Unintentional Fusion in Preserved Facet Joints without Bone Grafting after Percutaneous Endoscopic Transforaminal Lumbar Interbody Fusion

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Abstract:

Introduction: A percutaneous endoscopic transforaminal lumbar interbody fusion (PETLIF) procedure has been previously developed. During postoperative follow-up, in some patients, bone fusion occurred between opened facet joints, despite not having bone grafting in the facet joints. Here, we investigated facet fusion's frequency and tendencies following PETLIF.

Methods: A retrospective analysis was conducted on a prospectively collected, nonrandomized series of patients. Forty-two patients (6 males and 36 females, average age: 69.9 years) who underwent single-level PETLIF at our hospital from February 2016 to March 2019 were included in this study. Patients were assessed with lumbar X-ray images and computed tomography (CT) prior to, immediately after, and 1 year after surgery.

Results: Pseudarthrosis was not observed in any patients, and facet fusion was observed in 26 of 42 post-PETLIF patients (61.9%) by CT 1 year postoperatively. The average interfacet distance increased from 1.3 mm preoperatively to 4.5 mm postoperatively, and facet fusion was observed under the opened conditions of 3.8 mm at 1 year. Segmental lordotic angle of the fusion segment in the lumbar X-ray images was significantly larger in the facet fusion subgroup prior to surgery, immediately following surgery, and 1 year after surgery compared to the facet non-fusion group ($p=0.02$, $p<0.01$, $p=0.01$, respectively). There were no significant differences in patient background, correction loss of segmental lordosis, interfacet distance, or clinical score between the facet fusion and facet non-fusion subgroups.

Conclusions: Facet fusion was achieved over time within the facet joints that were opened through indirect decompression after PETLIF. We hypothesized that the preserved facet joints potentially became the base bed for spontaneous bone fusion due to the preserved facet joint capsule and surrounding soft tissue, which maintained cranio-caudal facet traffic and blood circulation in the facet joints. The complete preservation of the facet joints was a key advantage of minimally invasive lumbar interbody fusion procedures.

Level of evidence: Level III

Keywords:

facet fusion, lumbar interbody fusion, minimally invasive spinal surgery

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Introduction

Spinal instrumentation and fusion are established surgical treatments for degenerative spinal disorders associated with instability such as degenerative lumbar spondylolisthesis, spinal instability, and spinal foraminal stenosis[1-3]. Percutaneous pedicle screw (PPS), lateral lumbar interbody fusion (LLIF), and spinal endoscopic techniques have been developed in recent years, and reports have demonstrated their effectiveness in minimally invasive spinal fusion procedures[4-7]. An advantage of these techniques is that they are low invasive and avoid direct decompression; additionally, they allow

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for complete preservation of the facet joints. Facet preservation provides a great advantage over transforaminal lumbar interbody fusion (TLIF) and posterior lumbar interbody fusion (PLIF) that require facetectomy, in the event of pseudarthrosis or postoperative infection after spinal fusion surgery. Furthermore, some reports have indicated that bone fusion occurred between the preserved facet joints. However, details for how this occurred have not been revealed[8].

Nagahama et al. proposed a percutaneous endoscopic transforaminal lumbar interbody fusion (PETLIF) procedure as a minimally invasive lumbar spinal fusion surgery[9]. The procedure is a full-endoscopic lumbar interbody fusion that involves passing an interbody cage posterolaterally through Kambin's triangle using the original oval devices[9-11]. This surgical technique was developed from the full-endoscopic intervertebral disc curettage that was being performed for infectious lumbar spondylodiscitis[12]. Nagahama et al. have reported on the effectiveness of PETLIF in a previous clinical study[9]. In PETLIF, neurological symptom improvements are achieved by performing indirect decompression in degenerative spinal disorder patients with preserved bilateral facet joints[9]. Occasionally, during postoperative follow-up after PETLIF, patients have demonstrated bone fusion between opened facet joints, despite not having bone grafting in the facet joints.

Although the goal of minimally invasive lumbar interbody fusion, such as PETLIF, is to achieve bone fusion in the anterior vertebral elements, of course, the ability to obtain bone fusion between the facet joint and the intervertebral body is a major advantage for spinal fusion surgery. If facet-preserving minimally invasive spinal fusion surgery is more likely to result in facet fusion than conventional open TLIF or PLIF, it may be a better treatment option for spinal fusion surgery. However, to our knowledge, there is no study examining mechanisms and trends in facet joint fusion in PETLIF or similar techniques. Therefore, the present study aimed to retrospectively investigate the frequency and tendencies for facet fusion after PETLIF. This study is important in that it is the first report on the details of facet fusion without bone grafting, which demonstrates the benefits of preserving the facet joint in minimally invasive lumbar fusion surgery.

Materials and Methods

Patient background

The present study was conducted with approval from the relevant institutional review board. A total of 54 patients underwent single-level PETLIF at our hospital from February 2016 to March 2019. PETLIF procedure was indicated for patients with degenerative lumbar spondylolistheses with accompanying instability, lumbar canal stenosis, and degenerative lumbar scoliosis (e.g., leg pain and/or back pain that was resistant to conservative treatment, such as analgesic administration). PETLIF is a technique in which an interbody cage is inserted through Kambin's triangle[9,11], as described below, and is applied to either L3/4 or L4/5, where an anatomically safe working space can be assured in terms of the facet bone morphology and exiting nerve roots[9]. The contraindication for PETLIF includes patients with severe slip (Meyerding grade 3 or more). PETLIF can typically be performed on patients with narrow discs (or almost no disc space), and the disc height does not affect the indication for PETLIF. Patients with severe osteoporosis (T-score of −2.5 SD or less with osteoporotic vertebral fracture) who were considered to be at high risk for intraoperative pedicle screw pull-out were excluded from the surgical indication for PETLIF procedure. Of the 54 patients who underwent PETLIF, 3 patients who required additional surgery were excluded, and 42 patients who underwent computed tomography (CT) 1 year after surgery and in whom facet fusion assessment was possible were included in this study. Nine patients were unintentionally excluded because they had not appeared for follow-up 1 year postoperatively, and their lumbar CT images were not available. The diseases among the 42 patients (6 males and 36 females, average age: 69.9 years) were as follows: degenerative lumbar spondylolisthesis, 39 patients; lumbar canal stenosis, 2 patients; and lumbar degenerative scoliosis, 1 patient. The operative level was L3-4 in 2 patients and L4-5 in 40 patients.

Surgical procedures

The PETLIF surgical procedure was conducted as previously reported[9]. Surgery was performed under general anesthesia with nerve monitoring (NVM5; NuVasive, San Diego, CA). The patient was placed in a prone position on a frame that allowed radioscopy. A PPS (IBIS Spinal System; Japan Medical Dynamic Marketing, Tokyo, Japan) was inserted into the vertebral body to be fixed under fluoroscopic guidance, and spinal rods were inserted to correct the slippage of the vertebral body[9]. The Spine TIP Transforaminal Approach kit (Karl Storz GmbH, Tuttlingen, Germany) was used to approach the intervertebral disc from Kambin's triangle. PETLIF oval dilator and sleeve (Robert Reid, Inc., Tokyo, Japan) were set up within the intervertebral disc, and the interbody distance was expanded[9]. Bone from the iliac crest and/or spinous process was harvested percutaneously and used for grafting[9]. A ring curette and nuclear pulposus forceps were used to excise the intervertebral disc and create a graft-base bed through the oval sleeve, after which grafted bone (autogenous local bone or a mixture of local bone and artificial bone [Primabone; Japan Medical Dynamic Marketing, Tokyo, Japan]) was inserted. The PETLIF® half oval dilator and sleeve (Robert Reid Inc.) were inserted into the intervertebral disc to retract the exiting nerve root. Subsequently, an interbody cage of a 9 or 10 mm height (the same size as used in open surgery) was inserted[9]. Finally, screws were tightened to apply the compression load to the interbody cage. In this surgical procedure, the bilateral facets were preserved without exposure.

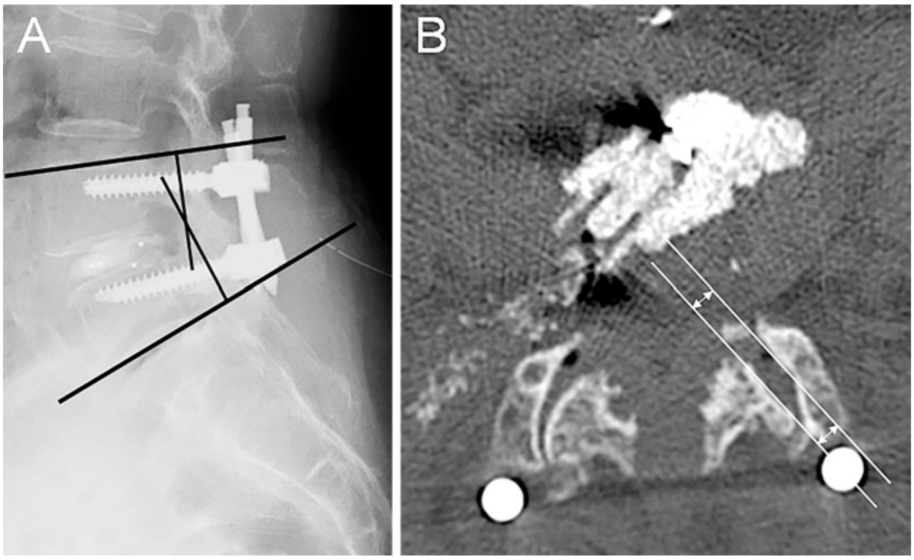

Figure 1. (A) X-ray image of the intermediary position of the lumbar profile. Segmental lordotic angle of the fused lumbar vertebrae was measured. (B) Computed tomography (CT) immediately after percutaneous endoscopic transforaminal lumbar interbody fusion (PETLIF). The maximum interfacet distance was calculated from CT axial images at the upper vertebral endplate level of the fused lower vertebral body.

Assessment

The patient background (age, sex, and drugs for osteoporosis treatment) and image findings were retrospectively analyzed. Image assessments were conducted with lumbar X-ray images and lumbar CT prior to surgery, immediately after surgery (1 week after surgery), and 1 year after surgery. Preoperative bone mineral density (BMD) of the hip was measured by dual energy X-ray absorptiometry. Radiographic outcomes were assessed in a blinded fashion by two independent coauthors. The extent of % slip (anterior slip) of the fusion segment was measured on the preoperative standing lateral X-ray image of the whole spine. The segmental lordotic angle of the fusion segment was calculated from an X-ray image of the intermediary position of the lumbar profile taken in decubitus neutral position (Fig. 1A). The maximum interfacet distance at the upper vertebral endplate level of the fused lower vertebral body was calculated from CT axial images (Fig. 1B). The presence or absence of caudal pedicle screw invasion to the facet joint was evaluated with lumbar CT axial images immediately after surgery. A screw invasion of 1 mm or more in the facet joint was judged as the presence of screw invasion. The facet joint was assessed with lumbar CT axial images and sagittal reconstruction images 1 year after surgery. Continuous bone bridging observed between the facet joints was determined as facet fusion (Fig. 2). Interbody bridging bone on CT of the lumbar spine 1 year after surgery was evaluated by comparing it with CT images immediately after surgery, using the fusion criteria reported by Choi et al.[13]. It was considered to be evidence of interbody bridging bone when there was fusion with remodeling and trabeculae or when the graft was intact, without being fully remodeled and incorporated but with no radiolucency present[13]. The presence of interbody cage subsidence (subsidence over 2 mm as compared to immediately after surgery[1]) and pedicle screw loosening (a lucent zone around the screw[14]) were assessed in CT multi-planar reconstruction images obtained 1 year after surgery[1]. Fusion criteria based on CT imaging were defined as any evidence of bridging bone in the interbody space and/or bridging of the facet joints[15]. Lumbar pseudarthrosis was defined as the presence of more than 5° of angular motion in flexion-extension radiographs at the fusion level and a loosening of the pedicle screws on CT 1 year postoperatively[1]. As a clinical assessment, the Japanese Orthopedic Association (JOA) score and the Roland-Morris Disability Questionnaire (RDQ) score were assessed preoperatively and 1 year postoperatively.

Statistical analysis

All data are expressed as the mean±standard deviation. Comparative statistical analyses were conducted for each parameter of the patient background and image findings between the facet fusion and facet non-fusion groups. An unpaired Student's *t*-test was used for analysis of continuous variables, and either a chi-squared test or Fisher's exact test was used for analysis of binomial and categorical variables. Statistical significance was defined as a $p\text{-value}<0.05$.

Results

Bone fusion by CT evaluation was obtained in 37 of 42 patients (88.1%); facet fusion was observed in 26 of 42 patients (61.9%); and interbody bridging bone was observed in 32 patients (76.2%) 1 year after PETLIF surgery. Bilateral facet fusion was observed in 15 patients, and unilateral facet

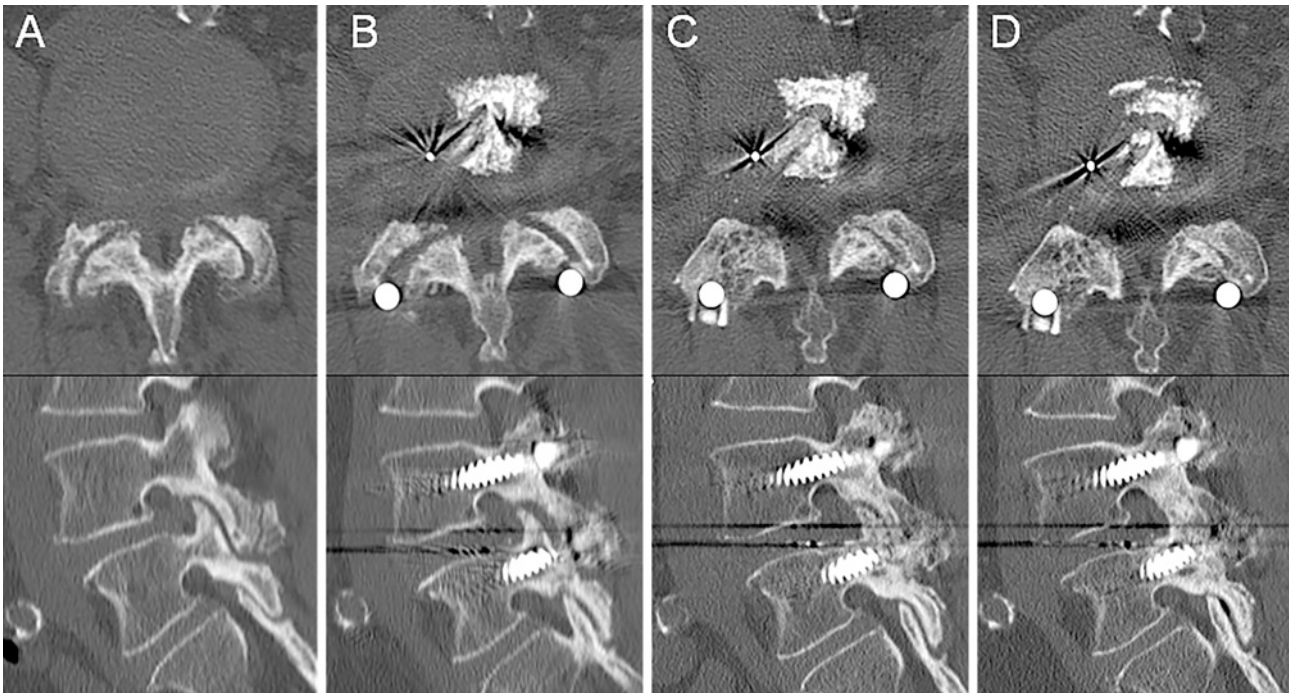

Figure 2. A 68-year-old female's computed tomography axial image after L4/5 percutaneous endoscopic transforaminal lumbar interbody fusion (PETLIF) (top row), right parasagittal reconstruction image (bottom row). (A) Prior to surgery, (B) immediately after surgery, (C) 6 months after surgery, and (D) 1 year after surgery. Bone fusion was observed between the opened facet joints, and bilateral facet fusion was observed 1 year after surgery.

Table 1. Characteristics of Patients in the Facet Fusion and Non-Fusion Groups after PETLIF (n=42).

		Facet fusion (n=26)	Facet non-fusion (n=16)	p value
Age, mean±SD (y)		70.9±9.4	68.2±9.5	0.19
Sex	Female	23 (88.5%)	13 (81.3%)	0.41
	Male	3 (11.5%)	3 (18.8%)	
Diagnosis				
	Degenerative spondylolisthesis	25 (96.2%)	14 (87.5%)	0.40
	Lumbar canal stenosis	1 (3.8%)	1 (6.3%)	
	Degenerative scoliosis	0 (0%)	1 (6.3%)	
Bone mineral density of the total hip, mean±SD (g/cm^2)		0.81±0.14	0.78±0.16	0.33
T-score of the total hip, mean±SD		−0.79±1.28	−1.10±1.28	0.23
Osteoporosis treatment				
	None	20 (76.9%)	11 (68.8%)	0.63
	Bisphosphonate	2 (7.7%)	3 (18.8%)	
	SERM	1 (3.8%)	0 (0%)	
	Vitamin D	3 (11.5%)	2 (12.5%)	

PETLIF: percutaneous endoscopic transforaminal lumbar interbody fusion, SD: standard deviation, SERM: selective estrogen receptor modulator

fusion was observed in 11 patients (5 patients: PETLIF-entering side and 6 patients: opposite side of PETLIF entry). Cage subsidence was observed in eight patients (19.0%), and pedicle screw loosening was observed in one patient (2.4%). In all cases, including the five cases in which bony fusion was not confirmed by CT, there was no angular instability of more than 5° in flexion-extension radiographs and no lumbar pseudarthrosis after PETLIF. The mean BMD was 0.80±0.15 g/cm^2, and the mean T-score was −0.91±1.29 at the left hip. The T-score of the patient with the loosened pedicle screw was −2.14.

We compared the facet fusion and facet non-fusion subgroups. No statistically significant differences were observed in terms of sex, diagnosis, BMD of the total hip, and osteoporosis treatment between the two subgroups (Table 1). Interbody bridging bone was seen in 80.8% and 68.8% in the facet fusion and the facet non-fusion groups, respectively, with the former group tending to have a higher rate of bone bridge formation. However, there were no statistically significant differences between the two groups (p=0.57) (Table

Table 2. Radiographic Assessment Between Facet Fusion and Non-Fusion Groups at 1 Year after PETLIF (n=42).

	Facet fusion (n=26)	Facet non-fusion (n=16)	p value
Lumbar pseudarthrosis	0 (0%)	0 (0%)	1.00
Interbody bridging bone	21 (80.8%)	11 (68.8%)	0.57
Cage subsidence	4 (15.4%)	4 (25.0%)	0.50
Pedicle screw loosening	0 (0%)	1 (6.3%)	0.33
Pedicle screw invasion to the facet joint	3 (5.8% of 52 facet joints)	3 (9.4% of 32 facet joints)	0.26
Preoperative % slip on standing X-ray (%)	20.5±5.7	15.9±10.0	0.04
Segmental lordotic angle (°)			
Prior to surgery	16.0±6.3	11.7±6.3	0.02
Immediately after surgery	18.5±5.5	13.9±5.6	<0.01
1 year after surgery	17.5±5.8	12.9±6.1	0.01
Correction loss (immediately after surgery to 1 year after surgery)	1.0±1.6	0.9±1.2	0.42
Interfacet distance (mm)			
Prior to surgery	1.3±0.9	1.7±1.1	0.12
Immediately after surgery	4.5±1.6	4.6±1.5	0.40
1 year after surgery	3.8±1.4	3.7±1.3	0.42
Immediately after surgery to 1 year after surgery	0.7±0.6	0.9±0.9	0.18

Data are given as number (%) or mean±standard deviation. PETLIF: percutaneous endoscopic transforaminal lumbar interbody fusion

2). Also, no statistically significant differences were observed for cage subsidence and pedicle screw loosening between the two groups (p=0.50 and p=0.33, respectively) (Table 2). Caudal pedicle screw invasion to the facet joint was observed in 3 of 52 facet joints (5.8%) in the facet fusion group and 3 of 32 facet joints (9.4%) in the facet non-fusion group, with no significant difference between the two groups (Table 2). The mean % slip of the fusion segment was significantly greater in the facet fusion group than that in the facet non-fusion group (20.5% and 15.9%, respectively, p=0.04). Segmental lordotic angle of the fusion segment in the lumbar X-ray images was significantly larger in the facet fusion subgroup prior to surgery, immediately following surgery, and 1 year after surgery compared to the facet non-fusion group (p=0.02, p<0.01, and p=0.01, respectively) (Table 2). Correction loss of the segmental lordotic angle from immediately after surgery to 1 year after surgery was equivalent in the two subgroups (p=0.42). The average interfacet distance in the facet fusion subgroup increased from 1.3 mm prior to surgery to 4.5 mm after surgery, and facet fusion was observed under the opened conditions of 3.8 mm at 1 year. The interfacet distance was equivalent between the two subgroups prior to surgery, immediately after surgery, and 1 year after surgery (p=0.12, p=0.40, and p=0.42, respectively) (Table 2).

In clinical assessment, the mean JOA score improved from 15.3±2.2 preoperatively to 27.1±2.0 1 year after surgery in the facet fusion group and from 13.8±3.9 to 27.4±1.7 in the non-fusion group. The JOA scores preoperatively and 1 year postoperatively were equivalent between the two groups (p=0.24 and p=0.35, respectively). The RDQ score improved from 10.1±4.8 preoperatively to 2.3±2.0 1 year after surgery in the facet fusion group and from 10.0±4.5 to 2.6±2.7 in the non-fusion group. The RDQ scores preoperatively and 1 year postoperatively were equivalent between the two groups (p=0.50 and p=0.37, respectively).

Case presentation

As a representative case, we describe a 68-year-old female. Right-entering L4/5 PETLIF was conducted for L4 degenerative spondylolisthesis. The spinal canal and bilateral facet joint openings were observed on CT immediately after surgery (Fig. 2A, 2B). Bone ingrowth progressed over time in the opened facets, and bilateral facet fusion was achieved 1 year after surgery (Fig. 2C, 2D).

Discussion

In the present study, we investigated the frequency and trend of facet joint fusion without bone grafting in patients undergoing PETLIF, a minimally invasive spinal fusion procedure. This is the first study to evaluate facet joint fusion in detail, and this study demonstrates the possibility of fusion of preserved facet joints without bone grafting after lumbar interbody fusion surgery. That is, the results of the current study demonstrated advantages of preserving the facet joints in minimally invasive spinal interbody fusion surgery.

Using the PETLIF technique, facet fusion was achieved in 61.9% of patients by 1 year after the procedure with preservation of bilateral facet joints. Bone grafts were not conducted for any of the patients' facets, and spontaneous fusion was achieved in facets without direct surgical invasiveness. There have been occasional studies reporting that bone fusion was achieved in the facet joints without surgical invasiveness following lumbar interbody fusion[7,8]. Satake et al.[8] reported that spontaneous facet fusion was achieved in 52 of 81 segments (64%), without bone grafting for the facet joints, 2 years after lumbar fusion surgery using LLIF and pedicle screws to preserve the bilateral facet joints. Kondo et al.[7] used CT to evaluate bone fusion after microendoscopic TLIF with a PPS system and reported that preserved contralateral facet joint fusion was achieved in 34 of 200 patients (17%) and 27 of 88 patients (31%) by an average of 15 and 40 months after surgery, respectively. Researchers have considered that the facet joint potentially becomes the base bed for spontaneous bone fusion[8]. We speculate that this may be as a result of maintaining blood circulation in the facet joints through preservation of the facet capsule and the surrounding soft tissue.

There have been no detailed reports on facet fusion, and it is not clear which types of patients have facet fusion. In this study, the preoperative % slip of the fusion segment in the facet fusion group was significantly higher than that in the facet non-fusion group. The degree of slippage may be associated with the severity of facet osteoarthritis changes, which in turn may have affected the postoperative facet fusion. In addition, the current study demonstrated that the fused segmental lordotic angle in the facet fusion group was significantly larger than that in the non-fusion group prior to surgery, immediately after surgery and 1 year after surgery. A large segmental lordotic angle results in an increase in the facet contact area on the cranio-caudal side, which could be advantageous for facet fusion. The cases who underwent PETLIF with bilateral facet joint preservation tended to have a higher rate of facet fusion than that of the cases that Kondo et al.[7] reported of microendoscopic TLIF with unilateral facet resection. Bilateral facet preservation may be advantageous for facet fusion over unilateral facet preservation[7,8].

Reports have described bone facet regrowth and unintended facet arthrodesis after lumbar decompression and lumbar dynamic stabilization surgery[16-21]. Dohzono et al.[16] evaluated bone regrowth at facet joints 2 years after microendoscopic lumbar decompression surgery and reported a significant correlation between bone regrowth and percentage slippage in lumbar spondylolisthesis. Similarly, Guigui et al.[17] reported that post-operation spinal instability greatly influenced the amount of bone ingrowth at the operation site after lumbar decompression surgery. Kanayama et al.[18,19] reported that facet fusion occurred in 12 of 64 patients (18.8%) and 14 of 43 patients (32.6%) by an average of 59.5 months and 82 months, respectively, after posterior lumbar dynamic stabilization surgery using the Graf artificial ligament. Fay et al.[21] reported that unintended facet fusion occurred in 52.1% of patients 4 years after Dynesys dynamic stabilization. Furthermore, Fay et al.[21] reported that facet fusion was significantly greater in patients with lumbar spondylolisthesis and those over the age of 65 years. These reports suggest that bone regrowth is likely to occur when spinal instability is present. The present study did not demonstrate statistically significant differences for screw loosening, interbody fusion disorders, and correction loss of the segmental lordotic angle between fusion and non-fusion subgroups. That is, spinal instability was thought to contribute minimally to facet fusion after PETLIF in the current study cases.

Facet fusion was observed over time after PETLIF between facet joints that were widely opened (to an average of 3 mm) immediately after surgery (Fig. 2). A characteristic of PETLIF is that slippage of the vertebral body is forcefully corrected with the PPS and oval retractor to expand the spinal canal[9]. In the PETLIF procedure, the facet joints are opened while interfacet traffic on the cranio-caudal side is maintained by the preserved facet joint capsule, along with the correction of the vertebral slippage. Microfractures and hemorrhaging are observed in the forcefully opened degenerated facet joints. Furthermore, the preservation of the surrounding soft tissue maintains favorable blood flow to the facet joints, which could promote bone ingrowth between the facet joints.

The present study demonstrated the possibility of fusion in facet joints preserved through minimally invasive lumbar fusion procedures. However, facet fusion was at most a secondary aspect. The objective of lumbar interbody fusion is to achieve bone fusion in the anterior vertebral elements, which support most of the imposed load[22]. We have examined not only the facet fusion but also the interbody bone fusion in detail on CT 1 year after PETLIF. Lumbar pseudarthrosis was not observed in any patients; however, interbody bridging bone was observed in 32 patients (76.2%). Compared with those of previous reports that have assessed intervertebral bridging bone formation on CT, the results of this study are comparable to the interbody fusion rate (80.6%) 1 year after open TLIF reported by Nagahama et al.[1] Even with minimally invasive lumbar interbody fusion surgery, the creation of an intervertebral bone graft-base bed and intervertebral bone grafting should never be neglected. Although bone fusion rates should not be reduced simply to minimize invasiveness of spinal fusion procedures, minimally invasive spinal fusion could be an option if the rate of bone fusion is comparable to that of conventional spinal fusion surgery.

A limitation of the present study was that the follow-up observation period was relatively short. Facet fusion may progress further over a longer period[7,8]. A second limitation was that the present study has no control group that underwent lumbar interbody fusion by other surgical techniques. Kondo et al. reported that facet joint fusion was achieved in 17% of patients who underwent microendoscopic TLIF 15 months after surgery[7]. In our case series, facet fusion was not obtained in approximately 90% of cases who underwent open TLIF without bone grafting after resection of the facet joint capsule 1 year after surgery. Although these cases are not comparable to the present study because there were differences in terms of patient background, the fusion level and diseases, it is suggested that preservation of the bilateral facet joints and surrounding tissue may be an advantageous factor in facet fusion after PETLIF. A comparative analysis with other lumbar interbody fusion surgery (e.g., open TLIF, low-invasive fusion procedure including LLIF and minimally invasive surgery—TLIF or PLIF) in multicenter studies is required to further analyze underlying facet fusion mechanisms. In addition, it is necessary to examine the difference in the facet fusion rate among different pathologies, such as lumbar degenerative scoliosis and lumbar canal stenosis, compared to that in degenerative spondylolisthesis.

In conclusion, facet fusion was observed in 61.9% of patients by 1 year after PETLIF. Facet fusion was achieved over time within the facet joints that were opened through indirect decompression. We inferred that the underlying mechanism involved progression of bone ingrowth between the degenerative facet joints due to preservation of the facet capsule and the surrounding soft tissue, which maintained cranio-caudal facet traffic and blood circulation in the facet joints. The complete preservation of the facet joints was considered a key advantage of minimally invasive lumbar interbody fusion procedures.

Conflicts of Interest: The authors declare that there are no relevant conflicts of interest.

Author Contributions: Katsuhisa Yamada and Ken Nagahama analyzed and wrote the manuscript, and all authors participated in the study design. All authors have read, reviewed and approved the article.

Ethical Approval: The present study was approved by the institutional review board of Wajokai Sapporo Hospital (approval code: 2017-1).

Informed Consent: Informed consent was obtained from all participants in this study.

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