Anterior Cervical Interbody Fusion Using Polyetheretherketone Cage Filled With Autologous and Synthetic Bone Graft Substrates for Cervical Spondylosis: Comparative Analysis Between PolyBone® and Iliac Bone

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Abstract

Clinical and radiological outcomes of cervical interbody fusion using a polyetheretherketone cage filled with PolyBone® (Kyungwon Medical Co., Ltd., Seoul, Korea), beta-tricalcium phosphate material, and autologous iliac bone were retrospectively compared in 47 patients who underwent anterior cervical discectomy and fusion (ACDF) between January 2007 and April 2008. Of these, 23 received iliac bone grafts and 24 received PolyBone. Numeric rating scale and neck disability index were used for clinical outcome assessments. Cervical radiography was performed immediately postoperatively, and at 1, 3, 6, 12, and 24 months postoperatively. Computed tomography (CT) was performed at 12 and 24 months postoperatively. Change in segmental lordosis, disk height, and fusion were compared at 12 and 24 months postoperatively. Clinical outcomes were similar between both groups. CT and radiography at 12 months showed that fusion had occurred in 22 patients in the iliac bone group and in 19 in the PolyBone recipients. Fusion was also identified in 22 patients in both iliac bone and PolyBone groups at 24 months postoperatively. The clinical outcomes of ACDF using PolyBone and iliac bone were similar, with similar cervical interbody fusion rates at 24 months postoperatively. However, the time taken for fusion was apparently longer in the PolyBone group.

Key words: anterior cervical discectomy and fusion, beta-tricalcium phosphate, iliac bone, PolyBone®

Introduction

Anterior cervical discectomy and interbody fusion (ACDF) with an iliac autograft is one of the most common surgical methods used to treat degenerative cervical disease. However, the complications associated with iliac harvest and allograft, including pain, infection, and numbness⁴,⁵,⁸,¹⁰,²⁰ have prompted surgeons to seek substitute bone graft materials. Hydroxyapatite and calcium phosphate have good biocompatibility and osteoconductive capacity¹³,²² and a mixture of calcium phosphate and hydroxyapatite has shown good clinical and radiological outcomes as an iliac bone graft alternative⁶,⁷,⁹,¹⁴–¹⁷,²¹,²⁴ PolyBone® (Kyungwon Medical Co., Ltd., Seoul, Korea) is a beta-tricalcium phosphate material designed to act as a substitute bone graft. To assess the efficacy of PolyBone for cervical interbody fusion, we retrospectively examined clinical and radiological outcomes in patients who underwent ACDF using PolyBone, and compared these with outcomes achieved in patients who underwent ACDF using iliac grafts.

Materials and Methods

Outcomes were retrospectively assessed in 47 patients (33 men, 14 women) who underwent ACDF between January 2007 and April 2008. The mean follow-up period was 30 months (range 24–39 months). Patients had radiculopathy, with or without neck pain, for which conservative management for >3 months was ineffective, or soft disk herniation or foraminal narrowing induced by spur formation.
Patients with multi-level disk disease, evidence of cervical instability on radiography, serious medical problems such as uncontrolled diabetes mellitus and osteoporosis (T-score ≤ -2.5), or those undergoing revision surgery were excluded. Graft material was selected by each patient after two physicians explained the advantages and disadvantages of each, both before and after admission. PolyBone was used as the graft material only if patients were aware of the possible inferiority of the fusion result, but wished to avoid the morbidity associated with iliac harvest. PolyBone was used in 24 cases and iliac bone was used in 23 cases. We received informed consent from all patients before surgery. Permission for this study was granted from the Asan Medical Center IRB (2011–0662).

The surgical procedure was similar to those described in previous reports. All patients underwent standard anterior cervical discectomy using a rightsided approach by a single surgeon. Endplate preparation was done with curettage. An appropriately sized trial implant was then placed into the disk space to confirm the size, position, and height of the implant to be used. In patients with foraminal narrowing, the posterior half of the uncovertebral joint was removed with a high speed burr. Cervical fusion was performed using a polyetheretherketone cage (Solis PEEK; Stryker Spine, Allendale, New Jersey, USA) filled with PolyBone or iliac bone (Fig. 1). The height of the cage (5- or 6-mm height) was determined considering stability overdistraction. The widest possible cage (14-mm width) was used. Where iliac bone was used as the graft material, cancellous bone was harvested via curettage from the right side iliac bone. No additional bone graft or PolyBone was inserted anterior or lateral to the cage. The implant was then inserted into the prepared disk space, taking care to ensure correct alignment and position under fluoroscopic guidance.

All patients were advised to wear an external orthosis for 3 months. Clinical outcomes were assessed using a numeric rating scale (NRS) for radiculopathy, and a neck disability index (NDI). NRS and NDI were assessed preoperatively and at 1, 3, 6, 12, and 24 months postoperatively. Cervical radiography was performed immediately after surgery and at 1, 3, 6, 12, 18, and 24 months postoperatively. Computed tomography (CT) and dynamic radiography were performed at 12 and 24 months to assess fusion. Fusion criteria included stability on dynamic view (motion between the adjacent spinous processes <2 mm) and evidence of formation of a contiguous bony bridge on lateral radiographs and CT scans. Radiological fusion was determined only all criteria were satisfied at 12 and 24 months.

Serial cervical segmental angle and disk height were measured using lateral radiography. The angle between the superior and inferior endplates of the adjacent vertebrae is the segmental angle (Fig. 2A). The intervertebral disk height is calculated as the mean of the sum of the anterior and posterior intervertebral disk heights (Fig. 2B). Data were analyzed using the Mann-Whitney U test, linear mixed model, and Fisher’s exact test. A p value of less than 0.05 was considered statistically significant.

Results

Demographic and clinical data are shown in Tables 1 and 2. The mean duration of operation was 97 and 111 minutes in the PolyBone and iliac bone groups, respectively (p = 0.158). There were no surgery-related complications, such as infection, incidental durotomy, or hematoma, in either group.

The NDI score decreased gradually for the first 3 months after surgery in both groups and remained steady thereafter (Fig. 3A). The mean NDI decrease over the 24-month postoperative period was from 23.7 to 10.01 in the PolyBone group, and from 22.74 to 8.36 in the iliac bone group, with no statistically
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significant difference (p = 0.172). The mean upper extremity and neck NRS scores also decreased over the 24-month period, from 8.89 to 1.97 and from 5.67 to 2.03, respectively, in the PolyBone group, and from 8.91 to 2.01 and from 6.21 to 2.05, respectively, in the iliac group, with no intergroup differences (p = 0.219 and p = 0.185, respectively). The NRS scores for radiculopathy decreased rapidly over the first month and remained constant thereafter in both groups (Fig. 3B).

The mean segmental angle of each group increased immediately after surgery, then gradually decreased over the next 24 months, ranging from 6.7 to 1.2 degrees in the PolyBone group and from 6.2 to 3.5 degrees in the iliac bone group, so the segmental angle decrease was greater in the PolyBone group than in the iliac bone group (Fig. 2A). In the PolyBone group, the mean segmental angle decreased gradually over the first 12 months after surgery, remaining constant thereafter, whereas in the iliac bone group, the angle decreased gradually over the first 6 months and remained constant thereafter. The difference in mean segmental angle between the
Fig. 3 Clinical outcomes of the two groups. Mean neck disability index (NDI) decreased gradually until 3 months postoperatively, and then remained steady over 24 months (A). Mean numeric rating scale (NRS) of radiculopathy decreased gradually until 1 month postoperatively, and then remained steady over 24 months (B). There was no statistically significant difference between the two groups at any stage.

Fig. 4 Postoperative computed tomography scans of a 53-year-old male patient in the PolyBone group. Although PolyBone resorption and radiological fusion were not complete at 12 months (left), complete fusion was observed at 24 months (right).

two groups was significant after 12 months (p = 0.027).

The mean disk height was greatest immediately after surgery in both groups, gradually decreasing over the next 24 months, ranging from 6.2 to 4.2 mm in the PolyBone group and from 6.5 to 5.4 mm in the iliac bone group (Fig. 2B). The magnitude of decrease was greater in the PolyBone group than in the iliac bone group. The mean disk height of the PolyBone group decreased for the first 12 months and remained constant thereafter, whereas the mean disk height of the iliac bone group decreased for the first 6 months and remained constant thereafter. The difference in mean disk height between the two groups was significant after 12 months (p = 0.039).

Cervical fusion was assessed using postoperative CT and dynamic radiography at 12 and 24 months postoperatively (Fig. 4). At 12 months, fusion had occurred in 19 of 24 cases in the PolyBone group and in 22 of 23 in the iliac bone group. At 24 months, fusion had occurred in 22 of 24 cases in the PolyBone group and in 22 of 23 in the iliac bone group. The difference of fusion rate was statistically significant at 12 months (p = 0.041) but not at 24 months postoperatively (p = 0.253).

Discussion

We compared clinical and radiological outcomes in patients undergoing ACDF using iliac bone and PolyBone, a substitute graft material made of beta-tricalcium phosphate. PolyBone pore sizes range from 200 to 500 \( \text{\mu m} \) macroscopically, and to smaller than 10 \( \text{\mu m} \) microscopically, with pores constituting 75% of each granule. Thus, the ceramic material beta-tricalcium phosphate acts as a scaffold, with the porosity providing spaces for newly generated bone.

Decreases in NDI and NRS scores after surgery were similar in both groups in our study. Such similar results bear relation to similarities in symptom improvement and lesion decompression and stabilization. We measured segmental angle and disk height as markers of subsidence. The decreases in both segmental angle and disk height progressed gradually for 6 months in the iliac bone group and for 12 months in the PolyBone group. Postoperative CT and radiography at 12 months showed complete fusion in 22 of 23 patients in the iliac bone group, compared with 19 of 24 in the PolyBone group. However, the two groups showed similar fusion rates at 24 months. These results suggested that fusion in the iliac bone group was nearly complete before 12 months, whereas fusion in the PolyBone group continued for 24 months. Although we could not determine the exact timing of complete fusion, our findings suggest that fusion in the PolyBone group occurred at a slower rate. Non-union rates have been reported to be 5–20% for single level cervical fusion surgery, and 50% for multi-level surgery.\(^{19,23}\) We observed fusion rates in our two groups that were similar to those reported previously.

Characteristics of the ideal graft material include no risk of disease transmission, reasonable cost, and...
capacity for osteogenesis. Like other ceramic materials, PolyBone has osteoconductive, not osteogenic, capacity. However, surgical procedures that expose cancellous bone between the cervical vertebra endplates may be important in osteogenesis, resulting in fusion. Our findings indicate that clinical outcomes using PolyBone and iliac bone were similar. However, cage subsidence was greater in the PolyBone group, with some patients experiencing segmental kyphosis. In addition, fusion was relatively delayed in the PolyBone group. We believe that the early bone union in the iliac bone group eventually results in less reduction in final segmental angle and disk height. We also believe that beta-tricalcium phosphate may act as autologous bone graft substitute, but does not generate the same radiological outcomes compared with autologous bone graft.

We performed surgery with a standalone cage without anterior plate fixation. Subsidence and segmental kyphosis associated with cervical standalone cage procedures have been previously reported. We recommend that every patient wear a brace for 3 months to avoid much subsidence, even though the immobilization may take too long. Therefore, we believe that the addition of an anterior plate as well as selection of the interbody cage could improve future study design. In addition, the modification of surgical procedures as well as selection of the interbody cage may be necessary to shorten the period of orthosis.

This study has several other limitations, including those associated with a retrospective cohort study, small case numbers, non-randomized case selection, and relatively short follow-up duration. Although additional well-designed prospective randomized controlled studies are required before firm conclusions can be drawn, our results suggest that PolyBone may be a promising synthetic alternative material for patients undergoing ACDF.

The clinical outcomes of ACDF using PolyBone and iliac bone were similar. Cage subsidence was frequently observed in PolyBone recipients. Although similar cervical interbody fusion rates were observed at 24 months postoperatively, a higher fusion rate at 12 months was identified for iliac bone grafts.

Conflicts of Interest Disclosure

The corresponding author is an individual institutional stockholder of Kyungwon Medical Co., Ltd. This study was not financially supported by Kyungwon Medical Co., Ltd. We don't have any financial interest on this manuscript. There is no ethical con-

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