadavers, the exclusion of the L3 and L4 vertebral bodies, the effect of the previous holding pins on the cadavers used for this study, and use of the lumbar vertebrae and surrounding musculature rather than the entire cadaver. The statistical analysis for the inclusion of 120 pins per approach was investigated. However the non-inferiority margin difference was minimal. The exclusion of the L3 and L4 vertebral body from this study may have affected results as these may have better landmarks and better surgical access compared to L1/L2 and L5/L6. Results from entire cadavers rather than harvested lumbar spinal columns as used in the current study may have more closely reflected effects in an in vivo study. However, access to previously obtained cadaveric spinal columns was the determining factor to perform the study in this fashion rather than with entire cadavers. The previous holding pins prevented placement of only one pin and this pin was excluded from analyses. Based on results of the current study, a controlled in-vivo study is recommended to assess the clinical outcomes of this technique relative to the dorsal approach.

In conclusion, the lateral approach is superior in terms of angle accuracy, bone purchase length and pin distance from the aorta and non-inferior to the dorsal

approach in regards to pin distance from the spinal canal. Surgeon experience appeared to affect angle accuracy in the dorsal approach but did not affect pin distance from spinal canal, bone purchase length or pin distance from the aorta. Our findings support the use of the lateral approach for surgical stabilization of lumbar vertebral instability.

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Table 1. Standard deviations, intra-class correlation coefficients, design effects and non-inferiority margins for a non-inferiority trial comparing lateral and dorsal approaches to spinal fixation in dog cadavers

	Standard deviation*		Assumed ICCC†	Design effect‡	Non-inferiority margin§	
	Dorsal	Lateral			80 pins per approach	120 pins per approach
Absolute value of pin angle deviation from target (degrees)	7.7	5.2	0.56	1.56	+3.8 degrees	+3.1 degrees
Bone purchase distance	0.47	0.48	0.48	1.48	-0.23 mm	-0.19 mm
Distance from pin to spinal cord (mm)	2.2	3.3	0.68	1.68	-1.68 mm	-1.38 mm
Distance from pin to aorta (mm)	3.1	4.6	0.92	1.92	-2.50 mm	-2.05 mm

*These are for data from Hall⁵ We assumed the within-approach standard deviation was the same as the largest of these standard deviations.

†Intra-class correlation coefficients (ie. correlations of measures between pins in the same vertebra) estimated using the data from Hall⁵

‡Calculated as described by Dohoo¹²

§For example, for absolute value of angle deviations from target, if the within-approach standard deviations is 7.7 degrees, the intra-class correlation is 0.56, and 80 pins were used with each approach, the study would have 80% power (ie. probability of 0.80) of detecting non-inferiority defined as a margin of 3.8 degrees.

Figure Legends

Figure 1: Assumed aorta position in relation to vertebral body for a non-inferiority trial comparing lateral and dorsal approaches to spinal fixation in dog cadavers

- 1.) Distance from ventral vertebral body midline to dorsal aortic wall = 3.7mm
- 2.) Diameter of proposed aorta = 17.9mm

Figure 2: Accuracy Measures for a non-inferiority trial comparing lateral and dorsal approaches to spinal fixation in dog cadavers

- a) Length of bone purchase
- b) Pin angle

(SC) Spinal canal

(Ao) Aorta

Figure 3: Safety measures for a non-inferiority trial comparing lateral and dorsal approaches to spinal fixation in dog cadavers

- c) Distance from Pin to the Aorta
- d) Spinal canal breach magnitude

(SC) Spinal canal

(Ao) Aorta

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Table 1. Standard deviations, intra-class correlation coefficients, design effects and non-inferiority margins for a non-inferiority trial comparing lateral and dorsal approaches to spinal fixation in dog cadavers

	Standard deviation [*]		Assumed ICCC [†]	Design effect [‡]	Non-inferiority margin [§]	
	Dorsal	Lateral			80 pins per approach	120 pins per approach
Absolute value of pin angle deviation from target (degrees)	7.7	5.2	0.56	1.56	+3.8 degrees	+3.1 degrees
Bone purchase distance (mm)	0.47	0.48	0.48	1.48	-0.23 mm	-0.19 mm
Distance from pin to spinal cord (mm)	2.2	3.3	0.68	1.68	-1.68 mm	-1.38 mm
Distance from pin to aorta (mm)	3.1	4.6	0.92	1.92	-2.50 mm	-2.05 mm

^{*}These are for data from Hall³ We assumed the within-approach standard deviation was the same as the largest of these

standard deviations.

[†]Intra-class correlation coefficients (ie. correlations of measures between pins in the same vertebra) estimated using the data from Hall⁵

[‡]Calculated as described by Dohoo¹²

[§]For example, for absolute value of angle deviations from target, if the within-approach standard deviations is 7.7 degrees, the intra-class correlation is 0.56, and 80 pins were used with each approach, the study would have 80% power (ie. probability of 0.80) of detecting non-inferiority defined as a margin of 3.8 degrees.

- 1.) Distance from ventral vertebral body midline to dorsal aortic wall = 3.7mm
- 2.) Diameter of proposed aorta = 17.9mm

94x112mm (300 x 300 DPI)

- a) Length of bone purchase
- b) Pin angle
- (SC) Spinal canal
- (Ao) Aorta

94x91mm (300 x 300 DPI)

A

c) Distance from Pin to the Aorta
d) Spinal canal breach magnitude
(SC) Spinal canal
(Ao) Aorta

88x112mm (300 x 300 DPI)

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