ANTERIOR LUMBAR INTERBODY FUSION WITH POROUS BIOACTIVE TITANIUM: AN EXPERIMENTAL STUDY IN A CANINE MODEL

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INTRODUCTION:
Porous biomaterials with adequate pore structure and appropriate mechanical properties are expected to provide a new generation of devices for spinal interbody fusion, because of their potential to eliminate the bone graft technique. For this purpose, a novel porous titanium implant (porosity = 50%, pore size = 303 ± 152 µm, yield compression strength = 116 MPa) was developed (Fig 1). This porous titanium implant was chemically and thermally treated to give it a bioactive microporous titania surface (Fig 1) [1]. The treated porous titanium possesses superior in vitro apatite-forming ability, with enhanced bone ingrowth into the porous structure [2]. Furthermore, titanium with a specific porous structure can acquire osteoinductive ability in dog muscle through this treatment [3][4]. Therefore, chemically and thermally treated porous titanium is expected to be an effective biomaterial for biological fixation in load-bearing conditions.

In this study, we developed a canine lumbar interbody fusion model to assess the radiographic and histological performance of the treated porous titanium implants. The osteoinductivity of chemically and thermally treated porous titanium was also investigated.

MATERIALS AND METHODS:
Sintered porous titanium implants were supplied by Osaka Yakin Co., Ltd. Porous titanium cylinders (ø7 or ø8 × 24 mm cylinders for interbody fusion and ø6 × 15 mm cylinders for intramuscular implantation) were prepared for this study. The titanium substrates were immersed in 5 M NaOH at 60 °C for 24 h. They were then immersed in 0.5 mM hydrochloric acid at 40 °C for 24 h, and then in ultrapure water at 40 °C for 24 h. The substrates were then heated to 600 °C at a rate of 5 °C/min, kept at 600 °C for 1 h, and allowed to cool in the furnace. The effect of the surface treatment was analyzed using SEM, SEM–EDX, and XRD. To check in vitro apatite-forming ability, samples were soaked in simulated body fluid (SBF) for 3 days and analyzed using SEM.

Ten female beagle dogs (12–18 months old) underwent anterior lumbar interbody fusion at L6–7, and additional posterior interspinous wiring and facet screw fixation. Each dog was randomly allocated to receive either a nontreated porous titanium (NT) implant or a bioactive-treated porous titanium (BT) implant. Radiographic evaluations were performed at 1, 2, and 3 months postoperatively using X-ray fluoroscopy. Any radiolucency in the anterior or posterior portion of the implant-vertebrae interface was recorded. Histological evaluations using micro-CT and light microscopy were performed 3 months after surgery. Titanium implants were also implanted intramuscularly, and examined histologically after 3 months.

This study was approved by the Animal Research Committee, Graduate School of Medicine, Kyoto University, Japan.

RESULTS:
The surface of the chemically and thermally treated porous titanium has a microporous structure (Fig 1). With soaking of the BT-implants in SBF, apatite deposited on the whole surface within 3 days. After intramuscular implantation for 3 months, BT-implants showed osteoinductivity (Fig 1). Three months after anterior lumbar interbody fusion, radiographic examination and micro-CT analysis showed interbody fusion had occurred in all five dogs in the BT group and in three of five dogs in the NT group (Fig 2 and 3). Histologically, we observed new bone formation with marrow-like tissue extending from the periphery to the center of the implants from the BT group (Fig 2), whereas fibrous tissue was observed in the NT group, even in the implants giving successful fusion. The fusion score and the results of the histomorphological examination of each group are shown in Figure 4. The percentage of bone area ingrowth was 16.7 for the BT group and 13.4 for the NT group. The percentage of bone–implant contact in the BT group was significantly larger than for the NT group (34.9 versus 10.5, p=0.0122). The percentage of well-differentiated pores (percentage of area of bone with bone marrow-like tissue) was 81.9 for the BT group and 40.8 for the NT group (p=0.0122).

DISCUSSION:
A bioactive surface was successfully applied to porous titanium implants by chemical and thermal treatment, and was confirmed to have in vitro apatite-forming ability and intramuscular osteoinductivity.

In the canine interbody fusion study, the percentages of bone–implant contact and well-differentiated pores were higher in the BT group. In the NT implants, new bone formation was observed mainly in the peripheral pores, with occupation of the entrance of the interconnections, which might disturb cell migration, angiogenesis and diffusion of growth factors from the surrounding marrow tissue, causing poor bone growth in the central pores. In contrast, new bone formation in BT implants was mainly observed along the implant surface without blockage of the interconnections. Preserved interconnections, together with the osteoconductivity of the treated surface, may play an important role in tissue differentiation in the central pores of the BT implants.

Although these results cannot be directly extrapolated to humans, porous bioactive titanium implants represent a new biomaterial for use in spinal interbody fusion.

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