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Background & Unmet Need

- Degenerative disc disease (DDD) is a condition in which the intravertebral discs (IVDs) in the spine degrade over time
- This degradation leads to nerve compression and chronic back pain
- DDD is widespread, affecting >90% of adults 50 years or older
- Surgical intervention for severe cases involves removing the entire IVD followed by fusion of the adjacent vertebrae or placement of a mechanical disc prosthesis to preserve motion
- However, fusion and disc replacement are associated with increased risk of pseudarthrosis and adjacent segment disease
- **Unmet Need:** An intervertebral disc implant that preserves a patient's spinal movement without the risk of developing complications or comorbidities

Technology Overview

- **The Technology:** Tissue-Engineered IVDs (TE-IVDs) combined with a bioresorbable stabilization system for improved treatment of DDD
- The bioresorbable support structure keeps the implant in place during the healing process but allows for segmental movement after the stabilization system dissolves
- **PoC Data:** In a canine model, the TE-IVD implants engrafted successfully and persisted in the spine for 16 weeks
- The TE-IVDs were stable and maintained disc height up to 70% of adjacent normal discs
- The TE-IVD implants did not generate a chronic immune response, supporting the use of allogeneic cells

Inventors: Roger Hartl Lawrence Bonassar Yu Moriguchi Gernot Lang Rodrigo Navarro-Ramirez

Patents:

US Patent <u>11,504,245</u> EP Application <u>3,583,213</u>

Publications:

Moriguchi et al. PLOS One. 2017.

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Cornell Reference: D-7728

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Technology Applications

 Treatment of degenerative disc disease in patients with severe back pain that doesn't respond to noninvasive approaches

Technology Advantages

- Replaces the entirety of the IVD utilizing viable tissues
- · Restores disc height and spinal flexibility
- Inclusion of a bioresorbable support system reduces
 the risk of implant displacement

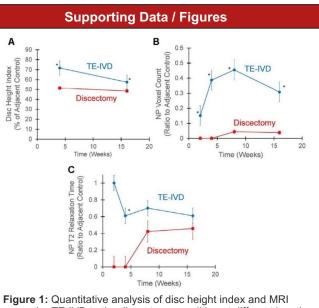


Figure 1: Quantitative analysis of disc height index and MRI Compares the TE-IVD to the discectomy condition at different lengths in time. Data demonstrates that the TE-IVD had greater height index, a higher NP Voxel Count, and a higher NP T2 Relaxation Time which indicates the implant was well hydrated within the body.

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