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Review

Comparison of anterior cervical discectomy and fusion with the zero-profile device versus plate and cage in treating cervical degenerative disc disease: A meta-analysis

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A B S T R A C T

Zero-profile device was applied to diminish the irritation of the esophagus in the treatment of cervical degenerative disc disease. However, the clinical application of the zero-profile device has not been testified with clinical evidence. The aim of the meta-analysis was to systematically compare the safety and effectiveness of anterior cervical discectomy and fusion with zero-profile device with plate and cage for the treatment of cervical degenerative disc disease. Electronic searches of PubMed and Embase were conducted up to May 2015. Relevant studies were included. Weighted mean difference (WMD) and 95% confidence intervals (CI) were assessed for continuous data. Risk ratio (RR) and 95% CI were assessed for dichotomous data. P value <0.05 was considered to be significant. Eleven studies were included in the meta-analysis. Compared with plate and cage, zero-p is associated with lower operation time of two-level surgery, less intraoperative blood loss, higher subsidence rate, higher JOA score, lower incidence of dysphagia in short-term (RR: 0.72, 95% CI [0.58, 0.90], $P = 0.005$, $I^2 = 22\%$) and long-term (RR: 0.12, 95% CI [0.05, 0.30], $P < 0.00001$, $I^2 = 0\%$) and lower Cobb angle of multilevel surgery (WMD: −3.16, 95% CI: [−4.35, −1.97], $P < 0.00001$, $I^2 = 0\%$). No significant difference was found in one-level and two-level Cobb angle, fusion rate and operation time of one-level and three-level surgery. Both zero-p implantation and the plate and cage have respective advantages and disadvantages.

1. Introduction

Cervical degenerative disc disease (CDDD) is one of the main causes of myelopathy and rediculopathy. Anterior cervical discectomy and fusion (ACDF) is considered as the gold-standard procedure [1] when conservative therapy fails, as was initially described by Smith [2] and Cloward [3] in 1950s. Due to the numerous donor site complications such as iliac crest fracture, hematoma and infection [4–7], autologous iliac bone graft has been replaced by allograft or synthetic cages.

The anterior cervical plate has been gradually applied to promote fusion rate, enhance rigidity of fixation, improve sagittal alignment and prevent the dislocation of interbody graft [6,8–10]. However, the addition of the anterior cervical plate would lead to some other complications such as tracheo-esophageal injuries, adjacent level degeneration, soft tissue injury and increased incidence of dysphagia [11–13]. The reported incidence of dysphagia in the early postoperative period varies from 2% to 67% [14–19]. For the majority of patients, the dysphagia disappeared within 3 months after surgery. But the others (about 3–35.1% of the patients) still suffer from dysphagia. [11,14,18,20–23].

The zero-profile device (zero-p), which not only provides immediate stability but also prevents the plate related dysphagia [24,25], was applied in clinical practice to diminish the irritation of the esophagus.

This article aims to perform a meta-analysis to compare the clinical efficacy, radiologic outcomes and incidence of complications between ACDF with "zero-p" and "plate and cage" in treating patients with CDDD.

2. Materials and methods

2.1. Search strategy

Electronic searches of PubMed and Embase (update to May 31, 2015) were conducted by using the combination of the following terms: "zero-profile" or "zero-p" or "SAAS" or "stand-alone anchored spacer" or "anchored cage" or "anchored spacer" or

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"no-profile" and "cervical". Only English studies were included. Reference lists of relevant articles were also reviewed for potentially relevant studies. Repetition of information can be avoided by means of retaining only the largest one in studies with overlapping patients, and the corresponding criteria included hospital, study period and treatment information.

2.2. Inclusion and exclusion criteria

Researches that met the following criteria were included: (1) original articles; (2) researches comparing the clinical and radiological outcomes between the ACDF with zero-p and plate and cage; (3) patients were clinically confirmed of degenerative disease of cervical spine in need of surgical intervention; (4) researches with follow-up of more than 6 months. Researches that met the following criteria were excluded: (1) researches that did not report both ACDF with zero-p and plate and cage; (2) human cadaveric studies; (3) unrelated researches; (4) literature review or meta-analysis; (5) case reports; (6) conference abstracts.

2.3. Data extraction

The information required was extracted by two of the authors independently from eligible studies, which includes: (1) author and year of publication; (2) country; (3) study design; (4) sample size; (5) intraoperative blood loss; (6) operation time; (7) incidence of dysphagia; (8) Japanese Orthopaedic Association (JOA) scores; (9) duration of follow-up; (10) cervical Cobb angle; (11) segmental Cobb angle and (12) subsidence rate.

2.4. Quality assessment

The quality of included ten observational studies were independently assessed by two authors using the Newcastle-Ottawa quality assessment scale (NOS). The NOS uses a star system (ranging from 0 to 9 stars) to evaluate the quality of case-control studies and cohort studies. Studies with a score of 7–9 were regarded as high quality. The quality of one included randomized controlled trial (RCT) was independently assessed by two authors using the Delphi list.

2.5. Statistical analysis

The meta-analyses were performed using Review Manager software (RevMan 5.3; Cochrane Collaboration) and the STATA 13.0 (StataCorp LP, College Station, TX, USA). Weighted mean difference (WMD) and 95% confidence intervals (CI) were assessed for continuous data (intraoperative blood loss, operation time, JOA scores and RR of JOA score and cervical Cobb angle). Risk ratio (RR) and 95% CI were assessed for dichotomous data (incidence of dysphagia and subsidence rate). A probability of P less than 0.05 was considered to be statistically significant. I^2 statistic (ranging from 0 to 100%) was used to assess the heterogeneity of included studies. I^2 statistic >50% was considered as obvious heterogeneity, under which circumstance, random effects analysis would be performed. When heterogeneity was not significant (I^2 statistic $\leqslant$50%), the fixed effects analysis would be performed. The publication bias was assessed through the "Metabias" procedure of STATA 13.0, which consists of two approaches, Begg's and Egger's tests. Trim-and-fill analysis was used to investigate possible publication bias.

3. Result

3.1. Identification of relevant studies

Ninety-four studies were identified by searching in PubMed and Embase. After removing of duplicate studies, 64 articles were retrieved. Nineteen unrelated studies, one literature review, one case report, five conference abstracts, 10 human cadaveric studies, one not written in English and 12 non-comparative studies, were excluded. Five studies [26–30] were conducted at the same institution, and we selected one article, for the patients studied may have overlapped. Eventually, 11 studies were eligible for the meta-analysis. A flow diagram of literature search strategy for relevant studies is shown in Figure 1.

3.2. Characteristics of included studies and quality assessment

Two RCT, one prospective study and eight retrospective studies were identified. The characteristics of the included studies and patients are presented in Table 1. There were 360 patients treated with ACDF with zero-p and 378 patients with plate and cage. Each included observational study was assessed according to NOS, which is shown in Table 2. The mean score (ranging from 7 to 9) of included studies was 8. All included studies were regarded as high quality. The included RCTs were assessed according to Delphi list, which is shown in Table 3.

3.3. Meta-analysis of outcomes

3.3.1. Operation time

Eight studies with 176 patients in the zero-p group and 194 patients in the plate and cage group were included in the meta-analysis of operation time in one-level, two-level and three-level surgery. No significant difference was found in one-level surgery (WMD: −0.92, 95% CI: [−9.33, 7.50], $P = 0.83$, $I^2 = 92\%$, Fig. 2) and three-level surgery (WMD: −8.94, 95% CI: [−52.93, 35.04], $P = 0.69$, $I^2 = 96\%$, Fig. 2). While significant difference was identified in two-level surgery (WMD: −19.38, 95% CI: [−28.34, −10.41], $P < 0.0001$, $I^2 = 0\%$, Fig. 2). However, obvious heterogeneity was

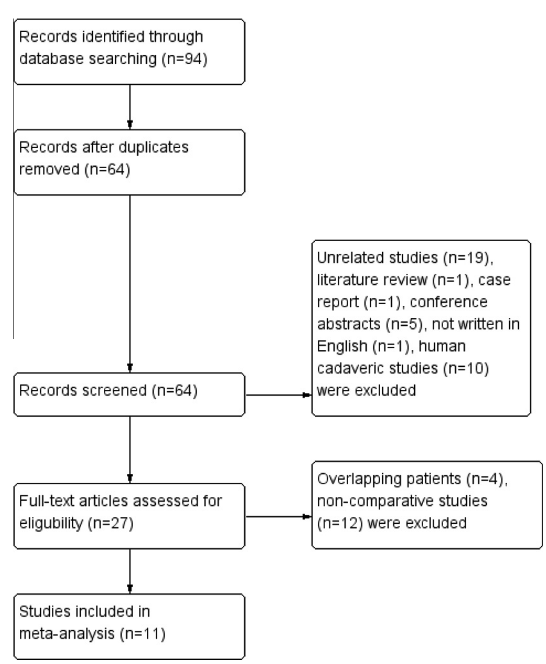

Fig. 1. Flow diagram of study selection.

Table 1
Patient and study characteristics of the eleven included studies in the meta-analysis

References	Year	Country	Study design	Sample size		Mean age		Male (%)		Follow-up	
				Zero ¯p	PC	Zero-p	PC	Zero ¯p	PC	Zero-p	PC
Hofstetter et al. [41]	2015	USA	R OS	35	35	56.8 ± 1.6	51.5 ± 2.0	45.7	51.4	13.0 ± 1.6	14.8 ± 2.1
Lee et al. [42]	2015	Korea	R OS	23	18	57.26 ± 13.2 8	52.89 ± 7.7 1	47.8	61.1	12.57 ± 2.09	28.89 ± 20.2 4
Shi et al. [33]	2015	China	R OS	18	20	56.2 ± 4.8	56.7 ± 3.9	61.1	60	30.5 ± 3.4	30.1 ± 2.8
Wang et al. [32]	2015	China	R OS	30	33	56.8 ± 11.0	54.0 ± 10.0	60	42.4	24.1 ± 7.8	23.8 ± 8.2
Nemoto et al. [43]	2014	Japan	P RCT	24	22	40.9 ± 7.2	41.6 ± 7.0	87.5	95.5	24	24
Wang et al. [44]	2014	China	R OS	22	25	50.86 ± 8.79	53.68 ± 8.9 6	50	40	33.59 ± 5.52	33.16 ± 5.97
Son et al. [45]	2014	Korea	R OS	21	27	55.4 ± 9.7	50.2 ± 10.9	NS	NS	6	6
Yan et al. [46]	2014	China	R OS	37	35	63.55 ± 7.12	64.28 ± 8.76	54.1	54.3	15.32 ± 2.13	14.26 ± 2.35
Vanek et al. [31]	2013	Czech	P OS	44	33	50.2 ± 10.3	51.8 ± 12.9	59.1	57.6	NS	NS
Qi et al. [30]	2013	China	R OS	83	107	43.6	44.9	56.6	54.2	18.6 ± 4.2	19.3 ± 4.1
Li et al. [47]	2013	China	P RCT	23	23	NS	NS	52.2	52.2	NS	NS

R = retrospective, P = prospective, OS = observational, NS = not specified, PC = plate and cage.

Table 2
Methodological quality assessment of studies included in the meta-analysis based on NOS

	References	Hofstetter et al. [41]	Lee et al. [42]	Shi et al. [33]	Wang et al. [32]	Wang et al. [44]	Son et al. [45]	Yan et al. [46]	Vanek et al. [31]	Qi et al. [30]
Selection	Representativeness of the exposed cohort	1	1	1	1	1	1	1	1	1
	Selection of the non-exposed cohort	1	0	1	1	1	1	1	1	1
	Ascertainment of exposure	1	1	1	1	1	1	1	1	1
	Demonstration that outcome of interest was not present at the start of study	1	1	1	1	1	1	1	1	0
Comparability	Study controls for age or gender	0	1	1	1	1	1	1	1	1
	Study controls for any additional factor	1	0	1	1	1	0	0	1	0
Outcome	Assessment of outcome	1	1	1	1	1	1	1	1	1
	Follow-up long enough for outcomes to occur	1	1	1	1	1	0	1	1	1
	Adequacy of follow-up of cohort	1	1	1	1	1	1	1	1	1
	Total	8	7	9	9	9	7	8	8	7

Table 3
Methodological quality assessment of the included randomized controlled trials based on the Delphi list

Reference	Was a method of randomization used?	Were the groups similar at baseline regarding the most important prognostic indicators?	Were the eligibility criteria specified?	Was the outcome assessor blinded?	Was the care provider blinded?	Was the patient blinded?	Were point estimates and measures of variability presented for the primary outcome measures?	Did the analysis include an intention-to-treat analysis?
Nemoto et al. [43]	Yes	Yes	Yes	No	No	No	Yes	No
Li et al. [47]	Yes	Yes	Yes	No	No	No	Yes	No

detected among these studies in one-level and three-level surgery. Subgroup analysis and sensitivity analysis were conducted to investigate the cause of heterogeneity which could not be found.

3.3.2. Intraoperative blood loss

There were six studies with 141 patients in the zero-p group and 150 patients in the plate and cage group included in the meta-analysis of intraoperative blood loss of one-level surgery. Significant difference was found in this aspect between the two groups (WMD: −9.83, 95% CI: [−16.12, −3.54], $P = 0.002$, $I^2 = 85\%$, Fig. 3). The heterogeneity was significant among these studies. We conducted subgroup analysis and sensitivity analysis to investigate the cause of heterogeneity which could not be ascertained.

3.3.3. Dysphagia

Ten studies with 337 patients in the zero-p group and 360 patients in the plate and cage group were included in the meta-analysis of long-term incidence of dysphagia which lasts more than 3 months after surgery. Significant difference was found between the two groups (RR: 0.12, 95% CI [0.05, 0.30, $P < 0.00001$, $I^2 = 0\%$, Fig. 4). Seven studies with 277 patients in the zero-p group and 302 patients in the plate and cage group were included in the meta-analysis of short-term incidence of dysphagia within 2 weeks. Significant difference was found between the two groups (RR: 0.72, 95% CI [0.58, 0.90], $P = 0.005$, $I^2 = 22\%$, Fig. 4).

3.3.4. JOA score

Five studies with 142 patients in the zero-p group and 148 patients in the plate and cage group were included in the meta-analysis of preoperative and postoperative JOA score (more than 1-year follow-up). Statistical significance between the two groups was found in both preoperative JOA score (WMD: −0.13, 95% CI: [−0.24, −0.01], $P = 0.04$, $I^2 = 0\%$, Fig. 5) and postoperative JOA score (WMD:0.19, 95% CI: [0.02, 0.36], $P = 0.02$, $I^2 = 1\%$, Fig. 5).

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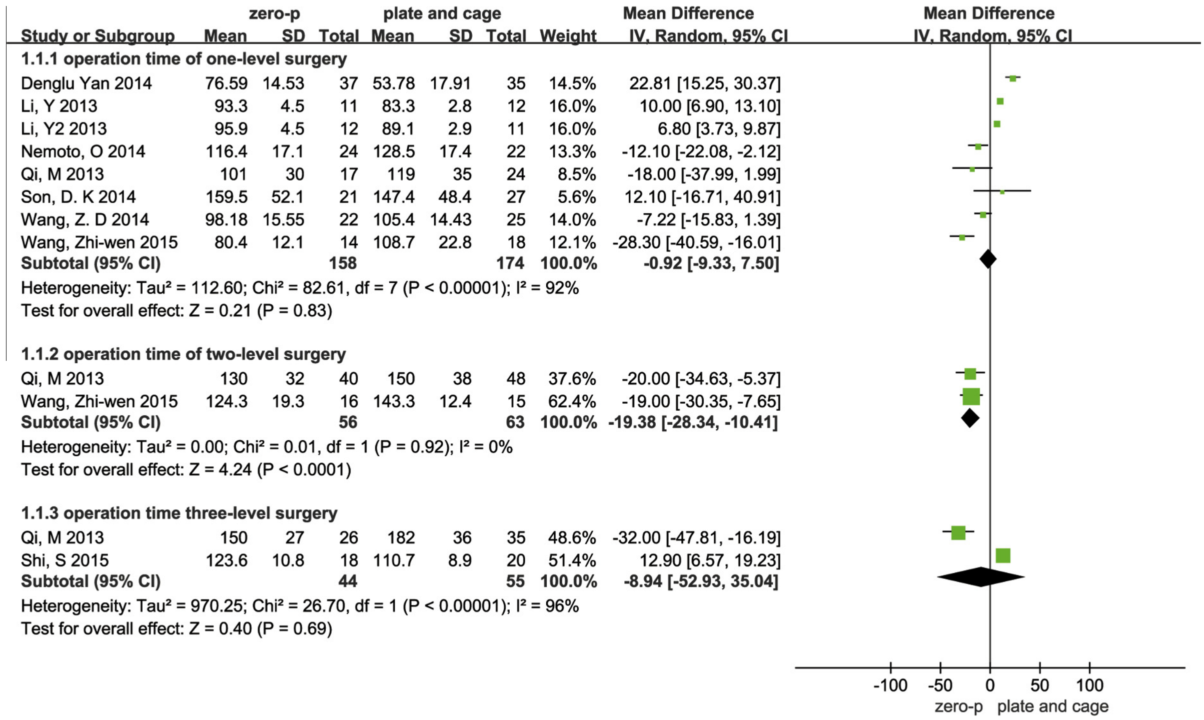

Fig. 2. Comparison of operation time.

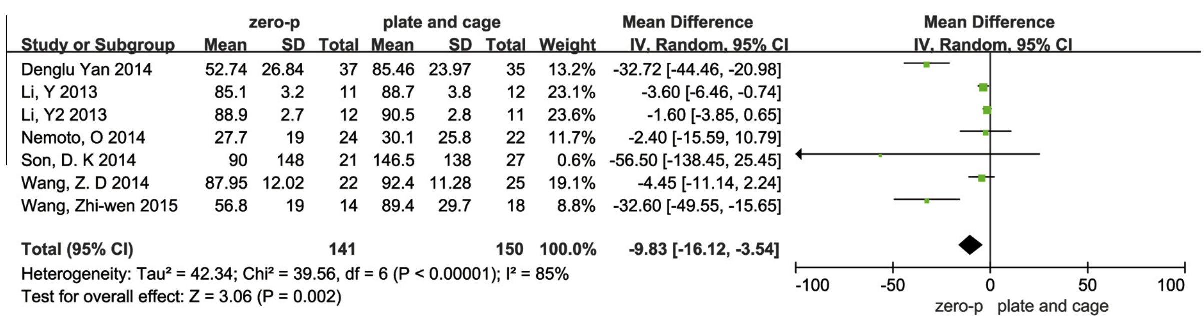

Fig. 3. Comparison of intraoperative blood loss.

3.3.5. Cobb angle

Six studies with 222 patients in the zero-p group and 233 patients in the plate and cage group were included in the meta-analysis of postoperative Cobb angle (more than 1-year follow-up). The Cobb angle in the zero-p group was significantly lower than that in the plate and cage group (WMD: −2.20, 95% CI: [−4.27, −0.13], $P = 0.04$, $I^2 = 87\%$, Fig. 6). Subgroup analysis was conducted for analysis of Cobb angle. No significant difference was identified in Cobb angle of one-level and two-level surgery (WMD: −1.80, 95% CI: [−4.63, 1.03], $P = 0.21$, $I^2 = 90\%$, Fig. 6). Significant difference was found in the Cobb angle of multilevel surgery (WMD: −3.16, 95% CI: [−4.35, −1.97], $P < 0.00001$, $I^2 = 0\%$, Fig. 6). Obvious heterogeneity was detected in the Cobb angle of one-level and two-level surgery. No significant difference was identified in segmental Cobb angle (WMD: −2.94, 95% CI: [−6.33, 0.45], $P = .09$, $I^2 = 93\%$, Fig. 7). Significant heterogeneity was detected. Sensitivity analysis showed that the main cause of the heterogeneity came from one study [31]. After elimination of this article, the heterogeneity of Cobb angle of one-level and two-level surgery was not obvious (WMD: 0.64, 95% CI: [−1.56, 0.29], $P = 0.18$, $I^2 = 33\%$, Fig. 8).

3.3.6. Radiological outcome

Seven studies with 259 patients in the zero-p group and 270 patients in the plate and cage group were included in the meta-analysis of the fusion rate (more than 1-year follow-up). The fusion rate between the two groups showed no statistical significance (RR: 0.99, 95% CI [0.96, 1.03], $P = 0.75$, $I^2 = 0\%$, Fig. 9). Three studies with 101 surgical levels and 100 surgical levels in zero-p group and plate and cage group respectively were included in the meta-analysis of the subsidence rate (more than 1-year follow-up). Significant difference was found between the two groups (RR: 3.11, 95% CI [1.29, 7.54], $P = 0.01$, $I^2 = 49\%$, Fig. 9).

3.4. Publication bias

We performed the Egger's test and the Begg's test to assess potential publication bias. Possible publication bias was detected regarding RR of short-term incidence of dysphagia (Begg's $P = 0.174$, Egger's $P = 0.015$). RR of long-term incidence of dysphagia (Begg's $P = 0.536$, Egger's $P = 0.887$), WMD of Cobb angle (Begg's $P = 0.711$, Egger's $P = 0.811$), WMD of JOA score (Begg's $P = 0.806$, Egger's $P = 0.416$) showed no publication bias. Trim-and-fill

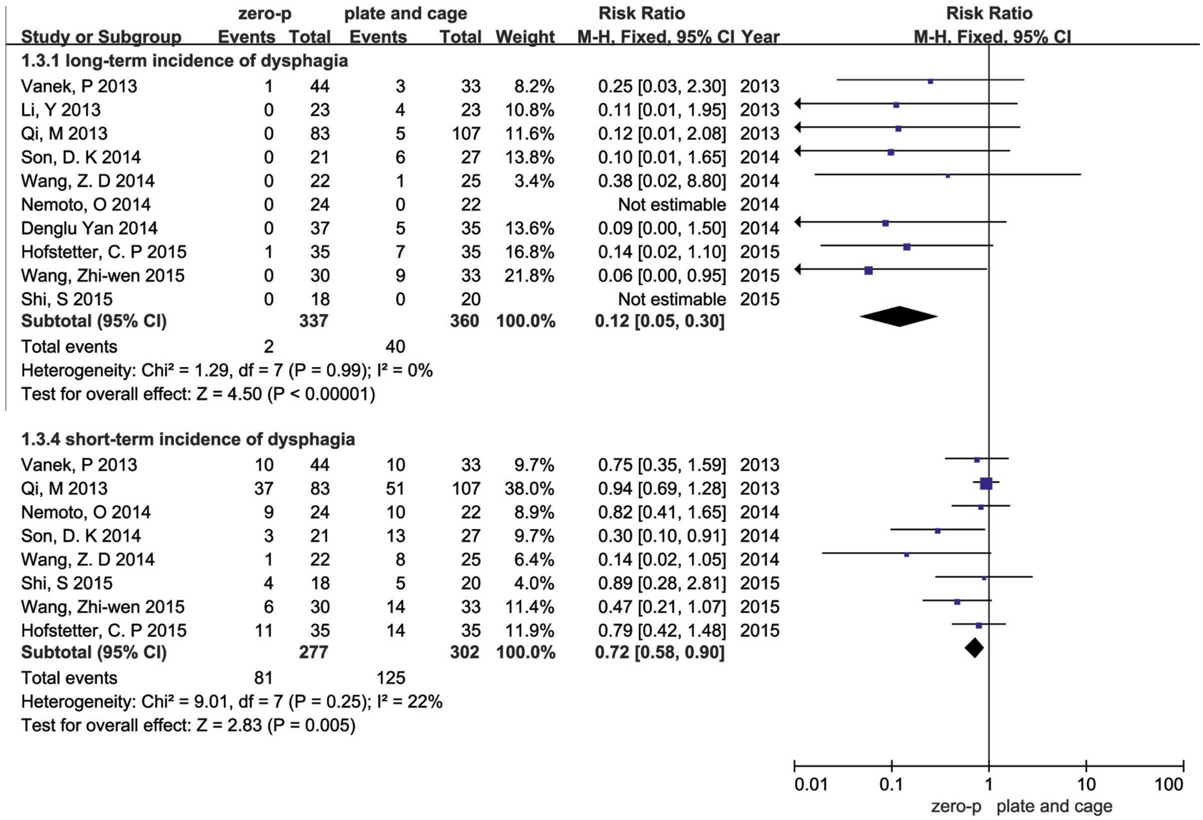

Fig. 4. Comparison of incidence of dysphagia.

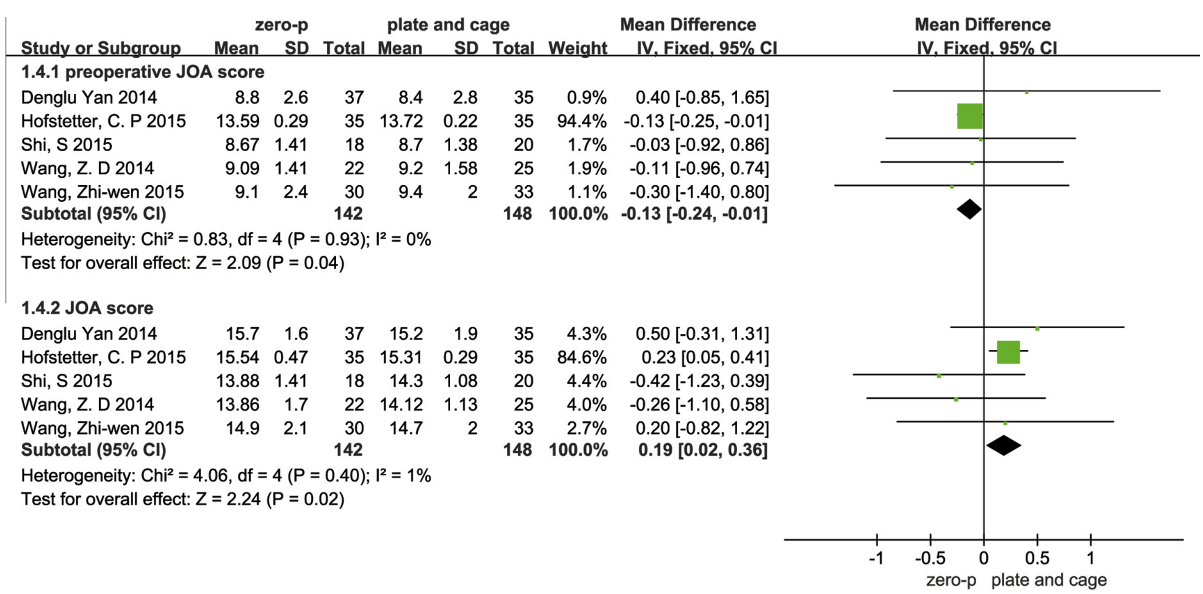

Fig. 5. Comparison of JOA score.

analysis showed no missing studies in the analysis of short-term incidence of dysphagia. The effect size changed from 0.72 (95% CI: [0.58, 0.90]) to 0.74 (95% CI: [0.56, 0.97]), which indicated that the possible publication bias was significant. These results suggest no presence of severe publication bias.

4. Discussion

The clinical application of the zero-p has not been testified with clinical evidence. Multicenter RCTs which directly compare the zero-p and the plate and cage are needed. In our meta-analysis,

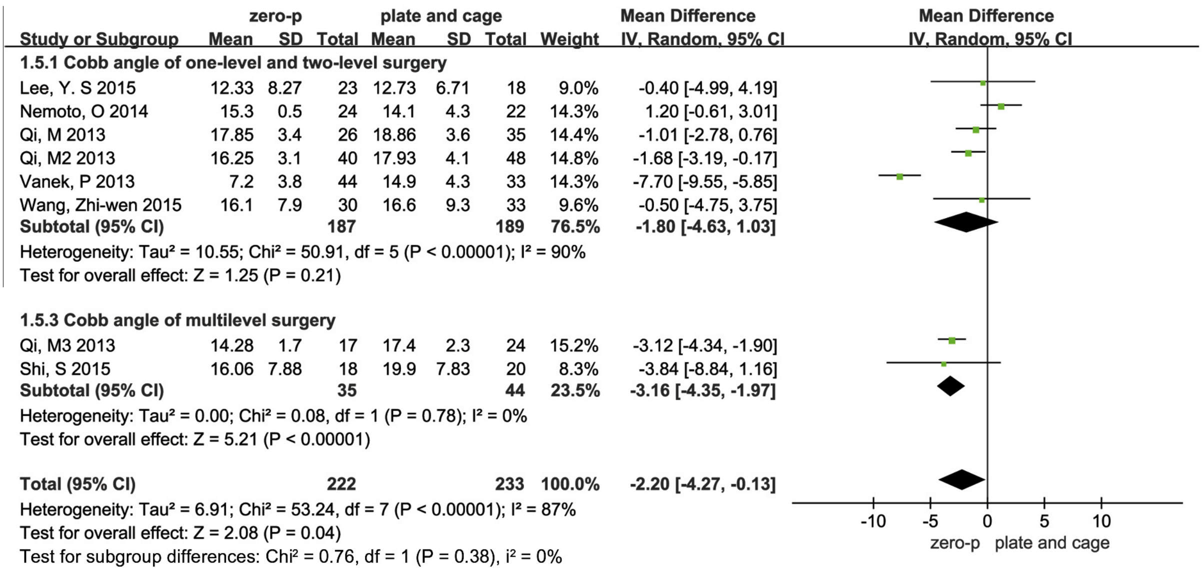

Fig. 6. Comparison of Cobb angle.

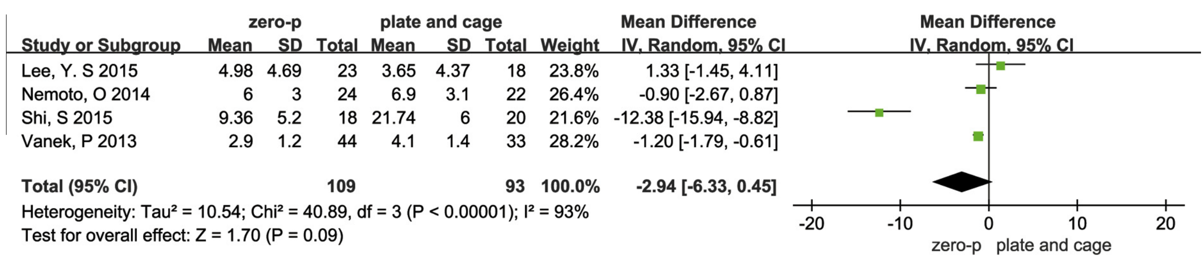

Fig. 7. Comparison of segmental Cobb angle.

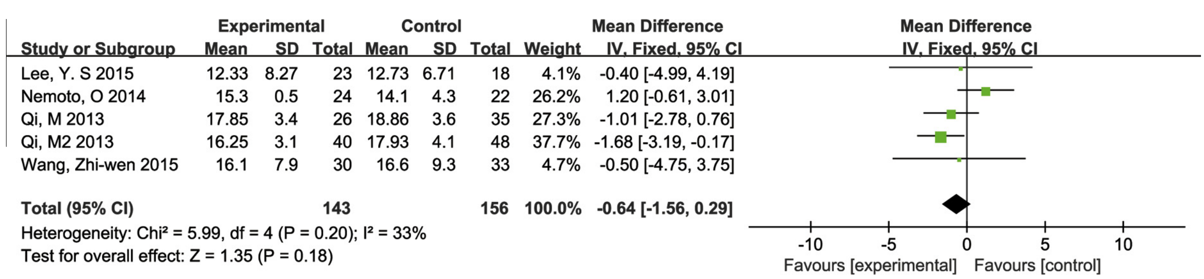

Fig. 8. Sensitive analysis of comparison of Cobb angle in one-level and two-level surgery.

no significant difference is found in operation time between zero-p group and plate and cage group in one-level and three-level surgery. While a significant reduction in intraoperative blood loss of one-level surgery and operation time of two-level surgery in zero-p group is identified. Wang et al. [32] reported that zero-p was associated with less intraoperative blood loss of two-level surgery. In addition, Shi et al. [33] reported that no significant difference was found in intraoperative blood loss of three-level surgery between the two groups. The results concerning operation time and intraoperative blood loss are difficult to explain. Obvious heterogeneity in operation time of one-level, three-level surgery and intraoperative blood loss exists among the included studies. The possible explanation for that might be the definition of the operation time. For instance, no agreement was reached whether the time under anesthesia should be counted into the operation time. In addition, as a new surgical procedure, the experience and the habits of the surgeons on zero-p implantation might also correlate with the operation time and intraoperative blood loss. A reduction in intraoperative blood loss and operative time could reduce the damage caused by surgery and incidence of complication, which may be helpful for the rehabilitation of patients after the surgery to get better clinical outcome. The safety of ACDF with zero-p may be better compared with ACCF in operation time and intraoperative blood loss. But due to the significantly high heterogeneity, the quality of evidence regarding the operative time and intraoperative blood loss are low.

The efficacy of cervical spine surgery was usually evaluated by JOA score regarding motor function, sensory function and bladder function. In our meta-analysis, zero-p is associated with significantly lower preoperative JOA score and higher postoperative

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Fixed, 95% CI	Year
1.7.1 fusion rate							
Qi, M 2013	83	83	109	109	36.7%	1.00 [0.98, 1.02]	2013
Vanek, P 2013	41	44	29	33	12.8%	1.06 [0.91, 1.23]	2013
Nemoto, O 2014	23	24	22	22	9.1%	0.96 [0.86, 1.08]	2014
Denglu Yan 2014	37	37	35	35	14.1%	1.00 [0.95, 1.05]	2014
Lee, Y. S 2015	19	23	17	18	7.4%	0.87 [0.70, 1.09]	2015
Shi, S 2015	18	18	20	20	7.5%	1.00 [0.91, 1.10]	2015
Wang, Zhi-wen 2015	30	30	33	33	12.4%	1.00 [0.94, 1.06]	2015
Subtotal (95% CI)		**259**		**270**	**100.0%**	**0.99 [0.96, 1.03]**	
Total events	251		265				
Heterogeneity: Chi² = 2.67, df = 6 (P = 0.85); I² = 0%							
Test for overall effect: Z = 0.32 (P = 0.75)							
1.7.2 subsidence rate							
Nemoto, O 2014	4	24	3	22	53.5%	1.22 [0.31, 4.86]	2014
Lee, Y. S 2015	9	54	0	60	8.1%	21.07 [1.26, 353.66]	2015
Shi, S 2015	5	23	2	18	38.4%	1.96 [0.43, 8.94]	2015
Subtotal (95% CI)		**101**		**100**	**100.0%**	**3.11 [1.29, 7.54]**	
Total events	18		5				
Heterogeneity: Chi² = 3.89, df = 2 (P = 0.14); I² = 49%							
Test for overall effect: Z = 2.52 (P = 0.01)							

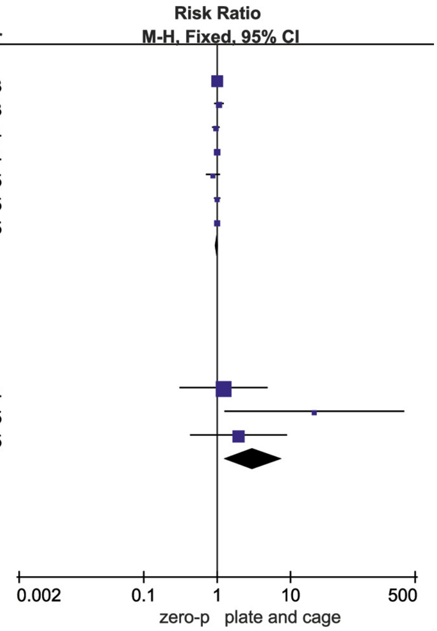

Fig. 9. Comparison of radiological outcome.

JOA score. Both groups significantly restore the function of the cervical spine. The results indicate that the ACDF with zero-p implantation and the plate and cage are both effective treatments for CDDD. The increase of JOA score after ACDF with zero-p was significantly higher than that after ACDF with plate and cage. Our result indicates that the clinical efficacy of ACDF with zero-p may be better than that of ACDF with plate and cage. ACDF with zero-p may be superior to ACDF with plate and cage in the aspect of the improvement of clinical symptoms and quality of life.

No significant difference is found in fusion rate between the two groups. Both groups significantly restore the stability of the cervical spine. No significant difference is found in postoperative Cobb angle of one-level surgery which indicates that zero-p implantation and the plate and cage are both effective treatment in one-level surgery. The segmental Cobb angle between the two groups shows no significant difference. The heterogeneity may be caused by the different number of surgical levels. The quality of evidence regarding segemental Cobb angle is low. ACDF with zero-p and ACDF with plate and cage are equally effective treatment with regard to the restoration of cervical lordosis in one-level and two-level surgery. The preoperative Cobb angle of the two groups showed significant difference in the study [31] which may cause the heterogeneity. In addition, no significant improvement of Cobb angle was achieved at two-year follow-up in this study [31]. Those could be the possible explanations of the heterogeneity. However, Cobb angle is significantly lower in zero-p group of multilevel surgery, which indicates that zero-p implantation is not as efficacious as the plate and cage in restoration of cervical lordosis in multilevel surgery. The loss of cervical lordosis was considered as a risk factor of degenerative changes of the cervical spine due to the increased biomechanical stress of adjacent levels [34].

In this study, both long-term and short term incidence of dysphagia in zero-p group are significantly lower. The exact mechanism of postoperative dysphagia remains unknown. A possible explanation for this might be that the postoperative dysphagia correlates with the design and thickness of plate [18]. The plate is placed anteriorly to the cervical vertebral body and posteriorly to the esophagus and may irritate the esophagus [14,18,35], causing the postoperative dysphagia. On the contrary, the zero-p is completely contained in the intervertebral space. No irritation to the esophagus and other prevertebral soft tissue is caused by the zero-p, resulting in the lower incidence of dysphagia postoperative. Furthermore, the zero-p is associated with significantly higher subsidence rate. A systematic review indicated that subsidence did not influence the clinical outcome and fusion rate [36]. Wu [37] and Barsa [38] reported that subsidence might lead to secondary kyphosis of the cervical spine. The possible reasons of subsidence reported [38–40] included preoperative Cobb angle, design of implant, age, using of plate, the distance of implanted device from the anterior vertebral rim and the spacer versus end plate surface ratio.

Our meta-analysis has several limitations that should be acknowledged. Only eleven studies (a total of 738 patients) were included in our meta-analysis, thus the sample size is relatively small. And only two RCT was included and most studies included were observational studies, the statistical power of which was lower than RCTs. Besides, all relevant studies were obtained from selected databases, some studies might not be retrieved and only English studies were included. Thus, more large sample, RCTs with long-term follow-up are needed to demonstrate the conclusion of this meta-analysis.

5. Conclusion

Zero-p implantation appears to be a safer and more effective procedure with reduced incidence of dysphagia and increased subsidence rate compare to plate and cage. But for the restoration of cervical lordosis of multilevel surgery, the plate and cage suggested better outcomes. More multicenter prospective randomized controlled studies with long-term follow-up are needed.

Conflicts of Interest/Disclosures

The authors declare that they have no financial or other conflicts of interest in relation to this research and its publication.

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