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Collagen Patch to Repair Intervertebral Disc Herniation and Degeneration (2015-050)

Helps Restore IVD Function and Alleviate Pain in Patients, Minimizing Healthcare Expenditures Associated with Re-operation and Spinal Fusion Surgeries

Market Overview

This collagen-based patch is a multi-laminate, ply-angle-ply sheet-based reinforcement used to biologically augment and facilitate repair of the annulus fibrosus (AF) of the intervertebral disc (IVD). Back pain is commonly associated with IVD pathologies including herniation and/or degeneration, resulting in structural defects within the AF. Nearly 500,000 lumbar discectomies are performed annually in the U.S. to aid in alleviating patient pain. During this procedure, a defect is created within the AF to remove herniated/degenerated nucleus pulposus (NP) tissue fragments. The resultant defect provides a path of least resistance for a reherniation to occur; resulting in costly reherniation operations (~$35k/re-operation) and eventually necessitates invasive spinal fusion surgery (~$115k/procedure). To date, no ideal biomaterial exists for AF repair. Clemson University researchers have developed a collagen-based, multi-laminate, cell friendly patch for AF repair using a simple and scalable process, resulting in a biomaterial that demonstrates biochemical and mechanical properties comparable to that of the native human AF tissue.

Application

Restoring IVD function

Stage of Development

Initial Large Animal Studies Complete

Advantages

- Mimics biological composition and mechanical strength of native AF tissue, allowing for tissue regeneration
- Reduces risk for re-herniation and implant migration, reducing costs associated with revision surgeries and need for spinal fusion procedures
- Produced via a simple, repeatable, and scalable batch process

Technical Summary

This biomaterial patch is used to effectively repair the AF of the intervertebral discs in the spine. It is composed of fully decellularized pig pericardium and is assembled in a manner which yields a multilaminate patch that has a ply-angle-ply architecture mimicking native human NP. Mechanical testing data suggest the AF patch behaves similar to the native human AF in both static and dynamic tensile loading conditions, providing instant mechanical strength following surgical implantation. Additionally, mechanical burst testing demonstrates the patch’s ability to withstand intradiscal pressures commonly observed. Cytocompatibility studies demonstrated the ability of the AF patch to support cell attachment and infiltration providing tissue regeneration capabilities.

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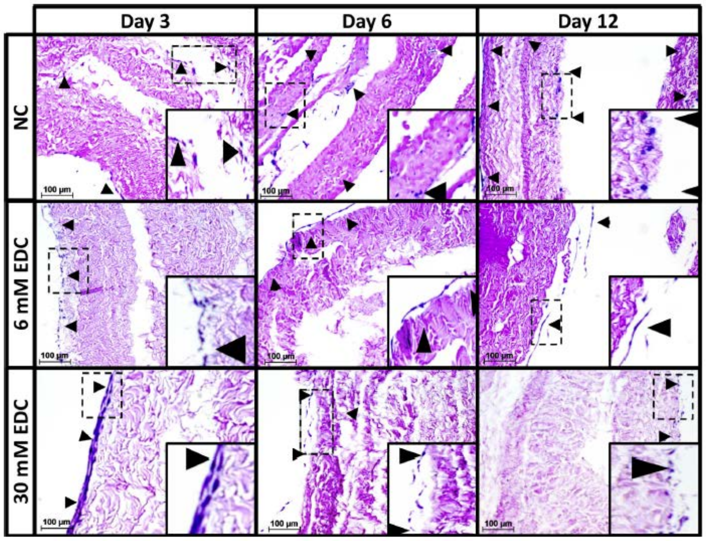

Figure 1: Cell infiltration in crosslinked AFRPS. Representative H&E images of non-crosslinked, 6mM EDC AFRPs following cell seeding. Crosslinked samples illustrate minimal cell infiltration into AFRPs in contrast to non-crosslinked samples at respective time points.

App Type	Country	Serial No.	Patent No.	CURF Ref. Number	Inventors
Provisional	United States	62/215,482	NA	2015-050	Jeremy Mercuri, Rachel McGuire, Ryan Borem, Sanjitpal Gill

About the Inventor

Dr. Jeremy Mercuri is an Assistant Professor of Bioengineering at Clemson University. Prior to joining Clemson, he was a senior research engineer at Stryker Orthobiologic and a research engineer at Medtronic Spinal & Biologics. Among his accomplishments, Dr. Mercuri holds two issued patents and has several applications in prosecution. He founded the Laboratory of Orthopaedic Tissue Regeneration and Orthobiologics at Clemson in August 2013 where he focuses on the development of regenerative medicine technologies. His research expertise lies in biomaterials development and the application of stem cells towards orthopaedic tissue engineering and regenerative medicine.

For More Information

To learn more about this technology, please submit an Inquiry Intake Form at:

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