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Development of Anterior Lumbar Interbody Fusion (ALIF) PEEK Cage Based On the Korean Lumbar Anatomical Information

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Abstract**—**The aim of this study is to develop an anterior lumbar interbody fusion (ALIF) PEEK cage suitable for Korean people. In this study, CT images were obtained from Korean male (173cm, 71kg) and 3D Korean lumbar models were reconstructed based on the CT images to investigate anatomical characteristics. Major design parameters of anterior lumbar interbody fusion (ALIF) PEEK Cage were selected using the morphological measurement information of the Korean Lumbar models. Through finite element analysis and mechanical tests, the developed ALIFPEEK Cage prototype was compared with the Fidji Cage (Zimmer. Inc, USA) and it was found that the ALIF prototype showed similar and/or superior mechanical performance compared to the FidJi Cage. Also, clinical validation for the ALIF PEEK Cage prototype was carried out to check predictable troubles in surgical operations. Finally, it is considered that the convenience and stability of the prototype was clinically verified.

Keywords**—**Interbody fusion, PEEK, implant, finite element analysis, lumbar, spine.

I. Introduction

INTER-body anterior fusion is a significant surgical method applied to patients with spinal disorders, and titanium cages are generally used[1], [2]. Recently, development of inter-body cages using PEEK (Polyetheretherketone) is being actively studied as high performance material that has secured biocompatibility and biomechanical safety, which makes it replaceable for titanium [3]–[5], [9], [10]. Most of the PEEK cages recently shown in Korea are foreign-made developed and designed by foreigners, making them unsuitable for Korean lumbar. This study developed an anterior lumbar inter-body fusion (ALIF) PEEK cage based on the morphological information of the Korean lumbar, and compared the biocompatibility and the biomechanical stability with a foreign-made cage (FidjiLumbar Cage, Zimmer Inc.). In addition, the convenience and safety of the surgery was clinically verified through animal tests

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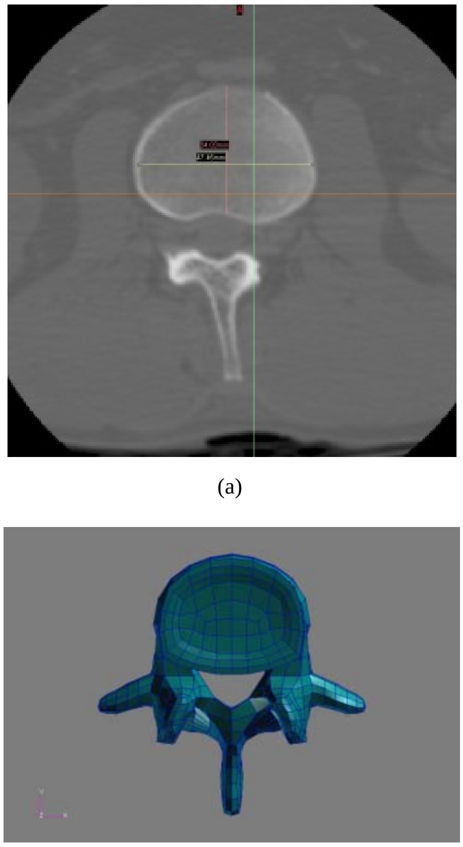
II. Methods

CT scans on a Korean male (173cm, 71kg) were taken to obtain the morphological information of the Korean lumbar. A 3D FE model was reconstructed based on the CT image (Fig. 1), and an ALIF PEEK cage suitable for Koreans was designed considering the anatomical configuration of the lumbar.



(a)

(b)

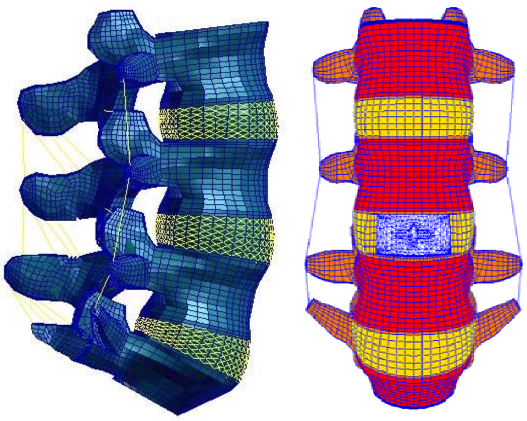
Fig. 1 (a) Korean Lumbar CT Images, (b) 3D Lumbar FE Model

Mechanical tests were conducted abiding by the ASTM F2077-03, while static compression and fatigue tests were conducted using the MTS 858 Table Top System, USA (Fig. 2). Analysis of the PEEK cage, which is based on Korean lumbar configuration, was carried out by ABAQUS 6.6 (HKS, USA) (Fig. 3). The FE model was applied with isotropy for the spinal cord, orthotropy for the fibrocartilage disc annulus, and incompressible fluid condition for the nucleus, respectively [6], [7]. The analysis results on the prototype and Fidji cage were compared and analyzed.

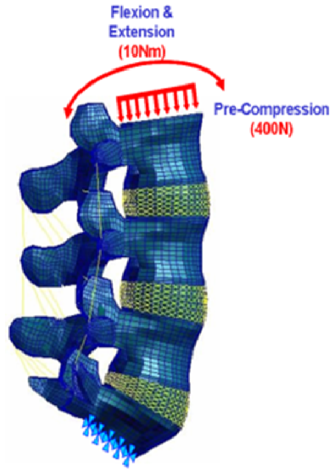
(a)

(b)

Fig. 2 (a) Static test of ALIF PEEK cages, (b) Fatigue test of ALIF PEEK cages



(a)



(b)

Fig. 3 (a) Spine FE model, (b) Boundary condition

In this study, the prototype and the Fidji cage were implanted into a pig's lumbar, and the assembly was X-rayed. The X-ray traceability of tantalum markers inserted in those cages was examined by an orthopedic surgeon, verifying the convenience and safety of the surgery using the ALIF PEEK cages.

TABLE I
MATERIAL PROPERTY

Material	Young's modulus E(MPa)	Poisson's ratio
Cortical bone	12000	0.3
Cancellous bone	100	0.2
Bony posterior element	3500	0.25
End plate	25	0.25
Annulus matrix	4.2	0.45
Nucleus pulposus	1.0	0.499 (incompressible)
Annulus fibers		
Layer 1/2	550	-
Layer 3/4	495	-
Layer 5/6	413	-
Layer 7/8	358	-
Ligament		
All	7.8(<12%) 20(>12%)	-
PLL	10(<11%) 20(>11%)	-
LF	15(<6.2%) 19(>6.2%)	-
CL	7.5(<25%) 33(>25%)	-
ITL	10(<18%) 59(>18%)	-
ISL	10(<14%) 12(>14%)	-
SSL	8(<20%) 15(>20%)	-

ALL: Anterior longitudinal ligament, PLL: Posterior longitudinal ligament, LF: Ligament flavum, CL: Capsule ligament, ITL: Intertansverse ligament, ISL: Interspinous ligament, SSL: Superspinous ligament

III. RESULTS AND DISCUSSIONS

The yield strength and the ultimate strength were reviewed through static compression tests. Both the prototype and the Fidji cage equally showed the yield strength of 19kN, and the ultimate strength of 32kN. From this, biomechanical stability is considered secured when reviewing that the physiological load in the human lumbar is approximately 7,000N [8]. According to the fatigue tests (5 million cycles with 5Hz) conducted under the 25% maximum compressive load condition, neither the prototype nor the Fidji cage had taken damage and/or remarkable deformation (Table II). FE analysis showed that the biomechanical stability of the prototype at the moment of flexion or extension was either equivalent or better than that of the Fidji cage (Table III, IV).

According to the X-ray traceability analysis on tantalum markers in the cages implantedin pig's lumbar, the prototype showed more accurate X-ray traceability than that of the Fidji cage in the anterior and/or posterior images of the lumbar. The side view image also showed similar results (Fig. 4).

TABLE II
COMPARISON OF FATIGUE TEST RESULTS

ALIF	Load (min/max)	Result	Remark
Prototype	800N /8,000N	No failure, no visible damage	25% of comp. ultimate load
Fidji Cage (Zimmer,Inc)	800N /8,000N		

TABLE III
RANGE OF MOTION AND STIFFNESS (FLEXION)

	Intact	Prototype	Fidji
ROM(Degree)	12.8	10.69	10.8
Stiffness(Nm/degree)	0.781	0.935	0.926

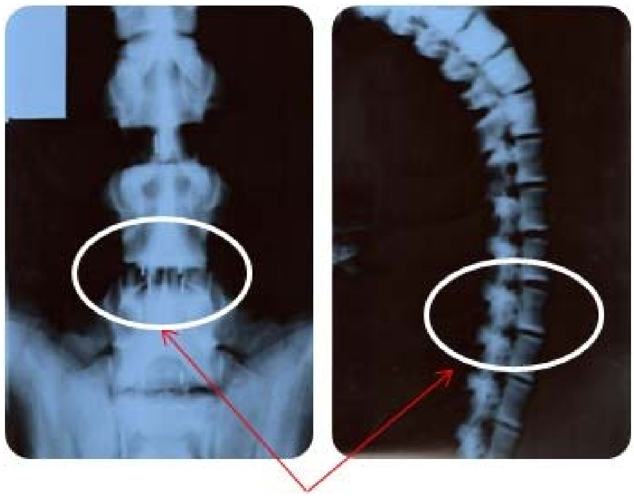
TABLE IV
RANGE OF MOTION AND STIFFNESS (EXTENSION)

	Intact	Prototype	Fidji
ROM(Degree)	5.08	4.28	4.25
Stiffness(Nm/degree)	1.969	2.336	2.353

IV. CONCLUSIONS

This study analyzed CT images of a Korean male's lumbar and developed an ALIF PEEK cage prototype. According to mechanical tests and FE analysis, the biomechanical stability of the prototype was found to be equivalent or superior to a foreign-made PEEK cage. In particular, the function of tantalum markers inside the prototype was clinically verified to be more accurate than that of the foreign-made one. The tracing of the prototype would not be difficult both during and post-operation in the future. Finally, it is considered that the convenience and stability of the prototype was clinically verified.

(a)



ALIF PEEK cages

(b)

Fig. 4 (a) Evaluation of the convenience and safety (b) Evaluation of X-ray traceability of ALIF PEEK cages in the pig's lumbar

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