In vitro Comparison of One and Two Level Posterior Dynamic Stabilization Device

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Background: Posterior dynamic stabilization devices have become of interest due to the potential for these implants, to internally support the spine. Ideally, dynamic lumbar implants should mitigate extraneous motion for the instrumented functional spinal unit (FSU) to prevent further degeneration of the pathologic FSU. The ability for the Stabilimax device to control the kinematic response and appropriate posterior load through the FSU should be fully characterized for both one and two-level constructs in order to understand the potential clinical implications of the device. This is particularly important because this class of devices has demonstrated disparate results between one and two-level constructs.

Methods: Six fresh frozen-human lumbar cadaveric specimens were stripped of all soft tissue excluding the osteoligamentous structures. Each specimen was subjected to pure moment flexion extension, lateral bending and axial torsion loading protocols with load limits equal to +/-7.5Nm in the intact condition, after destabilization, implantation with a one-level Stabilimax at L4-L5, a two-level Stabilimax extended to L5-S1 and a hybrid construct with rigid rod fixation at L5-S1. The motion of each vertebra was recorded during each test using an optoelectric motion tracking system (Optotrak, Waterloo Canada).

Results: Statistically significant differences were found in the flexion extension ROM between the Intact condition and all other treatments as well as between the Destabilized condition and all other treatments (p< 0.044). The lateral bending ROM was significantly less for the two-level Stabilimax compared to both the intact and one-level treatments (p=0.043 and 0.014 respectively). The destabilized, one-level and hybrid treatments resulted in significantly greater axial torsion ROM when compared to intact (p=0.016, 0.017, 0.049 respectively). At L4-L5 a superior shift in the Finite Helical Axis (FHA) was observed during flexion extension for the two-level condition compared to the intact (p=0.016), destabilized (p=0.013) and one-level (p=0.001) conditions. At L4-L5 during lateral bending, a statistically significant superior shift in the FHA was observed for the two-level condition with respect to destabilized (p=0.039). The same trend was observed compared to the intact condition, but the difference was not statistically significant based on the analysis conducted (p=0.055).

Implantation of the two-level device resulted in a statistically significant reduction in flexion extension and lateral bending ROM (p=0.04 and 0.025 respectively) compared to intact at the L5-S1 FSU. Implantation of the hybrid construct resulted in a significant decrease in lateral bending ROM as well (p=0.019). While the reduction in flexion extension ROM for the hybrid construct was not significant, it did show a trend toward significance (p=0.055).

Conclusions: The data presented indicate that the mechanics of the one and two-level Stabilimax may differ significantly, particularly in lateral bending. Furthermore, the FHA results indicate that implantation of the two-level system results in shifting the flexion extension center of rotation in the superior direction. A similar trend may exist in lateral bending. These findings may be attributed to the coupled design of the two-level device. Surprisingly, no argument can be made based on this ROM data that the two-level Stabilimax provides more motion than a rigid rod at L5-S1.