Comparison of bone fusion rate between titanium fiber mesh (TFM) cage and polyetheretherketone (PEEK) one in one-level transforaminal lumbar interbody fusion (TLIF)

Department of Orthopaedic Surgery Norihiro Akiyama

The surgical outcomes between PEEK cage and titanium fiber mesh one in one-level TLIF were investigated. Within 6 months, the bone union rates of TFM cage were higher than those of PEEK one.

keywords: titanium fiber mesh cage, PEEK, TLIF

1. Introduction

TLIF is widely performed surgical treatment for degenerative spinal disorder^{1, 2)}. Many types of cages are used as TLIF spacers. Cages made of titanium alloys have shown good results^{3~5)}. However, due to the stiffness of the titanium cage, problems such as the subsidence in the adjacent vertebrae are likely to occur^{6, 7)}.

Titanium enhances cell adhesion and osseointegration favoring bone fusion, but at the
same time, may have a higher rate of subsidence compared to polyetheretherketone
(PEEK) due to differences in the modulus of
elasticity^{8, 9)}. The mechanical properties analysis found that the Young's modulus and
compressive strength of titanium fiver mesh
were close to those of the bone structure, and
the overall stiffness was slightly lower than
that of the polyether ether ketone (PEEK)
material, and significantly lower than that
of the titanium alloy solid module.

So, the titanium cage with low elastic modulus is desired. Titanium fiber mesh cages, which have lower modulus than PEEK, have been used in our hospital. The purpose of this study is to compare surgical

outcomes between PEEK cage and titanium fiber mesh one in one-level TLIF.

2. Materials and methods

(1) Patients

We have conducted an observational retrospective study on medical records of all patients who had undergone one-level TLIF using cages, by three surgeons, from June 2017 to June 2019. A total of 40 patients with 24 months or more follow-up were included in this study. Of those 40 patients, 19 were treated using a PEEK cage (PEEK group), while a titanium fiber mesh (TFM) cage was used in 21 patients (TFM group).

(2) Surgical Procedure

The TLIF operations were performed by a single mid-line incision with unilateral exposure of the spine using pedicle screws bilaterally and a PEEK or TFM cage. The implants used were any one among ILLICO® SE/NOVEL® PEEK cage (Alphatec Spine, Inc., United States) and Associa (Zique)® /TFM-B® Titanium cage (KYOCERA Inc., Japan) (Fig. 1) filled with local bone graft from the lamina and spinous process and posterior instrumentation with pedicle screws. There were no differences in the techniques on the

implants between the two groups. After unilateral facetectomy and partial laminectomy, the intervertebral disc material and cartilaginous end plates were removed, one cage was inserted into the anterior end of the intervertebral space, and local bone chips were grafted, densely packed posterior to the cage.



Figure 1. TFMB® Titanium cage (KYOCERA Inc., Japan). It is made by compression molding and vacuum sintering of pure titanium wire.

(3) Radiologic Evaluations

Bony fusion status was judged by only the recognition of osseous continuity between bony endplate and implant on the CT sagittal images (Fig. 2(a)). The flexion - extension radiographs were used only for the confirmation of no mobility, in the case of fusion on the CT image (Fig. 2(b)). The fusion rates

of two groups were compared at 3-month, 6-month, 12-month and 24-month after surgery.

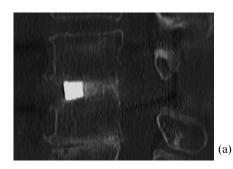
(4) Clinical Evaluations

Clinical results were assessed using the Japanese Orthopaedic Association (JOA) scoring system before surgery and at 1-year postoperative follow-up (Table 1). The preoperative scores and postoperative improvement rates of JOA were compared between the two groups.

Table 1. The Japanese Orthopaedic Association (JOA) Scoring system for low back pain disorders.

Item	Points
Subjective symptoms (9 points)	
Low back pain	3, 2, 1, 0
Leg pain and / or tingling	3, 2, 1, 0 3, 2, 1, 0 3, 2, 1, 0
Gait	3, 2, 1, 0
Clinical signs (6 points)	
Straight-leg-raising test	2, 1, 0
Sensory disturbance	2, 1, 0 2, 1, 0 2, 1, 0
Motor disturbance	2, 1, 0
Restriction of activities of daily living (14 points)	
Turning over while lying	2, 1, 0
Standing	2, 1, 0 2, 1, 0 2, 1, 0
Washing	2, 1, 0
Leaning forward	2, 1, 0
Sitting (~ 1h)	2, 1, 0 2, 1, 0 2, 1, 0 2, 1, 0
Lifting or holding heavy object	2, 1, 0
Walking	2, 1, 0
Urinary bladder function	0, -3, -6
Total*	29 to -6

^{*} A normal total JOA score is 29 points



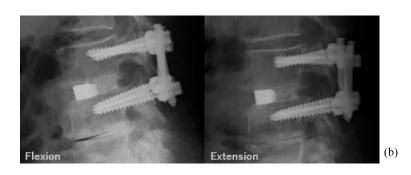


Figure 2. (a) CT sagittal image.

(b) Flexion extension radiographs in the case of fusion on the CT image.

(5) Statistical Analysis

The data from this study was analyzed by the using of R version 4.0.2. A p value < 0.05 was considered statistically significant.

The research has been approved by the ethical committee of our hospital. The requirement for informed consent was waived due to the retrospective nature of the study.

3. Results

Table 2 shows the baseline characteristics of both groups. There were no significant differences in age, gender, body mass index, JOA score, cage height, or pre-existing illness.

At 3-month after surgery, the bone union of no patient (0%) was found in the PEEK group, and that of 16 patients (76.2%) was found in the TFM group. (p<0.01) At 6-month after surgery, 9 patients (47.4%) in the PEEK group and 18 patients (85.7%) in the TFM group were confirmed as bone union. (p=0.017) At 12-month, 14 patients (73.7%) in the PEEK group and 18 patients (85.7%) in the TFM group were confirmed as bone union. (p=0.44)At 24-month after surgery, 15 patients (78.9%) in the PEEK group and 18 patients (85.7%) in the TFM group were confirmed as bone union (p=0.40) (Table 3). The statistically significant differences between the PEEK and TFM groups were observed at 3- and 6-month after surgery (Fig. 3).

Before surgery, JOA score of PEEK group was 16.9 ± 5.04 (mean \pm standard deviation) and that of TFM group was 15.8 ± 4.16 . No significant differences were found between both groups (Fig. 4). At one year after surgery, the improvement rate of JOA in the PEEK group was $84.5\pm14.1\%$ and that in the TFM group was $90.7\pm7.92\%$. No significant differences were found between both groups (Fig. 5).

Table 2. The baseline characteristics of patients in the PEEK and TFM groups.

	PEEK	TFM	р	
number	19 21			
Age(mean ± SD)	68.95 ± 15.10 68.10 ± 12.88		0.85	
Sex(Female number)	5	9		
BMI(mean ± SD)	24.30 ± 3.21	24.34 ± 5.92	0.98	
preoperative JOA score	1000 + 504	15.70 . 4.10		
(mean ± SD)	16.89±5.04	15.76 ± 4.16	0.44	
Cage height	0.70 + 1.00	0.76 + 1.00		
(mean ± SD)	8.79±1.23	8.76 ± 1.09	0.94	
Diabetes mellitus	4	3	0.88	
Hypertention	12	11	0.71	
Heart disease	3	4	1	
Kidney disease	3	0	0.196	
Liver disease	1	1	1	

Table 3. The bone union rates of the PEEK and TFM groups at each point after surgery.

	3month	6month	12month	24month	
PEEK	0	47.4	73.7	78.9	(%)
TFM	76.2	85.7	85.7	85.7	(%)

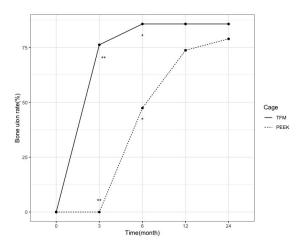


Figure 3. The fusion rates in the PEEK and TFM groups at 3, 6, 12, and 24 months after surgery. Significant differences between the two groups were observed at 3 and 6 months after surgery. $* \rho < 0.05 * * p < 0.01$

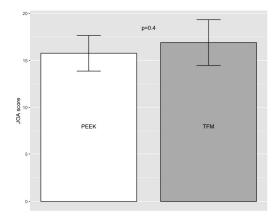


Figure 4. JOA scores between the PEEK and TFM groups before surgery.

No significant differences were found between the two groups.

4. Discussion

It is widely accepted that thorough disc space preparation is the most important factor in achieving fusion. However, the use of instrumentation can significantly enhance the chances of fusion success. There is an array of different materials used in interbody cage construction, including PEEK and titanium. The elastic modulus of PEEK is similar to that of bone, and it can decrease the risk of endplate fracture and subsidence¹⁰⁾. However, PEEK relies on large graft windows to allow fusion as its smooth surface, hydrophobic properties and the lack of porosity and osteoconductivity do not facilitate bony ongrowth, ingrowth and throughgrowth 11, 12). Its lack of incorporation into bone leads to shedding of submicron particles which drive osteolysis manifesting in inflammation^{13, 14)}.

It has been reported that fusion rates are far higher when using titanium over PEEK as the interbody cage material for TLIF procedures. Standard titanium block cages contain large graft windows and like PEEK, have no ability to allow bony ingrowth and

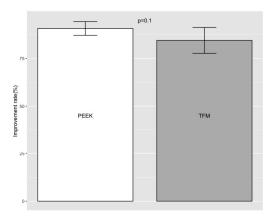


Figure 5. The improvement rate of JOA between the PEEK and TFM groups at one year after surgery. No significant differences were found between the two groups.

through-growth¹⁴⁾. Titanium has a greater elastic modulus than bone, resulting in increased risk of endplate fractures and subsidence¹⁵⁾. However, due to their biological inertness, titanium cages do not cause osteolysis¹⁴⁾. Although the elastic modulus of titanium is unalterable, the modulus can be manipulated and decreased by processes that introduce porosity. Titanium, which has an elastic and porous structure, should be useful as an interbody cage for TLIF.

Titanium with fiber mesh structure has a low modulus, reducing the risk of endplate fracture and subsidence. Futhermore, the three-dimensional porous structure is considerd to promote bony ongrowth, ingrowth and through-growth. It is reported that 3D-printed porous titanium-alloy facilitated greater bony ingrowth and ongrowth in comparison to solid PEEK and titanium-alloy in vivo ovine model¹⁶. The high ability of osteoconduction and osteoinduction in bioactive porous 3D titanium are also shown^{17, 18}).

In this study, only one-level TLIF was conducted not to be affected by the status of other vertebrae. Up to 6-month after surgery, the bone union rate was significantly higher in the TFM group than the PEEK group. It was suggested that the material and structural properties of the TFM cage were effective for early postoperative bone fusion. At least 12 months after operation, there was no significant difference in the bone fusion rate between the PEEK and TFM groups. Moreover, there was no significant difference in the JOA improvement rate 1 year after the operation between the two groups. Over long term of 1 year or more, the results of TFM and PEEK were the same, but the bone fusion rate on TFM was clearly faster. After TLIF using the TFM cage, early return to society can be expected.

References

- 1) Brantigan JW, Steffee AD, Lewis ML, et al.: Lumbar interbody fusion using the Brantigan I/F cage for posterior lumbar interbody fusion and the variable pedicle screw placement system: two-year results from a Food and Drug Administration investigational device exemption clinical trial. Spine 25(11): 1437-1446, 2000.
- 2) Videbaek TS, Christensen FB, Soegaard R, et al.: Circumferential fusion improves outcome in comparison with instrumented posterolateral fusion: long-term results of a randomized clinical trial. Spine 31(25): 2875-2880, 2006.
- 3) Tan JH, Cheong CK, Hey HWD: TTitanium (Ti) cages may be superior to polyetheretherketone (PEEK) cages in lumbar interbody fusion: a systematic review and meta-analysis of clinical and radiological outcomes of spinal interbody fusions using Ti versus PEEK cages. Eur Spine J 30(5): 1285-1295, 2021.
- 4) Massaad E, Fatima N, Kiapour A, et al.:

- Polyetheretherketone Versus Titanium Cages for Posterior Lumbar Interbody Fusion: Meta-Analysis and Review of the Literature. Neurospine 17(1): 125-135, 2020.
- 5) Sung-Soo Chung, Kyung-Joon Lee, Yoo-Beom Kwon, et al.: Characteristics and Efficacy of a New 3-Dimensional Printed Mesh Structure Titanium Alloy Spacer for Posterior Lumbar Interbody Fusion. Orthopedics 40(5): e880-885, 2017.
- 6) Seaman S, Kerezoudis P, Bydon M, et al.: Titanium vs. polyetheretherketone (PEEK) interbody fusion: Meta-analysis and review of the literature. JJ Clin Neurosci 44: 23-9, 2017.
- 7) Niu CC, Liao JC, Chen WJ, et al.: Outcomes of interbody fusion cages used in 1 and 2-levels anterior cervical discectomy and fusion: titanium cages versus polyetheretherketone (PEEK) cages. J Spinal Disord Tech 23(5): 310-316, 2010.
- 8) Chou YC, Chen DC, Hsieh WA, et al.: Efficacy of anterior cervical fusion: comparison of titanium cages, polyetherether-ketone (PEEK) cages and autogenous bone grafts. J Clin Neurosci 15(11): 1240-1245, 2008.
- 9) Chen Y, Wang X, Lu X, et al.: Comparison of titanium and polyetheretherketone (PEEK) cages in the surgical treatment of multilevel cervical spondylotic myelopathy: a prospective, randomized, control study with over 7-year follow-up. Eur Spine J 22(7): 1539-1546, 2013.
- 10) Carpenter RD, Klosterhoff BS, Torstrick FB, et al.: Effect of porous orthopaedic implant material and structure on load sharing with simulated bone ingrowth: A finite element analysis comparing titanium and PEEK. J Mech Behav Biomed Mater 80: 68-76, 2018.

- 11) Torstrick FB, Safranski DL, Burkus JK, et al.: Getting PEEK to Stick to Bone: The Development of Porous PEEK for Interbody Fusion Devices. Tech Orthop **32**(3): 158-166, 2017.
- 12) Walsh WR, Bertollo N, Christou C, et al.: Plasma-sprayed titanium coating to polyetheretherketone improves the bone-implant interface. Spine J **15**(5): 1041-1049, 2015.
- 13) Stratton-Powell AA, Pasko KM, Brockett CL, et al.: The Biologic Response to Polyetheretherketone (PEEK) Wear Particles in Total Joint Replacement: A Systematic Review. Clin Orthop Relat Res 474(11): 2394-2404, 2016.
- 14) Nemoto O, Asazuma T, Yato Y, et al.: Comparison of fusion rates following transforaminal lumbar interbody fusion using polyetheretherketone cages or titanium cages with transpedicular instrumentation. Eur Spine J 23(10): 2150-2155, 2014.

- 15) Niinomi M, Liu Y, Nakai M, et al.: Biomedical titanium alloys with Young's moduli close to that of cortical bone. Regen Biomater 3(3): 173-185, 2016.
- 16) Van Horn MR, Beard R, Wang W, et al.: Comparison of 3D-printed titanium-alloy, standard titanium-alloy, and PEEK interbody spacers in an ovine model. Spine J 21(12): 2097-2103, 2021.
- 17) Fujibayashi S, Nakamura T, Nishiguchi S, et al.: Bioactive titanium: effect of sodium removal on the bone-bonding ability of bioactive titanium prepared by alkali and heat treatment. J Biomed Mater Res 56(4): 562-570, 2001.
- 18) Fujibayashi S, Takemoto M, Neo M, et al.: A novel synthetic material for spinal fusion: a prospective clinical trial of porous bioactive titanium metal for lumbar interbody fusion. Eur Spine J **20**(9): 1486-1495, 2011.