Nucleus Replacement with an *in situ* Curable Balloon Contained Polymer and Restoration of Segmental Kinematics

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INTRODUCTION: Disc height and annular pre-tension losses due to discectomy often impose altered segmental kinematics. These changes may further lead to segmental instability, which may not only accelerate the degenerative process and recurrence of pain, but may promote degeneration of adjacent levels as well. Ultimately, surgical treatment of such conditions often leads to fusion. The goal of nuclear replacement technologies is to restore physiological motion at the pathological level and prevent adjacent segment pathology while minimizing the annulotomy necessary for a total nucleus removal and effective implantation. The used Disc Arthroplasty System (DASCOR™) is a unique contained injectable nuclear replacement device. It is implanted into the nucleus cavity by injecting a custom formulated polymer under controlled pressure into a cavity conforming balloon through a small annular incision. The polymer cures in situ in a matter of minutes to a firm but pliable implant.

METHODS: To determine whether segmental kinematics of a lumbar motion segment having undergone a nucleotomy, can be restored with implantation of the device to those experienced by an intact motion segment we tested twelve human lumbar functional spine units (FSUs; age: 54±6yrs) in nondestructively compression (1200N), axial rotation (5.5Nm), flexion/extension (7.5Nm) and lateral bending (7.5Nm). Moments were combined with 500N compression. Each FSU was tested in three conditions: Intact, after nuclectomy and with an implanted device. Neutral zone (NZ), range of motion (ROM) and stiffness were obtained from load displacement curves and statistically compared between conditions using a repeated measures analysis of variance.

RESULTS: Compared to the intact state, nuclectomy significantly increased the NZ during all load modalities (Table 1, significant differences between conditions noted with an asterisk). Furthermore, nuclectomy increased ROM during all load modalities except lateral bending. Finally, nuclectomy increased stiffness only during flexion/extension and lateral bending. Implantation of the study device restored all kinematic parameters to near intact values.

Table 1. Segmental Kinematic Changes (%) with Respect to Intact

Load	*NZ*	*NZ*	*ROM*	*ROM*	*Stiff*	*Stiff*
	Nucl	*Impl*	*Nucl*	*Impl*	*Nucl*	*Impl*
Comp	*34*	*4*	*73**	*-8**	*-11**	*-2**
AR	*24*	*8*	*13**	*2**	*-4*	*-3*
F/E	*84**	*2**	*12**	*4**	*39**	*-8**
LB	*62**	*12**	*3*	*2*	*13**	*0**

DISCUSSION & CONCLUSIONS: The results of this study demonstrate that the study device is able to restore the segmental flexibility lost after a nucleotomy while still preserving segmental level biomechanics. The results of this study suggest that the device is biomechanically well suited to act as a long-term replacement for the degenerative nucleus pulposus.

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