INTRODUCTION
The bioabsorbable material has partially become the alternative method of internal fixation for human bone fractures, especially for peri- or intraarticular fractures. However, there was no bioabsorbable implant to have enough mechanical strength, which could be applied to high load environment such as spine or long bones. Recently, the new ultra-high strength bioabsorbable material has developed by compounding hydroxyapatite (HA) with poly-L-lactide (PLLA). The purpose of this study was to investigate the efficacy of HA/PLLA composite used for spinal fixation device in a sheep model.

MATERIALS AND METHODS
The HA/PLLA composite material with a content of 40 wt% of unsintered-HA was used, and the rod with a diameter of 6.4mm was molded. Using six sheep, the intervertebral discs at the L2/3 and 4/5 levels were totally replaced by artificial discs through a retroperitoneal approach. The combination of Kaneda SR screw and HA/PLLA composite rod stabilized each spinal segment. At six months postoperatively, three of six sheep were euthanized, and the others at 15 months. The radiographic evaluation was performed at 0, 12, and 15 months postoperatively. Histologic analysis of the tissue around the rod was performed with decalcified and undecalcified sections, and the rod surface was analyzed by scanning electron microscopy (SEM). To evaluate mechanical property, a part of the rod was sectioned, and subjected to compression test along the rod axis according to the method of Japan Industry Standard, calculating compressive strength (MPa) and compressive modulus (GPa). To investigate a degradation process, viscosity average molecular weight (VAMW) and crystalinity were measured by a ubbelohde viscometer and a differential scanning calorimeter, respectively. Kruskal-Wallis test and Fisher’s protected least significant difference was used for statistical analysis.

RESULTS
At six months postoperatively, there was no breakage of the HA/PLLA composite rods with their initial shape intact macroscopically and radiographically. The radiographic findings at 12 months demonstrated the failure at four of six rods, and at 15 months, the fracture was detected in all of the rods macroscopically. The dislodgement or loosening of the artificial discs was not observed in all operated segments. The histologic findings showed that fibrous tissue surrounded the rods and no specific inflammatory reaction such as foreign body giant cell or layer of histiocytes was detected in all sections. The average compressive strength at six months was statistically equivalent to preoperative level, however, it significantly decreased to 49.3% of 0 month value at 15 months (P<0.01) (Figure 1). The average compressive modulus was 9.28, 4.67, and 2.47 GPa at post-operative 0, 6, and 15 months, respectively. There were statistical differences among three groups (P<0.05). The VAMW of the rods decreased to 21.1% at 6 months when compared to 0 month, and reached 7.1% at 15 months (Figure 1). The average crystalinity increased from 49.6% to 62.2% at 6 months and reached 65.4% at 15 months. The SEM analysis revealed that the rod surface had become porous structure, increased from 49.6% to 62.2% at 6 months and reached 65.4% at 15 months. The VAMW of the rods decreased to 21.1% at 6 months when compared to 0 month value at 15 months (P<0.01) (Figure 1). The average compressive strength at six months was statistically equivalent to preoperative level, however, it significantly decreased to 49.3% of 0 month value at 15 months (P<0.01) (Figure 1). The average compressive modulus was 9.28, 4.67, and 2.47 GPa at post-operative 0, 6, and 15 months, respectively. There were statistical differences among three groups (P<0.05). The VAMW of the rods decreased to 21.1% at 6 months when compared to 0 month, and reached 7.1% at 15 months (Figure 1). The average crystalinity increased from 49.6% to 62.2% at 6 months and reached 65.4% at 15 months. The SEM analysis revealed that the rod surface had become porous structure, especially at 15 months.

DISCUSSION
The HA/PLLA composite has advantage that its initial bending strength is 270 MPa over that of human cortical bone. This material can be used where previous bioabsorbable implant does not sustain much stress. This study firstly applied bioabsorbable material to spinal fixation device. Over six months postoperatively, all of the rods did not break down, and no dislodgement or loosening of the artificial disc was detected. The implant provided the segmental stability over six months preserving initial shape and mechanical strength, and the absorption led a subsequent fracture of the implant by 15 months. This biodegradable behavior in spine will afford various benefits to the patients, such as no need of secondary removal, reduction of stress-shielding effect at the fixed segment, and the decrease of stress concentration at adjacent segment.

In the previous paper, PLLA alone lost its bending strength and molecular weight to 40% and 90% of initial value after 3 months in rabbit subcutis. On the other hand, in this study, the HA/PLLA composite successfully retained initial compressive strength and lost 78.9% of molecular weight after 6 months in sheep spine. Containing HA provides excellent degradation property for the PLLA implant, and segmental stabilization during six months in spine was achieved. Moreover, no foreign body reaction was detected in 15 months period. Although further investigation on implant design and biomechanics is required for clinical application, this preliminary study emphasizes that the HA/PLLA composite has a potential for spinal internal fixation device.

Figure 1. The change of compression strength and viscosity average molecular weight of the ultra-high strength HA/PLLA composite