

# Nonunion of Transposas Lateral Lumbar Interbody Fusion Using an Allograft: Clinical Assessment and Risk Factors

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## Abstract:

**Introduction:** This retrospective study was performed to evaluate the clinical influence of - and to identify the risk factors for nonunion of transposas lateral lumbar interbody fusion (LLIF) with use of allograft.

**Methods:** Sixty-three patients who underwent transposas LLIF ( $69.8 \pm 8.9$  years, 21 males and 42 females, 125 segments) were followed for a minimum 2 years postoperatively. For all LLIF segments, polyetheretherketone (PEEK) cages packed with allogenic bone were applied with supplemental bilateral pedicle screws (PSs). Bone bridge formation was evaluated by computed tomography (CT) 2 years postoperative, and a segment without any bridge formation was determined to be a nonunion. Sixty-one participants (96.8%) were classified into two groups for clinical evaluation: Group N that contained one or more nonunion segments and Group F that contained no nonunion segment. Visual analogue scales (VAS) scores and the effective rates of the five domains of the Japanese Orthopedic Association Back Pain Evaluation Questionnaire (JOABPEQ) were compared between Groups N and F. The risk factors for nonunion were determined by univariate and multivariate analyses.

**Results:** Twenty segments (16%) were diagnosed as nonunion. There were no significant differences in all VAS scores, and the ratio of effective cases in all domains of JOABPEQ between Group N ( $n = 14$ ) and F ( $n = 47$ ). Multivariate analysis identified percutaneous PS (PPS) usage (odds ratio [OR]: 3.14, 95% confidence interval: 1.13-8.68,  $p = 0.028$ ) as a positive risk factor for nonunion.

**Conclusions:** We should be aware of the higher nonunion rate in the LLIF segments supplemented with PPS, though nonunion does not affect significantly clinical outcomes at 2 years postoperative.

## Keywords:

lateral lumbar interbody fusion, allograft, nonunion, body mass index, percutaneous pedicle screw

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## Introduction

In lateral lumbar interbody fusion (LLIF) procedure, the direct lateral access enables insertion of a large footprint cage into the intervertebral space without compromise of the spinal canal, longitudinal ligaments, or facet joints. If sufficient amount of graft materials are available to fill the cage, the large cage covering the peripheral apophyseal ring and the preserved spinal structures may be advantageous to achieve rigid segmental stabilization and subsequent solid bony fusion.

There have been various papers reporting the fusion rate of LLIF<sup>1-10)</sup>. Probably due to their lower rates of nonunion, only a few papers analyzed the clinical impact or risk fac-

tors of nonunion in detail. Furthermore, the graft materials and supplemental fixation tools were not standardized in most previous reports on nonunion.

The purpose of this study is to investigate the influence on clinical symptoms of nonunion and to identify the risk factors for it at 2 years postoperative in a consecutive transposas LLIF cohort with use of allogenic cancellous bone and polyetheretherketone (PEEK) cage.

## Methods

### Patient demographics

Sixty-three consecutive patients ( $69.8 \pm 8.9$  years, 21

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**Table 1.** Patients' Demographics.

	Patients (n=63)
Age (years)	69.8±8.9
Sex	Male 21 Female 42
Diagnoses	Degenerative scoliosis/kyphoscoliosis 28 Spondylolisthesis 23 Adjacent segmental disease 7 Stenosis 4 Others 1
Smoking status	Yes 9 No 54
BMI (kg/m <sup>2</sup> )	24.8±4.1
Diabetes	Yes 15 No 48
BMD (T-score of DXA, SD)	-0.80±1.37
Previous multiple vertebral fractures	Yes 3 No 60
Remedy for osteoporosis	Teriparatide 19 Bisphosphonate 2 Vitamin D3 1 None 41
Number of LLIF levels	2.0±1.1
Number of posterior fixation levels	3.3±2.8

BMI: body mass index, BMD: bone mineral density, DXA: dual-energy X-ray absorptiometry, SD: standard deviation, LLIF: lateral lumbar interbody fusion

males and 42 females, 125 segments) who underwent LLIF in minimally invasive transpoas fashion (XLIF; NuVasive Inc., San Diego, CA, USA) at a single institute were enrolled in this study. Diagnoses were 28 degenerative kyphoscoliosis/scoliosis, 23 spondylolistheses, 7 adjacent segmental diseases after lumbar fusion, 4 canal stenosis, and 1 others. All of them were followed for a minimum 2 years post-operatively. Patients' demographic data are shown in Table 1.

### Surgical details

The procedure was performed strictly in compliance with the method described by Ozgur et al.<sup>11)</sup> All LLIF segments were applied with PEEK cages of 18 mm width (CoRoent XL; NuVasive Inc., San Diego, CA, USA). As for graft material, allogenic cancellous bone harvested from the femoral heads was used for all cases. Femoral heads were collected from patients who underwent a total hip arthroplasty at the same institute. They were preserved in a -80°C freezer for a minimum of 3 months. Prior to LLIF procedure, they were thawed in a Marburg Bone Bank System Lobator sd-2 (telos, Marburg, Germany) for thermal disinfection<sup>12)</sup>. The femoral head was irrigated thoroughly with sterilized saline, broken into small chips, and packed into the LLIF cage. These handlings of the allogenic bone strictly adhered to the guideline and the manual issued by the Japanese Orthopedic

Association<sup>13,14)</sup>. All segments were supplemented with bilateral pedicle screws (PSs) (open PS [OPS] for 94 segments and percutaneous PS [PPS] for 31 segments) in prone position following LLIF procedure. All PSs were polyaxial screws. OPS was applied mainly for deformity cases combined with canal stenosis that required curve correction and direct decompression procedure or for adjacent segmental disease cases following previous lumbar fusion ( $n = 43$ ). PPS was applied in degenerative or mild deformity cases to fix the construct *in situ* position ( $n = 20$ ). Bone graft for the facet joints were performed in 44 segments (46.8%) with OPS but not in the segments with PPS. In 70 segments (74.5%) of OPS and 21 segments (67.7%) of PPS, PSs were placed under intraoperative three-dimensional image (O-arm; Medtronic, Memphis, TN, USA)-based navigation system. The other PSs were placed using conventional fluoroscopy. All PSs were aimed to be parallel to the superior endplate of the vertebral body in the lateral image. Surgical data are summarized in Table 2.

### Radiological evaluation

Two independent coauthors (N. S. and J. O.) evaluated the fusion status of each LLIF segment with use of CT multiplanar reconstruction obtained from all patients at postoperative 2 years. For each segment, bone trabeculae formation inside and outside the cage and the formation at the poste-

rior bilateral facet joints were evaluated in the coronal and sagittal planes. Continuous bone bridge formation connecting the two vertebrae or between the facing surfaces of the facet joints were determined as a sign of fusion (Fig.1A-C), and a segment without any bridge formation was diagnosed as a nonunion (Fig. 2). Intraobserver and interobserver variances were assessed by calculating  $\kappa$  values.

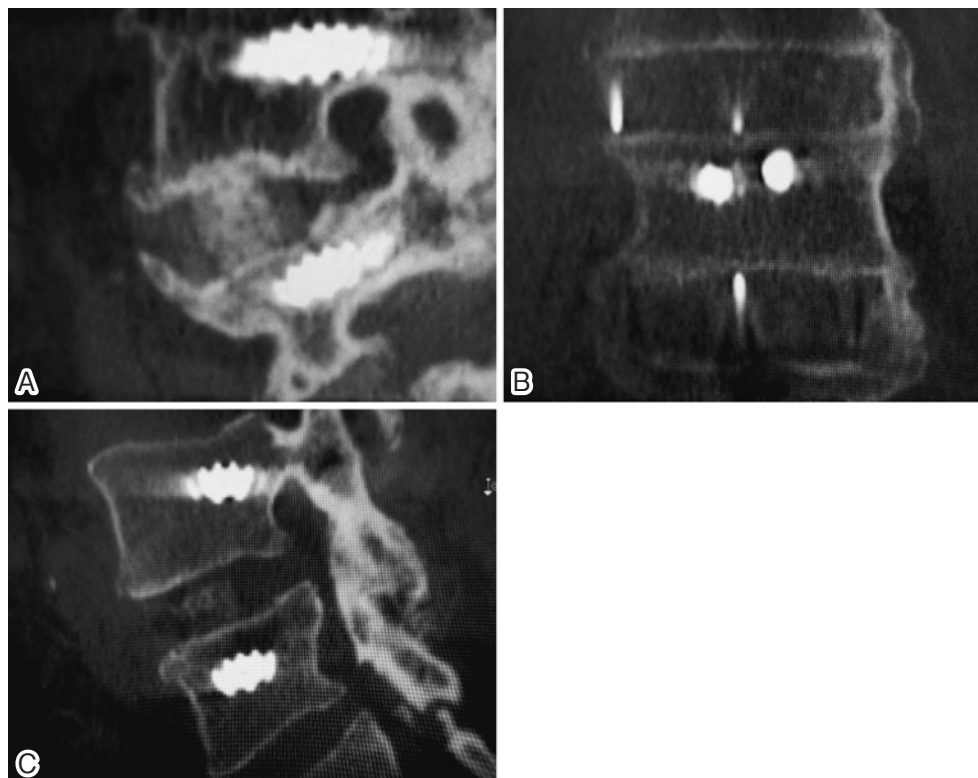
**Table 2.** Surgical Details.

	Segments (n=125)
Surgical site	L1/2 12 L2/3 25 L3/4 45 L4/5 43
Cage height (mm)	9.7±1.1
Cage length (mm)	49.5±5.0
Cage lordosis	-10° 123 0° 2
Intraoperative endplate injury	Yes 21 No 104
Cage position (mm)	1.5±2.7
Posterior fixation	Open pedicle screw (OPS) 94 Percutaneous pedicle screw (PPS) 31

### Clinical outcomes

Sixty-one patients (96.8%) responded to the following questionnaire. Participants were classified into two groups according to CT evaluation: Group N that contained one or more nonunion segments and Group F that contained no nonunion segment.

For each patient, visual analogue scales (VAS) scores of three lesions (low back pain, leg pain, and leg numbness) and the five domains (pain-related disorders, lumbar spine dysfunction, gait disturbance, social life dysfunction, and psychological disorders) of the Japanese Orthopedic Association Back Pain Evaluation Questionnaire (JOABPEQ) were asked at preoperative and postoperative 2 years. The VAS scales and the questionnaire of the five domains were displayed on the touch-panel screen of a tablet, and the patients could answer them without any assistance from the medical staff. For each domain of JOABPEQ, a patient who increased 20 points or more in the improvement score (the difference of the scores between 2 years postoperatively and preoperatively) was determined as an effective case of the treatment<sup>15</sup>. VAS scores of three lesions and the ratio of effective cases (%) in each domain of JOABPEQ were compared between Groups N and F with use of chi-square test.



**Figure 1.** Fused segments with continuous bone bridge formation.

A; inside the cage.

B; outside the cage.

C; facet joint.

**Statistical analyses and the identification of the risk factors for nonunion**

Various parameters of patient backgrounds (age, sex, smoking status, body mass index [BMI], history of diabetes mellitus, T-score for bone mineral density [BMD] measured at the left femoral neck using dual-energy X-ray absorptiometry [DXA], number of previous vertebral fractures, and remedy for osteoporosis) and surgical details (number of LLIF segments, number of posterior fixation segments, surgical site, intraoperative endplate injury that was diagnosed by the lateral X-ray taken immediately postoperatively<sup>16</sup>, LLIF cage height (mm), cage lordosis (0° or -10°), cage position in the lateral view (deviation from the midpoint of the disc [mm]), and the approach of PS (OPS or PPS) were collected from clinical charts, surgical records and X-rays.

These parameters were compared between the nonunion segments and the fused segments with use of univariate analyses. Unpaired Student *t*-test was used for continuous variables and  $\lambda$  square test or Fisher's exact test was used for dichotomous and categorical variables. A *p*-value of < 0.05 was accepted as significant. The parameters with *p* < 0.1 in univariate analyses were entered directly into a multivariate logistic regression analysis as independent factors to

identify the risk factors for nonunion. All analyses were performed using SPSS Version 22 (IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY, USA: IBM Corp.).

**Results**

Among the 125 segments, 69 segments (55.2%) and 86 segments (68.8%) were diagnosed as fused inside the cage and at the facet joints respectively by CT evaluation 2 years postoperatively. Fifty-two segments achieved a facet fusion spontaneously without posterior bone graft. Twenty segments (16%) were determined to be nonunion. K values for intraobserver and interobserver reliability for the classification of cage subsidence were 0.85 and 0.73, respectively. Consequently within 61 patients who completed the self-administered questionnaire, 14 patients (23%) were classified into Group N and 47 patients (77%) into Group F.

There were no significant differences in all VAS scores or in the ratio of effective cases of all domains of JOABPEQ between the two groups (Table 3).

Univariate analyses revealed that PPS usage was significantly higher in nonunion segments than fused segments (45% vs 21%, *p* = 0.04). Besides, BMI showed a lower tendency in the nonunion segments than fused segments (23.2 kg/m<sup>2</sup> ± 4.2 vs 25.0 kg/m<sup>2</sup> ± 4.2, *p* = 0.07) (Table 4).

Multivariate analysis identified PPS usage (odds ratio [OR]: 3.14, 95% confidence interval: 1.13-8.68, *p* = 0.028) as a positive significant risk factor for nonunion (Table 5).

**Discussion**

Generally, LLIF has been reported to demonstrate a low rate of nonunion or pseudoarthrosis in previous literature. The total pooled pseudoarthrosis rate was 4.3% in a meta-analysis for LLIF in adult degenerative scoliosis series<sup>2</sup>. Basically CT is thought to be more reliable than functional X-rays to detect nonunion or pseudoarthrosis of interbody fusion<sup>17-21</sup>. Limited to CT-based study, the reported pseudoarthrosis rate of LLIF was 2.6-19%<sup>1,3,6,7,9,10</sup>.

In LLIF procedure, it is difficult to obtain an adequate



**Figure 2.** A nonunion segment.

**Table 3.** Clinical Outcomes.

	Group N (n=14, 23%)	Group F (n=47, 77%)	p value
VAS at PO2Y			
low back pain	25.7±28.8	33.2±27.0	0.43
leg pain	18.6±22.3	31.1±28.8	0.13
leg numbness	33.5±30.8	32.0±32.0	0.89
The ratio of effective cases in JOABPEQ (%)			
Pain-related disorders	41.7	65.9	0.18
Lumbar spine dysfunction	41.7	18.6	0.13
Gait disturbance	46.2	66.7	0.21
Social life dysfunction	53.8	53.5	1.00
Psychological disorders	38.5	31.1	0.74

VAS: visual analogue scale, PO2Y: postoperative two years, JOABPEQ: Japanese Orthopedic Association Back Pain Evaluation Questionnaire

**Table 4.** Univariate Analyses.

	Nonunion segments (n=20, 16%)	Fused segments (n=105, 84%)	p value
Age (years)	72.1±9.2	70.5±9.2	0.49
Sex	Male 8 (40%) Female 12 (60%)	Male 25 (23.8%) Female 80 (76.2%)	0.17
Diagnoses	Degenerative scoliosis/kyphoscoliosis 12 (60%) Spondylolisthesis 6 (30%) Adjacent segmental disease 0 (0%) Stenosis 2 (10%) Others 0 (0%)	Degenerative scoliosis/kyphoscoliosis 68 (64.8%) Spondylolisthesis 24 (22.8%) Adjacent segmental disease 9 (8.6%) Stenosis 3 (2.9%) Others 1 (0.9%)	1.00
Smoking status: Yes	2 (10%)	12 (11.4%)	1.00
BMI (kg/m <sup>2</sup> )	23.2±4.2	25.0±4.2	0.07
Diabetes: Yes	3 (15%)	25 (22.9%)	0.56
BMD (T-score of DXA, SD)	-0.48±1.28	-1.09±1.39	0.12
Previous multiple vertebral fractures: Yes	2 (10%)	6 (5.7%)	0.61
Treatment for osteoporosis	Teriparatide 7 (35%) Bisphosphonate 0 (0%) Others 0 (0%) None 13 (65%)	Teriparatide 38 (36.2%) Bisphosphonate 3 (2.9%) Others 1 (0.9%) None 63 (60%)	0.83
Number of LLIF levels	2.5±1.3	2.6±1.1	0.75
Number of posterior fusion levels	3.9±3.1	4.5±3.0	0.44
Surgical site	L1/2 2 (10%) L2/3 4 (20%) L3/4 7 (35%) L4/5 7 (35%)	L1/2 10 (9.5%) L2/3 21 (20%) L3/4 38 (36.2%) L4/5 36 (34.3%)	1.00
Cage height (mm)	10.1±1.2	9.6±1.1	0.14
Cage lordosis	-10° 20 (100%) 0° 0 (0%)	-10° 103 (98.1%) 0° 2 (1.9%)	1.00
Intraoperative endplate injury: Yes	2 (10%)	19 (18.1%)	0.52
Cage position (mm)	1.0±3.0	1.6±2.6	0.39
Posterior fixation	OPS 11 (55%) PPS 9 (45%)	OPS 83 (79%) PPS 22 (21%)	0.04

BMI: body mass index, BMD: bone mineral density, DXA: dual-energy X-ray absorptiometry, SD: standard deviation, LLIF: lateral lumbar interbody fusion, OPS: open pedicle screw, PPS: percutaneous pedicle screw

**Table 5.** Multivariate Logistic Regression.

	Odds ratio	95% confidence interval	p value
BMI	0.88	0.76-1.01	0.07
PPS usage	3.14	1.13-8.68	0.028

BMI: body mass index, PPS: percutaneous pedicle screw

amount of local cancellous bone to fill the cage due to its minimally invasive fashion. Harvesting of a large amount of autologous iliac bone has a potential risk for donor site morbidity. In terms of artificial bone substitutes, recombinant human bone morphogenetic protein-2 (rhBMP-2) is used widely. However, potential adverse effects such as hematoma formation or heterotopic ossification are worrying and rhBMP-2 is not available in some countries. Considering

these backgrounds, allogenic cancellous bone is a useful material as a bone graft<sup>22,23)</sup> even for LLIF if ample supply is guaranteed.

Deukmedjian et al.<sup>24)</sup> performed LLIF with use of allograft for seven adult spinal deformity cases; however, the fusion rate was not reported. Rodgers et al.<sup>7)</sup> reported three uncertain levels for fusion (3.4%) out of 88 LLIF levels with use of local bone augmented with demineralized bone matrix and cancellous allograft. Caputo et al.<sup>6)</sup> reported an 11.8% pseudoarthrosis rate in 30 consecutive LLIF series with use of allograft cellular bone matrix.

The nonunion rate in this study was 16%. This higher rate might be due to the poorer bone quality of allograft. All allogenic cancellous bone in this series was harvested from the femoral heads suffering some degenerative disorders requiring a hip arthroplasty.



In terms of clinical outcomes, nonunion did not affect significantly any VAS scores or any domain of JOABPEQ. Watkins et al.<sup>3)</sup> reported that significantly the fused patients had less pain compared with nonunion patients. Contradictorily, Berjano P. et al.<sup>10)</sup> analyzed the relationship between the fusion status and clinical outcomes in LLIF surgery. They concluded that there was no significant differences in Oswestry Disability Index or VAS scales between fused and not fused groups.

The large footprint cage of LLIF supplemented with bilateral PSs may have a role in stabilizing even the segment of nonunion and consequently minimize the influence of nonunion on clinical outcomes. Spontaneous facet fusion without posterior bone graft was also observed frequently in this LLIF series. Different from posterior lumbar interbody fusion or transforaminal lumbar interbody fusion, LLIF does not always require the resection of the facet joints. The intact facet joint may provide a good base for spontaneous bony fusion. Anyway we should pay attention to the patients with nonunion segments in longer follow-up.

LLIF procedure in this study was standardized for cage material (PEEK), graft material (allogenic cancellous bone obtained from femoral heads), and the supplemental fixation (bilateral PSs). Furthermore, all of them were followed for minimally 2 years postoperatively. This homogeneous cohort may have an advantage in identifying the risk factors for nonunion in patient background or surgical parameters.

As for patient's background, lower BMI demonstrated an upward trend of nonunion rate though it was not significant. Weight loss in old age decreases lean mass and could accelerate sarcopenia<sup>25)</sup> as well as bone loss that involves decreased bone formation and/or increased bone resorption<sup>26)</sup>. Lower BMI might be an indicator for nonunion in elderly patients. DXA does not always reflect an accurate bone strength<sup>27-29)</sup>.

The rate of the patients who received osteoporosis remedy was similar in nonunion and fusion groups. Although some previous studies demonstrated the promoting effect of teriparatide on bony fusion in spinal arthrodesis<sup>30,31)</sup>, we did not find similar results in this allograft series.

Surprisingly, PPS usage is determined as a significant risk factor of nonunion. Nonunion rate of the LLIF segments with PPS resulted in more than twice with OPS.

PPS is one of the most common supplemental fixations for LLIF and is thought to minimize injury to the dynamic stabilizing structures of the spine such as the multifidus muscle<sup>32,33)</sup>. In meta-analysis papers, PPS has been reported to have great advantage in reducing intraoperative blood loss, postoperative pain, and consequently the incidence of surgical site infection<sup>34,35)</sup>. However, there were only a few papers comparing OPS and PPS directly in terms of biomechanical behavior or the influence on fusion status.

Kubosch et al.<sup>36)</sup> showed the stiffness inferiority of PPS for fixed-angle screws for conventional open method in biomechanical tests. Shim et al.<sup>37)</sup> revealed a lower fusion rate of anterior lumbar interbody fusion combined with PPS

than with open posterior spinal fusion in elderly patients with L5/S1 isthmic spondylolisthesis though they did not mention the rationale of these radiological outcomes. Barbagallo et al.<sup>38)</sup> reported a high incidence of nonunion in their PPS fixation series for elderly patients.

There are some biomechanics studies on LLIF constructs showing that bilateral PS is the most rigid supplemental fixation for LLIF<sup>39,40)</sup>. However, OPS and PPS should be considered separately in terms of the influence for bony fusion according to the results of this study.

Segmental stability is required to reduce micromotion across the intervertebral segment to allow bone formation and progression of fusion<sup>41)</sup>. In terms of initial stability, there could be one speculation concerning the PS trajectory. PPS is likely to be inserted at a more convergent angle than OPS because of its paramedian approach. Furthermore, the insertion point of PPS is likely to be moved out more laterally in cases with hypertrophic facet joints. This larger angulation of insertion from the outer point tends to lead PPS to the midportion of the vertebral body where the trabeculae is sparse<sup>42)</sup>. This convergence of PPS may decrease the screw bone purchase.

In addition, the blind maneuver in the small incision is likely to fail to place PPS deeply enough in the vertebral body. Surgeons may examine it by finger palpation; however, in severely degenerative segments, it is difficult even under a navigation system. These technically demanding points of PPS placement may correlate to the higher nonunion rate.

There are some limitations in this study. The number of the patients is small because of the limitation on graft and cage materials. In addition, this cohort involves various spinal disorders; some were deformity cases that required multi-level alignment correction, and some were degenerative cases that aimed to fuse one level *in situ*. The impact of a nonunion segment on clinical outcomes might be different between the former and the latter cases. The quality of allogenic bone cannot be made uniform. Each femoral head could be traced to the donor's age and sex; however, the information did not contain the donor's bone quality such as BMD.

In conclusion, nonunion of LLIF with use of allograft did not correlate significantly to postoperative VAS scores or to the ratio of effective cases in JOABPEQ. However, we should be aware of the higher nonunion rate in the segments supplemented with PPS than those with OPS.

**Conflicts of Interest:** Tokumi Kanemura holds an advisory role in AOSpine, NuVasive, DePuySynthes Japan, and Medtronic Japan. Other authors declare that there are no conflicts of interest.

**Author Contributions:** Kotaro Satake wrote and prepared the manuscript, and all of the authors participated in the study design. All authors have read, reviewed, and approved the article.

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