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ANIMAL STUDY





MEDICAL

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Background

Compared with the standard anterior cervical discectomy and fusion, cervical disc replacement (CDR) is an alternative method that can restore and maintain the mobility and function of the treated and adjacent motion segments [1–3]. Clinical results of single-level and multiple-level implantation have demonstrated that CDR is a safe method that shows encouraging clinical and radiological outcomes [4–7]. The benefits of CDR over anterior cervical discectomy and fusion (ACDF), the gold standard technique, have been demonstrated in several prospective randomized controlled trials [4,6,8–10].

Many surgeons recommend the removal of degenerative or hypertrophic posterior longitudinal ligament (PLL) after resection of the proliferative osteophytes and herniated disc in ACDF. It has been shown in the literature that removal of the PLL during anterior decompression procedures for cervical spondylotic myelopathy can provide more decompression and better postoperative clinical results [11–13]. However, the effect of PLL removal in cervical disc arthroplasty remains unclear. According to McAfee et al. [14], PLL plays an important role in postsurgical stability in CDR. Nevertheless, Yang et al. [15] suggested that the PLL resection method could improve the clinical outcomes of CDR; additionally, it does not have a large effect on the motion and balance of the cervical spine. However, the exact role of the PLL in CDR still remains uncertain.

The Prestige LP (Medtronic Sofamor Danek Inc., USA) prosthesis (Figure 1) is an internationally recognized prosthesis model that has provided excellent clinical outcomes and that preserves the overall cervical alignment and the range of motion (ROM) of the treated and adjacent levels [16].

Human spinal specimens are frequently used for *in vitro* biomechanical analyses. However, the use of human cadaver specimens involves some confounding factors such as age, gender, height, bone quality, and grade of degeneration, which can bias the results of these analyses. Additionally, human cadaver specimens are very difficult to obtain. In contrast, spinal specimens from animals are usually more homogeneous and easier to obtain. Several studies have suggested the use of ovine cervical spine as an accepted model for research on human cervical spine [17–19].

In this study, ovine cervical spines were used to quantify changes in kinematics. The ROMs were compared under the same conditions. We tested the specimens' physiological motion function using the intact cervical spine, the spine after CDR with the Prestige LP prosthesis and PLL preservation, and the spine after CDR with the Prestige LP prosthesis and PLL removal.



Figure 1. The Prestige LP prosthesis.

Material and Methods

Specimen preparation

Twenty-four freshly frozen cadaveric cervical spines from twoyear-old sheep were utilized in this study. Before starting the biomechanical tests, all specimens were evaluated for bone mineral density (BMD) with dual-energy X-ray absorptiometry scanning to ensure that none of the spines had pathological low BMD (t-score >-2.5). Following the preparation for the biomechanical analysis, the specimens were frozen at $-20^{\circ}C$ [20,21], then thawed at room temperature for 24 hours before analysis. The ligamentous attachments of each ovine specimen were deliberately preserved. Only muscular and fatty tissues were carefully removed. The C2-C5 vertebrae of the ovine cervical spines were tested in a polysegmental setup. For stabilization purpose, the proximal (C2) and distal (C5) ends of the specimen were embedded in cold curing resin adhesive (HEI-CAST 8012, Heisen Yoko Co. Ltd., Japan). The C2 vertebra was attached to the upper fixture, and the C5 vertebra was mounted to the lower testing platform. Motion capture markers of the optical tracking system were inserted into the vertebral bodies of C2-C4.

Three-dimensional motion testing

The proximal and distal ends of the specimen were mounted on a six-axis spinal robot (Shanghai Sanyou Medical Co. Ltd., Shanghai, China). The moment arm attached to the proximal end of the specimen could apply an axial load and a pure moment, whereas the distal end of the specimen remained fixed to the socket of the robot. The robot was programmed to apply three continuous loading-unloading cycles of applied moment along each primary axis of motion to simulate flexionextension (FE), lateral bending (LB), and axial rotation (AR). An axial preload of 50 N was given on the C2 vertebra to simulate



Figure 2. An intact spine specimen. Each rigid rod connected the motion capture markers to the vertebral bodies for detection by the optical tracking system.

head weight. All specimens were subjected to three cycles of FE, LB, and AR under nondestructive pure moment of ± 2.0 N·m, and the data of the third cycle were used for analysis [22]. The ROM of the C2–C5 polysegment was measured by the optical tracking system. During the biomechanical tests, all specimens were moistened with normal saline to prevent desiccation.

Segmental ROM

An optical tracking system (OptiTrack, NaturalPoint Inc., USA) was used to evaluate the ROM of the C2/C3, C3/C4, and C4/C5 segments. A rigid rod connected to a motion capture marker was inserted into each vertebral body of C2, C3, and C4 (Figure 2). Every motion capture marker was composed of three noncollinear optical balls to ensure it could be detected by the optical tracking system. A marker was placed on the socket to attach the C5 vertebra due to its immovability. The angular ROM value was directly measured by the optical tracking system.

Reconstructive conditions

Twenty-four intact cervical spines were divided into three groups (group 1, group 2, and group 3), with eight specimens per group. A complete discectomy of C3/C4 was performed on



Figure 3. The specimens of C3/C4 CDR with the Prestige LP prosthesis.

all spines of groups 2 and 3. Additionally, PLL resection was performed on the eight cadaveric cervical spines of group 3. Thereafter, the endplates of the ovine spines of groups 2 and 3 were prepared using a high-speed burr to ensure adequate implant positioning, and then CDR was performed. The Prestige LP prostheses were inserted at the C3/C4 level for the two groups (Figure 3). The specimens of the three groups were analyzed.

Radiographic control

Radiographs were taken to ensure that the implants were correctly positioned in the intervertebral space (Figure 4).

Data and statistical analysis

The third loading cycle data for the six spinal motions were used for statistical analysis. The ROM at the C2/C3, C3/C4, and C4/C5 segment levels and the total ROM were quantified at maximum load. The ROM values of the CDR groups and the intact group were compared. The ROMs of group 1 (intact spine) were compared with the ROMs of group 2 (CDR and PLL preservation) and group 3 (CDR and PLL removal) using the unpaired Student's t-test. The level of significance was set at p<0.05. Statistical analyses were performed using IBM SPSS Statistics for Windows, version 19.0 (IBM Corp., USA).



Figure 4. A radiograph showing the correct position of the Prestige LP prosthesis.

Results

After biomechanical testing, all ovine spines of groups 2 and 3 were dissected and visually evaluated for damage. No fracture or hardware failure was observed.

Table 1. ROM of C2/C3, C3/C4 and C4/C5.



Figure 5. Mean total ROM (±SD) of intact spine (group 1), C3/C4 CDR with PLL preservation (group 2), and C3/C4 CDR with PLL removal (group 3) in the three motion directions. An asterisk (*) indicates a significant difference between the corresponding groups (as indicated by the horizontal bar) at p<0.05.</p>

As shown in Figure 5, the mean total ROMs of groups 1 and 2 were not significantly different (p>0.05) regardless of the motion direction (FE: mean total ROM=26.07°±2.18° for group 1 vs. 27.24°±3.97° for group 2; LB: mean total ROM=38.54°±4.39° for group 1 vs. 40.10°±4.25° for group 2; AR: mean total ROM=21.02°±4.04° for group 1 vs. 20.89°±3.92° for group 2). For group 3, the mean total ROMs were 29.11°±2.21° (FE), 40.73°±5.05° (LB), and 22.19°±3.27° (AR). Compared with the mean total ROM of group 1, the mean total ROM of group 3 significantly increased only in FE (p<0.05). The mean total ROM in the three motion directions was always recorded at a maximum loading of ±2 N·m.

The mean ROMs of C2/C3, C3/C4, and C4/C5 segments in the three motion directions and for each of the three groups are listed in Table 1. Compared with group 1 (intact spine), the C3/C4 ROM in group 3 (CDR with PLL removed) significantly increased (p<0.05) in FE and AR (FE: $10.45^{\circ}\pm1.51^{\circ}$ for group 3 vs. $8.87^{\circ}\pm1.28^{\circ}$ for group 1; AR: $8.34^{\circ}\pm1.37^{\circ}$ for group 3 vs. $6.65^{\circ}\pm1.67^{\circ}$ for group 1). In addition, the ROM in group 2 (CDR

Segment		FE	LB	AR
C2/C3	Group 1	7.49°±1.37°	12.38°±2.07°	7.53°±1.54°
	Group 2	7.13°±2.15°	12.82°±2.40°	6.72°±1.15°
	Group 3	7.89°±1.62°	12.87°±2.14°	7.04°±1.24°
C3/C4	Group 1	8.87°±1.28°	12.62°±2.53°	6.65°±1.67°
	Group 2	9.56°±1.56°	14.57°±3.08°	7.23°±1.98°
	Group 3	10.45°±1.51°	14.53°±2.82°	8.34°±1.37°
C4/C5	Group 1	9.71°±2.08°	13.54°±2.51°	7.02°±1.44°
	Group 2	10.55°±1.74°	12.72°±3.32°	6.94°±1.47°
	Group 3	10.39°±1.79°	13.34°±2.70°	6.80°±1.37°



Figure 6. Mean ROM (±SD) for each of the three groups in flexion-extension (A), lateral bending (B), and axial rotation (C). An asterisk (*) indicates a significant difference between the corresponding groups (as indicated by the horizontal bar) at p<0.05.

with PLL preserved) was not significantly different from that in group 1 (intact spine) regardless of the motion direction and the vertebral segment (p>0.05) (Figure 6).

Discussion

Cervical fusion sacrifices segmental mobility and increases ROM stress at the adjacent segment. Overloading at the adjacent segments caused by fusion is known to contribute to adjacent segment degeneration [23,24]. Cervical disc replacement is a successful and promising nonfusion technique aimed at restoring normal articular motion and spine kinematics.

Because CDR is of great interest in the operative management of degenerative disc disease in the cervical spine, *in vitro* studies are of great interest in order to analyze the biomechanics of the different implants. Human cadaveric specimens are very difficult to acquire for such studies. Therefore, animal spines are commonly used to simulate the human spine. ROM testing on many animal spines has confirmed that the ROM of sheep is most similar to that of humans [18]. Moreover, the C2/C3 and C3/C4 segments appear suitable for biomechanical testing. In this study, we tested the kinematics of cadaveric cervical spines from sheep under three conditions (intact, CDR with preserved PLL, and CDR with removed PLL). Whether to cut off the PLL in cervical disc arthroplasty is a surgeon's decision. Because of the traditional opinion stating that PLL contributes to the balance and stability of the cervical spine, some authors have suggested preserving the PLL as much as possible if the PLL is not degenerative or hypertrophic [25,26]. However, other authors prefer to remove the PLL in the cervical anterior approach, considering some results that show a better effect of decompression and a similar ROM when PLL is removed compared with when it is preserved [15]. Thus, it appears controversial whether the PLL should be removed during a CDR surgery.

In our study, the CDR with PLL removal partly increased ROM as compared with the intact spines. In addition, the ROM in the CDR with preserved PLL was not significantly different from that in the intact group. Therefore, these findings show that the PLL plays a key role in keeping the balance and stability of the cervical spine.

The PLL lies behind the vertebral bodies, beginning from the occipital bone to the sacrum [27]. The PLL, which is composed of two layers, links up with the intervertebral disc at multiple levels [11,28]. A normal PLL is believed to prevent the disc contents and bone fragments from protruding into the spinal canal [28]. The PLL can also protect the spinal cord if the prosthesis loosens backwards [29]. In addition, the risk of damaging

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nerve roots, spinal cord, dura, and epidural vascular plexus can increase when the PLL is removed. However, the PLL's normal biomechanical function of preventing disc protrusion into the spinal canal can be obviously weakened in cases of degeneration or injury, because of the breakdown of the PLL's elasticity and tensile strength [12]. Moreover, the disc contents may protrude into the degenerative PLL, thus becoming a disc-PLL complex. In that case, the entire disc should be removed to prevent future symptoms. As a result, it is also beneficial to remove the degenerative PLL in CDR. Therefore, we recommend the preservation of the PLL in CDR when the PLL is not degenerative. In cases of degeneration, we recommend that the PLL be routinely removed.

Chen et al. [30] reported that PLL resection can significantly increase the ROM in FE, LB, and AR. McAfee et al. [14] described the importance of the PLL through a biomechanical experiment in CDR. In the present study, the ROMs of the treated levels were significantly increased in FE and AR for group 3 (CDR with removed PLL) compared with group 1 (intact spine), and the mean total ROM of group 3 during FE was significantly larger than that in group 1. In addition, the ROM in group 2 (CDR with preserved PLL) was not significantly different from the ROM observed in group 1 (intact spine), regardless of the motion direction. These results more adequately demonstrate the importance of PLL removal. However, our specimens originated from 2-year-old sheep, which had healthy PLL. Consequently,

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the present findings only apply to healthy PLL; compared with a healthy PLL, the resection of a degenerative PLL may have a different effect on the cervical spine.

A limitation of our study is that we mainly focused on the extent of motion without considering the stabilizing influence of the paraspinal muscles, the quality of motion, or neural control mechanisms, which is a common limitation in any *in vitro* cadaveric biomechanical analysis of the cervical spine. Therefore, our results cannot represent the long-term effect of CDR.

Conclusions

Cervical disc replacement with Prestige disc and PLL removal partly increased ROM in a sheep cadaver model, as compared with the intact spines. In addition, the ROM in CDR with PLL preservation did not significantly differ from that in the intact group. Consequently, the PLL appears to contribute to the balance and stability of the cervical spine and should be preserved in CDR if the PLL is not degenerative and the compression can be removed without PLL takedown.

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