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Research Article

Effectiveness of Zero-Profile Spacer versus Traditional Cage and Plate in Anterior Cervical Discectomy and Fusion: A Meta-Analysis

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ABSTRACT

Objective: To evaluate the clinical effectiveness of Zero-Profile spacer versus traditional cage and plate in anterior cervical discectomy and fusion.

Methods: An electronic search was conducted in the databases of PubMed, the Cochrane Library, Embase, Web of Science, Science Direct, Chinese Science and Technology Periodical Database, the China National Knowledge Infrastructure, and Wanfang. A meta-analysis was performed using review manager 5.3.

Results: Seven trials were included in the study, and the meta-analysis found Zero-Profile spacer was superior to traditional cage and plate in decreasing the incidence of adjacent segment degeneration(OR = -0.06, 95% CI: 0.02, 0.18, heterogeneity: $X^2 = 0.28$, $I^2 = 0$, $p < 0.00001$), but in terms of operative time (MD = -7.2, 95% CI: -21.19, 6.80, heterogeneity: $X^2 = 387.84$, $I^2 = 99\%$, $p = 0.31$), blood loss (MD = -8.72, 95% CI: -18.82, 1.39, heterogeneity: $X^2 = 213.61$, $I^2 = 98\%$, $p = 0.09$), JOA score(MD = .63, 95% CI: -0.67, 1.93, heterogeneity: $X^2 = 38.71$, $I^2 = 92\%$, $p = 0.34$), NDI scores (MD = -6.65, 95% CI: -20.18, 6.89, heterogeneity: $X^2 = 39.72$, $I^2 = 97\%$, $p = 0.34$), incidence of dysphagia (OR = 0.37, 95% CI: -0.13, 1.03, heterogeneity: $X^2 = 10.36$, $I^2 = 52\%$, $p = 0.06$), and Cobb angles(MD = -0.85, 95% CI: -2.50, 0.80, heterogeneity: $X^2 = 1.42$, $I^2 = 29\%$, $p = 0.31$), the Zero-profile spacer didn't show a significantly better outcome.

Conclusion: Zero-Profile spacer showed a favorable effect in the incidence of adjacent segment degeneration, but didn't in operative time, blood loss, JOA score, dysphagia incidence, NDI scores, and cervical Cobb angle when compared with traditional cage and plate group in ACDF.

Keywords: Zero-Profile spacer; Traditional cage and plate; Anterior Cervical Discectomy And Fusion (ACDF); Meta-Analysis

INTRODUCTION

Anterior Cervical Discectomy and Fusion (ACDF) is a commonly used surgical procedure to treat Cervical Spondylotic Myelopathy (CSM). During ACDF, cage and anterior plate are usually employed to enhance stabilizing properties and fusion rate. However, not without side effects of ACDF and anterior plating, up to 67 % of patients complain of dysphasia in the early post-operative period [1]. The factors including postoperative soft tissue edema, esophageal injury, postoperative hematoma, and adhesions around the anterior plates may contribute to the occurrence of dysphagia. In addition, a correlation between dysphagia and plate thickness was also confirmed [2].

Zero-Profile system is a new kind of cervical interbody cage, consisting of titanium alloy plate and PEEK spacer with locking head screws [3]. The implant has a smaller volume than traditional anterior plates, leading to limited resection of the anterior longitude ligament, less exposure of the longus colli muscle and lower rate of dysphagia. In a prospective controlled study of 46 patients, Li and colleagues concluded that Zero-Profile system had a greater reduction in dysphagia at all follow-up intervals when compared with traditional anterior plate and cage [2]. However, in another study of 50 patients, Nemoto found no significant difference in the rate of dysphasia between the two systems [1]. Hence, the conclusion is controversial.

Moreover, some scholars have evaluated the effectiveness of these two systems using meta-analysis. In these meta-analyses, the authors concluded that the zero-profile system showed reduced intraoperative blood loss, improved postoperative cervical lordosis, and decreased incidence of dysphasia and adjacent segment degeneration [4-7]. However, in these meta-analyses, most of the included studies were not randomized controlled trials, but retrospective or cohort studies, which may affect the final conclusion adversely.

Nowadays, more randomized controlled trials have been performed to compare the efficacy of Zero-Profile spacer versus traditional cage and plate in ACDF. We believe it is necessary to carry out an updated meta-analysis to evaluate the effectiveness of these two systems. Therefore, we carried out this study, and our aim was to evaluate (1) the rate of dysphasia, and (2) the clinical effectiveness of other aspects of Zero-Profile spacer versus traditional cage and plate in ACD.

METHODS

Inclusion criteria

Studies were included based on the following criteria: (1) Randomised Controlled Trials (RCTs); (2) studies that compared the efficacy of Zero-Profile spacer versus traditional cage and plate in ACDF; (3) studies published in Chinese or English; (4) studies in which CSM was diagnosed by symptoms, signs and imaging.

Exclusion criteria

The following studies were excluded: (1) non-RCT; (2) duplicate studies; (3) animal or human specimen experiments; (4) literature reviews; (5) case reports or expert opinions; (6) studies without complete data.

Data sources

An electronic search was conducted in the following databases from their inception through 31 July 2019: PubMed, the Cochrane Library, Embase, Web of Science, Science Direct, Chinese Science and Technology Periodical Database, the China National Knowledge Infrastructure, and Wanfang database. The language of these studies was restricted to Chinese and English. Searches were carried out using medical subject headings (MeSH) and key words. Boolean search expressions were performed as follows: (zero-p OR zero-profile OR anchored fusion OR low profile) AND (cage and plate) AND ((anterior cervical discectomy and fusion OR anterior cervical fusion) OR ACDF) AND (randomized). Two investigators performed the search independently to ensure the consistency.

Data extraction

The abstracts and titles of the included articles were scanned independently by two investigators, and irrelevant articles were excluded. Discrepancies were reevaluated by a third investigator. Data, including author, study type, demographic characteristics, random sequence generation, blinding, allocation concealment, intervention measurements, treatment course, outcome measurements, were recorded. Missing data in the included trials were sought from the original investigators by phone or email.

Assessment of risk of bias

Based on the Cochrane Handbook of Systematic Reviews

of Interventions, the methodological quality of the included trials, including randomization sequence generation, allocation concealment, blinding, incomplete outcome data, selective reporting and other biases, was evaluated by two investigators independently using the Cochrane risk of bias assessment tool. The risk of bias in each domain was rated as 'low,' 'high' or 'unclear'.

In addition, the quality of evidence was classified as high, moderate, low or very low based on the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system.

Statistical analysis

A meta-analysis was performed using Review Manager Version 5.3 (The Nordic Cochrane Centre, Copenhagen, Denmark). Dichotomous data were summarised as Risk Ratio (RR) and continuous data as Standard Mean Difference (SMD). I_2 is employed to assess heterogeneity among trials, I_2 ≥50% indicates a substantial level of heterogeneity. A fixed-effects model was used when there was no significant heterogeneity among trials, otherwise a random-effects model was employed. 95% Confidence Intervals (CI) were calculated, and $p < 0.05$ was regarded as significance.

RESULTS

Study selection

128 potential studies were identified in our initial search, out of which 39 studies were removed because of duplicates, 28 were excluded after reading titles and abstracts, and full texts of 61 studies were assessed. During further evaluation, 29 studies were excluded because they failed to meet the inclusion criteria, sixteen because of not RCTs and ten because they were review articles, and the remaining six studies were included [1-3, 8-10], in which Li's study focused on both cervical spondylotic myelopathy and cervical spondylotic radiculopathy separately, so the study was regarded as two trials. Finally, seven studies were included in the study. The search process is shown in the flowchart (figure 1).

Study characteristics

In the seven trials, three were published in Chinese and four in English, six trials were conducted in China, and one in France. The trials involved 427 participants, and the sample sizes ranged from 23 to 98. All the trials were two-arm parallel group design. In terms of the surgical level, one trial was single-level CSM, two trials were multi-level CSM, and three trials didn't mention the level.

Risk of bias assessment

The risk of bias assessment, based on the Cochrane criteria, is summarized in figure 2. The patients in the seven included trials were all randomly assigned to Zero-Profile spacer group or traditional cage and plate group; six trials used random number table [1, 2, 8-10] to fulfil the random sequence generation, 1 trial didn't mention the method of randomization (3). One trial reported allocation concealment (1), two trials mentioned the method of blinding (2), no trials reported dropouts or withdrawals, all trials reported complete outcome, complications and follow-up.

Sensitivity analysis

A random-effects model was used and a sensitivity analysis was conducted using the leave-one-out approach when there was high heterogeneity between studies. Results of meta-analysis

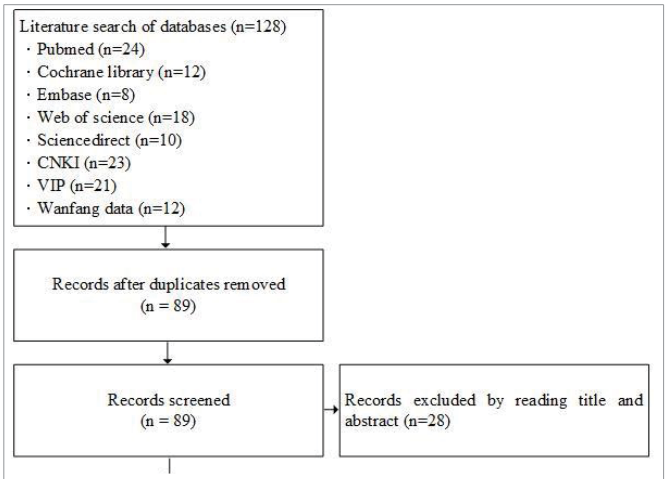

Figure 1: Flowchart of study selection.

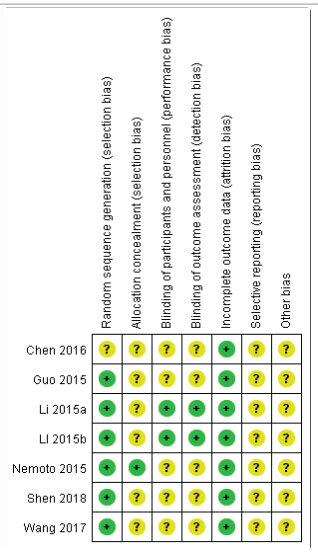

Figure 2: Risk of bias summary.

Results of meta-analysis

Operation Time

A total of 6 studies reported the operation time, which showed no significant difference between the two groups (MD = -7.2, 95% CI: -21.19, 6.80, heterogeneity: $X^2 = 387.84$, $I^2 = 99\%$, $p = 0.31$) (Figure 3).

Blood loss

Six studies reported blood loss as outcome measurement, which showed no significant difference between the two groups (MD = -8.72, 95% CI: -18.82, 1.39, heterogeneity: $X^2 = 213.61$, $I^2 = 98\%$, $p = 0.09$) (Figure 4).

JOA score

Four studies reported JOA score as outcome measurement, demonstrating no significant difference between the two groups (MD = 0.63, 95% CI: -0.67, 1.93, heterogeneity: $X^2 = 38.71$, $I^2 = 92\%$, $p = 0.34$) (Figure 5).

Dysphagia incidence

Six studies reported dysphagia incidence, indicating no significant difference between the two groups (OR = 0.37, 95% CI: -0.13, 1.03,

Table 1: The quality of the evidence of the outcomes.

Outcomes	Illustrative comparative risks* (95% CI)		Relative effect (95% CI)	No of Participants (studies)	Quality of the evidence (GRADE)
	Assumed risk	Corresponding risk			
	With comparator	With intervention			
Operation time		The mean operation time was 7.2 lower (21.19 lower to 6.8 higher)		355 (6 studies)	⊕⊕⊖⊖ low
Blood loss		The mean blood loss was 8.72 lower (18.82 lower to 1.39 higher)		355 (6 studies)	⊕⊕⊖⊖ low
JOA scores		The mean JOA was 0.63 higher (0.67 lower to 1.93 higher)		335 (4 studies)	
Dysphagia incidence	Study population		OR 0.37 (0.13 to 1.03)	429 (6 studies)	⊕⊕⊖⊖ low
	219 per 1000	94 per 1000 (35 to 224)			
	Moderate				
	220 per 1000	94 per 1000 (35 to 225)			
Adjacent segment degeneration	Study population		OR 0.06 (0.02 to 0.18)	156 (3 studies)	⊕⊕⊖⊖ low
	434 per 1000	44 per 1000 (15 to 121)			
	Moderate				
	452 per 1000	47 per 1000 (16 to 129)			
NDI scores		The mean NDI was 6.65 lower (20.18 lower to 6.89 higher)		170 (2 studies)	⊕⊕⊖⊖ low
Cobb angle		The mean cobb angle was 0.85 lower (2.5 lower to 0.8 higher)		144 (2 studies)	⊕⊕⊖⊖ low

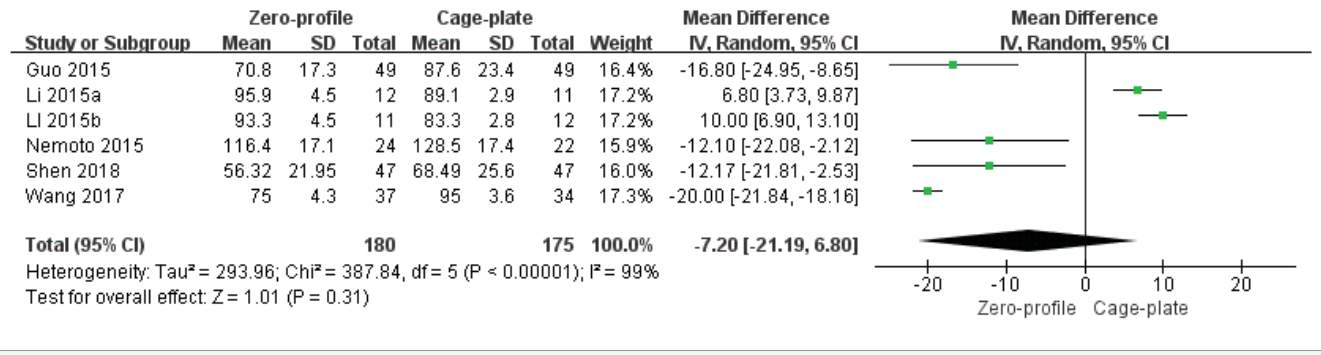

Figure 3: Forest plot for operative time.

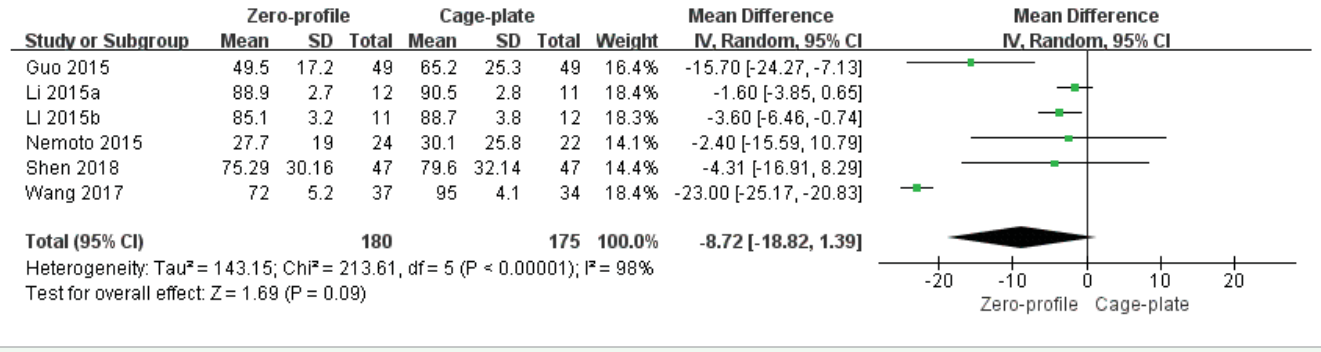

Figure 4: Forest plot for blood loss.

heterogeneity: $X^2 = 10.36$, $I^2 = 52\%$, $p = 0.06$) (Figure 6).

NDI scores

Two studies used NDI score as outcome measurement, demonstrating no significant difference between the two groups (MD = -6.65, 95% CI: -20.18, 6.89, heterogeneity: $X^2 = 39.72$, $I^2 = 97\%$, $p = 0.34$) (Figure 7).

Cobb angle

Two studies used Cobb angle as outcome measurement, which showed no significant difference between the two groups (MD = -0.85, 95% CI: -2.50, 0.80, heterogeneity: $X^2 = 1.42$, $I^2 = 29\%$, $p = 0.31$) (Figure 8).

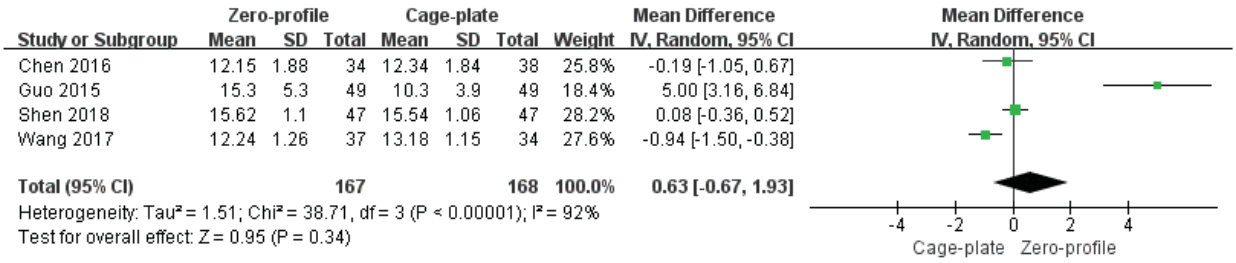

Figure 5: Forest plot for JOA score.

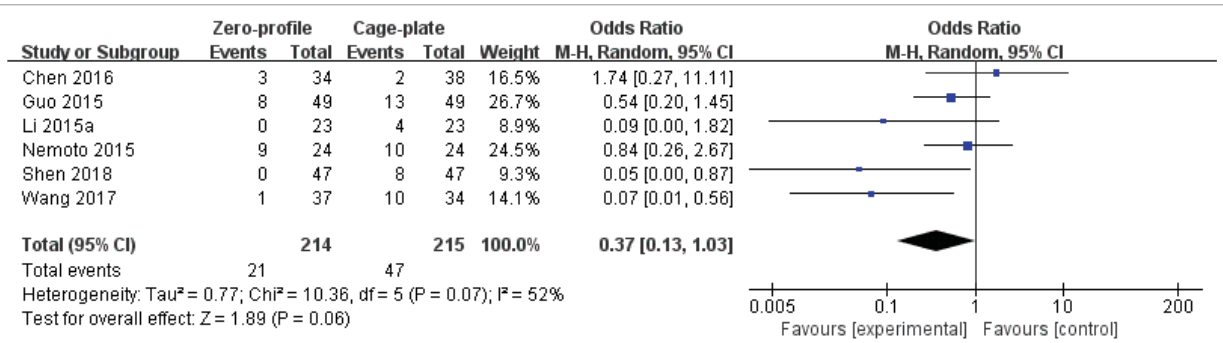

Figure 6: Forest plot for dysphagia incidence.

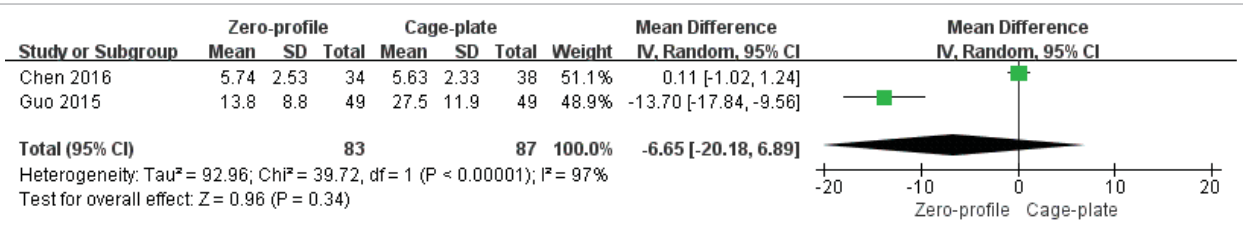

Figure 7: Forest plot for NDI scores.

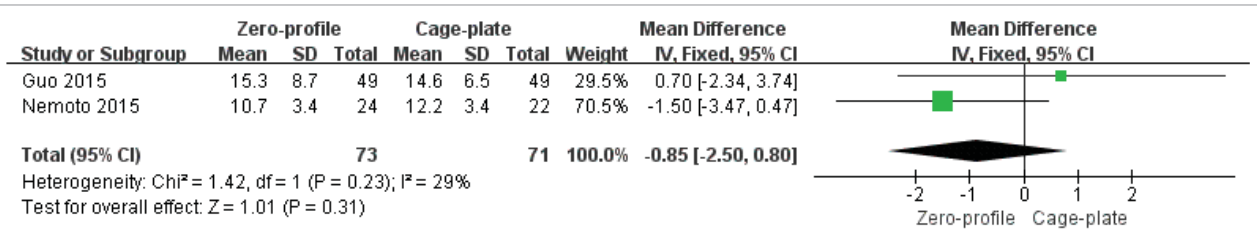

Figure 8: Forest plot for Cobb angle.

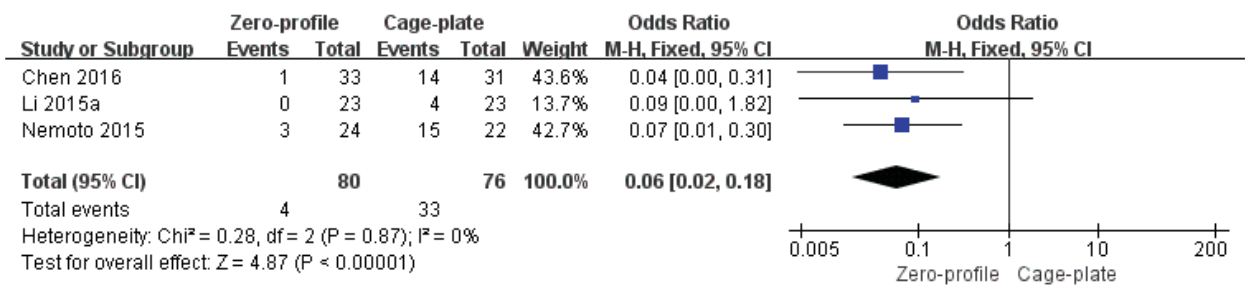

Figure 9: Forest plot for incidence of adjacent segment degeneration.

Incidence of adjacent segment degeneration

Three studies used incidence of adjacent segment degeneration as outcome measurement, which showed Zero-Profile spacer was superior to traditional cage and plate in decreasing the incidence of adjacent segment degeneration (OR = -0.06, 95% CI: 0.02, 0.18, heterogeneity: $X^2 = 0.28$, $I^2 = 0$, $p < 0.00001$) (Figure 9).

Quality of evidence

The quality of evidence for outcome measures shows in table 1.

DISCUSSION

In the current study, seven trials were included and merged, and this meta-analysis showed that there were no significant differences in operative time, blood loss, JOA score, dysphagia incidence, NDI scores, and cervical Cobb angle between Zero-Profile spacer and traditional cage and plate group in ACDF. However, Zero-Profile spacer group was superior to traditional cage and plate group in decreasing the incidence of adjacent segment degeneration.

Compared with Sun or Yang's meta-analysis, some viewpoints of the current study are identical, but some are different, especially in terms of the incidence of dysphagia, the two published meta-analysis suggested Zero-Profile spacer presented with a significantly lower incidence of dysphagia than traditional cage and plate [4,5]. Liu's meta-analysis also concluded a similar conclusion [7]. However, in the current study, we found there was no significant difference in this outcome between the two groups. Many factors such as soft tissue edema, esophageal injury, hematoma, plate thickness, and adhesions after anterior cervical surgeries as well as individual variation in toleration of surgery and dietetic habits may be correlated to the occurrence of dysphagia [2], but the primary cause is still unknown. The current result demonstrate that the profile of the anterior plate may not be the most important cause for the occurrence of dysphagia.

In addition, our meta-analysis demonstrated an identical viewpoint in terms of the incidence of adjacent segment degeneration, as the published meta-analyses. After ACDF, the change of biomechanical environment and malposition of the plate play important roles in the generation of adjacent segment degeneration [11]. Insertion of Zero-Profile spacer requires less resection of prevertebral fascia, which ensures a better preservation of the adjacent cervical disc and decreases the incidence of adjacent segment degeneration [2]. Moreover, in a biomechanical study, compared with traditional cage and plate, Zero-Profile spacer showed a decreased stiffness [12], so it leads to a lower incidence of adjacent segment degeneration. Our study further confirm the abovementioned viewpoints

Our study has some limitations. First, most of the trials lacked information of allocation concealment, blinding of participants and investigators, blinding of outcome assessment, and withdrawals/dropouts, and the evidence levels were relatively low. Second, high heterogeneity was found in most of outcome measurements, and sensitivity analysis was performed, significant heterogeneity was still available when articles were removed one at a time. The heterogeneity, resulted from many factors of experimental design rather than the methodology of a single RCT, might have affected the final results. Third, most of the trials were performed in China, so potential publication bias might exist.

In brief, this meta-analysis demonstrated that Zero-Profile spacer showed a favorable effect in the incidence of adjacent segment degeneration, but didn't in operative time, blood loss, JOA score, dysphagia incidence, NDI scores, and cervical Cobb angle when compared with traditional cage and plate group in ACDF. However, as the quality of the included trials was relatively low, further rigorously designed, large-scale RCTs are needed to confirm the current conclusion.

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