Comparison of Fusion Rate and Functional Outcome Between Local Cancellous Bone Plus Demineralized Bone Matrix and Local Bone in 1-Level Posterior Lumbar Interbody Fusion

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Study Design: Retrospective study with prospectively collected data.

Objective: The purpose of this study is to investigate the difference in fusion rate and clinical outcome of patients with local bone as filler for the graft and demineralized bone matrix (DBM) plus only the cancellous bone from local bone as a filler for cage in 1-level posterior lumbar interbody fusion (PLIF) with cage.

Summary of Background Data: Cancellous bone is more advantageous than cortical bone in the local bone for improving bone formation in spine fusion surgery. There are little studies on the difference in fusion rate and reduction of fusion time using only these cancellous bones.

Methods: Of the 40 patients who underwent 1-level PLIF using cage, 20 patients in group A used local bone and 20 patients in group B used mixture of cancellous bone extracted separately from local bone and commercially available DBM as filler for cage. Changes in fusion rate and intervertebral spacing were measured using lateral radiography, and fusion was determined as nonunion using the Brantigan-Steffee classification. The clinical outcome was evaluated.

Results: There was no difference in height change over time between the two groups. Regarding union grade, group B showed better union grade than group A. However, no difference in union grade change over time was observed between the 2 groups. In group B, Oswestry Disability Index (ODI), Rolland-Morris Disability Questionnaire (RMDQ), and SF-36 mental component score (MCS) significantly decreased, but there was no difference in change over time.

Conclusions: In 1-level PLIF for degenerative lumbar disease, better fusion rate was observed in the group that used only cancellous bone from local bone plus DBM than that in the group that used local bone; however, there was no difference in fusion grade change over time in the 2 groups.

Key Words: degenerative spine, interbody fusion, local bone, cancellous bone

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As surgical treatment for degenerative lumbar disease, posterior decompression surgery and posterior lumbar interbody fusion (PLIF) using pedicle screws are the most widely used methods. Many types of graft materials are used to fill the cage. The autologous iliac bone shows excellent results in bone fusion, however, several disadvantages, such as donor-site pain, bleeding, and delay in operative time, have also been reported.[1–3] Therefore, to overcome these shortcomings, demineralized bone matrix (DBM), allogenic bone, and local bone obtained during posterior decompression as a substitute for autogenous iliac bone have shown successful results.[4–6] The authors reported not only negative[7–9] but also positive results[10–13] of the effectiveness of allograft. In contrast, Malloy and Hilibrand[14] argued that the disadvantage of low fusion rate should be overcome despite the few donor-site complications. However, since allogenic cancellous bone has no bone formation ability, recently, it is more often used as a cage filler by mixing with local bone obtained during posterior decompression rather than allogenic bone alone.

In the case of 1-level decompression and posterior interbody fusion, local bone obtained from the lamina, spinous process, and facet joint, which are removed, have more cortical bones than cancellous bone. It is thought that cancellous bone is more advantageous than cortical bone in the local bone for improving bone formation. However, there are no studies on the difference in fusion rate and reduction of fusion time using only these cancellous bones.

This study aimed to investigate the difference in fusion rate, functional outcome, and quality of life of patients using as filler for the graft by local bone mixed with cancellous and cortical bone and using only the cancellous bone from local bone and mixing it with commercially available demineralized bone graft as a filler for cage in 1-level PLIF with cage for lumbar degenerative disease.

METHODS

Patient Populations

From January 2014 to December 2017, 1-level PLIF using a cage was performed at one spine center for degenerative lumbar diseases, such as lumbar spinal stenosis with instability, lumbar spinal stenosis with foraminal stenosis and lumbar spinal stenosis with spondylolisthesis requiring surgery, and follow-up was possible for at least 1 year. There were 40 patients who were retrospectively analyzed (Table 1), and patients were divided into 2 groups: group A (20 patients), who used mixture of local bone (mixture cortical bone and cancellous bone) plus commercially available DBM (SurFuse; HansBiomed Corp., Seoul, Korea) and group B (20 patients), who used mixture of cancellous bone extracted separately from local bone and same DBM as filler for cage.

Management

Surgery was performed by 1 spine surgeon, exposing bilateral medial border of facet joints through a midline skin incision and then inserting pedicle screws using the Weinstein method. For sufficient decompression, laminectomy, facet joint resection, disc removal, and end plate were removed with a curet and prepared for interbody fusion. In group A, the soft tissue around the local bone and the cartilage part were removed, and the entire local bone fragment and 5 mL of DBM were mixed and filled into the cage. In group B, the soft and cartilaginous tissues around the local bone were removed, and only cancellous bone extracted from the local bone and 5 mL of DBM were mixed and filled into the cage. One type of cage was used in both groups, and the amount of bone filled in the entire cage was the same. Finally, the pedicle screws were firmly fixed to each other using a rod, and the surgery was completed.

TABLE 1. Epidemiology of All Participants

Participants	Group A (n = 20)	Group B (n = 20)	*P*
Age	67.2 ± 7.84	68.7 ± 8.01	0.677
Sex			0.639
Female	14 (70)	12 (60)	
Male	6 (30)	8 (40)	
Level			0.842
L3–L4	6 (30)	4 (20)	
L4–L5	8 (40)	8 (40)	
L5–S1	6 (30)	8 (40)	
Spine pathology			
A	6	8	
B	8	8	
C	6	4	

Data was expressed as mean ± SD or the number of patients (percentage).

A indicates lumbar spinal stenosis with instability; B, lumbar spinal stenosis with foraminal stenosis; C, lumbar spinal stenosis with spondylolisthesis; DBM, demineralized bone matrix; group A, DBM Plus local bone group; group B, DBM plus cancellous bone group.

Radiologic Outcome Measurement

Follow-up observation through simple radiography was performed at 3, 6, and 12 months postoperatively. The evaluation was conducted by three orthopedic surgeons who were not related to this study and did not know the patient's clinical information and functional results and decided by a majority vote. Changes in fusion rate and intervertebral spacing were measured using lateral radiography, and fusion was determined as nonunion in steps 1, 2, and 3 and as fusion in steps 4 and 5 using the Brantigan-Steffee classification.[15] Particularly, in anteroposterior radiography, the osseous connection between the vertebrae inside the cage and between the vertebrae around the cage was applied. Intervertebral spacing was determined by drawing a vertical line from the center point of the upper vertebral body end plate and meeting the lower vertebral body end plate.

Functional Outcome Measurement

Basic patients' epidemiological data and questionnaire of functional outcomes were collected by a research nurse independent of this study. We used the Oswestry Disability Index (ODI) and Rolland-Morris Disability Questionnaire (RMDQ), which are the functional outcomes of the spine that are routinely recorded preoperatively and 3, 6, and 12 months postoperatively. Quality of life was evaluated by dividing into physical component score (PCS) and mental component score (MCS) using SF-36 for 6 and 12 months.

Statistical Analysis

Statistical analyses were performed using IBM SPSS Statistics version 23.0 program. Data were expressed as mean ± SD in the tables. ODI, RMDQ, PCS, MCS, and distance showed normal distribution as assessed by the Shapiro-Wilk test. The differences between groups A and B over the follow-up period were compared using repeated measures analysis of variance with ODI, RMDQ, PCS, MCS, and distance. If the analysis of variance for repeated measures was significant, the least significant difference test was applied for post hoc pairwise multiple comparisons within four paired means (0, 3, 6, and 12 mo) and between the 2 groups (A and B). The grade of bone union was treated as an interval scale, and statistical significance was examined (eg, A = 1, E = 5). The differences between groups A and B and over the follow-up period were compared using generalized estimating equation with bone union grade. Moreover, least significant difference was applied for post hoc test. The significance level was set at P-value <0.05.

RESULTS

Epidemiological Characteristics of All Participants

The mean age of all patients was 67.95 ± 7.76 years, the mean age of group A was 67.20 ± 7.84 years, and the mean age of group B was 68.70 ± 8.01 years. There was no statistically significant difference between the two groups

TABLE 2. Repeated Measures ANOVA of Distance Between the 2 Groups

	Mean ± SD				
Distance	**3 mo***	**6 mo†**	**12 mo‡**	***P* for Time Differences**	
Group A (n = 20)	10.61 ± 1.56*	10.43 ± 1.65†	10.23 ± 1.53‡	0.007	a > c (0.014)
Group B (n = 20)	10.44 ± 1.93*	10.04 ± 1.77†	9.91 ± 1.72‡	0.056	No significance
P for group differences	0.836	0.624	0.669		

*Data of 3 months.
†Data of 6 months.
‡Data of 12 months.
ANOVA indicates analysis of variance; DBM, demineralized bone matrix; group A, DBM plus local bone group; group B, DBM plus cancellous bone group.

($P = 0.677$). Among the 40 patients, 14 were male (group A, 6; group B, 8) and 26 were female (group A, 14; group B, 12). Regarding level, in group A, 6 patients had L3–L4, 8 had L4–L5, and 6 had L5–S1, and in group B, 4 had L3–L4, 8 had L4–L5, and 8 had L5–S1 (Table 1).

Result of Radiologic Findings

In the case of distance, there were a significant change over time in group A ($P = 0.007$) and a significant difference compared with that at 12 months ($P = 0.014$). There was no significant difference in distance ($P = 0.705$) and time×group interactions ($P = 0.650$) between the 2 groups (Table 2). In group A, there was a significant decrease in height with time, but there was no difference from group B. There was no difference in height change over time between the 2 groups.

In the case of union grade, there was a significant change over time in both groups ($P < 0.001$), and there was a significant difference in scores between all follow-up periods. There was a significant difference in union grade between the 2 groups ($P = 0.002$), but there was no significant difference in time×group interaction ($P = 0.372$) (Table 3). The union grade of both groups A and B increased with time, and at 3 and 12 months, group B showed better union grade than group A. However, there was no difference in union grade change over time between the 2 groups.

Result of Functional Outcome

There was no statistically significant difference in ODI measured preoperatively between the 2 groups ($P = 0.268$). There was a significant change in ODI value in point of time only in group B ($P < 0.001$). There was a significant difference in ODI of group B among all follow-up periods, except for 3–6 months. There were no significant differences in ODI score ($P = 0.994$) and time×group interaction ($P = 0.152$) between the 2 groups (Table 4). In group B, there was a significant decrease in ODI over time, but there was no difference from group A, and there was no difference in change over time.

There was no statistically significant difference in RMDQ measured preoperatively between the 2 groups ($P = 0.824$). In the case of RMDQ, there was a significant change over time in both groups ($P = 0.041$, 0.004), and at 12 months, there was a significant difference compared with that at baseline. There was no significant difference in the RMDQ score ($P = 0.782$) between the 2 groups and the time×group interaction ($P = 0.701$) (Table 5). There was a significant decrease in RMDQ over time in groups A and B, but there was no difference between the 2 groups, and there was no difference in change over time.

Result of Quality of Life

In the case of preoperative PCS and MCS, there was no significant difference between the 2 groups ($P = 0.251$, 0.118). In the case of PCS, there was a significant change with time in both groups ($P < 0.001$). In both groups, there was a significant increase in score at 3, 6, and 12 months compared with that at baseline; in addition, group B had a significant increase in score at 12 months to 3 and 6 months. There was no significant difference in PCS ($P = 0.053$) and time×group interactions ($P = 0.202$) between the 2 groups. There was a significant difference in

TABLE 3. Generalized Estimating Equation (GEE) of Fusion Grade Between the 2 Groups

	Mean ± SD				
Fusion Grade	**3 mo***	**6 mo†**	**12 mo‡**	***P* for Time Differences**	
Group A (n = 20)	2.5 ± 0.52*	3.2 ± 0.63†	3.7 ± 0.48‡	< 0.001	a < b (0.001) a < c (< 0.001) b < c (0.002)
Group B (n = 20)	2.9 ± 0.31*	3.6 ± 0.51†	4.4 ± 0.51‡	< 0.001	a < b (< 0.001) a < c (< 0.001) b < c (< 0.001)
P for group differences	0.030	0.102	0.001		

*Data of 3 months.
†Data of 6 months.
‡Data of 12 months.
DBM indicates demineralized bone matrix; group A, DBM plus local bone group; group B, DBM plus cancellous bone group.

TABLE 4. Repeated Measures ANOVA of ODI Between the 2 Groups

ODI	Mean ± SD				*P* for Time Differences	
	Initial*	3 mo†	6 mo‡	12 mo§		
Group A (n = 20)	22.3 ± 10.77*	17.9 ± 9.42†	18.9 ± 9.89‡	15.2 ± 11.38§	0.121	No significance
Group B (n = 20)	26.8 ± 6.23*	18.9 ± 7.07†	16.4 ± 7.87‡	12.3 ± 6.46§	< 0.001	a > b (0.020) a > c (0.020) a > d (< 0.001) b > d (0.024) c > d (0.018)
P for group differences	0.268	0.791	0.540	0.492		

*Data of initial.
†Data of 3 months.
‡Data of 6 months.
§Data of 12 months.
ANOVA indicates analysis of variance; DBM, demineralized bone matrix; group A, DBM plus local bone group; group B, DBM plus cancellous bone group; ODI, Oswestry Disability Index.

the 2 groups at 3 and 6 months, but no difference at 12 months (Table 6). In both groups A and B, PCS increased over time. There was no difference between the 2 groups, and there was no difference over time.

For MCS, there was a significant increase over time only in group B ($P < 0.001$). There was a significant increase compared with baseline at 6 and 12 months, and there was a significant difference at 12 months compared with that at 6 months. There was no significant difference in MCS ($P = 0.069$) and time×group interaction ($P = 0.645$) between the 2 groups. In group B, there was a significant increase in MCS over time, but there was no difference from group A, and there was no difference in change over time (Table 7).

DISCUSSION

The formation of a complete solid fusion mass is essential for the success and good prognosis of spinal fusion.[16–20] In the literature, the radiologic fusion rate of 1-level PLIF varies from 71% to 96%.[21–25] For this, autologous iliac bone grafts with both osteogenic and osteoconductive effects are the gold standard,[26] but because of donor-site morbidity,[27–29] the local bone (spinous process, lamina, and facet joints), which are removed during decompression, have shown good results.[17,19,22] Since the amount that can be used during interbody fusion is insufficient, the use of an additional graft extender is beneficial in obtaining successful fusion.[26,30–34] According to some authors, local bone as a by-product of decompression surgery is quantitatively and qualitatively sufficient to obtain 1-level or 2-level fusion, citing cost-effectiveness and skeptically reporting additional graft extenders.[17,19] However, the amount of graft material obtained during decompression surgery, which is one of the major factors of successful fusion, has not been clearly identified.[33] Lee et al[18] reported the volume of the graft based on the fact that the clinical results were not satisfactory despite robust radiologic fusion because of insufficient bone bridges for effective load transfer between fusion segments. Kim et al[31] argued that, from these 2 perspectives, the quality of fusion at PLIF depends on the amount of bony bridge between the end plates, which are important for load transfer, or the fusion area ratio, which ultimately leads to inconsistency between fusion rate and clinical outcomes. It could be a factor to explain this. Therefore, using an additional graft extender when using these local bones will be beneficial in obtaining successful fusion.[26,30–34]

There are also several studies on the union time of PLIF using local bone. Miura et al[6] reported that the union rate was 72.4% at 6 months and 100% at 12 months.

TABLE 5. Repeated Measures ANOVA of RMDQ Between the 2 Groups

RMDQ	Mean ± SD				*P* for Time Differences	
	Initial*	3 mo†	6 mo‡	12 mo§		
Group A (n = 20)	12.1 ± 6.85*	13.1 ± 6.06†	9.7 ± 7.43‡	7.6 ± 6.75§	0.041	a > d (0.047) b > d (0.004)
Group B (n = 20)	12.7 ± 4.78*	11.3 ± 4.00†	10 ± 7.51‡	5.9 ± 6.08§	0.004	a > d (0.004) b > d (0.020)
P for group differences	0.823	0.444	0.929	0.562		

*Data of initial.
†Data of 3 months.
‡Data of 6 months.
§Data of 12 months.
ANOVA indicates analysis of variance; DBM, demineralized bone matrix; group A, DBM plus local bone group; group B, DBM plus cancellous bone group; RMDQ, Rolland-Morris Disability Questionnaire.

TABLE 6. Repeated Measures ANOVA of PCS Between the 2 Groups

	Mean ± SD					
PCS	**Initial***	**3 mo†**	**6 mo‡**	**12 mo§**	***P* for Time Differences**	
Group A (n = 20)	26.09 ± 19.26*	45.71 ± 24.34†	49.43 ± 17.63‡	56.23 ± 27.32§	< 0.001	a < b (0.021) a < c (0.003) a < d (0.003)
Group B (n = 20)	17.59 ± 11.94*	26.51 ± 11.49†	28.68 ± 10.77‡	49.66 ± 18.61§	< 0.001	a < b (0.027) a < c (< 0.001) a < d (< 0.001) b < d (0.006) c < d (0.005)
P for group differences	0.251	0.037	0.005	0.538		

*Data of initial.
†Data of 3 months.
‡Data of 6 months.
§Data of 12 months.
ANOVA indicates analysis of variance; DBM, demineralized bone matrix; group A, DBM plus local bone group; group B, DBM plus cancellous bone group; PCS, physical component score.

For a more rigorous evaluation, Ito et al[17] evaluated that fusion was achieved at 1/2 at 6 months in bone mass assessment using simple radiography and that the remaining 1/2 obtained fusion within 12 months. Therefore, in the study, when the degree of fusion was evaluated, the group with only the cancellous bone filled among the local bone showed faster progression of fusion. When only cancellous bone is used, the amount is small, so it can be filled only in the cage, and since obtaining the bone with a Kerrison punch during decompression surgery is necessary, there are limitations in applying the problems that increase the operative time. Several authors argue that obtaining robust fusion for a successful clinical outcome after posterior interbody fusion is important, but the radiologic robust fusion rate and clinical results do not necessarily coincide.[21,35] In the results of this study, there was no difference in the fusion rate between the 2 groups, but group B showed faster fusion time. However, there was no difference in the clinical outcome and quality of life to the time of fusion between the 2 groups. Fusion grade must be over 4 to signify fusion. Since group B showed fusion grade 4 between 6 and 12 months, it was faster than that of group A at 12 months, indicating that the fusion time was fast. Both group showed 100% fusion rate. There is a statistically significant difference in the degree of fusion grade between the 2 groups at 3 and 12 months, so there is a difference in the fusion grade, but there is no difference in the fusion grade at 6 months.

This study has several limitations. The first and most important limitation is that the number of patients in the analysis group is small (n = 40 each). Therefore, the small cohort makes it difficult to generalize the study results. The reason for the relatively high fusion rate may also be affected by the small number of patients in the analysis group. When evaluating the fusion rate, using computed tomography can determine the exact fusion,[36] which would have resulted in clearer results. The amount of local bone used was inconsistent, and the amount of DBM used was different in the 2 groups, so it is believed that there was some bias. Moreover, the authors assume that the stability of the fused segment of the local bone obtained during decompression surgery is provided by the cage, and the osteoinductive and osteogenic activities of the vertebrae are superior to the cortical bone. In the case of filling, it was assumed that more successful bone fusion would be achieved. To confirm these assumptions, more accurate results will be derived if quantitative in vitro studies on bone induction ability, bone conduction ability, and bone formation ability will be conducted in the future.

TABLE 7. Repeated Measures ANOVA of MCS Between the 2 Groups

	Mean ± SD					
MCS	**Initial***	**3 mo†**	**6 mo‡**	**12 mo§**	***P* for Time Differences**	
Group A (n = 20)	45.35 ± 25.29*	49.63 ± 18.17†	53.54 ± 14.30‡	64.61 ± 26.41§	0.157	No significance
Group B (n = 20)	29.85 ± 15.79*	33.85 ± 11.75†	46.53 ± 13.36‡	59.09 ± 20.95§	< 0.001	a < c (0.013) a < d (0.001) b < d (0.003)
P for group differences	0.118	0.033	0.273	0.611		

*Data of initial.
†Data of 3 months.
‡Data of 6 months.
§Data of 12 months.
DBM indicates demineralized bone matrix; group A, DBM plus local bone group; group B, DBM plus cancellous bone group; MCS, mental component score.

CONCLUSION

In 1-level PLIF for degenerative lumbar disease, better fusion rate was observed in the group that used only cancellous bone from local bone plus DBM than the other group that used local bone mixed with cancellous bone and cortical bone; however, there was no difference in fusion grade change over time in the 2 groups. The functional outcome and quality of life did not show any better results in the group that used only the cancellous bone. There were several limitations, such as a small number of enrolled patients, and accurate evaluation of the fusion. For better fusion rate, it is better to mix the cancellous bone and DBM of the local bone rather than sticking to the local bone only.

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