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ORIGINAL ARTICLE

Bone loss of the superior adjacent vertebral body immediately posterior to the anterior flange of Bryan cervical disc

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Abstract
Background No previous reports have mentioned bone loss of the superior adjacent vertebra immediately posterior to the anterior flange of Bryan cervical disc (Medtronic Sofamor Danek, Memphis, TN, USA), which plays a central role to prevent posterior migration of the device. The purpose of this study is to describe a new potential complication, bone loss immediately posterior to the anterior total disc replacement (TDR) flange on the superior adjacent vertebra following the Bryan cervical TDR and to discuss the possible mechanism.
Methods The authors retrospectively reviewed 37 patients undergoing cervical TDR with the Bryan cervical disc. The clinical and radiological outcome data were collected at 1, 3, 6, 12, 24, and 36 months postoperatively, and at last follow-up, which ranged from 42 to 113 moths (average, 60.1 months). Clinical evaluation included the visual analog scale and neck disability index, and the radiographic evaluation included measurements of the functional spinal unit range of motion on flexion and extension and identification of radiographic changes such as bone loss.
Results The Bryan TDR showed good mid-term clinical and radiological outcomes. Interestingly, however, bone loss was noted immediately posterior to the TDR flange on superior adjacent vertebra in 3 total patients; at 3 months ($n = 2$) and 6 months ($n = 1$). Although the bone loss was increased up to 6 months, this did not progress and no degradation of clinical and radiological outcomes occurred at last follow-up.
Conclusions Bone loss immediately posterior to the anterior TDR flange on the superior adjacent vertebra can occur in the early postoperative period due to possibly stress shielding effect. However, it did not result in clinical changes or increased rates of graft failure at last follow-up. A long-term follow-up study is mandatory to evaluate the long-term effects of the bone loss.

Keywords Cervical disc disease · Disc degeneration · Total disc replacement · Bryan disc

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Introduction

Anterior cervical discectomy and fusion (ACDF) has been considered as the gold standard for surgical treatment of degenerative cervical disc diseases [1]. However, loss of motion at the surgical level may result in hypermobility, subsequent mechanical instability and accelerated degeneration at the adjacent segment [2, 3]. Consequently, there has been a more recent increased interest in artificial cervical discs designed to preserve motion and prevent potential adjacent segment degeneration (ASD). A number of such devices have been devised in an effort to achieve this aim, and cervical total disc replacement (TDR) has been shown to be a potentially viable alternative to fusion, with encouraging early clinical results.

The Bryan cervical disc prosthesis (Medtronic Sofamor-Danek, Memphis, TN, USA) is one of several artificial cervical discs designed to allow for intervertebral motion. This device has been placed for the treatment of degenerative cervical disc disease and has good mid-term results; despite device-related complications such as migration, prosthesis failure, heterotopic ossification (HO), and peri-device vertebral body bone loss [4–10]. Until now, however, no previous reports have discussed bone loss of the superior adjacent vertebra, specifically, in the area immediately posterior to the anterior flange of the Bryan disc. The goal of this flange is to inhibit posterior device displacement into the spinal canal.

In the present study, we describe the new potential complication, bone loss immediately posterior to the anterior TDR flange on the superior adjacent vertebra following the Bryan cervical TDR and discuss the possible mechanism of bone loss.

Materials and methods

Study design

Data were collected through a prospective registry, with retrospective analysis performed on 37 consecutive patients treated with cervical TDR with Bryan cervical disc, by a single surgeon, from December 2003 to June 2007. Adult patients with a soft disc herniation at single level between C3 and C7 causing either radiculopathy or myelopathy were carefully selected for surgery. Surgery was performed only after failure of appropriate conservative management with compressive pathology from herniated disc. No patients had undergone previous surgery at the symptomatic level. Exclusion criteria for cervical TDR included loss of disc height greater than 50 %, severe kyphosis and osteoporosis, cervical instability, infection, and metabolic bone disease. Minimal patient follow-up for inclusion in the study was 3 months.

Preoperative flexion and extension radiographs were performed to assess cervical spine range of motion (ROM) and exclude cervical instability (defined by translation of greater than 3 mm and/or more than 11 degrees of rotational difference to that of either adjacent levels [11]). Preoperative MRIs were obtained to determine the level of disc herniation and degree of neural compression. Complimentary CT scans were performed to evaluate the posterior osteophyte, disc consistency, ossification of the posterior longitudinal ligament, and facet joint degeneration of the index segment.

Clinical outcome measurements

Patient-reported outcomes were collected preoperatively and postoperatively at 1, 3, 6, 12, 24 and 36 months, and then at the last follow-up. Clinical outcomes were evaluated using visual analog scale (VAS 0–10) for neck and arm pain, neck disability index (NDI 0–100 %) functional score [12], Odom's scale [13], and adverse events.

Prosthesis

All patients underwent TDR with the Bryan disc. The Bryan cervical disc is composed of two porous-coated titanium endplate shells that contain a polyurethane nucleus. Each shell has an anterior flange to articulate with the inserting device and prevent posterior migration of the prosthesis. The prosthesis has a relatively unconstrained range of motion and has similar characteristics of movement and shock absorption to those of an intact human disc [14].

Surgical technique

The patient was positioned supine on the operating table and a right transverse cervical incision was used to access the target cervical disc level. After exposure of the disc space, discectomy was performed and the disc space was distracted by parallel placement of Caspar pins. The center of the disc space was determined by a simple gravitational referencing system. After confirming the center of the disc space, the end plates were smoothed out with a burr, and the correct size of the implant was verified with a trial device. The end plates were then machined with a milling tool that exactly matches the size and contour of the implant. Complete decompression of the nerve roots and spinal cord was then performed. The anterior cortex of the vertebral body was carefully preserved. A chosen suitable Bryan cervical disc was filled with saline and the prosthesis was inserted parallel to the angle of the intervertebral space.

Radiological assessment

Radiologic assessment consisted of conventional anteroposterior (AP) and lateral radiographs, as well as lateral views at maximum extension and flexion to assess functional spinal unit (FSU) ROM and potential device migration. These cervical spine radiographs were obtained preoperatively, immediate postoperatively, 1, 3, 6, 12, 24, and 36 months after operation, and at last follow-up. CT scan and MRI were preoperatively performed in all patients, but postoperative CT and MRI were not taken routinely.

For correct selection of the appropriate implant size, continuous cross-sectional images were obtained parallel to the endplates of C2–T3 on a CT scan. The AP diameter and the lateral diameter of the upper and lower endplates of the symptomatic disc level were measured preoperatively. The AP diameter was defined to be in the mid-sagittal plane and the lateral diameter was defined to be a perpendicular line bisecting the AP diameter [15].

The FSU ROM of the treated segment was assessed on lateral flexion–extension radiographs using Cobb method with the Picture Archiving Communication System (PACS, M-view; Marosis, Seoul, Korea) software. Lines were drawn through the endplates of the superior end plate of the upper vertebra and the inferior end plate of the lower vertebra at the index level [16, 17]. The program measured the Cobb angle automatically (Fig. 1a). Radiographic changes at the implanted and adjacent levels were also evaluated, in particular for evidence of prosthesis migration, osteolysis, HO, and adjacent segment degeneration (ASD). ASD above and/or below the index level was defined as radiographic evidence of radial osteophyte and disc space narrowing [14]. Bone loss posterior to the anterior flange on the superior adjacent vertebra was quantified, when it occurred, by measuring the distance from the base of the anterior TDR flange to the anterior cortex of superior adjacent vertebra on a lateral radiograph (Fig. 1b).

The imaging data were separately and independently measured blindly by two experienced spine surgeons (K.S.H, C.Y.S). In particular, they independently performed the measurement of FSU ROM of the treated level. Each observer then repeated the analysis of the same sequences 4 week later and all examiners were blinded to their prior measurements. The intraclass correlation coefficient (ICC) was used to measure the consistency of measurements [18]. The value of the ICC can range from 0 to 1, with a higher value indicating better reliability. ICC less than 0.40 was considered as poor; 0.40–0.59 as fair; 0.60–0.74 as good, and 0.75–1.00 as excellent [19].

Statistical analysis

We calculated VAS score for pain, NDI, and FSU ROM from preoperative to final follow-up, and comparison between preoperative and follow-up data was performed using paired t test. Continuous variables were presented as mean $\pm$ standard deviation. Inter- and intra-reliability was examined using ICC with 95 % confidence interval. All statistical analyses were performed using SPSS software version 17.0 (SPSS Inc, Chicago, IL, USA). A p value less than 0.05 was considered statistically significant.

Results

Thirty-seven consecutive patients treated with Bryan cervical disc were included in analysis. The mean age of the patients was 45.4 years (range 27–55 years) and 24 (65 %) were male. Of the 37 patients who underwent cervical TDR, 15 patients had myelopathy, 16 patients had

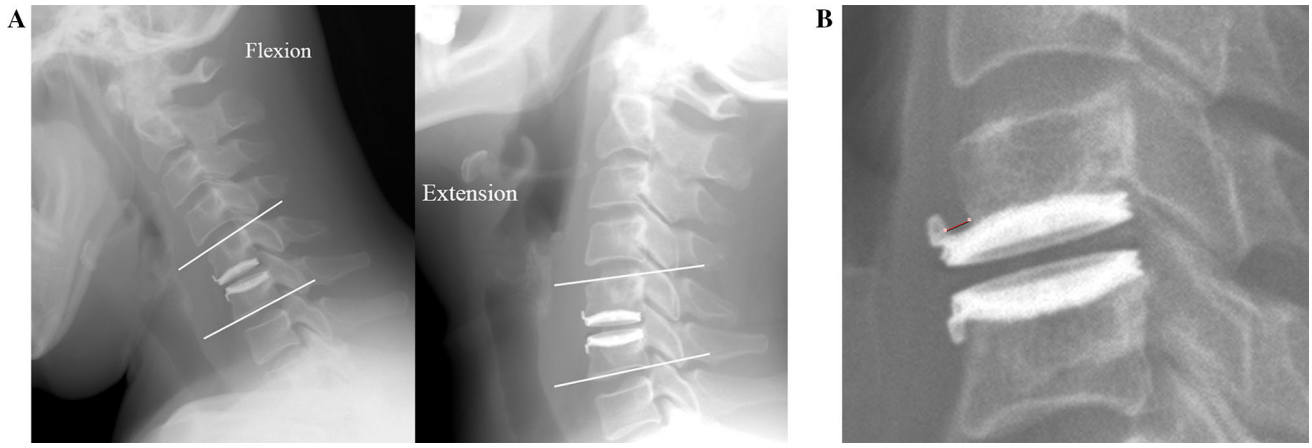

Fig. 1 Flexion–extension lateral cervical radiograph showing range of motion of functional spinal unit measured by Cobb's method (**a**). Linear measurement of bone loss by measuring the distance from the base of anterior flange of Bryan cervical disc to the anterior cortex of the superior adjacent vertebra

radiculopathy, and 5 patients had both myeloradiculopathy. The Bryan cervical disc was implanted at C3–C4 in 2 patients, C4–C5 in 5 patients, C5–C6 in 24 patients, and C6–C7 in 6 patients. No perioperative complications were noted. The mean follow-up period was 60 months (range 42–113 months). Ten patients were followed up for 42 months, 15 patients for 60 months, 11 patients for 72 months, and 1 patient for 113 months.

Patient outcomes

According to the Odom's scale, the outcomes of 37 patients were rated as excellent in 21, good in 10 and fair in 6 at the last follow-up, meaning that 83.8 % of the patients had a good to excellent outcome rating. The mean score of neck pain VAS improved from 7.1 preoperatively to 2.9 at 3 years and 2.1 at last follow-up. The arm pain VAS before surgery was 7.2 and it was 1.9 at last follow-up. The mean NDI score was also reduced significantly at each follow-up time point compared to preoperative condition and the mean NDI score before surgery was 47 % and it was 15 % at last follow-up. All outcome measures were significantly improved ($p < 0.0001$).

No serious adverse events occurred. However, temporary symptoms including voice change and dysphagia were recorded in 7 patients, but all symptoms disappeared within 2 weeks. Furthermore, these complications are well described in the literature for both TDR and ACDF. No reoperations were performed due to prosthesis failure and persistent or recurrent pain.

Radiological results

Reliability of ROM

Radiological evaluation of the mean FSU ROM of the treated level demonstrated the ability of the device to preserve the segmental motion at last follow-up. The mean FSU ROM of treated segment was $12.7° \pm 2.1°$ preoperatively, $11.3° \pm 2.2°$ at 3 months, $11.6° \pm 2.0°$ at 6 months, $12.3° \pm 2.4°$ at 1 year, $12.5° \pm 2.1°$ at 2 years and $12.4° \pm 2.3°$ at last follow-up. The mean FSU ROM temporarily decreased during initial month, but recovered to preoperative levels and there was no significant difference in FSU ROM between last follow-up and preoperative ($p = 0.18$). Reliability tests for the ROM measures showed that the intraobserver ICC and interobserver ICC was excellent as 0.90 and 0.87, respectively, indicating that the ROM measurements were consistent at each follow-up.

Heterotopic ossification and adjacent segment degeneration

Heterotopic ossification was detected in 7 patients (18.9 %) and the mean occurrence-free period was 15.6 months (from 5.7 to 43.7 months). There were 9 patients (24.3 %) with ASD at last follow-up. Based on paired t test, however, the development of HO formation or ASD did not negatively influence the clinical outcomes such as VAS and NDI during the follow-up period.

Bone loss immediately posterior to the flange of Bryan disc

At the early follow-up time points, 3 patients (2 patients; 3 months, 1 patient; 6 months) showed bone loss immediately posterior to the anterior TDR flange on the superior adjacent vertebra. There was no radiographic evidence that the device shifted relative to the posterior cortex of the vertebrae. Table 1 shows the results of bone loss with respect to each follow-up time point. At last follow-up, all patients with the bone loss showed good clinical and radiographic outcomes.

Case series

Case 1

A 39-year-old female presented with 1-year history of right upper extremity radicular symptoms consistent with a clinical diagnosis of cervical radiculopathy. Spurling's maneuver to the right reproduced concordant pain with

Table 1 Summary of three patients with bone loss

Age (years)	Sex	Level	Size of Bryan disc (mm)	Odom criteria	HO	ASD	FSU ROM (°)					Linear measurement of bone loss (mm)			
							Preop	6 months	1 year	2 years	Last FU	3 months	6 months	1 year	Last FU
39	F	C5–C6	14	Good	No	No	13.2	12.4	12.9	12.8	12.7	0	3.0	3.0	3.0
42	F	C5–C6	16	Good	No	Yes	12.4	11.6	12.1	12.2	12.1	1.2	2.7	2.7	2.7
50	M	C5–C6	16	Good	No	No	12.9	12.0	12.5	12.5	12.4	1.0	2.0	2.0	2.0

HO heterotopic ossification, *ASD* adjacent segment degeneration, *FSU* functional spinal unit, *ROM* range of motion, *Preop* preoperative, *FU* follow-up

exacerbation of radicular symptoms down to the right arm. A cervical spine MRI showed right posterolateral C5–C6 intervertebral disc herniation. The AP and transverse diameter of the endplates at the C5–C6 level were 15.5 and 22 mm, respectively. Based on preoperative measurements of diameter and intraoperative finding, a 14-mm Bryan cervical disc prosthesis was successfully implanted. Although the patient's symptoms improved after surgery and did not progress, 6-month follow-up lateral radiograph showed bone loss immediately posterior to the anterior TDR flange on the superior adjacent vertebra. The distance from the bottom of the anterior TDR flange to the anterior cortex of superior adjacent vertebra was 3 mm. At 113-month follow-up, however, no further bone loss had occurred, the FSU ROM of the device was maintained and the patient achieved good result according to Odom's criteria (Fig. 2).

Case 2

A 42-year-old female presented with radiating right arm pain and numbness. A cervical spine MRI demonstrated a right posterolateral C5–C6 intervertebral disc herniation. The AP and transverse diameter of the endplates at the C5–C6 level were 18 mm and 23 mm, respectively, and a 16-mm Bryan cervical disc prosthesis was implanted. After surgery, the patient's symptoms improved. At 3-month follow-up, bone loss immediately posterior to the anterior TDR flange on the superior adjacent vertebra was noted without any change of patient's symptoms. The distance from the TDR flange to the anterior cortex of superior adjacent vertebra was 1.2 mm, and this increased to 2.7 mm at 6-month follow-up. Two years after surgery, ossification of the anterior longitudinal ligament was noted at inferior adjacent level. At last follow-up (36 months), however, bone loss did not progress, the FSU ROM of the device was maintained, and the patient achieved a good clinical outcome (Fig. 3).

Case 3

A 50-year-old male presented with radiating left arm pain and numbness. The patient underwent cervical arthroplasty due to a left posterolateral C5–C6 intervertebral disc herniation. The AP and transverse diameter of the endplates at the C5–C6 level were 19.3 and 20.4 mm, respectively, and a 16 mm Bryan cervical disc prosthesis was implanted. After surgery, the patient achieved satisfactory clinical results. At 3-month follow-up, bone loss of the superior adjacent vertebra was noted with no change of clinical results. The distance from the TDR flange to the anterior cortex of superior adjacent vertebra was 1.0 mm and this distance increased to 2.0 mm at 6-month follow-up. However, no further bone loss occurred at later follow-ups, the FSU ROM of the device was maintained, and the patient continued to have a good clinical result at last follow-up (24 months) (Fig. 4).

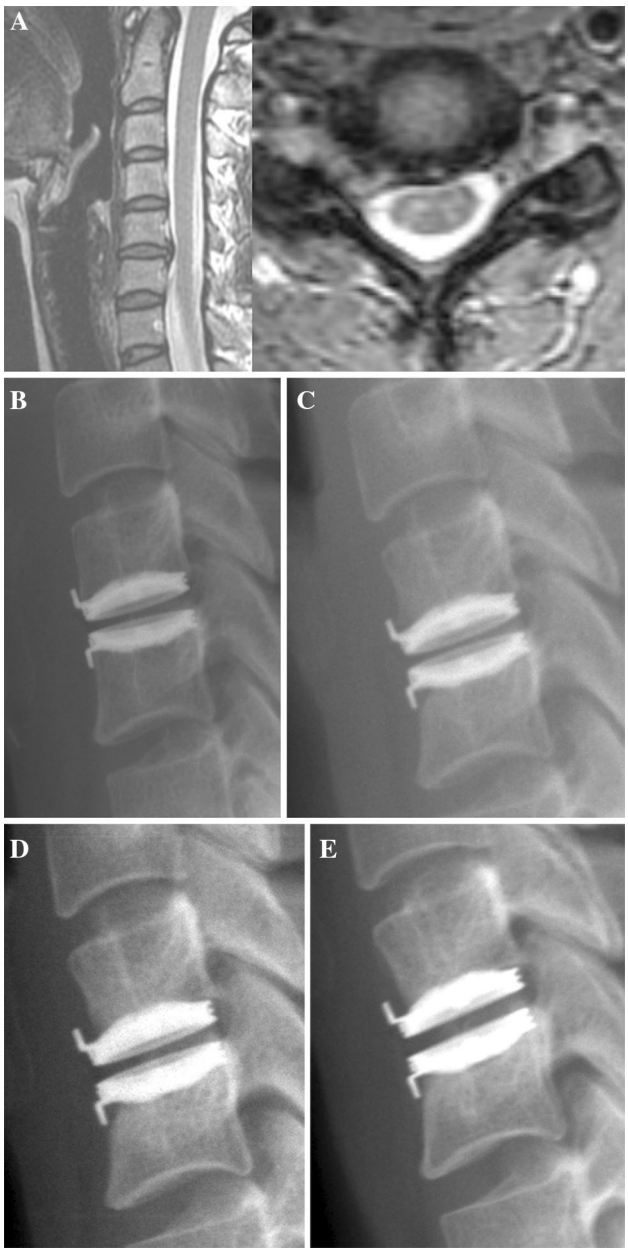

Fig. 2 Preoperative magnetic resonance image showing C5–C6 disc herniation (**a**). Postoperative neutral lateral radiographs showing the prosthesis in normal position 1 week (**b**) and 3 months (**c**) postoperatively, 3.0 mm of bone loss of upper adjacent vertebral body at 6-month follow-up (**d**), and 3.0 mm of bone loss of upper adjacent vertebral body at 113-month follow-up (**e**)

Discussion

The aim of this study is to make spine surgeons aware that bone loss immediately posterior to anterior TDR flange on

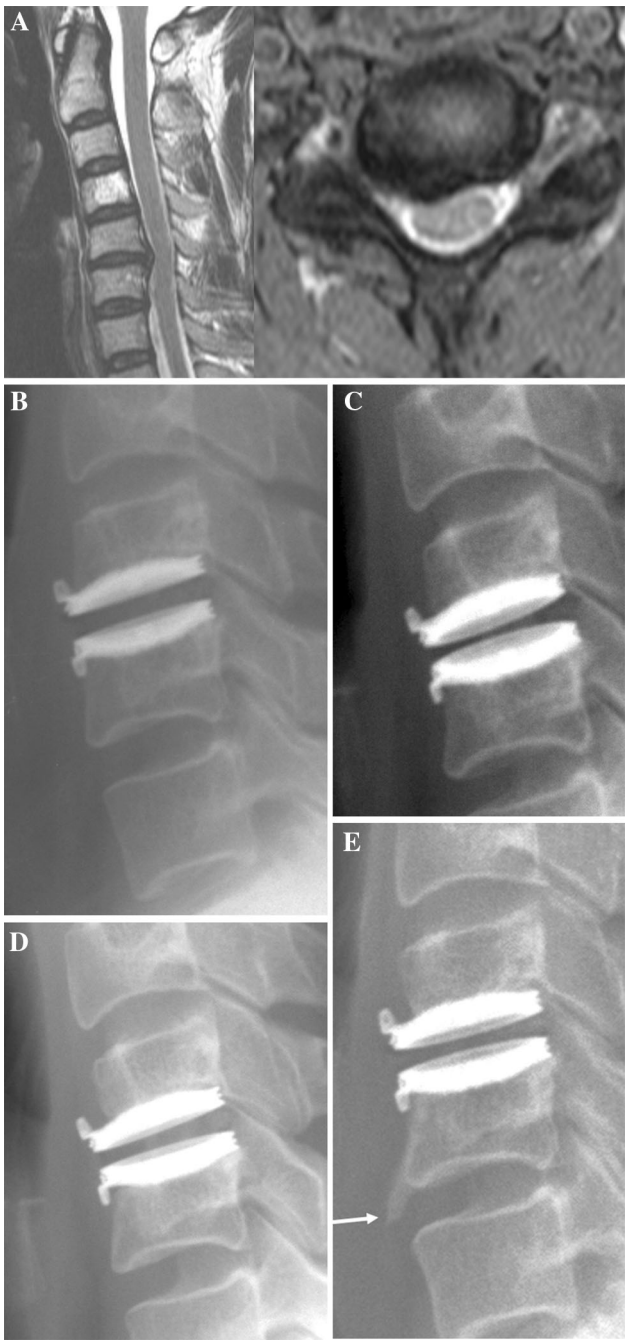

Fig. 3 Preoperative magnetic resonance image showing C5–C6 disc herniation (**a**). Postoperative neutral lateral radiographs showing the prosthesis in normal position 1 month (**b**) postoperatively, 1.2 mm of bone loss of upper adjacent vertebral body at 3-month follow-up (**c**), 2.7 mm of bone loss of upper adjacent vertebral body at 6-month follow-up (**d**), and 2.7 mm of bone loss of upper adjacent vertebral body and the ossification of the anterior longitudinal ligament over lower adjacent disc space at 42-month follow-up (**e**)

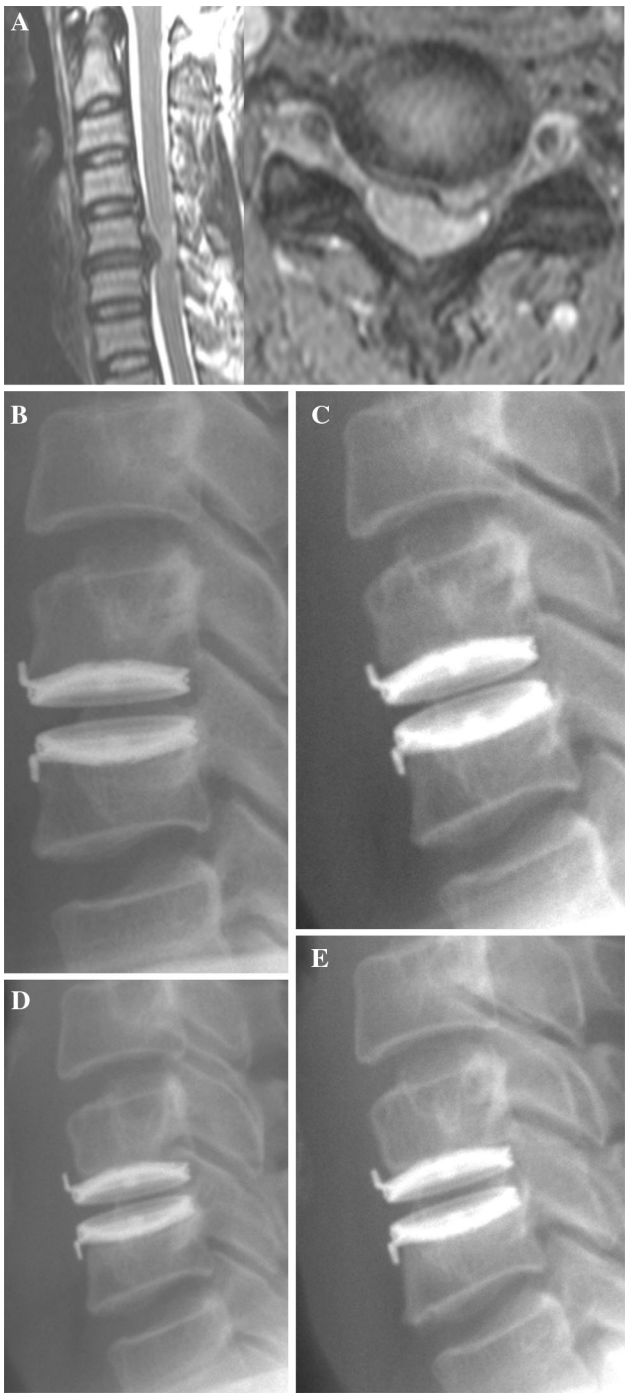

Fig. 4 Preoperative magnetic resonance image showing C5–C6 disc herniation (**a**). Postoperative neutral lateral radiographs showing the prosthesis in normal position 1 month (**b**) postoperatively, 1.0 mm of bone loss of upper adjacent vertebral body at 3-month follow-up (**c**), 2.0 mm of bone loss of upper adjacent vertebral body at 6-month follow-up (**d**), and 2.0 mm of bone loss of upper adjacent vertebral body at 48-month follow-up (**e**)

the superior adjacent vertebra may occur in the early postoperative period. Surgical placement of TDR device has been reported to have good mid-term clinical and radiological results, as it did in the current study, but it has been reported that device failure can occur due to osteolysis around spinal implants [4, 7–10, 20–22]. Recent reports described several cases of treatment failure after

metal-on-metal cervical TDR (Prestige ST; Medtronic Sofamor Danek, Memphis, TN, USA) or metal-on-polymer keeled TDR (ProsDisc-C; DePuy Synthesis Spine, Raynham, MA, USA) due to progressive vertebral body osteolysis [20–22]. The osteolysis of the vertebral body was evident on radiographs by 7–15 months after TDR and appeared to result from delayed type of hypersensitivity and lymphocytic reaction. However, no one has described bone loss immediately posterior to the anterior flange of Bryan disc on the superior adjacent vertebra in the early postoperative follow-up period as we described this potential complication in the present study.

Originally, bone loss has been widely documented in large joint arthroplasty [23–30]. Bone loss around the implants has been considered to be one of the main flaws of the large joint replacements, but the etiology of bone loss remains uncertain. It has been reported that bone loss after joint replacement surgery could be associated with foreign body response to wear debris, micromovement between surfaces, stress shielding effect, and other rare osteolysis instances [23–30]. Micromovement does occur at the prosthesis bone interface and it may cause mechanical damage to the underlying bone and subsequent bone loss [25]. Wear particles, which are generated as the artificial knee or hip joint undergoes normal wear, have long been implicated in causing bone loss adjacent to total joint replacement [20, 26, 27]. Wear particle generation is one of the most important factors in stimulating inflammatory reaction and osteoclastic activity and finally osteolysis around the implant occurs. Stress shielding effect has been reported to be another significant factor in the development of bone loss after total joint replacement of the hip and knee [23, 24, 28, 29]. After hip replacement surgery, femur remodeling and bone loss continue especially in the proximal femur and the stress shielding of the proximal femur is considered to be the mechanical cause of bone loss. Bone loss and cortical thinning eventually lead to joint prosthesis failure [28].

In the present study, the bone loss of the superior adjacent vertebra immediately posterior to TDR flange was found to occur in the early postoperative follow-up period. The bone loss was increased up to 6-month follow-up, but clinical outcomes did not deteriorate following bone loss in all patients and it did not progress or increased rates of graft failure in last follow-up lateral radiographs.

We propose two reasons for bone loss behind the flange of Bryan cervical disc. First, stress shielding seems to play an important role in the development of bone loss around the flange. Stress shielding, a mechanical effect occurring in structures combining stiff with more flexible materials, is considered to be the major reason for triggering the loosening and resorption processes around the implant [28–30]. The flanges, by design, prevent posterior migration of the device into the canal immediately after operation. Probably in the subacute recovery period, bony ingrowth of the endplates into the adjacent device surface occurs with stability. This would shift the stress to the endplates rather than from the junction of the flange and the anterior cortex. This helps explain why the bone loss is no longer progressive, as there is no more stress against this cortex with "fusion" of the device into the intervertebral space.

Second, friction and wear between the flange and vertebral body may cause wear debris, which may play a critical role in critical to bone loss of the adjacent vertebral body. Based on studies of Bryan cervical discs, the dome shape of shells resists anterior or posterior movement in the milled recess in the endplate. However, insufficiently milled endplates and the smaller size may cause the prosthesis to be unstable and produce friction and wear. The wear debris may induce pro-inflammatory response in the adjacent vertebral body, and pro-inflammatory cells from surgical site may further exacerbate the inflammatory response to particulate wear debris. However, wear debris is not a suitable explanation because this would take longer time to develop and would be progressive based on previous reports [20–22].

The limitation of this study is the low number of patients exhibiting bone loss and linear measurements of bone loss. Due to the low number of patients in which bone loss was observed, it is not possible for the authors to perform a statistical analysis to determine whether the bone loss can influence on clinical and radiological results. Postoperative CT was not obtained and it can be fairly difficult to diagnose bone loss accurately because linear measurements were carried out rather than volumetric measurements using postoperative CT. However, this study could point to the bone loss being a potential complication following the Bryan TDR even though the bone loss does not give rise to clinical deterioration.

In conclusion, the current study described bone loss immediately posterior to anterior TDR flange on the superior adjacent vertebra after implantation of Bryan cervical disc. The bone loss occurred in the early follow-up period and it was no longer progressive 6 months after implantation. Furthermore, it did not result in clinical changes or increased rates of graft failure. Therefore, bone loss immediately posterior to the TDR flange is not regarded as a cause of failure in itself. However, long-term follow-up study is needed to evaluate the outcomes and effect of bone loss of adjacent vertebral bodies. Additionally, it would be interesting in the future to find out what kind of tissue is between anterior flange and bone.

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Conflict of interest The authors report no conflict of interest concerning the materials or methods used in this study or the findings described in this paper. No benefits in any form have been or will be received from any commercial party related directly or indirectly to the subject of this manuscript.

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