BIOMECHANICAL EVALUATION OF EXPULSION FORCES FOR PAIRED AND SINGLE PROSTHETIC DISC NUCLEUS DEVICE DESIGNS

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INTRODUCTION

A prosthetic disc nucleus (PDN® device), consisting of a hydrogel core encased in a woven polyethylene jacket, has been developed as an alternative to fusion in the treatment of degenerative disc disease. The core of the device is dehydrated when implanted, and subsequently absorbs fluid and swells within the disc. Previous studies have reported the ability of the device to restore disc height and biomechanical function in vitro (Eysel 1999; Wilke 2001).

The PDN device was originally designed to be implanted in a paired configuration (Figure 1). A new single device design has recently been developed for use in smaller discs that cannot accommodate two devices. The objective of this study is to evaluate the likelihood of device expulsion from the intervertebral disc space for both the paired and single device designs.

METHODS

Twelve intact motion segments (L2–L3 and L4–L5) from six fresh frozen cadaveric lumbar spines (ages 33–69 years) were implanted with fully hydrated devices. For each spine, paired devices were implanted at one level and a single device was implanted at the other; levels were alternated with each successive spine to minimize the effect of implantation level on the results. Device models used were properly sized to the disc height.

The protocol for expulsion testing was similar to test methods employed for intervertebral body fusion devices (ASTM Standard 2077-00). An axial compressive preload of 500 N was applied to each implanted motion segment. A stainless steel wire threaded through the woven polyethylene jacket of the device was then used to pull the device out of the intervertebral disc space through a posterior opening in the anulus. The force required to pull the device out of the intervertebral space was applied (constant displacement rate of 1.27 mm/sec) and measured using a servo-hydraulic materials testing system.

RESULTS AND DISCUSSION

The maximum expulsion force for the paired devices ranged from 210 N to 316 N, with a mean maximum force of 251.0 N (± 47.2 N). The maximum expulsion force for the single device design ranged from 183 N to
541 N, with a mean maximum force of 364.5 N (± 119.1 N). In five of the six spines tested, the maximum expulsion force for the single device exceeded that of the paired device (Figure 2). When analyzed by motion segment, the mean maximum expulsion force for the single device was greater than that of the paired device at both lumbar levels, with the difference being more evident at L4–L5.

This study was designed to assess the propensity of a prosthetic disc nucleus device to migrate out of the intervertebral disc space. Although the standardized test method employed in this study does not necessarily recreate the mechanism responsible for expulsions seen in clinical use and cannot be used to predict the frequency of expulsion, it is able to reproduce the expulsion failure mode and provide an accurate, quantitative measurement of the forces required to extract a device from the disc cavity.

**SUMMARY**

Expulsion of both paired and single prosthetic disc nucleus devices was reproduced using a standardized test method. The single device design required an average of approximately 44% more force to remove than did the paired design, which was implanted at another level in the same spine. These data suggest that the single device is no more likely, and may be less likely, to migrate compared to the paired devices and are consistent with the migration complication rate reported for these two designs in clinical use.

**REFERENCES**
