INTRODUCTION:

Historically, treatments of cervical pathologies requiring surgical intervention have been concerned with preserving and restoring the neurologic function of afflicted spinal units. The advent of fixation implants, e.g., anterior cervical plates (ACP’s), has promoted anterior cervical decompression and fusion procedures. Additionally, these products, allow patients to rapidly return to normal activity through immediate stabilization and fixation. With fusion treatments, the long term goal remains arthrodesis which ultimately obsoletes the fixation hardware.

Traditional methods of comparing fusion treatments have utilized load control algorithms and pure moment testing has been a common protocol used in applying consistent amounts of torque at each level. Fixation technologies have been subjected to comparisons performed under these flexibility test protocols. As motion preservation technologies continue to evolve, methods of characterizing the performance require additional parameters. Considerations, including new test protocols, would facilitate the understanding of these technologies.

Preliminary studies have suggested detecting adjacent level effects may be more apparent under hybrid testing. Such hybrid test protocols require the intact displacement be measured in load control and subsequent spine treatments to utilize this displacement parameter to define limits for the displacement control testing. The objective of this study was to determine the treated level and adjacent level kinematic response under a hybrid test protocol.

METHODS:

Six fresh frozen human cadaveric cervical specimens were harvested and stored in a -20°C freezer. The extraneous tissue from each spine was removed except for the osteoligamentous structures.

Initially, the flexion extension protocol was loaded to ±2.5Nm under a standard pure moment bending load control protocol for both the superior and inferior motors. Both the superior and inferior motor displacements for each cervical spine were recorded for the third cycle. In addition, the instrumented level C5-C6 FSU kinematic response expressed in terms of range of motion (ROM) along with the adjacent level C4-C5 kinematic response was tracked via an optoelectronic system capable of submillimeter accuracy. With independent control of the counter acting flexion extension motors, the superior and inferior motor’s angular displacement were independently programmed and the spines were then tested in displacement control. Following the intact treatment, each spine was subjected to implantation at the index level with an appropriately sized Discovery cervical disc (DePuy Spine, Raynham, MA) as shown in Figure 1.

RESULTS:

The mean intact ROM for the C5-C6 level was 7.30°±1.69° (mean±std dev). Under the same conditions, the mean intact ROM for C4-C5 was 7.83°±3.31°. The mean ROM for C5-C6 with the implanted disc resulted in a mean response of 8.41°±3.49°. The mean ROM for the adjacent C4-C5 with a disc implanted at C5-C6 was 7.09°±2.65° again in displacement control. Figure 2 is a graphical comparison of the ROM for each treatment along with the standard deviation.

The results of the statistical analysis suggest the mean ROM in flexion extension was statistically no different for one level disc treatment at the index level when compared to the ROM of the intact control (C5-C6 p=0.921). In addition, the mean ROM in flexion extension was statistically no different for one level disc treatments at the adjacent level (C4-C5 p=0.943).

DISCUSSION:

Biomechanically, motion preservation devices of the cervical spine are clinically optimized when the device provides sufficient stability to the instrumented FSU while maintaining some degree of motion for a given FSU. Methods for evaluating cervical motion devices continually evolve with more physiologic test protocols. Recently, several descriptions of hybrid testing have been reported in the literature and may capture the adjacent level effects under more clinically relevant test protocols. Such test protocols attempt to predict clinically relevant conditions associated with normal daily activity based on achieving certain postures, e.g., dressing or lifting.

Thus, hybrid test protocols characterize the intact spine and determine the effects of surgical implants on the treated FSU in achieving the same displacement. The kinematic response is an important parameter in flexibility testing and may be equally important in hybrid testing. With flexibility studies, the design goal of fixation treatments is to reduce ROM. However, motion preservation devices have different design intent and require additional physiologic test protocols and comparison metrics. Hybrid testing would appear to be a means to this end.

The mean ROM for the DePuy Discovery cervical disc in a single level was statistically no different compared to the intact spine in the tested protocol. With the hybrid test protocol, adjacent level effects were also considered. The effects of motion preservation implants at both the index level and adjacent levels were quantified in this hybrid study. In conclusion, the biomechanical results of DePuy Discovery disc warrants further investigation for optimal patient outcomes.

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References:

Figure 1. 7mm Discovery cervical disc used in the hybrid test protocol.

Figure 2. Flexion extension ROM for index and adjacent levels.