A Novel Shear Expulsion Protocol for Evaluating the Holding Strength of Cervical Disc Arthroplasty Devices

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Introduction: The gold standard for determining the holding strength of keel or screw-retained interbody devices is to place the implant under a simple pull-out or distraction force. However, pull-out tests do not consider the effects of joint orientation, nor do they simulate complex internal shear and bending loads that lead to device expulsion. In the cervical spine, these loads are typically greatest during extension. A novel testing protocol was developed that simulated expulsion failure of a spinal implant device during extension. The objective was to compare the holding strength of a disc implant using two different testing methods: a novel shear-expulsion protocol and a traditional pull-out test.

Methods: Six human cadaveric cervical spines were dissected into 12 MSUs: six (C4-C5) and six (C6-C7) and instrumented with a screw-retained ball-trough device (Prestige ST, Medtronic). For the shear-expulsion tests, the specimens were mounted in a programmable testing apparatus in neutral alignment and rotated six degrees in extension about the center of rotation of the implant. A 20N compressive load was applied across the joint that engaged the superior ball component with the posterior aspect of the inferior trough component. The superior body was then translated backwards at a rate of 7.7mm/min along the 6 degree rotated plane of the implant until implant failure occurred. For the pull-out tests, a cable was passed underneath the anterior flange of the implant and distracted at a rate of 5.5 mm/min until the implant was unseated. Measurements included peak distraction force, overall resistance stiffness, and expulsion/pull-out work and compared with a t-test (p=0.05).

Results: The mean values of the peak force, resistive stiffness, and expulsion/pull-out work for the shear-expulsion and pull-out tests are shown in Figure 1. A significant difference occurred in the peak force and work required to fail the implant with the shear expulsion method compared to the traditional pull-out technique. There were no significant differences in the resistive stiffness values between the two testing methods. During the shear expulsion tests, 5 implants failed by collapse and expulsion of the superior component and one by subluxation of device. For the pull-out tests all disc components failed by distraction along the screw axis.

Conclusion: The shear-expulsion model applied a force through the center of the ball that induced an internal rotational moment on the implant which transferred to the vertebral body through the retaining screws, no longer placing them under tension. This complex loading scenario resulted in a bearing stress that crushed the screw into the bone (often leading to a windshield wiper effect). This methodology provides a more physiologic evaluation of the failure mechanism that occurs during extension and allows for better comparison of retaining features used in spinal implants (screws, keels, teeth).
[Figure 1: Comparison of Peak Force, Resistive Stiffness, and Expulsion/Pull-out Work]