Introduction

Total disc replacement is intended to treat low back pain secondary to degenerative disc disease, a common, disabling medical condition. Replacement of a diseased intervertebral disc with a joint replacement serves to restore the disc height and reestablish normal motion and stability at the affected spinal segment. Maintaining normal motion and load distribution in unaffected adjacent levels prevents further degeneration, making disc replacement an attractive alternative to fusion surgery, which has a high rate of recurrent pain and complications and often leads to the need for further surgery.1

In this study, we compared the range-of-motion (ROM) of the lumbar spine before and after implantation of an intervertebral disc prosthesis in a human cadaver model. The ROM in flexion/extension, lateral bending and torsion was measured first in intact specimens and then with specimens implanted with the Prodisc II intervertebral disc prosthesis (Spine Solutions, Inc., NY, NY) (Fig. 1) in the L5-S1 motion segment.

Methods

Six human fresh frozen L1-S1 spine segments (age/gender 65M, 65M, 65F, 49M, 53M, 44M) were thawed and dissected free of all soft tissue except for ligamentous structures. Following radiographic evaluation, the L5 vertebra and the sacrum were potted in epoxy, and the exposed portion of the segment wrapped in saline soaked gauze. The potting orientation was such that, in the intact spine, the posterior edge of the L3 vertebral body was aligned with the center of the potting. This was achieved by potting the sacrum with the spine intact up to the L3 vertebra so as to use it as an alignment guide. The L3-L4 segment was then disarticulated from the L5-S1 segment and the L5 vertebra potted.

The potted specimens were placed in a 6 degree of freedom spine testing apparatus coupled to an MTS biaxial load frame (Fig. 2). The apparatus allows for the application of a pure bending moment, enabling the specimen to travel freely in all other directions. A 1200 N compressive joint load was applied to seat the specimen in the apparatus. After seating, the intact specimens were then cycled in torque control to a maximum of ±10 Nm in three axes of rotation, flexion/extension, lateral bending and torsion with both 600 N and 1200 N compressive loads. These compressive loads approximate sitting and lifting loads, respectively.2 For each test the specimens were loaded cyclically for 5 cycles, and the ROM at 8Nm after the 5th cycle of loading was documented. After the intact testing, each specimen was removed from the load frame, and the Prodisc II device was implanted.

Implantation was performed under fluoroscopic control simulating the recommended surgical procedure. All surgeries were performed by a single surgeon with assistance from a second surgeon. The implanted specimens were then tested using the same protocol as the intact.

Statistical Analysis

ROM measurements were analyzed by repeated-measures analysis of variance to examine the effects of two factors: implant condition (intact, post-implant) and compressive load (600N, 1200N). Both main effects and interactions were evaluated. The alpha level (significance level) was set at 0.05.

Results

Results were obtained on 5 of the 6 specimens (Table 1): testing was aborted for specimen #3 after the first three tests because the ligamentous structure ruptured.

Based on the analysis of variance, the presence of the prosthesis did not significantly affect ROM in any of the three directions (flexion/extension, p=0.19; lateral bending, p=0.07; external rotation, p=0.31). Increasing the compressive load reduced ROM in axial rotation (p=0.007) but not in flexion/extension (p=0.08) or in lateral bending (p=0.06). The interaction term between implant and compressive load was not significant for any of the three directions (flexion/extension, p=0.94; lateral bending, p=0.27; axial rotation, p=0.29).

Discussion

No significant difference in ROM before and after implantation was found although with more samples, the increase in lateral bending in the implanted specimens might have achieved statistical significance. The reduced ROM with increasing load was statistically significant for axial rotation; again, with more samples, the reduction in motion might have reached statistical significance for flexion/extension and lateral bending. No interaction was found between implant condition and compressive load (the implant behaved similarly under both loading conditions).

The average ROM data of the implanted spines are similar to data reported by Panjabi, et al. for the L5-S1 level in the normal spine.3 They reported ROM of approximately 14 degrees in flexion/extension as compared to 3 degrees post-implanted, 8 degrees lateral bending as compared to 7 degrees post-implanted, and 2 degrees axial rotation as compared to 2 degrees post-implanted, though they applied a lower compressive load (100N) to slightly younger specimens (mean age of 51 versus 55 years for our study).

In conclusion, implantation of the Prodisc II prosthesis did not significantly affect ROM of the L5-S1 segment in a study using five human spines. The mean ROM values of the implanted spines matched values in the literature.

Acknowledgments

This study was supported by Spine Solutions, Inc.

References


49th Annual Meeting of the Orthopaedic Research Society
Poster #1153