Cervical Total Disc Arthroplasty Replicates Center of Rotation in Experimental Cadaveric Model

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INTRODUCTION: Cervical total disc arthroplasty (cTDA) has become a prominent alternative to anterior cervical discectomy and fusion (ACDF) for the treatment of degenerative disc disease, radiculopathy, and/or myelopathy. cTDA is thought to prevent adjacent segment disease compared to ACDF by preserving motion at the index level. Many designs of cTDA are available currently with different levels of constraint to promote and maintain stable range of motion. In this study, a mobile core cTDA was compared to the intact state in an experimental cadaveric study to measure the differences of cervical spine biomechanics.

METHODS: Ten cadaveric cervical spine specimens were harvested from five donors. The functional spine units (FSU's) at C3-C4 and C5-C6 were harvested from two donors, and C4-C5 and C6-C7 levels were harvested from three additional donors. Each FSU was prepared for biomechanical testing by removing all musculature and adipose tissue while preserving all ligamentous and connective tissue. The cranial and caudal ends of the FSU's were potted into polyester resin with wood screws used as reinforcement. Each specimen was tested in three cycles of flexion/extension up to 2 Nm using a servo-hydraulic uni-gimbal spine simulator (Bionix Spine Kinematics System, MTS Corporation). Range of motion analysis was performed using the data collected during the last cycle. The specimens were tested in the native or intact state. Then, a fellowship-trained surgeon, with more than 10 years of experience with cTDA, implanted a mobile core cTDA device (Mobi-C®, ZimVie Inc.). The cTDA intervention results were compared against the intact intervention of the same specimen, with the intact state acting as an internal control. An equivalence test was used by performing two one-sided paired t-tests to assess for statistical differences between the native and cTDA interventions in total flexion/extension ROM (p=0.05). Also, during the last cycle of testing, live fluoroscopic imaging was captured. The video was analyzed by Medical Metrics Inc. to evaluate vertebral body motion and calculate biomechanical motion metrics. Angular motion, superior vertebrae translation relative to the inferior vertebrae, and instantaneous center of rotation data were calculated approximately every 3 degrees during the loading regions of the flexion and extension curves. The translation was plotted against the angular rotation for all specimens, and a linear regression was performed to determine whether or not the slopes of the two interventions were significantly different from each other (p=0.05). Finally, the x-y coordinates of each center of rotation were plotted for both cTDA and intact interventions. A 95% equal-frequency elliptical region was calculated for each data set, and the ellipses were compared using a 95% binomial distribution to determine whether the cTDA population was significantly different from the intact "model" population (p=0.05).

RESULTS SECTION: No significant differences were seen in total flexion/extension ROM between the intact and cTDA interventions (p=0.075 and p=0.075). The pairing was found to be significant (p=0.003) with a correlation coefficient of 0.80. No significant differences were found between the slopes of the translation vs. angular motion regression lines for both data sets (p=0.11). The pooled slope of the data was 0.14 mm/deg or 7.0 deg/mm. When comparing the center of rotation datasets to each other, no significant differences were found (p=1.0). The 95% equal-frequency ellipse for the cTDA intervention lay completely within the 95% equal-frequency ellipse for the intact intervention.

DISCUSSION: The mobile core cTDA device was found to replicate cervical biomechanics of the healthy native spine in every test. The ROM of the cervical spine implanted with cTDA was found to be equivalent to the ROM of the intact healthy cervical spine. In addition, the translation of the superior vertebrae during rotation was not statistically significantly different than that of the intact healthy intervention, indicating that the cTDA produces a similar motion arc to the intact native condition. Finally, no significant differences were found between the centers of rotation between the two interventions. The introduction of the cTDA seemed to produce more stable constructs, with a tighter grouping of centers of rotation compared to the intact healthy state. These biomechanics results indicate that this mobile core cTDA design is able to restore healthy biomechanics to a degenerated cervical disc.

SIGNIFICANCE/CLINICAL RELEVANCE: cTDA devices aim to replicate healthy disc biomechanics, with greater replication of healthy metrics likely leading to better replication of healthy biomechanics. Benchtop cadaveric studies like this can be useful in measuring biomechanical metrics useful to understanding clinical experience without subjecting patients to undue clinical risk or radiation exposure. Although this is not an in-vivo clinical study of cTDA biomechanics, experimental human cadaveric biomechanics studies can be useful in measuring factors that would be difficult to impossible to measure in a clinical setting. For this reason, studies like this are valuable to better understanding spinal biomechanics.

IMAGES:

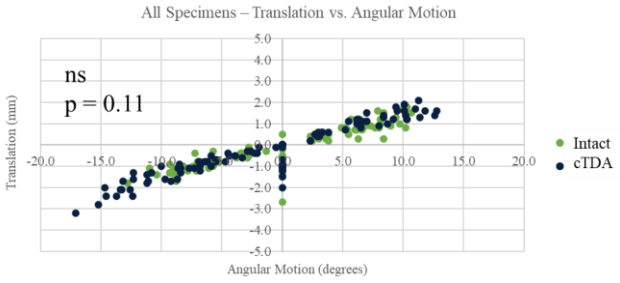

Figure 1: Scatter plot of translation vs. angular motion for all specimens. No significant difference was measured between the slopes for the intact and cTDA interventions.

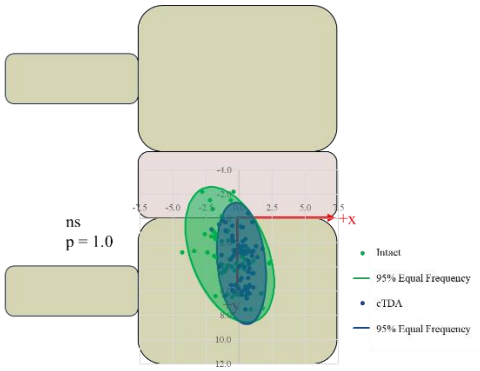

Figure 2: Scatter plot of center of rotation for both interventions with 95% equal-frequency ellipses for each dataset. No significant differences were measured between the two interventions, with the cTDA ellipse lying completely within the intact 95% ellipse.