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Original Article

A new lumbar facet cage to enhance facet joint fusion: an experimental beagle study

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Abstract: Lumbar facet joint is the main motion unit of the spine in the posterior column. Improving facet fusion rate has been a subject of intense interest in the spine surgery field. Even though a number of implants like autogenous bone graft, facet screws, translaminar facet screw, allograft bone dowel have been proposed, the facet joint fusion rate varies from 10.14% to 97.3%, combined with multiple screw related complications. An experimental beagle dog lumbar facet fusion study was conducted to compare the fusion performance of a new lumbar facet cage filled with autogenous cancellous bone with that of autogenous bone block alone. A total of 12 beagle dogs were randomly divided into the facet cage group and the autogenous bone alone group. They all underwent L3-L5 lumbar facet joint fusion surgery with either facet cage filled with autogenous cancellous bone or autogenous bone block alone. Six months after the surgery, lumbar segment fusion state was analyzed with manual palpation, CT, micro-CT and histology method. And the bone fusion rate in the facet cage group was 87.5% compared with 41.6% in the autogenous bone block alone group ($p<0.05$). Micro-CT and histology study further confirmed more bone formation in the facet cage group. In conclusion, the new lumbar facet cage could yield a satisfactory fusion rate, which was significantly higher than that of autogenous bone alone in the Beagle dog lumbar facet joint fusion model.

Keywords: Facet joint, fusion, cage, canine

Introduction

Spinal fusion is a common surgical procedure for treating lumbar disorders that has been proposed for decades. Posterolateral fusion is one of the most common types of spinal fusion, but it yields a nonunion rate ranging from 5% to 35% in patients with single-level fusions, which can be even higher in patients with multiple-level fusions [1-4]. Nonunion often leads to unsatisfactory relief of clinical symptoms that require revision surgery, thus yielding greater medical costs and higher morbidity [5]. In order to improve the fusion rate, some authors have suggested combining lumbar interbody fusion with posterolateral fusion [6-8]. However, it could inevitably cause more surgical trauma and potential complications.

Lumbar facet joint is the main motion unit of the spine in the posterior column. Theoretically, facet joint fusion can limit lumbar motion in all planes, thus playing an important role in a successful PLF. In addition, the distance between the facet joint interface and two adjacent spinal segments is the shortest anatomically, thus providing great potential for successful fusion. Improving facet joint fusion rate has been a subject of intense interest in the spine surgery field. Facet joint fusion with screws was initially described by King in 1944 [9] and modified by Boucher in 1959 [10]. More recently, there were more modern techniques and new implants immerging into application, such as translaminar facet screw [11], autogenous cancellous bone graft [12], allograft bone dowel [13] and other facet fixation devices [14, 15]. These studies clearly showed that facet joint fusion was essential to the stability of the posterior column, but the facet joint fusion rate still varies from 10.14% to 97.3% [12, 13, 15-17]. So we aimed to design a new lumbar facet cage

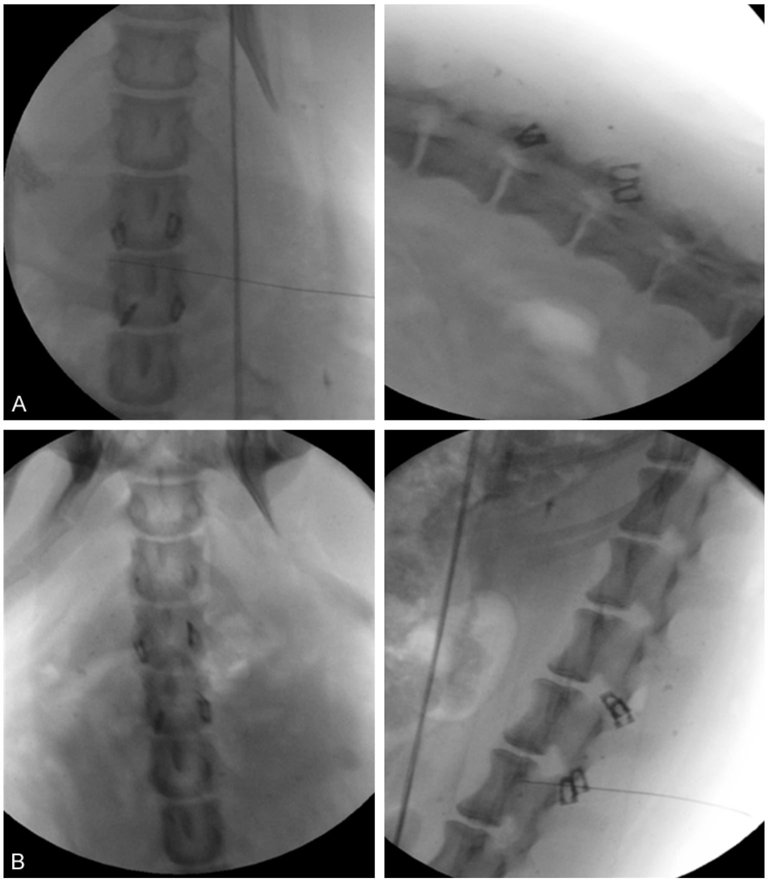

Figure 1. A. X-ray of post-surgery showing L3-L5 bilateral facet cage. B. X-ray of 6 months after surgery.

to promote the fusion of the lumbar facet joint. The purpose of this preliminary study was to investigate the differences between the facet cage with autogenous bone and the autogenous bone block alone in terms of facet joint fusion rate in vivo.

Materials and methods

Animal model and preparation

All animal surgeries and experimental procedures were conducted under the approval of Animal Ethics Committee. This study followed the appropriate institution or the National Research Council Guide for the care and use of laboratory animals. As the vertebrae and facet joints of Beagle dogs were similar to those of humans, a canine model was chosen. Twelve male Beagle dogs weighing 8.1-14.2 kg (average 11.5 kg) with an average age of 11 months old (ranging from 10 to 12 months old) were randomly divided into the facet cage (FC) group and the autogenous bone block (ABB) group.

After confirming their health status, animals were sedated with intravenous injection (IV) of ketamine (10 mg/kg) and diazepam (0.25 mg/kg) anesthetic medications, followed by endotracheal intubation and general anesthesia with 1.5% to 2.0% isoflurane. With the animal positioned prone, the posterior lumbar region was shaved, aseptically prepared and draped in sterile fashion. Prophylactic antibiotics (cefazolin sodium 1 g, IV) were administered pre- and postoperatively [18].

Surgical procedure

A localization radiograph was obtained before surgical intervention, which ensured exposure of the appropriate L3-L5 vertebral levels. The facet joints were exposed through a midline incision, followed by excising the posterior capsules and denuding the articular cartilages. By drilling the superior and inferior articular process cartilages inside the joint, we created a space with a size of 3 mm*5 mm*8 mm and punctate bleeding could be observed. ABB or FC with cancellous bone were grafted bilaterally into the facet joints at the L3-L5 levels (**Figure 1**, Supplementary Figure 2). Finally, the wounds were irrigated and closed in routine fashion.

After complete wound healing, the dogs were kept in a large room without restrictions. Eating habits, ambulatory activities and health status were monitored daily.

Lumbar facet cage

The facet depth among dogs (8-12 mm) was independent of their weight [19]. Lumbar facet cages were wedge-shaped with the size of 3 mm in height, 5 mm in width and 8 mm in depth. It was made of titanium alloy (Ti-6Al-4V, 110Gpa), and the surface design was in toothy

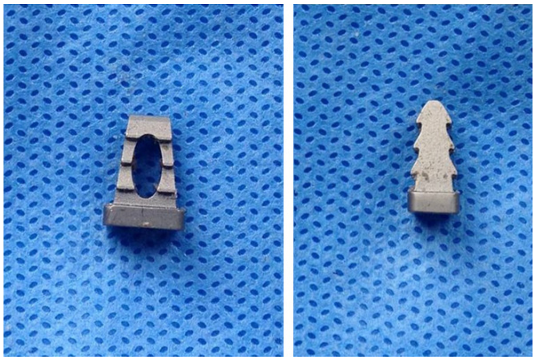

Figure 2. Wedge-shaped lumbar facet cage with the external diameters of 3*5*8 mm.

shape. The rear part of the device was larger than the front supporting part. Each cage had an empty space in the medium part that could be filled with autogenous cancellous bone (**Figure 2**).

Specimen preparation

A follow-up of 6 months was conducted for both groups. Animals were humanely sacrificed at the predetermined postoperative time interval with an overdose (150 mg/kg, IV) of concentrated pentobarbital sodium (concentration 390 mg/ml). After sacrifice, x-ray images were taken *in situ, and* the lumbar spine segment was dissected and frozen at -25°C in double-thickness plastic bags.

Manual palpation

The authors gently palpated each motion segment to assess the presence or absence of movement across the fused area (Supplementary Figure 1). The segments exhibiting any motion in sagittal or coronal plane were graded as "not solid union", while those with no motion were regarded as with a "solid union" [20] and those with uncertainties were regarded as "not solid union".

Radiological assessment

CT scans were obtained with a model 9800 scanner (GE Medical Systems, Milwaukee) with high-resolution bone algorithm and 1.5-mm cuts, and the exposure settings were 120 kV/100-76 mA s. Micro-CT were also conducted by VersaXRM-500 3D X-Ray Microscope (Xradia, California) at 70 kV/114 mA (intensity) with a spatial resolution of 30 um. It facilitated the reconstruction of high-resolution and 3-dimensional images of the facet joint that allowed examination for the continuity of bone bridging.

Radiologically, successful fusion was defined as complete and continuous bone bridging the fusion area [21]. In addition, each facet was rated and scored with Sandhu's fusion rating scale: 0 stands for no fusion; 1 stands for bone formation, but no fusion; 2 stands for unilateral fusion; 3 stands for bilateral fusion [22]. The fusion rate and score were determined based on CT and Micro-CT reviewed by three independent observers blinded to groups.

Histological evaluation

Undecalcified samples were embedded in PMMA. Horizontal sections were performed along the fusion sites. Using the Microgrinder device (EXAKT Technologies, Oklahoma City, OK), the embedded specimens were cut into 300 μm to 500 μm-thick sections and ground and polished to 75 μm in thickness. Sections were stained with toluidine blue (T-blue) for histologic evaluation.

Statistical analysis

All data were shown as mean ± standard deviation. Statistical analysis was performed using a paired t test between FC group and ABB group.

Results

Animal model and surgical complications

No animals died during the surgery. There were six dogs in the FC group with 4 facet cages implanted in each dog. There were six dogs in the ABB group with 4 autograft fusion facets in each dog. No wound infection, cage migration, or neurological complications was observed after the surgery, and all animals lived well during the 6-month follow-up.

Manual palpation assessment

The fusion assessment was obtained by manual palpation: in the FC group, 83.33% (5 of 6) of spine segments were fused, while only 50% (3 of 6) of spine segments were fused in the ABB group ($p<0.05$).

Radiological assessment

1.5 mm-thick CT sections and three-dimensional reconstructions of series of 30 um-thick

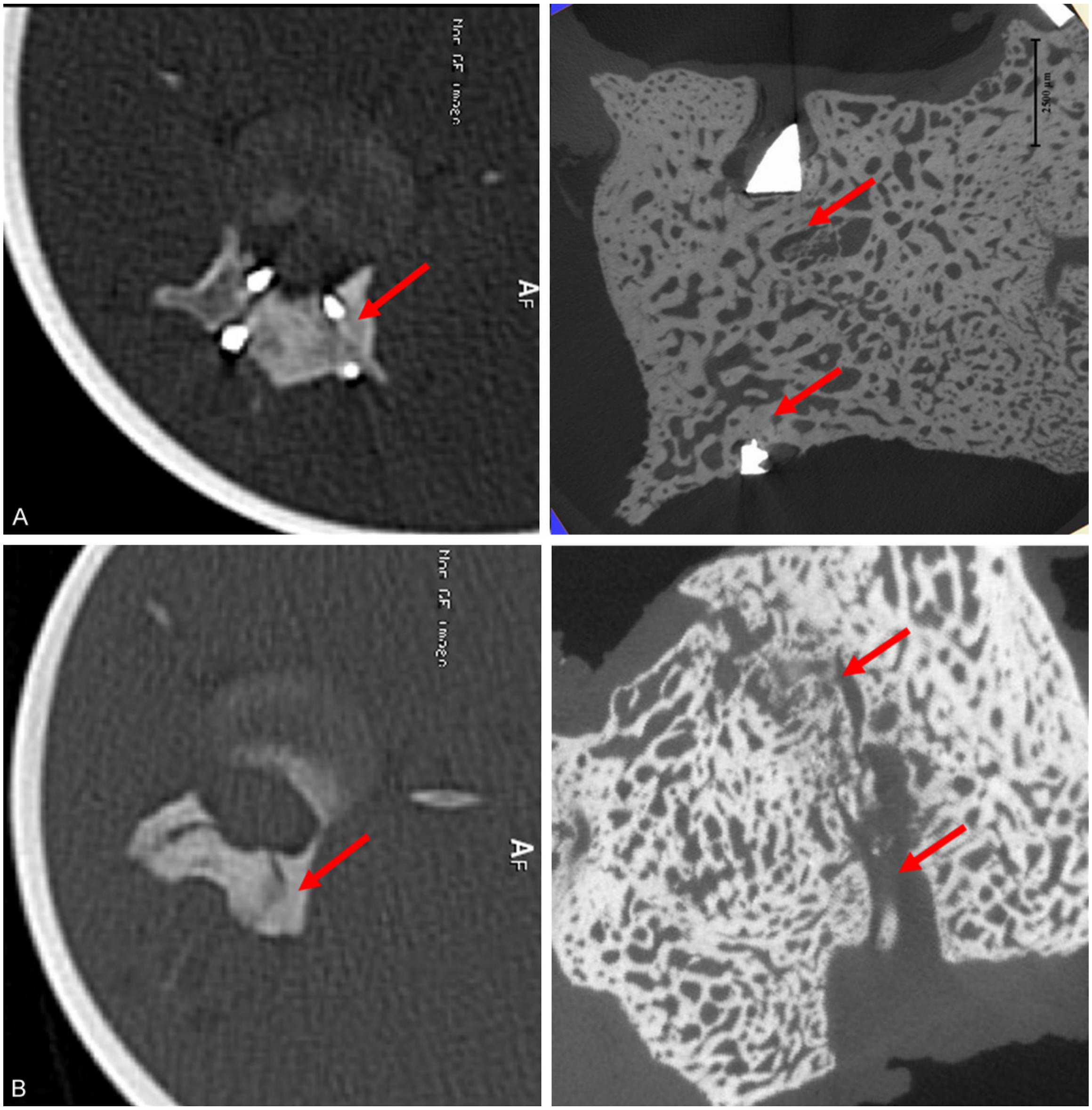

Figure 3. A. 6 months after surgery, CT showed FC site with fusion. Micro-CT showed solid bone bridge across the facet cage. B. 6 months after surgery, CT showed ABB site with suspected fusion. Micro-CT showed little bone bridge across the facet joint.

micro-CT sections were reviewed for all samples. Fused sites presented solid bone bridge across the cage in FC group (**Figure 3**). CTs of postoperative six months were obtained and revealed a fusion rate of 91.67% in the FC group (22 of 24), including 10 bilateral facet successful fusion, 2 unilateral fusion, and a fusion rate of 45.8% in the ABB group (11 of 24), including 3 bilateral facet successful fusion, 5 unilateral fusion, $p<0.05$. Micro-CT analyses showed the fusion rate for the facet cage group was 87.5% (21 of 24), while the fusion rate was 41.6% in the autograft sites (10 of 24), $p<0.05$. Fusion scores were further evaluated for bone formation and fusion, and the FC group presented significantly higher scores than the ABB group (2.58 vs 0.96 in CT, 2.5 vs 0.88 in Micro-CT), indicating de novo bone tissue formation as well as fusion. Fusion assessments were summarized in **Table 1**.

Histological study

Histological study was performed using 50-mm-thick, decalcified, toluidine blue stained sagittal sections (**Figure 4**). The fusion sites of the

Table 1. Fusion assessment at 6th month after operation

Groups	Fusion rate			Fusion score	
	Manual palpation	CT	Micro-CT and histology	CT	Micro-CT and histology
FC	83.33% (5/6)	91.67% (22/24)	87.5% (21/24)	2.83±0.4	2.75±0.5
ABB	50% (3/6)	45.8% (11/24)	41.6% (10/24)	1.67±1.2	1.58±1.2

t test, $p<0.05$.

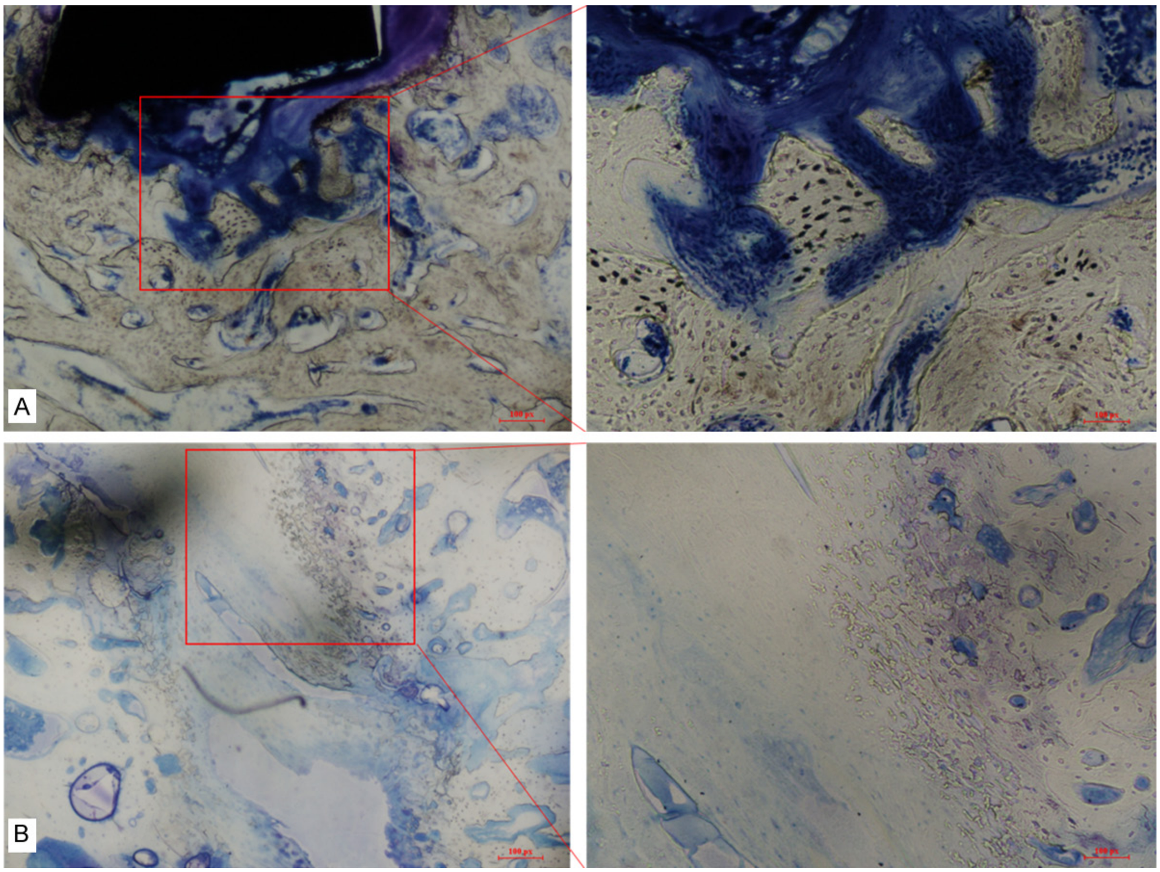

Figure 4. A. 6 months after surgery, histological results of FC fusion site showing newly formed woven and continuous bone and trabecular across the cage. B. 6 months after surgery, histological results of ABB fusion site showing low density bone trabecula.

FC group presented more trabecular bone bridges. The histomorphometric analysis showed trabecular bone area (%) within 6 months after surgery at the FC sites was significantly greater than that at the ABB sites (**Figure 5**).

Discussion

The concept of lumbar facet joint fusion with bone packed in or around facet joint has been described for decades. There are several advantages of facet fusion over pedicle screw based procedures for lumbar fusion, including: (1) less invasive, which means that facet joint can be simply and safely exposed with less soft-tissue disruption [17]; (2) requiring little bone graft, as the facet joint connects the shortest distance between two adjacent spine segments [23]; (3) decreased risk of neurological lesions compared with fixation systems anchored in the pedicles [13]. Apart from its advantages, the fusion rate differed across the reports and could be as low as 10.14% [16]. In this study, we evaluated the performance of a newly designed lumbar facet cage for facet joints fusion in a canine model. We found that the fusion rate of the facet cage filled with autogenous cancellous bone was significantly

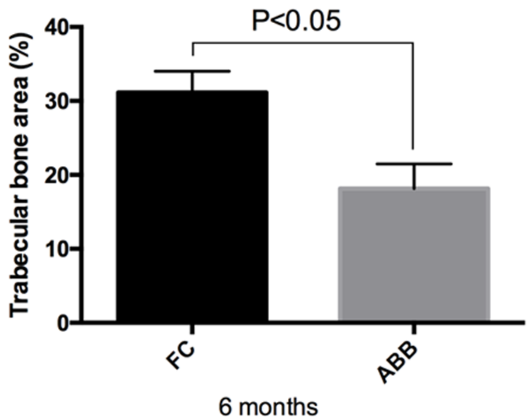

Figure 5. The trabecular bone area was significantly higher at the FC sites than at the ABB sites at 6 months after surgery ($p<0.05$) by histomorphometric analysis.

higher than that in the cancellous bone only group.

Different methods have been developed regarding to facet fusion since the appearance of Boucher technique in 1959, which utilized a facet screw entering into the inferior articular process and crossing the joint into the ipsilateral articular surface, and the author reported a satisfactory fusion rate of 97.3% [10]. Later, translaminar facet screw fixation associated with posterolateral fusion was successively developed by Magerl [11], and the fusion rate was reported to be over 90%. In spite of the satisfactory fusion rate, the facet screw related complications could not be neglected, including screws break, screws loosening, lamina fracture, dural tear and nerve root injury, et al. [24]. Facet bone dowel has recently been developed to overcome the complexity of the surgical procedures required to place screws across the facet joint. TruFUSE facet fusion implant is a newly introduced allograft bone dowel. A recent clinical study showed that TruFuse bone dowel implantation yielded favorable results in terms of intraoperative blood loss, operative time and length of stay compared with pedicle screw placement. Furthermore, the patients with bone dowel fusion had a 95% dynamic stability rate, and 100% of them had signs of early fusion at an average six months post-operation [25]. But it should be noted that X-ray was used to judge the facet fusion in that study, and the statement of "no dynamic instability" might not be equal to fusion. In a study by Pirris et al., they reported a relatively low fusion rate of 10.4%. Of the 96 patients undergoing NuFix cylindrical threaded facet allograft bone dowels, 6 (6.3%) had a fusion verified by CT and 4 did not exhibit any movement on dynamic lumbar X-rays, with a total fusion rate of 10.4% (10/96) [16]. In their report, facet bone dowel yielded low fusion rate and implant migration problems.

In light of many complications of the facet screws as well as low fusion rate of facet bone dowel, we designed a new facet cage. Based on animal facet anatomy, it was designed with a height of 3 mm, a width of 5 mm, and a depth of 8 mm, which could enhance the stability of facet joint and create a good mechanical environment for facet fusion. Its depth was designed not to exceed the depth of the facet joints, and the rear part of the device was designed to be larger than the front supporting part, which could effectively prevent the fusion cage from sliding into nerve root and subsequent neuronal compression. The insertion of the facet cage within the joint cavity is technically easier and safer than the insertion of facet screws that could be accomplished with mini-invasive procedures. The upper and lower teeth of the fusion device could improve the resistance to pulling out, and we observed no facet cage migration at the 6^{th} month after the operation. The CT and Micro-CT were used in this study to evaluate the facet joint fusion, which could reflect the true fusion situation [20]. The fusion rate at the 6^{th} month was 87.5%, which was significantly higher than that of the autograft bone (41.6%). Excision of the capsule and cartilage of the facets could lead to lumbar mechanical instability [26]. Autogenous bone block used in this study may not maintain the impaired lumbar stability, which could affect bone formation and cause bone resorption. Although the fusion rate achieved by our facet cage was not as high as reported in the studies mentioned before, we assessed the actual fusion rate with CT, which is a more specific criterion for spinal fusion. Based on its satisfactory fusion rate, we believe that the facet cage can be applied in situations like minimally invasive implant treating simple facet related pain and facet fusion alone instead of posterolateral fusion after lumbar decompression.

This study also has several limitations. First, there are anatomical differences between dogs and humans, which may affect the facet fusion process. Second, the number of samples in our study is limited. Third, the study evaluated only short-term fusion rates and further studies are required to clarify long-term outcomes after FC fusion. Fourth, autogenous bone is lack of stability and could not provide enough mechanical support, which may result in low autograft fusion rate. In addition, as pedicle screw fixation could further increase spine stability, a combination of our cage and pedicle screw fixation could possibly yield a higher fusion rate.

In conclusion, in a Begeal dog lumbar facet joint fusion model, the fusion rate of our newly designed facet cage was higher than with autograft bone alone. Lumbar facet cage would be an effective fusion method for the future clinical application.

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Disclosure of conflict of interest

None.

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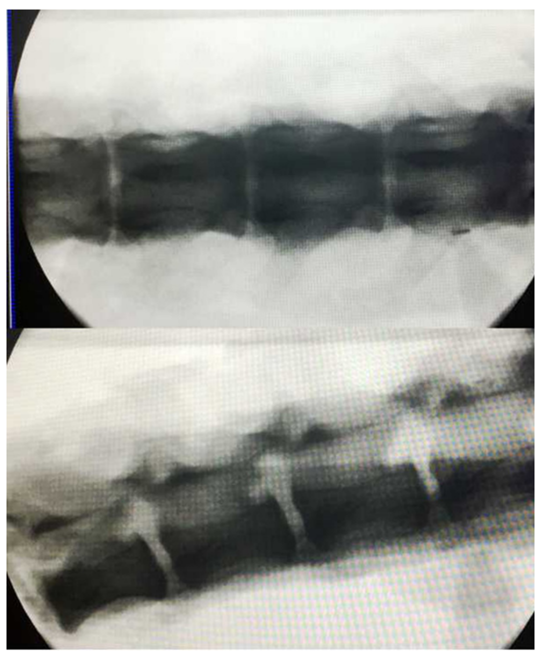
Supplementary Figure 1. Manual palpation assessment of spine.



Supplementary Figure 2. X-ray of ABB group.