Unique Characteristics of New Bone Formation Induced by Lateral Lumbar Interbody Fusion Procedure

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Abstract:

Introduction: Despite the absence of bone grafting in the area outside the cage, lateral bridging callus outside cages (LBC) formation is often observed here following extreme lateral interbody fusion (XLIF) conversely to conventional methods of transforaminal lumbar interbody fusion and posterior lumbar interbody fusion. The LBC, which may increase stabilization and decrease nonunion rate in treated segments, has rarely been described. This study aimed to identify the incidence and associated factors of LBC following XLIF.

Methods: We enrolled 136 consecutive patients [56 males, 80 females; mean age 69.6 (42-85) years] who underwent lumbar fusion surgery using XLIF, including L4/5 level with posterior fixation at a single institution between February 2013 and February 2018. One year postoperatively, the treated L4/5 segments were divided into the LBC formation and non-formation groups. Potential influential factors, such as age, sex, body mass index, bone density, height of cages, cage material (titanium or polyetheretherketone [PEEK]), presence or absence of diffuse idiopathic skeletal hyperostosis (DISH), and radiological parameters, were evaluated. Multivariate logistic regression analysis was performed for factors significantly different from the univariate analysis.

Results: The incidence of LBC formation was 58.8%. Multivariate logistic regression analysis showed that the length of osteophytes [+1 mm; odds ratio, 1.29; 95% confidence interval, 1.17-1.45; p<0.0001] was significant LBC formation predictive factors. Receiver operating characteristic curve analysis demonstrated that the cut-off value for osteophyte length was 14 mm, the sensitivity was 58.8%, the specificity was 84.4%, and the area under the ROC curve for this model was 0.79.

Conclusions: The incidence of LBC formation was 58.8% in L4/5 levels one year after the XLIF procedure. We demonstrated that the length of the osteophyte was significantly associated with LBC formation.

Keywords:

Lateral bridging callus outside cages, Lateral lumbar interbody fusion, Extreme lateral interbody fusion, Autogenous bone grafting, Osteophytes, Multivariate logistic regression analysis, Bone union

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Introduction

Lateral lumbar interbody fusions (LLIF) have brought about a paradigm shift in spinal surgery. Reports show that LLIF (XLIF: extreme lateral interbody fusion, NuVasive Inc., CA, USA) is an excellent type of minimally invasive spinal surgery[1]. In LLIF surgeries, cages filled with the grafted bone are inserted into the disc space to promote bone union in the area where the bone was grafted. Previous studies have achieved high bone union rates with excellent intervertebral stability using cages with a large footprint[2-5]. It is well-known that one of the most effective methods to promote bone union is by using autogenous bone grafting[2,4,5] or recombinant human bone morphogenetic protein-2 (rhBMP-2)[3,5,6].

Lateral bridging callus outside cages (LBC) formation is often observed postoperatively in patients who undergo XLIF despite no bone grafting took place outside the cages (Fig. 1). However, LBC formation is observed at a low rate in patients after conventional surgeries, such as posterior lumbar interbody fusion (PLIF) or transforaminal lumbar interbody fusion (TLIF)[7]. XLIF may promote LBC formation

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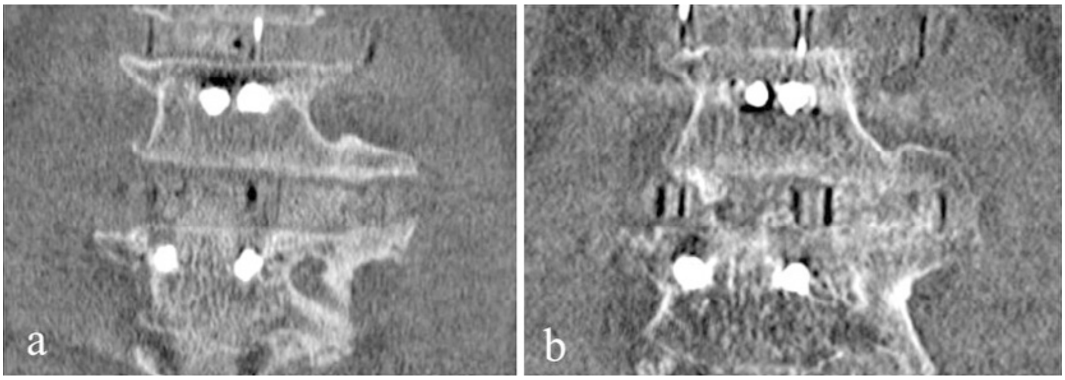

Figure 1. a. Computed tomography (CT) image 1 week after surgery with lateral lumbar interbody fusion. b. CT image 1 year after surgery with lateral lumbar interbody fusion and showing formation of lateral bridging callus outside cages.

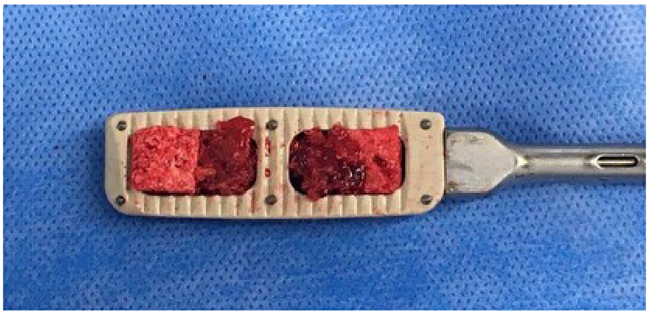

Figure 2. Image of extreme lateral interbody fusion filled with artificial and autogenous bone grafting.

more than conventional interbody fusion methods because the enthesis of the disc is partially broken in XLIF, unlike in PLIF or TLIF. LBCs are different from the preoperative osteophytes and may cause an increase in interbody stabilization and decrease in nonunion rates following lumbar fusion surgery. The current literatures do not thoroughly explain the LBC formation in XLIF procedures. Therefore, this study aims to investigate the incidence of LBC and the factors that can lead to LBC formation in patients who undergo XLIF.

Materials and Methods

Study design and patients

The institutional review board of our university approved the study design before initiating the study. The patients or their family members were informed that the patient data would be submitted for publication, and their written consent was obtained.

136 consecutive patients who underwent lumbar fusion surgery using XLIF, including L4/5 level with posterior fixation in our institute from February 2013 to February 2018, were enrolled in this study. In total, 56 males and 80 females were included, and their mean age was 69.6 years (range: 42-85 years). The diagnosis was adult spinal deformity (ASD) in 90 patients, lumbar spinal stenosis in 41 patients, and lumbar instability in 5 patients. All L4/5 levels were evaluated using computed tomography (CT) one year postoperatively.

Surgical procedures

In all patients, posterior fusion surgery was performed in the prone position after performing XLIF in the lateral position on the same day. In the surgical course of the XLIF procedure, the disc material was resected after penetrating the annulus fibrosus of the intervertebral disc using the Cobb elevator opposite to the invasive side. Fundamentally, surgeons did not remove the osteophytes during surgery. The autologous iliac crest bone and artificial bone made of hybridized hydroxyapatite and type I collagen (ReFit®, HOYA Technosurgical Co., Tokyo, Japan) were mixed in a 50/50 proportion and inserted into the XLIF cage (Fig. 2). If there are any foreign objects around the cage after insertion of the XLIF cage, they were all removed because Refit® may cause a foreign body reaction. Percutaneous pedicle screw (PPS) fixation or open surgery was performed as necessary. Neither rhBMP-2 nor allograft bone was used. A hard corset was used for approximately three months postoperatively.

Factors influencing LBC formation

LBC is the continuous cortical bone between the cranial and caudal vertebrae outside an XLIF cage. All the treated interbody levels were divided into two groups. When LBC formation was observed on at least one side at each interbody level, this level was allocated into the formation group (F group). When no LBC was observed, the level was allocated to the non-formation group (N group). The following factors that may lead to LBC formation were investigated: sex, age, body mass index (BMI), bone density (T-score), injection of teriparatide (daily, not biosimilar) two months or more before surgery, height of cages, cage material (titanium or polyetheretherketone [PEEK]), Cobb angles, degrees of vertebral body wedging of L4 and L5, and lengths of the osteophytes in the frontal view on X-ray, presence or absence of diffuse idiopathic skeletal hyperostosis (DISH) in the parent body to which the concerned interbody belonged, pelvic incidence (PI), and method of posterior fixation (with

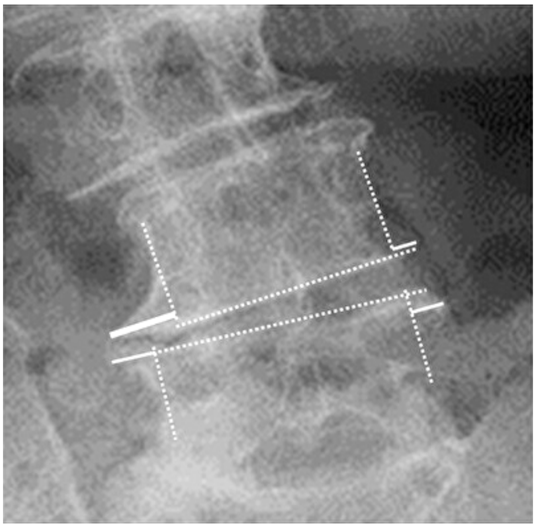

Figure 3. Measurement of the length of vertebral osteophytes using frontal view X-rays.

PPS or open surgery). Cobb angles were measured between the cranial vertebra's caudal endplate and the caudal vertebra's cranial endplate at L4/5 level. The presence or absence of DISH was decided according to the report by Resnick et al.[8].

Laterality of LBC formation

The laterality of LBC formation was also evaluated. We investigated whether LBCs appeared on the approach or non-approach side and on the concave or convex side of the scoliosis curve. The approach side was determined based on the location between the iliac crest and the L4/5 disc, the position of the colon and kidney, and the previous abdominal surgery. The concave or convex side was evaluated after patients with small Cobb angles (<3 degrees) before surgery were excluded, considering a measurement error of the Cobb angle[9]. When LBCs were formed on both sides, the patients were excluded from the statistical evaluation.

Association between LBCs and treated levels with XLIF

The association between LBCs and treated levels with XLIF was evaluated in 92 patients who underwent single-staged corrective fusion surgery, including multiple XLIF at L2/3, L3/4, and L4/5 levels.

Association between LBCs and pathologies

The association between LBCs at L4/5 and pathologies (ASD, lumbar spinal stenosis, and lumbar instability) was evaluated in 136 patients.

Association between LBCs and bone union inside cages

The association between LBCs and bone union inside cages was investigated. The Berjano classification[2] was used to evaluate bone union inside the cages; that is, bone union was divided into three types: "complete bone union," in cases where continuous bony bridging calluses were observed between the cranial and caudal bony endplates in the disc space; "stable union," in cases where bony bridging calluses in the disc space were not observed on the multiplanar reconstruction (MPR) of CT images but there was no clear zone around the cage; and "pseudoarthrodesis," in cases where the grafted bone in the cage was absorbed and a clear zone around the cage was observed.

Measurement of lengths of osteophytes

On the frontal view radiograph of the lumbar spine, we drew a perpendicular line from a dent in the middle of the vertebra to the endplate. Subsequently, we measured the shortest distance (SD) between this line and the tip of the osteophytes (Fig. 3). If LBC formation was observed on both sides in the F group or if no LBC formation was observed, we defined the longest length of the four SDs as the length of the osteophyte. If LBC formation was observed on only one side in the F group, we defined the longest length of the two SDs on the formation side as the length of the osteophyte.

Evaluation of LBC formation on CT

LBC formation was detected using MPR images from CT data and careful observation of the coronal view. To evaluate the intraobserver variability in detecting the presence or absence of LBC formation, the same observer evaluated CT films of 35 randomly selected patients after more than four weeks of the first reading. Two spine surgeon supervisors, certified by the Japanese Society for Spine Surgery and Related Research, also evaluated 35 other patients' CT films to determine the interobserver variability. The intraobserver variability for evaluating LBC formation was confirmed satisfactory with a kappa coefficient of 0.84. Interobserver variability was also satisfactory at 0.80.

CT image acquisition

All examinations were undertaken using a 320-slice CT scanner (Aqilion ONE / GENESIS Edition, Canon Medical Systems Corporation, Otawara, Japan). The following parameters were used: peak voltage (120 kVp), tube current (automatic exposure control setting [SD:20]), detector coverage (80 mm), gantry rotation time (0.5 s), and beam pitch (0.813). All images were reconstructed with a slice thickness and slice interval of 0.5 mm each.

Statistical analysis

All parameters were evaluated statistically. Comparisons between the two groups based on sex, use of teriparatide (daily, not biosimilar), cage material, DISH, and methods of posterior fixation were conducted with Fisher's exact test. The Mann-Whitney U test was used for analyzing age, BMI, bone density, cage height, Cobb angles at L4/5 level, degrees of vertebral body wedging of L4 and L5, lengths of osteophytes, and PI.

A multiple logistic regression analysis was performed to determine the association between predictive factors and LBC formation. During the analysis, we used LBC forma-

Table 1. Characteristics of the Patients.

		Patients (n=136)
Sex (male/female)		56/80 (41.2%/58.8%)
Age (years-old)		69.6±8.7*
Body mass index		23.0±3.4*
Bone density (T-score)		−1.0±1.2*
Teriparatide (used)		75 (55.1%)
Number of treated level (s)	1	26 (19.1%)
	2	18 (13.2%)
	3	54 (39.7%)
	4	38 (27.9%)
Diffuse idiopathic skeletal hyperostosis		16 (11.8%)
Pelvic incidence		50.0±10.4*
Method of posterior fixation (percutaneous pedicle screws/open)		79/57 (58.1%/41.9%)

*mean±standard deviation.

tion as the objective variable and potential associated factors selected with a significant association with LBC formation in the univariate analysis as the explanatory variable. Moderator variables included sex, age, and BMI. The Results section describes the chosen explanatory variables for logistic regression analysis. A receiver operating characteristic (ROC) curve analysis was performed, and the area under the ROC curve (AUC) was calculated for internal validation. When the ROC curve analysis showed statistically significant findings, the analysis also estimated a cut-off value using the Youden index. All statistical analyses were performed using JMP data analysis software, version 13.0 (SAS Institute, Japan, Tokyo, Japan), and p-values <0.05 were considered to indicate statistical significance.

The binomial test was used to examine differences in the laterality of LBC formation. Pearson's chi-square test and Cochran-Armitage trend test were employed to evaluate the association between LBCs and treated levels with XLIF. A Fisher's exact test was used to analyze differences in the association between LBC and pathologies and between LBC and bone union inside cages, except for "pseudoarthrodesis" levels.

Results

Characteristics of the patients

Table 1 summarizes the characteristics of all patients. The mean patient BMI was 23.0±3.4, the mean T-score was −1.0 ±1.2, and the mean PI was 50.0±10.4 (mean±standard deviation). Preoperative teriparatide injections were administered to 55.1% of the patients, DISH was observed in 11.8% of the patients, and PPSs were used as posterior fixations in 58.1% of the patients. The distribution of the number of treated level(s) was as follows: 1 level: 19.1%, 2 levels: 13.2%, 3 levels: 39.7%, and 4 levels: 27.9%.

Incidence of LBC

Of 136 levels, LBC formation was observed in 80 levels (58.8%).

Factors influencing LBC formation

Table 2 shows the comparisons between the F and N groups according to sex, age, BMI, bone density (T-score), injection of teriparatide, cage height, cage material, Cobb angle, degrees of vertebral body wedging of L4 and L5, length of the osteophytes on X-rays, DISH, PI, and posterior fixation methods. In the univariate analysis, sex, age, BMI, bone density, injection of teriparatide, intervertebral levels, cage height, cage material, Cobb angle, degrees of vertebral body wedging of L4 and L5, DISH, PI, and posterior fixation methods were not significantly associated with LBC formation. However, there were significant correlations between LBC formation and the length of osteophytes (p< 0.001) (Table 2).

A multivariate logistic regression analysis revealed that the length of osteophytes (+1 mm; odds ratio [OR], 1.29; 95% confidence interval [CI], 1.17-1.45; p<0.0001) was significant predictive factors of LBC formation (Table 3). ROC curve analysis demonstrated that the cut-off value for osteophyte length was 14 mm, the sensitivity was 58.8%, the specificity was 84.4%, and the AUC for this model was 0.79 (Fig. 4).

Laterality of LBC formation

LBC formed on the approach and non-approach sides in four cases, and it occurred on the convex and concave sides in two cases. We omitted these duplicate cases and performed a statistical evaluation. After excluding these patients, LBCs appeared in 32 patients (42.1%) on the approach side and in 44 patients (57.9%) on the non-approach side, and there was no statistically significant difference (P= 0.103). After excluding patients with a Cobb angle of less than three degrees, the evaluation of 50 patients revealed that LBCs formation was observed in 32 patients (66.7%) on the concave side and in 16 patients (33.3%) on the convex side, and there was a statistically significant difference (P=0.015) (Table 4).

Table 2. Comparison between the Characteristics in the Formation and Non-formation Group of Lateral Bridging Callus outside Cages.

	Formation (n=80)	Non-formation (n=56)	*p*-value
Sex (male)*	26 (32.5%)	16 (28.6%)	0.708
Age (years-old)†	70.4±8.1	68.8±9.5	0.412
Body mass index†	23.2±3.5	22.6±3.2	0.391
Bone density (T-score)†	−0.9±1.4	−1.2±1.0	0.309
Teriparatide (used)*	45 (56.3%)	30 (53.6%)	0.861
Height of cages (mm)†	9.0±1.0	9.4±1.2	0.066
Materials of cages (Titanium)*	4 (5.0%)	2 (3.6%)	1.000
Cobb angles (degrees)†	5.6±5.5	7.0±7.9	0.853
Degrees of vertebral body wedging (L5)†	2.1±3.0	2.2±2.6	0.460
Degrees of vertebral body wedging (L4)†	3.0±3.4	3.9±4.2	0.286
Lengths of vertebral osteophytes (mm)†	14.3±5.3	8.9±3.6	<0.001
Diffuse idiopathic skeletal hyperostosis*	11 (13.8%)	5 (8.9%)	0.432
Pelvic incidence†	50.6±10.0	49.2±11.1	0.434
Method of posterior fixation* (percutaneous pedicle screws)	43 (53.8%)	36 (64.3%)	0.290

*Fisher's exact test, †Mann–Whitney *U* test.

Table 3. Association of Selected Factors with Lateral Bridging Callus outside Cages.

Explanatory variable	Odds ratio†	95%CI	*p* value
Lengths of vertebral osteophytes (+1 mm)	1.29	1.17–1.45	<0.0001

†Multiple logistic regression analysis calculated the odds ratio after adjustment for age, sex, and body mass index (BMI).
95% CI; 95% confidence interval

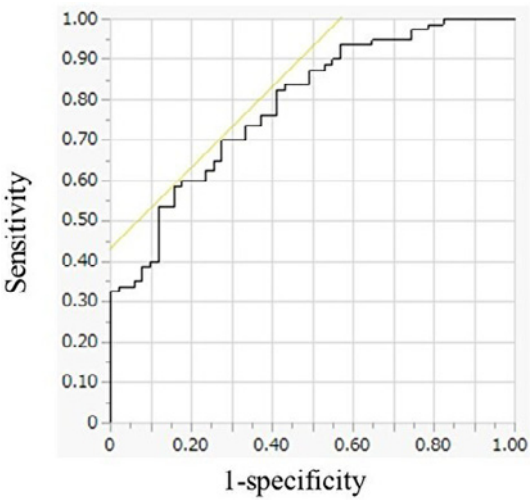

Figure 4. Receiver operating characteristic curve analysis showing that the area under the curve for this model is 0.79.

Table 4. Evaluation of Laterality in Formation of Bridging Callus outside Cages.

		P-value
Approach side	32/76 (42.1%)	0.103
Non-approach side	44/76 (57.9%)	
Concave side	32/48 (66.7%)	0.015
Convex side	16/48 (33.3%)	

Duplicate counting was allowed, Binomial test.

Association between LBCs and treated levels with XLIF

Pearson's chi-square test showed significant differences among the three groups at L2/3, L3/4, and L4/5 levels (P= 0.0004). Cochran-Armitage trend test showed that LBCs were significantly more frequently formed at the caudal level (Table 5).

Association between LBCs and pathologies

Table 6 summarizes the association between ASD and LSS-instability in LBC formation. There was a statistically significant correlation between LBC formation and pathologies.

Association between LBC and bone union inside cages

Table 7 summarizes the association between LBC formation and bone union inside cages. In the F group, "complete bone union" was found in 75 levels (93.8%), "stable union" was found in 5 levels (6.3%), and "pseudoarthrodesis" was absent. In the N group, "complete bone union" was observed in 29 levels (51.8%) and a "stable union" in 23 levels (41.1%). "Pseudoarthrodesis" was observed in 4 levels (7.1%) in the N group. There was a statistically significant

Table 5. Association with LBC Formation and Operated Levels in 92 Patients Treated by Multiple XLIF at L2/3, L3/4, and L4/5.

Levels	LBC Formation	LBC non-formation	*p* value by Pearson's chi-square test	*p* value by Cochran-Armitage trend test
L2/3	34 (37.0%)	58 (63.0%)		
L3/4	41 (44.6%)	51 (55.4%)	0.0004**	0.0001**
L4/5	60 (65.2%)	32 (34.8%)		

LBC; lateral bridging callus outside cages, XLIF; lateral lumbar interbody fusion, *$p<.05$. **$p<.01$.

Table 6. Association with the Formation of Lateral Bridging Callus outside Cages and Lumbar Pathologies.

Disease	LBC formation	LBC non-formation	*p* value
ASD	60 (65.9%)	31 (34.1%)	0.026
LSS-instability	20 (44.4%)	25 (55.6%)	

ASD; adult spinal deformity, LSS-instability; Lumbar spinal stenosis and lumbar instability, Fisher's exact test.

Table 7. Association with Lateral Bridging Callus outside Cage and Bone Union inside Cage.

	Intra-cage bone union type		
	C	S	P
LBC (+)	75 (93.8%)	5 (6.3%)	0 (0.0%)
LBC (-)	29 (51.8%)	23 (41.1%)	4 (7.1%)

C; complete bone union, S; stable union, P; pseudoarthrodesis, LBC; lateral bridging callus outside cage

correlation between LBC formation and "complete bone union" (p<0.0001).

Case presentation

A 71-year-old woman with low back pain from degenerative lumbar kyphoscoliosis underwent surgical treatment. She had no diffuse idiopathic skeletal hyperostosis. However, she had long osteophytes at each lumbar interbody level, as shown in the preoperative radiograph (Fig. 5a). A single-staged long corrective fusion surgery, including XLIF with PEEK cages at 3 levels (L2/3, L3/4, and L4/5) from the right side, PLIF at L5/S1, and posterior open surgery at T9-S2, were performed (Fig. 5b). CT one year after surgery showed obvious bridging callus formation outside the cages at L2/3 on the right side and at L3/4 and L4/5 on the opposite side where long osteophytes were observed preoperatively (Fig. 5b, c).

Discussion

To the best of our knowledge, this pioneers the investigation regarding LBC formation in detail after an XLIF procedure. In this study, we determined that LBC formation incidence was 58.8% at L4/5 after the XLIF procedure, and the factors influencing LBC formation were the length of osteophytes.

Numerous studies have generated data regarding bone fusion in XLIF cages. Fusion rates were reported to be low when filling the cage with allogenic bone only (71%) or artificial bone only (85%)[5,10]. Conversely, other studies have reported a bone union rate of 87-97% in XLIF by filling the cage with autogenous bone grafting, with the addition of some artificial bone[2,4,5]. Moreover, many reports have suggested that rhBMP-2 can substitute for autogenous bone grafts, with equivalent or higher fusion rates in XLIF[3,5,6]. There have been few available reports concerning LBCs. Hrabálek et al. described the frequency of LBC formation in a small cohort study that examined bone union rates after XLIF[11]. Proietti et al. recently established radiological grading of bony bridge localization patterns, including LBC after XLIF[12]. However, both reports did not examine detailed factors regarding LBC formation.

Despite the absence of bone grafting in the area outside the cage, bridging callus formation is often observed outside the cage in XLIF, unlike the more conventional methods of TLIF and PLIF. The outer layer of the disc's annulus fibrosus is usually preserved in TLIF or PLIF. Conversely, XLIF, a technique that partially breaks the biologically active enthesis of the disc, may lead to a secondary effect of promoting LBC as an ectopic bone formation. This may lead to a high interbody stabilization and reduce the number of nonunion cases. It has been reported that injury to Sharpey's fibers penetrating the bone tissue from the periosteum at the annular ligament leads to osteophyte formation by ligament ossification or endochondral ossification of the fibrocartilaginous repair tissue[13]. Additionally, bone union in the XLIF procedure may be similar to that in callotasis, which promotes secondary bone formation to regenerate healing[14-16]. In XLIF, vertebral bodies are fixed in the same environment where soft tissues, such as the periosteum around the vertebrae, are relatively preserved after a distraction force is added to an affected interbody by inserting the cage. LBCs' frequent formation on the concave side, instead of the approach side, suggests that bone union is induced by distraction force. However, the LBC development mechanism needs further investigation to clarify the specific conditions for LBC formation.

We found a significant correlation between LBC formation and "complete bone union." Ergo, vigorous bone formation occurred within the cage at the interbody where LBCs were formed. Although knowing the timing of LBC formation is important, determining whether LBCs are formed af-

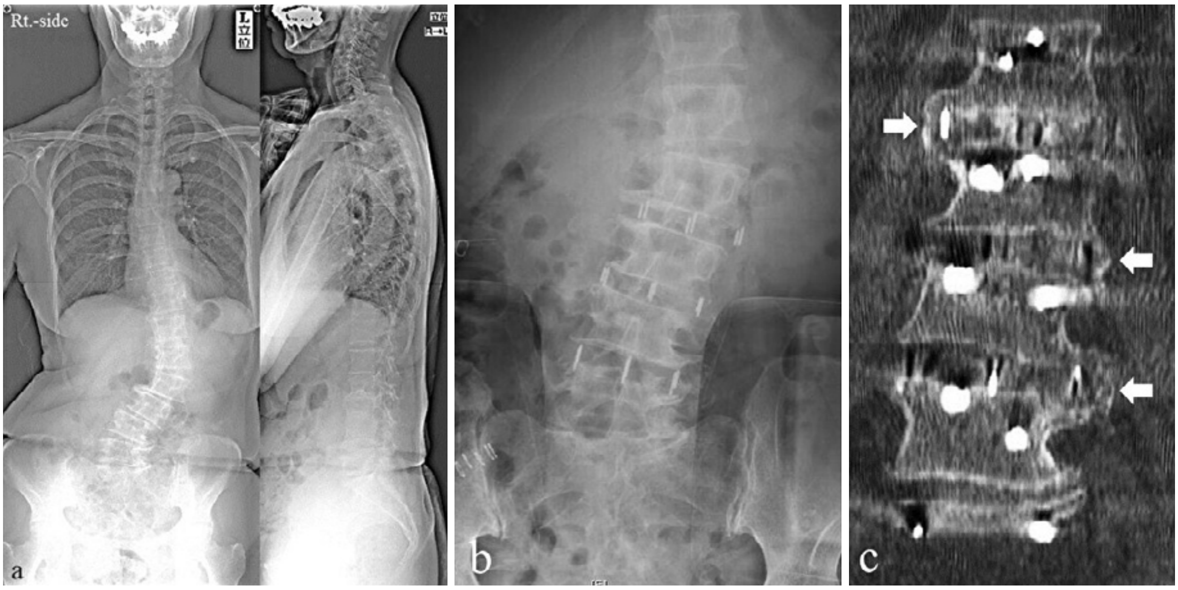

Figure 5. a. Front and lateral whole spine radiographs of a 71-year-old woman with low back pain owing to degenerative lumbar kyphoscoliosis. b. Radiograph taken immediately after XLIF surgery. c. Computed tomography image 1 year after surgery showing obvious bridging callus formation outside the cages at L2/3 on the right side and at L3/4 and L4/5 on the opposite side (white arrows).
XLIF; extreme lateral interbody fusion

ter bone union with the cage or vice versa is difficult because longitudinal survey with postoperative CT is limited. XLIF may lead to higher interbody stabilization than conventional PLIF and TLIF due to LBC formation, which may reduce nonunion rate in clinical practice.

The results of this study show that only artificial bone may be implanted without the autologous bone in the cage at intervertebral levels with osteophytes of 14 mm or more. This may reduce the amount of bone harvested and decrease pain at the bone harvest site. Of the 136 patients, 49 (36.0%) had osteophyte formation of 14 mm or more, including 37 patients with ASD and 12 with lumbar spinal stenosis. Therefore, we are considering the prospective study in patients who require corrective fusion surgery for ASD.

We acknowledge that this study had some limitations. First, our study was not performed as a prospective study, which may have distorted the results. Although the two groups in this study received the same implant, XLIF procedure and postoperative therapy course, our results should be further clarified in a prospective study. Second, the measurement method of the length of osteophytes in this study referred to the unconventional method of Jimbo et al.[17]. Previously reported methods were not effective because patients with ASD have severe degenerative changes of the vertebra[18,19]. More precise measurements using CT have also been reported[20]. However, we adopted our method to facilitate quick measurements that can be easily applied in clinical practice using a simple routine radiograph. Third, there are no data on LBC formation in LLIFs other than XLIFs in this study (e.g., oblique lumbar interbody fusion), and there is limited on this subject. Therefore, it is unclear whether the results of this study can be generalized entirely to LLIF. Ergo, future studies must also be conducted in other LLIF.

In conclusion, the incidence of LBC formation was 58.8% at L4/5 levels one year after XLIF surgery. We demonstrated that the length of the osteophyte was significantly associated with LBC formation. ROC curve analysis demonstrated that the cut-off value for osteophyte length was 14 mm.

Disclaimer: Yamada and Hashizume are the Editors of Spine Surgery and Related Research and on the journal's Editorial Committee. They were not involved in the editorial evaluation or decision to accept this article for publication at all.

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

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Ethical Approval: This study was conducted with the approval of the Research Ethics Committee of Wakayama Medical University (No. 2823).

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

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