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Range of motion after 1, 2, and 3 level cervical disc arthroplasty

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ABSTRACT

Background: Motion of a solid body involves translation and rotation. Few investigations examine the isolated translational and rotational components associated with disc arthroplasty devices. This study investigates single- and multi-level cervical disc arthroplasty with respect to index and adjacent level range of motion. The investigators hypothesized that single- and multilevel cervical disc replacement will lead to comparable or improved motion at implanted and adjacent levels.

Methods: Seven human cervical spines from C2 to C7 were subjected to displacement-controlled loading in flexion, extension, and lateral bending under intact, 1-Level (C5–C6), 2-Level (C5–C6, C6–C7) and 3-Level (C5–C6, C6–C7, C4–C5) conditions. 3D motions sensors were mounted at C4, C5, and C6. Motion data for translations and rotations at each level for each surgical condition and loading mode were compared to intact conditions.

Results: 1-Level: The index surgery resulted in statistically increased translations in extension and lateral bending at all levels with statistically increased translation observed in flexion in the superior and inferior levels. In rotation, the index surgeries decreased rotation under flexion, with remaining levels not statistically different to intact conditions.

2-Level: A device placed inferiorly resulted in statistically increased translations at all levels in extension with statistically increased translations superior and inferior to the index level in flexion. Lateral bending resulted in increased nonsignificant translations. Rotations were elevated or comparable to the intact level for all loading.

3-Level: Translations were statistically increased for all levels in all loading modes while rotations were elevated or were comparable to the intact level for all loading modes and levels.

Conclusions: Micromotion sensors permitted monitoring and recording of small magnitude angulations and translations using a loading mechanism that did not over constrain cervical segmental motion. Multilevel cervical disc arthroplasty yielded comparable or increased overall motion at the index and adjacent levels compared to intact conditions.

Introduction

As an alternative treatment method for cervical disc pathology and associated pain, cervical disc arthroplasty (CDA) offers a nonfusion surgical option. Total disc replacement surgery has been indicated in patients with radiculopathy or myelopathy with at least one of; disc herniation or loss of disc height [1]. The goal of the surgery is to preserve motion following height restoration while mitigating adjacent segment pathology progression [2,3]. A meta-analysis comparing CDA to fusion with respect to adjacent segment surgery found that while short-term (2-year) results were comparable, the procedures displayed different outcomes at 7 years where fusion patients manifested increased adjacent segment operation with respect to those patients treated with CDA [4].

FDA device/drug status: Not applicable.

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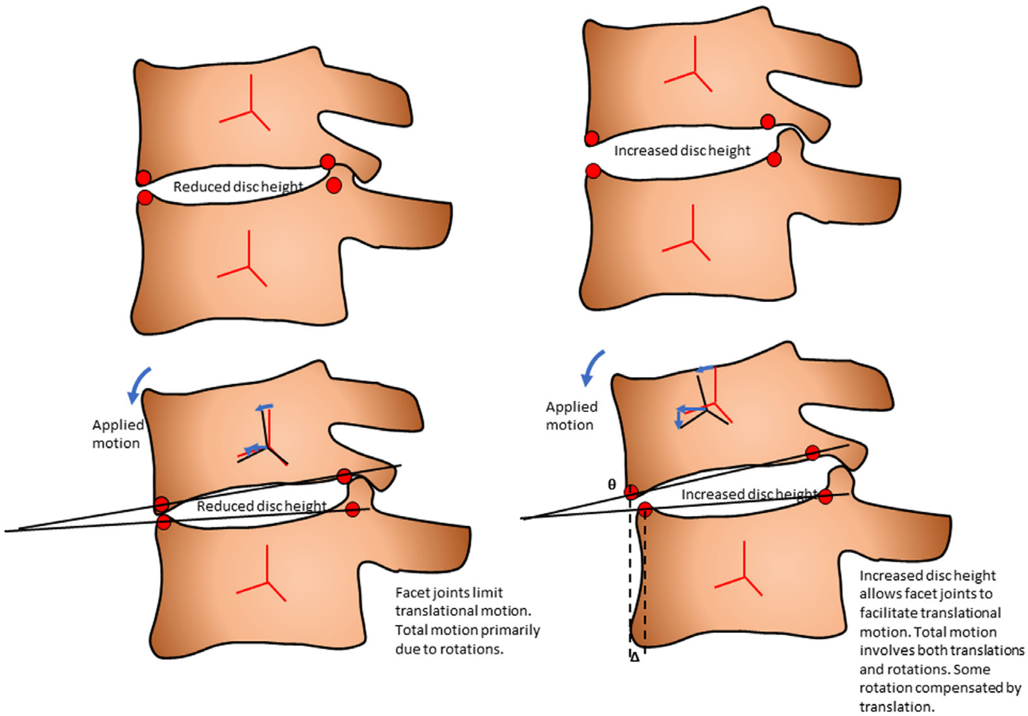

Fig. 1. Effects of disc height restoration to include both translation and rotation during loading.

At a 7-year follow-up of 209 patients, Janssen reported a secondary procedure rate for fusion patients at approximately twice that of CDA patients [5]. A literature review of CDA by Shin, et al., concluded that CDA preserved segmental motion and decreased the incidence of adjacent segment disease [6]. However, the authors do caution that CDA is not universally appropriate across all patients and that patient selection and proper technique are required for an effective alternative to fusion.

Motion tracking systems have been used in a variety of settings, including the monitoring of spinal motion during dynamic biomechanical testing [7–10]. Most commonly, an optoelectronic motion measurement system is used to measure the degree of motion in a specific area. The investigators of the current study used an electromagnetic motion capture system to collect data throughout the testing process. The major benefit of an electromagnetic motion capture system is high-resolution data collection without the need of a direct line of sight for the sensor to capture the data [11].

There is a paucity of literature regarding the translational components of the intervertebral segments during dynamic motion of the specimen. In contrast, there are numerous studies reporting the angular values of the index and segmental spinal levels associated with surgical interventions as compared to intact specimen response. Such an approach assumes that the vertebral centers of rotation remain fixed throughout the motion cycle. The spinal segment translates as well as rotates within the plane of applied loading [12,13]. In traversing the flexion-extension plane, the head translates anterior to posterior in addition to displaying angular rotations evident during nodding of the head. In the case of a pathologically collapsed intervertebral disc, the inclusion of an appropriately sized CDA device will increase the endplate separation distance between intervertebral levels and respective facet joints, thereby permitting increased motion [14].

Fig. 1 depicts the effects of a degenerated intervertebral disc subjected to flexion. The facet gap distance limits the angular Range of Motion (ROM) to the capabilities of the restraining soft tissues. Facet engagement limits the translation of the superior and inferior components and results in minimized intervertebral disc motion under an applied ROM. In contrast, restoration of the disc space elongates the restraining tissues and allows for an increased facet joint gap. The reporting of angular data as the sole measure of prosthesis performance may not be sufficient, especially in light of multilevel device insertions.

The current in-vitro biomechanical study aims to investigate the efficacy of single- and multilevel cervical disc arthroplasty and may be one of the few biomechanical investigations involving a 3-level intervention with respect to cervical arthroplasty. The goal is to quantify if there is an improvement to the motion of the cervical spine relative to the original degenerated intact condition. The investigators tested the hypothesis that single- and multilevel cervical disc replacement will offer similar or improved motion to that of the intact specimen. The investigators recorded the total translational and angular motion of the intervertebral disc space by means of 3D motion tracking to quantify the change in movement between the different loading modalities and implantation conditions.

Methods and methods

Seven human cervical spines from C2 to C7 (age range 56–79, 4 females, 3 males) were prepared by removing excess soft tissue and preserving the intervertebral spinous ligaments. The specimens were subjected to 20 continuous loading cycles to minimize hysteresis effects under flexion, extension, and lateral bending at a loading frequency of 0.1 Hz [15]. The testing configuration permitted orientation and loading of the specimen without removal from the testing apparatus (Fig. 2) [16,17]. The loading modes were obtained by rotating the specimen into the loading axis of the testing apparatus. The testing configuration permitted minimal constraint during loading as rotational and translational degrees of freedom were permitted. Such a configuration facilitates coupled kinematics by the specimen during loading [18,19].

Loading was performed in displacement control such that the central vertebra was subjected to a 3 mm displacement as recorded by the actuator of the testing frame (ELF3300, TA Instruments, New Castle, DE). Using the span distance between supports, this resulted in an angulation of 3 degrees per side for the embedded vertebral bodies in each loading mode [8]. Testing conditions included the intact specimen followed by sequential artificial disc implantations (prodisc-C (Vivo), Centinel Spine, West Chester, PA) by experienced spine surgeons at the index (C5–C6),

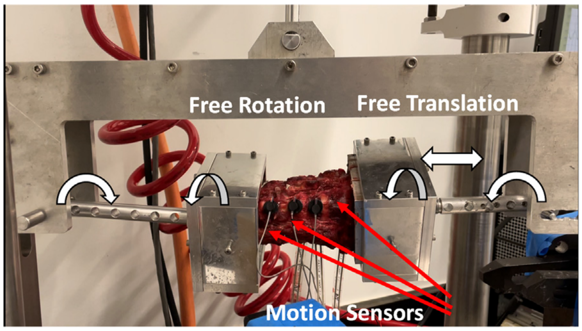

Fig. 2. Loading apparatus that permitted unconstrained flexion, extension, and lateral bending.

inferior (C6–C7), and superior (C4–C5) levels. All specimens displayed degenerated discs with reduced intervertebral disc height.

Specimens were subjected to the loading regimen under intact conditions followed by implantation of the total disc replacement at (C5–C6) which served as the index level. Sizing of all implants for insertion was based upon fluoroscopic imaging and direct visualization by board certified spine surgeons. In addition to resection of the posterior longitudinal ligament, the surgical technique employed for this study involves extensive uncovertebral joint resection bilaterally to decompress the neuro-foramen on both sides. The testing regimen was applied following subsequent implantations inferiorly at (C6–C7) and again superiorly at (C4–C5) (Fig. 3).

3D motion data was collected for each of the loading modalities and conditions. This was collected using the Polhemus VIPER (Polhemus, Colchester, VT) electromagnetic motion tracking system and Micro Sensor 1.8 (Polhemus, Colchester, VT) with static accuracy of 0.38 mm RMS (Fig. 4). Micro sensors were affixed on anterior side of the intervertebral discs at (C4–C5), (C5–C6), and (C6–C7) to monitor the motion of the intervertebral disc space prior to and following implantation of a cervical disc replacement. 3D data was acquired at 60 frames/s.

Theory/calculation

Range of motion was calculated by finding the range of the maximum and minimum coordinates associated with the final loading cycle. The magnitude was then calculated from the X, Y, and Z directional components to determine the translatory magnitude change in motion between intact versus 1-, 2-, and 3-Level implantations. With respect to rotations, 3D orthogonal angles were combined in the X (θ) -Y (φ) plane followed by subsequent addition of the Z (δ) axis angle.

$$\mathrm{X-Y\ plane\ }(\Delta):\ \Delta = 2\sin^{-1}\left(\frac{\sqrt{2}}{2}\sqrt{sin^2\left(\frac{\theta}{2}\right)+sin^2\left(\frac{\varphi}{2}\right)}\right)$$

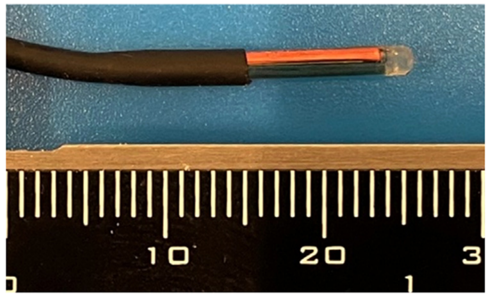

Fig. 4. 3D motion sensors.

$$\mathrm{X-Y-Z\ plane\ }(\Omega):\ \Omega = 2\sin^{-1}\left(\frac{\sqrt{2}}{2}\sqrt{sin^2\left(\frac{\Delta}{2}\right)+sin^2\left(\frac{\delta}{2}\right)}\right)$$

Motion data (rotation and translation) for the implanted specimens was expressed as fraction of the intact specimen and compared using 1 sample t-test (Intact = 1) for each loading mode using GraphPad Prism (Prism 9.4, GraphPad, San Diego, CA). Significance was set at p<.05.

Results

1-Level: C5–C6 Implantation (Fig. 5)

The index surgery resulted in statistically increased translations in extension and lateral bending at all levels (p<.0422 for all). While statistically increased translation was observed in flexion in the superior and inferior levels (p<.0278), increased but not significant translation was seen at the index level (p=.0883). With respect to rotational motion, implantation of the device at the index level resulted in decreased rotation under flexion (p=.0275). All other levels at the respective loading modes did not display a statistical difference compared to the intact condition (p>.0654).

2 Level: C5–C6 Implantation + C6–C7 Implantation (Fig. 6)

The inclusion of a device placed inferiorly at C6–C7 resulted in statistically increased translations at all levels when subjected to extension (p<.0115 for all). Flexion produced statistically increased translations superior and inferior to the index levels (p<.0301) but did not statistically increase translation at the index level (p=.0814). In lateral bending, increases in translation were observed but were not statistically significant (p>.0524 for all). Rotations were elevated or were comparable to, the intact level for all loading modes and were not statistically different from intact values (p>.1409 for all).

3 Level: C5-C6 Implantation + C6-C7 Implantation + C4-C5 Implantation (Fig. 7)

Translations were statistically increased for all levels in all loading modes with the implantation of devices inferior and superior to the index level (p<.0472 for all). Rotations were elevated or were comparable

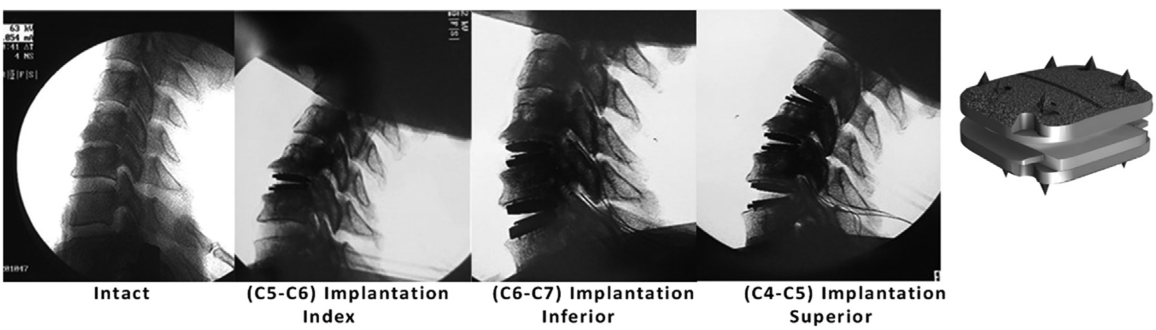

Fig. 3. Multiple level implantation of the disc replacement (Right).

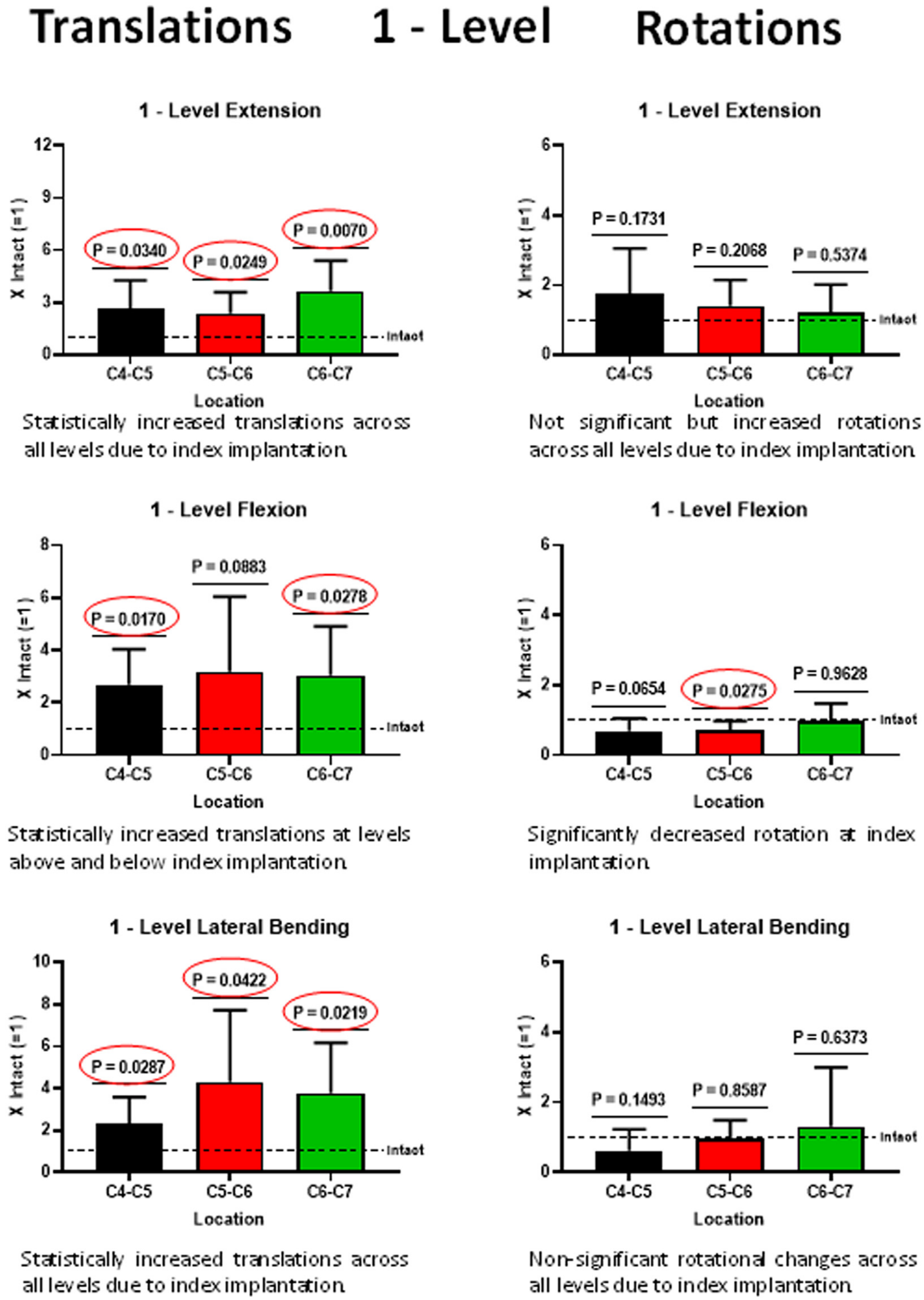

Fig. 5. Results of 1-Level implantations in flexion, extension, and lateral bending at the index, inferior and superior levels.

to, the intact level for all loading modes and were not statistically different from intact values (p>.1138 for all).

Discussion

CDA possesses several advantages over cervical fusion. The inclusion of an arthroplasty device provides a mechanism for retainment of motion and mitigates the likelihood of adjacent segment degeneration. These aspects are achieved through a combination of disc height restoration which reduces neurological involvement and replacement of pathologic or damaged tissues within the disc. [6,20,21] In the case of a degenerated intervertebral disc, there are several scenarios that contribute to reduced motion. The pathology of the intervertebral disc in isolation leads to stiffening of the disc annulus material which is manifested in a reduction of disc flexibility under applied loading.

Compounding the disc material stiffening are the surrounding soft tissue contributions to vertebral restraint. The loss of disc height through hydrostatic fluid and nucleus material loss is another manifestation of reduced motion. The decrease in disc space between adjacent vertebral bodies limits the available flexibility of the disc. Furthermore, the re-

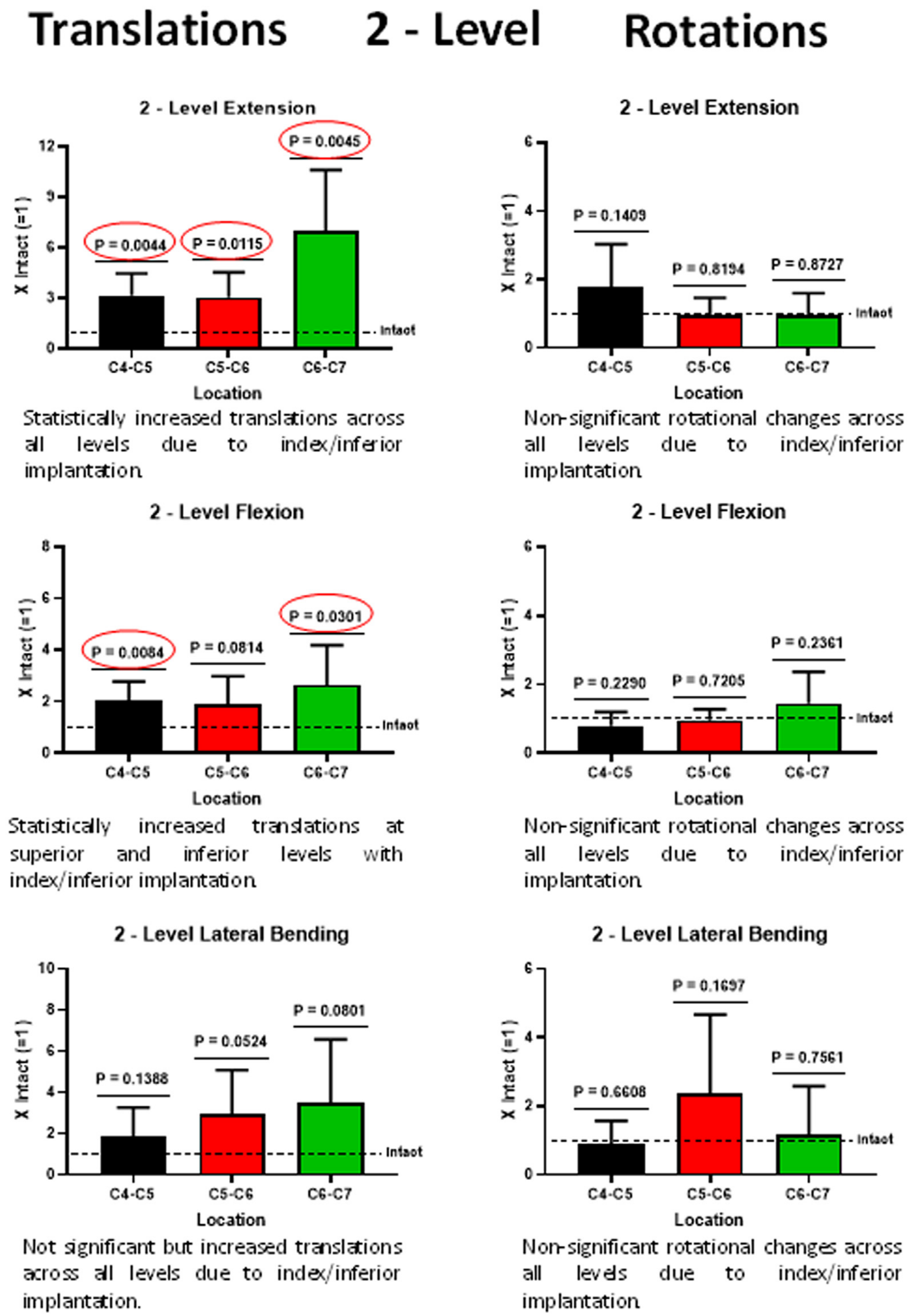

Fig. 6. Results of 2-Level implantations in flexion, extension, and lateral bending at the index, inferior and superior levels.

duction of the intervertebral space results in early engagement of facet joint contact during applied loading.

With the introduction of a CDA device, the disc space between the intervertebral bodies is increased. In this study, each interverbal level was implanted with a device height and footprint appropriate for the segment based on fluoroscopy. The result of insertion was an increase in disc space leading to delayed engagement of the corresponding facet joints. Such a geometric reconfiguration of the segment permits the retention of available rotation which is constrained by surrounding soft tissues but also allows for translational motion as the facet joints are engaged later in the loading cycle. This motion is analogous to femoral rotation relative to the tibia. The surrounding ligaments limit the available rotation, but translation of the femur relative to the tibia permits increased range of motion [22].

In this study, the use of CDA device resulted in increased motion primarily due to increases in translation while rotations were generally comparable to intact levels. Reports of increased motion generally report angular data. Furthermore, as was demonstrated in this study, other studies examining comparisons to preoperative levels with respect to rotational ROM revealed nonstatistical differences or marginal increases

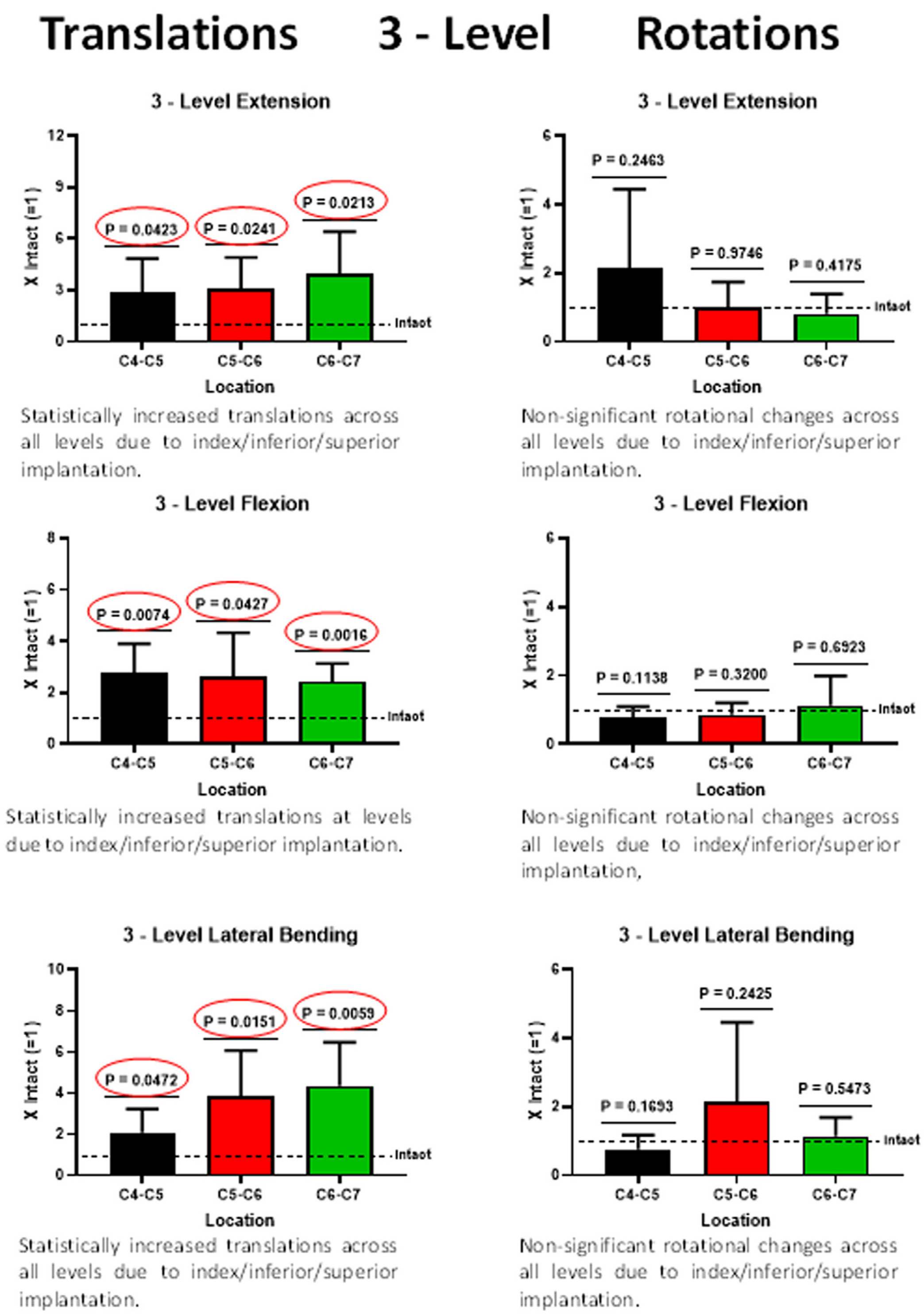

Fig. 7. Results of 3-Level implantations in flexion, extension, and lateral bending at the index, inferior and superior levels.

[9,23–25]. Lou, et al., examined the ROM from a fixed and mobile core device as compared to a fusion construct using optical markers. Only in the case of a fusion construct were statistical differences noted in ROM for the intact, mobile- and fixed-core CDR devices.

In comparing the CDR devices to the intact specimen, no statistical differences were noted for either total segment ROM or individual level ROM with respect to the measured rotations [7]. In examining a flexible core CDA device in 2-level constructs, Phillips, et al., reported increased flexion-extension ROM compared to intact (8.6±1.0)° versus (12.3±3.3)° for the index implantation. A second inferior implantation displayed ROM comparable to intact values in all loading modes [8].

While ROM is an important determinate parameter for CDA, examination of the resulting facet forces is essential. Zhao, et al., reported that the (C5–C6) implantation of a CDA device did not yield statistically significant differences with respect to intact ROM regardless of loading mode or segmental level. As well, a similar finding was observed with respect to facet joint forces [10]. It has been reported that the implant height selection is an important aspect in CDA. Insertion of a device that does not sufficiently restore the appropriate intervertebral disc space may not alleviate limitation in the segmental range of motion while continuing to subject the facet joints to undue compressive forces [26,27].

Conversely, insertion of a device that distracts the disc space can increase facet joint separation, thereby allowing for increase motion via a combination of rotation and translation. It should be noted that while the use of increased height devices increased intervertebral disc height, ensuring that the corresponding facet joints are not rotated into compression (as in extension) is important. Furthermore, the increased disc space may force the adjacent segments into unfavorable biomechanical loading. Wang, et al., reported the effects of increased device height on the (C5–C6) ROM. With increasing device height from 4 mm to 6 mm, ROM at the index level decreased. With decreased ROM, facet joint pressures increased [14]. This study emphasizes the need for proper height restoration. Excessive height will engage the surrounding soft tissues and hence limit free ROM.

Examination of translational motion is not common in the literature of CDA kinematics. One of the few studies examining in-vivo translations associated with CDA was conducted by Koller, et al. [28]. Postoperatively, index translation values in the sagittal plane ranged from (0.1 to 5.2) mm in flexion-extension, though this increase was not statistically significant. In the current study, translational motion was acquired. The translational components reported include the total translation magnitude from the X, Y, and Z directions of the motion sensor at each level under each loading mode and implantation condition. In this study, the 1-Level translational values across the segments ranged from (4.8 to 2.3) mm with respect to the segmental translation magnitudes in combined flexion and extension, respectively.

The effects of appropriately sized CDA devices within the intervertebral disc space can provide the needed gap distance within adjoining facet joints to permit the additional increases in translation while maintaining the appropriate rotational response [29]. That is, in the current study, the increased translational components did not force the rotational components into hyper-rotation. It is well known that the center of articulation during loading is not stagnant and can translate in response to the loading mode. While the device location may be fixed upon the endplate, the ROM can be adjusted through appropriate sizing and positioning.

Clinical relevance

Few investigations have documented the physical separation between the translational and rotational components associated with disc arthroplasty devices and under in vivo conditions [30,31]. 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 translation and rotation. The traditional reporting of arthroplasty device performance as a single angular quantity physically implies that vertebral motion occurs about a single point when bending loads are applied across a segment.

Clinically such a phenomenon is not observed. More realistic is that a disc replacement device results in a combination of both rotation and translation in various loading modes not only due to the device but to the remaining anatomical and ligamentous structures. Future motion studies associated with motion preserving devices should identify and isolate the rotational and translational components comprising the specimen motion due to device implantation.

Conclusions

This study addressed both the 3D total translatory and angular motions displayed by 1-, 2- and 3- Level CDA device implantations as compared to the intact spine. The use of micro-motion sensors permitted the monitoring and recording of small magnitude angulations and translations using a novel loading mechanism that did not unduly constrain cervical segmental motion in flexion, extension, and lateral bending. The effects of a CDA device insertion resulted comparable or increased overall motion at the index and adjacent levels. The continued insertion of devices inferiorly and superiorly to the index level displayed similar trends of improved or comparable total translatory and rotational motion as compared to the intact level.

Declaration of competing interest

Todd H. Lanman: Nothing to Disclose; Jason M. Cuellar: Consultant for Centinel Spine whose technology is examined in this manuscript; Nicole Mottole: Nothing to Disclose; Michael Wernke: Nothing to Disclose; Elizabeth Carruthers: Nothing to Disclose; Antonio Valdevit: Institutional Support as PI from Centinel Spine whose technology is examined in this manuscript.

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