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Incidence of dysphagia of zero-profile spacer versus cage-plate after anterior cervical discectomy and fusion

A meta-analysis

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Abstract

Background: The purpose of this study is to evaluate the rate of dysphagia between zero-profile spacer versus cage-plate for the treatment of multilevel cervical spondylotic myelopathy (CSM).

Methods: The authors searched electronic databases for relevant studies that compared the clinical effectiveness of zero-profile spacer versus cage-plate for the treatment of patients with multilevel CSM. The following outcome measures were extracted: the Japanese Orthopaedic Association (JOA) scores, Neck Disability Index (NDI) score and fusion rate, dysphagia rate, adjacent segment degeneration, and cervical lordosis. Newcastle-Ottawa Quality Assessment Scale was used to evaluate the quality of each study. Data extraction and quality assessment were conducted, and RevMan 5.2 was used for data analysis.

Results: A total of 10 studies were included in our meta-analysis. Our pooled data revealed that zero-profile spacer was associated with decreased dysphagia rate at postoperatively 1, 3, and 6 months, and the final follow-up when compared with cage-plate group. No significant difference was observed in terms of postoperative JOA score, NDI score, and fusion rate. Compared with zero-profile spacer, the postoperative adjacent segment degeneration was significant higher in cage-plate. Pooled data from the relevant studies revealed that cervical lordosis was significantly lower in zero-profile spacer compared with cage-plate.

Conclusions: Our meta-analysis reveals zero-profile spacer is better than the cage-plate in terms of dysphagia. This suggests zero-profile spacer is a superior alternative invention for the treatment of multilevel CSM to reduce the risk of dysphagia.

Abbreviations: ACDF = anterior cervical decompression and fusion, CI = confidence intervals, CSM = cervical spondylotic myelopathy, JOA = Japanese Orthopaedic Association, NDI = Neck Disability Index, RCT = randomized controlled trial, WMD = weighted mean difference.

Keywords: cage-plate, cervical spondylotic myelopathy, zero-profile spacer

1. Introduction

Cervical spondylotic myelopathy (CSM) is a clinically symptomatic condition associated with degeneration of intervertebral discs and adjacent vertebral structures. The degeneration of the intervertebral disc, uncovertebral joint, facet joint, posterior longitudinal ligament, and ligamentum flavum causes spinal cord compression and cervical myelopathy.[1] At present, patients diagnosed with single-level symptomatic CSM were often recommended to receive anterior cervical decompression and fusion (ACDF).[2–5] However, ACDF for multilevel CSM means a long cervical plate and may be associated with longer operative times, and also complications such as breakage or loosening of plate and screws, trachea-esophageal injury, neurovascular injury, and postoperative dysphagia.[6,7]

To reduce the dysphagia complication, the zero-profile anchored spacer had been advocated for multilevel CSM. The device generally consists of a polyetheretherketone cage with self-locking clips or screws passing through the spacer into the endplates of the adjacent vertebral bodies.[8] Zero-profile cage utilizes an integrated, low-profile plate design to avoid plate-to-soft tissue impact, reducing dysphagia incidence and other plate-associated complications. Satisfactory clinical and fusion outcomes have been reported using this device in ACDF for multilevel CSM.[9]

There is, at present, no consensus concerning the superiority of zero-profile spacer versus cage-plate regarding the incidence of dysphagia in the treatment of multilevel CSM.[10,11] To further clarify controversies in the current literature, we performed present meta-analysis to evaluate the rate of dysphagia between zero-profile spacer versus cage-plate after ACDF for the patients with multilevel CSM.

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ZY and YZ equally contributed to this work.

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The authors declare that they have no competing interests.

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2. Materials and methods

2.1. Search strategy and study selection

Electronic databases, including MEDLINE, EMBASE, Cochrane Controlled Trial Register, and ISI Web of Knowledge (all databases) were searched for relevant reports published up to May 31, 2018. The MeSH Terms and Other Term used for our searches included “anterior cervical fusion,” “anterior plate,” “anterior cervical discectomy and fusion,” “ACDF,” “interbody fusion,” “low profile,” “zero profile,” “zero-p,” “anchored fusion,” “anchored spacer device,” and “stand alone.” The conjunctions “AND” and “OR” were used during the literature retrieval. We restricted the language to English. Reference lists of all included studies were scanned to identify additional potentially relevant studies. Two reviewers independently screened the titles and abstracts of identified papers, and full-text copies of all potentially relevant studies were obtained.

2.2. Inclusion and exclusion criteria

Two authors reviewed the articles, including randomized controlled trials (RCTs) and retrospective or prospective studies, in detail. The inclusion criteria for this study were as follows: all patients with multilevel CSM undergoing ACDF involving 2 or more levels; studies involving 2 cervical fusion groups: zero-profile versus cage-plate; a follow-up time of no less than 12 months. The following articles were excluded: meeting abstracts, review articles, editorial comments, letters, technical reports, case reports, biomechanical studies, and animal experiments; studies that did not meet the inclusion criteria; articles considered as duplicate publications.

2.3. Quality assessment of included studies

Risk of bias assessment was performed using the checklist proposed by Cowley[12] for nonrandomized studies. The items

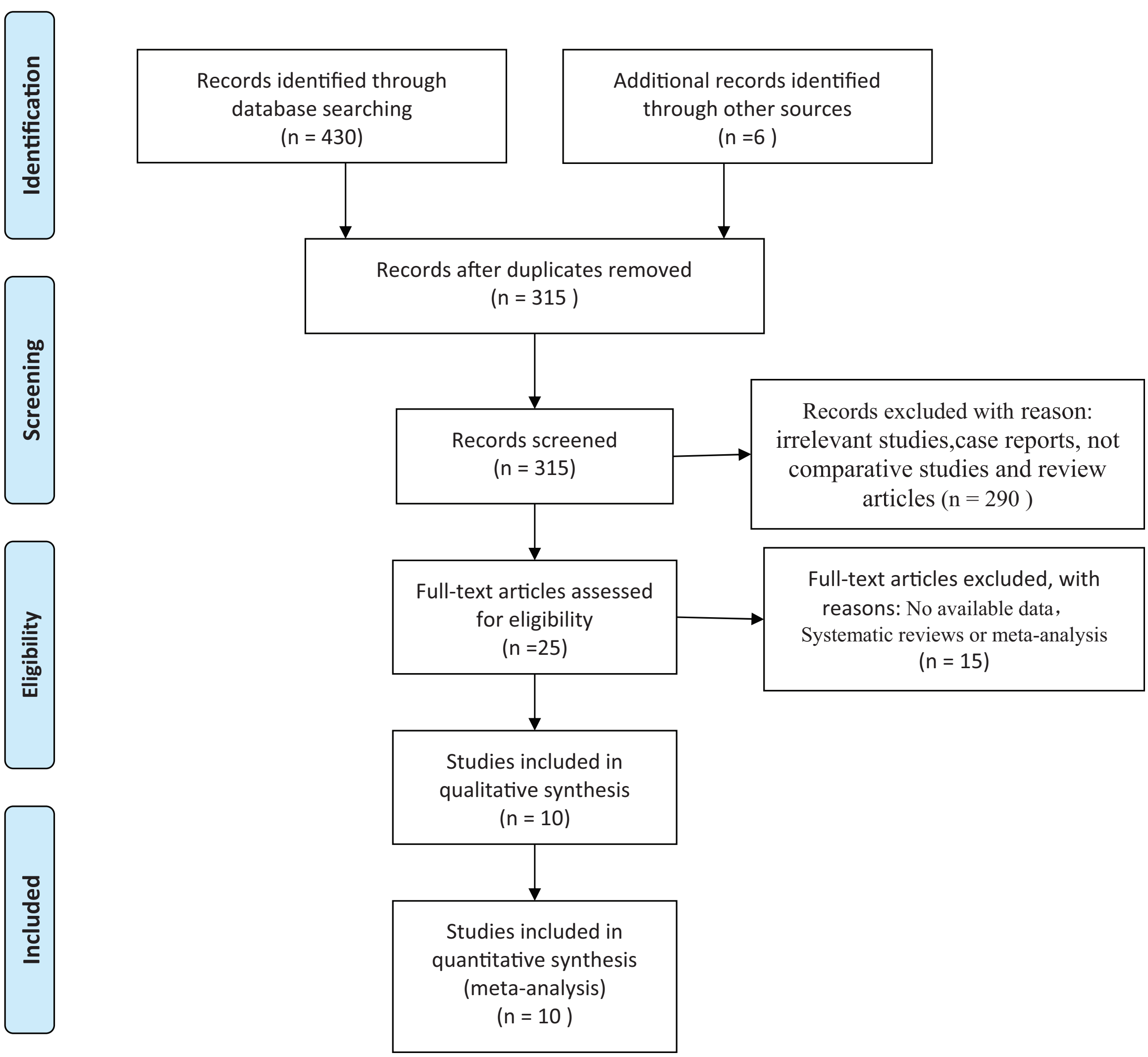

Figure 1. The flow chart shows the article selection process we performed.

were scored with "yes," "no," or "unclear." A Furlan score of 6 or more out of a possible 12, or a Cowley score of 9 or more out of a possible 17, was considered to reflect "high methodological quality." These studies were independently evaluated by 2 reviewers, and any discrepancies were resolved by discussion and consensus.

2.4. Data extraction

The data were extracted by 2 reviewers independently from each included study based on the following items: basic characteristics, including country, study design, age, enrolled number, and length of follow-up; function outcomes including postoperative Japanese Orthopedic Association (JOA) score, Neck Disability Index (NDI) score, and percentage of clinical success; radiological outcomes including postoperative total and segmental cervical lordosis, and disc height; complication types and complication rates. Any disagreement between the reviewers was resolved by discussion.

2.5. Data analysis

We performed all meta-analyses with the Review Manager software (RevMan Version 5.2; Cochrane Collaboration, Oxford, UK). Heterogeneity was tested using chi-square test and quantified by calculating I^2 statistic, for which $P<.1$ and $I^2<50\%$ was considered to be statistically significant. For the pooled effects, weighted mean difference (WMD) or standard mean difference (SMD) was calculated for continuous variables according to the consistency of measurement units, and odds ratio (OR) was calculated for dichotomous variables. Continuous variables are presented as mean differences and 95% confidence intervals (CIs), whereas dichotomous variables are presented as ORs and 95% CI. Random-effects or fixed-effects models were used depending on the heterogeneity of the studies included.

3. Results

The process of identifying relevant studies is summarized in Fig. 1. From the selected databases, 436 references were obtained. By screening the titles and abstracts, 415 references were excluded due to duplicates, irrelevant studies, case reports, not comparative studies, and review articles. The remaining potentially relevant 25 studies underwent a detailed and comprehensive evaluation. Finally, 10 studies were included in our meta-analysis.[13–22] The characteristics of these studies are summarized in Table 1.

3.1. Quality assessment

Newcastle-Ottawa Quality Assessment Scale was used to evaluate the quality of each study. This scale for nonrandomized case controlled studies and cohort studies had a maximum of 9 points, which included the quality of selection, comparability, exposure, and outcomes for study participants. Of these studies, 6 scored 8 points and 4 scored 7 points. Therefore, the quality of each study was relatively high (Table 2).

3.2. Clinical outcome

3.2.1. Postoperative JOA. Postoperative JOA scores were reported in 7 studies. No significant difference in postoperative visual analog scale score was found between zero-profile spacer and cage-plate groups (WMD −0.06; 95% CI −0.26, 0.13; $I^2=0\%$; $P=.51$) (Fig. 2).

3.2.2. Postoperative NDI. Postoperative NDI were reported in 8 studies. There was no significant difference between zero-profile spacer and cage-plate groups (WMD −0.02; 95% CI −0.35, 0.32; $I^2=0\%$; $P=.93$) (Fig. 3).

3.2.3. Postoperative cervical lordosis. Postoperative cervical lordosis was reported in 10 studies. Pooled data from the 10 relevant studies revealed cervical lordosis was significantly lower

Table 1

Characteristics of included studies.

Study ID	Design	Country	Number of patients	Mean patient age	Average follow-up (mos)
Chen et al[13]	Retrospective Comparative	USA	Z-P: 28, C-P:26	Z-P: 54.1 ± 8.8 C-P: 54.7 ± 12.1	Z-P:28.8 ± 9.7 C-P: 29.6 ± 8.3
Zhang et al[14]	Retrospective Comparative	China	Z-P: 23, C-P:21	Z-P: 53.3 ± 8.8 C-P: 57.8 ± 9.2	Z-P: 34.7 ± 7.6 C-P: 36.2 ± 5.2
Chen et al[15]	Retrospective Comparative	China	Z-P: 37, C-P:32	Z-P: 48.9 ± 4.0 C-P: 49.5 ± 4.2	Z-P: 40.6 ± 9.2 C-P: 43.5 ± 10.4
Chen et al[16]	Retrospective Comparative	China	Z-P: 34, C-P:38	Z-P: 56.9 ± 5.9 C-P: 56.2 ± 5.7	Z-P:NA C-P: NA
Liu et al[17]	Retrospective Comparative	China	Z-P: 28, C-P:32	Z-P: 56.6 ± 9.7 C-P: 57.5 ± 9.5	Z-P: 23.3 ± 6.9 C-P: 24.2 ± 6.4
Chen et al[18]	Retrospective Comparative	China	Z-P: 33, C-P:38	Z-P: 49.3 ± 3.7 C-P: 48.8 ± 3.9	Z-P: 30.2 ± 5 C-P: 31.5 ± 4.5
Shi et al[19]	Retrospective Comparative	China	Z-P: 18, C-P:20	Z-P: 56.2 ± 4.8 C-P: 56.7 ± 3.9	Z-P: 30.5 ± 3.4 C-P: 30.1 ± 2.8
Lu et al[20]	Retrospective Comparative	China	Z-P: 22, C-P:24	Z-P: 56.6 ± 6.4 C-P: 58.6 ± 7.2	Z-P:NA C-P: NA
Yang et al[21]	Retrospective Comparative	China	Z-P: 23, C-P:28	Z-P: 55.26 ± 8.98 C-P: 56.36 ± 7.97	Z-P:NA C-P: NA
Yun et al[22]	Retrospective Comparative	Korea	Z-P: 31, C-P:32	Z-P: 53.29 ± 7.55 C-P: 54.18 ± 9.87	Z-P:NA C-P: NA

C-P = cage-plate, NA = not available, Z-P = zero-profile.

Table 2

Quality assessment of included studies in the meta-analysis according to NOQAS.

Study	Selection	Comparability	Exposure	Total score
Chen et al[13]	3	2	3	8
Zhang et al[14]	3	2	2	7
Chen et al[15]	3	2	3	8
Chen et al[16]	3	2	3	8
Liu et al[17]	3	2	2	7
Chen et al[18]	3	2	3	8
Shi et al[19]	3	2	2	7
Lu et al[20]	3	2	2	7
Yang et al[21]	3	2	3	8
Yun et al[22]	3	2	3	8

The Newcastle-Ottawa scale contains 8 items that are divided into 3 categories: selection (4 items, 1 star each), comparability (1 item, up to 2 stars), and exposure/outcome (4 items, 1 star each). NOQAS = Newcastle-Ottawa Quality Assessment Scale.

in zero-profile spacer compared with cage-plate at final follow-up (WMD −0.87; 95% CI −1.73, −0.06; $I^2=26\%$; $P=.04$) (Fig. 4).

3.2.4. Fusion rate. Nine studies reported fusion rate. Pooled estimates revealed no significant difference between the 2 groups with no evidence of statistical heterogeneity (OR 0.77; 95% CI 0.35, 1.66; $I^2=0\%$; $P=.5$) (Fig. 5).

3.2.5. Adjacent segment degeneration. Five studies reported adjacent segment degeneration. Pooled data from the 5 relevant studies revealed a significant difference with no evidence of statistical heterogeneity (OR 0.44; 95% CI 0.2, 0.96; $I^2=0\%$; $P=.04$) (Fig. 6).

3.2.6. Dysphagia. All studies reported dysphagia. Pooled data revealed no significant difference between the 2 groups in postoperative 48 hours (OR 0.67; 95% CI 0.41, 1.11; $I^2=0\%$; $P=.12$) (Fig. 7). However, pooled data from the relevant studies revealed that a significantly low rate was found in the zero-profile spacer group compared with cage-plate group with no evidence of statistical heterogeneity at postoperative 1 month ($I^2=0\%$; $P=.002$), 3 months ($I^2=0\%$; $P=.0001$), 6 months ($I^2=0\%$; $P=.002$), and the final follow-up ($I^2=34\%$; $P=.004$) (Fig. 7).

4. Discussion

Anterior cervical decompression and fusion has been commonly regarded as 1 of the gold-standard operation for CSM when conservative treatment fails.[23] An anterior cervical plate is widely used in ACDF to enhance the interbody fusion rate, and increase the cervical stability and avoid subsidence or graft dislocation.[24,25] However, the application of anterior cervical plate is closely associated with several postoperative complications

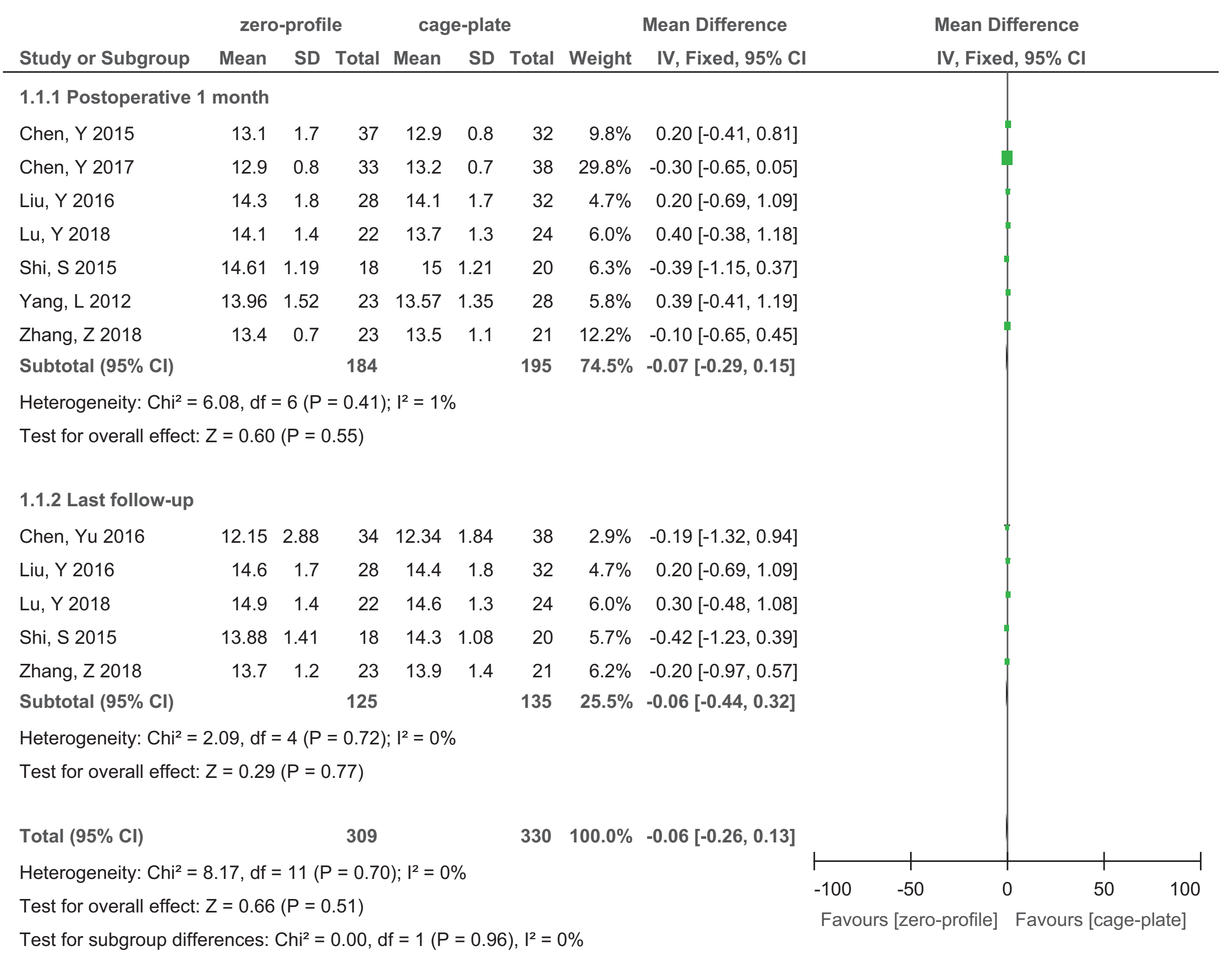

Figure 2. Forest plot of postoperative JOA scores between zero-profile spacer and cage-plate groups. JOA = Japanese Orthopaedic Association.

Study or Subgroup	zero-profile Mean	zero-profile SD	zero-profile Total	cage-plate Mean	cage-plate SD	cage-plate Total	Weight	Mean Difference IV, Fixed, 95% CI
2.1.1 Postoperative 1 month								
Liu, Y 2016	13.5	3.4	28	14	3	32	4.1%	-0.50 [-2.13, 1.13]
Lu, Y 2018	14.9	4.9	22	15.4	4.7	24	1.4%	-0.50 [-3.28, 2.28]
Zhang, Z 2018	13.7	5.3	23	13.5	6.1	21	0.9%	0.20 [-3.19, 3.59]
Subtotal (95% CI)			**73**			**77**	**6.4%**	**-0.40 [-1.70, 0.90]**
Heterogeneity: Chi² = 0.14, df = 2 (P = 0.93); I² = 0%								
Test for overall effect: Z = 0.60 (P = 0.55)								
2.1.2 Final follow-up								
Chen, Y 2015	5.5	1.1	37	5.4	1.9	32	19.5%	0.10 [-0.65, 0.85]
Chen, Y 2017	5.5	1.3	33	5.6	1.1	38	34.2%	-0.10 [-0.66, 0.46]
Chen, Yu 2016	5.74	2.53	34	5.63	2.33	38	8.6%	0.11 [-1.02, 1.24]
Liu, Y 2016	13.1	3.1	28	13.5	3.2	32	4.3%	-0.40 [-2.00, 1.20]
Lu, Y 2018	13.1	5.7	22	12.7	5.7	24	1.0%	0.40 [-2.90, 3.70]
Shi, S 2015	5.72	1.43	18	5.55	1.45	20	13.0%	0.17 [-0.75, 1.09]
Yang, L 2012	3.56	1.77	23	3.39	1.66	28	12.1%	0.17 [-0.78, 1.12]
Zhang, Z 2018	12.5	4	23	13.9	6.8	21	1.0%	-1.40 [-4.74, 1.94]
Subtotal (95% CI)			**218**			**233**	**93.6%**	**0.01 [-0.33, 0.35]**
Heterogeneity: Chi² = 1.45, df = 7 (P = 0.98); I² = 0%								
Test for overall effect: Z = 0.06 (P = 0.95)								
Total (95% CI)			**291**			**310**	**100.0%**	**-0.02 [-0.35, 0.32]**
Heterogeneity: Chi² = 1.95, df = 10 (P = 1.00); I² = 0%								
Test for overall effect: Z = 0.09 (P = 0.93)								
Test for subgroup differences: Chi² = 0.35, df = 1 (P = 0.55), I² = 0%								

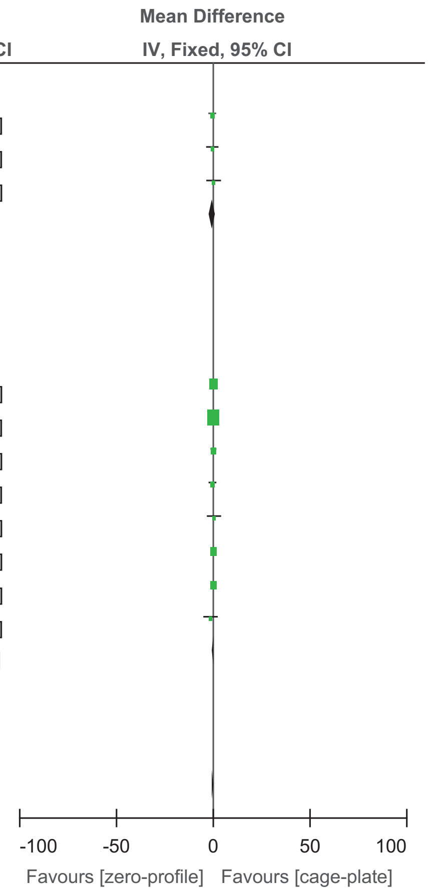

Figure 3. Forest plot of postoperative NDI between zero-profile spacer and cage-plate groups. NDI = Neck Disability Index.

including neck pain, hoarseness, and dysphagia. Zero-profile implant is a stand-alone anchored spacer designed to minimize these complications, simultaneously providing adequate stability and avoiding the implant contact with the anterior soft tissue.[8] Although several relevant studies comparing the zero-profile spacer and cage-plate have been reported,[13,14,17,18,20,22] it remains ambiguous on which method, zero-profile or cage-plate, is superior. Therefore, we conducted a meta-analysis to evaluate which device is the optimal implant for cervical fusion.

Our meta-analysis demonstrates that there was no significant difference in terms of postperative JOA score, NDI score, and fusion rate between zero-profile and cage-plate. Compared with cage-plate group, postoperative dysphagia rate was significantly lower in the zero-profile spacer group. Pooled data from the relevant studies revealed a significant difference in postoperative adjacent segment degeneration and cervical lordosis.

The JOA and NDI scores were often used to evaluate the improvement of nerve function. Our study shows that there was no statistically difference in JOA scores, and also NDI scores between zero-profile and cage-plate. Our findings are in line with previous studies confirming that surgical management of multilevel CSM by zero-profile or cage-plate shows no significant differences in terms of achieved nerve improvement.[26,27] Hence, these results suggest that both procedures can have sufficient decompression and improve the patients' neurological function.

Dysphagia is 1 of the most concerning postoperative complication after ACDF with anterior plate fixation, especially after multilevel surgeries. The exact etiology of dysphagia remained unknown. Previous study reported that esophageal injury, postoperative soft tissue edema, adhesive formations around implanted cervical plates, and postoperative hematoma may be the possible reasons for dysphagia-related symptoms.[28,29] In addition, with the raise of fused segment, the risk of dysphagia increases.[10] Cho et al[30] found that the rate of postoperative dysphagia could be as high as 71% within the first 2 weeks after surgery, which gradually decreased during the following months. The results of this meta-analysis suggested that the zero-profile group was associated with lower incidence of dysphagia at postoperative 1, 3, and 6 months, and final follow-up, when compared with the cage-plate group. Recently, a meta-analysis performed by Tong et al[27] revealed that significantly lower dysphagia rates were observed in the zero-profile group at postoperative 2, 3, and 6 months. Our finding was comparable with previous studies.[27] However, our study revealed no significant difference between the 2 groups at postoperative 48 hours. At the early stage (2 weeks postoperatively), it could partly be attributed to longer intraoperative esophagus retraction time and greater retraction extent to fix the anterior plates.

We believe that our result of meta-analysis is affected by several reasons. Firstly, in this meta-analysis, most of the studies selected were not RCTs, although it did not influence the credibility of the

	zero-profile			cage-plate				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Random, 95% CI
3.1.1 Postoperative 1 month								
Chen, Y 2015	20.4	2.2	37	21.3	3.2	32	16.1%	-0.90 [-2.22, 0.42]
Chen, Yuqiao 2016	16.5	6.4	28	20.1	7.7	26	2.3%	-3.60 [-7.39, 0.19]
Liu, Y 2016	19.5	7.5	28	18.9	7.9	32	2.2%	0.60 [-3.30, 4.50]
Lu, Y 2018	20.1	4.6	22	20.7	4.8	24	4.4%	-0.60 [-3.32, 2.12]
Zhang, Z 2018	19.2	9	23	18.3	9.7	21	1.1%	0.90 [-4.64, 6.44]
Subtotal (95% CI)			**138**			**135**	**26.1%**	**-0.89 [-1.95, 0.18]**
Heterogeneity: Tau² = 0.00; Chi² = 2.97, df = 4 (P = 0.56); I² = 0%								
Test for overall effect: Z = 1.63 (P = 0.10)								
3.1.2 Final follow-up								
Chen, Y 2015	15.2	2.3	37	16.3	3.3	32	15.2%	-1.10 [-2.46, 0.26]
Chen, Y 2017	13.1	5.9	33	17.1	7.8	38	3.2%	-4.00 [-7.19, -0.81]
Chen, Yu 2016	17.53	1.96	34	17.79	1.72	38	30.3%	-0.26 [-1.12, 0.60]
Chen, Yuqiao 2016	16	6.7	28	19.1	7.9	26	2.2%	-3.10 [-7.02, 0.82]
Liu, Y 2016	19	7.8	28	18.7	7.8	32	2.1%	0.30 [-3.66, 4.26]
Lu, Y 2018	15.9	3.7	22	16.3	3.9	24	6.5%	-0.40 [-2.60, 1.80]
Shi, S 2015	16.06	7.88	18	19.9	7.83	20	1.3%	-3.84 [-8.84, 1.16]
Yang, L 2012	16.93	2.78	23	18.36	3.67	28	9.7%	-1.43 [-3.20, 0.34]
Yun, D. 2017	15.55	8.6	30	13.1	7.47	31	2.0%	2.45 [-1.60, 6.50]
Zhang, Z 2018	18.7	8.6	23	17.7	8.3	21	1.3%	1.00 [-4.00, 6.00]
Subtotal (95% CI)			**276**			**290**	**73.9%**	**-0.89 [-1.73, -0.06]**
Heterogeneity: Tau² = 0.41; Chi² = 12.13, df = 9 (P = 0.21); I² = 26%								
Test for overall effect: Z = 2.09 (P = 0.04)								
Total (95% CI)			**414**			**425**	**100.0%**	**-0.82 [-1.40, -0.23]**
Heterogeneity: Tau² = 0.10; Chi² = 15.17, df = 14 (P = 0.37); I² = 8%								
Test for overall effect: Z = 2.75 (P = 0.006)								
Test for subgroup differences: Chi² = 0.00, df = 1 (P = 0.99), I² = 0%								

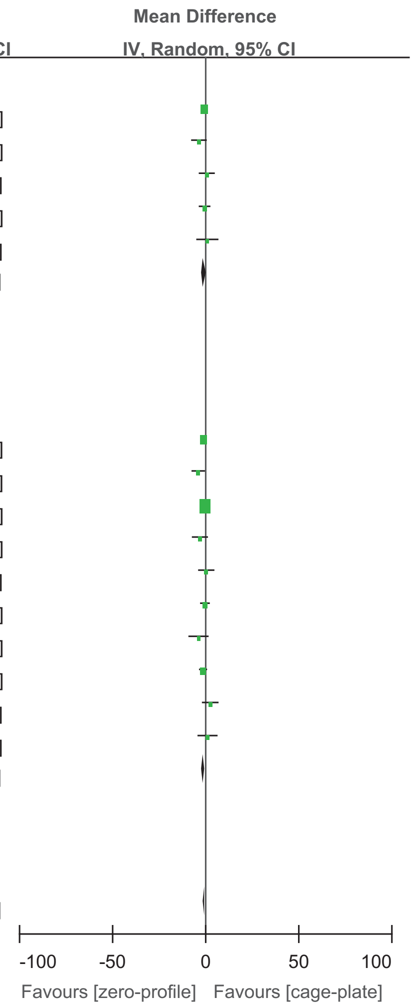

Figure 4. Forest plot of postoperative cervical lordosis between zero-profile spacer and cage-plate groups.

	zero-profile		cage-plate			Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI
Chen, Y 2015	37	37	32	32		Not estimable
Chen, Y 2017	31	33	34	38	13.0%	1.82 [0.31, 10.66]
Chen, Yu 2016	0	0	0	0		Not estimable
Chen, Yuqiao 2016	24	28	24	26	24.1%	0.50 [0.08, 2.99]
Liu, Y 2016	0	0	0	0		Not estimable
Lu, Y 2018	22	24	24	24	16.6%	0.18 [0.01, 4.04]
Shi, S 2015	18	18	20	20		Not estimable
Yang, L 2012	23	23	28	28		Not estimable
Yun, D. 2017	22	31	24	32	46.4%	0.81 [0.27, 2.48]
Total (95% CI)		**194**		**200**	**100.0%**	**0.77 [0.35, 1.66]**
Total events	177		186			
Heterogeneity: Chi² = 1.98, df = 3 (P = 0.58); I² = 0%						
Test for overall effect: Z = 0.68 (P = 0.50)						

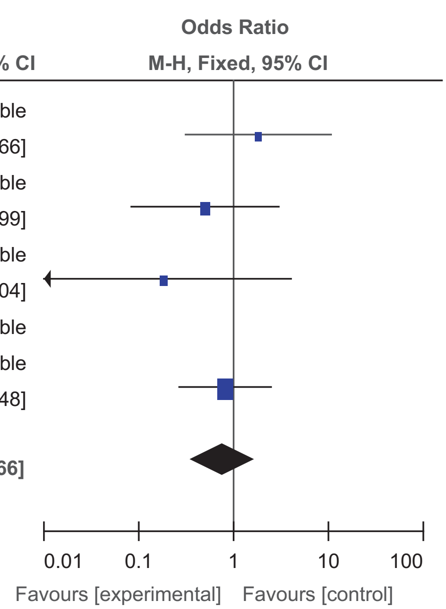

Figure 5. Forest plot of postoperative fusion rate between zero-profile spacer and cage-plate groups.

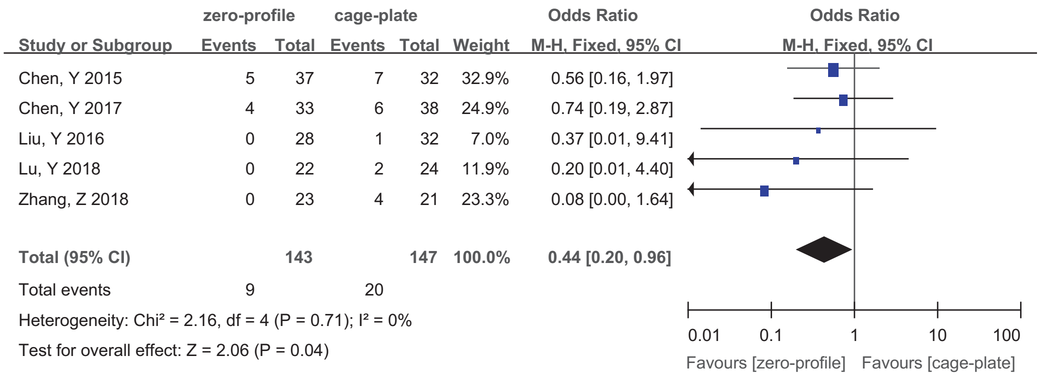

Figure 6. Forest plot of postoperative adjacent segment degeneration rate between zero-profile spacer and cage-plate groups.

results. Secondly, only 10 studies were included, and their sample sizes were relatively small. Finally, most studies originated from China, and there may be demography bias. Due to these limitations, the combined results of this meta-analysis should be cautiously accepted, and high-quality RCTs with long-term follow-up and large sample size are needed.

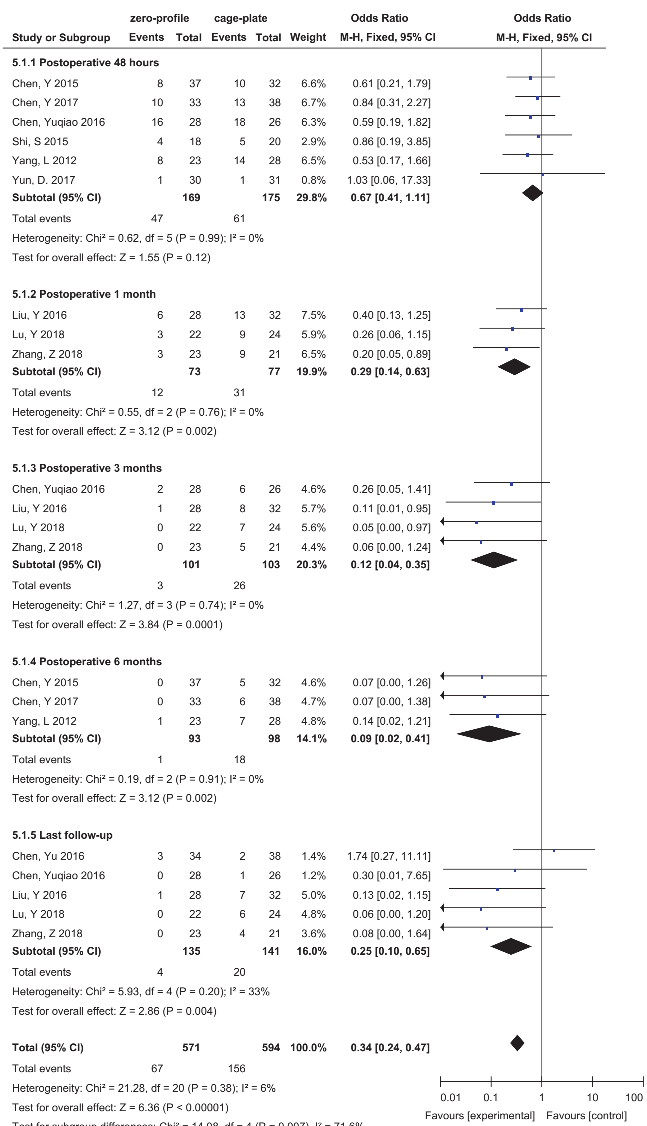

Figure 7. Forest plot of postoperative dysphagia rate between zero-profile spacer and cage-plate groups.

5. Conclusions

In conclusion, our meta-analysis reveals zero-profile spacer is better than the cage-plate in terms of dysphagia. This suggests zero-profile spacer is a superior alternative invention for the treatment of multilevel CSM to reduce the risk of dysphagia. This requires further validation and investigation in larger sample-size prospective and randomized studies.

Author contributions

Conceptualization: Zhongmeng Yang.
Data curation: Yao Zhao, Jiaquan Luo.
Formal analysis: Yao Zhao.
Investigation: Zhongmeng Yang, Jiaquan Luo.
Methodology: Zhongmeng Yang, Yao Zhao.
Supervision: Jiaquan Luo.
Writing – original draft: Zhongmeng Yang.
Writing – review & editing: Jiaquan Luo.

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