Incidence and outcomes of anterior bone loss in single-level Prestige LP cervical disc replacement

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To the Editor: Total cervical disc replacement (TDR) has been widely used to treat cervical degenerative disc diseases (CDDD). However, implant-related complications, including implant migration, implant subsidence, heterotopic ossification (HO), and anterior bone loss (ABL), have been reported by many studies. ABL has received more attention in recent years; however, this phenomenon has been recognized only in cervical artificial discs without keels, including Bryan, Baguera-C, Discocerv, and Mobi-C.¹⁻⁶ Therefore, the first aim of this study was to evaluate the incidence of ABL in a keeled artificial disc, the Prestige-LP cervical disc system (Medtronic Sofamor Danek Inc., Memphis, TN, USA).

Previous studies have reported that ABL could result in persistent neck pain,¹⁻⁵ endplate exposure, and implant failure (such as subsidence and grade 4 HO).¹⁻⁶ However, the impact of ABL on adjacent segments and implant subsidence remains unknown. Therefore, the other aim of our study was to identify the impact of ABL on these complications.

This study was approved by the Institutional Review Board of West China Hospital, Sichuan University. Patients who received single-level Prestige LP TDR with a minimum of 24 months of follow-up were reviewed. The inclusion criteria were: patients aged between 18 and 65 years; single-level CDDD causing symptomatic myelopathy or radiculopathy between C3 and C7; failed conservative treatment for 12 weeks. The exclusion criteria were: new or enlarged osteophyte formation of the posterior longitudinal ligament; cervical spine tumor; ossification of the posterior longitudinal ligament; ankylosing spondylitis; rheumatoid arthritis; metabolic bone disease; osteoporosis; radiological signs of instability; or irreducible kyphosis at the surgical level or severe global kyphotic deformity; severe spondylodiscitis or facet joint degeneration; previous cervical spine surgery. All patients received dual-energy X-ray bone density screening before surgery, and osteoporosis (T-score ≤−2.5) was one of the contraindications for TDR. All surgeries were performed by the same senior surgeon who used the same surgical techniques. Radiological data and clinical outcomes were collected before and immediately after surgery and at the 3, 6, 12-month, and final follow-ups. ABL was measured as described previously.⁷ Radiological outcomes were measured based on radiographs, as performed by prior studies,⁸⁻¹⁰ and the parameters included cervical curvature (C2−C7), global range of motion (ROM) (C2−C7), and segmental ROM at the surgical level. For the patient-reported clinical outcomes, we used the visual analog scale scores, neck disability index score, and Japanese Orthopaedic Association score.

The other outcomes that were measured included implant subsidence and migration. Implant subsidence was defined as ≥2 mm height loss of the anterior or posterior functional spinal height (FSU) height.⁹ Radiological adjacent segment degeneration (RASD) was identified on lateral radiographs based on one of the following lines of evidence:¹⁰⁻¹¹: (1) new or enlarged osteophyte formation at the anterior border of the vertebral body; (2) narrowing of the intervertebral disc space; (3) ossification of the anterior longitudinal ligament.

Statistical analysis was performed using the SPSS software (Version 23.0, SPSS Inc., Chicago, IL, USA). Quantitative variables were analyzed using the Student t test (for normally distributed data) or the Mann-Whitney U test (for non-normally distributed data). Classified variables were analyzed using the Chi-square test or the Fisher exact test. A two-tailed P < 0.05 was defined as statistically significant.

Finally, a total of 131 patients (65 males and 66 females) and 262 endplates were reported in this study. The mean
The patient-reported clinical outcome scores of all patients significantly improved at the 12-month and final follow-ups. No significant difference was found between the ABL and non-ABL groups in terms of the outcome scores at each follow-up ($P > 0.05$). As a group, the C2 to C7 cervical curvature, global ROM, and segmental ROM were preserved post-operatively, and the pre-operative cervical curvature and ROM were comparable between the two groups. However, the C2 to C7 cervical curvature of the ABL patients was significantly larger than that of the non-ABL group at the 12-month ($P = 0.044$) and final ($P = 0.011$) follow-ups. In addition, both global and segmental ROM values were significantly higher in patients with ABL ($P < 0.05$). Neither the implant subsidence nor the RASD was affected by the presence of ABL [Table 1].

Until now, the hypothetical mechanisms of ABL include stress shielding, immunoreaction caused by wear debris, and micro-motion.[1-6] However, these hypotheses have several limitations. First, stress shielding is a common condition in large joint arthroplasty and usually shows a progressive course over several years, while most ABL in TDR occurs within the first 3 months after surgery. Second, wear debris and micro-motion may induce immunoreaction, which occurs around the implant rather than presenting confinement to the ventral part of the vertebral body.

In our point of view, stress may be one of the critical factors in the development of ABL. The hypo-pressure in the anterior region of the bone-implant interface may lead to resorption of the vertebral body. The following evidence supports our hypothesis: First, in agreement with the basic orthopedic principle, if the loading on a particular part of the bone decreases, the bone will become less dense and finally resorb. Second, the incidence of ABL significantly varies among different artificial discs. Third, finite element studies have shown that each cervical artificial disc has a specific stress distribution pattern. For example, the anterior part of the Prestige LP cervical disc system imposes a low-stress level[12] which might resorb according to Wolff law and present as ABL. We encourage further studies to assess ABL in other kinds of implants to address our hypothesis.

Previously, ABL was considered as a complication after TDR; however, those studies did not fully describe the long-term effects of ABL. Our study was conducted with a maximum of 10-year follow-up and showed that ABL did not affect clinical outcomes nor increase the risk of post-operative complications. Therefore, we hold the view that ABL is a radiographic anomaly rather than a potential complication.

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**Table 1: Incidence and outcomes of anterior bone loss in single-level Prestige LP cervical disc replacement.**

| Variables                        | Non-ABL group | ABL group | $P$  |
|----------------------------------|---------------|-----------|------|
| No. of patients                  | 50            | 81        |      |
| (12-month follow-up)             |               |           |      |
| Age (years)                      | 42.9 ± 9.2    | 43.2 ± 7.2| 0.817|
| Sex                              |               |           | 1.000|
| Male                             | 25            | 40        |      |
| Female                           | 25            | 41        |      |
| Follow-up (months)               | 66.6 ± 14.4   | 65.7 ± 10.0| 0.808|
| Level operated, $n$              |               | 0.733     |      |
| C3/4                             | 1             | 0         |      |
| C4/5                             | 4             | 7         |      |
| C5/6                             | 40            | 67        |      |
| C6/7                             | 7             |           |      |
| VAS-neck                         |               |           |      |
| Pre-operation                    | 5.8 ± 1.2     | 5.9 ± 1.5 | 0.691|
| 12-month follow-up               | 2.7 ± 0.9     | 2.8 ± 1.1 | 0.590|
| Last follow-up                   | 1.4 ± 0.7     | 1.5 ± 0.5 | 0.343|
| VAS-arm                          |               |           |      |
| Pre-operation                    | 5.8 ± 1.2     | 5.8 ± 1.5 | 1.000|
| 12-month follow-up               | 1.2 ± 0.6     | 1.2 ± 0.8 | 1.000|
| Last follow-up                   | 0.6 ± 0.5     | 0.7 ± 0.6 | 0.326|
| NDI score                        |               |           |      |
| Pre-operation                    | 22.3 ± 5.1    | 21.9 ± 4.9| 0.656|
| 12-month follow-up               | 12.5 ± 3.7    | 13.0 ± 3.2| 0.415|
| Last follow-up                   | 5.7 ± 0.7     | 5.7 ± 0.9 | 1    |
| JOA score                        |               |           |      |
| Pre-operation                    | 12.0 ± 2.0    | 12.1 ± 1.4| 0.737|
| 12-month follow-up               | 15.8 ± 0.9    | 15.6 ± 1.0| 0.250|
| Last follow-up                   | 16.1 ± 0.6    | 16.0 ± 0.9| 0.488|
| Cervical alignment ($^\circ$)    |               |           |      |
| Pre-operation                    | 13.3 ± 10.8   | 12.0 ± 10.9| 0.504|
| 12-month follow-up               | 13.3 ± 6.6    | 16.5 ± 9.5| 0.044|
| Last follow-up                   | 10.7 ± 5.5    | 15.1 ± 9.9| 0.011|
| C2–7 ROM ($^\circ$)              |               |           |      |
| Pre-operation                    | 52.6 ± 15.3   | 53.1 ± 16.5| 0.876|
| 12-month follow-up               | 53.1 ± 12.3   | 57.5 ± 14.0| 0.066|
| Last follow-up                   | 50.6 ± 15.3   | 55.9 ± 12.1| 0.030|
| Segmental ROM ($^\circ$)         |               |           |      |
| Pre-operation                    | 9.1 ± 5.0     | 10.2 ± 4.5| 0.224|
| 12-month follow-up               | 8.3 ± 5.8     | 10.4 ± 4.7| 0.022|
| Last follow-up                   | 6.3 ± 4.3     | 9.7 ± 5.1 | 0.001|
| Implant subsidence, $n$           | 4             | 9         | 0.765|
| Radiological djacent segment degeneration, $n$ | 10 | 18 | 0.829|

ABL: Anterior bone loss; VAS: Visual analog scale; NDI: Neck disability index; JOA: Japanese Orthopaedic Association; ROM: Range of motion.
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Conflicts of interest
None.

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