

A Proof of Concept: Total Disc Replacement in Ex-vivo Beagle Model Using Tissue-engineered Intervertebral Discs Combined with a Bio-absorbable Stabilization System

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### Introduction

Total disc replacement using tissue-engineered intervertebral discs (TE-IVD) offers an alternative biological treatment option to traditional therapies for degenerative disc disease (DDD). The aim of this study was to investigate the biomechanical responses of composite TE-IVDs combined with a bio-resorbable stabilization system (BSS) undergoing static compression in an ex vivo model utilizing canine cervical spines.

### Methods

Cervical IVDs from skeletally mature beagles were obtained, washed in phosphate-buffered saline, and separated into AF and NP tissues by macroscopic appearance. Whole cervical spinal motion segments from skeletally mature beagles were dissected, and the mechanical compatibility was assessed for each motion segment at different time points: (1) intact, (2) after discectomy, (3) after implantation of the TE-IVD and (4) after implantation of the TE-IVD and application of the BSS ventrally. Unconfined stress relaxation tests were performed up to 15% strain and instantaneous modulus and equilibrium modulus were calculated for each segment. Oneway ANOVA was performed with significant differences being when p = 0.05 (\*).

## Results

Intact motion segments displayed a mean equilibrium modulus of  $174 \pm 36$  kPa and mean instantaneous modulus of  $1760 \pm 430$  kPa, which were significantly greater than the discectomy (Dx), TE-IVD implant without BSS (IVD -), and TE -IVD implant with BSS (IVD +) motion segments . Mechanical properties of the Dx motion segments were equal to  $14 \pm 6\%$  of the intact equilibrium modulus, and 13 + 4% of the intact instantaneous modulus. Mechanical testing revealed that equilibrium and instantaneous moduli of the BSS (IVD+) were twice as large as for motion segments with TE-IVD implants only (p= 0.05).

# Conclusions

The significant increase in mechanical properties of the motion segment supported with a bioabsorbable plate suggests that the BSS increases the stability of the TE-IVD construct and helps reduce implant displacement outside of the disc space.

## Learning Objectives

Current treatment options for symptomatic DDD are largely invasive and subject patients to rare but significant complications. Moreover, no surgical intervention, including interbody fusion or total disc replacement, address the underlying pathology contributing to degeneration. This study aims to develop an alternative, minimally-invasive treatment strategy by restoring disc biomechanics with implanted biomaterials and simultaneously inducing regeneration of disc tissue by biological manipulation. The biological replacement of degenerated discs may have a significant impact on our management of spinal disease.

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