

# Annulus Fibrosus Tissue Model Hydrogel Medical Device: Orthopedic



### Summary

An estimated 12 million people in the US suffer from degenerative disc disease. Recent therapies involve replacement of the nucleus pulposus (NP) with an artificial material using the existing vertebral endplates and annulus fibrosus (AF) as confinement for the implant. Testing these materials is difficult because of natural tissue variability and limited life. Existing silicone rubber approaches are inadequate because of their poorly matched mechanical properties. Leveraging our strong hydrogel and custom test design expertise, CPG has developed a more relevant composite structure that simplifies fatigue testing of these devices.

#### Description

The CPG AF analog has anisotropic properties and nonzero permeability to more closely model native AF tissue. Monofilament fibers coated in hydrogel solution are wound with an approximate  $30^{\circ}/60^{\circ}$  orientation into an annular ring. This fiber orientation mimics the lamellae in the natural AF and plays a large role in distribution of disc compressive load. The solution is then gelled around the fibers. The resultant AF is a composite fiber/hydrogel that is both permeable (due to ~50% water) and mechanically anisotropic, yet fully customizable. The mechanical properties of the AF can be optimized by adjusting the concentration in the gel solution, the gelation process, and the fiber characteristics.



CPG PVA/PVA AF

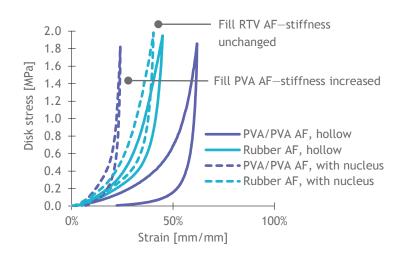


ASTM RUBBER AF



## Discussion

The compressive properties of the PVA/PVA AF were compared to the conventional ASTM rubber model in both a hollow and nucleus-filled configuration. No bowing or slipping was seen during the PVA/PVA AF compression testing; however, the rubber AFs exhibited bowing. The artificial NP approximates the mechanical properties of the native NP and translates the compressive load into a hoop stress within the PVA/PVA AF fibers.



## **Applications**

Improved model for bench top testing of nucleus pulposus replacements

ANALYTICAL TESTING BIOMEDICAL MATERIALS MATERIALS CONSULTATION RESEARCH & DEVELOPMENT



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 100 TradeCenter Drive, Suite 200, Woburn, Massachusetts 01801

 P: 617-629-4400 • F: 617-629-9100 • info@campoly.com • www.campoly.com

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