

The Significance of Extra-Cage Bridging Bone via Radiographic Lumbar Interbody Fusion Criterion

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Abstract

Study Design: Prospective observational study.

Objectives: We aimed to analyze the distributional patterns of the intra- and extra-cage bridging bone (InCBB and ExCBB) and the significance of ExCBB using suggested lumbar interbody fusion criterion.

Methods: This study included the patients with planned single-level transforaminal lumbar interbody fusion. We divided bridging bone into InCBB (in void of right or left cage) and ExCBB (outside of cages; anterior, posterior, intermediate, right, or left) and graded bridging scores from 0 to 2 on postoperative 1-year computed tomography. The fusion was defined as at least having one or more graded 2 and the evaluation were conducted twice by 2 raters.

Results: Sixty-five patients were enrolled. All values of intra- and inter-rater reliability in left InCBB, anterior, and posterior ExCBB showed good agreements (≥ 0.75). Both InCBBs showed similar mean bridging scores (Rt: 1.43 vs Lt: 1.48), and in ExCBBs, the anterior was the highest (1.43), followed by the posterior (1.14); the right and left were the lowest (0.49 and 0.52 respectively). In subjects determined as fusion (85.4%), complete bridging was observed more in ExCBB (88.8%) than in InCBB (69.9%).

Conclusions: Given the higher bridging scores in both InCBBs and Ant. ExCBB, bone grafting is important promoting factor to increase the interbody bridging bone regardless of outside or in void of cages. Based on our suggested criterion, ExCBB has a greater proportion compared to InCBBs for determining the fusion and extra-cage bone grafting should be considered as important procedures for interbody fusion.

Keywords

fusion criterion, lumbar spine, interbody fusion, bridging bone, extra-cage, computed tomography

Introduction

Lumbar interbody fusion is performed to obtain stability for eliminating painful movements or recurrent prolapse from pathological discs.^{1–4} If stable fusion is not achieved, complications such as pseudarthrosis, implant loosening, and cage subsidence occur, resulting in poor clinical outcomes.^{5,6} To achieve stable interbody fusion, disc space preparation and proper bone graft and cage placements are essential.⁷ Interbody cages are commonly used for maintaining the height of the prepared intervertebral space and inducing bridging bone through their void. In addition, most surgeons perform bone grafting not only inside the cages but also outside the cages to increase the fusion rates.

When assessing clinical outcomes, radiographic determination of the fusion status is an important factor. Surgical

exploration is regarded as the gold standard; however, its clinical use is limited.^{2,8} Among several radiographic modalities, computed tomography (CT) scan is considered the best option for assessing fusion^{9–11}; especially, its various technical developments including fine-cuts and multi-planar reconstruction have enabled more detailed analysis. However, despite these advances, the radiographic fusion criteria, commonly defined

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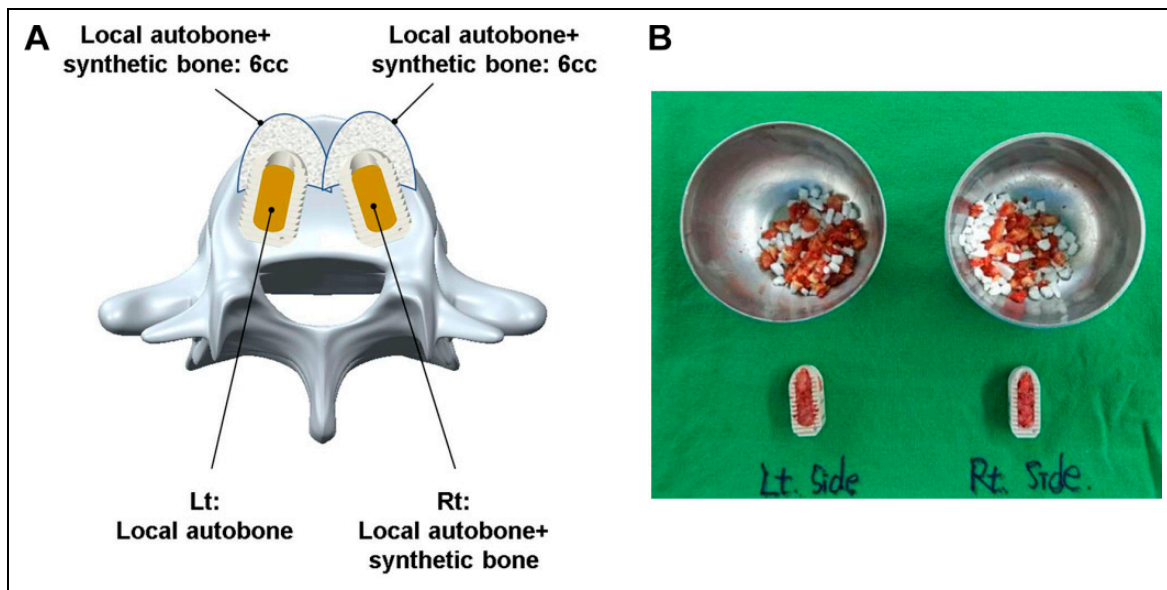


Figure 1. Schematic and intraoperative images of the bone graft. A and B, Half-mixed each 6 cc of local autobone and synthetic bone grafting was performed on the anteriorly prepared disc space, and 2 cages with different bone compositions (left [Lt.] cage: filled with only local autobone, right [Rt.] cage: filled with local autobone + synthetic bone) were inserted bilaterally.

as “bridging bone without any radiolucency between adjacent vertebrae,” have not been changed both on radiographs or CT scans, and the detailed criteria for determining fusion are still lacking and could be subjective.⁵ Also, when evaluating the fusion status, the bridging bone through the void of the cage has been focused and the bridging bone outside the cage has been relatively marginalized.

Extra-cage grafted bone is voluminous and might be important for fusion. However, there have been few studies demonstrating the effects and fate of bone graft outside of cages, and the significance of an extra-cage grafted bone in assessing lumbar interbody fusion. Therefore, we aimed to analysis the distributional patterns of the bridging bone based on the relative location to the cages consisting of intra- and extra-cage bridging bone (InCBB and ExCBB, respectively) and evaluated the significance of the ExCBBs with a radiographic lumbar interbody fusion criterion using multi-directional reconstructed CT scan.

Methods

This study was observational study in prospective manner. Consecutive patients aged 18-80 years with spinal stenosis or spondylolisthesis who planned to undergo single-level lumbar transforaminal interbody fusion (TLIF) with pedicle screw fixation between May 2015 and September 2016 were included. Patients who had diseases including malignancy, infection, and metabolic bone disease were excluded. All operations were performed at a single institution by a single surgeon. The enrolled patients had plain radiographs at postoperative 3, 6, and 12 months and fine-cut multiaxial reconstructed CT scan at postoperative 12 months to evaluate for bone-bridging patterns. The clinical outcomes were

assessed by the gluteal or leg pain using Numeric Rating Scale (NRS) and Oswestry Disability Index (ODI) scores preoperatively and 12 months after surgery.

Operation Methods

After disc preparation following bilateral decompression with facetectomies, extra-cage bone grafting, consisting of half-mixed each 6 cc of local autobone and synthetic bone (OSTEON, Genoss, Korea), was performed on the prepared anterior disc space bilaterally; then, bilateral polyetheretherketone cages (ABB cage, Genoss, Korea) with different graft compositions (left cage: filled with local autobone, right cage: filled with local autobone + synthetic bone) were inserted (Figure 1).

Radiographic Fusion Criterion

We used the concept of InCBB and ExCBB to evaluate the fusion status.¹² InCBB was defined as the bridging bone between the upper and lower vertebrae through the void of the cage(s) and divided into right (Rt.) and left (Lt.) InCBB according to the cage position. ExCBB was defined as the bridging bone between the 2 vertebrae in extra-cage areas of the disc space and divided into 5 zones based on their relative positions to the cages in the disc space: anterior ExCBB: front of the cage; posterior ExCBB: back of the cage; intermediate ExCBB: between 2 cages; right: at the right side of the right cage; and left ExCBB: at the left side of the left cage (Figure 2). We graded bridging scores from 0 to 2 based on the degree of completion of the bridging bone in InCBBs and ExCBBs (grade 0: no bridging at the superior and inferior endplates; grade 1: incomplete bridging; bridging at the superior or

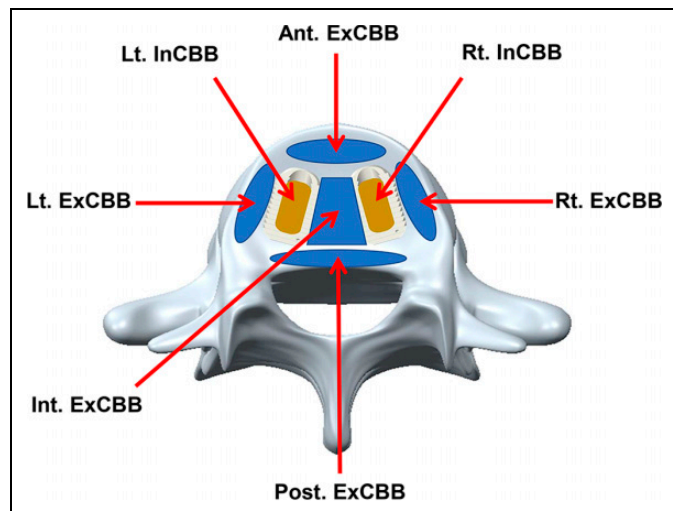


Figure 2. Distribution of intra-cage bridging bone (InCBB) and extra-cage bridging bone (ExCBB). Anterior (Ant.) ExCBB: front of the cage; posterior (Post.) ExCBB: back of the cage; intermediate (Int.) ExCBB: between 2 cages; right (Rt.) ExCBB: at the right side of the right cage; and left (Lt.) ExCBB: at the left side of the left cage.

inferior endplate, but with a clear radiolucent line; grade 2: complete bridging) (Figure 3).

InCBB and ExCBB were evaluated using a software program (Extended Brilliance Workspace 4.5 workstation, V4.5.2.4031, Philips Healthcare Nederland BV, the Netherlands) that allows users to control the axis of the image planes. Three planes were set at each level as follows: the axial plane was set parallel to the operated disc space on coronal and sagittal views; the sagittal plane was set perpendicular to the disc space on coronal view and the posterior margin of the vertebrae on axial view; and the coronal plane was set perpendicular to the disc space on sagittal view and parallel to the posterior margin of the vertebrae on the axial view.¹² The sagittal and coronal views were then serially examined for ExCBBs and InCBBs. The fusion was defined as meeting the following 3 criteria: no subsidence of 3 mm or more on serial postoperative 3, 6, 12 months radiographs until postoperative 12 months; at least having one or more grade 2 among InCBBs or ExCBBs (InCBB/ExCBB: 0/2, 1/2, 2/2, 2/1, 2/0); and the complete bridging bone, graded 2, should be confirmed on both sagittal and coronal views simultaneously. All measurements were recorded twice at a 2-month interval by 2 raters (rater 1: a fourth-year orthopedic resident, rater 2: a spine specialist with 15 years of experience). We analyzed all the values measured twice by 2 raters, without making a consensus for the different values. From this, we divided surgical levels into fused group and non-fused group.

Statistical Analysis

In calculating sample size, the primary endpoint of this study was the proportion of InCBB in fusion group and the anticipated

proportion of InCBB in fusion group at postoperative 12 months was 90%. With 2-sided, 95% confidence interval of 18%, we needed 55 patients with fused segment. Assuming fusion rate at 85%,¹³ a total 65 patients were needed. Considering dropout rate of 5%, we enrolled 69 patients in this study.

The reliability of InCBB and ExCBB was expressed as intra-class correlation coefficients (ICCs) and the values were categorized by the Portney and Watkins criteria (≥ 0.75 : good, 0.50–0.74: moderate, 0.26–0.50: fair, and ≤ 0.25 : poor).¹⁴ The differences between the fused and non-fused groups based on our suggested criterion were examined using independent t-tests for continuous variables. A P value < 0.05 was considered statistically significant. All statistical analyses were performed using SPSS version 23.0 (SPSS, Chicago, IL, USA).

Ethics Statement

The study was approved by the institutional review board of the authors' center, under protocol no. C2015030(1488) and all study participants provided informed consent.

Results

Out of the total study participants, 4 patients dropped out because they failed to undergo CT scan at postoperative 12 months; thus, 65 patients (male: 22, female: 43) were finally enrolled. The demographic data of the enrolled patients is shown in Table 1.

Bridging Scores of InCBBs and ExCBBs

Overall, both InCBBs and Ant. ExCBB demonstrated the highest bridging scores and Lt. and Rt. ExCBBs showed the lowest bridging scores. The mean bridging scores tended to be higher in Lt. InCBB than in Rt. InCBB, and the number of complete bridging bone (grade 2) was higher in Lt. InCBB ($n = 125$, 48.1%) than in Rt. InCBB ($n = 112$, 43.1%). Ant. ExCBB showed the highest bridging score of 1.43, followed by Post. and Int. ExCBBs, with values of 1.14 and 1.06, respectively, while Rt. and Lt. ExCBBs had the lowest values of 0.49 and 0.52, respectively. Ant. ExCBB ($n = 124$, 47.7%) had the most complete bridging, followed by Post. ExCBB ($n = 80$, 30.8%) and Int. ExCBB ($n = 78$, 30.0%). Lt. ExCBB ($n = 15$, 5.8%) and Rt. ExCBB ($n = 12$, 4.6%) showed the lowest values (Table 2).

Reliability of InCBB and ExCBB

The intra-rater reliability values ranged from 0.648 to 0.918 for rater 1 and from 0.744 to 0.902 for rater 2, whereas the inter-rater reliability ranged from 0.605 to 0.836. All values showed moderate (0.50–0.74) to good (≥ 0.75) agreement. Overall, all intra- and inter-rater reliability values showed good agreement were observed only in Lt. InCBB and Ant. and Post. ExCBBs.

Lt. InCBB showed higher values than Rt. InCBB in all inter- and intra-rater reliability assessments. All values for both Ant. and Post. ExCBBs showed good agreement; however, both Rt. and the Lt. ExCBBs had relatively low values that showed

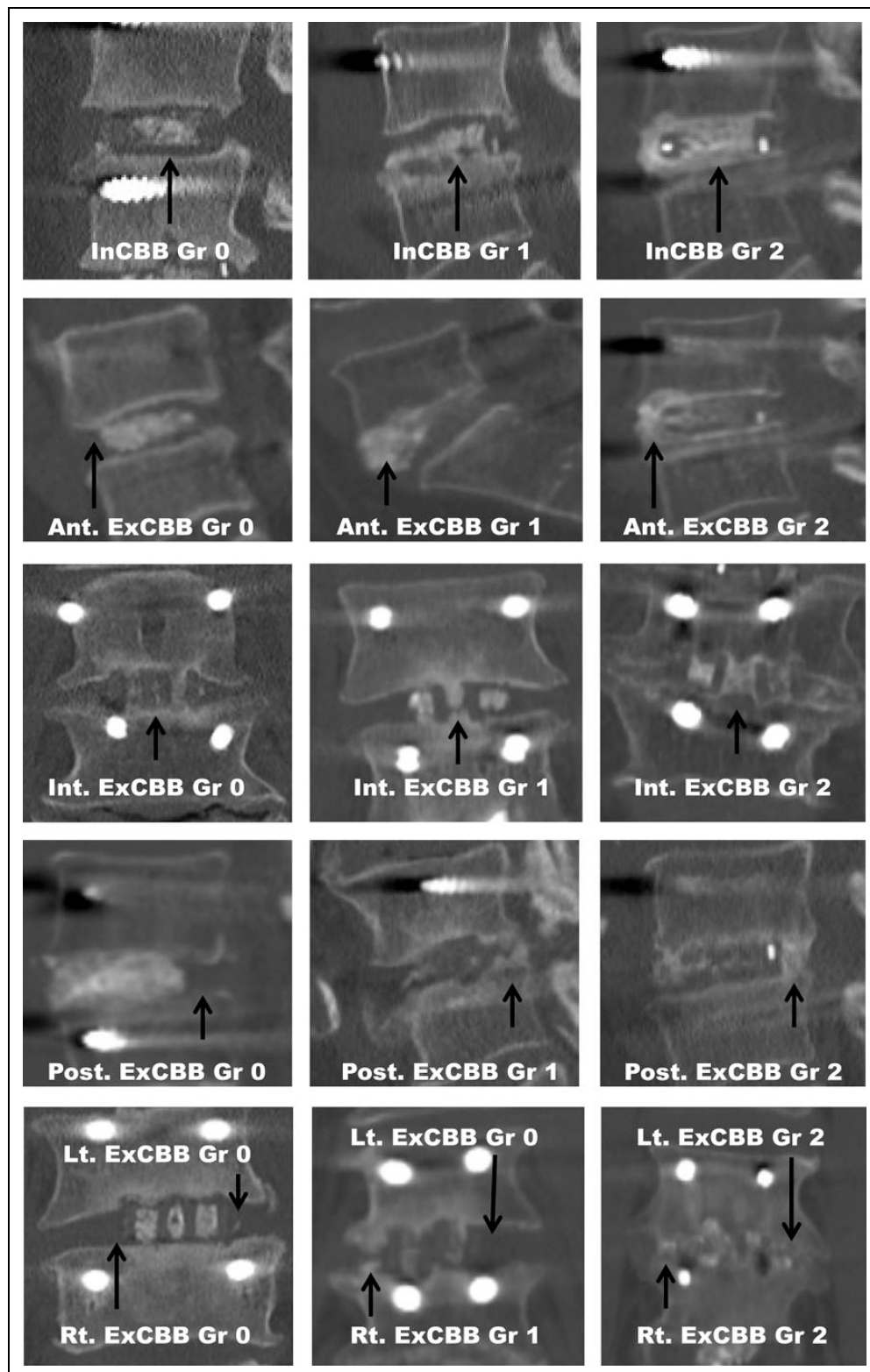


Figure 3. Bridging score of InCBB and ExCBB. Grade 0-no bridging at the superior and inferior endplates. Grade 1-incomplete bridging; bridging at the superior or inferior endplate, but with a clear radiolucent line Grade 2-complete bridging. InCBB: intra-cage bone bridging; ExCBB: extra-cage bone bridging; Ant.: anterior; Post.: posterior; Int.: intermediate; Rt.: right; Lt.: left.

Table 1. Demographic Data of the Study Patients.

Total patients (n)	65
Mean age (95% CI, years)	66.7 (65.7-67.7)
Male : Female	22 : 43
Height (95% CI, cm)	157.7 (155.4-160.0)
Weight (95% CI, cm)	63.6 (59.8-67.4)
BMI (95% CI, kg/m ²)	25.3 (24.3-26.3)
Preoperative NRS (95% CI)	8.1 (7.7-8.4)
Preoperative ODI (95% CI, %)	49.2 (45.7-52.7)

CI: confidence interval, BMI: body mass index, NRS: numerical rating scale, ODI: Oswestry Disability Index.

moderate agreement except for intra-rater reliability values of rater 2 for Lt. ExCBB. Int. ExCBB had intra-rater reliability values showing good agreement, but inter-rater ICC value showing moderate agreement (Table 3).

Fusion Contribution Rates of InCBBs and the ExCBBs

In 130 levels measured by rater 1 and rater 2, 83.8% and 86.9%, respectively, were classified as fusion. Overall, 85.4% levels (n = 222) were classified as fused and 14.6% as non-fused (n = 38) (Figure 4). The rate of fusion determined as Grade 2 by only InCBB was 11.3%, by only ExCBB was 30.2%, and by both InCBB and ExCBB was 58.6%. That is, in fused levels, complete bridging (grade 2) of InCBB and ExCBB was found in 69.9% and 88.8%, respectively. Among the 67 levels that were determined as grade 2 by only ExCBB, Ant. ExCBB was the most (n = 50, 74.6%), followed by Post. ExCBB (n = 23, 34.3%), Int. ExCBB (n = 13, 19.4%), and Rt./Lt. ExCBB (n = 3, 4.5%) (Figure 5).

Clinical Outcomes in the Fused and Non-fused Groups

Preoperative NRS (for gluteal or leg pain) and ODI scores were not significantly different between fused and non-fused groups. Postoperative 1-year NRS score was significantly lower in the fused group than in the non-fused group (2.70 vs. 3.29, P = 0.049). Postoperative 1-year ODI score was also statistically significantly lower in the fused group than in the non-fused group (13.00 vs. 19.24, P = 0.004). The NRS score improvement (preop.—postop. 1-year) was 5.40 in the fused group, which was significantly higher than 4.55 in the non-fused group (P = 0.019). The ODI score improvement (preop.—postop. 1-year) was 36.49 in the fused group, which was significantly higher than 28.25 in the non-fused group (P = 0.001) (Table 4). When comparing the clinical outcomes based on different fusion types (ExCGG+InCBB, InCBB only, and ExCBB only) there were no statistically significant differences between them.

Discussion

In this study, we analyzed the distributional patterns of the bridging bone and assessed the feasibility of our suggested lumbar interbody fusion criterion based on multi-directional

Table 2. Bridging Scores of InCBBs and ExCBBs.

	InCBB				ExCBB			
	Rt.	Lt.	Ant.	Post.	Int.	Rt.	Lt.	
Mean bone bridging score, 0-2 (95% CI)	Rater 1 (n = 130) 1.45 (1.39-1.52)	1.48 (1.42-1.55)	1.44 (1.36-1.52)	1.14 (1.05-1.22)	0.84 (0.74-0.95)	0.53 (0.45-0.60)	0.53 (0.45-0.60)	
	Rater 2 (n = 130) 1.41 (1.35-1.47)	1.48 (1.42-1.55)	1.43 (1.36-1.50)	1.14 (1.05-1.23)	1.28 (1.21-1.35)	0.46 (0.39-0.53)	0.51 (0.43-0.59)	
No. of complete bridging bone (%)	Rater 1 +2 (n = 260) 1.43 (1.39-1.48)	1.48 (1.44-1.53)	1.43 (1.38-1.49)	1.14 (1.08-1.20)	1.06 (0.99-1.13)	0.49 (0.44-0.55)	0.52 (0.46-0.57)	
	Rater 1 +2 (n = 260) 1.12 (43.1%)	1.25 (48.1%)	1.24 (47.7%)	80 (30.8%)	78 (30.0%)	12 (4.6%)	15 (5.8%)	

InCBB: intra-cage bridging bone, ExCBB: extra-cage bridging bone, Ant: anterior, Post: posterior, Int: intermediate, Rt: right, Lt: left, CI: confidence interval.

Table 3. Intraclass Correlation Coefficients of InCBBs and ExCBBs.

	InCBB			ExCBB				
	Rt.	Lt.	Ant.	Post.	Int.	Rt.	Lt.	
ICC	0.708† (0.582-0.797)	0.847* (0.781-0.893)	0.818* (0.738-0.873)	0.823* (0.746-0.877)	0.918* (0.883-0.943)	0.680† (0.541-0.776)	0.648† (0.495-0.755)	
(95% CI)	0.769* (0.668-0.839)	0.879* (0.827-0.916)	0.875* (0.820-0.913)	0.902* (0.855-0.933)	0.788* (0.695-0.852)	0.744† (0.633-0.822)	0.794* (0.704-0.856)	
Inter-rater	0.697† (0.610-0.765)	0.794* (0.735-0.841)	0.788* (0.727-0.836)	0.836* (0.788-0.873)	0.605† (0.298-0.756)	0.690† (0.600-0.759)	0.734† (0.656-0.793)	

*Good ICC (≥ 0.75).

†Moderate ICC (0.50–0.74).

ICC: Intraclass correlation coefficient, InCBB: intra-cage bridging bone, Ant: anterior, Post: posterior, Int: intermediate, Rt: right, Lt: left, CI: confidence interval.

reconstructed CT scan. The results highlight the significance of ExCBBs, which have greater effect than InCBBs for determining fusion (88.8% vs 69.9%). Intra- and inter-rater reliability values of all zones were in good or moderate agreement; in particular, the Lt. InCBB and Ant. and Post. ExCBBs showed good agreement in all reliability assessments (≥ 0.75 ICC values). Despite large differences in clinical experiences between the 2 raters, the acceptable agreements and similar fusion rates (83.8% vs 86.9%) were observed. Furthermore, the results for fusion status using the criterion were well correlated with patients' clinical outcomes.

In the analysis of InCBBs, the intra- and inter-rater ICC values and bridging scores were similar in both InCBBs, but relatively higher for Lt. InCBB than for Rt. InCBB. These findings may be attributed to the difference in the graft material used at both sides (Lt. cage: only local autobone, Rt. Cage: half-mixed synthetic bone + local autobone). In general, the synthetic bone used (OSTEON, 30% hydroxyapatite, and 70% β -tricalcium phosphate) has the tendency to be brighter than the local autobone on CT scans, and this could affect reliability and bridging scores; however, the differences were almost insignificant.⁷ Some preoperative coronal deformities in operated level would have led to greater compressive forces in the concave side to affect the fusion processing, but there were no difference of coronal deformities (5 degrees or more) on preoperative standing radiograph in our subjects (right concave: 23 cases, left concave: 20 cases, and parallel: 22 cases).

In the analysis of ExCBBs, Ant. ExCBB demonstrated significantly higher bridging score followed by Post. ExCBB, Int. ExCBB, and Lt. and Rt. ExCBB. Among 67 levels for which fusion was determined based on only ExCBBs, Ant. ExCBB (n = 50, 74.6%) was the majority compared to other zones (Figure 5). In contrast, the Rt. and Lt. ExCBBs had the lowest bridging scores and only 6 levels of complete bridging bone in 222 levels classified as fusion. These results were expected because the extra-cage bone graft was mainly placed in the anterior zone in our subjects, and the grafted bone would be more compressed anteriorly as inserting the cages. Meanwhile,

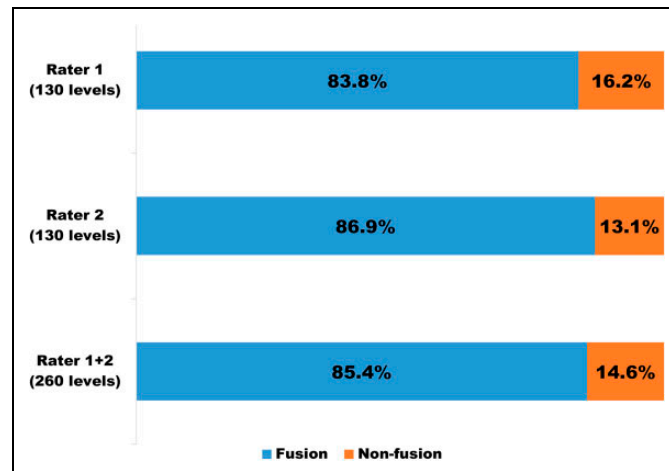


Figure 4. Fusion rates evaluated by both raters.

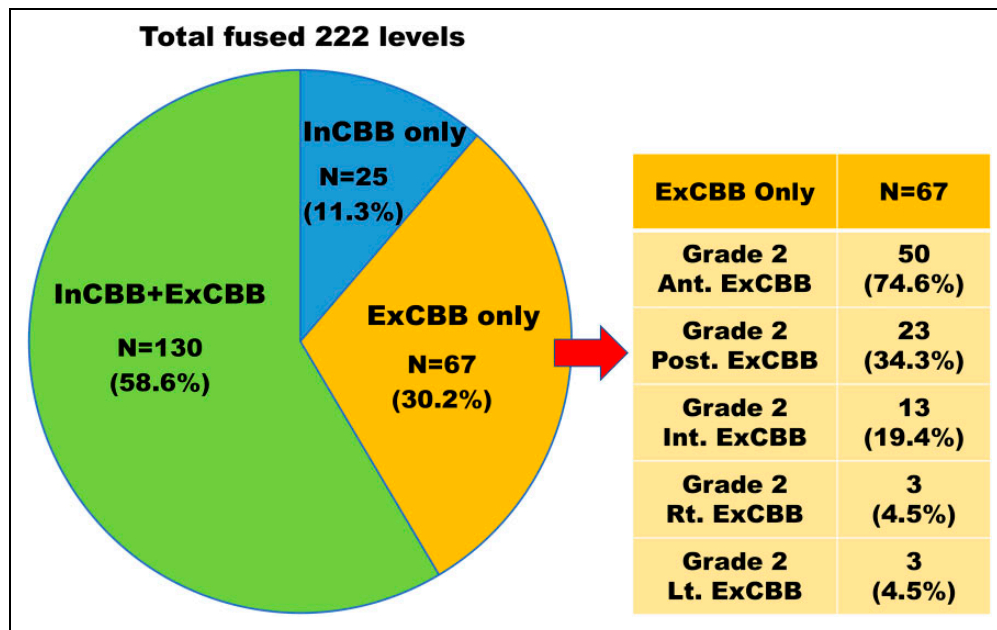


Figure 5. Fusion contribution rates of InCBB and ExCBB. In 222 levels classified as fusion, complete bridging (grade 2) of InCBB and ExCBB was found in 69.9% and 88.8%, respectively. Among the cases where only the ExCBBs were determined as grade 2, complete bridging was found most in anterior ExCBB, followed by posterior, intermediate, right, and left ExCBBs. InCBB: intra-cage bone bridging; ExCBB: extra-cage bone bridging; Ant.: anterior; Post.: posterior; Int.: intermediate; Rt.: right; Lt.: left.

Table 4. Clinical Outcomes of NRS for Gluteal or Leg Pain and ODI in the Fused and Non-Fused Groups.

		Fused group (n = 222)	Non-fused group (n = 38)	P value
Clinical scores (95% CI)	Preop. NRS	8.10 (7.92-8.27)	7.84 (7.41-8.28)	0.262
	Preop. ODI (%)	49.49 (47.58-51.40)	47.49 (43.99-50.98)	0.315
	Postop. 1-year NRS	2.70 (2.40-3.00)	3.29 (2.78-3.80)	0.049*
	Postop. 1-year ODI (%)	13.00 (11.38-14.63)	19.24 (15.28-23.20)	0.004*
	Preop.—Postop. 1-year NRS	5.40 (5.04-5.76)	4.55 (3.94-5.17)	0.019*
	Preop.—Postop. 1-year ODI (%)	36.49 (34.52-38.45)	28.25 (24.30-32.19)	0.001*

NRS: numerical rating scale, ODI: Oswestry Disability Index, CI: confidence interval, Preop.: preoperative, postop.: postoperative, * P < 0.05.

relatively insufficient bone graft and disc preparation at both lateral ends of the disc space occur in our TLIF procedures. Seo et al. reported better results in regard to complete bridging for the lateral spaces of the 2 cages than for the inter-cage space.¹⁵ They inserted 2 cages and then performed a bone graft on the lateral side of the cage. Given these results, there is no doubt that the efforts of bone grafting outside of cages is an important procedure to obtain successful bridging bone. In addition, careful endplate preparation and sufficient disc removal in bone graft site to obtain blood supply are surgical methods that must not be left out.

Of note, complete bridging bone for Post. ExCBB occurred in 30.8% and the bridging score of Post. ExCBB was the second highest after Ant. ExCBB, despite this area with no grafted bone at all (Table 2). These findings have also been reported in other studies. Burkus et al. reported that trabecular bone formation in the space behind the cage is the best radiographic indication that interbody fusion has been achieved.¹⁶ In a study by Kim et al., 88% of patients who received posterior lumbar

interbody fusion attained successful fusions not only inside the cage but also behind the cage. They suggested that if the disc materials were completely removed, new bone could grow in the empty spaces filled by hematoma.¹⁷ In our study, complete bone bridging was observed along the surrounding ligament structures as well as in the empty intervertebral space. Such remodeling features observed in the regions without the grafted bone could occur in adequately stable spinal segments and should be regarded as the most reliable signs of stable fusion. In terms of reliability assessments, only Ant. and Post. ExCBBs were within the range of good agreement. Int. ExCBB showed a good agreement for all intra-rater reliabilities, but moderate agreement in inter-rater reliability, which might be influenced by slightly different position of inserted cages. In case of Rt. and the Lt. ExCBB, they showed relatively lower reliabilities than others. Osteophytes or traction spurs could be one of the reasons. Considering the results, it follows that Ant., Post., and Int. ExCBBs are important areas; in comparison, Rt. or Lt. ExCBB might exhibit low significance to determine fusion

status in our conventional TLIF procedures, especially with anteriorly placed bone grafting.

Previous studies have reported higher fusion rates than 85.4%, value observed in our current study.¹⁸ However, many studies did not describe the details of how the fusion status was determined. For example, it is important to observe complete bridging bone in both on coronal and sagittal views simultaneously when determining fusion status. Moreover, some studies determined fusion status based on plain radiographs or vague fusion criteria.^{17,19-21} Accordingly, it is possible that previously described criteria were subjective, and their fusion rates were overestimated.²² The detailed description of our criterion will potentially eliminate the subjectivity and yield reliability. Furthermore, the results that determined fusion status were strongly associated with clinical outcomes, suggesting that the criterion might be feasible for clinical application.

However, our suggested criterion is not without limitations. First, it can only be used for interbody fusion evaluation. Second, the observations may be influenced based on the type of cages used; in particular, for metal cages, the interpretation for InCBBs can be hampered due to artifacts.²³ In such cases, the segmental motion may be checked through stress radiographs, but the accuracy is controversial. In our opinion, the careful evaluation for subsidence on serial radiographs and ExCBBs, which had a greater impact than InCBBs in determining fusion, could be helpful to assess the correct fusion status. Finally, we did not have the any significant clinical correlations based on different fusion types (ExCGG+InCBB, InCBB only, and ExCBB only). As such, further study in larger subjects may be required for fully assessing the clinical feasibility of suggested detailed criterion.

In conclusion, Both InCBBs and Ant. ExCBB, where bone grafts were mainly placed, demonstrated higher bridging scores, and such findings support bone grafts outside of cages as well as inside of cages might be important to promote bridging bone in lumbar interbody arthrodesis. Based on our suggested criterion, which demonstrated acceptable reliability and clinical feasibility, the significance of ExCBB for determining fusion is greater than InCBB, Therefore, extra-cage bone grafting should be considered as important procedures for interbody fusion.

Declaration of Conflicting Interests

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