Zero-Profile Versus Cage and Plate in Anterior Cervical Discectomy and Fusion for the Treatment of single- level Traumatic Cervical Disc Herniation: A Minimum of Three-Year Follow-Up Study

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Research Article

Keywords: Anterior cervical discectomy and fusion, Traumatic cervical disc herniation, Zero-Profile, Fusion, Dysphagia, Subsidence

Posted Date: November 30th, 2022

DOI: https://doi.org/10.21203/rs.3.rs-2321739/v1

Abstract

Background

Compared with cage and plate, Zero-Profile device in single and multi-level anterior cervical discectomy and fusion (ACDF) for the treatment of cervical degenerative disc diseases shows similar efficacy in improving functional and radiologic outcomes, and reducing incidence of complication rate, especially dysphasia. Whether Zero-Profile device is appropriate for ACDF in the treatment of single-level symptomatic traumatic cervical disc herniation is still unknow. We compare the mid-term efficacy and safety in ACDF using Zero-Profile device with cage and plate for the treatment of single-level traumatic cervical disc herniation.

Methods

From Aug 2014 to Aug 2018, 53 patients with symptomatic traumatic cervical disc herniation underwent ACDF with Zero-Profile device (Group ZP) or cage and plate (Group CP) were included. The clinical outcomes (Japanese Orthopedic Association score (JOA), Neck Disability Index (NDI) score, Visual Analogue Scale (VAS) score, radiological outcome and complications were reviewed and compared.

Results

All procedures were successfully performed in all patients. The JOA score, NDI score, VAS score and cervical lordosis were significantly improved postoperatively in both groups ($P < 0.05$), but there were no significant differences between the two groups at each follow-up time ($P > 0.05$). There were no significant differences in fusion rate and cage subsidence rate between the two groups ($P > 0.05$). However, the dysphagia rate at postoperative immediately, 1 week and 1 month in Group ZP (14.8%, 11.10% and 3.7%) were lower than those of Group CP (21.7%, 17.4% and 13.0%) ($P > 0.05$). All patients achieved solid fusion and no patient had dysphagia at final follow-up.

Conclusions

ACDF with Zero-Profile device can not only obtain similar surgical effects compared with cage and plate in the treatment of single-level traumatic cervical disc herniation, but may reduce the incidence of dysphagia rate at early post operative period. Therefore, ACDF with Zero-Profile can be used as an effective and reliable treatment for single-level traumatic cervical disc herniation.

Introduction

Cervical spine trauma ranged from minor sprain to catastrophic spinal cord injury is a common problem in adults[1]. Most of the patients experienced minor neck trauma while playing sport or catching road traffic accident. Symptomatic traumatic cervical disc herniation without adjacent fracture or dislocation is not a common condition, occurring in only 3% of cervical spine injury victims and 0.08% of all trauma patients[2]. The herniated cervical disc can cause further compression of spinal cord and increase the risk of neurological deterioration during conservative treatment[3,4]. The clinical manifestations are usually either incomplete or complete quadriplegia with or without spinal cord compression. The purpose of surgical treatment is to remove the herniated and injured disc, prevent additional functional loss, and restore spinal stability[5]. Anterior cervical discectomy and fusion (ACDF) is considered as the gold-standard procedure for the treatment of symptomatic traumatic cervical disc herniation[1,6]. ACDF could not only remove broken disc and the possible compression on the spinal cord, but also provide immediate biomechanical stability by plate and cage.

The addition of anterior plate in ACDF surgery can reduce cage subsidence, promote fusion, improve cervical sagittal alignment and maintain cervical stability[7, 8]. However, anterior cervical plate is associated with several unavoidable complications such as dysphagia, soft tissue injury and higher incidence of adjacent segment disease[8–10]. Recently, Zero-Profile device was invented to reduce potential complications and maintain the benefits of traditional interbody cage with plate[11]. Previous studies have demonstrated that Zero-Profile device used in single and multi-level ACDF shows similar efficacy in improving functional and radiologic outcomes, and reducing incidence of complication rate, especially dysphasia[12–14].

Whether Zero-Profile device is appropriate for ACDF in single-level symptomatic traumatic cervical disc herniation is still unknown. There are few studies on the efficacy of Zero-Profile device in patients with traumatic cervical disc herniation. The aim of the present study was to evaluate the surgical parameters, clinical and radiological outcomes of single-level symptomatic traumatic cervical disc herniation patients underwent ACDF with Zero-Profile device.

Methods

Study Design and Patient Population

This was a retrospective cohort study approved by the Institutional Ethics Committee of Clinical Medical College of Yangzhou University. From Aug 2014 to Aug 2018, a total of 53 patients with single-level symptomatic traumatic cervical disc herniation underwent ACDF with Zero-Profile device or cage and plate were enrolled in the study. Written informed consent to participate in the study was obtained from all patients. All patients were examined preoperatively and assessed by radiography (anteroposterior and lateral), magnetic resonance imaging (MRI), and multiplanar reconstructed computed tomography (CT) (Fig. 1–4).

Inclusion criteria were as follows: 1) diagnosis of one-level traumatic cervical disc herniation underwent ACDF with Zero-Profile device or cage and plate, 2) operative level at C3-C4 to C6-C7, and 3) follow-up period > 36 months. The exclusion criteria were: 1) significant segmental instability, 2) requirement of posterior surgery, 3) bony fracture, 4) metabolic bone disease, 5) active infection or uncorrectable bleeding diatheses, and 6) severe comorbidity in heart, liver, kidney, and lung intolerance to surgery.

Fifty-three patients initially fulfilled the study criteria, and 3 patients were lost to follow-up. According to the surgical method, 50 patients were divided into two groups. A total of 27 patients receiving ACDF with Zero-Profile device were classified as Group ZP. Meanwhile, another 23 patients who underwent ACDF with cage and anterior plate served as Group CP. There were no statistically significant differences between the two groups in terms of age, sex, treated levels and follow-up time ($P > 0.05$; Table 1,2).

Surgical Management

All surgeries were performed via the anterior Smith-Robinson approach by an experienced spinal surgeon of our department as we described previously[12]. Patient underwent routine surgery in a supine position with mild neck hyperextension after general anesthesia and a right-sided transverse incision was implemented to expose the target segment. After confirmation and exposure of the appropriate operation level, a Caspar cervical distractor was placed in the adjacent vertebral bodies. After complete decompression and endplate preparation were finished, trial spacer was used to determine the most suitable implant shape and size. For Group ZP, an appropriate Zero-Profile device filled with excised local osteophytes and demineralized bone matrix was implanted into the prepared target space and then the implant was fixed with 4 screws cranially and caudally. For Group CP, an appropriate interbody cage instrumented with cervical plate and screws were implanted as the method we described before[12]. After the release of the Casper distractor, a manual pullout test was conducted to confirm the stability of the segments. All patients were immobilized by a Philadelphia collar for 1 months post-operatively.

Clinical Evaluation

All patients were followed up at 3 months and final follow-up postoperatively to conduct a clinical and radiological assessment after discharge. The demographic data and perioperative details, including operative time, intraoperative blood loss and complications in the intraoperative/postoperative period were recorded. Clinical outcomes were evaluated using visual analogue scale (VAS), neck disability index (NDI) score and Japanese Orthopaedic Association (JOA) score. The incidence of dysphagia was evaluated at postoperative immediately, 1 week, 1 month and 3 months after surgery according to the criterion defined by Bazaz et al[15].

Radiological Evaluation

The radiological evaluation was blindly assessed by two independent surgeons. Standard anterior-posterior/lateral radiographs were performed at 1 months postoperatively, 3 months and final follow-up after surgery and measured by two independent radiologists. The cervical lordosis was assessed by the

Cobb angle method between the line parallel to the upper vertebral body of C3 and the lower vertebral body of C7 on the standing lateral plain radiograph.

Fusion was assessed by static and flexion-extension cervical lateral images. Solid fusion was defined according to the following criteria[13,16]: (1) presence of continuous bridging bony trabeculae present across the intervertebral space, (2) less than 2°of fused segments on flexion/extension radiographs, and (3) absence of transparent belt between the cage and endplates. The radiographic subsidence was defined as the loss of anterior intervertebral disc height or posterior intervertebral disc height greater than 2 mm[17]. The adjacent segment degeneration (ASD) was assessed by lateral plain X-ray at final follow-up[18]. New anterior osteophyte formation or enlargement, increased narrowing of the interspace, and calcification of the anterior longitudinal ligament were radiologic findings indicating ASD.

Statistical Analysis

Data were shown as mean ± standard deviation. All the analyses were performed using the SPSS (Version 23.0, Chicago, IL). Independent sample t-tests were performed for the intergroup comparisons in surgical parameters, clinical outcomes and radiographic parameters. Comparisons between before and after operation were made using paired t-test. The differences of dysphagia and cage subsidence ratio between the two groups were assessed using Chi-square test. Statistical significance was considered as P value less than 0.05.

Results

Surgical Parameters

The surgery procedures were successfully performed in all patients. There were 27 patients in Group ZP (C3-4, n = 1; C4-5, n = 7; C5-6, n = 14; C6-7, n = 5), and 23 patients in Group CP (C3-4, n = 2; C4-5, n = 3; C5-6, n = 15; C6-7, n = 3) (Table 1). The mean intraoperative blood loss and operative time was 71.7 ± 26.7 ml and 78.1 ± 13.3 min in Group-ZP and 86.1 ± 35.0 ml and 84.6 ± 15.0 min in Group CP. The differences of operative time and intraoperative blood loss between the two groups were not statistically significant (P > 0.05; Table 2).

Clinical Outcomes

The mean follow-up time was 38.9 ± 2.3 months in Group ZP and 38.4 ± 3.6 months in Group CP, and the difference was not statistically significant (P > 0.05; Table 2). The JOA score, NDI score, VAS score for the neck and arm were significantly improved postoperatively compared with preoperative in both groups (P < 0.05) (Table 3). All the improvements were maintained over time, and there were no statistically significant differences between postoperative and last follow-up (P > 0.05; Table 3). In addition, there were no significant differences between the two groups in terms of all the clinical values at each follow-up time.

Radiological Outcomes

The cervical lordosis was significantly corrected from 13.2 ± 8.0° preoperatively to 18.6 ± 7.9° at 3 months and 20.1 ± 8.9° at final follow-up postoperatively in Group ZP, and from 11.6 ± 7.4° preoperatively to 17.3 ± 7.3° at 3 months and 17.2 ± 7.4° final follow-up postoperatively in Group CP (Figs. 3–4 and Table 3). No significant differences in cervical lordosis were found between the two groups at each follow-up time ($P > 0.05$) (Table 3). The fusion rate at 3 months postoperatively was 81.5% (22/27) in Group ZP and 87.0% (20/23) in Group CP, which was not significantly different ($P > 0.05$; Table 4). All patients achieved solid fusion at final follow-up.

Complication Outcomes

All patients tolerated the procedure well and no implant failure happened during follow-up. According to the Bazaz criteria, the dysphagia rate at postoperative immediately, 1 week and 1 month in Group ZP (14.8%, 11.10% and 3.7%) was lower than those of Group CP (21.7%, 17.4% and 13.0%) ($P > 0.05$; Table 4). However, none of these patients complained of dysphagia at 3 months postoperatively. In addition, 3 patients in Group ZP and 2 patients in Group CP complained of cage subsidence at 1 month postoperatively ($P > 0.05$; Table 4). These patients were asked to wear a Philadelphia collar for another 1–2 months and none of these patients complained of cage subsidence at 3 months postoperatively. Meanwhile, the incidence of ASD was 3.7% (1/27) in Group ZP and 8.7% (2/23) in Group CP at final follow-up, but the difference between the two groups was not statistically significant ($P > 0.05$; Table 4). Fortunately, none of the patients showed clinical symptoms associated with ASD.

Discussion

The Efficacy of ACDF Treatment in Traumatic Cervical Disc Herniation

Traumatic cervical disc herniation is an uncommon injury pattern in general. The aim of surgical treatment is to avoid further damage to the spinal cord, remove compression on the nerve roots and spinal cord, reestablish the cervical lordosis and restore spinal stability[5]. ACDF has become the standard procedure for the treatment of degenerative cervical disc disease due to direct neural decompression and reconstruction of spinal stability[19]. ACDF with or without posterior fixation has been proven to be a safe and effective procedure for traumatic cervical injury[1,6]. In this study, ACDF was used in selected patients who had no bony fracture, severe segmental instability, or kyphotic deformity. Satisfactory clinical outcomes were obtained in almost all patients of both groups. Although cage subsidence were observed in Group ZP (3/27) and Group CP (2/23) at 1 month postoperatively, and 2 of these patients were found with osteoporosis. We considered that osteoprosis may influence cage subsidence, then all these patients were asked to wear a Philadelphia collar for another 1–2 months and receive anti-osteoprosis treatment. None of these patients complained of cage subsidence at 3 months postoperatively, the interbody fusion and clinical outcome were not impact by cage subsidence. Thus, ACDF can be used successfully in traumatic cervical disc herniation without bone involvement.

Safety and Efficacy of Zero-Profile Device in ACDF for Traumatic Cervical Disc Herniation

Zero-Profile device is a new type of cervical integrated intervertebral fusion device consisted of a small titanium alloy plate, polyether-ether ketone (PEEK) cage, and 4 screws for fixing into the vertebral body. The safety and efficacy of Zero-Profile device in ACDF have been demonstrated in previous studies[13, 20, 21]. Zero-Profile device was also used successfully in singl-level ACDF with osteoporosis as we reported before[22]. Previous studies have demonstrated that Zero-Profile device used in ACDF not only had a similar radiologic fusion rate and clinical outcomes compared with anterior plate and cage, but also decreased complication rate including dysphagia and ASD[20, 21, 23]. Zero-Profile device has been accepted as a effective fusion method for ACDF in the treatment of single level and multi-level cervical degenerative disc disease[11, 22, 24, 25]. In the present study, we also found that ACDF with Zero-Profile device can be used as a safe and effective treatment for patients with single-level traumatic cervical disc herniation.

In the present study, the cervical lordosis, JOA, NDI and VAS scores in all patients of the two groups were significantly improved at final follow-up. Meanwhile, solid bony fusion was observed in all patients at final follow-up. Subsidence of the implant is a normal complication in ACDF with stand-alone cage. It was reported that subsidence often happens at 3 months after surgery, and the subsidence rate ranges from 9.3 to 62.5%[25–28]. In the present study, cage subsidence rate was 11.1% in Group ZP and 8.6% in Group CP, which were within the range of previous studies. No significant difference was found between the two groups. Igarashi H et al. found that a greater cage height had a higher risk of cage subsidence in ACDF[29]. Park JY et al. reported that cage location is the risk significant factor for cage subsidence in ACDF, and the cage location within 3 mm from the anterior margin of the vertebral body showed lower incidence of subsidence[30]. Although previous studies confirmed that cage subsidence does not appear to affect clinical outcome[26, 31], it still needs to be evaluated in the long-time follow-up. Although we observed 3 case in Group ZP had cage subsidence, these patients still showed a satisfied clinical outcomes and bony fusion at final follow up.

Wu et al. reported that the improvement of cervical lordosis is more important than the impact of cage subsidence in the long-term study[31]. A number of studies confirmed that maintenance of cervical lordosis is associated with clinical outcomes[32,33]. The axial load of normal cervical spine is distributed on the posterior column in the upright neutral position[34]. Axial load shifts anteriorly as the progress of cervical lordosis loss, which will increase the incidence of implant failure, ASD and even cervical kyphosis[8,35]. In additionally, insufficient recovery of cervical lordosis after ACDF may result in neck pain, shoulder pain, cervical instability, cord compression, and even poor functional recovery [33,35]. In the present study, cervical lordosis were significantly improved and maintained over time at final follow-up in all patients. Therefore, ACDF with Zero-Profile device can obtain similar improvment of cervical lordosis compared with cage and plate.

Solid interbody bony fusion is one of the aims of ACDF surgery, and Kaiser MG et al. reported that bony fusion failure is linked to poor clinical outcomes[36]. Some studies reported that postoperative kyphotic deformity with concomitant foraminal stenosis can be prevented by solid bony fusion[37, 38]. A systematic literature review reported that bony fusion rate of 3971 ACDF patients who received cage with plate was 91.4% at final follow-up, and bony fusion rate of 499 patients who received a cage with screws attached (no plate) was 96.6%[39]. According to the result of our study, there was no statistically significan difference in fusion rate between the two groups at 3 month postoperatively. All patients achieved solid fusion at final follow-up. Consequently, Zero-Profile device can obtain similar bone fusion compared with cage and plate in ACDF for single-level traumatic cervical disc herniation.

Advantages of Zero-Profile Device in ACDF for Traumatic Cervical Disc Herniation

Swallowing dysfunction or dysphagia is one of the major complications after ACDF with anterior plate fixation. Previous studies reported that the incidence of dysphagia after anterior cervical fusion with plate vary from 1–62%[9, 40, 41]. The dysphagia-related symptoms may be explained by postoperative hematoma, esophageal injury, postoperative soft-tissue edema, and adhesive formations around implanted cervical plate[8]. It has been found that there is a correlation between plate thickness and dysphagia rate[42]. Zero-Profile device can be inserted into the intervertebral space, avoiding stimulating esophagus and other pre-vertebral soft tissues[9, 20]. According to the result of present study, the incidence of postoperative dysphagia in Group ZP was lower than that of Group CP at postoperative immediately, 1 week and 1month, but there were not significantly difference. The reason may be the sample size was small and the included cases were all single segment. Therefore, the application of Zero-Profile device in ACDF may reduce the incidence of early postoperative dysphagia, but further confirmation is needed in more cases and multi-segment cases.

ASD is another complication after ACDF with anterior plate fixation, and the exact pathophysiologic mechanism is still unknown[8,16,20]. Some scholars believed that ACDF may change the natural history of cervical spondylosis and the plate may increase the motion and intradiscal pressure in the untreated levels adjacent to fused levels[43]. Meanwhile, the anterior plate close to the adjacent disc may cause adjacent level disc degeneration, and the diatance between plate and cage < 5 mm may reduce the incidence of ASD[18]. In the present study, the incidence of ASD in Group ZP was 3.7% and 8.7% in Group CP, but the difference between the two groups was not statistically significant. However, a long-time study with more patients should be performed to investigate whether or not the Zero-P device can reduce the rate of ASD.

However, this study still has some limitations. First, it is a single-center retrospective cohort study. Moreover, the sample size was small. Further multicenter prospective randomized studies and larger patient samples are needed to confirm the results. Meanwhile, only single-level traumatic cervical disc

herniation was erolled in the present study, whether multi-level segment can influence the complations or clinical outcomes still needed further research.

Conclusion

ACDF with Zero-Profile device can not only obtain similar surgical effects compared with cage and plate in the treatment of single-level traumatic cervical disc herniation, but may reduce the incidence dysphagia rate at early post operative period. Therefore, ACDF with Zero-Profile can be used as an effective and reliable treatment for single-level traumatic cervical disc herniation.

Abbreviations

ACDF
anterior cervical discectomy and fusion
NDI
Neck Disability Index
JOA
Japanese Orthopedic Association
VAS
Visual Analogue Scale
ASD
adjacent segment degeneration.

Declarations

Acknowledgements

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

Wenjie Zhao and Yu Zhang: drafted the manuscript and data collection. Man Hu, Xin Liu, Jiandong Yang: data collection and data analysis. Yuping Tao, Yongxiang Wang: study conception and study design. Xinmin Feng: Writing-Reviewing and Editing. Liang Zhang: Funding acquisition and Supervision.

Funding

Key Funding Project of Maternal and Child Health Research of Jiangsu Province (F201801); High-level Health Professionals "Six projects" Top-notch Talent Research Program of Jiangsu Province

(LGY2019035); Traditional Chinese Medicine Science and Technology Development Plan Project of Jiangsu Province (YB2020085)

Availability of data and materials

The datasets used during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Current research study was approved by the Institutional Ethics Committee of Clinical Medical College of Yangzhou University. Patient Consent: Informedwritten consent was obtained from the participants included in this study.

Consent for publication

Not applicable.

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Tables

Table 1
Number of treated levels

Level	Group ZP	Group CP
C3-4	1	2
C4-5	7	3
C5-6	14	15
C6-7	5	3

Table 2
Demographic data of patients in Group ZP and Group CP

Characteristic	Group ZP	Group CP	*P* Value
Number of patients	27	23	
Gender			0.31
Male	15	16	
Female	12	7	
Age (years)	46.4 ± 10.9	50.3 ± 9.8	0.20
Operative time (minutes)	78.1 ± 13.3	84.6 ± 15.0	0.12
Blood loss(ml)	71.7 ± 26.7	86.1 ± 35.0	0.08
Follow-up period (months)	38.9 ± 2.3	38.4 ± 3.6	0.60
Data presented as number of patients or mean ± standard deviation.			

Table 3
Preoperative and postoperative scores in Group ZP and Group CP

Scale	Group ZP	Group CP	*P* Value
JOA score			
Preoperative	7.3 ± 1.6	7.6 ± 1.4	0.55
Postoperative 3 months	13.6 ± 1.2*	13.6 ± 1.3*	0.95
Final follow-up	13.7 ± 1.0*	14.1 ± 0.8*	0.26
NDI score			
Preoperative	30.9 ± 4.4	30.4 ± 4.1	0.71
Postoperative 3 months	13.0 ± 1.7*	12.1 ± 1.9*	0.09
Final follow-up	12.5 ± 2.0*	11.1 ± 2.0*	0.14
VAS score (neck)			
Preoperative	5.8 ± 1.2	6.0 ± 1.4	0.75
Postoperative 3 months	3.2 ± 0.8*	3.2 ± 1.0*	0.77
Final follow-up	2.5 ± 0.7*	2.7 ± 0.7*	0.29
VAS score (arm)			
Preoperative	4.1 ± 1.1	4.2 ± 1.0	0.84
Postoperative 3 months	2.4 ± 0.6*	2.5 ± 0.5*	0.45
Final follow-up	1.7 ± 0.7*	1.7 ± 0.7*	0.84
Cobb angle (^{o})			
Preoperative	13.2 ± 8.0	11.6 ± 7.4	0.53
Postoperative 3 months	18.6 ± 7.9*	17.3 ± 7.3*	0.53
Final follow-up	20.1 ± 8.9*	17.2 ± 7.4*	0.23

Data presented as mean ± standard deviation. JOA, Japanese Orthopaedic Association; NDI, neck disability index; VAS, visual analog scale.

*Statistically significant improvement compared to respective preoperative score ($P < 0.05$).

Table 4
Comparison of dysphagia rate, cage subsidence rate and fusion rate in Group ZP and Group CP

Variable	Group ZP	Group CP	*P* Value
Dysphagia rate			
postoperative immediately	14.8 (4/27)	21.7 (5/23)	0.79
Postoperative 1 week	11.1 (3/27)	17.4(4/23)	0.82
Postoperative 1 month	3.7 (1/27)	13.0 (3/23)	0.49
Postoperative 3 months	0 (0/0)	0 (0/0)	
Cage subsidence rate			
Postoperative 1 month	11.1 (3/27)	8.6 (2/23)	1.00
Postoperative 3 months	0 (0/0)	0 (0/0)	
Final follow-up	0 (0/0)	0 (0/0)	
Fusion rate			
Postoperative 3 months	81.5 (22/27)	87.0 (20/23)	0.89
Final follow-up	100 (27/27)	100 (23/23)	
ASD Rate at Final follow-up	3.7 (1/27)	8.7 (2/23)	0.89
ASD, adjacent segment degeneration. Data presented as % (n/N).			

Figures

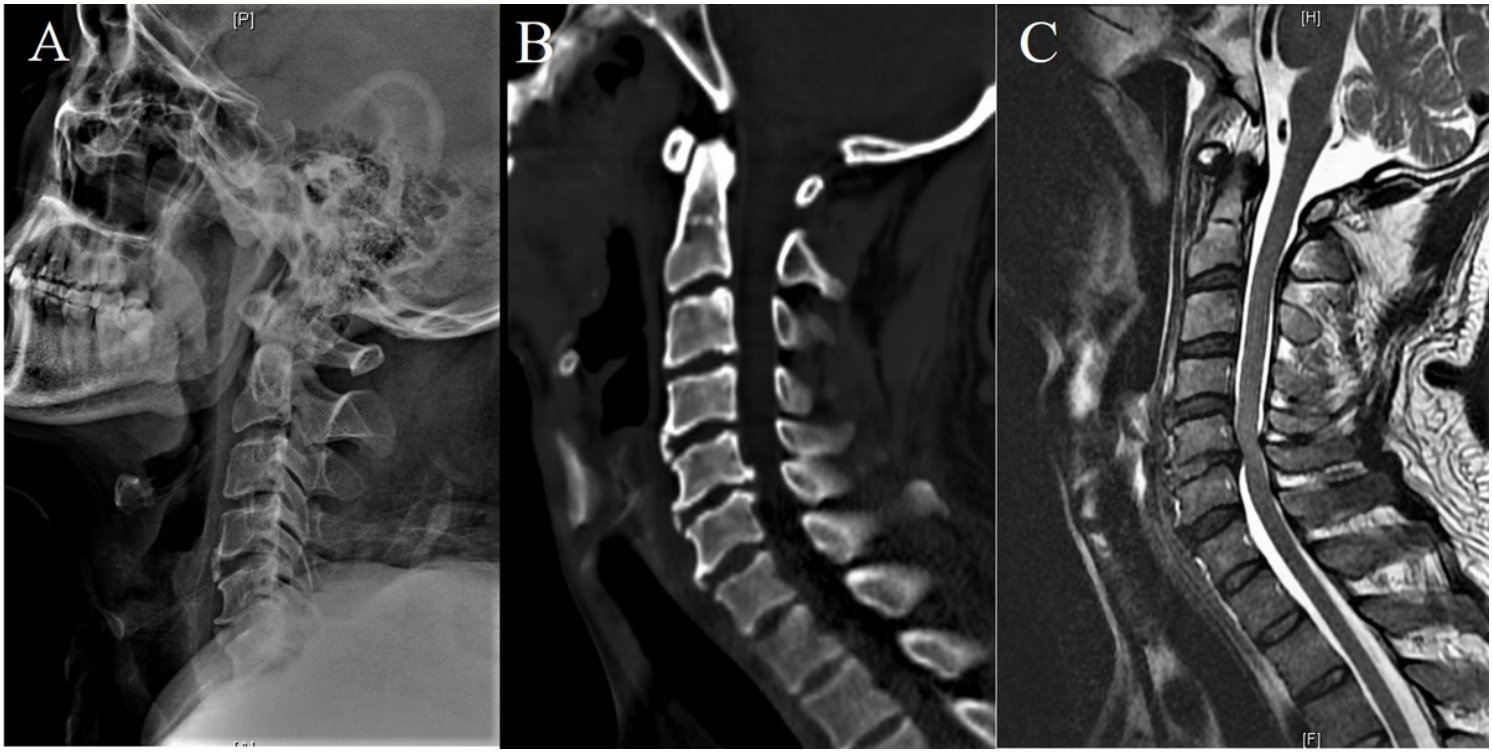

Figure 1

Preoperative lateral radiograph (A), computed tomography (B) and T2-weighted magnetic resonance imaging (C) in Group ZP (Zero-Profile device) showing cervical disc herniation with spinal cord compression but without adjacent vertebra fracture at C5-C6 level.

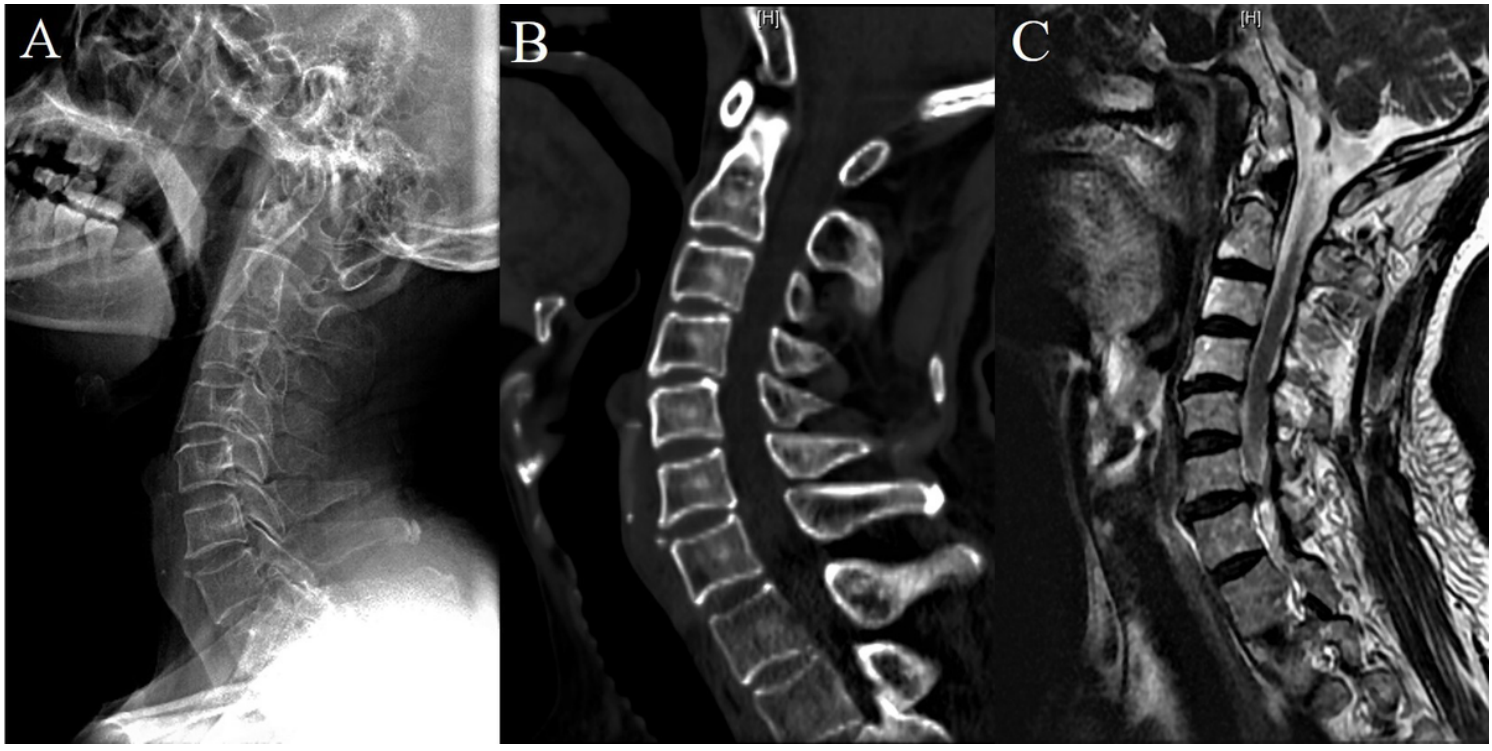

Figure 2

Preoperative lateral radiograph (A), computed tomography (B) and T2-weighted magnetic resonance imaging (C) in Group CP (cage and plate) showing cervical disc herniation with spinal cord compression but without adjacent vertebra fracture at C6-C7 level.

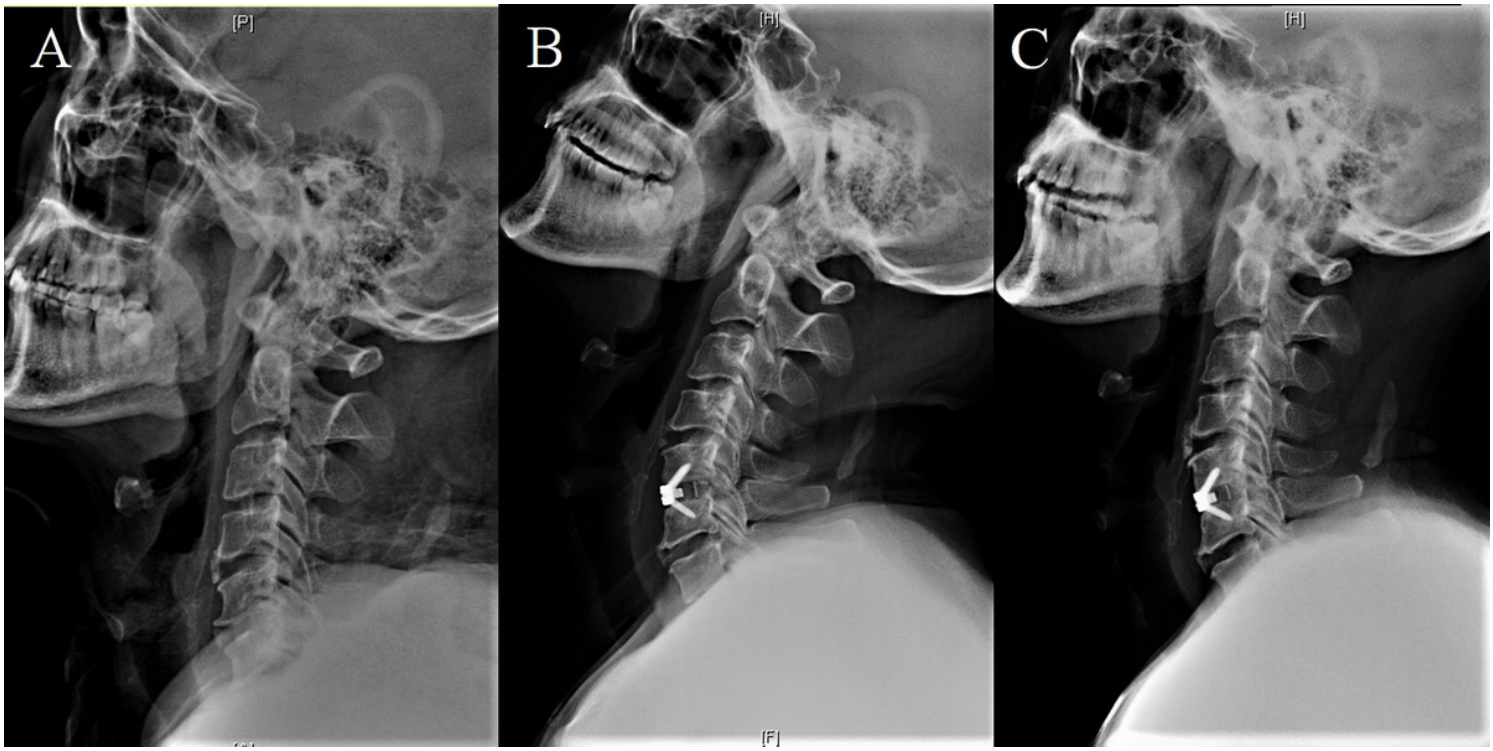

Figure 3

Lateral radiographs of the cervical spine in Group ZP (Zero-Profile device) at preoperative (A), 3 months postoperatively (B), and final follow-up (C) showing improvement of cervical lordosis and solid fusion.

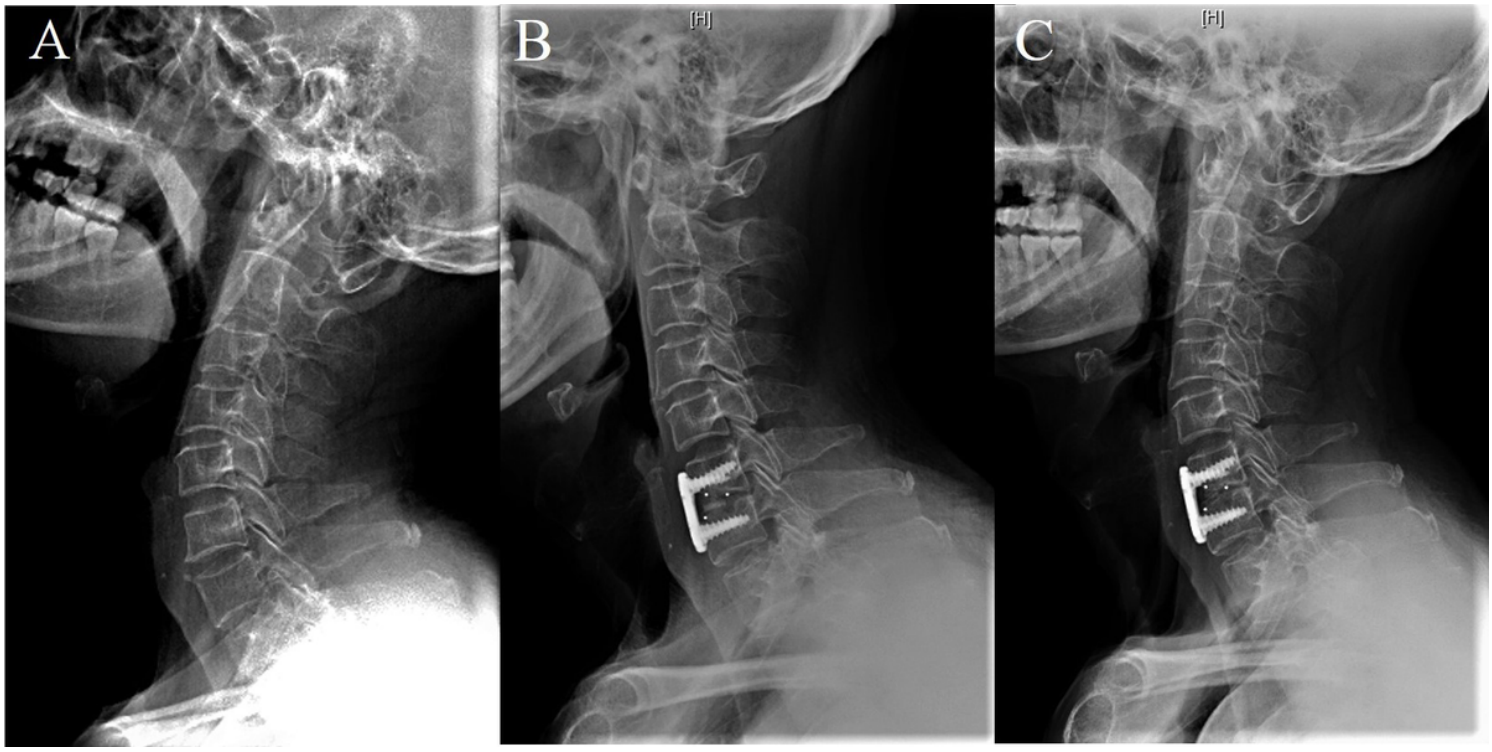

Figure 4

Lateral radiographs of the cervical spine in Group CP (cage and plate) at preoperative (A), 3 months postoperatively (B), and final follow-up (C) showing improvement of cervical lordosis and solid fusion.