A Large Preclinical Animal Study on a Novel Intervertebral Fusion Cage Covered with High Porosity Titanium Sheets with a Triple-pore-structure used for Spinal Fusion

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Disclosures:

Introduction: Spinal fusion using vertebral interbody cages is popular in spinal surgery. Because cages do not bond directly to the surrounding bone, interbody cages combined with bone grafts are used to obtain biological bone fusion. Complications related to bone graft harvest, as well as the migration and subsidence of the intervertebral cages, have been observed and may be caused by the lower osteoconductive properties of interbody cages. Therefore, developing materials that can bond directly to the surrounding bone without bone grafts is critical for achieving interbody fusion. Metallic implants are used in spinal reconstruction surgery because of their mechanical strength. Although a porous structure in metallic implants can make them more osteoconductive, its osteoconduction is not optimal and there is a need to improve the same.

We have developed a novel porous titanium (Ti) sheet with 80% porosity along with a triple-pore-structure (Fig. 1), which is a cancellous bone-like structure that comprised 3 different pore sizes and shapes. In addition, it has been shown to be the most suitable pore structure for bone regeneration [1].

![Figure 1](image)

Scanning electron microphotographs of a porous titanium (Ti) sheet. The unique triple-pore structure consists of macropores, interconnecting pores (asterisk) and micropores in porous Ti.

We hypothesized that intervertebral cage covered with the porous Ti sheets could achieve better intervertebral fusion even without any bone graft. Therefore, we investigated the osteoconductivity and bonding strength of a new intervertebral cage in a large animal model.

Methods: This animal study was approved by an institutional review board at our institution.

A 1-mm-thick porous Ti sheet was produced using the slurry foaming method [2]. A newly developed porous Ti sheet was firmly attached to the surfaces of a box-shaped intervertebral spacer (Fig. 2). A total of 12 sheep underwent anterior lumbar interbody fusion at L2-3 and L4-5 using either a new porous Ti cage (Group-P: porous Ti cage) or a conventional Ti alloy cage with autogenous iliac bone (Group-C: control cage). The animals were euthanized 2 and 4 months after the surgery and their lumbar spine was resected. Computed tomography (CT) scans (n=6 from each group/time-point), biomechanical detachment tests (n=5), and histological analyses (n=6) were performed.

Statistical analyses were performed using unpaired t-tests. P values < 0.05 were considered statistically significant.
**Results:** CT analyses showed that the ratio of bone contact area in Group-P was significantly increased at 4 months compared with that at 2 months. Although the ratio of bone contact area in Group-C was significantly higher than Group-P at 2 months, there was no statistically significant difference between the two groups at 4 months (Fig. 3). The bonding strength in Group-P significantly increased with time, although there was no significant difference between the two groups at either 2 or 4 months (Fig. 4). Histological analyses revealed that active bone ingrowths in the porous Ti layer were noted in samples from Group-P. The bone apposition ratio increased significantly with time in Group-P. Although Group-C showed significantly higher bone apposition ratio than Group-P at 2 months, there was no statistical difference between the two groups at 4 months (Fig. 5).

**Figure 2**

![A porous titanium (Ti) cage and a control cage made of Ti - alloy (cage size: 8 × 8 × 20 mm).](image)

**Figure 3**

Computed tomographic analysis of porous titanium and control cages.
Discussion: This newly developed porous Ti cage achieved direct bonding to the bone. There was abundant bone ingrowth into the porous Ti sheet, and bonding capacity of the porous Ti cage to the host bone increased with time. The high osteoconductivity of the porous Ti sheet is possibly because of its high porosity and its pore structure, which enhanced cell infiltration and bone ingrowth deep into the porous Ti sheet. The results of the current study suggested this material could achieve interbody fusion without the need for a bone grafts. However, the speed of union of the bone with a porous Ti cage was
marginally lower than a conventional cage along with an autogenous bone graft. Encouraging cell recruitment and attachment to the porous Ti sheet can possibly improve bone ingrowth into the porous Ti cage and thereby lead to improved bone regeneration.

**Significance:** An intervertebral cage covered with 80% porous titanium sheets along with a triple-pore-structure achieved direct bone bonding in sheep lumbar interbody fusion model, possibly because it could achieve interbody fusion without the need of bone grafts.

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