Ceramic-based synthetic bone grafts such as hydroxyapatite (HA) and b-tricalcium phosphate (b-TCP) provide scaffolds similar to those of autologous bone, are plentiful and less expensive than BMPs or demineralized bone matrix (DBM), and are not associated with donor morbidity. Scaffolds made of HA and b-TCP mixtures provide osteoconduction for bone production as well as long-term stability and immediate osteogenic activity.

PolyBone® (Kyungwon Medical, Korea) is made of beta-tricalcium phosphate. PolyBone® pore size ranges from 200-500 micrometers macroscopically, and to smaller than 10 micrometers microscopically, and pores constitute 75% of each granule.

This retrospective study analyzed the clinical outcome and radiological fusion rate following the use of mixture of local autologous bone and PolyBone® for instrumented posterolateral fusion.
fusion (PLF) in degenerative lumbar spine surgery. In addition the authors report the serial radiological change of PLF mass and quantitative radiodensity ratio of fusion mass calculated with the function of picture archiving and communication system (PACS) (PetaVision 2.1, Seoul, Korea). We also discuss the relation between the radiological change of fusion mass and bone resorption, which is routinely observed radiologically and histologically\(^3,12\).

**MATERIALS AND METHODS**

We retrospectively assessed outcomes in 32 patients (11 men, 21 women) who underwent lumbar spinal surgery including PLF using mixture of local autologus bone and PolyBone\(^*\) from January to August, 2008. All patients had degenerative lumbar spinal disease. The mean patient age was 58 years (range, 23-77 years), and the mean follow-up period was 24 months (range, 21-28 months). Patient characteristics are shown in Table 1.

All patients first underwent wide decompression. In the majority of operated levels, interbody fusion using polyetheretherketone (PEEK) cages filled with local autologous bone was done. PLF of all the operated levels was attempted by connecting each transverse process with remained local autologous bone after interbody fusion and PolyBone\(^*\). Before paving with those fusion materials, the transverse process was decorticated with a drill. We paved approximately one layer of local autologous bone (2.5 cc per one level), remained after use for interbody fusion, on the transverse processes and intertransverse membrane. Then 2.5 cc of PolyBone\(^*\) per one level were then added to each side as PLF expander (Fig. 1).

Clinical and radiological follow-up was done at postoperative 1, 3, 6 and 12 months. We used a Numeric Rating Scale (NRS) to measure back and leg pain, and the Oswestry Disability Index (ODI) to assess clinical outcome.

Serial radiological X-rays were done at 1, 3, 6 and 12 months postoperatively. The radiographs were digitized at 200 um spatial resolution and 16-bit gray-scale resolution. In addition, computed tomography (CT) at 12 months postoperatively was checked to assess a precise status of PLF mass.

Radiological assessment was done by a neurosurgeon and a radiologist. We classified fusion mass on X-ray AP image into 4 stages according to its serial change: stage I, the fusion mass density is slightly denser compared with that of the adjacent vertebrae; stage II, the fusion mass becomes denser than stage I and the fusion mass particles can be seen more prominently; stage III, the particles begin to disappear, the density decreases, and the gap among bone chips decreases; stage IV, the fusion mass appears as a connected bone bridge with a density similar to that of the adjacent vertebra (Fig. 2).

Quantitative radiodensity of fusion mass on the AP X-ray was calculated. We used the radiodensity of the titanium rod as a reference for correcting any variations in film exposure or processing. The frame of the PLF bridge and the titanium rod was drawn twice by a neurosurgeon and a radiologist in simple AP X-ray image. If the frame was determined, the mean radiodensity on the X-ray image could be calculated.

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### Table 1. Patient characteristics

| Characteristics | Statistic |
|-----------------|----------|
| Mean age, years (range) | 58.38 (23-77) |
| Male (%) | 11 (34.4) |
| Smoking (%) | 4 (12.5) |
| Chronic alcoholic (%) | 3 (9.4) |
| Mean BMI kg/m\(^2\) (range) | 25.56 (20.96-33.51) |
| Mean T-score of BMD (range) | -0.36 (-2.9-1.5) |

Chronic alcoholic: Patient who consumes >40 g alcohol/day. BMI: Body Mass Index [Weight (kg)/Height\(^2\) (m)]. T-score of BMD (Bone Mineral Density) was measured using Dual Energy X-ray absorptiometry at L2-4.
with our PACS system. We used the mean of two values calculated this way. Interclass correlation coefficient (ICC) value was 0.878 (0.744-0.944). A ICC value >0.8 was considered to indicate valid inter/intra variability. The ratio of mean density (PLF mass/Titanium rod) could be determined using a simple AP X-ray image (Fig. 3). The serial change of radiodensity ratio was analyzed.

SAS 9.1 and R 2.9.0 software were used for statistical analysis. Data were analyzed using the Linear Mixed Model, Wilcoxon Rank sums test and Fisher's exact test.

RESULTS

We performed surgical correction on 32 patients with degenerative lumbar disease using decompression, interbody fusion and posterolateral fusion with PolyBone®. The diseases comprised 17 cases of spondylolisthesis (10 degenerative and 7 lytic).

Table 2. The Changes of Posterolateral Graft with Time

| Case | Age (years)/Sex | Smoking | Alcohol | T-score of BMD | BMI (kg/m²) | Diagnosis | Level | 3D | 1M | 3M | 6M | 12M | Comment |
|------|----------------|---------|---------|---------------|-------------|-----------|-------|----|----|----|----|-----|---------|
| 1    | 51/F           | No      | No      | 0.6          | 33.51       | SPL       | L5-S1 | I  | II | III | IV | IV  |         |
| 2    | 71/F           | No      | No      | -1.1         | 23.93       | STE       | L2-3-4-5| I  | II | III | IV | IV  |         |
| 3    | 68/F           | No      | No      | -1.8         | 22.44       | SPL       | L4-5   | I  | II | III | IV | IV  |         |
| 4    | 42/M           | Yes     | No      | 0.6          | 27.52       | SPL       | L4-5   | I  | II | III | F  | F   | Fusion failure |
| 5    | 62/M           | Yes     | Yes     | 0.8          | 23.07       | SPL+STE   | L4-5-S1| I  | II | III | IV | IV  |         |
| 6    | 51/F           | No      | No      | -1.5         | 24.93       | SPL       | L4-5   | I  | II | III | IV | IV  |         |
| 7    | 54/F           | No      | No      | 1.5          | 25.21       | SPL       | L4-5   | I  | II | III | IV | IV  |         |
| 8    | 67/F           | No      | No      | 0.6          | 23.10       | SPL+STE   | L3-4-5-S1| I  | II | III | IV | IV  |         |
| 9    | 63/F           | No      | No      | 1.0          | 29.38       | SPL       | L4-5-S1| I  | II | III | IV | IV  |         |
| 10   | 63/M           | No      | No      | 1.0          | 24.66       | SPL       | L4-5   | I  | II | III | IV | IV  |         |
| 11   | 71/F           | No      | No      | -2.9         | 24.47       | SPL       | L4-5   | I  | II | III | IV | IV  |         |
| 12   | 53/F           | No      | No      | -0.3         | 25.05       | SPL+STE   | L4-5-S1| I  | II | III | IV | IV  |         |
| 13   | 52/F           | No      | No      | -0.5         | 23.72       | SPL       | L4-5   | I  | II | III | IV | IV  |         |
| 14   | 53/M           | Yes     | Yes     | -0.6         | 27.76       | SPL       | L5-S1   | I  | I  | NI  | NI | IV  |         |
| 15   | 65/F           | No      | No      | -0.3         | 28.13       | SPL+STE   | L3-4-5-S1| I  | II | III | IV | IV  |         |
| 16   | 62/M           | No      | No      | -0.4         | 24.80       | SPL+STE   | L2-3-4  | I  | II | III | IV | IV  |         |
| 17   | 59/F           | No      | No      | -2.0         | 33.24       | SPL+STE   | L2-3-4-5| I  | II | III | IV | IV  |         |
| 18   | 51/F           | No      | No      | -0.2         | 26.93       | STE       | L3-4-5-S1| I  | II | III | IV | IV  |         |
| 19   | 65/M           | No      | Yes     | -0.8         | 23.53       | SPL       | L5-S1   | I  | II | III | IV | IV  |         |
| 20   | 58/F           | No      | No      | -0.5         | 28.87       | SPL       | L4-5   | I  | II | III | IV | IV  |         |
| 21   | 59/M           | No      | No      | -2.0         | 25.61       | STE       | L3-4-5  | I  | II | III | IV | IV  |         |
| 22   | 50/F           | No      | No      | 0.7          | 25.32       | SPL+STE   | L3-4-5  | I  | II | III | IV | IV  |         |
| 23   | 23/M           | No      | Yes     | 0.5          | 26.08       | SPL       | L5-S1   | I  | II | III | NI | IV  |         |
| 24   | 49/F           | No      | No      | -0.4         | 20.96       | SPL+STE   | L3-4-5  | I  | II | III | IV | IV  |         |
| 25   | 48/F           | No      | No      | -0.5         | 24.84       | SPL       | L4-5   | I  | II | III | NI | IV  |         |
| 26   | 61/F           | No      | No      | -0.5         | 29.66       | SPL+STE   | L2-3-4-5| I  | II | NI  | III | IV  |         |
| 27   | 55/F           | No      | No      | 1.0          | 22.03       | SPL       | L4-5   | I  | II | III | IV | IV  |         |
| 28   | 73/M           | No      | No      | -0.7         | 21.41       | SPL+STE   | L3-4-5  | I  | NI | NI  | NI | NI  | F/L     |
| 29   | 60/F           | No      | No      | -1.3         | 22.97       | SPL       | L4-5   | I  | II | III | IV | IV  |         |
| 30   | 66/M           | No      | No      | 0.1          | 25.84       | SPL+STE   | L1-2-3-4-5| I  | II | NI  | III | IV  |         |
| 31   | 77/M           | Yes     | No      | -0.1         | 22.79       | SPL       | L4-5   | I  | III | III | F  |     | Fusion failure |
| 32   | 66/F           | No      | No      | -0.3         | 26.04       | SPL+STE   | L2-3-4-5-S1| I  | II | III | III | IV  |         |

Alcohol : Patient consumed>40 g alcohol/day (i.e., alcoholic), T-score of BMD (Bone Mineral Density) : Measured using Dual Energy X-ray absorptiometry in L2-L4, BMI : Body Mass Index [Weight (kg)/Height^2 (m^2)], SPL : spondylolisthesis, ST : stenosis, 3D : fusion stage on postoperative 3 day image, 1M : fusion stage on postoperative 1 month image, 3M : fusion stage on postoperative 3 month image, 6M : fusion stage on postoperative 6 month image, 12M : fusion stage on postoperative 12 month image, F : fusion failure (absence of fusion bridge), NI : no image was obtained, F/L : follow-up loss.

Fig. 3. We used the mean radiodensity from the red frame (fusion mass) and blue frame (titanium rod) drawn two times by different assessors. (i.e., the mean radiodensity from the red frame/the mean radiodensity from the blue frame).
We defined fusion at postoperative 12 months if PLF mass showed stage IV in X-ray image and CT coronal image also showed complete fusion bridge. The failure was defined if PLF mass disappeared in X-ray or CT. We didn’t consider interbody fusion result in our study. Therefore, the rate of PLF success at postoperative 12 months was 83.3% (25/30). Failure rate of PLF was 10% (3/30) and other 2 cases were remained undetermined (Table 2).

The mean radiodensity ratios in all cases were serially analyzed. The mean density ratio value increased up to 1 month postoperatively \( (p < 0.01) \), remained stable up to 3 months, and then decreased up to 6 months \( (p < 0.01) \). The mean ratio at 12 months decreased to a level similar to that of the immediate postoperative state (Fig. 5).

Clinical outcome assessment at 12 months showed that the mean NRS score for leg and back pain decreased from 8.0 to 1.0 and 6.7 to 1.7, respectively. The mean ODI score decreased from 60.5 (range, 31.0-85.0) to 17.7 (range, 0-45.0) \( (p < 0.05) \).

Radiological assessment

The PLF fusion mass on the AP X-ray image of all patients showed stage I state in the immediate postoperative period. The 1-month postoperative X-rays showed all but 6 cases were at stage II. Of those 6 cases, 4 moved rapidly to stage III, one case remained at stage I, and the other case was lost to follow-up. Postoperative 3-month X-rays were not performed in 5 cases. For the remaining cases, 11 were at stage II, and 16 were at stage III. Postoperative 6-month X-rays showed loss of the fusion mass in two cases, and five cases were not X-rayed. Of the remaining cases, one was at stage II, 14 were at stage III, and 10 were at stage IV. At 12 months, 2 cases were lost to follow-up, 3 cases showed loss of fusion mass, 2 cases were at stage III and 25 cases were at stage IV, and those stage IV fusion mass were also identified as a complete fusion bridge in postoperative 12 month CT images. In addition, CT image also showed loss of fusion mass in 3 patients who showed identical finding in X-ray image. CT of 2 cases who were at stage III showed incomplete fusion bridge, because fusion mass in the CT seem to contain unabsorbed particle (Fig. 4).

We defined fusion at postoperative 12 month, if PLF mass showed stage IV in X-ray image and CT coronal image also showed complete fusion bridge. The failure was defined if PLF mass disappeared in X-ray or CT. We didn’t consider interbody fusion result in our study. Therefore, the rate of PLF success at postoperative 12 months was 83.3\% (25/30). Failure rate of PLF was 10\% (3/30) and other 2 cases were remained undetermined (Table 2).

The mean radiodensity ratios in all cases were serially analyzed. The mean density ratio value increased up to 1 month postoperatively \( (p < 0.01) \), remained stable up to 3 months, and then decreased up to 6 months \( (p < 0.01) \). The mean ratio at 12 months decreased to a level similar to that of the immediate postoperative state (Fig. 5).
We could not find any correlation between PLF success and smoking, alcohol abuse, body mass index (BMI) or T-score of bone mineral density (BMD).

**DISCUSSION**

Autogenous iliac bone is the ‘gold standard’ material for spinal fusion. However, such grafts are associated with increased surgical time, significant blood loss, postoperative pain and iliac fracture. Therefore, ceramics such as hydroxyapatite and b-tricalcium phosphate have been used as bone graft materials, and good results have been reported.[2,3,4,5,6,7].

We used PolyBone® which is made of b-tricalcium phosphate, with local autologous bone which was harvested during laminectomy, for lumbar posterolateral fusion. We believe this approach reduced operative times and morbidity related to iliac harvest. Like other ceramics, PolyBone® is an osteoconductive material.[2,3]. We also used local autologous bone which was left over after interbody fusion, and has osteogenic capacity for posterolateral fusion. We always used 5 cc PolyBone® with 5 cc local autologous bone for bilateral one-level fusion to make optimum use of the osteoinductivity of autologous bone.

Clinical outcomes were assessed using NRS and ODI scores. Both scores decreased over 12 months postoperatively, indicating improvement. Those improvements were likely due to degeneration and stabilization.

Radiological fusion assessment was done using plain AP X-rays and coronal CT reconstruction by a radiologist and a neurosurgeon. We didn’t consider the result of interbody fusion in our study because we wanted to find the efficacy of PolyBone® as a bone graft expander. We achieved an 83% radiological fusion rate at 12 months postoperatively. We believe that fusion was continuing to occur in the two cases at stage III at 12 months. The lumbar posterolateral fusion rate when using autologous iliac bone is reported to be 40-98%[1,2]. The present results indicate the use of a mixture of local autologous bone and PolyBone® results in comparable fusion rates and reduces morbidity associated with iliac harvest.

Bone graft status cannot be quantified simply using radiodensity alone. However, using the ratio of the graft and titanium rod radiodensities is likely to reduce variability associated with obesity alone. However, using the ratio of the graft and titanium rod radiodensities is likely to reduce variability associated with obesity, clothing, and viewing angle for radiation exposure. In addition, we used the mean value measured within frame the graft and rod drawn by the two assessors to make much accuracy. The mean density ratio serially changed over time. The mean density ratio value increased up to 1 month postoperatively, then decreased up to 6 months, and increased up to 12 months. This trend was probably due to an inflammatory reaction in response to graft resorption until 6 month and subsequent graft stabilization after 6 months[5]. Although more studies are required, the present results suggest that the radiodensity ratio may be one of predictive indicator of graft status, such as resorption or stabilization.

Even though we did not find that other factors, such as smoking, obesity, alcohol and osteoporosis were linked to failure, we believe more cases may show such factors become statistically significant.

**CONCLUSION**

We retrospectively analyzed outcomes following the use of PolyBone® as a fusion expander for posterolateral fusion in degenerative lumbar spine surgery. We found that pain and ODI improved postoperatively, and that the radiological posterolateral fusion success rate was 83.3%. The graft radiodensity ratio significantly changed at postoperative 1 and 6 months, possibly reflecting the inflammatory response and stabilization. The present results indicate that the use of a mixture of local autologous bone and PolyBone® results in posterolateral fusion rates comparable to those achieved using autologous bone, and has the advantage of reduced morbidity. Although more data are needed, the change of radiodensity ratio are promising predictive value of the status of graft material.

**Disclosure**

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