Fatigue study of cancellous and cortical stainless steel screws used with polymethymethacrylate and the SOP plate system for immobilisation of vertebral luxation in canine cadavers

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Abstract

Globally, vertebral fracture and luxation (VFL) are one of the most common neurological injuries in dogs and cats. The standard care for vertebral body stabilisation of canine VFL is the use of screws with polymethylmethacrylate (PMMA) and the string of pearls (SOP) plate system fixation. VFL with implants are usually exposed to force in a repetitive or cyclic loading fashion. Indeed, stress on the implant cyclically at a load significantly less than its ultimate tensile strength can cause fatigue failure, one of the major causes of implant breakage. This study aims to compare the fatigue property and failure mode of four different implants in canine cadaveric VFL. The four different implants were constructed as follows: 3.5 mm cancellous screw with manually applied PMMA (MP), 3.5 mm cancellous screws with syringe application of PMMA (CanP), 3.5 mm cortical screws with syringe application of PMMA (CorP) and 3.5 mm cortical screws with a SOP plate (SOP). Results revealed that the SOP group tolerated the most cycles before failure, followed by the CorP, CanP and MP groups, respectively. The point of weakness, as defined by the failure mode, occurred in the middle of PMMA bridge (MP group), neck of the cancellous screw (CanP group), PMMA at the screw neck (CorP group), and 3.5 mm cortical screw (SOP group), respectively. In conclusion, based on the fatigue properties of the four implants tested in this study, the SOP plate is recommended as a standard fixation device for VFL in dogs.

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Introduction

Globally, vertebral fracture and luxation (VFL) is one of the most common neurological injuries in dogs and cats (Bruce et al., 2008; Jeffery, 2010). VFL is often the consequence of a vehicular injury, with the lumbar vertebrae being the most commonly affected in dogs (39%) (Feeney and Oliver, 1980). Lumbar VFL causes severe clinical outcomes such as paralysis of both hindlimbs. For the treatment of VFL, procedures can be broadly divided into conservative treatment and surgical treatment depending on the condition of the patient (Shores, 1992). In case of patients with severe neurological deficit, acute compression of the spinal cord or an instable spine should be treated with a surgical procedure. The purpose of surgical treatment is to reduce the fracture or luxation, decompress the spinal cord and rigidly stabilise the vertebral column. There are various methods to stabilize the vertebral column, including vertebral body plating, external splinting, spinous process plating, Lubra plates, pins or screws with polymethylmethacrylate (PMMA), external skeletal fixation, modified segmental fixation and tension band technique (Lumb and Brasmer, 1970; Shores et al., 1989; Bruecker, 1996; Voss and Montavon, 2004; Wheeler et al., 2007; Krauss et al., 2012). Currently, the gold standard immobilisation method for VFL is the use of screws (or pins) with PMMA fixation because this method is practical for clinical application and provides sufficient rigid stabilisation (Blass and Iii, 1984; Bruecker and Seim, 1992; Aikawa et al., 2007; Jeffery, 2010)

PMMA, known as bone cement, is generally used for implant fixation in various orthopedic and traumatic surgeries. PMMA acts as a space-filler that makes a tight space which holds the implant against the bone. There are various methods for the application of PMMA such as manual or syringe application. In addition, different methods for PMMA application cause changes in the porosity, which is the air entrapped inside the cement, leading to mechanical failure (Oh et al., 1983). Moreover, the bone anchoring part of the PMMA construction, which are the cancellous and cortical screws in this context, affects the strength as well as the stiffness of the contruction (Merk et al., 2001).

Recently, many studies have proved the stability of screws (or pins) with PMMA implants (Garcia et al., 1994; Zotti et al., 2011). Indeed, Garcia et al. (1994) and Zotti et al. (2011) reported that screws (or pins) with PMMA implants gave the greatest strength and rigidity in VFL cases. These studies tested the strength and the stiffness of the implant using a single cycle four-point bending model.

A standard treatment option for VFL is the string of pearls (SOP) plate system, which was designed to serve as a locking plate system for the veterinary and human orthopedic community. As with all locking plate systems, the SOP can be assumed as an internal-external fixator. The SOP comprises a series of stainless steel cylindrical units and spherical components made in three different sizes which accommodate 3.5 mm, 2.7 mm and 2.0 mm cortical stainless steel screws (Cronier et al., 2010).

However, after stabilising VFL with implants, the force that reacts to the implant is usually in a repetitive or cyclic loading fashion. Fatigue failure is one of the major causes of implant breakage. In human medicine, the fatigue failure of implant is very important as reported by many studies (Graham et al., 2000; Arora et al., 2013; Ajaxon and Persson, 2014). In addition, the weakest point of PMMA is the well-established fatigue property. Fatigue limit or endurance limit is used to compare the fatigue properties in PMMA with different implants. Fatigue limit is the highest stress that a material can tolerate for an infinite number of cycles (more than 10^6 cycle loading) without breaking (Saha and Pal, 1984). The British Stainless Steel Association reported the fatigue limit of 316L stainless steel as 270 Megapascal (MPa), while the fatigue limit of PMMA is significantly lower, with only 8.8 MPa. Thus, according to the fatigue property, the SOP plate is considered the standard treatment instead of screws (or pins) with PMMA implants. However, there are no studies regarding the fatigue properties of screws (or pins) with PMMA in a canine vertebral model. Therefore, this study aims to investigate the fatigue properties of cancellous and cortical stainless steel screws with PMMA and a SOP plate system using a specifically designed fatigue testing machine (FTM) in canine cadaveric VFL models.

Materials and Methods

Study Design: Lumbar (L1-L6) vertebral column specimens collected from 20 canine cadavers were assigned equally to one of the four testing constructions, which were cancellous screws with manually applied PMMA (MP), cancellous screws with syringe application PMMA (CanP), cortical screws with syringe application PMMA (CorP) and cortical screws with SOP plate (SOP), matching the body weight of the cadaver. All specimens were subjected to fatigue testing by a specifically designed fatigue testing machine (FTM) after fixation of the L3-L4 vertebral bodies. Mean number of cycles to failure and failure mode of all fixation methods were compared.

Specimen Collection and Preparation: The study was performed at the Department of Veterinary Surgery, Faculty of Veterinary Science, Chulalongkorn University. The lumbar vertebral specimens (L1-L6) were collected from mature canine cadavers (15-25 kg body weight) which died at the Small Animal Teaching Hospital, Faculty of Veterinary Science, Chulalongkorn University. Specimens which had a history of vertebral column disease were excluded. Laterolateral and dorsoventral radiographs were done to confirm the skeletal maturity and the absence of vertebral pathology of the specimen. Hypaxial and epaxial muscles, spinal ligaments (supraspinous and interspinous ligaments, and ligamentum flavum), and joint capsules were stored. The specimens were kept

moist with 0.9% saline solution during preparation, storage, and testing. Subsequently, the specimens were wrapped in saline soaked towels and plastic bags prior to storage at -20°C (Balligand, 2016). The specimens were thawed at room temperature on the day of testing. The vertebral column specimen was secured in the FTM by inserting Steinman pins (4 mm diameter) transversely through L1 and L6, passing through the hole on the specimen's fixator part of the FTM. Then, the spines were disarticulated at the L3-L4 intervertebral disc space by total removal of the entire L3-L4 disc (nucleus pulposus and annulus fibrosus excised). The joint facet was sectioned dorsally via a ventral approach through the disc space and canal by using a scalpel blade number 21. All tissues at L3-L4 vertebrae except the bone were removed. All specimens were exposed to two landmarks which were the accessory process and the base of the transverse process. Finally, the specimen was completely separated into two sections at L3-L4 junction.

Fatigue Testing Machine (FTM; Fig. 1): A fatigue testing machine (FTM) was specifically designed to simulate the dorsoventral bending force to the specimen via a conical wedge and the amount of load was specified by changing the weight inside the loading unit, which was generated in cooperation with the Department of Mechanical Engineering, Faculty of Engineering, Chulalongkorn University. FTM generated the load to the specimen at a frequency of 80 rpm. To limit the effect of acceleration of the loading unit, the level of the lever arm was set perpendicular to the specimen and the contact time of the eccentric piece to the lever arm was reduced to as low as possible.

Constructions
Cancellous screws with manually applied PMMA (MP) group: Four 3.5 mm stainless steel cancellous screws were inserted into both sides of the vertebral body of L3 and L4, just above the base of the transverse process, below the accessory process. For each screw, a hole was drilled into the ciscortex with a 2.5 mm drill bit and tapped with a 3.5 mm thread tap only ciscortex. Direction of the screw was directed at an angle of 70-80° from the spinous process. The length of screw was estimated based on measurements from pre-fixation lateral radiographs of the vertebral bodies and the distance between the screw and vertebral body was maintained at approximately 1 cm to be filled with PMMA (Refoboacin®). Luxation was reduced using towel clamps that grasped each side of the articular process. Then, the PMMA was mixed until the paste no longer adhered to the instruments or surgical gloves. Then, it was applied around both sides of the screw heads, connecting the PMMA from the screw head to another screw head on the same side (Fig. 2A).

Cancellous screws with syringe application PMMA (CanP) group: Four 3.5 mm stainless steel cancellous screws were applied in the same way as for the MP group. The luxation of vertebrae was also reduced using towel clamps that grasped each side of the articular process. Subsequently, plastic taken from a normal saline bottle was used as a mold for the PMMA, creating a hole for inserting the screw through the plastic and then, suturing the plastic to make it into a cylinder-shaped mold which was 2 cm in diameter. Finally, a 10 millilitre syringe was filled with well-mixed PMMA before doughing phase and injected into the plastic cylinder mold (Fig. 2B).

Cortical screws with syringe application PMMA (CorP) group: The four 3.5 mm stainless steel cortical screws were applied as described previously for the MP group. Also, PMMA was applied in a similar way to the CanP group (Fig. 2C).

Cortical screws with SOP plate (SOP) group: The specimens were fixed with 2 parallel 3-hole 3.5 mm SOP plates (Orthomed, Halifax, West Yorkshire, UK) which were applied to both sides of the lateral vertebral body surfaces. Then, the plates were placed just above the base of the transverse process and below the accessory process. The middle hole of the SOP plate was placed on the intervertebral disc space and the rest were placed on the vertebral body. A 2.5 mm drill bit and a specific drill guide (Orthomed, Halifax, West Yorkshire, UK) were used to drill the cis and trans cortex, using a 3.5 mm tapping to create thread only cis cortex. The 3.5 mm non-self-tapping stainless steel cortical screws were placed bicortically. The length of the screw was assessed based on measurements from pre-fixation lateral radiographs of the vertebral bodies as well as the approximate distance between the screw head and bone surface (Fig. 2D).

Biomechanical Testing: Each specimen was positioned in the specimen fixator on the FTM. The height of the rotating generator and connector was adjusted to the level of the lever arm perpendicular to the specimen and the conical wedge was close to the specimen. Dorsoventral bending loading was applied to the specimen, with each specimen subjected to 8 kg loading at 80 rpm to simulate postoperative forces. The fatigue testing was performed until implant failure and number of cycles to failure were recorded for each group.

Failure Mode: During fatigue testing, a sagittal plane video of the specimens was simultaneously acquired using a video camera (AS200V, Sony, Tokyo, Japan) at a rate of 30 fps. After construction failure, photographs of the area that caused construction failure were acquired.

Statistical Analysis: All data were tabulated in Microsoft Excel. Cycles to failure from the fatigue testing were analysed in Microsoft Excel. Data were tested for normality visually using histograms and numerically using the Shapiro-Wilk test. Two-way ANOVA was used to compare differences in means of the number of cycles until fatigue failure, with Tukey's post hoc tests used to determine differences between the groups. A P-value < 0.05 was considered as statistically significant.
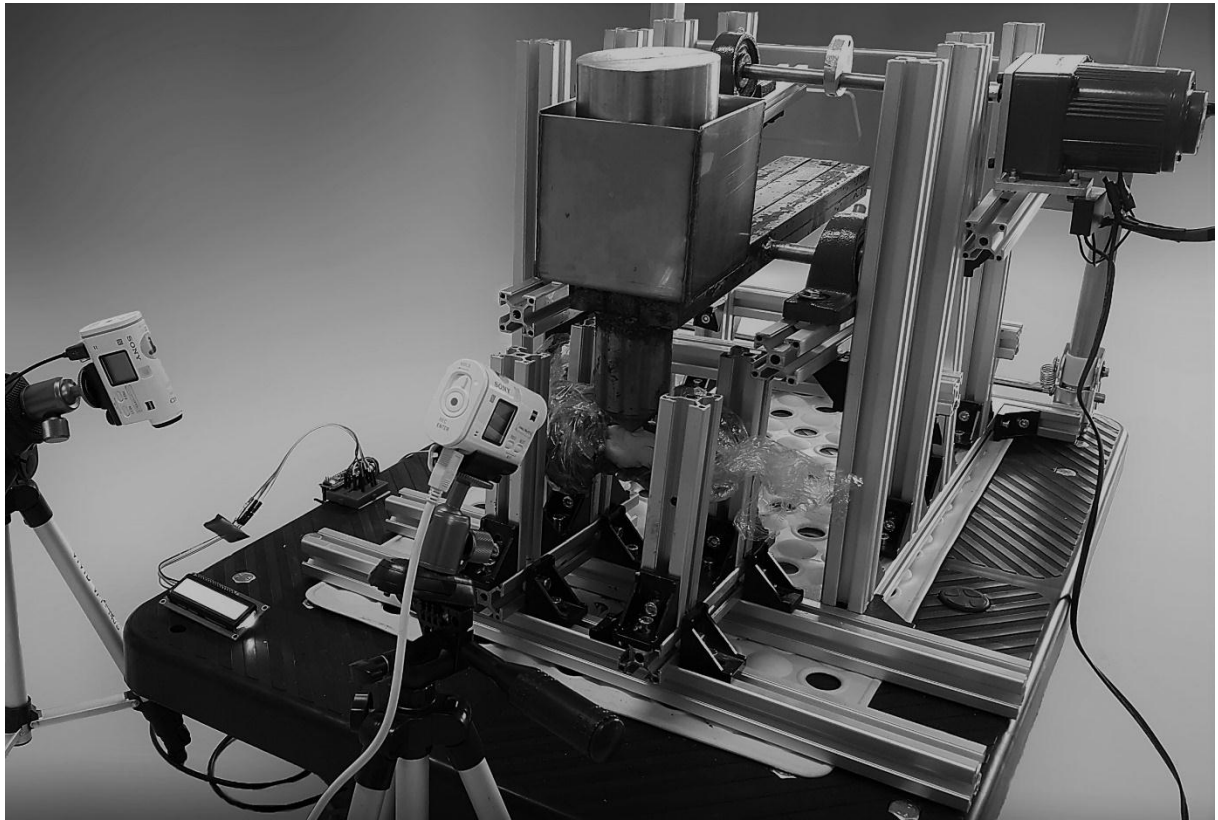
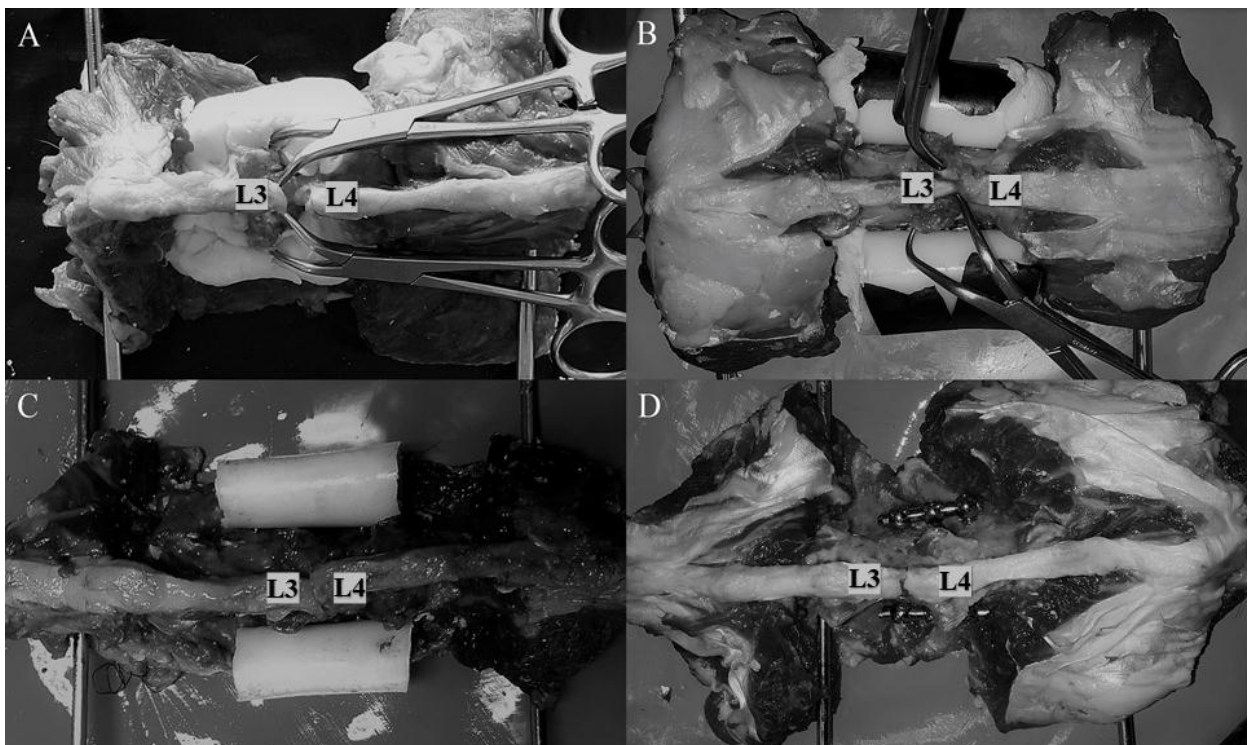**Figure 1**   Specifically designed fatigue testing machine (FTM).

Figure 2   Four testing constructions
(Fig. 2A) Cancellous screws with manually applicated PMMA (MP) construction
(Fig. 2B) Cancellous screws with syringe application PMMA (CanP) construction
(Fig. 2C) Cortical screws with syringe application PMMA (CorP) construction
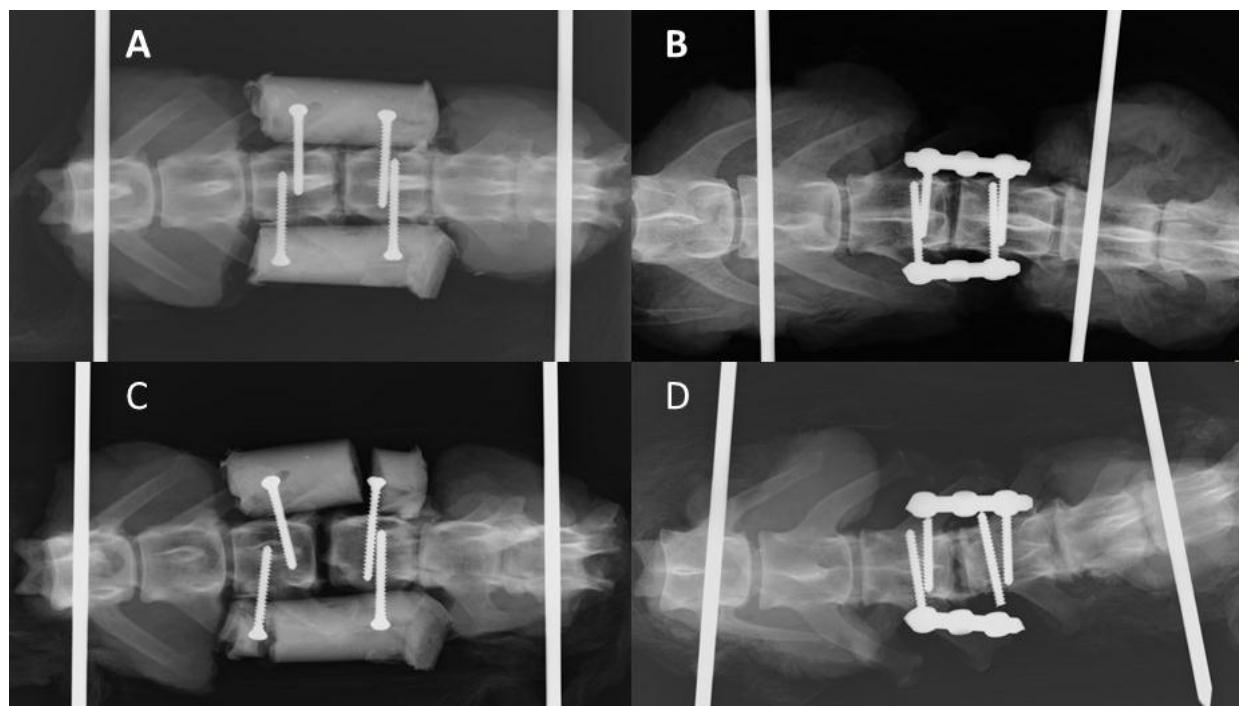(Fig. 2D) Cortical screws with SOP plate (SOP) construction.

Figure 3 Radiograph of screw fixation
(Fig. 3A) Cortical screws with syringe application PMMA (CorP) fixation
(Fig. 3B) Cortical screws with SOP plate (SOP) fixation
(Fig. 3C) PMMA at screw neck of CorP group construction failure
(Fig. 3D) Cortical screw of SOP group construction failure

Results

Vertebral Column Specimens: Vertebral column specimens were collected from 20 dogs (male = 10, female = 10) that met the inclusion criteria. The mean ± SD of body weight were 20.80 ± 3.03 kg (MP group), 19.00 ± 2.45 kg (CanP group), 21.00 ±3.67 kg (CorP group), and 21.20 ± 3.70 kg (SOP group), respectively. There is no significant difference between the groups with regard to weight and age as shown in Table 2.

Fatigue Testing Data Analysis
Cycles to Failure: Cycles to failure (CTF) of each group tested was normally distributed (Shapiro-Wilk, P = 0.201) and passed an equal variance test (Brown-Forsythe). ANOVA confirmed significant differences between the groups of implants (F = 457.006, P < 0.0001). According to the Holm-Sidak post hoc test, there were significant differences among the different construction groups; the SOP group tolerated the most cycles before failure, followed by the CorP, CanP and MP groups, respectively (Table 1).

Table 1 Mean ± SD of cycles to failure and failure mode of each construction group

	Cycles to failure			Failure mode	
				Bridging compartment	Bone anchoring compartment
MP group	6,314	±	1,727[a]	Manually applicated PMMA*	3.5 mm cancellous screw
CanP group	13,580	±	1,608[b]	Syringe application PMMA	3.5 mm cancellous screw*
CorP group	49,550	±	6,392[c]	Syringe application PMMA*	3.5 mm cortical screw
SOP group	112,820	±	7,562[d]	SOP plate	3.5 mm cortical screw*

[a,b,c,d] Values within the same row with different superscript letters are statistically different (P ≤ 0.05).
* Compartment that caused construction failure

Failure Mode: All implants contained two compartments, the bridging and bone anchoring compartments. Only one compartment caused construction failure, occurring in the middle of the PMMA bridge (MP group), the neck of cancellous screw (CanP group), PMMA at the screw neck (CorP group), and the 3.5 mm cortical screw (SOP group), respectively (Table 1).

Table 2   Mean ± SD of body weight and age of canine cadavers.

	Body weight (kg)	Age (years)
MP group (n=5)	20.8 ± 3.0	5.4 ± 1.3
CanP group (n=5)	19.0 ± 2.5	5.6 ± 1.8
CorP group (n=5)	21.0 ± 3.7	5.2 ± 1.8
SOP group (n=5)	21.2 ± 3.7	5.6 ± 1.8

Discussion

One of the most common causes of implant breaking, especially in human medicine, is fatigue failure (Graham et al., 2000; Arora et al., 2013; Ajaxon and Persson, 2014). Fatigue failure is caused by cyclic stress at a load significantly less than the component's definitive tensile strength. Eventually, any construction will fail after a given number of cycles, except if the load is less than the fatigue limit (Merk et al., 2001). Fatigue properties are determined by the cycles to failure and failure mode of the construction. Cycles to failure or the fatigue life of an implant is the number of cycles that can be tolerated at a given load and failure mode is the area which causes the construction failure. Many factors impact on the fatigue properties of the construction, the two most common factors are the stress concentration effect and the fatigue limit of the material. A reduction in area or geometric discontinuities, such as notches or heterogeneity, can result in a localised increase in the stress concentration, which will finally cause failure via a propagating crack. The homogeneity (unnotched) of the implant makes it stronger, with more fatigue life due to the even distribution of the force over its area (Pilkey, 2008).

In this study, the SOP implant was the most resistant to failure, with the highest number of cycles before the implant failed, followed by the CorP, CanP and MP groups. The SOP plate system is a pure stainless steel in contrast to the mixed PMMA and stainless steel construction of the other three implants. According to Saha and Pal (1984), the fatigue limit of stainless steel is thirty times greater than PMMA. The SOP plate system possessed the greatest fatigue properties in this study; however, the failure mode still occurred at the cortical screw neck. This implies that the SOP plate system failed due to the stress concentration effect. In contrast, the failure mode of the CorP construction occurred on the PMMA bridge, at the junction between the cortical screw and PMMA. This mixed material construction was also affected by fatigue limit, which was lower than stainless steel, indicating that the PMMA bridge was the weakest point of the CorP construction.

In the CanP construction, the failure mode was at the cancellous stainless steel screw neck. Even though stainless steel has a greater fatigue limit than PMMA, the cancellous stainless steel screw has a significantly smaller core diameter than the cortical stainless steel, thus, the stress concentration effect could overcome the fatigue limit. According to Merk et al. (2001), a smaller core diameter screw has significantly shorter cycles to failure than a larger core diameter screw composed of the same material. This suggests that if the construction has a significantly huge notch, the stress concentration factor will overcome the fatigue limit factor.

The MP group had the least cycles to failure, with a failure mode at the middle of the PMMA bridge. Due to the syringe technique for the PMMA application in the CanP and CorP groups, the homogeneity of the PMMA bridge compartment of CanP and CorP was greater than in the MP construction. The PMMA bridge of the MP construction had a huge notch due to the manual application of PMMA and the low fatigue limit from the PMMA. Consequently, the weakest point of the MP construction was the PMMA bridge, resulting in the lower numbers of cycles to failure in this study.

In summary, manually applied PMMA with 3.5 mm cancellous screw, which is currently the surgical standard of care for VFL cases, is not recommended for treating VFL due to the increase in stress concentration at the middle of the PMMA bridge. Changing from the manual to the syringe application of PMMA resulted in the stress concentration occurring at the cancellous screw thread instead. Even though the CoP construction had more cycles to failure, the cortical screw did not provide resistance to the screw pull-out effect, one of the most important causes of implant failure in VFL. Increasing the size of the cancellous screw in combination with the syringe application of PMMA may be a potential solution for this problem. However, the vertebral body size needs to be considered as a limitation to increasing the screw size. In conclusion, based on the results of this study, it is recommended that the SOP system should be used as the standard treatment for VFL in dogs as it is the most resistant to implant failure.

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บทคัดย่อ

การวิเคราะห์การล้าของอุปกรณ์ในสกรูสแตนเลสสำหรับกระดูกฟ่ามและสกรูสแตนเลสสำหรับกระดูกทึบที่ใช้ร่วมกับพอลิเมทิลเมทาคริเลต และในแผ่นดามกระดูกชนิดเอสโอพีที่ใช้ดามกระดูกสันหลังหักและเคลื่อนในร่างนิ่มสุนัข

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กระดูกสันหลังหักและเคลื่อนเป็นหนึ่งในสาเหตุที่พบได้บ่อยที่ทำให้เกิดความเสียหายของระบบประสาทในสุนัขและแมว วิธีการรักษาที่ได้มาตรฐานในปัจจุบัน คือ การใช้สกรูร่วมกับพอลิเมทิลเมทาคริเลตและการใช้แผ่นดามกระดูกชนิดเอสโอพี ภายหลังการยึดดามกระดูกสันหลังหักและเคลื่อนด้วยอุปกรณ์ยึดดาม   แรงส่วนมากที่กระทำต่ออุปกรณ์ยึดดามจะเป็นแรงลักษณะกระทำซ้ำหรือกระทำเป็นรอบ โดยหากแรงดังกล่าวน้อยกว่าความทนแรงดึงของอุปกรณ์นั้น ๆ อย่างมีนัยยะสำคัญและกระทำซ้ำมากพอ จะส่งผลทำให้เกิดการล้มเหลวจากการล้าตัวของอุปกรณ์   การศึกษานี้จึงทำการศึกษาเปรียบเทียบจำนวนรอบที่ทำให้เกิดการล้มเหลวของอุปกรณ์จากความล้าตัวและลักษณะการล้มเหลวของอุปกรณ์จากการล้าตัว โดยใช้เครื่องทดสอบความล้าที่ออกแบบขึ้นเองเพื่อวัตถุประสงค์นี้โดยเฉพาะ ทำการทดสอบในอุปกรณ์ยึดดามสันหลัง 4 ชนิด ประกอบด้วย กลุ่มที่ 1 ใช้สกรูสำหรับกระดูกฟ่ามขนาด 3.5 มิลลิเมตรร่วมกับพอลิเมทิลเมทาคริเลตที่ใช้ในลักษณะการปั้นมือ (MP) กลุ่มที่ 2 ใช้สกรูสำหรับกระดูกฟ่ามขนาด 3.5 มิลลิเมตรร่วมกับพอลิเมทิลเมทาคริเลตที่ใช้เทคนิคกระบอกฉีดยา (CanP) กลุ่มที่ 3 ใช้สกรูสำหรับกระดูกทึบขนาด 3.5 มิลลิเมตรร่วมกับพอลิเมทิลเมทาคริเลตที่ใช้เทคนิคกระบอกฉีดยา (CorP) และกลุ่มที่ 4 ใช้สกรูสำหรับกระดูกทึบขนาด 3.5 มิลลิเมตรร่วมกับแผ่นดามกระดูกชนิดเอสโอพี (SOP) การศึกษาพบว่า กลุ่ม SOP ต้องใช้จำนวนรอบที่มากที่สุดในการทำให้เกิดการล้มเหลวของอุปกรณ์จากการล้าตัว โดยมากกว่ากลุ่ม CorP CanP และกลุ่ม MP ตามลำดับจากมากไปน้อย ยิ่งไปกว่านั้นลักษณะการล้มเหลวของอุปกรณ์จากการล้าตัวสามารถบ่งชี้ถึงส่วนที่อ่อนแอที่สุดของอุปกรณ์ยึดดามได้ โดยพบว่า พอลิเมทิลเมทาคริเลตที่ใช้ในลักษณะการปั้นมือ สกรูสำหรับกระดูกฟ่ามขนาด 3.5 มิลลิเมตร พอลิเมทิลเมทาคริเลตที่ใช้เทคนิคกระบอกฉีดยา และสกรูสำหรับกระดูกทึบขนาด 3.5 มิลลิเมตร เป็นส่วนที่อ่อนแอที่สุดของอุปกรณ์ยึดดามในกลุ่ม MP CanP CorP และ SOP ตามลำดับ จากผลการศึกษาคุณสมบัติเชิงการล้าตัวของอุปกรณ์ทั้ง 4 ชนิด สามารถสรุปได้ว่า แผ่นดามกระดูกสันหลังชนิดเอสโอพีอาจเป็นอุปกรณ์การรักษาที่ได้มาตรฐานในสุนัขที่มีภาวะกระดูกสันหลังหักและเคลื่อน

คำสำคัญ: จำนวนรอบที่ทำให้เกิดการล้มเหลวของอุปกรณ์จากความล้าตัว ลักษณะการล้มเหลวของอุปกรณ์จากการล้าตัว พอลิเมทิลเมทาคริเลต แผ่นดามกระดูกชนิดเอสโอพี

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