Dynamics of an Intervertebral Disc Prosthesis in Human Cadaveric Spines

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Abstract Low-back pain is a common, disabling medical condition, and one of the major causes is disc degeneration. Total disc replacements are intended to treat back pain by restoring disc height and re-establishing functional motion and stability at the index level. The objective of this study was to determine the effect on range of motion (ROM) and stiffness after implantation of the ProDisc[®]-L device in comparison to the intact state. Twelve L5–S1 lumbar spine segments were tested in flexion/extension, lateral bending, and axial rotation with axial compressive loads of 600 N and 1,200 N. Specimens were tested in the intact state and after implantation with the ProDisc[®]-L device. ROM was not significantly different in the implanted spines when compared to their intact state in flexion/extension and axial rotation but increased in lateral bending. Increased compressive load did not affect ROM in flexion/extension or axial rotation but did result in decreased ROM in lateral bending and increased stiffness in both intact and implanted spine segments. The ProDisc[®]-L successfully restored or maintained normal spine segment motion.

Key words total disc replacement · biomechanics · lumbar spine · ProDisc[®]-L

Introduction

Back pain is the second most common medical complaint, after the common cold, and is the most common reason for job-related disability [1]. Degenerative disc disease (DDD) is one of the most frequent causes of persistent disabling low-back pain. Although there is no standard definition of DDD, which may be post-traumatic or a natural consequence of the aging process, it begins with subtle anatomic and biochemical alterations within the disc and is ultimately characterized by disc dehydration, disc space narrowing, endplate irregularities, formation of osteophytes, annular cracks or tears, and possible herniation. There have been numerous epidemiologic studies on disc degeneration, and the overall conclusion is the dominant factor is heredity where mechanical stresses superimposed on genetically susceptible disc material initiate the cascade of degeneration. When conservative treatment fails, surgery is often the only remaining option for persistent disabling back pain when the pain generator can be clearly identified as originating in the disc or its surrounding soft tissue restraints.

For nearly 8 years, spinal fusion has been considered the only surgical option for disabling mechanical low-back pain because of DDD refractory to conservative care. Although there are various surgical approaches and methods of achieving fusion, all share the same theme of stabilizing the vertebral column and restricting motion across the affected segment. Although this method may be successful in decreasing pain for select patients, it clearly changes the overall biomechanics of the spine. Short-term outcomes [1–3] are good, but fusion is often difficult to achieve and even if successful, alters the mechanics of the spine, perhaps accelerating the rate of degeneration at adjacent levels [4–7]. As a consequence, further surgery is

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required in as many as 40% of cases within the first 10 years post-operation [8–14, 26].

The design philosophy behind total disc replacement (TDR) is to restore functional motion to the diseased level and improve the overall mechanical environment by replacing the diseased disc with a device capable of mimicking the natural motion. One lumbar TDR is currently available clinically in the USA (CHARITE, DePuy Spine, Raynham, MA), while many others are under Investigational Device Exemption clinical investigation such as the Maverick™ (Medtronic, Memphis, TN), FlexiCore® (Stryker Spine, Mahwah, NJ), and ProDisc®-L (Synthes Spine, L.P., West Chester, PA). All of these TDRs are currently available clinically in Europe.

The CHARITE™ and Maverick™ underwent biomechanical testing under controlled conditions [15, 16] and, along with the ProDisc®-L, have shown clinical success in restoring disc height and normal motion [17–21]. While biomechanical testing was performed by Rousseau et al. [22] to determine the effect of TDR on instant axis of rotation (IAR) and facet joint forces, no testing has been performed on the ProDisc®-L to determine its dynamic behavior in restoring joint motion [25]. Therefore, the objective of this study was to determine the effect of the ProDisc®-L device on range of motion (ROM) and stiffness of an intact spinal segment by performing tests on cadaveric specimens.

Materials and methods

Twelve human (ages 35–65) fresh frozen lumbar L5–S1 segments were thawed and dissected free of all soft tissue except for ligamentous structures. Radiographic evaluation was performed on each specimen before testing to ensure the absence of conditions (e.g., tumors, poor bone quality, and previous surgery) that could adversely affect the results. Before testing, the superior and inferior vertebrae were potted in epoxy and the exposed portion of the segment wrapped in saline-soaked gauze. The radiographs

were used together with implant trials (provided by the manufacturer) to determine the appropriately sized implant for each specimen.

Mechanical testing of the potted specimens was performed in a custom 6-degree-of-freedom spine-testing apparatus coupled to an MTS Bionix biaxial load frame (Fig. 1). The apparatus allows for the application of a pure bending moment, while allowing the specimen free travel in all other directions. An initial 1,200-N compressive preload was applied across the joint to seat the specimen in the apparatus. After application of the preload, the intact specimen was cycled in torque control to ± 10 N m at 0.1 Hz in flexion/extension, lateral bending, and axial rotation. Flexion/extension and lateral bending were achieved by rotation of the MTS actuator. Axial rotation was achieved using an air motor ('Pneu Turn' rotary actuator, Bimba, Monee, IL) connected to the sacral grip by a coupler. When the coupler is disconnected, free rotation is permitted; when the coupler is connected, the air motor torques the specimen. Torque was regulated by a pressure transducer and a pressure controller (Proportion Air, McCordsville, IN). The torque provided by the air motor caused axial rotation of the spine. For each of the three modes, testing was performed with 600-N and 1,200-N compressive loads. These loads approximate the loads across L5–S1 for the activities of sitting and lifting loads, respectively [23]. The order of testing mode and compressive load were randomized within each specimen.

The entire set of tests (with randomization) was then repeated after insertion of the ProDisc®-L implant. The cartilaginous endplates were removed with curettes so as not to compromise the integrity of the subchondral bony endplates. The posterior longitudinal ligament was exposed to ensure posterior remobilization. The ProDisc®-L instrumentation set contains 12 trials that correspond to the 12 possible ProDisc®-L implant sizes. The implant trials are placed into the disc space intraoperatively to determine the appropriate footprint size (medium or large), lordotic angle (6 or 11°), and disc height (10, 12, or 14 mm). Under lateral fluoroscopic control, the trial is advanced to

Fig. 1. Custom six-degree-of-freedom spine testing apparatus that was attached to the load frame of the MTS Bionix system

Fig. 2. **a** Pre-implantation lateral radiograph. **b** Post-implantation lateral radiograph. **c** Anterior view of the implant in situ. **d** Axial radiographic post-implantation

the posterior margin of the vertebral bodies. Appropriate trial size thus provides a footprint for maximum endplate coverage, a disc height appropriate to that of a normal adjacent disc space, and the best lordotic angle that matches the anatomy. Under lateral fluoroscopic control, the chisel is safely advanced onto the stem of the implant trial, proper rotation of the osteotomy cut is assured, and the chisel is advanced into the vertebral bodies using a mallet until the chisel is fully seated against the adjustable stop on the trial. Confirmation is done both fluoroscopically as well as visually. After the chisel and implant trial are removed from the prepared disc space, the ProDisc[®]-L implant endplates are inserted in a collapsed and nested fashion, with the keel following the slot cut by the chisel. Once the keel engages the slot, rotational and translational position is automatically maintained. The endplates are then briefly distracted for the polyethylene inlay insertion. Pre- and post-implantation anterior–posterior, lateral, and axial views were obtained in all specimens (Fig. 2).

Throughout the testing, the motion of S1 relative to L5 was measured by the rotary capacitive displacement transducer of the MTS system for flexion/extension and lateral bending. For axial rotation, a magnetic tracking system (Polhemus, Colchester, VT) attached to the grip for S1 measured the motion (Fig. 1). Motion data and applied torque were monitored continuously during the test and output to a personal computer sampling at 5 Hz using Labview software (National Instruments, Austin, TX). At the fifth loading cycle, ROM was determined as the difference in motion between the values at 8 N m in each direction. Stiffness was taken as the slope of the torque versus motion curve, again at 8 N m.

To compare ROM and stiffness measurements before and after implantation, repeated measures analyses of variance were performed. The effects of implant condition (intact versus implanted) and compressive load (600 N versus 1,200 N) were examined for each testing mode. The alpha level was set at 0.05.

Table 1 Range of motion (degrees) for each specimen tested intact and implanted, and with 600-N and 1,200-N compressive loads in flexion/extension, lateral bending, and axial rotation

Specimen	Flexion/Extension				Right and Left Lateral Bending				Axial Rotation			
	600 N		1,200 N		600 N		1,200 N		600 N		1,200 N	
	Intact	Implanted	Intact	Implanted	Intact	Implanted	Intact	Implanted	Intact	Implanted	Intact	Implanted
1	2.2	1.3	1.5	1.0	1.5	7.2	1.1	4.0	0.9	1.3	0.6	0.6
2	1.4	1.3	1.1	1.0	1.0	3.5	0.8	2.0	0.7	0.9	0.4	0.3
4	4.8	2.4	2.0	2.1	5.5	11.4	4.7	12.9	1.0	4.0	0.9	2.3
5	2.5	1.7	1.7	1.2	2.2	6.2	1.3	3.3	0.4	2.3	0.3	1.0
6	10.3	6.0	8.8	1.5	5.4	5.9	3.7	2.3	1.8	0.6	1.0	0.8
9	3.7	11.5	3.2	11.6	1.7	3.3	1.5	1.0	N/A	N/A	N/A	N/A
10	14.3	17.9	14.4	17.1	9.2	17.9	8.2	14.3	N/A	N/A	N/A	N/A
11	12.9	11.3	8.6	17.5	4.7	26.7	4.1	8.7	N/A	N/A	N/A	N/A
12	11.4	4.7	11.3	8.9	6.8	3.2	7.8	8.3	N/A	N/A	N/A	N/A
13	7.0	7.8	4.8	5.8	4.8	5.7	3.0	10.1	N/A	N/A	N/A	N/A
Mean	7.0	6.6	5.7	6.8	4.3	9.1	3.6	6.7	0.9	1.8	0.7	1.0
Stdev	4.8	5.6	4.7	6.6	2.7	7.7	2.7	4.8	0.5	1.4	0.3	0.8

Results

Testing was aborted for 1 of the 12 specimens after the first three tests when one of the ligamentous structures was compromised. Another specimen was eliminated after intact testing when a fracture occurred because of the presence of spondylosis. The results from this specimen were excluded. Axial rotation data from half the specimens were lost because of operator error in which the test was inadvertently overconstrained. This did not influence the flexion/extension and lateral bending tests, which were performed separately on these spines. Therefore, conclusions concerning axial rotation were based on six specimens.

The ROM in flexion/extension was not significantly different between intact and implanted spines ($p=0.77$) or between tests with 600-N and 1,200-N applied compressive loads ($p=0.61$; Table 1). However, ROM significantly increased in lateral bending in the implanted compared to the intact spines ($p=0.004$) and was significantly larger with a 600-N compressive load applied compared to when the applied compressive load was 1,200 N ($p=0.04$). No significant differences occurred in axial rotation at either compressive load between intact and implanted mode.

The stiffness of the construct in flexion/extension was not significantly different between intact and implanted specimens ($p=0.37$). However, the construct was significantly stiffer with a 1,200-N compressive load when compared to the 600-N compressive load. This was true overall ($p=0.003$) and within the intact ($p=0.03$) and implanted ($p=0.003$) groups (Table 2).

Discussion

The stiffness of the intact spinal segments increased nearly 23% when the compressive load was increased from 600 N to 1200 N during flexion/extension and 11% during lateral

bending. Comparatively, the stiffness values in the TDR-implanted spinal segments increased with increased compressive load in flexion/extension by 31% and by 7% in lateral bending. This finding is supported by other studies in which an increase in compressive load across the joint space decreased ROM [24] and increased stiffness during flexion/extension [14, 25–27] and lateral bending [14, 25, 26].

Biomechanical and clinical evaluations have been performed on the Maverick™ and CHARITÉ™ devices. Hitchon et al. reported an increase of 5.4° in flexion/extension (from 10.9 to 16.3°) when Maverick™ devices were implanted at L4–L5 in cadaveric spinal segments. Clinically, LeHeuc et al. described a series of 64 patients receiving TDR with Maverick and measured an average ROM at L4–L5 of 9.4° at 1–3 years follow-up. Similarly, Lemaire et al. found a flexion/extension ROM of 9.6° and a lateral bending ROM of 5.4° at L4–L5 for 100 CHARITÉ™ devices followed for 10–13 years. Cunningham et al., in a biomechanical study of the CHARITÉ™, reported a 3% increased ROM in flexion/extension and a 16.3% increased ROM in lateral bending over the intact condition at this same level, although absolute values were not reported.

Our post-implantation ROM results correlate well with the post-implantation ROM found during clinical trials for the ProDisc®-L implant. Bertagnoli et al. [28], Delamarter et al. [18], and Huang et al. [29] measured ROM in flexion/extension with the ProDisc®-L implant to range from 4.1 to 7.6°. The average ROM during flexion/extension in the current study was 6.6 and 6.8° with 600-N and 1,200-N compressive loads, respectively.

There are limitations to this study. Only one implant design was investigated, and because testing apparatus and protocols vary among laboratories, direct comparisons among implants of different designs are impossible. Standardizing testing methods have been proposed, but until they are adopted, this problem will persist. A second limitation is that the cadaveric specimens used were

Table 2 Stiffness data (N m/deg) for each specimen tested intact and implanted, and with 600-N and 1,200-N compressive loads in flexion/extension and lateral bending

Specimen No.	Flexion/Extension				Right and Left Lateral Bending			
	600 N		1,200 N		600 N		1,200 N	
	Intact	Implanted	Intact	Implanted	Intact	Implanted	Intact	Implanted
1	5.2	7.6	7.5	12.1	8.4	4.4	11.4	5.6
2	8.3	8.9	13.0	12.8	16.2	2.9	20.3	5.7
4	0.9	5.0	5.8	5.4	3.8	8.6	4.0	1.9
5	3.3	8.2	5.7	12.3	6.6	5.0	9.7	8.0
6	2.2	0.8	1.4	6.8	3.4	1.2	3.2	1.5
9	5.2	1.7	5.3	1.6	6.5	2.7	9.4	3.2
10	1.3	0.9	1.4	1.6	3.9	1.0	4.0	0.8
11	0.6	0.5	1.0	1.7	2.5	0.8	2.9	1.3
12	2.6	2.2	2.5	4.9	5.2	2.5	4.5	1.7
13	2.8	1.1	4.5	0.7	4.5	1.6	4.5	1.0
Mean	3.2	3.7	4.8	6.0	6.1	3.1	7.4	3.0
Standard deviation	2.4	3.4	3.6	4.8	4.0	2.4	5.5	2.53

stripped of soft tissues, thus eliminating the impact that muscle forces and other soft tissue structures might have on spinal motion. A final limitation is that only one level was tested. Disc replacements are expected to influence the mechanics and kinematics of adjacent levels; a study involving adjacent levels could, therefore, provide valuable additional data. It was the intent of our investigation to test only one level so as to eliminate a potentially confounding variable from the ROM and stiffness measurements.

The ROM remained within physiologic ranges for the L5–S1 segment [23] in flexion/extension and axial rotation. However, the ProDisc®-L implant allowed a significantly greater ROM in lateral bending. Rousseau et al. also found changes between intact and implanted measurements in IAR and facet joint force during lateral bending of L5–S1. They attributed the finding to a lack of incongruity between the IAR and the geometric center of the polyethylene-bearing surface of the ProDisc®-L. The increase in lateral bending ROM may not be seen clinically because of the support of surrounding soft tissue and muscle forces. The increase in ROM was larger with 600 N as compared to the 1,200-N compressive load because the larger axial load increases the stiffness of the construct reducing the amount of motion.

Conclusion

The ProDisc®-L appears to successfully restore or maintain normal spine segment motion.

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