

Mechanical and Biomechanical Characterization of a Polyurethane Nucleus Replacement Device Injected and Cured In Situ Within a Balloon

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ABSTRACT

BACKGROUND

The DASCOR device has recently been introduced as an innovative nucleus replacement alternative for the treatment of low-back pain caused by degenerative intervertebral disc disease. The purpose of this study was to characterize, through a series of preclinical mechanical bench and biomechanical tests, the effectiveness of this device.

METHODS

A number of samples were created using similar preparation methods in order to characterize the nucleus replacement device in multiple mechanical bench tests, using ASTM-guided protocols, where appropriate. Mechanical bench testing included static testing to characterize the device's compressive, shear properties, and fatigue testing to determine the device's compressive fatigue strength, wear, and durability. Biomechanical testing, using human cadaveric lumbar spines, was also conducted to determine the ability of the device to restore multidirectional segmental flexibility and to determine its resulting endplate contact stress.

RESULTS

The static compressive and shear moduli of the nucleus replacement device were determined to be between 4.2–5.6 MPa and 1.4–1.9 MPa, respectively. Similarly, the ultimate compressive and shear strength were 12,400 N

and 6,993 N, respectively. The maximum axial compressive fatigue strength of the tested device that was able to withstand a runout without failure was determined to be approximately 3 MPa. The wear assessment determined that the device is durable and yielded minimal wear rates of 0.29mg/Mc. Finally, the biomechanical testing demonstrated that the device can restore the multidirectional segmental flexibility to a level seen in the intact condition while concurrently producing a uniform endplate contact stress.

CONCLUSIONS

The results of the present study provided a mechanical justification supporting the clinical use of the nucleus replacement device and also help explain and support the positive clinical results obtained from two European studies and one US pilot study.

CLINICAL RELEVANCE

Nucleus replacement devices are rapidly emerging to address specific conditions of degenerative disc disease. Preclinical testing of such devices is paramount in order to potentially ensure successful clinical outcomes post implantation

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