Overstuffing a Total Disc Replacement Device Significantly Reduces Index Level and Total Range of Motion: A Biomechanical Study

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Introduction

Total disc replacement (TDR) is a popular treatment option for cervical disc degeneration.[1] One of the key benefits of this now well-established technology is the ability to replicate motion comparable to the natural state.[1,3,4,5] This is contrary to anterior cervical discectomy and fusion (ACDF) in which the motion segment is fused. TDR's ability to replicate motion of the natural spine maintains the natural stiffness of the cervical spine as opposed to ACDF, in which the stiffness of the spine is increased. Therefore, the risk for adjacent level disease is diminished with TDR compared to ACDF.[1,2,3,4,5]

However, some TDR devices have limited sizes, especially limited heights. Implanting a TDR device that is too tall may stiffen the joint, leading to a quasi-fused state, although this effect has not been physically tested. Therefore, the goal of this biomechanics study is to measure what effect "overstuffing", or implanting an inappropriately tall TDR device has on range of motion and loading of the cervical spine.

Methods

Eight cadaveric cervical spine specimens (C2-T1) were dissected and prepared for biomechanical testing. Each vertebra was instrumented with an optoelectronic marker for motion capture (Optotrak Certus Motion Capture System; Northern Digital Inc. Waterloo, ON, Canada). All specimens were first tested in two interventions: intact or native, followed by implantation of the Mobi-C (Highridge Medical, Westminster, CO) TDR at both C4-C5 and C5-C6. The third intervention involved "overstuffing", replacing an appropriately sized Mobi-C device for another Mobi-C device with the identical footprint but 1 mm taller core (e.g. replacing a 13x15 H5 Mobi-C with a 13x15 H6 Mobi-C). The overstuffing was performed at C4-C5 for four of the eight specimens and at C5-C6 for the remaining four specimens (Figure 1). Mobi-C disc sizes and heights were recorded for all interventions.

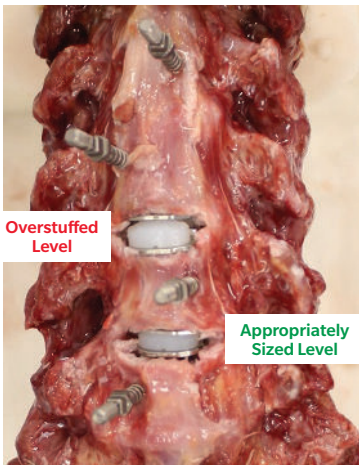

Fig. 1 *Specimen with overstuffed level.*

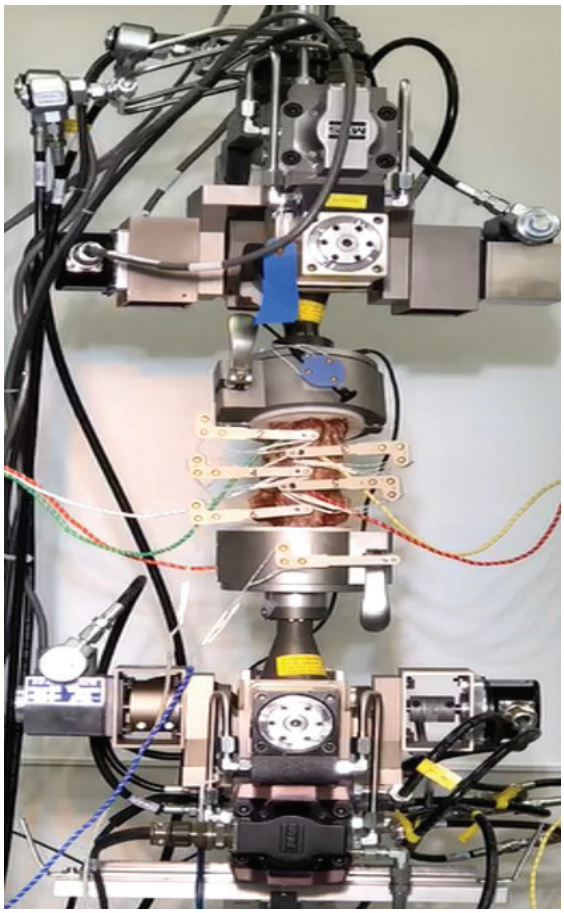

Fig. 2 *Spine simulator*

The specimens were tested following each intervention using a 6 degree of freedom servo-hydraulic spinal simulator (Figure 2: Bionix Spine Kinematics System, MTS Corporation, Eden Prairie, MN, USA) in 3 cycles of pure-moment flexion/extension (Figures 3 and 4) up to 2 Nm.

The maximum range of motion (ROM) for the entire specimen and individual levels was calculated during the third loading cycle of each test. In addition, the maximum total ROM for each specimen in the native condition was recorded and used as a target to determine deficits in total ROM at the second and third interventions.

A logarithmic curve was fit to the elastic zone of the total rotation vs. moment curve for both flexion and extension of the second and third interventions; the amount of additional moment needed to compensate for the deficiency in ROM between the intervention of interest and the native state was recorded. Finally, additional moment was applied to the levels adjacent to the index levels to determine what increase in motion could be expected using the same logarithmic fitting technique previously described. However, the ROM at which the moment was achieved was recorded, rather than finding the moment at which the target ROM would be reached.

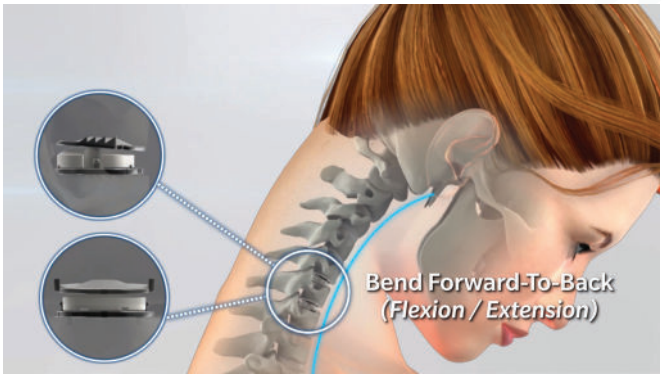

Fig. 3

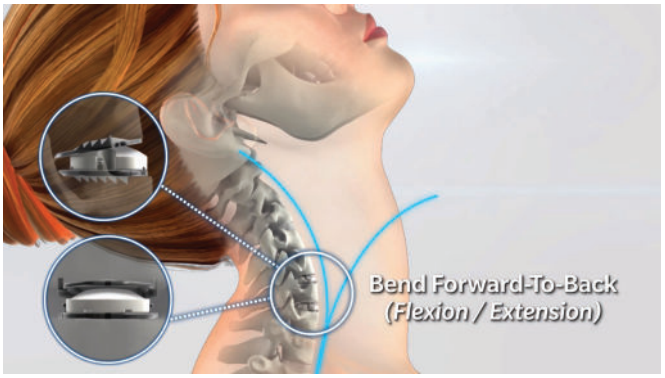

Fig. 4

Quality of motion was also assessed for each intervention. A logarithmic curve was fit to the flexion and extension curves for the index levels of each specimen at each intervention. From these curves, an average flexion and extension curve was calculated for each intervention.

To assess for significance differences between groups vs. interventions, a two-way ANOVA with one-way repeated measures was performed. If the effect of group and interaction of group and intervention were found to be insignificant for the value of interest, the groups were combined, a Shapiro-Wilk test was performed to assess normality, and the appropriate (either parametric or non-parametric) one-way repeated measures ANOVA was performed to assess for statistical significance ($p<.05$).

Results

For all eight C4-C5 levels tested, a H5 disc was implanted initially. For the C5-C6 levels, a H5 disc was implanted initially in five of the eight levels, with the remaining levels receiving a H6 disc. For the overstuffing intervention, all four C4-C5 levels received a H6 disc, while at C5-C6, two of the four received an H6 and two received a H7.

For total ROM, both groups were combined, as the effects of group and interaction of factors were found to be insignificant. Across all specimens, the overstuffed intervention significantly decreased total ROM compared to the Intact and 2-level Mobi-C interventions, with overstuffing decreasing ROM by 15% compared to the native state. No significant difference was found between the native and 2-level Mobi-C interventions (Figure 5).

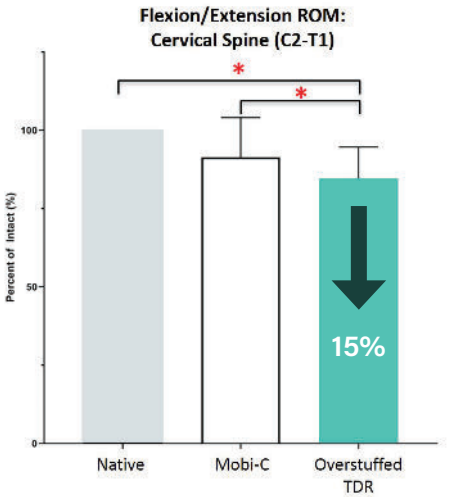

Fig. 5

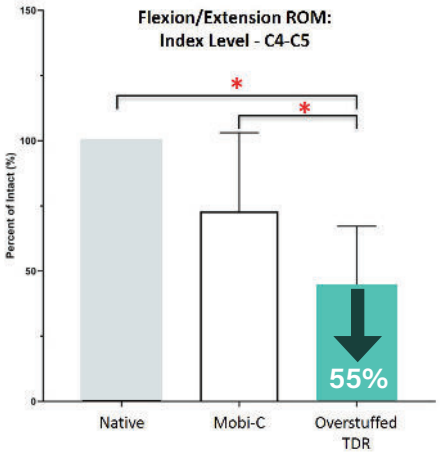

Fig. 6

At the index levels, the overstuffed disc significantly decreased ROM at both C4-C5 and C5-C6 by 55% and 53% respectively compared to the intact state (Figures 6 and 7). Due to the significant drop in total ROM due to overstuffing, a significant increase in compensatory moment was measured between the overstuffed disc intervention and the 2-level Mobi-C intervention. In addition, significant increases in compensatory ROM were seen at both adjacent levels, C3-C4 (h10%) and C6-C7 (h11%), compared to both the native state and the 2-level Mobi-C intervention (Figures 8 and 9).

Comparable quality of motion was found between the intact condition and the 2-level Mobi-C intervention. The 2-level Mobi-C intervention demonstrated progressive resistance to rotation, similar to the intact condition. An example of this is shown in Figure 10.

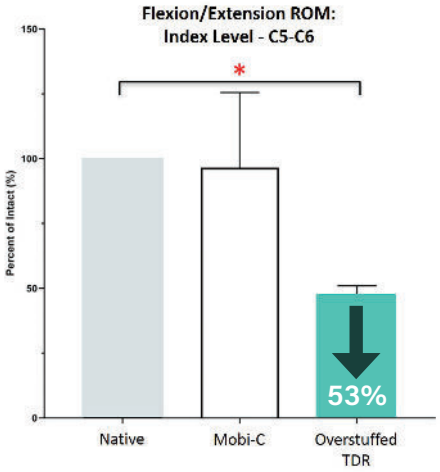

Fig. 7

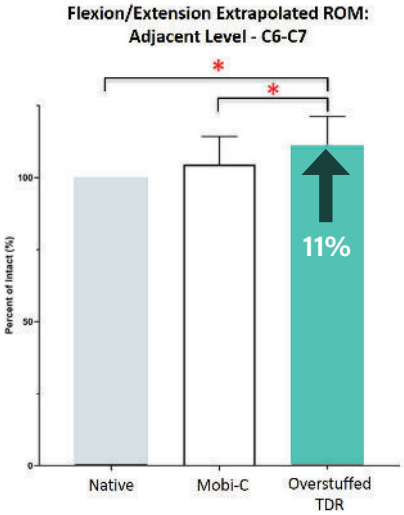

Fig. 9

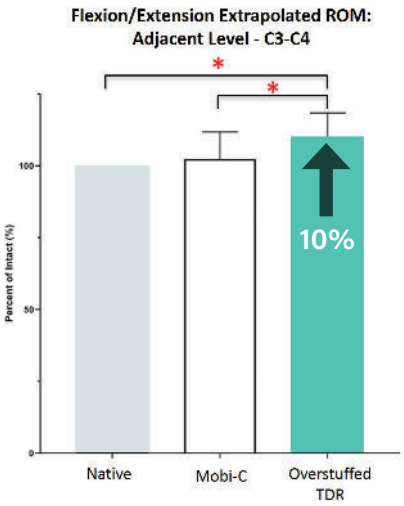

Fig. 8

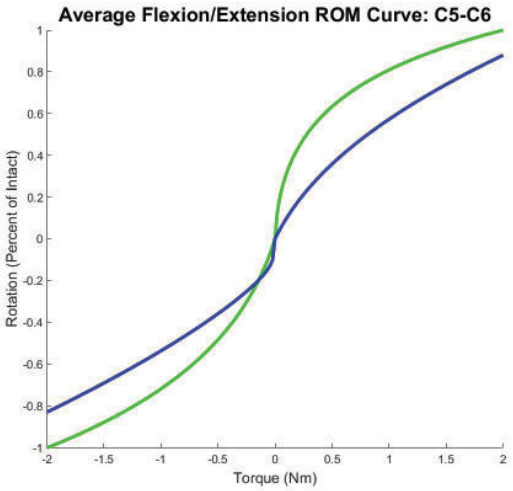

Fig. 10

DISCUSSION AND CONCLUSIONS

Introduction of the Mobi-C device replicated flexion/extension ROM well, with no significant differences detected between the native state and the 2-level Mobi-C intervention for the entire cervical spine ROM, ROM at both index levels, C4-C5 and C5-C6, and ROM at both adjacent levels, C3-C4 and C6-C7. In addition, no significant increase in compensatory moment was seen between the 2-level Mobi-C and the intact states. Finally, quality, not just quantity, of motion was preserved, complete with progressive resistance to rotation, between the intact and 2-level Mobi-C conditions.

However, overstuffing the TDR device by just 1 mm stiffened the spine, leading to a significant 15% drop in ROM for the total specimen compared to the native state. At the index level, overstuffing effectively created a quasi fusion; ROM at C4-C5 and C5-C6 significantly decreased by 55% and 53% respectively with the introduction of the overstuffed disc. For 100% of the C4-C5 levels and 50% of the C5-C6 levels tested, this significant drop in ROM was caused by a 6 mm height disc. Overstuffing also led to increased compensatory motion at the adjacent levels C3-C4 and C6-C7. In summary, implantation of appropriate height TDR devices is important to maintain physiologic motion, and 5 mm height often is the best option.

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