• IN VIVO ANIMAL DEMONSTRATION OF SAFETY, STABILITY AND MOTION PRESERVATION OF AN ANNULUS SPARING LUMBAR DISC PROSTHESIS

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Introduction
Various lumbar disc prostheses are under investigation as alternatives to spinal fusion for chronic severe low back pain. First generation total disc replacements have potential for migration, are difficult to implant at L4-5, may result in neuropaxia due to overdistraction of the disc space, and may produce abnormal biomechanics with secondary facet syndrome. Nucleus replacements require an annulotomy and some may migrate, many erode the endplates, and others cannot be used in the presence of posterior annular tears. An alternative is an annulus sparing device which is implanted transosseously through the adjacent vertebral body. The device’s compressible nuclear component deforms to allow bending and axial compression. This in vivo study assessed device safety and stability in an animal model.

Methods
Four mature (2-3.5 year old, 250 to 300 Kg.) runt cows (Corrientes breed) had an annulus sparing prosthesis (Dynamic Spine, Inc.) implanted at L4-5 after IACUC approval. This animal model was chosen since prior studies have shown that the endplate sizes and in vivo axial loads are similar to human. Disc height and flexibility of the animal motion segment are comparable to that of the degenerated human case. The metallic device has 2 components; compressible components and fixation components which are modular and designed in a variety of sizes. Implantation entailed a lateral approach to L4, making a window in L4 vertebral body, and using specialized instruments to access and remove the nucleus via the L4 inferior endplate and thus avoiding manipulation or instrumentation of the disc annulus. The superior L5 endplate was prepared with a reamer. The compressible component was placed in the nucleus space and then the fixation component attached. For all animals, the compressible components were preloaded to approximately 100N via the extensible fixation component. Vertebral body bone obtained when making the window was replaced except for one (worse case) animal (Fig 1). There were no operative or post-operative complications. Lumbar spines were harvested, 2 each, at 4 and 6 months for gross and histological evaluation. Radiographs and fluoroscopic cine were also obtained.

Results
Implantation time was 2 hours, and maximum EBL < 200ml. Animals ambulated independently within 2-3 hour after surgery. All implants were stable with no dissociation of the device components, device migration, or subsidence. At 4 and 6 month explantation, histology found all vertebral body reconstructions were healed, there were no autofusions of the disc space, as well as, normal annulus, and normal adjacent discs (Fig 1). Additionally, bony ingrowth into the porous surfaces of the fixation components of the device was found for all specimens and varied from 20% to over 70% (Fig 2a, 2b). Manual flexibility testing confirmed retained motion through the reconstructed disc by intended deformation of the compressible element of the device (Fig 3a, 3b).

Discussion
This annulus sparing device, which also retains the ALL, may be safely implanted in a timely fashion. Since it is wholly within the spine, it cannot migrate and appears stable in both short- and intermediate-term in this animal study. Fixation seems to be reliable in this animal model which has similar in vivo loading as in humans. It retains intended motion of the reconstructed disc. The device stability and motion preservation may be predictive for future clinical trials and it has advantages that avoid short-comings related to purely total disc or nucleus replacements.

Figure 1. Low power histology of 16 week implant.
Figure 2a, High power of device upper plate to bone interface.
Figure 2b, High power of device lower plate to bone interface.
Fig. 3a, Right bend at 6 months. Fig. 3b, Left bend at 6 months.

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