Translational and Rotational Response of a Keeled Total Disc Replacement After One-, Two-, and Three-Level Implantation

Mottole N,[1] Lanman T,[2] Cuellar J,[2] Wernke M,[1] Carruthers E,[1] Valdevit A.[1]
[1]SEA, Ltd., Columbus, OH; [2]Cedars-Sinai Spine Center, Los Angeles, CA
Email of Presenting Author: avaldevit@sealimited.com

Disclosures: Mottole N (N), Lanman T (N), Cuellar J (2, 3B), Wernke M (N), Carruthers E (N), Valdevit (5)

INTRODUCTION: The goal of cervical disc replacement (CDR) surgery is to restore the height of the disc space to remove the compression on the nerve roots surrounding the cervical spine. This procedure restores the ability of the spinal segment to undergo increased motion compared to the initial degenerated condition when loading is applied. The gold standard for alleviating symptoms has been anterior cervical discectomy and fusion (ACDF). However, common complications with fusion surgery involve the prevalence of adjacent segment disease (ASD). While motion associated with cervical disc arthroplasty has been studied, few investigations have documented the physical separation between the translational and rotational components associated with disc arthroplasty devices. Current in-vitro biomechanical literature is concentrated on the angular global motion of the spinal segment rather than the necessary translational motion of the intervertebral disc space required for total motion. The purpose of this study was to examine the effects of segment motion above, below, and at the surgical index level induced by a keeled artificial disc implantation with distinction between translational and rotational motion. The investigators hypothesized that single- and multi-level CDR offers similar or improved motion to that of the intact specimen.

METHODS: Seven human cervical spines (C2-C7, age range: 38 to 66 years) were secured in aluminum sleeves with resin. To acquire the motion data, 3D sensors (Micro Sensor 1.8™, Polhemus VIPER™) were affixed to the lateral aspect of C4, C5 and C6. Specimens were inserted into a testing fixture permitting flexion, extension, and lateral bending without disruption of specimen orientation and were subjected to cyclic loading (TA 3300, TA Instruments, Figure 1). A 3 mm deflection was applied to the central (index) vertebra at a rate of 0.1 Hz for 20 cycles in each loading mode with data collection at 60 frames/s. Testing conditions included the intact specimen followed by sequential implantation of a keeled CDR at the index (C5-C6), inferior (C6-C7), and superior (C4-C5) levels (Figure 2). The loading regimen described was repeated between implantations. Prothesis insertion was performed under fluoroscopic visualization by experienced spine surgeons. The resulting motion was then calculated from the X, Y, and Z directional components of the three sensors relative to each other and expressed as fraction of the intact specimen. Comparative changes to the intact specimen were computed using a 1 sample t-test (Intact = 1) within each loading mode. Significance was set at $P \leq 0.05$.

RESULTS: In flexion (Figure 3), compared to the intact specimens, all three vertebral levels displayed a significant increase in translation ($P<0.025$) with increased rotation distal to the index surgery ($P<0.035$). Continued implantations resulted in statistically increased translations at (C5-C6) with increased rotations at (C5-C6) and (C6-C7), ($P<0.036$). Superior implantation resulted in increased translation at the index level with increased but non-statistically significant rotations at all levels. Extension resulted in increased translations at index and distal segments ($P<0.022$) for one- and two-level surgeries. A three-level surgery only increased translation distal to the index level. Rotation was not different from intact in extension. Lateral bending displayed increased translations for the index ($P<0.017$, all segments) and two-level surgery ($P<0.025$, (C5-C6), (C4-C5)). No statistical differences were detected for a three-level implantation in either translation or rotation.

DISCUSSION: Implantation of this keeled total disc replacement device placed inferior, superior, and at index level increased, or retained the translation and rotation associated with the intact specimens. The study represents the physical separation of motion into the translational and rotational components manifested by a keeled cervical disc replacement. One-, two-, or three-levels of keeled device implantations resulted in increased and/or retained specimen motion relative to intact specimens. The results demonstrated that multi-level prosthesis implantation does not lead to detrimental motion but can also provide increased range of motion based on loading mode and insertion site.

SIGNIFICANCE/CLINICAL RELEVANCE: Comparing to clinical study involving up to 4 levels, investigators have found significantly improved outcomes from multi-level disc implantation compared to implantation at a single level. This clinical outcome has been substantiated in this study through use of 3D motion sensors that recorded the relative segmental motion in this study. The hypothesis that multi-level CDR does not unduly alter adjacent and may improve segmental motion was verified.

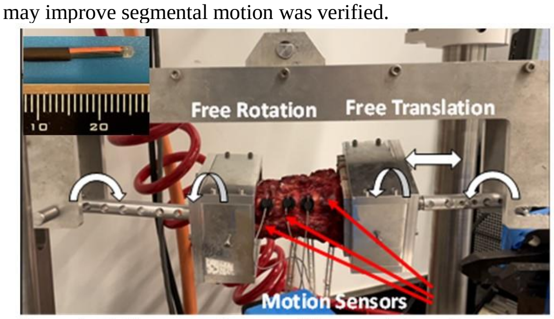

Figure 1. Testing apparatus permitting coupled motion during dominant loading in flexion, extension, and lateral bending for intact, one-, two, and three-level implantations with 3D motion sensors (Inset).

Figure 2. Testing was performed for Intact, Index (C5-C6), Inferior (C6-C7) and Superior (C4-C5) implantations using a keeled disc replacement.

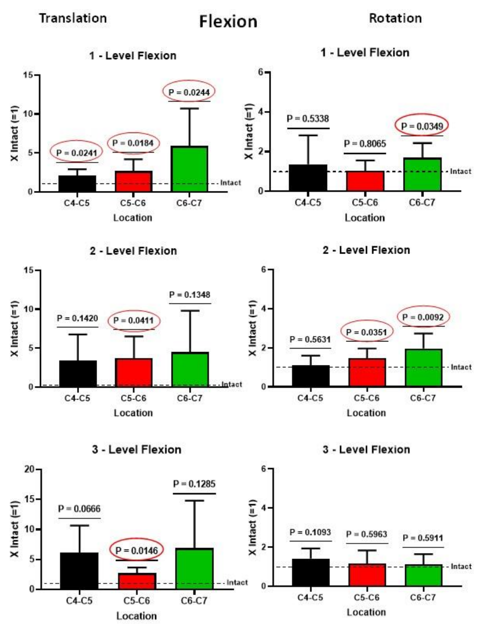

Figure 3. Cervical level response in flexion due to implantation indicating the separation of translations and rotations that constitute the implant motion response.