BONDING STRENGTH BETWEEN VERTEBRAL BODY AND ARTIFICIAL INTERVERTEBRAL DISC USING BIOCERAMIC-COATED THREE-DIMENSIONAL FABRIC

INTRODUCTION
We have developed a new artificial intervertebral disc prosthesis consisting of a triaxial three-dimensional fabric (3-DF) woven by a biocompatible polyethylene fiber. Our previous reports have demonstrated that its biomechanical property is similar to human intervertebral disc. To biologically fix the 3-DF to vertebral body, the surfaces of the disc were coated with sintered-hydroxyapatite powder. Consequently, the bone ingrowth to the fabric has been successfully demonstrated in our preliminary animal studies. However, its bond strength has not been clarified yet. The objectives of this study were: 1) to evaluate the bond strength between 3-DF and vertebral body in comparison with that of bioceramic interface, and 2) to investigate its alteration in vivo, and 3) to clarify the relationship between bond strength and interface histology.

MATERIALS AND METHODS
Twelve sheep were used in this study with experimental protocol approved by University animal review board. The intervertebral discs at L2/3 and L4/5 levels were totally replaced with the scale-downed 3-DF discs (20×17×10 mm) or porous surfaced apatite-wollastonite glass ceramic (A-WGC) blocks (23×13×10 mm) through retroperitoneal approach. The animals were divided into two groups; group I: spinal segments replaced with 3-DF disc; group II: it replaced with A-WGC. In group I, three animals were euthanized at each of three periods; four, six and fifteen months postoperatively. In group II, three animals were euthanized at six months. All the operative segments except those of group I at fifteen months were stabilized with Kaneda SR one-rod system, while those of group I at fifteen months were stabilized with bioabsorbable Hydroxyapatite/Poly-L-lactid (HA/PLLA) rods spanning two screws. After the vertebral body-implant-vertebral body complex were obtained, four of six specimens in each time period group were subjected to detaching test, and other two to histological interface evaluation. In a detaching test, the isolated interface between vertebral body and 3-DF (or A-WGC) was pulled perpendicularly at a crosshead speed of 0.5 mm/sec using MTS material tester. The tensile failure strength (MPa) was calculated with the failure load divided by interfacial area. The histological analysis of undecalcified sagittal section was performed to evaluate the interface histology and to identify the failure mode microscopically.

RESULTS
Postoperatively, all implants were in place, and the 3-DF discs were covered with noninfectious scar tissues. In group I at fifteen months, all HA/PLLA rods were broken and the specimens restored the segmental flexibility. The tensile failure strength (MPa) in group I at four, six and fifteen months were 1.8 ± 0.6, 1.8 ± 0.3 and 3.0 ± 1.0 (Mean ± SD) respectively (Fig. 1). There was no significant difference between four and six months. The value of fifteen months was significantly greater than those of four and six months (P < 0.05). The tensile failure strength (MPa) of group II was 0.2 ± 0.1, that was significantly lower than that of group I at six months. In detaching tests, the failure occurred at the bone-implant interface except a specimen at fifteen months, showing fractures inside the upper vertebral body (Fig. 2A). Histological findings showed that the new bone grew into the textile space of the 3-DF (Fig. 2B), and the extent of bone ingrowth into the 3-DF at fifteen months was apparently higher than that at four and six months.

DISCUSSION
This study revealed that the bone-bonding strength of the 3-DF was greater than that of the A-WGC at six months, although previous reports demonstrated that the A-WGC had a superior capability to form a strong chemical bonding with bone tissues when compared to other ceramic and metal materials, and also porous structure provided further bond strength. This result supports the idea that the textile structure and bioceramics powder coating are useful for acquisition of bone-bonding. Histologically, newly formed bone inside the 3-DF was found to be interlocked with polyethylene 3-DF fiber, being continued from vertebral bone. We may go on from these histological findings to conclusion that mechanical interlock between bone and 3-DF fiber plays a major role in bond strength. The observation of the specimens at fifteen months using the bioabsorbable rods provided a further important information about the changes of bony fusion and bond strength with time. In spite of alteration of mechanical environment at the interface after restoration of segmental flexibility, both bone ingrowth and bond strength continue to develop at fifteen months without bony absorption and loss of bond strength. It follows from this information that fixation of 3-DF disc by bone ingrowth may produce a physiological interfacial environment.

In conclusion, this study emphasize that the 3-DF disc have a potential for the clinical application of intervertebral disc replacement.