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Original Article

Comparison of the incidence of post-operative dysphagia between anterior cervical discectomy and fusion with the zero-profile implant system and with the traditional anterior plate

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Abstract: The use of the Zero-profile Implant System (Zero-P) in cervical spine surgery has been investigated in several studies, which mainly focused on fusion rate, symptom relief, and instrumental complications, but not the occurrence of dysphagia after operation. Dysphagia in a total of 243 consecutive cases (divided into Zero-P group, *N* = 120 and Plate group, *N* = 123) who underwent anterior cervical discectomy and fusion (ACDF) was retrospectively assessed. The assessment was conducted based on the Bazaz grading system (0-none, 1-mild, 2-moderate, and 3-severe) at 1 week, and at 1, 3, 6, 12, and 24 months post-operatively. The chi-squared test, the student *t*-test, the Mann-Whitney *U*-test, and ordinal logistic regression were performed, as appropriate, to analyse the data. The two groups did not show significant differences in the gender, age, and levels (all, $P > 0.05$). The patients in the Zero-P group (Plate group) exhibited total incidences of post-operative dysphagia of 35.00% (59.35%), 17.50% (37.39%), 8.33% (30.89%), 4.17% (16.26%), and 2.50% (12.19%) at one week, one month, three months, six months, and at the final follow-up after surgery (all, $P < 0.05$). Results of ordinal logistic regression revealed that female patients, anterior cervical plating, C4/5 surgery, and multi-level surgery are risk factors causing postoperative dysphagia (all, $P < 0.05$). Compared with anterior cervical plating, ACDF using Zero-P can significantly reduce the incidence of persistent and transient dysphagia post-operatively. Anterior cervical plating, C4/5 surgery, being female, and multi-level surgery, may be related to the higher incidence of dysphagia after ACDF. Future prospective controlled, and randomised, multi-centre investigations with larger sample sizes are needed.

Keywords: Dysphagia, zero-profile, ACDF, cervical spine, plate, deglutition, deglutition disorders

Introduction

Anterior cervical discectomy and fusion (ACDF) has been regarded as the "gold standard" to treat symptomatic cervical disc diseases for several decades [1, 2]. Swallowing dysfunction, also known as dysphagia, has been deemed to be an early complaint happening most commonly after ACDF [3]. Dysphagia, as a clinical symptom, refers to difficulties in forming or moving an alimentary bolus safely from the mouth to the stomach [4]. Scales such as the Bazaz grading scale for dysphagia, the dysphagia short questionnaire and the eating assessment tool are often used for the clinical assessment of dysphagia [5]. In addition, there are evaluation methods used to assess swallowing including video-fluoroscopy and fibre-optic endoscopic evaluation with the utilisation of the appropriate instruments [6].

The mechanisms governing incidence of dysphagia, as a result of multiple factors, have not been completely clarified. It has been reported that numerous factors can affect the incidence of dysphagia after surgery. These factors include revision procedures, multi-level surgery, age, gender, involvement of C4-C5 and C5-C6 levels, tracheal/oesophageal traction exercise, operating time, pre-operative treatment, endotracheal tube cuff pressures and oesophagal retraction, bone morphogenetic proteins, plate

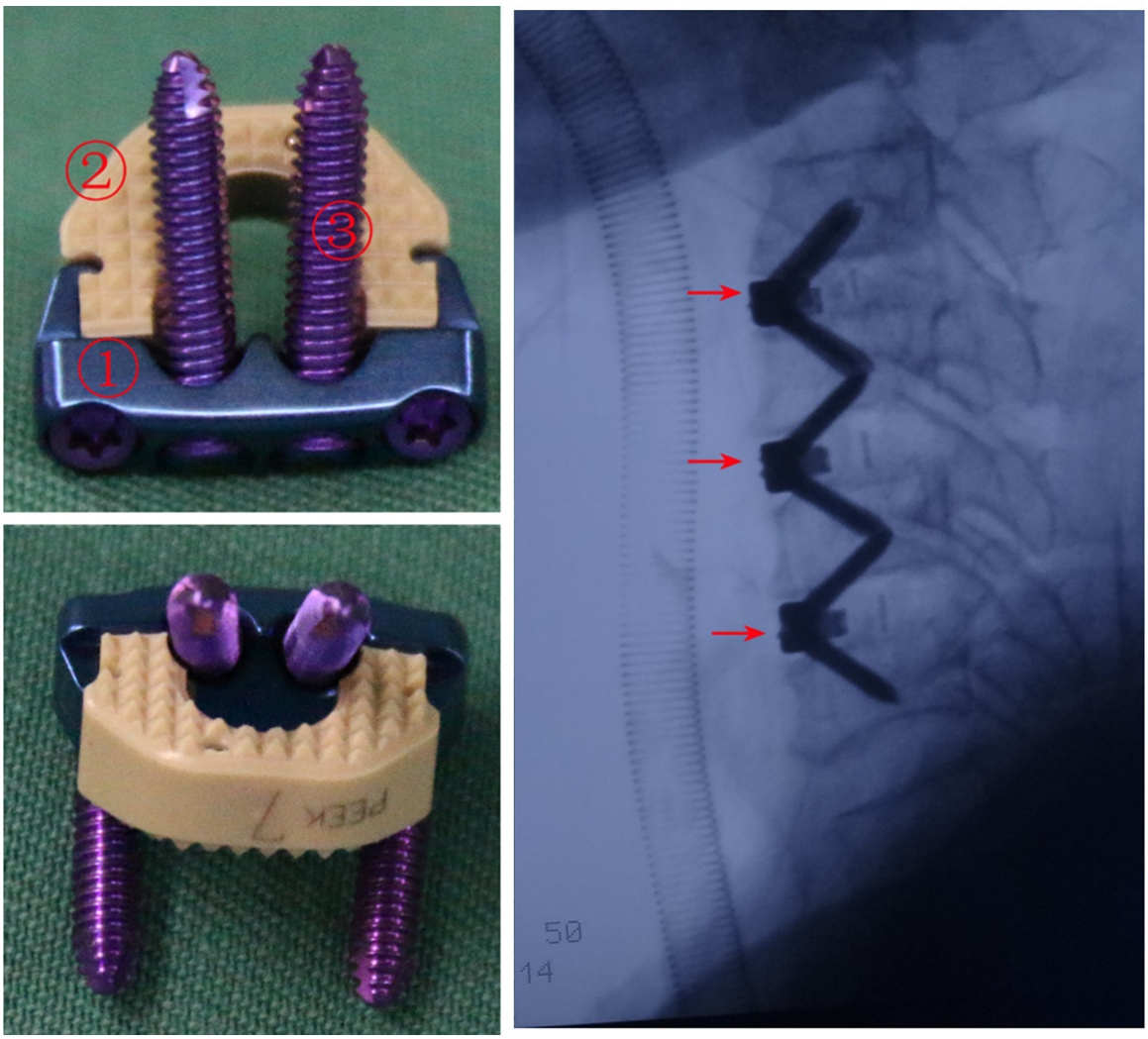

Figure 1. Images of the Zero-profile Implant System (① a titanium alloy plate, ② a PEEK interbody spacer, and ③ locking head screws).

thickness and design, surgical approach, steroids in the retropharyngeal region, and dissection plan-lateral or medial-to the omohyoid muscle [7]. Among them some risk factors cannot be controlled by patients or surgeons but for some risk factors we can attempt to control, and reduce, the incidence of dysphagia after surgery. Since the 1990s, ACDF has been applied with an anterior cervical plate in cervical spine surgery [8]. Previous studies have reported that, with the use of an anterior cervical plate, ACDF is able to maintain, or increase, the alignment and stability of the cervical sagittal, increase fusion rate, and decrease the potential for graft extrusion and subsidence, particularly in surgery involving multiple segments [9-11]. However, possible weaknesses, along with complications such as dysphagia, were also reported to be associated with anterior plating. It is reported by Rihn *et al*. [12] that, after ACDF with an anterior cervical plate, the possibility of the incidence of dysphagia is as high as 71%.

Theoretically, putting an anterior cervical plate directly posterior to the oesophagus, is likely to cause post-operative dysphagia. This is because any mechanical stimulation or impact on the oesophagus can probably contribute to dysphagia. It is found by Lee *et al*. [13] that, compared with a slightly larger, and rougher, plate, using a smoother, smaller-profile plate is able to decrease the incidence of dysphagia; however, more evidence is needed to support, or

refute, such a conclusion. In recent years a new stand-alone device with zeroprofile (Zero-P, Synthes GmbH, Switzerland) has been produced for ACDF to handle the unfavourable effects of traditional methods of cervical anterior plating [14]. The Zero-P Implant System includes three major components: a titanium alloy plate, a PEEK interbody spacer, and locking head screws (**Figure 1**). The utilisation of the Zero-P Implant System in cervical spine surgery has been studied while existing research often focuses on symptom relief, fusion rate, and instrumental complications. Several recent case-control and case series studies, based on small sample sizes, have reported the incidence of post-ACDF dysphagia where the Zero-P Implant System has been used, but results still remain controversial (ranges from 3% to 76%) [15-18]. Many spinal surgeons are confused as to whether, or not, the Zero-P Implant System can reduce the incidence of dysphagia after surgery compared with ACDF with traditional cervical anterior plates. Due to the limited knowledge of this subject, the authors carried out a retrospective study based on 243 patients focusing on post-operative dysphagia in an attempt to compare the incidences of dysphagia after ACDF with the Zero-P Implant System and a traditional anterior plate.

Patients and methods

The current retrospective research has been approved by Medical Ethical Committee of West China Hospital, Sichuan University, China. All of the patients have provided informed consents to the use of their data in this retrospective analysis.

The retrospective review was conducted on 266 consecutive patients (Zero-P group, *N* = 132; Plate group, N = 134) experiencing ACDF with anterior plates or Zero-P from April, 2011 to April, 2015 in our department. The medical records and charts of all patients were reviewed. The following data for each patient were collected: gender, age, estimated blood loss, intra-operative time, length of hospital stay, smoking or non-smoking, alcohol-drinker or not, hypertension or not, diabetes mellitus or not, operating levels, and kinds of instrumentation. The treatment and follow-up for all of the patients were carried out at the West China Hospital of Sichuan University in Chengdu, China.

The inclusion criteria included: patients who presented with radiculopathy or myelopathy from single-level or multi-level cervical disc disease with correlating magnetic resonance imaging findings, no response to conservative treatment for at least six weeks, and such patients had ACDF using an anterior plate or Zero-P implant system from C3 to T1, aged over18 years, and showing no psychological conditions.

Exclusion criteria included: presence of active infections, metabolic bone disease or osteoporosis, pathologic fractures of the vertebrae and those with spinal deformity, allergy to the implant material (titanium or polyether), ankylosing spondylitis or rheumatoid arthritis, continuous or combined ossification of the posterior longitudinal ligament (OPLL), developmental stenosis, patients who underwent ACDF not using an anterior plate or Zero-P device, patients who underwent ACDF involving C2/3, and previous cervical spine surgery. Patients with pre-operative dysphagia, psychological diseases such as hysteria, a history of disorders in the central nervous system such as stroke and traumatic brain injury, previous neck surgery, and oesophageal diseases were excluded.

Surgical technique

Patients were chosen to undergo either Zero-P or traditional anterior plate following pre-operative discussion with spinal surgeons. All surgical procedures were performed by senior spinal surgeons in our department using a standard, right Smith-Robinson approach after induction of general anaesthesia [19, 20]. The incision point was determined by fluoroscopy and metal markers. A horizontal right side skin incision (about 7 cm long) was conducted to reach the perpendicularly spreading fibres of the platysma muscle. The disc level was re-confirmed by fluoroscopy, discectomy was undertaken, and long-shaft Caspar screws for interbody retraction were inserted into the middle of the adjacent vertebral bodies. The subchondral endplate of each vertebral body was prepared with a high-speed drill and curette. The surgical approach, discectomy, and preparation of subchondral endplate, were the same in both

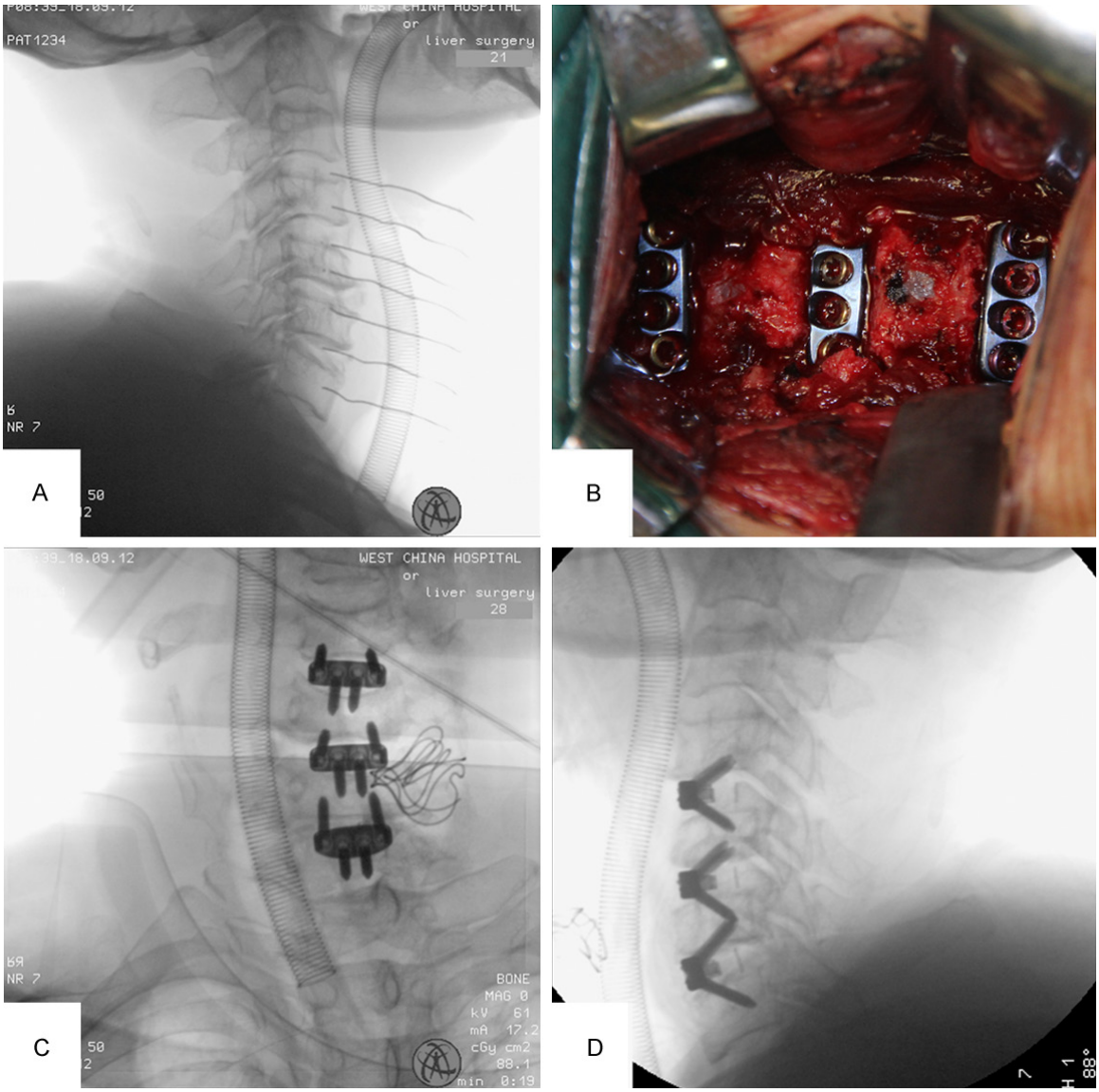

Figure 2. Intra-operative fluoroscopy (A: Determining skin incision with the help of fluoroscopy and metal markers; B: Inserting the three implants and inserting the screws; C and D: Confirming final implant position with the help of fluoroscopic X-rays).

groups of patients as described above. After thorough decompression and scraping off of the cartilaginous endplate, the Zero-P implant of an appropriate size, and filled with composite synthetic bone graft (beta-tricalcium phosphate, β-TCP, ChronOS; DePuySynthes, Paoli, CA, USA), was implanted in the Zero-P group patients. In Plate group patients, traditional anterior plates incorporated with polyether-etherketone cages (CornerStone-SR Cage System, Medtronic SofamorDanek USA Inc.) or autogenous iliac bone were used. Final imaging of the device, as implanted, was performed before the wound was closed in a layer-by-layer fashion after drainage insertion (**Figure 2**). In both groups, the rhBMP-2 was not used. As for corticosteroids, all the patients in these two groups received methylprednisolone at a dose of 500 mg per person during the operation, and 100 mg per day during the three days after surgery.

Dysphagia evaluation

Dysphagia was evaluated based on the Bazaz grading system [21] which is commonly used by

Table 1. The Bazaz grading system for the evaluation of dysphagia

Severity	Liquid	Solid
0-None	None	None
1-Mild	None	Rare
2-Moderate	None or rare	Occasionally
3-Severe	None or rare	Frequent

spinal surgeons (0, 1, 2, and 3 represent none, mild, moderate, and severe dysphagia, separately, as shown in **Table 1**). The Bazazscale is a qualitative information-based non-validated grading scale used to obtain patient perception of difficulties with liquids *versus* solids. The qualitative information is obtained by an investigator (over the telephone). The Bazaz grading system scores were rated as: none, mild, moderate, and severe denote no episodes of swallowing problems, rare episodes of dysphagia, occasional swallowing difficulties with specific food, and frequent swallowing difficulties with major food. The incidence of dysphagia in this study is reported by patients. Dysphagia was evaluated by telephone interviews at 1 week, as well as 1, 3, 6, 12, and 24 months after surgery. Transient dysphagia and persistent dysphagia after surgery here referred to the symptoms of swallowing difficulties lasting for less, and more than, 90 days after surgery, respectively.

By retrospectively reviewing the medical records, the authors obtained variables including: gender, age, alcohol, smoking, hypertension, diabetes mellitus, operation time, number of levels, involvement of C4-5 or C5-6, and Zero-P. However, we did not consider the use of rhBMP-2 and corticosteroids. This is because, according to the same standard, rhBMP-2 was not used while methylprednisolone was used for all patients. Involvement of C2-3 was also not included as patients operated at C2-3 were excluded from this study.

Statistical analysis

The program SPSS, Version 19.0, (SPSS Inc. for Windows) was used for the statistical analysis. The authors used descriptive statistics such as means, percentages, and standard deviations to determine the categorical and quantitative variables. The student *t*-test and a chi-squared test were conducted for continuous and categorical data, respectively. The Mann-Whitney *U*-test was carried out for ranked data including incidence of dysphagia (0-None; 1-Mild; 2-Moderate; 3-Severe). While for multi-factor regression of ranked data, ordinal logistic regression was performed. The results were regarded significant when the *P*-values were less than 0.05.

Results

Two hundred and sixty-six consecutive patients were studied. They were divided into Zero-P group ($N = 132$) and Plate group with ($N = 134$). However, 12 patients in the Zero-P group and 11 patients in the Plate group were not considered in the statistical analysis because they failed to complete the eventual follow-up. So, the outcomes of 120 and 123 patients in the Zero-P and the Plate groups, respectively, were enter for final analysis. The Zero-P group consisted of 120 consecutive patients, including 74 males and 46 females aged 51.9 years on average, with an average follow-up period of 1.5 years (ranging from 1 to 2 years). While the Plate group contained 88 males and 35 females (a total of 123 consecutive cases) with an average age of 51.03 years. The mean follow-up period for these patients was also 1.5 years (in the range of 1 to 2 years).

It can be found from **Table 2** that demographic factors such as gender and age were similar for the patients in the two groups (in all cases, $P > 0.05$). The intra-operative time was 145.50 ± 17.674 minutes and 167.89 ± 26.091 minutes on average in the Zero-P and the Plate groups ($P < 0.01$). As for the estimated blood loss, it was found to be 80.54 ± 69.372 ml and 80.49 ± 34.209 ml in the Zero-P and the Plate groups on average ($P = 0.994$). Besides, patients in the Zero-P group and the Plate group stayed, on average, 13.68 ± 4.110 and 12.13 ± 2.180 days in hospital ($P < 0.01$). In the Zero-P group, the numbers of patients of three-level, two-level, and single-level surgery were 6, 40, and 74, while they were 5, 38, and 80 in the Plate group.

The overall incidence of dysphagia in the Zero-P group was 35.00%, 17.50%, 8.30%, 4.20%, and 2.50% at one week, one month, three months, six months, and final follow-up, respectively. In the Plate group, the overall incidence was 59.30%, 37.40%, 30.90%, 16.30%, and

Table 2. Patient demographic and baseline data

Group	Zero-P Group (N = 120)	Plate Group (N = 123)	P
Levels			
Three level	6	5	0.844
Two level	40	38	
Single level	74	80	
Age (y): Mean SD	51.90 ± 11.84	51.03 ± 13.06	0.585
Gender (Female/Male)	46/74	35/88	0.102
Intraoperative time (min)	145.50 ± 17.674	167.89 ± 26.091	P < 0.01
Estimated blood loss (ml)	80.54 ± 69.372	80.49 ± 34.209	0.994
Length of hospital stay (d)	13.68 ± 4.110	12.13 ± 2.180	P < 0.01

12.20% at one week, one month, three months, six months, and final follow-up, separately. Even though the incidence in the two groups is not low, most patients showed mild dysphagia which gradually weakened after surgery. Five patients, and one patient, in the Plate, and Zero-P, groups reported having severe dysphagia one week after surgery, while no one reported severe dysphagia one month after surgery. The Mann-Whitney *U*-test showed that compared with the Zero-P group, the incidence of dysphagia in the Plate group was notably higher (all, $P < 0.05$). So the incidences of both transient, and persistent, dysphagia in the Plate group were higher than that in the Zero-P group. The details of the incidence of dysphagia in both groups are listed in **Table 3**. Female patients (odds ratio, OR = 11.186; 95% confidence interval, 95% CI [5.184, 24.135]), anterior cervical plating (OR = 4.444; 95% CI [2.301, 8.582]), and multi-level surgery (OR = 3.578; 95% CI [1.644, 7.789]), C4/5 surgery (OR = 2.609; 95% CI [1.337, 5.090]) were related to the higher incidences of post-ACDF dysphagia on a multi-factor analysis using the ordinal logistic regression model (**Table 4**).

Discussion

Swallowing dysfunction, or dysphagia, as a "multi-factorial" result, is reported to be the most common as an early complaint after ACDF [3, 22, 23]. With a follow-up lasting for 7.2 years on average, persistent dysphagia after ACDF with an anterior cervical plate is found by Yue *et al*. to have an incidence of 35.1% at final follow-up [24]. Dysphagia is likely to be caused by disordered oesophageal and/or oropharyngeal conditions. Oropharyngeal dysphagia is connected with damage to the cortical areas or the swallowing centre in the central nervous system, impaired efferent neural or muscular drive, and/or decreased pharyngolaryngeal sensitivity. While oesophageal dysphagia is generally associated with primary or secondary oesophageal motility disorders which influence the oesophageal muscular layers or the enteric nervous system [4]. It is possible that any mechanical stimulation of, or impact on, the oesophagus can induce dysphagia, including intra-operative traction of the oesophagus, post-operative swelling of soft tissues and the oesophageal wall, and when implanting the anterior cervical plate directly posterior to the oesophagus [25, 26]. The Zero-P Implant System has been developed in recent years to overcome the disadvantages and limitations of the traditional anterior plate. Theoretically the Zero-P Implant System probably reduces the incidence of dysphagia after surgery since it can avoid the direct irritation and oppression caused by anterior plates. Previous studies have focused on the safety and efficacy of the instrument; however, studies focussing on post-operative dysphagia are rare [27-29]. Considering the paucity of knowledge of this topic, the authors conducted a retrospective study highlighting the incidence of dysphagia after surgery.

In the Plate group, the overall incidences of dysphagia were 59.30% and 12.20% at one week after the surgery and final follow-up, which was similar to that found in previous studies. Several studies (most of them are case series studies) based on small sample sizes have also reported the incidence of dysphagia after ACDF using the Zero-P Implant System but results remain controversial. Shin *et al*. [30] compared the Zero-P Implant System with the anterior cervical plate with iliac bone graft and use of a stand-alone cage in ACDF in a retrospective study based on 60 patients: they found that the Zero-P Implant System is a valuable substitute for ACDF showing a low incidence of post-operative dysphagia (5% versus 30%). In a prospective case series study based on 38 patients, Scholz *et al*. [31] reported the short-term incidence with use of the Zero-P Implant System was 60% and the medium-term incidence of

Table 3. The incidences of dysphagia for two groups

Time	Zero-P group					Plate group					P#
	None	Mild	Moderate	Severe	Total incidence	None	Mild	Moderate	Severe	Total incidence	
One week	78	33	8	1	0.350	50	43	25	5	0.593	P < 0.001
One month	99	20	1	0	0.175	77	39	7	0	0.374	P < 0.001
Three months	110	9	1	0	0.083	85	33	5	0	0.309	P < 0.001
Six months	115	4	1	0	0.042	103	18	2	0	0.163	0.002
The final follow-up	117	2	1	0	0.025	108	13	2	0	0.122	0.004

#Mann-Whitney U test.

Table 4. Results of multivariate ordinal logistic regression

Variables		Estimate	Std. Error	Wald	P	OR[b]	95% Confidence Interval	
							Lower Bound	Upper Bound
Age	Age > mean age (51.95 years)	0.125	0.298	0.176	0.675	1.133	0.632	2.032
	Age < mean age (51.95 years)	0[a]						
Operation time	Time > mean time (156.83 min)	0.175	0.332	0.279	0.598	1.191	0.622	2.283
	Time < mean time (156.83 min)	0[a]						
Smoking	Yes	0.260	0.424	0.376	0.539	1.297	0.565	2.976
	None	0[a]						
Alcohol	Yes	0.223	0.414	0.289	0.591	1.250	0.555	2.814
	None	0[a]						
Diabetes mellitus	Yes	0.325	0.529	0.378	0.539	1.384	0.491	3.900
	None	0[a]						
Hypertension	Yes	0.009	0.423	0.000	0.983	1.009	0.441	2.310
	None	0[a]						
Involvement of C4-5	Yes	0.959	0.341	7.910	0.005	2.609	1.337	5.090
	None	0[a]						
Involvement of C5-6	Yes	0.227	0.372	0.371	0.542	1.255	0.605	2.601
	None	0[a]						
Number of levels	Three levels	2.659	0.770	11.916	0.001	14.281	3.156	64.624
	Two levels	1.275	0.397	10.318	0.001	3.578	1.644	7.789
	Single level	0[a]						
Method of fixation	Plate	1.492	0.336	19.733	P < 0.001	4.444	2.301	8.582
	Zero-P	0[a]						
Gender	Female	2.415	0.392	37.871	P < 0.001	11.186	5.184	24.135
	Male	0[a]						

[a], This parameter is set to zero because it is redundant. [b]OR, odd ratio.

dysphagia decreased to 2.9%. In a retrospective case-control study based on 60 patients, Yanget *al*. [18] reported that, compared with the plate group, the incidence of dysphagia was lower in the Zero-P group, with a much shorter symptom period ($P < 0.01$). In a retrospective case series study based on 37 patients, Njoku *et al*. [32] reported that immediate post-operative dysphagia was found in 58.4% of all patients while, at final follow-up, the complete response was shown in 87.8% of the affected patients. Wang *et al*. [33] performed a retrospective study based 52 consecutive patients with a one year follow-up duration and reported an 11.5% incidence of dysphagia. In our study, based on 243 patients, in the Zero-P group, the incidences of post-operative dysphagia were 35.00%, 17.50%, 8.30%, 4.20%, and 2.50% at one week, one month, three months, six months, and final follow-up, respectively. A majority of patients exhibited mild, and moderate, dysphagia which weakened in the subse-

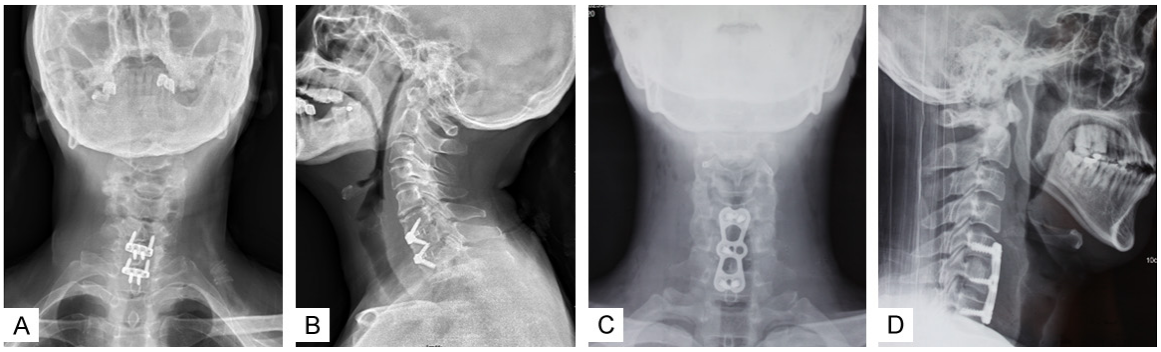

Figure 3. Post-operative anteroposterior and lateral X-rays in two groups (A, B: ACDF with the Zero-profile Implant System; C, D: ACDF with anterior cervical plating).

quent period. We noticed that the incidence of dysphagia varied greatly in different studies. This large variance is possibly caused by variations in age, gender, surgical technique, number of operating levels, use (or not) of corticosteroids and rhBMP-2, extent of surgery, time intervals between post-operative evaluations, variations in the definitions and measurements of dysphagia, and the small sample size used in the existing research. Besides, owing to the incidence of dysphagia being reported by patients, another possible reason for the varying incidences of dysphagia is probably cultural factors pertaining to different regions.

The patients in the two groups showed similar gender, age, and number of operating levels. To make the baseline comparable, the operation was conducted on all patients using the right Smith-Robinson method, all patients received standard corticosteroids, and there was no use of rhBMP-2 in our study. The dysphagia reported was ranked in different grades (0-None; 1-Mild; 2-Moderate; 3-Severe) to enable use of the Mann-Whitney *U*-test. Results from the Mann-Whitney *U*-test demonstrated that the Zero-P Implant System is capable of reducing the incidence of dysphagia by a significant amount compared with that arising from the use of traditional anterior plates in ACDF surgery. Concerning other confounding factors, the authors performed a multi-factor regression analysis using ordinal logistic regression to facilitate the clarification of the real impact of "zero-profile" on the incidence of dysphagia after ACDF. The results obtained from the ordinal logistic regression verified that, compared with that of a traditional anterior plate in ACDF surgery (OR = 4.444, 95% CI [2.301, 8.582]), the Zero-P Implant System is able to reduce the incidence of dysphagia to a significant extent ($P < 0.001$). In addition, multi-level surgery, female patients, and C4/5 surgery were closely related to the higher incidence of post-operative dysphagia in our study. However, operation time and age were not found to be closely related to the incidence of post-operative dysphagia in this study. After induction of general anaesthesia, ACDF surgeries with the Zero-profile Implant System or an anterior cervical plate were conducted through a classic right Smith-Robinson method (**Figure 3**). The surgical method, decompression method, and scraping off of the cartilaginous endplate are the same, while different fixation methods were used. An anterior cervical plate was first put directly behind the oesophagus, possibly impacting, or compressing, the oesophagus, while the Zero-profile Implant System is zero-profile, as the name suggests. Secondly, more resection of pre-vertebral tissue, and a much more powerful traction are needed by the spinal surgeons to expose a much larger space so as to place the plate and insert the screws more conveniently. So the increased traction power used in the Plate group may make a contribution to the damage suffered by the oesophagus. Lastly, as the Zero-profile Implant System is easier to implant, it requires a shorter traction time, thus reducing the irritation, or impact, on the oesophagus. Certainly, future studies are needed to refute, or support, such explanations.

A primary limitation of this study is that we evaluated dysphagia by adopting the Bazaz scale. Although the method is used by many spinal surgeons, it is a less accurate measurement method. This is because it is a grading scale

which has not been validated and determines patient perceptions of difficulties with liquids *versus* solids based on qualitative information acquired by a researcher. As it is based on patient reports, it cannot explain those sensory disruptions possibly occurring in post-operative dysphagia. Gold standard evaluation methods are more accurate, including assessments of swallowing through fibre-optic endoscopic evaluation or video-fluoroscopy [34-37]. The second limitation of this study is the retrospective design, and therefore future randomised controlled studies are needed. The third limitation of this study is that the ENT-evaluation was not carried out for those patients with dysphagia and the retraction and decompression times of patients in the two groups were not computed. The fourth limitation of this study is that we have not fully investigated the mechanisms governing why Zero-P can reduce dysphagia after ACDF surgery so future studies need to focus on the mechanisms controlling dysphagia. The fifth limitation of this study is that we may not have considered all potential risk factors in the multi-factor regression analysis, so future studies including more variables may be required.

Conclusion

ACDF using the Zero-P Implant System can notably reduce the incidence of post-operative persistent, and transient dysphagia, compared with that using anterior cervical plating. Most dysphagia was mild and gradually decreased during the subsequent three months. Moderate, severe, and persistent dysphagia were uncommon. Female patients, C4/5 surgery, multi-level surgery, and anterior cervical plating are possibly related to the higher incidence of post-operative dysphagia. However, the mechanisms underpinning dysphagia have not been clarified due to the existence of many confounding variables. In the future, prospective, controlled, randomised studies with larger sample sizes will be needed and those highlighting the mechanisms of dysphagia and methods for reducing the incidence of dysphagia are also warranted.

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Disclosure of conflict of interest

None.

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