ORIGINAL

Radiological Outcomes of Posterior Lumbar Interbody Fusion Using a Titanium-coated PEEK Cage

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Abstract : INTRODUCTION Titanium (Ti) coated polyether ether ketone (PEEK) interbody cages (IBCs) have been introduced to overcome any disadvantages. The purpose of this study was to investigate the radiological outcomes of lumbar interbody fusion (LIF) surgery using the Ti-coated PEEK IBC with a minimum of 1-year of follow-up. METHODS A total of 26 intervertebral spaces in consecutive 21 patients who underwent posterior/transforaminal LIF using the Ti-coated PEEK IBC were evaluated. Rates of bone union, screw loosening, cage subsidence and bone cyst formation around the endplate were evaluated on computed tomography scans acquired at least 1 year postoperatively. RESULTS AND DISCUSSION At the 1-year follow-up, bone fusion was achieved in 23 (88.4%) of 26 intervertebral spaces. Cage subsidence was found in 5 intervertebral spaces ; however, bone fusion was achieved in all these spaces. Bone cysts formed in 4 intervertebral spaces and 4 of 94 screws were found to be loosened. Three of the loosened screws were found in vertebral bodies adjacent to intervertebral spaces with nonunion. However, there was no association between these events. Although more scientific evidence is required to determine the advantages of Ti-coated PEEK IBCs, we believe the clinical outcomes achieved were favorable at the 1 year minimum follow-up. J. Med. Invest. 66 : 119-122, February, 2019

Keywords **:** *Lumbar interbody fusion, Interbody cage, Bone cyst, Bone union, Titanium-coated PEEK cage*

INTRODUCTION

Posterior/transforaminal lumbar interbody fusion (PLIF/TLIF) surgery is widely performed to relieve pain and allow functional recovery in patients with a number of spinal diseases, include spondylolisthesis and instability. It is important to achieve bone union and stabilize the affected segments to obtain better clinical outcomes (1, 2).

Autologous bone with an interbody cage (IBC) is usually used for the anterior strut in PLIF/TLIF. The IBC should have sufficient mechanical stability but it should not be able to impede bone union due to its biomaterial composition. Several factors have been reported to impede bone union when an IBC is used. Cyst formation in the vertebral endplate and cage subsidence are well-known predictors of nonunion after PLIF/TLIF(3, 4). IBCs are usually made of titanium (Ti) or polyether ether ketone (PEEK), but each material has advantages and disadvantages (5-7). Ti-coated PEEK (Ti-PEEK) IBCs have now been introduced to compensate for these shortcomings of these materials (8). Although the internal structure of this cage is PEEK, its surface is all covered with Ti except for the connection part of the impact device.

The purpose of this study was to evaluate the postoperative radiological outcomes of LIF surgery using the Ti-coated PEEK IBC after a minimum of 1-year of follow-up.

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MATERIALS AND METHODS

A total of 26 intervertebral spaces in 21 consecutive patients (15 women, 6 men ; mean age 70.6 years) who underwent PLIF/TLIF using the Ti-PEEK IBC were retrospectively evaluated (Table 1). The indication for treatment was degenerative spondylolisthesis in 15 patients, degenerative scoliosis in 4, and lumbar spinal canal stenosis in 2. Two patients with multiply operated back were included. Five patients had been treated preoperatively with a bone-modifying agent (2 with teriparatide, 2 with a bisphosphonate, and 1 with denosumab). Four IBCs were placed at L3-4, 14 at L4-5, and 8 at L5-S1.

The rates of bone union, screw loosening, cage subsidence, bone cyst formation around the endplate, and adjacent segment

Table 1. Patient demographics and indications for lumbar interbody fusion

Variable	n (%)
Mean age (range)	70.6 (39–84)
Sex	
Male	6 (28.6)
Female	15 (68.2)
Disease	
Degenerative spondylolisthesis	15 (71.4)
Degenerative scoliosis	4 (19.1)
Lumbar spinal stenosis	2 (9.5)
Locations and levels	
L3/4	4(15.4)
L4/5	14 (53.8)
L5/S	8 (30.8)

disease were evaluated on computed tomography (CT) scans after a minimum follow-up of 1 year. Computed tomography (CT) was obtained with 16- or 320-slice multi-detector row CT scanner (Aquilion, Toshiba Medical Systems Corporation, Tochigi, Japan). For all CT examinations, 1 mm-slice thickness axial images were obtained with high-spatial-frequency (bone) algorithm. All CT examinations were evaluated with 1 mm-thickness multiplanar reconstruction (MPR) images with three orthogonal direction (axial, sagittal and coronal) using commercial imaging viewer software (Aquarius NET Viewer, TeraRecon Inc., San Meteo, CA, USA). CT was basically imaged after surgery, 3 months, 1 year to 1 year and a half. All intervertebral spaces were filled with bone chips and two cages were packed with local bone chips. Artificial bone was added in three patients and allogenic bone chips in one patient.

Bone union was deemed to have occurred when partial bone continuity could be identified between the vertebral bodies (Figure 1 A). Screw loosening was defined as the presence of the "halo sign" (indicating osteolysis) around the pedicle screws (Figure 1B). Cage subsidence was defined as sinking of the cage when compared with its position immediately after surgery (Figure 1C). Bone cyst formation was defined as a newly generated circular low-density area postoperatively (Figure 1D). Adjacent segment disease was defined as an obvious progression of intervertebral disc degeneration and/or instability. Intra-observer and inter-observer agreement concerning bone fusion were estimated using the κ statistic and Statistical Package for Social Sciences version 21 software (IBM Corp., Armonk, NY). The observers had not known precise information such as the clinical information and surgical procedure of the patient, intra-observer agreement analysis. The intra-observer agreement analysis was applied 8 weeks interval.

The study protocol was approved by the ethical review board at our institution.

RESULTS

Bone union rate

At the 1-year follow-up, bone union was achieved in 23 of the 26 intervertebral spaces. The bone union rate was 88.4% (Figure 2A, Table 2). There was nonunion in two intervertebral spaces at L4-5 and one at L5-S1. Bone union was obtained in all patients who had received a bone-modifying agent.

Screw loosening

Screw loosening was found in 4 of 94 screws (4.2%) ; 3 of these loosened screws were found in vertebral bodies adjacent to intervertebral spaces where nonunion had occurred (Figure 2B).

Cage subsidence

Cage subsidence was found in 5 intervertebral spaces (19.2%) (figure 1C). The mean subsidence in these cases was 2.58 (range, 1.8 to 3.7) mm by 1 year postoperatively. Bone union was achieved in all of the 5 intervertebral spaces.

Formation of bone cysts around the endplate

Bone cysts were found to have formed in 4 intervertebral spaces (15.4%) (figure 1D). All the cysts were identified at primary surgical sites and had appeared on CT by 3 months postoperatively. The cysts remained at the 1-year follow-up and had not disappeared at the final follow-up. However, there was no association with nonunion.

Adjacent segment disease

Disc herniation was observed in one patient and progression of intervertebral instability in another. There were no clinical complications attributable to the implant device.

Intra-observer and inter-observer agreement regarding bone fusion

Intra-observer and inter-observer repeatability showed substantial agreement for bone union. The κ coefficient was 0.617 for intra-observer reliability and 0.604 for inter-observer reliability.

DISCUSSION

Various materials have been used for IBCs. The Ti cage has been the most widely used and has favorable outcomes. However, several shortcomings have been reported, including subsidence of the cage into the vertebral body and difficulty in radiological assess-

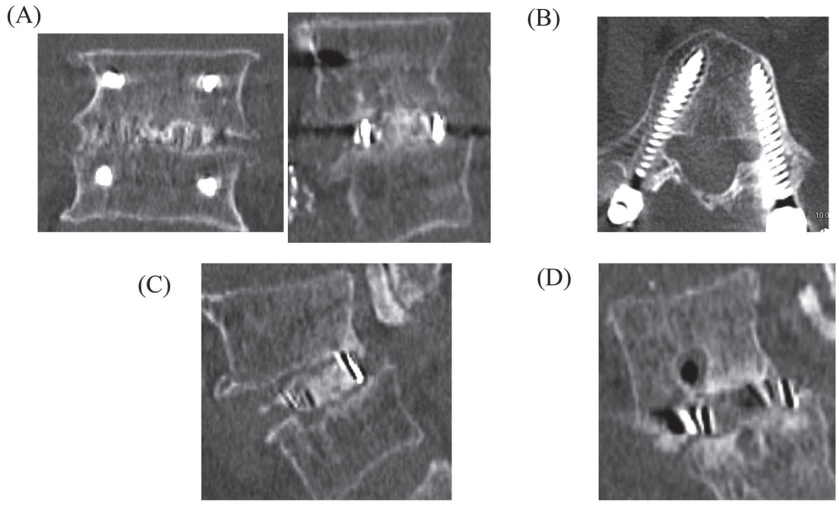

Figure 1
(A) Bone union, defined as bone continuity between the vertebral bodies.
(B) The "halo sign" (i.e., a clear zone around the pedicle screw) indicates screw loosening.
(C) Cage subsidence, defined as sinking beyond the cortical line.
(D) Postoperative bone cyst formation around the endplate, indicated by a newly generated circular area of low density.

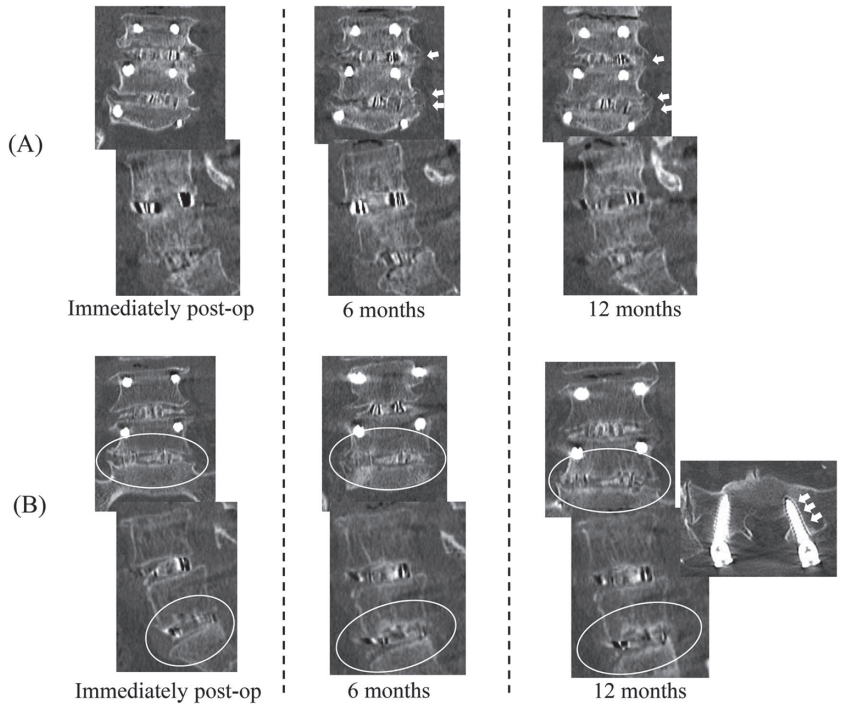

Figure 2
Computed tomography scans show typical changes immediately after surgery and at 6 and 12 months postoperatively.
(A) Arrow indicates bone formation in a case of successful bone union.
(B) Circle shows nonunion and the arrow indicates the "halo sign" in a case of nonunion.

Table 2. Postoperative radiologic findings

Outcome	n (%)
Bone union	23 (88.4%)
Screw loosening	4 (4.2%)
Cage subsidence	5 (19.2 %)
Bone cyst formation	4 (15.4%)
ASD	2 (9.5%)

ASD indicate adjacent segment degeneration

ment of bone fusion (7). PEEK, which is biomechanically similar to cortical bone as well as radiolucent, has been developed in an effort to resolve these problems ; however, high rates of bone cyst formation and breakage of the cage have been reported (9, 10). Ti-PEEK, which has the advantages of both Ti and PEEK, has recently been introduced. The Ti-PEEK cage combines the biomechanical stiffness of PEEK, which is similar to that of cortical bone, and the osteoinductivity of the Ti coating. In addition, the Ti-PEEK cage is mostly radiolucent and does not produce artifacts on CT or magnetic resonance imaging scans.

The bone union rate was favorable (88.4%) in the present study, and the radiological findings were comparable with those in previous reports on IBCs made of other materials. Tanida *et al.* and Nemoto *et al.* reported that Ti group was 75.2% and 96%, and PEEK group was 74.5% and 64% at 12 months postoperatively (6, 11). In our study, bone union was achieved in all patients who had received medication for osteoporosis. Bone formation by osteoblasts is known to occur after bone resorption by osteoclasts on the implant surface, but no bone absorption was observed radiologically in any of the cases in this study, suggesting that the Ti coating on the surface of the IBC has osteoinductive capability (12).

Fujibayashi *et al.* proposed that the mechanism by which an endplate cyst forms is similar to that by which a periarticular cyst forms in osteoarthritis in that a cartilage defect exerts mechanical stress on the subchondral bone and causes a microfracture (3). They also showed that a positive cyst sign could be a predictor of nonunion. Olivares-Navarrete *et al.* suggested that inflammatory mediators may be released at the interface between fibrous tissue and the PEEK implant, leading to apoptosis or necrosis (9). Therefore, we need to consider not only mechanical stress but also the cell environment around the implant, which varies depending on the material used. In the present study, bone cyst formation around the endplate was observed in 4 (15.4%) of 26 intervertebral spaces and all cysts were identified at primary surgical sites. The finding of bone cysts was not associated with nonunion, despite a report by Fujibayashi *et al.* suggesting that a positive cyst sign and a multiply-operated back were significant risk factors for nonunion (3). It has also been reported that cage subsidence and endplate failure are associated with an increased likelihood of nonunion (13-15). In this study, the average cage subsidence at 5 intervertebral spaces was 2.58 mm ; however, bone union was eventually obtained. Vadapalli *et al.* reported that the PEEK cage, unlike Ti spacers, has the biomechanical advantage of an elastic modulus similar to that of cortical bone (16). Ti-PEEK retains the elasticity of PEEK, so the mechanical stress on the endplate can be reduced to prevent sedimentation. In addition to the differences of the mechanical stress due to their material of the cages, we considered that it may be important to carefully perform the curettage of discs to obtain contact between the endplates, also to prevent subsidence.

This study has several limitations. First, the study had a retrospective design and did not include a control group. Randomized controlled trials with blinded assessment are needed to clarify the usefulness of the Ti-PEEK cage. Second, we did not investigate patient factors that could have potentially influenced the outcome, such as smoking, body mass index, bone mineral density, and type of postoperative brace used. Future research should include a detailed assessment of these patient factors and measurement of bone mineral density. Third, we did not examine the correspon-

dence between radiological progression and clinical outcome. However, although the clinical outcome is important, the focus of this research was radiological evaluation. Although plain radiographs have previously been used to evaluate bone union, CT became the preferred method for evaluation of interbody fusion because of the improved image quality and scanning methods (17-21). Currently, dynamic extension-flexion radiographs and CT are the mainly used modalities for radiological evaluation. There are problems with CT in terms of radiation exposure and cost ; however, this imaging modality has the advantage of ease of evaluation (22, 23). The κ coefficient for intra-observer and inter-observer repeatability was reliable, so it was considered that CT is an appropriate imaging method. Finally, the minimum follow-up period of 1 year did not allow assessment of the results in the long term. A longer follow-up duration would be needed to evaluate the long-term results.

In conclusion, cage subsidence and bony cyst formation were relatively common after LIF surgery using the Ti-coated PEEK IBC in this study. However, these cages had the advantages of achieving good bone union and facilitating image evaluation.

CONFLICTS OF INTEREST

All authors confirm that there are no conflicts of interest with people or organizations that could bias the nature of this report.

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