INTRODUCTION
Several artificial intervertebral discs have been developed to preserve physiological segmental motion and to obtain a biological bony bonding at the bone-implant interface. However, the loss of biological fusion at the bone-implant interface has resulted in early dislodgment or loosening. We have developed a new artificial intervertebral disc consisting of a triaxial three-dimensional fabric (3-DF) woven by a high molecular weight polyethylene (UHMWPE) fiber, and spray-coated bioactive ceramics on the disc surface. Our previous report demonstrated a partial interface bony union in the total intervertebral replacement using a sheep model. However, the segmental motion significantly decreased at the operative level. The objective of this study was to further evaluate the segmental biomechanics and interface histology of the total intervertebral disc replacement using 3-DF disc, under different initial fixation conditions.

MATERIALS AND METHODS
Using twenty-three sheep, the intervertebral discs at L2/3 and L4/5 levels were totally replaced with scale-downed 3-DF disc (20x17x10mm) through a retroperitoneal approach. The animal surgery, handling and housing protocols were previously approved by University animal review board. After circumferential removal of intervertebral disc, two types of 3-DF discs coated either by sintered hydroxyapatite (s-HA) or apatite-wollastonite glass ceramics (AW) were randomly assigned. The animals were divided into two groups; group I: no initial fixation (N=9) and group II: temporarily instrumented with Kaneda SR one-rod system (N=14). Even in group I, the 3-DF was in place without dislodgement. Four and six months postoperatively, the animals were euthanized and disc-body units (DBUs) were obtained followed by the removal of instrumentation. The biomechanical tests were conducted with the pure moment application of 0-5 Nm to the DBUs in flexion-extension, axial rotation, and lateral bending with loading increments of three stages. Three-dimensional motion of spinal segment was analyzed with the stereophotogrammetry method. Ten normal DBU harvested from non-surgical sheep served as the control. The range of motion (ROM) and neutral zone (NZ) were calculated from torque-angle curves. For histologic analysis, the undecalcified sagittal sections of 40 microns were created and stained with Cole’s hematoxylin and eosin, and Toluidine blue O. The interface histology was classified into three grades. In grade 1, the continuous trabeculae without soft tissue membrane, inserting into fabrics inside were observed. The grade 2 showed the gap below 90 microns between 3-DF fiber and trabeculae with occasional existence of calcified fibrocartilage. In grade 3, apparent soft tissue membrane occupied at the interface.

RESULTS
The operative segments at six months postoperatively were covered with noninfectious tight scar and incomplete bony bridging in group I. However, in group II, these changes were dramatically decreased. The total ROM of control group DBU at maximum moment of 5Nm showed 11.4, 3.5, and 10.5 degrees in flexion-extension, axial rotation, and lateral bending, respectively. In group I, the ROM of DBU decreased to 28%, 60%, and 26%, in flexion-extension, torsion, and lateral bending, respectively, when compared to the control (Figure 1). In group II, they increased to 105%, 231%, and 58% in primary fixation. In group II, these changes were dramatically decreased. The total ROM of DBU at maximum moment of 5Nm showed 38% and 50% in grade 1 and 2, respectively, six months histology was improved up to 63% of grade 1, and 38% of grade 2.

DISCUSSION
This study successfully demonstrated the biological bony bonding of 3-DF disc to the vertebral body. A previous attempt of surface modification with bioactive ceramics demonstrated no biological bony union with dense soft tissue occupied at the interface between artificial disc and vertebral body. In our 3-DF disc, bioactive ceramics distributed evenly to the designed depth of fabric permitted direct bone bonding and bone ingrowth to the fabric inside. In the total disc replacement without the initial fixation, the segmental mobility dramatically decreased except axial rotation due to scar and osteophyte formation. The initial segmental instabile at immediate postoperative periods may enhance the increased biological reaction. As in vivo alteration toward the immobilization was also reported in human application of artificial intervertebral disc, this trend was not an exclusive experimental issue. Contrarily, the use of temporary fixation provided a nearly physiological mobility as well as the increased fusion rate. The initial stabilization has an important role in reducing a biological reaction such as a bony bridging and scar formation.

However, when considering a human application of 3-DF disc in the near future, the artificial disc has to support larger loads as well as allowing three-dimensional motion. Although the initial fixation condition is necessary to obtain the interface fusion, the secondary operation of metal removal is not practical. The experimental use of new absorbable implant for initial fixation is in progress.

References
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