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Zero-Profile Anchored Spacer Versus Conventional Cage-and-Plate in ACDF: A Meta-Analysis of Clinical, Radiological, and Adjacent-Segment Outcomes

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Abstract. This systematic review and meta-analysis aimed to compare the clinical, radiological, and adjacent-segment outcomes of anterior cervical discectomy and fusion (ACDF) using zero-profile anchored spacers versus conventional cage-and-plate constructs. PubMed, Embase, the Cochrane Library, CNKI, Wanfang, and the Chinese Biomedical Literature Database were searched for relevant studies published between January 2012 and June 2019. Two reviewers independently performed study selection, data extraction, and risk-of-bias assessment, with evidence certainty evaluated using GRADE. Meta-analyses were conducted using Review Manager 5.4. Ten studies involving 690 patients at final follow-up were included, comprising one randomized controlled trial, one prospective study, and eight retrospective studies. Compared with conventional cage-and-plate constructs, zero-profile devices were associated with a lower overall incidence of adjacent segment degeneration (OR = 0.49, 95% CI: 0.30–0.82; P = 0.006), although most subgroup analyses showed no significant differences. Zero-profile devices also demonstrated lower rates of early postoperative dysphagia (OR = 0.44, 95% CI: 0.28–0.67; P = 0.0002), dysphagia at 3 months (OR = 0.14, 95% CI: 0.06–0.38; P < 0.00001), and late postoperative dysphagia (OR = 0.12, 95% CI: 0.03 – 0.45; P = 0.002). Additionally, zero-profile devices were associated with reduced intraoperative blood loss (MD = −12.64 mL, 95% CI: −24.14 to −1.13; P = 0.03) and shorter operative time (MD = −11.11 min, 95% CI: −17.44 to −4.78; P < 0.00001). No significant differences were observed in Japanese Orthopaedic Association scores (P = 0.83), Neck Disability Index scores (P = 0.40), or postoperative Cobb angle (P = 0.09). Both techniques achieved comparable functional outcomes and postoperative cervical alignment, while zero-profile devices may offer advantages in reducing dysphagia, adjacent segment degeneration, and perioperative morbidity. However, these findings should be interpreted cautiously because of the predominance of retrospective studies and heterogeneity in implant designs. Further high-quality randomized trials with long-term follow-up are warranted.

Keywords: Anterior cervical discectomy and fusion; Zero-profile anchored spacer; Cage-and-plate construct; Adjacent segment degeneration; Dysphagia; Meta-analysis

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1. Introduction

Anterior cervical discectomy and fusion (ACDF), first described by Smith and Robinson [1] and Cloward [2] in the 1950s, remains the standard surgical treatment for cervical radiculopathy and cervical spondylotic myelopathy. Adequate decompression combined with stable interbody fusion is essential for neurological recovery and for maintenance of cervical alignment.

Stand-alone interbody cages were initially used to restore disc height and promote fusion. However, especially in multi-level disease, stand-alone cages provide limited primary stability and have been associated with graft subsidence, displacement, and pseudoarthrosis [3]. To address these shortcomings, anterior cervical plating combined with an interbody cage was introduced. The cage-and-plate construct improves immediate stability, increases fusion rates, and restores cervical lordosis. Nevertheless, the anterior plate requires extensive soft-tissue dissection and lies close to the prevertebral structures, and has been associated with plate-related complications, including dysphagia, soft-tissue irritation, screw loosening, and stress shielding of the adjacent segments, which may contribute to adjacent segment degeneration (ASD).

To reduce plate-related morbidity, zero-profile anchored spacers were developed and have been increasingly used since 2008. These devices integrate the interbody spacer and the fixation elements into a single low-profile implant, thereby avoiding a stand-alone anterior plate. It should be emphasised, however, that "zero-profile" is a category rather than a single product, and that the devices differ substantially in design: the Zero-P spacer (Synthes) uses an integrated plate with angle-stable screws [4-8]; the ROI-C device (LDR) achieves fixation through vertical titanium wings anchored into the adjacent endplates [9,10]; and the Fidji cervical cage represents a further self-locking, zero-profile design [11]. Because their biomechanical behaviour and clinical profiles are not equivalent, evidence derived from one device cannot be directly generalised to another, and these devices should be analysed and discussed separately.

Comparative evidence between zero-profile devices and conventional cage-and-plate constructs remains conflicting. Several studies and previous meta-analyses have reported shorter operative time, less intraoperative blood loss, and a lower incidence of early and late dysphagia with zero-profile devices, presumably because the absence of an anterior plate reduces retraction and irritation of the oesophagus and prevertebral soft tissues [8]. The effect on radiographic outcomes is less consistent. Data on ASD are particularly heterogeneous, since the included cohorts differ in the number of fused levels, follow-up duration, definition of ASD (radiographic degeneration versus symptomatic adjacent segment disease requiring

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reoperation), and, importantly, in the specific zero-profile device used.

The present systematic review and meta-analysis was therefore conducted to compare zero-profile anchored spacers with conventional cage-and-plate constructs in ACDF with respect to (i) the incidence of adjacent segment degeneration and of symptomatic adjacent segment disease, (ii) perioperative parameters including operative time and intraoperative blood loss, (iii) clinical outcomes assessed by the JOA and NDI scores, (iv) the Cobb angle, and (v) the incidence of early, 3-month, and late postoperative dysphagia. We further performed subgroup analyses according to the number of degenerated adjacent segments. A subgroup analysis according to the specific zero-profile device was not feasible, because most devices contributed to fewer than three studies each; the evidence for each device type is therefore synthesised narratively in the Discussion.

2. Methods

2.1. Study design and reporting

This systematic review and meta-analysis was conducted in accordance with the Cochrane Handbook for Systematic Reviews of Interventions [12] and is reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement [13]. The protocol defining the eligibility criteria, search strategy, outcome definitions, risk-of-bias assessment, and analysis plan was finalised before data extraction and is available from the corresponding author on request; the review was not prospectively registered in PROSPERO. As only previously published aggregate data were analysed, no ethical approval or informed consent was required.

2.2. Eligibility criteria

Studies were selected according to the PICOS framework.

Population. Adults (≥18 years) with cervical radiculopathy or cervical spondylotic myelopathy who underwent ACDF, including single-level, two-level, and non-contiguous (jumping) level procedures.

Intervention. ACDF performed with a zero-profile anchored spacer (ZPAS), defined as a self-locking interbody device that provides anterior fixation without a separate anterior cervical plate. This category comprises the Zero-P spacer (Synthes), the ROI-C device (LDR), the Fidji cervical cage, and other self-locking stand-alone cages.

Comparator. ACDF performed with an interbody cage combined with a conventional anterior

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cervical plate (cage-plate construct).

Outcomes. The primary outcomes were the incidence of adjacent segment degeneration (ASDeg) and of symptomatic adjacent segment disease (ASDis), as defined by Hilibrand et al. [14]; reoperation for adjacent segment disease was analysed as an indirect outcome. ASDeg was defined as new radiographic degeneration at a level adjacent to the fused segment, including disc height loss, anterior or posterior osteophyte formation, or endplate sclerosis. ASDis was defined as new or recurrent clinical symptoms attributable to adjacent segment pathology, with or without reoperation. Secondary outcomes were operative time, intraoperative blood loss, Japanese Orthopaedic Association (JOA) score, Neck Disability Index (NDI), Cobb angle, and dysphagia assessed in the early postoperative period (as defined by each study, generally within 1 month), at 3 months, and in the late period (>6 months).

Study design. Randomised controlled trials, prospective comparative studies, and retrospective comparative studies reporting at least one outcome of interest in both groups.

Studies were included if they (1) directly compared a ZPAS with a cage-plate construct in ACDF; (2) enrolled patients undergoing single-level, two-level, or jumping-level surgery; (3) reported the incidence of ASDeg, ASDis, or reoperation for adjacent segment disease, or provided data from which these could be calculated; (4) had a minimum follow-up of 1 year; (5) included at least 30 patients per treatment arm; and (6) were published as full-text articles.

Studies were excluded if they (1) were narrative reviews, systematic reviews, meta-analyses, case reports, cadaveric or biomechanical studies, or conference abstracts without extractable data; (2) had a follow-up shorter than 1 year; (3) included patients with cervical tumour, infection, trauma, inflammatory arthropathy, or revision surgery, or in whom these conditions could not be separated from the study population; (4) reported overlapping or duplicate cohorts; or (5) provided insufficient data for pooling despite contact with the corresponding authors.

2.3. Search strategy

PubMed, EMBASE, the Cochrane Library, CNKI, Wanfang Data, and the China Biomedical Literature Database (CBM) were searched from January 2012 to June 2019. The start date was chosen because ZPAS devices entered clinical practice in 2008 and comparative studies matured thereafter; the end date corresponds to the completion of the literature search, and the search was not subsequently updated. No language restriction was applied; all eligible studies ultimately identified were published in English. The search strategy combined free-text terms and controlled vocabulary, including "anterior cervical discectomy and fusion", "ACDF",

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"adjacent segment degeneration", "adjacent segment disease", "zero-profile", "Zero-P", "ROI-C", "Fidji", "anchored spacer", "stand-alone cage", "self-locking cage", "cage and plate", "anterior cervical plate", "dysphagia", and "Japanese Orthopaedic Association score". The full search strings used for each database are available from the corresponding author on request. In addition, the reference lists of all included studies and of relevant reviews were hand-searched, and ClinicalTrials.gov and the WHO International Clinical Trials Registry Platform were screened for ongoing or unpublished trials.

2.4. Study selection

Retrieved records were imported into EndNote X9 (Clarivate Analytics, Philadelphia, PA, USA) and duplicates were removed. Two reviewers independently screened titles and abstracts, and subsequently assessed the full text of potentially eligible articles against the predefined criteria. Disagreements were resolved by discussion and, where necessary, by arbitration by a third reviewer. The selection process is summarised in a PRISMA 2020 flow diagram (Figure 1).

2.5. Data extraction

Two reviewers independently extracted data using a standardised, pre-piloted electronic form. The form was tested on three randomly selected eligible articles before formal extraction and revised accordingly. Disagreements were resolved by discussion and, if unresolved, by a third reviewer. When required information was missing or reported only graphically, the corresponding author was contacted by e-mail; if no response was received within 4 weeks, the study was excluded from the specific analysis or, where possible, the missing standard deviation was imputed using Cochrane-recommended methods.

The following data were extracted: (1) study characteristics — first author, year, country, study design, recruitment period, and number of centres; (2) participant characteristics — sample size per arm, age, sex, diagnosis, number of operated levels, and mean follow-up; (3) intervention details — specific device used (Zero-P spacer, ROI-C device, Fidji cervical cage, or other self-locking stand-alone cage) and manufacturer; (4) comparator details — cage type and plate type; (5) outcomes — number of events and total patients for ASDeg, ASDis, reoperation for adjacent segment disease, and dysphagia at each time point, and mean and standard deviation for operative time (minutes), intraoperative blood loss (millilitres), JOA score, NDI, and Cobb angle; and (6) items relevant to the risk-of-bias assessment.

Outcome definitions were harmonised across studies before pooling. When a study reported

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both radiographic degeneration and symptomatic adjacent segment disease, both were extracted and entered separately into the corresponding analysis. For non-contiguous level surgery, only the segments actually operated on were counted as index levels.

2.6. Risk of bias assessment

Risk of bias was assessed independently by two reviewers, with disagreements resolved by a third reviewer.

The randomised controlled trial was assessed with the Cochrane Risk of Bias 2 (RoB 2) tool [15] across five domains: bias arising from the randomisation process; bias due to deviations from intended interventions; bias due to missing outcome data; bias in measurement of the outcome; and bias in selection of the reported result. Each domain and the overall judgement were rated as low risk, some concerns, or high risk.

The non-randomised comparative studies were assessed with the Risk Of Bias In Non-randomised Studies of Interventions (ROBINS-I) tool [16] across seven domains: confounding, selection of participants, classification of interventions, deviations from intended interventions, missing data, measurement of outcomes, and selection of the reported result. Each domain and the overall judgement were rated as low, moderate, serious, or critical risk of bias. Because all included non-randomised studies were comparative cohort or case-control studies of two surgical techniques, confounding by indication — number of operated levels, baseline severity of myelopathy, and surgeon preference — was considered the most relevant potential source of bias.

No study was excluded solely on the basis of risk of bias; instead, risk of bias informed the sensitivity analyses and the GRADE assessment.

2.7. Certainty of evidence

The certainty of evidence for each outcome was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach [17], following the GRADE Handbook and the Cochrane Handbook [12], and was managed with GRADEpro GDT software.

Evidence derived from randomised trials started as high certainty and evidence derived from non-randomised studies started as low certainty. Certainty was then downgraded according to five domains: (1) risk of bias, judged from the RoB 2 and ROBINS-I assessments; (2) inconsistency, judged from unexplained statistical heterogeneity ($I^2 \geq 50\%$) or inconsistent

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direction of effect across studies; (3) indirectness, judged from differences in population, device type, number of operated levels, or outcome definition across studies; (4) imprecision, judged from confidence intervals crossing the threshold of clinical importance or from an optimal information size that was not reached; and (5) publication bias, judged from funnel-plot asymmetry where at least ten studies contributed. Certainty was rated as high, moderate, low, or very low.

Because most outcomes were informed by fewer than ten studies and several by only two to five, formal summary-of-findings tables were not constructed. The certainty rating for each outcome is therefore reported in the corresponding paragraph of the Results section, together with the domain or domains responsible for any downgrading.

2.8. Statistical analysis

All analyses were performed with Review Manager 5.4 (The Nordic Cochrane Centre, Copenhagen, Denmark). Dichotomous outcomes were pooled as odds ratios (OR) with 95% confidence intervals (CI). Continuous outcomes were pooled as mean differences (MD), with operative time expressed in minutes and intraoperative blood loss in millilitres. Two-sided P values < 0.05 were considered statistically significant.

Statistical heterogeneity was assessed with the Cochran Q test, with $P < 0.10$ considered indicative of statistically significant heterogeneity, and was quantified with the I^2 statistic, where I^2 values of 25%, 50%, and 75% were interpreted as low, moderate, and high heterogeneity, respectively, together with the between-study variance τ^2. A fixed-effect model was applied when I^2 was $< 50\%$, and a random-effects model with the DerSimonian-Laird estimator when I^2 was $\geq 50\%$.

A prespecified subgroup analysis was performed according to the number of degenerated adjacent segments reported (one, two, three, or multiple), in order to examine whether the effect of the implant on adjacent segment degeneration depended on the extent of adjacent segment involvement. Because each subgroup contained only two to five studies, formal tests for subgroup differences were underpowered and are not reported; subgroup estimates are presented for descriptive purposes only. A subgroup analysis according to the specific ZPAS device was not feasible, because most devices contributed to fewer than three studies each; the evidence for each device type was therefore synthesised narratively in the Discussion.

Sensitivity analyses were performed by sequentially omitting one study at a time to examine the influence of each individual study on the pooled estimate, and by comparing fixed-effect

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and random-effects estimates for each outcome.

Funnel plots were constructed only for outcomes to which at least ten studies contributed. Because fewer than ten studies contributed to most analyses, and because the subgroup analyses included only two to five studies each, funnel-plot asymmetry could not be reliably distinguished from genuine heterogeneity, small-study effects, or chance; funnel plots were therefore interpreted descriptively and were not used to draw definitive conclusions about publication bias.

Deviations from the protocol were limited to the two analyses described above: the device-specific subgroup analysis was not performed, and tests for subgroup differences were not reported, both because of an insufficient number of contributing studies.

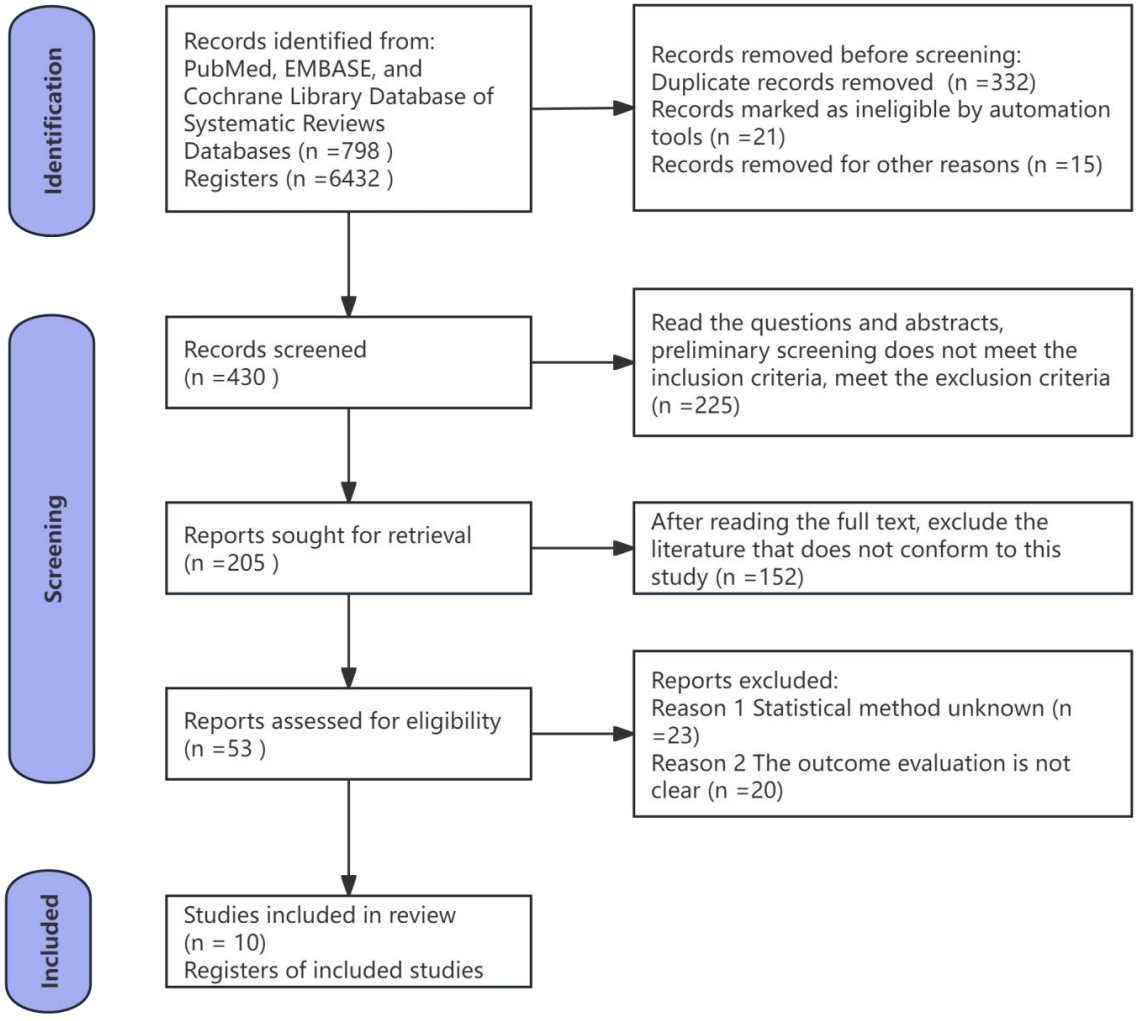


Figure 1. PRISMA 2020 flow diagram of study selection.

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3. Results

3.1. Study selection

The literature search was completed in June 2019 and identified the records summarised in Figure 1. After removal of duplicates and of records excluded by automation tools, titles and abstracts were screened, and the full texts of potentially eligible reports were assessed against the eligibility criteria. Ten studies [4-11,18,19] were included in the meta-analysis. The number of records remaining at each stage and the reasons for exclusion are given in Figure 1.

3.2. Characteristics and risk of bias of included studies

A total of 10 studies (1 randomised controlled trial [7], 1 prospective controlled study, and 8 retrospective studies) were included, enrolling 707 patients. Of these, 690 patients (97.6%) completed the final follow-up; 349 patients were in the zero-profile group and 358 in the cage-plate group. The baseline characteristics of the included studies are summarised in Table 1. The single randomised trial [7] was assessed with RoB 2, and the nine non-randomised studies with ROBINS-I; the latter were predominantly at moderate to serious risk of bias, chiefly because of confounding by indication, that is, systematic differences between groups in the number of operated levels, the baseline severity of myelopathy, and surgeon preference for one technique. No study was excluded on the basis of its risk-of-bias assessment.

Extracted outcomes comprised binary variables (adjacent segment degeneration overall and at one, two, three, and multiple segments; symptomatic adjacent segment disease; postoperative new-onset adjacent segment disease; and early, 3-month, and late postoperative dysphagia) and continuous variables (intraoperative blood loss, operative time, JOA score, NDI score, and Cobb angle).

3.3. Adjacent segment degeneration

3.3.1. Overall adjacent segment degeneration

Ten studies [4-11,18,19] compared the incidence of adjacent segment degeneration (Figure 2A). There was no heterogeneity ($P = 0.72$, $I^2 = 0\%$), and a fixed-effect model was used. The incidence was significantly lower in the zero-profile group (OR 0.49, 95% CI 0.30–0.82; $Z = 2.75$, $P = 0.006$). The certainty of evidence was low, downgraded for risk of bias.

3.3.2. Degeneration at one adjacent segment

Two studies [5,7] compared the incidence of degeneration at one adjacent segment (Figure 2B). There was low heterogeneity ($P = 0.24$, $I^2 = 29\%$), and a fixed-effect model was used. No

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significant difference was found (OR 0.44, 95% CI 0.17–1.12; Z = 1.72, P = 0.09). The certainty of evidence was very low, downgraded for risk of bias and imprecision.

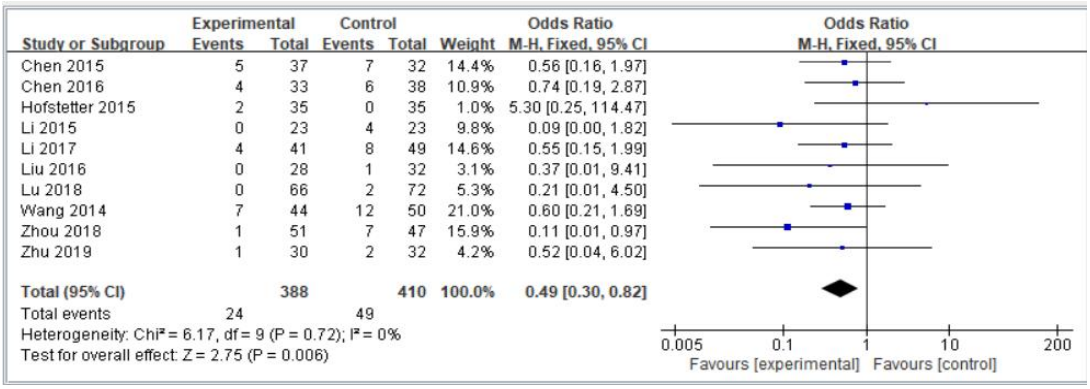


Figure 2A. Forest plot of the overall incidence of adjacent segment degeneration, zero-profile versus cage-and-plate (fixed-effect model).

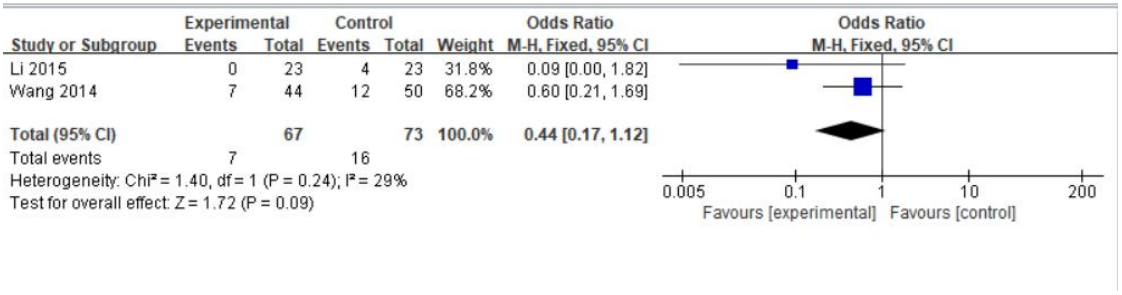


Figure 2B. Forest plot of the incidence of degeneration at one adjacent segment, zero-profile versus cage-and-plate (fixed-effect model).

3.3.3. Degeneration at two adjacent segments

Two studies [4,10] compared the incidence of degeneration at two adjacent segments (Figure 2C). There was no heterogeneity (P = 0.56, I^2 = 0%), and a fixed-effect model was used. No significant difference was found (OR 0.47, 95% CI 0.15–1.46; Z = 1.31, P = 0.19). The certainty of evidence was very low, downgraded for risk of bias and imprecision.

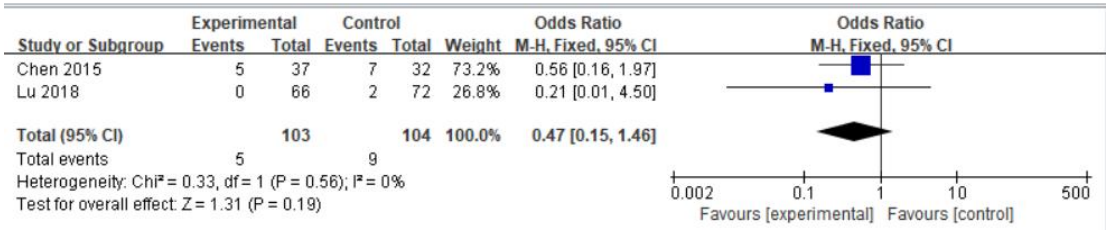


Figure 2C. Forest plot of the incidence of degeneration at two adjacent segments, zero-profile versus cage-and-plate (fixed-effect model).

3.3.4. Degeneration at three adjacent segments

Two studies [6,18] compared the incidence of degeneration at three adjacent segments

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(Figure 2D). There was no heterogeneity (P = 0.81, I^2 = 0%), and a fixed-effect model was used. No significant difference was found (OR 0.68, 95% CI 0.21–2.21; Z = 0.65, P = 0.52). The certainty of evidence was very low, downgraded for risk of bias and imprecision.

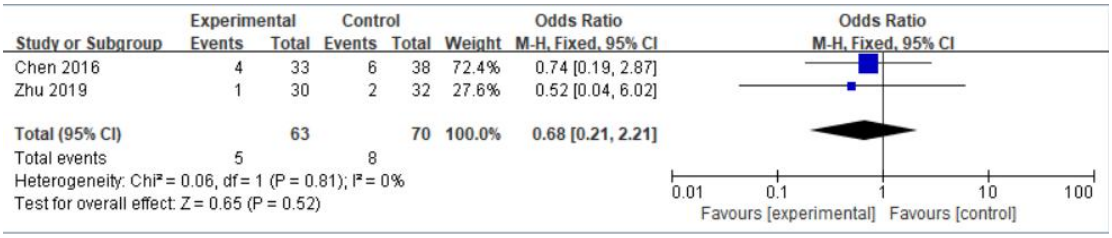


Figure 2D. Forest plot of the incidence of degeneration at three adjacent segments, zero-profile versus cage-and-plate (fixed-effect model).

3.3.5. Degeneration at multiple adjacent segments

Five studies [4,6,9,10,18] compared the incidence of degeneration at multiple adjacent segments (Figure 2E). There was no heterogeneity (P = 0.96, I^2 = 0%), and a fixed-effect model was used. No significant difference was found (OR 0.54, 95% CI 0.24–1.20; Z = 1.51, P = 0.13). The certainty of evidence was very low, downgraded for risk of bias and imprecision.

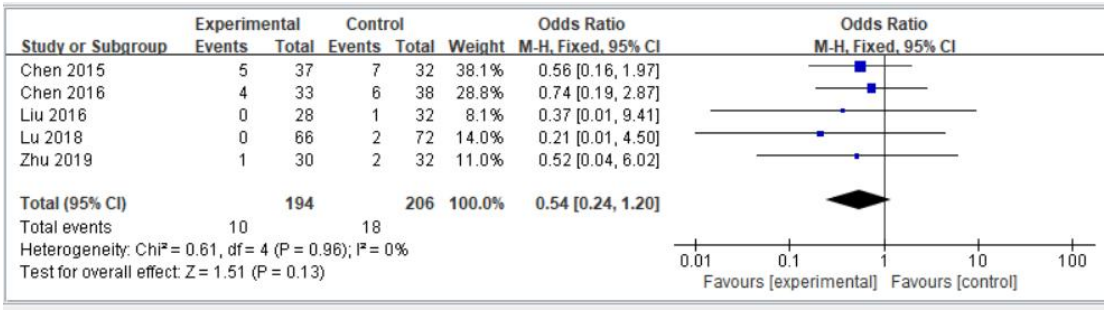


Figure 2E. Forest plot of the incidence of degeneration at multiple adjacent segments, zero-profile versus cage-and-plate (fixed-effect model).

3.3.6. Symptomatic adjacent segment disease

Four studies [4-7] compared the incidence of symptomatic adjacent segment disease, defined as new or recurrent symptoms attributable to adjacent segment pathology, with or without reoperation (Figure 3A). There was no heterogeneity (P = 0.66, I^2 = 0%), and a fixed-effect model was used. No significant difference was found (OR 0.54, 95% CI 0.27–1.02; Z = 1.91, P = 0.06). The certainty of evidence was low, downgraded for risk of bias and imprecision.

3.3.7. Postoperative new-onset adjacent segment disease

Six studies [4,7-9,18,19] compared the incidence of adjacent segment disease newly diagnosed after the index operation, irrespective of whether the index level had itself been operated on for adjacent segment pathology (Figure 3B). There was no heterogeneity (P = 0.38,

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I^2 = 5%), and a fixed-effect model was used. The incidence was significantly lower in the zero-profile group (OR 0.40, 95% CI 0.19–0.87; Z = 2.31, P = 0.02). The certainty of evidence was low, downgraded for risk of bias.

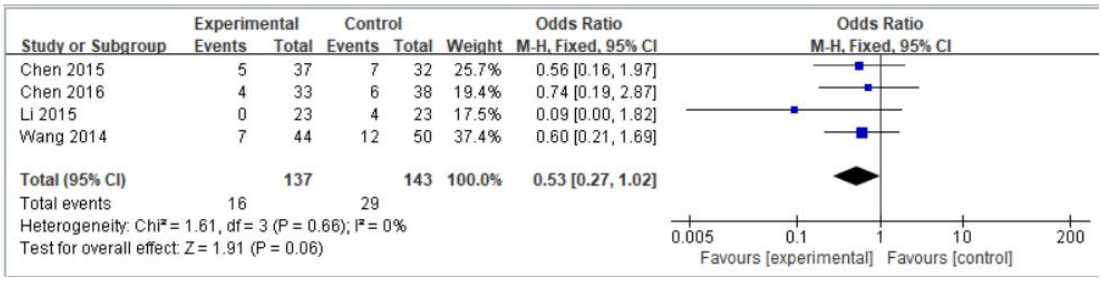


Figure 3A. Forest plot of the incidence of symptomatic adjacent segment disease, zero-profile versus cage-and-plate (fixed-effect model).

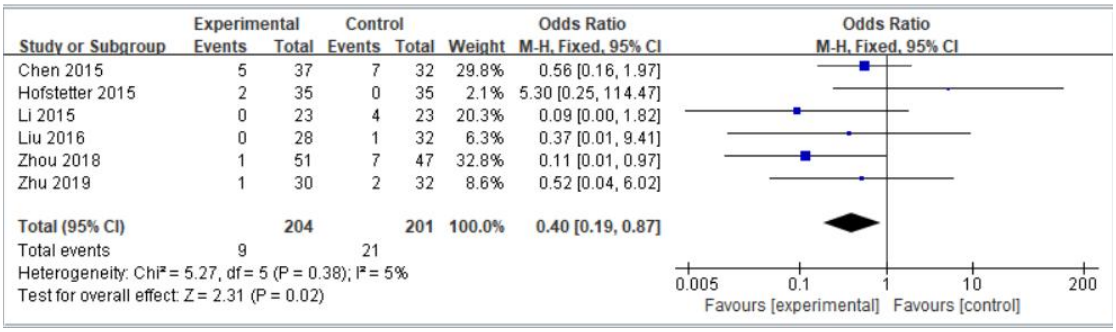


Figure 3B. Forest plot of the incidence of postoperative new-onset adjacent segment disease, zero-profile versus cage-and-plate (fixed-effect model).

3.4. Perioperative parameters

3.4.1. Intraoperative blood loss

Seven studies [4-6,8,10,11,18] compared intraoperative blood loss (Figure 4A). There was significant heterogeneity (P < 0.00001, I^2 = 96%), and a random-effects model was used. Blood loss was significantly lower in the zero-profile group (MD −12.64 mL, 95% CI −24.14 to −1.13; P = 0.03). Sequential omission of individual studies did not identify a single study responsible for the heterogeneity, and the direction of the pooled estimate was unchanged. The certainty of evidence was very low, downgraded for risk of bias and inconsistency.

3.4.2. Operative time

Seven studies [4-6,8,10,11,18] compared operative time (Figure 4B). There was significant heterogeneity (P < 0.001, I^2 = 92%), and a random-effects model was used. Operative time was significantly shorter in the zero-profile group (MD −11.11 min, 95% CI −17.44 to −4.78; Z = 3.44, P < 0.001). Sequential omission of individual studies did not identify a single study responsible for the heterogeneity, and the direction of the pooled estimate was unchanged. The

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certainty of evidence was very low, downgraded for risk of bias and inconsistency.

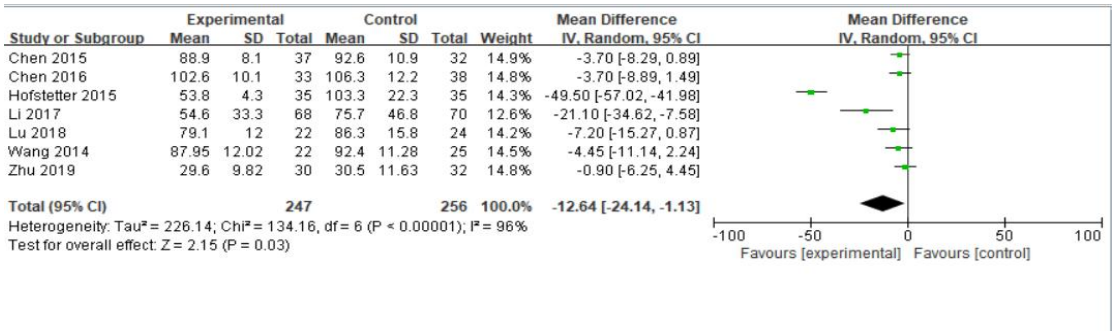


Figure 4A. Forest plot of intraoperative blood loss, zero-profile versus cage-and-plate (random-effects model).

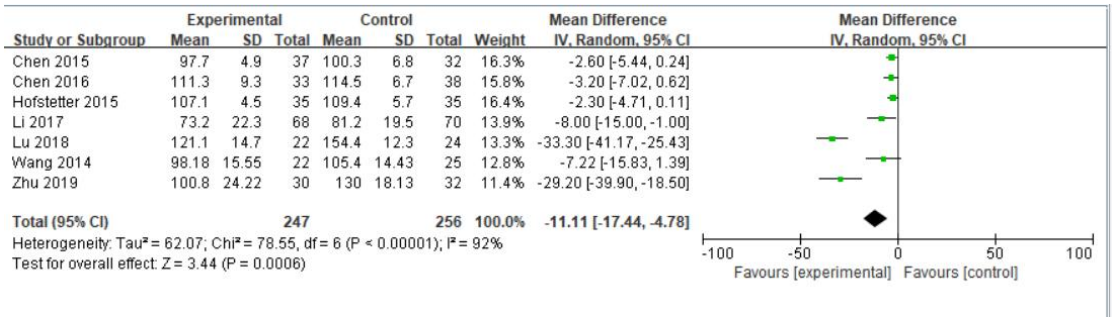


Figure 4B. Forest plot of operative time, zero-profile versus cage-and-plate (random-effects model).

3.5. Clinical scores

3.5.1. JOA scores

Eight studies [4-6,9-11,18,19] compared JOA scores (Figure 5A). There was no heterogeneity (P = 0.63, I^2 = 0%), and a fixed-effect model was used. No significant difference was found between the zero-profile and cage-plate groups (MD 0.02, 95% CI -0.14 to 0.17; Z = 0.21, P = 0.83). The certainty of evidence was low, downgraded for risk of bias.

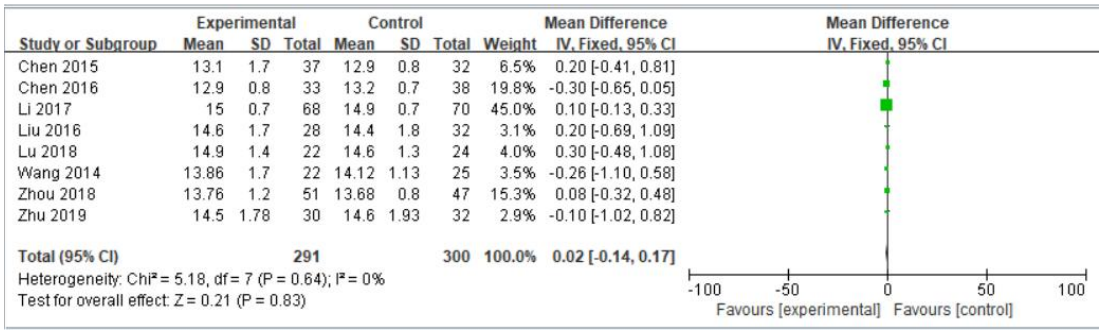


Figure 5A. Forest plot of JOA scores, zero-profile versus cage-and-plate (fixed-effect model).

3.5.2. NDI scores

Seven studies [4,6,9-11,18,19] compared NDI scores (Figure 5B). There was no

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heterogeneity (P = 0.91, I^2 = 0%), and a fixed-effect model was used. No significant difference was found (MD −0.12, 95% CI −0.39 to 0.16; Z = 0.84, P = 0.40). The certainty of evidence was low, downgraded for risk of bias.

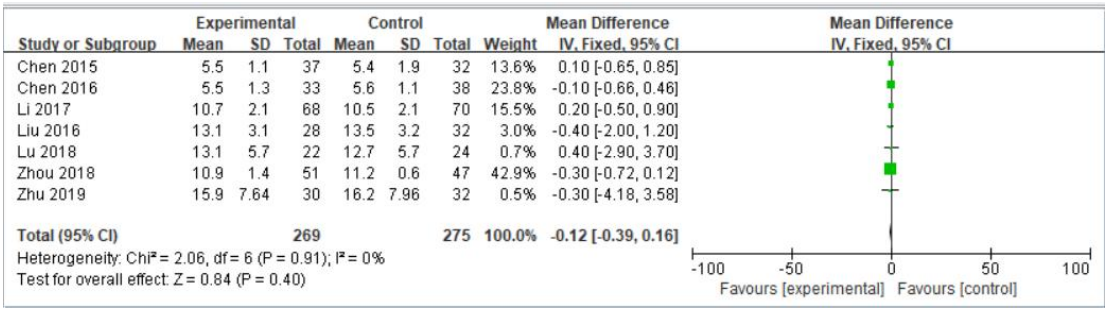


Figure 5B. Forest plot of NDI scores, zero-profile versus cage-and-plate (fixed-effect model).

3.6. Cobb angle

Seven studies [4,6,9-11,18,19] compared the postoperative Cobb angle (Figure 5C). There was significant heterogeneity (P < 0.00001, I^2 = 84%), and a random-effects model was used. No significant difference was found (MD −0.94, 95% CI −2.02 to 0.15; P = 0.09). The certainty of evidence was very low, downgraded for risk of bias and inconsistency.

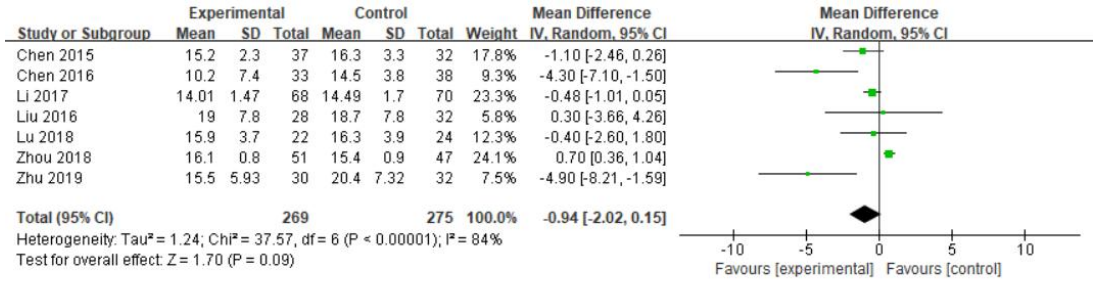


Figure 5C. Forest plot of the postoperative Cobb angle, zero-profile versus cage-and-plate (random-effects model).

3.7. Dysphagia

3.7.1. Early dysphagia

Eight studies [4-6,8,10,11,18,19] compared the incidence of early postoperative dysphagia, generally assessed within 1 month of surgery (Figure 6A). There was no heterogeneity (P = 0.51, I^2 = 0%), and a fixed-effect model was used. The incidence was significantly lower in the zero-profile group (OR 0.44, 95% CI 0.28–0.67; Z = 3.76, P = 0.0002). The certainty of evidence was low, downgraded for risk of bias.

3.7.2. Dysphagia at 3 months

Seven studies [5,8-11,18,19] compared the incidence of dysphagia at 3 months (Figure 6B).

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There was no heterogeneity (P = 0.97, I^2 = 0%), and a fixed-effect model was used. The incidence was significantly lower in the zero-profile group (OR 0.14, 95% CI 0.06–0.38; Z = 3.96, P < 0.00001). The certainty of evidence was low, downgraded for risk of bias.

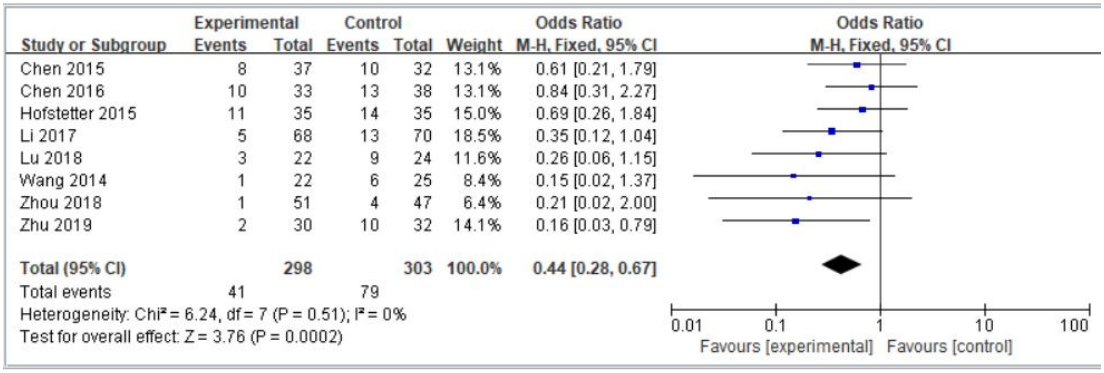


Figure 6A. Forest plot of the incidence of early postoperative dysphagia (within 1 month), zero-profile versus cage-and-plate (fixed-effect model).

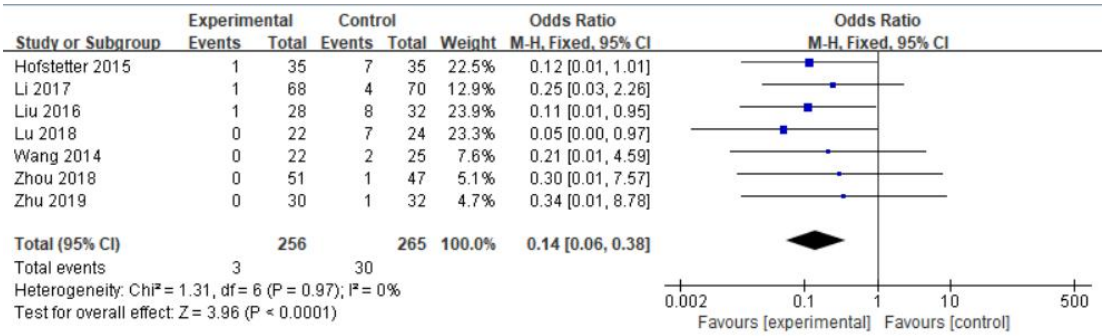


Figure 6B. Forest plot of the incidence of dysphagia at 3 months, zero-profile versus cage-and-plate (fixed-effect model).

3.7.3. Late dysphagia (>6 months)

Five studies [5,7,9,10,18] compared the incidence of dysphagia beyond 6 months (Figure 6C). There was no heterogeneity (P = 0.88, I^2 = 0%), and a fixed-effect model was used. The incidence was significantly lower in the zero-profile group (OR 0.12, 95% CI 0.03–0.45; Z = 3.13, P = 0.002). The certainty of evidence was low, downgraded for risk of bias.

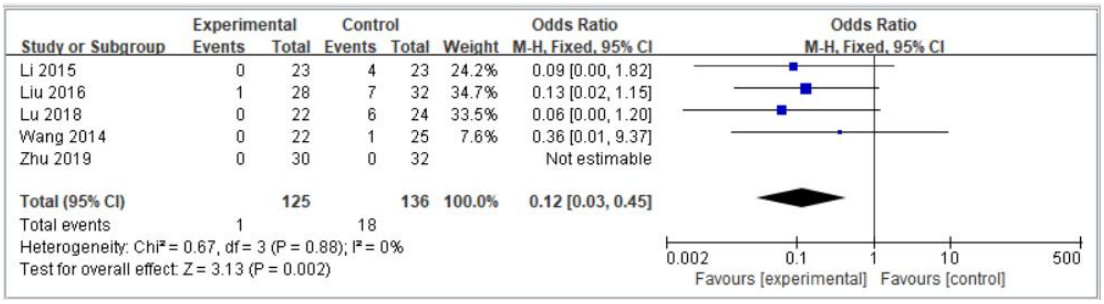


Figure 6C. Forest plot of the incidence of dysphagia beyond 6 months, zero-profile versus cage-and-plate (fixed-effect model).

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3.8. Publication bias

A funnel plot was constructed for the overall analysis of adjacent segment degeneration, the only outcome to which ten or more studies contributed (Figure 7). The plot showed asymmetry, but with ten studies this could not be reliably distinguished from genuine heterogeneity, small-study effects, or chance. The plot was therefore interpreted descriptively, and no definitive conclusion about publication bias was drawn.

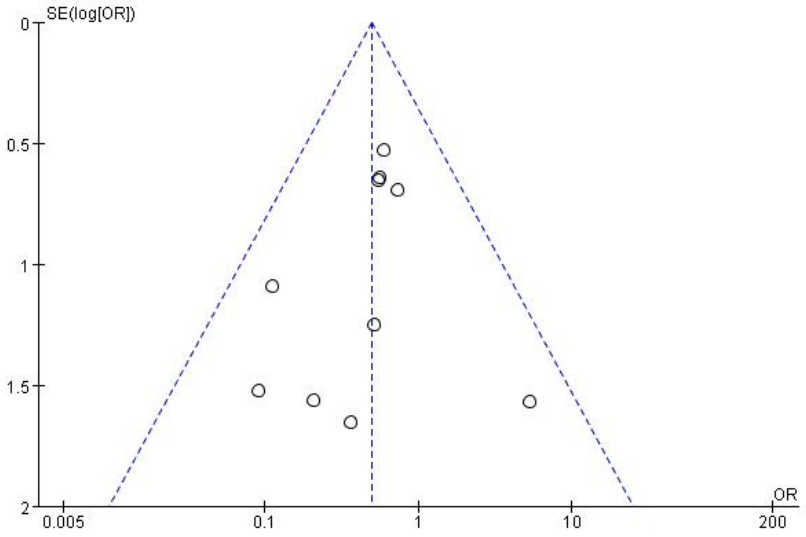


Figure 7. Funnel plot of the overall analysis of adjacent segment degeneration, zero-profile versus cage-and-plate.

4. Discussion

4.1. Principal findings

ACDF, first described by Smith and Robinson [1] and by Cloward [2] in the 1950s, remains the standard operation for degenerative cervical spondylosis. Decompression with bone grafting alone, particularly at multiple levels, provides insufficient stability and has been associated with graft displacement and low fusion rates [3]. The addition of an anterior cervical plate improved stability and fusion, but introduced a new set of plate-related problems, including dysphagia and the potential for accelerated degeneration at adjacent segments. The zero-profile anchored spacer (ZPAS) was introduced into clinical practice in 2008 in an attempt to preserve the stability of an anchored construct while avoiding the anterior profile of a plate; whether this design translates into a measurable clinical advantage over a conventional cage-plate construct has remained uncertain.

In this meta-analysis of ten comparative studies enrolling 707 patients, the zero-profile group showed a lower incidence of overall adjacent segment degeneration, a lower incidence of

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postoperative new-onset adjacent segment disease, shorter operative time, less intraoperative blood loss, and a lower incidence of dysphagia at all three time points. JOA score, NDI score, and Cobb angle did not differ significantly between groups. These findings should be interpreted in the context of the certainty of the evidence, which was low for the outcomes without substantial heterogeneity and very low for the three outcomes with unexplained heterogeneity.

4.2. Operative time and intraoperative blood loss

Operative time was shorter in the zero-profile group (MD −11.11 min, 95% CI −17.44 to −4.78; $P < 0.001$) and intraoperative blood loss was lower (MD −12.64 mL, 95% CI −24.14 to −1.13; $P = 0.03$), but both analyses showed substantial heterogeneity ($I^2 = 92\%$ and 96%, respectively), and the certainty of evidence was very low for both.

Part of this heterogeneity is likely to reflect differences in the surgical procedures themselves rather than in the patients. In the study by Lu et al. [10], mean operative time was 121.1 min in the zero-profile group and 154.4 min in the cage-plate group, a difference large enough to contribute disproportionately to the pooled estimate; in the study by Chen et al. [4], blood loss was 102.6 mL and 106.3 mL respectively, a difference small enough that its inclusion dilutes the pooled effect. Differences in the severity of preoperative myelopathy and radiculopathy, in the number of operated levels, and in surgeon experience with each technique are all plausible additional sources of between-study variation, and none of the included studies reported a learning-curve analysis. Sequential omission of individual studies did not identify a single study responsible for the heterogeneity, and the direction of the pooled estimate was unchanged for both outcomes; the heterogeneity therefore appears to be distributed across cohorts rather than attributable to any one study, and the small number of contributing studies precluded exploration by meta-regression.

The absolute differences are modest: approximately 11 min of operating time and 13 mL of blood loss. Whether differences of this magnitude are clinically meaningful is uncertain, and they are unlikely on their own to determine the choice of implant. The reduction in operative time may, however, be relevant in patients with limited physiological reserve, and a shorter procedure with less dissection is consistent with the design rationale of the anchored spacer.

4.3. Clinical efficacy

Postoperative JOA score (MD 0.02, 95% CI −0.14 to 0.17; $P = 0.83$), NDI score (MD −0.12, 95% CI −0.39 to 0.16; $P = 0.40$), and Cobb angle (MD −0.94, 95% CI −2.02 to 0.15; $P = 0.09$)

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did not differ significantly between groups, with no heterogeneity for the two functional scores and substantial heterogeneity for Cobb angle (I^2 = 84%). Within the limits of the available follow-up, the two constructs therefore appear to achieve comparable neurological and functional improvement and comparable correction and maintenance of cervical alignment.

These null findings should not be read as evidence of equivalence. The confidence intervals are wide, the analyses are based on means reported at heterogeneous follow-up intervals, and the included studies were not powered for these comparisons. In particular, the Cobb angle estimate crosses zero, but its lower bound is compatible with a clinically relevant difference in alignment, and the pooling of a radiographic parameter across cohorts with different fusion techniques and different measurement conventions is itself a source of imprecision.

4.4. Complications

4.4.1. Dysphagia

Dysphagia is one of the most characteristic complications of ACDF, and it is the outcome for which the design of the zero-profile spacer offers the most direct rationale: omission of the anterior plate reduces the volume of anterior hardware, the extent of retraction, and the profile against the prevertebral soft tissues. In this analysis, the odds of dysphagia were lower in the zero-profile group at all three time points: early after surgery (OR 0.44, 95% CI 0.28–0.67; P = 0.0002), at 3 months (OR 0.14, 95% CI 0.06–0.38; P < 0.00001), and beyond 6 months (OR 0.12, 95% CI 0.03–0.45; P = 0.002), with no heterogeneity in any of the three analyses.

These are odds ratios, not incidence rates. An OR of 0.44 corresponds to a 56% reduction in the odds of early dysphagia, and ORs of 0.14 and 0.12 to reductions of 86% and 88% in the odds at 3 months and beyond 6 months; the corresponding absolute risks depend on the baseline incidence in each population, which varied substantially across the included studies and cannot be recovered from the pooled odds ratio alone. The apparent attenuation of the effect over time should therefore be interpreted cautiously: the number of studies contributing to the late analysis was five, events were few, and the confidence intervals of the three estimates overlap, so a genuine decline in effect cannot be distinguished from differences in the study populations contributing to each time point.

Several mechanisms have been proposed for post-ACDF dysphagia, including retraction injury to the oesophagus and prevertebral soft tissues, ischaemia, haematoma, adhesion, and foreign-body-related inflammation around the implant. The lower odds observed with the zero-profile spacer are compatible with a reduction in hardware-related irritation and in the extent of

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anterior retraction, but the included studies did not report the severity of dysphagia or its duration in a form that would allow this mechanism to be tested.

4.4.2. Adjacent segment degeneration

Adjacent segment degeneration (ASDeg) and adjacent segment disease (ASDis) are the principal long-term concerns after ACDF, and their definitions are not interchangeable: ASDeg denotes new radiographic change at a level adjacent to the fused segment, whereas ASDis denotes new or recurrent symptoms attributable to that change [14]. In this review, the overall incidence of ASDeg was lower in the zero-profile group (OR 0.49, 95% CI 0.30–0.82; P = 0.006) with no heterogeneity across ten studies, and the incidence of postoperative new-onset adjacent segment disease was also lower (OR 0.40, 95% CI 0.19–0.87; P = 0.02). By contrast, the analysis of symptomatic adjacent segment disease in four studies did not reach significance (OR 0.54, 95% CI 0.27–1.02; P = 0.06), and none of the four analyses stratified by the number of degenerated adjacent segments showed a significant difference.

This pattern is internally consistent: the benefit of the zero-profile construct was evident for radiographic degeneration and for new-onset disease, but not for symptomatic disease or for any individual stratum defined by the number of involved adjacent segments. Two explanations are plausible. First, the stratified analyses each contained only two to five studies and were therefore underpowered; the point estimates for one, two, and three segments (OR 0.44, 0.47, and 0.68) lie on the same side of unity as the overall estimate, which argues for a lack of power rather than a genuine absence of effect. Second, the outcome definitions differed between studies, and radiographic degeneration is a more sensitive but less clinically specific endpoint than symptomatic disease.

It should be noted that the two analyses of adjacent segment disease were based on partially overlapping subsets of the same ten studies (four studies for symptomatic disease and six for new-onset disease), and that the two subsets share two cohorts [4,7]. The estimates are therefore not independent, and the apparent difference in statistical significance between them should not be interpreted as evidence that the two endpoints behave differently; the overlapping confidence intervals are compatible with a single underlying effect.

The mechanisms proposed for adjacent segment degeneration after ACDF include altered stress distribution at the adjacent disc, increased intradiscal pressure, and compensatory hypermobility at the level adjacent to a fused segment, together with patient-related factors such as age, bone quality, and postoperative neck motion. Whether a zero-profile construct modifies these mechanisms more favourably than a plate is not established. The lower incidence

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observed here may reflect a smaller anterior profile and less disruption of the anterior longitudinal ligament and longus colli, but it may equally reflect differences in the number of operated levels, in follow-up duration, or in the radiographic criteria applied; the included studies were not designed to distinguish these possibilities.

4.5. Device-specific considerations

A pooled analysis according to the specific device was not feasible, because most devices contributed to fewer than three studies each. Five studies evaluated the Zero-P spacer [4-8], two the ROI-C device [9,10], one the Fidji cervical cage [11], and two other self-locking stand-alone cages [18,19]. These devices differ in material, in the geometry of the anchoring teeth or rails, and in the number and configuration of screws or clips, and it cannot be assumed that they are clinically interchangeable. The available comparisons were too few to determine whether the magnitude of effect differs between them, and the pooled estimates reported here should be regarded as a class effect of anchored spacers rather than as evidence applicable to any particular device. This limitation is particularly relevant to the dysphagia findings, since the mechanism most often invoked to explain them — reduction of the anterior hardware profile against the prevertebral soft tissues — is itself device-specific: a spacer with an integrated anterior plate and a spacer anchored through endplate wings do not necessarily present the same profile or require the same extent of retraction.

4.6. Limitations

Several limitations should be considered.

First, nine of the ten included studies were non-randomised comparative studies, and the single randomised trial contributed to only a subset of outcomes. Confounding by indication is therefore a substantial concern: the choice of implant was made by the operating surgeon, and the number of operated levels, the severity of preoperative myelopathy, and surgeon preference may all have differed systematically between groups. The included studies did not adjust for these factors, and the pooled estimates are unadjusted.

Second, the certainty of evidence was low to very low for every outcome. Evidence from non-randomised studies started at low certainty, and three outcomes — intraoperative blood loss, operative time, and Cobb angle — together with the four stratified analyses of adjacent segment degeneration were further downgraded to very low for inconsistency (I^2 between 84% and 96%) or for imprecision, the latter reflecting the small number of contributing studies and confidence intervals that included both no effect and a clinically important effect.

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Third, the search was completed in June 2019 and was not subsequently updated, so studies published since that date are not represented. No language restriction was applied at the search stage, although all included studies were ultimately published in English; relevant reports in other languages may therefore have been missed.

Fourth, the analyses of adjacent segment disease were based on two partially overlapping subsets of studies rather than on a single prespecified outcome, and the number of studies contributing to each stratified analysis was small. The findings for adjacent segment outcomes should therefore be regarded as hypothesis-generating.

Fifth, publication bias could be assessed graphically for only one outcome, the overall analysis of adjacent segment degeneration, because no other analysis included ten or more studies. The funnel plot for that outcome was asymmetric, but with ten studies the asymmetry could not be reliably distinguished from genuine heterogeneity between cohorts, from differences in methodological quality, or from chance.

Sixth, the review was not prospectively registered, and the protocol was not publicly available; deviations from the protocol are described in the Methods. Follow-up intervals and the instruments used to assess dysphagia and functional outcome varied across studies, which limits the comparability of the pooled estimates and precludes any analysis of time-to-event outcomes. Multicentre randomised trials with standardised outcome definitions, uniform follow-up, and adequate power are needed before the superiority of either construct can be regarded as established.

5. Conclusions

In patients undergoing ACDF, the zero-profile anchored spacer was associated with a lower incidence of radiographic adjacent segment degeneration and of postoperative new-onset adjacent segment disease, shorter operative time, less intraoperative blood loss, and lower odds of dysphagia in the early, intermediate, and late postoperative periods, while JOA score, NDI score, and Cobb angle were comparable to those achieved with a cage-plate construct. The certainty of this evidence is low to very low, owing to the predominance of retrospective designs, the likelihood of confounding by indication, substantial heterogeneity for the perioperative and radiographic outcomes, and the small number of studies contributing to each stratified analysis. The findings support the use of anchored spacers as a reasonable alternative to cage-plate constructs, particularly where reduction of dysphagia risk is a priority, but they do not establish the superiority of one construct over the other.

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