Comparison of the Pre- and Post-Fatigue Viscoelastic Properties of a Prosthetic Disc Nucleus

Allison C. Bain and Britt K. Norton
Raymedica, Inc., 9401 James Ave. S., Suite 120, Bloomington, MN 55431

INTRODUCTION

A prosthetic disc nucleus (PDN® Prosthetic Disc Nucleus, Raymedica, Inc., Bloomington, MN) has been designed to replace the degenerated lumbar intervertebral disc (IVD) nucleus, in order to restore the height and normal biomechanical behavior of the disc. The PDN device consists of a hydrogel pellet encased in a woven polyethylene jacket. The device is implanted in pairs in a dehydrated state in the nuclear space in the intervertebral disc (Figure 1). Over a period of 72 hours, the hydrogel swells through the absorption of 80% of its dry weight of water. The high water content in the hydrogel imparts viscoelastic properties to the device. Previous studies have shown that the viscoelastic properties of the PDN device are similar to those of the lumbar IVD[1]. However, IVDs in the spine are subjected to thousands of loading cycles every day. Therefore, a spinal implant must retain its biomechanical properties for several million cycles. In this investigation, we evaluated the viscoelastic properties of the PDN device after 20 million cycles of compressive load.

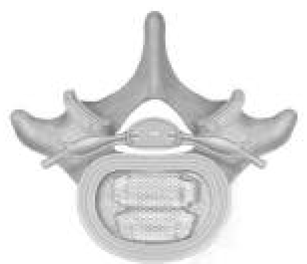

Figure 1: Schematic of a pair of devices implanted in the lumbar spine

METHODS

Six fully hydrated PDN devices - tested in pairs to replicate the in vivo condition - were subjected to a creep test, which consisted of a rapid ramp (100 mm/min) to 800 N, followed by a constant 800 N load for three hours. The devices were then placed in plastic bags with a small amount of fluid and subjected to 20 million cycles of compressive loading between 200-800 N at 4 Hz. The load levels were chosen to simulate in vivo loading conditions in the human lumbar spine. Immediately after the fatigue test, the devices were again tested in creep.

To quantify the viscoelasticity of the devices pre- and post-fatigue, the creep data was modeled with a three-parameter standard linear solid (Equation 1).

$$e(t) = \frac{s_o}{E_1}\left(1 - e^{-\frac{E_1 t}{h}}\right) + \frac{s_o}{E_2} \qquad \textbf{Equation 1}$$

The deformation of the devices recorded during the creep tests were converted to strain (ε) using the height of the device prior to the test. The applied constant stress (σ_o) in the devices was determined using the calculated surface area of the device pair. The elastic constants (E_1, E_2) and the viscous constant (η) that describe the viscoelastic behavior of the devices were determined using a least-squares regression procedure (KaleidaGraph, Synergy Software, Reading, PA).

RESULTS

The creep behavior of the PDN devices after fatigue testing was similar to that measured pre-fatigue (Figure 2). The pre-fatigued devices exhibited a nearly equal average initial strain (0.25 ± 0.03) as the devices post-fatigue (0.26 ± 0.02). However, the rate of deformation during the three hours of constant load was slightly greater for the devices pre-fatigue.

The three parameter linear solid model estimated the viscoelastic properties of the devices with very high correlation coefficients ($R^2 > 0.96$). The initial stiffness of the devices, represented by the stiffness constant E_2, did not change appreciably after fatigue (Figure 3). The model predicted that the long term deformation of the devices, which is dictated by the sum of both stiffness constants ($E_1 + E_2$), will be greater for the pre-fatigued devices. When combined with the increase in the constant E_1/η, predicted by the model for the fatigued devices, this information indicates that the post-fatigue devices will reach a steady state deformation level more quickly than the pre-fatigued devices.

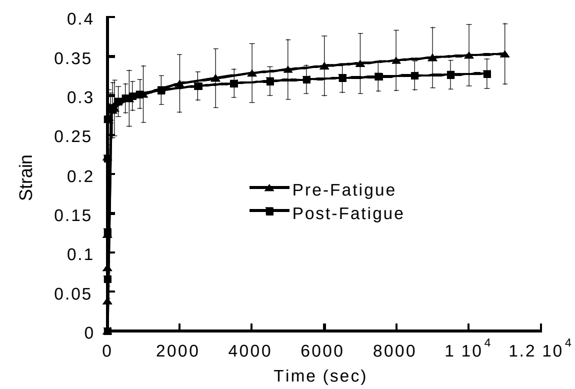

Figure 2: Average and standard deviation of the creep behavior of the devices exhibited pre- and post-fatigue.

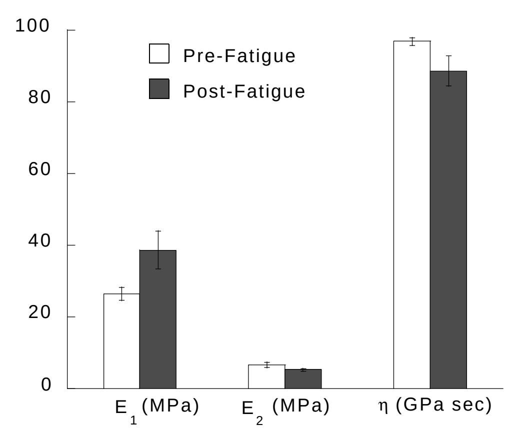

Figure 3: Comparison of the stiffness and viscous constants of the devices pre- and post-fatigue.

CONCLUSION

The long term creep behavior and viscoelastic properties of the PDN devices do not appear to be significantly affected by 20 million compressive fatigue cycles. When combined with previous comparisons to cadaveric motion segments, these results suggest that the PDN device is well suited to act as a long term replacement for a degenerated disc nucleus.

REFERENCES

1. Bain AC, Sherman T, Norton BK, Hutton WC. "A comparison between the viscoelastic properties of a prosthetic disc nucleus and the human intervertebral disc." IITS 13th Annual Meeting, Williamsburg VA, June 2000.

ACKNOWLEDGMENTS

This work was supported by Raymedica, Inc.