Does zero-profile anchored cage accompanied by a higher postoperative subsidence compared with cage-plate construct? A meta-analysis

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Abstract

Background

Zero-profile anchored cage (ZP) has been widely used for its lower occurrence of dysphagia. However, it is still controversial whether it has the same stability as the cage-plate construct (CP) and increases the incidence of postoperative subsidence. We compared the rate of subsidence after anterior cervical discectomy and fusion (ACDF) with ZP and CP to determine whether the zero-profile device had a higher subsidence rate?

Methods

We performed a meta-analysis of studies which compared the subsidence rate of ZP and CP. An extensive and systematical search covered Medline, Embase and Web of Science databases according to PRISMA guidelines and identified ten articles that satisfied our inclusion criteria. Relevant clinical and radiological data were extracted and analysed by RevMan 5.3 software.

Results

Ten trials involving 626 patients were included in this meta-analysis. The incidence of postoperative subsidence in ZP group was significantly higher than with CP group [15.1% (89/588) vs. 8.8% (51/581), OR = 1.97 (1.34, 2.89), P = 0.0005]. In subgroup analysis, we found that the definition of subsidence did not affect the higher subsidence rate in the ZP group. Considering the quantity of operative segments, there was no significant difference in the incidence of subsidence between the two groups after single-level fusion (OR 1.43, 95% CI 0.61-3.37, P = 0.41). However, the subsidence rate of the ZP group was significantly higher than the CP group (OR 2.61, 95% CI 1.55-4.40, P = 0.0003) after multi-level surgery. There were no significant differences in intraoperative blood loss, JOA score, NDI score, fusion rate and cervical aligment in the final followup between the two groups. In addition, the CP group had a longer operation time and a higher incidence of dysphagia at each follow-up time than the ZP group.

Conclusion

ZP had a higher risk of postoperative subsidence than CP. Although there was a high occurrence of swallowing discomfort, we are more agreed that the anterior plate should be used in multi-level surgery as far as possible to reduce the subsidence and adverse clinical symptoms in the long term.

Introduction

Anterior cervical discectomy and fusion (ACDF) is the standard surgical procedure for cervical degenerative disc disease (CDDD) [1]. The use of anterior plate can increase the stability of cervical spine, promote early intervertebral fusion after surgery, and is widely used in clinical practice [2–4]. However, studies over the past decade have shown that the use of anterior plate can increase the incidence of postoperative dysphagia, and even cause long-term unremitting swallowing discomfort [5–8]. In order to solve this complication, many researchers have adopted a variety of new self-locking zero-profile anchored cage (ZP), such as Zero-P, MC + and ROI-C, etc [9–13]. These types of devices can reduce the compression of prevertebral soft tissue, and has similar stability and clinical efficacy as traditional cage-plate construct [14–16]. Meanwhile, the new devices are easy placement and can reduce the operation time and blood loss significantly [10, 13], so the clinical application has gradually increased in recent years.

However, some studies have found that these ZP are prone to subsidence because they did not have strong fixation ability to maintain the height of intervertebral space [9, 11]. This may lead to narrowing of the foramen, reducing of cervical lordosis, neurological symptoms, affecting the long-term efficacy of patients [17–20]. At present, there is no consistent conclusion about whether the ZP has a higher subsidence rate than the traditional cage-plate construct (CP) in the literature.

Therefore, we reviewed the literature and conducted this meta-analysis to compare the postoperative subsidence and other clinical data of ACDF with the ZP and CP, and to figure out whether the ZP has a higher postoperative subsidence rate and similar clinical efficacy as cage-plate construct.

Materials And Methods

Search strategy

Our research complied with the guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) [21,22]. The electronic databases of Medline, Embase and Web of Science were searched from their inception dates till April 30, 2019. The study used several search terms including “anterior cervical discectomy and fusion”, “cervical spondylosis”, “degenerative cervical disease”, “zero-profile”, “Zero-P”,

“self-locking”, “anchored spacer”, and “stand-alone cage” with different combinations by the connectives “AND”, “OR”, and “NOT”. According to the selection methods of the inclusion criteria, the relevant articles as well as references were reviewed.

Selection Criteria

All systematic review and meta-analysis on clinical controlled trials for cervical degenerative cervical disease were reviewed. The inclusion criteria of studies in this research as follows: (1) patients had a failure of non-operative treatments for cervical degenerative cervical disease at least 6 months; (2) included comparsion of patients who accepted zero-profile anchored cage with those who received conventional plate-cage construct; (3) analysed and compared the radiological outcomes of subsidence; (4) evaluating index of clinical effects were involved: Japanese Orthopaedic Association (JOA) score, Neck Disability Index (NDI) score, operative time, intraoperative blood loss, fusion rate, cervical alignment and complications; and (5) follow-up period of more than 12 months.

We excluded researches that were not in line with clinical controlled studies, such as case reports, meta-analysis, conference abstracts, reviews, commentaries, letters to the editor and etc. Besides, we only filtered English language articles in this study.

Data extraction

Articles were totally searched and reviewed from the literature by two reviewers (YJL and YPF) individually and repeatedly. A sound of discord was resolved through consultation with a third reviewer (XSZ) in the procedure. The data extracted from the details of article text, tables and graphs in qualified studies, which contained study design, sample size, patient characteristics, follow up duration, type of implants, clinical and radiological data. If partial informations of one study were missing, the corresponding author would be contacted for the missing data.

Quality assessment

Two reviewers independently assessed the quality of evidence for all included studies using the 6 criteria and instructions recommended by Meta-analysis Of Observational Studies in Epidemiology (MOOSE) [23]. The items were scored with ‘yes’, ‘no’, or ‘unclear’. If consensus could not be reached, a third reviewer was consulted to resolve the disagreement as before.

Statistical analysis

Data analysis was completed by using the Review Manager software (RevMan 5.3; the Cochrane Collaboration). The evaluations of continuous variables were choosed by weighted mean difference (WMD), while dichotomous variables were odds ratio (OR). I^2 statistic was used to reflect the degree of heterogeneity. When I^2 statistic > 50% was identified as obvious heterogeneity, random-effects models would be performed. And if I^2 statistic ≤ 50% (low heterogeneity), the fixed-effects models would be selected. The study used a funnel plot to evaluate publication bias. While a p value of 0.05 or less was considered statistical significance.

Results

Literature Search and study characteristics

A total of 221 related records were yielded through searching the database above. After removing 26 duplicated studies and 22 non-English language articles, there were 173 studies left for screening and 163 of records were excluded according to the selection criteria. As a result, ten controlled trials [2, 9–13, 24–27] were screened out for this meta-analysis. The literature search procedure was shown in Fig. 1. All the clinical trials came from different research centers. The study characteristics and quality assessment according to the MOOSE guidelines were summarized in Tables 1 and 2, respectively.

Table 1
Summary of study characteristics and demographics

Study	Type	Time	Study period	Country	Surgical levels (ZP/CP)	Patients (ZP/CP)	Gender (male/female)		Mean age		Follow-up (months)	Design of zero-profile device
							ZP	CP	ZP	CPC		
Nemoto [12]	RCT	2015	2010–2012	Japan	One:24/22	46 (24/22)	21/3	21/1	40.9 ± 7.2	41.6 ± 7.0	24	PREVAIL
Shin [25]	Retro	2014	2008–2013	Korea	One:20/20	40 (20/20)	7/13	13/7	50.0 ± 12.0	44.3 ± 9.7	13.5	Zero-P
Lee [2]	Retro	2015	2005–2011; 2012–2013	Korea	One:23/18	41 (23/18)	11/12	11/7	57.26 ± 13.28	52.89 ± 7.71	19.9	Zero-P
Shi [9]	Retro	2015	2010–2011	China	Three:18/20	38 (18/20)	11/7	12/8	56.2 ± 64.8	56.7 ± 63.9	30.3	Zero-P
Chen [11]	Retro	2016	2010–2012	China	Three:18/20	71 (33/38)	18/15	21/17	49.3 ± 3.7	48.8 ± 3.9	30.8	Zero-P
Li [13]	Retro	2017	2009–2013	China	One:32/34; Two:21/23; Three:11/10; Four:4/3	138 (68/70)	41/27	45/25	50.6 ± 7.5	51.3 ± 7.9	24	Fidji
Yun [26]	Retro	2017	2006–2015	Korea	Two:31/32	63 (31/32)	22/9	29/3	53.29 ± 7.55	54.18 ± 9.87	13.2	Zero-P
Zhou [10]	Retro	2018	2010–2013	China	One:20/21; Two:18/14; Three:13/12	98 (51/47)	23/28	22/25	62.3 ± 6.7	64.4 ± 3.2	36	ROI-C
Lu [24]	Retro	2018	2011–2015	China	Two:22/24	46 (22/24)	13/9	15/9	56.6 ± 6.4	58.6 ± 7.2	24	ROI-C
Zhu [27]	Retro	2019	2013–2014	China	Three:30/32	62 (30/32)	12/18	18/14	56.6 ± 12.6	55.3 ± 11.3	36	MC+

ZP: zero-profile group; CP: cage-plate group; RCT: randomized controlled study; Retro: retrospective study

Table 2
The quality assessment of included studies according to the MOOSE guidelines

	Nemoto [12]	Shin [25]	Lee [2]	Shi [9]	Chen [11]	Li [13]	Yun [26]	Zhou [10]	Lu [24]	Zhu [27]
Clear definition of study population	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Clear definition of outcomes and outcome assessment	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Independent assessment of outcome parameters	Y	U	Y	Y	Y	Y	U	U	Y	Y
Sufficient duration of follow-up	Y	U	U	Y	Y	Y	U	Y	Y	Y
No selective loss during follow-up	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Important confounders and prognostic factors identified	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

Y yes, U unclear

Patient demographics

The 10 studies enrolled 626 patients (315 in the ZP group and 311 in the CP group) tolally, which included 380 males and 236 females. The ZP used in the studies included Zero-P (Synthes GmbH, Oberdorf, Switzerland), ROI-C, ROI-MC+ (LDR, Troyes, France), PREVAIL (Medronic Sofamor Danek, Memphis, TN, USA), and Fidji cervical cage (Abbott Spine, Bordeaux, France). The control group was treated with anterior plating system and bone graft materials. Mean age, gender, follow-up durations, surgical levels and other informations of patients in each study was listed in Table 1.

Operative Data

Seven studies consisted with 447 patients (ZP group: 221; CP group: 226) noted operation time [9,11-13,24,26,27]. Mean operation time was greater for the CP group in six studies, and the operation time was significantly greater in the CP group compared to the ZP group (WMD -15.87, 95% CI -30.62 to -1.11, *P* = 0.04) (Fig. 2).

For the outcome regarding intraoperative blood loss, senven studies included 447 patients (ZP group: 221; CP group: 226) were reported [9,11-13,24,26,27]. The ZP group was noted to have a lower blood loss in six studies. Overall, the CP group had a comparable amount of blood loss versus to the ZP group (WMD -5.51, 95% CI -11.69 to 0.67, *P* = 0.08) (Fig. 3).

Clinical evaluation

Data regarding JOA and NDI scores postoperatively were documented in six studies consisting of 436 patients (ZP group: 217; CP group: 219) [9-11,13,24,27]. Mean difference of JOA scores at final follow-up between ZP and CP groups were not significant (WMD 0.07, 95% CI -0.12 to 0.25, *P* = 0.48). In addition, pooled data of NDI scores at final follow-up did not reveal significant difference between the two groups (WMD -0.16, 95% CI -0.47 to 0.16, *P* = 0.33). Figs. 4 and 5 describe above informations in forest plots.

Radiological assessment

The results of radiographic fusion were described in nine studies [2,9-13,24,26,27], with fusion rate varying from 71 to 100%. Successful bone union was achieved in 348/377 cases (92.3%) in the ZP group, and 359/379 cases (94.7%) in the CP group. The forest plot analysis showed no significant difference between the two groups (OR 0.66, 95% CI 0.36 to 1.20, *P* = 0.17) (Fig. 6).

There was a significant difference regarding cervical alignment between the ZP and CP groups 3 months postoperatively (WMD -0.53, 95% CI -0.98 to -0.09, *P* = 0.02). Nevertheless, Mean difference of cervical alignment between the two groups at the final follow-up were not significant (WMD -0.75, 95% CI -1.76 to 0.25, *P* = 0.14). The corresponding forest plot analysis is shown in Fig. 7.

Dysphagia

The incidence of dysphagia was reported in seven studies [9-13,24,27], with results of 2.0%-57.1% in ZP group and 10.6%-73.1% in CP group at early period, respectively. In the early postoperatively (< 1 month), rate of dysphagia was noted to be lower in the ZP group (OR 0.39, 95% CI 0.24 to 0.64, *P* = 0.0002). Besides, the ZP group also had a lower incidence of dysphagia at 3 month postoperatively (OR 0.17, 95% CI 0.06 to 0.48, *P* = 0.0008) and final follow-up (OR 0.11, 95% CI 0.01 to 0.91, *P* = 0.04). Post-operative and follow-up dysphagia forest plots are described in Fig. 8.

Subsidence

A total of ten studies were included in the comparison of the incidence of subsidence between the ZP and CP groups [2,9-13,24-27]. The subsidence rates were 15.1% (89/588) in the ZP group and 8.8% (51/581) in the CP group. It was significant higher in the patients following the zero-profile device (OR 1.97, 95% CI 1.34 to 2.89, *P* = 0.0005). The forest plot analysis of subsidence and funnel plot for publication bias are presented in Figs. 9 and 10, respectively.

We performed a subgroup analysis stratified by definition of subsidence, which included subsidence ≥ 2mm in five studies [2,9,12,13,26] and ≥ 3mm in four studies [10,11,24,25]. In the ZP group, the incidence was 16.5% (42/255) and 12.3% (30/243) in the definition of ≥ 2mm and ≥ 3mm, respectively. Correspondingly, it was 10.2% (26/254) and 7.4% (17/231) in the CP group. The results showed that there was higher risk of subsidence in the ZP group, while the definition of subsidence ≥ 2mm (OR 1.78, 95% CI 1.03 to 3.06, *P* = 0.04) and ≥ 3mm (OR 1.98, 95% CI 1.00 to 3.91, *P* = 0.05).

A subgroup analysis stratified by quantity of operative segment was also performed, which included single-level surgery in three studies [2,12,25] and multi-level surgery in five studies [9,11,24,26,27]. In the operation of single-segment, incidence of subsidence between the ZP and CP groups were not significant (OR 1.43, 95% CI 0.61 to 3.37, *P* = 0.41). As for the multi-level surgery, the ZP group had a higher incidence of subsidence (OR 2.61, 95% CI 1.55 to 4.40, *P* = 0.0003). The forest plots of subsidence for subgroup analysis are described in Figs. 11 and 12, respectively.

Discussion

ACDF is a classic procedure in treating cervical degenerative diseases that can remove the prominent disc, osteophyte, and relieve the compressions of spinal cord and nerve root. It is effective and widely used in the treatment of patients with cervical degenerative disc disease (CDDD) [1]. Anterior plating system not only stabilizes the upper and lower vertebral bodies, but also improves the rate of intervertebral fusion and avoids the risk of pseudarthrosis [3, 4]. Futhermore, it can maintain the cervical sagittal alignment and prevent graft extrusion or subsidence [2].

However, the application of anterior plate brings high incidence of postoperative dysphagia [5–8]. In response to this problem, various stand-alone anchored spacers have been designed for clinical treatment. Wang et al. [8] found that the dysphagia rate was only 4.5% after one-level ACDF with Zero-P device, which was significantly lower than that of 32% by using the cage-plate construct. Yang et al. [5] reported the Zero-P device has a lower incidence of dysphagia compared to anterior plating system after multi-level fusion (4.3% vs. 25%; p = 0.04). Hofstetter et al. [7] also found that the use of zero-profile anchored spacer (MC + or ROI-C) had significantly lower rates of dysphagia than conventional plate instrument after surgery (2.9% vs. 20%; p = 0.027).

Subsidence is another equally important adverse event after ACDF. It usually refers to an object with a greater elastic modulus (e.g., cage or spacer) entering another object of relatively lower elastic modulus (e.g., vertebral body). The subsidence of cage causes the loss of intervertebral disc height can result in narrowing of the foramen, nerve root compression, pseudoarthrosis due to cervical instability [28]. Eventually, the cervical spine loses physiological curvature, resulting in kyphosis. It means that segmental subsidence arouses significant morbidity during the postoperative period [18].

A systematic review of seventy-one studies reported that the mean incidence of cage subsidence after ACDF was 21%, ranging from 0–83% [28]. Many studies reported the use of plates can reduce the incidence of subsidence after ACDF. Lee et al. [18] comfirmed the non-use of plate was a risk factor for subsidence and has a significantly high subsidence rate after single-level ACDF (40% vs 12.5%; p = 0.025). Kim et al. [29] found that the postoperative subsidence rate of patients using stand-alone cage was higher than cage-plate construct after two-level fusion (66.6% vs 30%; p = 0.049), which indicated that the use of plate could maintain the height of the intervertebral disc and play an pivotal role in reducing postoperative subsidence. However, the incidence of subsidence for ZP compared to CP after reviewing literature is not clear. Therefore, we conducted this meta-analysis to determine whether there is a statistically high risk of cage subsidence after ACDF with ZP.

Ten trials including 10 cohorts with a total of 626 patients were contained in this study. There were no significant differences in blood loss, JOA score, NDI score, fusion rate and cervical aligment of the final followup between the two devices by meta-analysis. Meanwhile, we found that the incidence of dysphagia in CP group was significantly higher than that in ZP group at each follow-up time, which was consistent with previous studies. Xiao et al. [30] conducted a meta-analysis which included 1066 patients to compare the postoperative dysphagia rate between zero-profile anchored spacer and cage-plate construct after ACDF. Their study found that the ZP group had a significantly lower risk of dysphagia. Nambiar et al. [31] and Tong et al. [32] also found the ZP group achieved a lower incidence of dysphagia after single-level and multi-level fusion, respectively.

The results of this study suggested that the ZP group was associated with high incidence of subsidence, when compared with the CP group. Considering the different definitions of subsidence of the above ten studies, we conducted subgroup analysis of subsidence ≥ 2 mm and ≥ 3 mm, respectively. However, we found that the incidence of subsidence in ZP group was still higher than CP group. Therefore, it could be considered that different definitions of subsidence did not affect the consequences. Then, we performed subgroup analysis according to the quantity of operative segments. It was found that there was no significant difference in the rate of subsidence between ZP group and CP group after single-segment ACDF, while the subsidence rate of ZP group was significantly higher than CP group after multi-segment ACDF. Therefore, we believed that there was no significant difference in the occurrence of cage subsidence after single-level ACDF with ZP or CP. However, considering the plate-related complications and the incidence of dysphagia after surgery, we preferred ZP for the treatment of single-level CDDD. As for multi-level surgery, due to the high subsidence rate of ZP and avoiding subsequent loss of cervical aligment and kyphosis deformity, CP should be preferred without considering the risk of dysphagia.

Our meta-analysis was restricted by some limitations. Firstly, retrospective and nonrandom studies were included in this study, which inevitably gave rise to selection bias. Secondly, only 10 studies were included, the sample sizes were relatively small and the follow-up time was different. Besides, a variety of zero-profile devices were contained which could affect the accuracy of our conclusions, although they had similar fixation mechanisms and structures. Finally, clinical heterogeneity maybe caused by the various surgical approaches and types of implants in different research centers.

To the best of our knowledge, this study was the first meta-analysis to compare the subsidence of ZP to CP after ACDF, despite the above shortages. Our study showed that ZP had a higher postoperative subsidence compared with CP, especially in multi-level surgery. Meanwhile, both devices were safe, effective and achieved similar clinical outcomes. A high-quality, large-sample RCT was required to validate our findings in the future.

Currently, there is no consensus on the relationship between subsidence and clinical effectiveness. The research performed by Lee et al. [18] found that the cage subsidence was associated with the higher neck and arm VAS scores. Kim et al. [20] also reported the existence of subsidence was significantly related to unfavorable clinical outcomes at all follow-up assessments, which evaluated by Odom's criteria. However, Park et al. [33] recruited 77 patients and divided into subsidence and non-subsidence groups, and found subsidence did not correlate with fusion rate or clinical outcomes. Yson et al. [34] also demonstrated that the subsidence did not seem to be predictive of clinical outcomes of ACDF. More longitudinal multi-center RCTs should be explored the role of subsidence in clinical prognosis. Meanwhile, the surgeon should pay more

attention to the deuteropathy of subsidence. We suggested that it was more likely to use zero-profile implant for one-level surgery and plate fixation in multi-level fusion.

Conclusion

The ZP which has been in full swing in recent years could not reduce the subsidence rate compared to CP. There was no significant difference of subsidence between these two fixed apparatus after single-level ACDF, while the risk of subsidence in ZP was significantly higher after multi-level fusion. Although there was a high incidence of swallowing discomfort, we would more agree that the anterior plate should be used in multi-level surgery as far as possible to reduce the subsidence and adverse clinical symptoms in the long term. We thought that this study provide new opinions for the rational use of ZP.

Abbreviations

ZP: Zero-profile anchored cage;

CP: Cage-plate construct;

ACDF: Anterior cervical discectomy and fusion;

OR: Odds ratio;

CI: Confidence interval;

CDDD: Cervical degenerative disc disease;

PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analysis; JOA: Japanese Orthopaedic Association;

NDI: Neck Disability Index;

MOOSE: Meta-analysis Of Observational Studies in Epidemiology;

WMD: Weighted mean difference;

RCT: Randomized controlled trial

Declarations

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and materials

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

Concept, literature search and data collection: YJL, YPF, XSZ, MFG.

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Figures

Figure 1

The graph shows the flow diagram of search strategy according to guidelines of PRISMA.

Figure 2

The forest plot shows operation time of anterior cervical discectomy and fusion by using zero-profile anchored cage versus to cage-plate construct.

Figure 3

The forest plot shows intraoperative blood loss of anterior cervical discectomy

Figure 4

The forest plot shows JOA score of anterior cervical discectomy and fusion by using zero-profile anchored cage versus to cage-plate construct at final follow-up.

Figure 5

The forest plot shows NDI score of anterior cervical discectomy and fusion by using zero-profile anchored cage versus to cage-plate construct at final follow-up.

Figure 6

The forest plot shows the fusion rate of anterior cervical discectomy and fusion by using zero-profile anchored cage versus to cage-plate construct at final follow-up.

Figure 7

The forest plots show cervical aligment of anterior cervical discectomy and fusion by using zero-profile anchored cage versus to cage-plate construct at 3 month postoperatively (A) and final follow-up (B).

Figure 8

The forest plots show the dysphagia of anterior cervical discectomy and fusion by using zero-profile anchored cage versus to cage-plate construct at early postoperatively (A), 3 month postoperatively (B) and final follow-up (C).

Figure 9

The forest plot shows subsidence of anterior cervical discectomy and fusion by using zero-profile anchored cage versus to cage-plate construct at final follow-up.

Figure 10

A funnel plot for publication bias of subsidence at final follow-up.

Figure 11

The forest plot shows subgroup analysis for subsidence stratified by definition of ≥ 2mm and ≥ 3mm after anterior cervical discectomy and fusion with zero-profile anchored cage compared to cage-plate construct.

Figure 12

The forest plot shows subgroup analysis for subsidence stratified by one-level and mutil-level surgery after anterior cervical discectomy and fusion with zero-profile anchored cage compared to cage-plate construct.