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Case Report

Three-level anterior cervical decompression and fusion using the Zero-profile implant system

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Abstract: Owing to the complications and limitations associated with anterior plating, a new zero-profile, standalone device (Zero-P, Synthes GmbH, Switzerland) for ACDF has been designed in an attempt to overcome the adverse effects associated with traditional cervical anterior plating. Even the excellent outcomes showed in single or two-level ACDF, however, the safety and efficacy of the Zero-P implant applied in three-level ACDF has been little explored. Results from previous biomechanical studies showed that segmental stability decreases with the number of instrumented segments regardless of the used implant but the locking plate and cage construct was stiffer in all test modes than the Zero-P devices in multilevel constructs. However, whether this difference will affect the clinical outcomes still remains unclear. By presenting the clinical and radiographic outcomes of six cases with a short follow-up of 24 months, we are hoping to clarify the safety and effectiveness of three-level ACDF with the zero-profile implant system. The overall results of our study were good. Postoperative complications such as hoarseness, dysphagia, cerebrospinal fluid leakage, malposition of the prosthesis and screw loosening or pull-out were not observed. The patients' clinical symptoms were relieved 6 months after surgery. All the patients reached bony fusion at the sixth month follow-up according to the standard definition. The preliminary clinical and radiographic outcomes from this case series study demonstrated that the Zero-P implant system may be a safe and efficacious device in ACDF surgery. However, as this is just a case series study, larger randomized controlled studies of longer duration are warranted.

Keywords: Anterior cervical decompression and fusion, ACDF, case series, zero-profile, three-level, fusion

Introduction

For a long time, anterior cervical decompression and fusion (ACDF) has been regarded as the gold-standard surgery procedure in the treatment ofsingle-level and multiple-level cervical disc diseases [1-3]. Intervertebral cages, without or with an additional anterior cervical plate, has been the most widely used intervertebral devices in recent decades [4]. Even the great advances of techniques and instruments, the fusion rates of ACDF has not achieved 100%. Fairen et al. reported the pseudoarthrosis ratecan be as high as 15.2% in a prospective randomized controlled study [5]. A recent meta-analysis based on 17 prospective studies reported the overall pseudoarthrosisrate is 2.6% (95% CI: 1.3-3.9) [6]. ACDF with an anterior cervical plate can increase fusion rates, maintain or improve cervical sagittal alignment and stability, and reduce the risk of graft extrusion and subsidence, particularly in multiple-level surgery [7, 8]. However, anterior plating may also be associated with potential disadvantages and complications such as including increased dysphagia rates, tracheoesophageal lesions and plate malposition.

Owing to the complications and limitations associated with anterior plating, a new zero-profile, standalone device (Zero-P, Synthes GmbH, Switzerland) for ACDF has been designed in an attempt to overcome the adverse effects associated with traditional cervical anterior plating. A number of studies have reported the application of the Zero-P in single or two-level ACDF with excellent clinical and radiographic outcomes [9-11]. However, three-level ACDF with Zero-P has been little reported. The biomechanical stability, and fusion rates of three-lev-

Table 1. Characteristics of Patients included in this study

NO.	Age	Gender	Smoking status	Segments	Intraoperative time (min)	Estimated blood loss (ml)	Length of hospital stay (d)	Follow-up time (month)
Case 1	61	M	NO	C4/5, C5/6, C6/7	200	300	14	38
Case 2	74	M	Yes, 30 years	C3/4, C4/5, C5/6	180	80	14	21
Case 3	61	M	Yes, 40 years	C3/4, C5/6, C6/7	220	100	12	19
Case 4	73	M	NO	C4/5, C5/6, C6/7	175	100	13	15
Case 5	64	F	NO	C4/5, C5/6, C6/7	210	120	19	9
Case 6	62	F	NO	C4/5, C5/6, C6/7	230	110	9	9

M, Male; F, Female.

Table 2. Clinical and radiographic outcomes of six patients

NO.	VAS for arm*	VAS for neck	NDI (0-50)	ROM (C2-7)	Fusion
Case 1	9; 3; 1	7; 4; 2	41; 20; 10	52; 23; 20	Bony Fusion
Case 2	8; 4; 2	7; 3; 2	42; 18; 8	54; 26; 21	Bony Fusion
Case 3	9; 3; 0	8; 3; 1	41; 18; 10	49; 22; 19	Bony Fusion
Case 4	7; 4; 0	7; 2; 1	41; 20; 8	50; 21; 18	Bony Fusion
Case 5	8; 3; 1	7; 3; 2	42; 16; 8	53; 19; 19	Bony Fusion
Case 6	7; 2; 0	8; 3; 1	41; 20; 10	52; 22; 19	Bony Fusion

VAS, visual analogue scale for pain; NDI, neck disability index; ROM. range of motion. *All data was listed as preoperative, 3 months after surgery, the final follow- up in order and separated by semicolons.

el ACDF with the Zero-P remains controversial. Scholz et al. compared the multilevel stability of Zero-P with established fixation techniques in eight fresh-frozen human cadaveric cervical spines (C3-C7, nondestructively tested in a biomechanical 3-dimensional spine test setup) and the results showed that segmental stability decreases with the number of instrumented segments regardless of the used implant but the locking plate and cage construct was stiffer in all test modes than the Zero-P devices in multilevel constructs [12]. However, they also conclude that whether this difference will affect the clinical outcomes still remains unclear.

By presenting the clinical and radiographic outcomes of the special six cases with a short follow-up of 24 months, we are hoping to clarify the safety and effectiveness of three-level ACDF with the zero-profile implant system.

Case report

A total of six consecutive patients who underwent three-level ACDF with Zero-P between September 2012 and September 2012 were retrospectively reviewed in this study. All patients underwent three-level ACDF with Zero-P during this period were included in this study. All of the six patients were free of active infections, pathologic fractures of the vertebrae, spinal deformity, osteoporosis and acute or chronic serious diseases which might increase the perioperative risk. The study was approved by Medical Ethical Committee of West China Hospital, Sichuan University, China. All of the six patients provided informed consent for the retrospective analysis of their clinical and radiological data. All patients were treated and followed-up at the West China Hospital, Sichuan University in Chengdu city, China.

The following data for each patient including age, gender, the body mass index (BMI), location and duration of pain, the visual analogue scale for pain (VAS) scores, neck disability index (NDI), range of motion (ROM) were collected. Plain radiographs (including flexion/extension views) and magnetic resonance imaging (MRI) were performed prior to surgery.

Anterior cervical decompression and fusion with Zero-P was performed via a classic right Smith–Robinson approach after induction of general anesthesia by a very experienced spinal surgeon. The correct incision point was determined with the help of fluoroscopy and metal markers. A horizontal right side skin incision (about 7 cm long) was performed to reach the perpendicularly spreading fibres of the platysma muscle. The disc level was confirmed by fluoroscopy, discectomy was done and long shaft Caspar screws for interbody retraction were inserted into the middle of the adjacent vertebral bodies. The subchondral endplateof each vertebral body was prepared with a high-

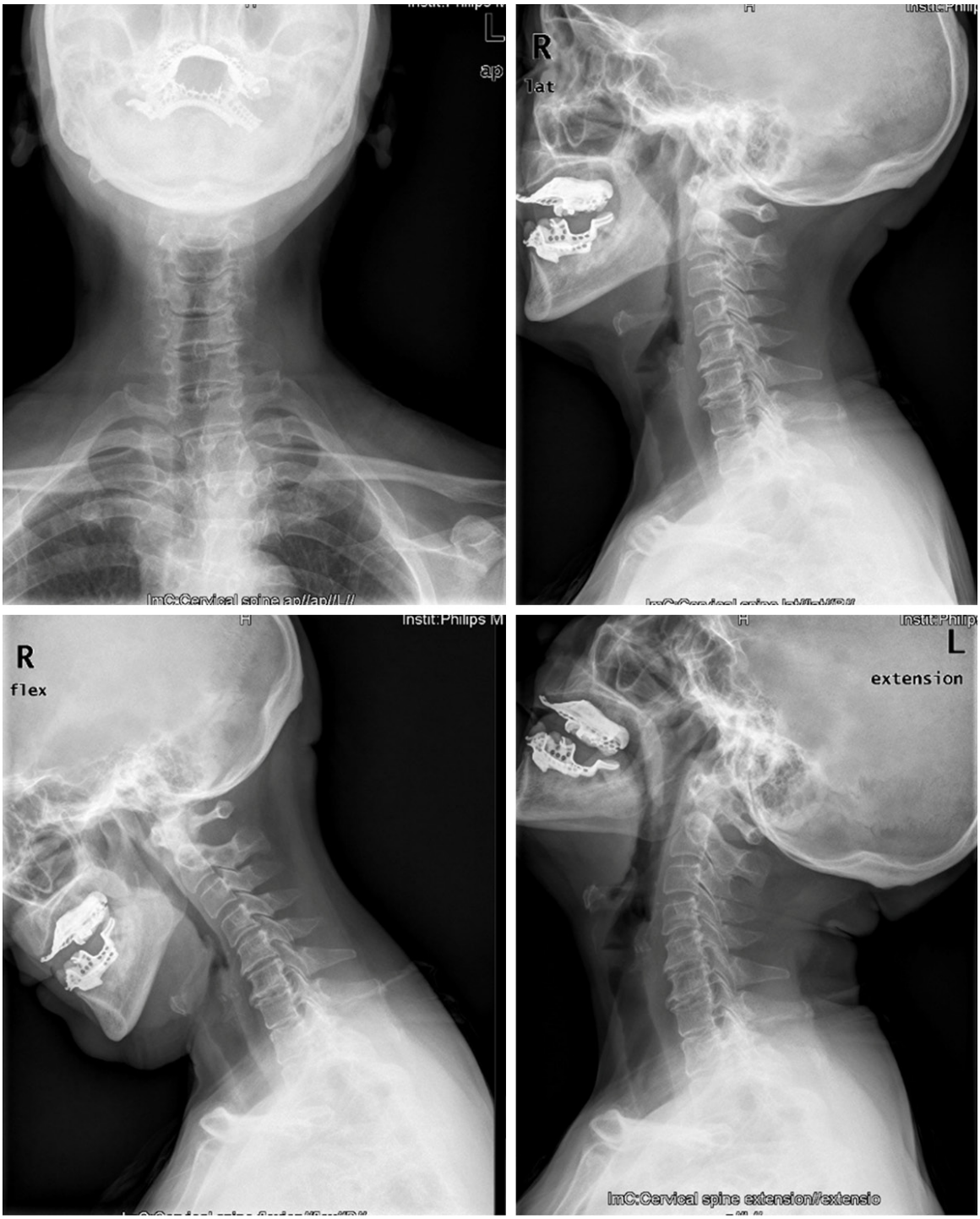

Figure 1. Preoperative anteroposterior, lateral and functional X-rays.

speed drill and curette. When the endplate preparation completed, the disc space was distracted and a Zero-P implant of appropriate size fulfilled with artificial bone was inserted with the help of fluoroscopy. Final imaging of the device implantation is performed before wound closure. Then, the wound wasclosed in a layer-by-layer fashion after drainage insertion.

Charts and medical records of six patients were reviewed. Neurological examination and functional assessment were recorded pre-opera-

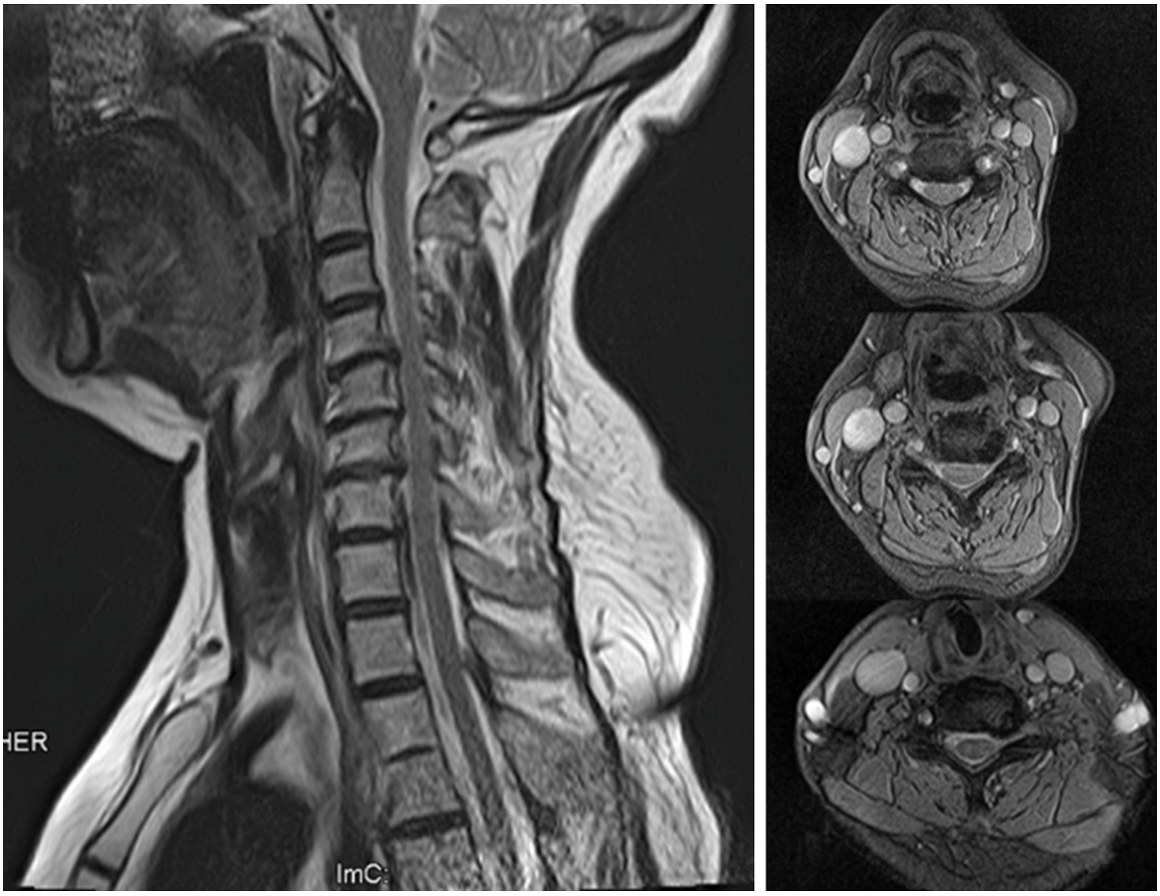

Figure 2. Preoperative magnetic resonance imaging.

tively, at 3, 6, 12 and 24 months and at the latest follow-up assessment. The assessment including the VAS for neck and arm pain and NDI score were performed by 2 specialists under supervision of the attending surgeons. All of the patients underwent pre-operative plain radiographs and MRI. Antero-posterior, lateral and functional radiographs and CT scan were performed at each follow-up. Range of motion was measured as the difference in angulation between extension and flexion X-rays. Implant failure, including screw loosening or breakage was recorded. An initial halo sign, defined as a radiolucent line around the implant > 1 mm wide, followed by a double halo sign on later plain radiographs or computerized tomography scans was recognized as screw loosening [13]. Fusion was assessed according to the standard definition which was widely applied in previous studies: evidence of continuous bridging bone between the adjacent endplates of the involved motion segment, radiolucent lines at 50% or less of the graft-vertebra interfaces in CT scan, and 2° or less of segmental rotation on lateral flexion/extension radiographs [14].

This case series study included six patients (four males and two females) who rangedin age from 61 to 74 years (mean, 65.8 years). The characteristicsof these six patients are summarized in **Table 1**. Four patients were at segments C4/5, C5/6, C6/7; One patient was at segments C3/4, C4/5, C5/6 and one patient was at segments C3/4, C5/6, C6/7. The mean follow-up duration is 18.5 months which ranged from 9 months to 38 months. All the patients reached bony fusion at the sixth month follow-up according to the standard definition which was described in the method section. Postoperative complications such as hoarseness, dysphagia, cerebrospinal fluid leakage, malposition of the prosthesis and screw loosening or pull-out were not found. The patients' clinical symptoms were totally relieved 6 months after surgery. The VAS for neck and arm, the NDI

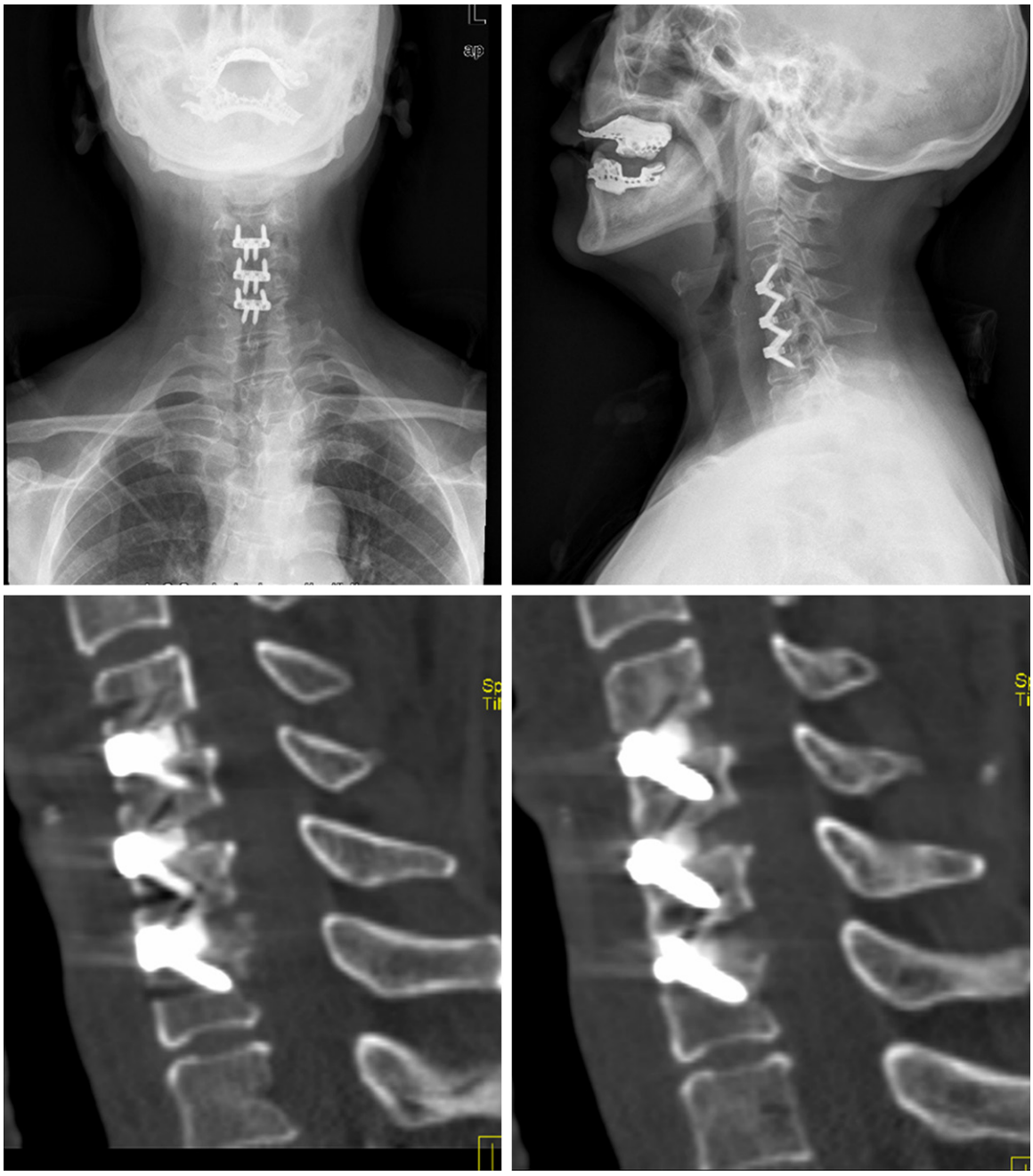

Figure 3. One week postoperative X-rays and CT scan.

were all greatly improved at the third month. Range of motion from C2 to C7 were significantly impaired after surgery. All of the clinical and radiographic outcomes of six patients were summarized in **Table 2**.

A 64-year-old female was referred to our department who presented with neck and shoulders pain for 4 years and numbness and weakness of left arm for 12 months. Mild spondylotic changes were detected on preoperative anteroposterior, lateral and functional X-rays (**Figure 1**). Preoperative MRI (**Figure 2**) confirmed multilevel cervical disc herniation (C3/4, C4/5, C5/6, C6/7). One week postoperative X-ray and CT scan showed the good positon of implant and a satisfying cervical lordosis (**Figure 3**). Three months postoperative X-rays

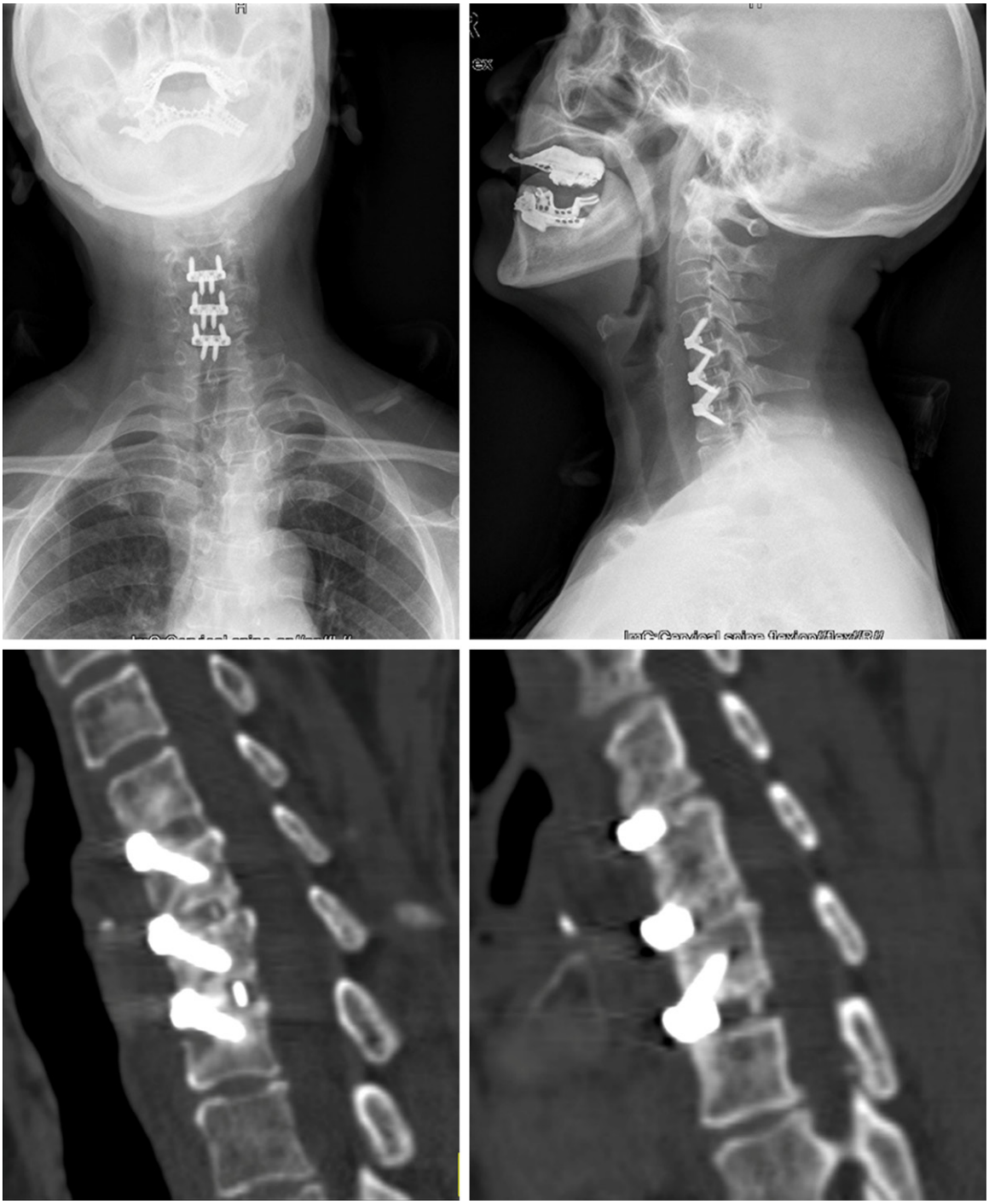

Figure 4. Three months postoperative X-rays and CT scan.

and CT scan confirmed bony fusion at segments C4/5, C5/6 but not C6/7 (**Figure 4**). Six months postoperative X-rays and CT scan confirmed the bony fusion at all three segments and there was no instrumental complications such as screw loosening or screw pull-out (**Figure 5**).

Discussion

Previous studies have explored the application of Zero-P in single level ACDF and demonstrated good clinical and radiographic outcomes. In 2011 Vaněk et al. reported the Zero-P implant system in one and two level ACDF in a prospec-

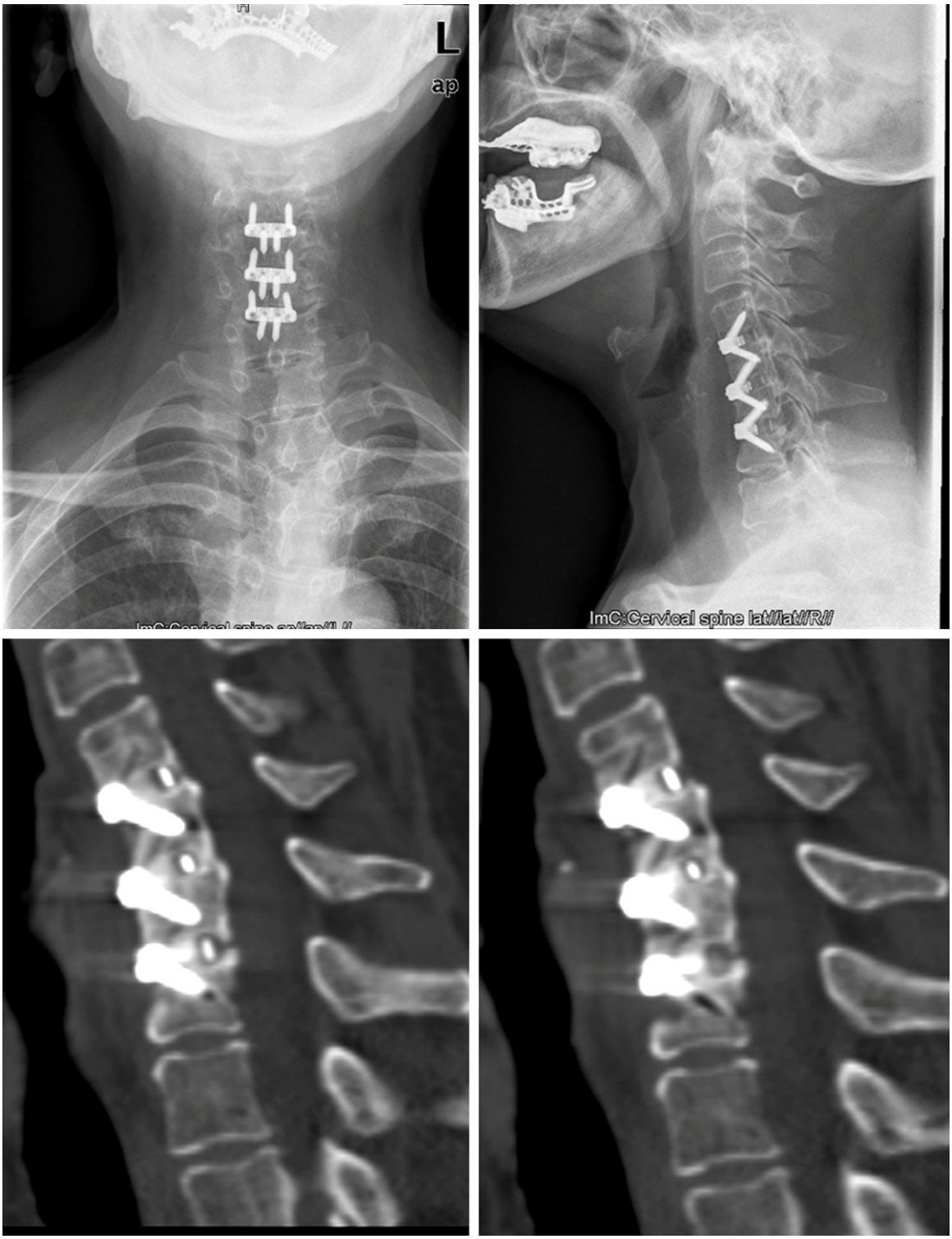

Figure 5. Six months postoperative X-rays and CT scan.

tive study with a minimum follow-up of one year and they concluded that the Zero-P provides biomechanical stability for the cervical spine similar to the cage and dynamic plate construct and the fusion rates were the same in two groups at 12 months after surgery [15]. In 2012 Azab et al. reported the Zero-P implant system in one and double level ACDF in 84

patients and they concluded that the Zero-P implant is a valid alternative to anterior cervical plating after ACDF with a very low incidence of postoperative dysphagia and no implant-related complications [16]. In 2015 Yang et al. compared the safety and efficacy of the Zero-P implant to that of an anterior cervical plate and cage in patients undergoing ACDF and the results from their study demonstrated that the Zero-P implant is safe and efficacious after ACDF and it can reduce the rate of adjacent-level ossification development and dysphagia compared to anterior plate and cage. Results from a recent meta-analysis based on seven randomized controlled trials (RCTs) and prospective or retrospective comparative studies to compare the safety, efficacy, radiological outcomes and complications associated with the use of a Zero-P versus an anterior plate in ACDF showed that Zero-P is a safer and effective procedure, with a similar fusion rate and lower incidence of earlier and later postoperative dysphagia [17]. Another meta-analysis based on 12 studies also suggested that surgical treatments of single or multiple levels of cervical spondylosis using Zero-P and cage plus plate were similar in terms of JOA score, NDI score, cervical lordosis, and fusion rate. The results also indicated that the Zero-P group had a higher subsidence rate than cage plus plate the group, Zero-P had a lower postoperative dysphagia rate and might have a lower adjacent-level ossification rate [18].

Even the excellent outcomes showed in single or two-level ACDF, however, the safety and efficacy of the Zero-P implant applied in three-level ACDF has been little explored. A number of surgeries worries the fusion rate and stability of the Zero-P implant in three-level ACDF, since results from previous biomechanical studies showed that segmental stability decreases with the number of instrumented segments regardless of the used implant but the locking plate and cage construct was stiffer in all test modes than the Zero-P devices in multilevel constructs [12]. However, whether this difference will affect the clinical outcomes still remains unclear. By presenting the clinical and radiographic outcomes of the special six cases with a short follow-up of 24 months, we are hoping to clarify the safety and effectiveness of three-level ACDF with the zero-profile implant system. The overall results of our study were good. Postoperative complications such as hoarseness, dysphagia, cerebrospinal fluid leakage, malposition of the prosthesis and screw loosening or pull-out were not observed. The patients' clinical symptoms were totally relieved 6 months after surgery. All the patients reached bony fusion at the sixth month follow-up according to the standard definition.

The most obvious limitation of our study is the small sample size, only six patients were included and reviewed; however, considering three-level ACDF with the Zero-P is a rarely performed and reported, this study can also add some new information and experience to the literature. The second limitation of this study is that we did not compare three-level using the Zero-P and using traditional cage plus anterior plate as it is a case series study. However, three-level ACDF using cage plus anterior plate has been widely reported in previous studies.

In summary, the preliminary clinical and radiographic outcomes from this case series study demonstrated that the Zero-P implant system may be a safe and efficacious device in ACDF surgery. The stability and fusion rate is satisfying, while postoperative complications such as hoarseness, dysphagia, cerebrospinal fluid leakage, malposition of the prosthesis and screw loosening or pull-out were not found. Of course, as this is just a case series study, larger randomized controlled studies of longer duration are warranted.

Disclosure of conflict of interest

None.

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