



# Improved Dysphagia Outcomes in Anchored Spacers Versus Plate-Screw Systems in Anterior Cervical Discectomy and Fusion: A Systematic Review

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## Abstract

**Study Design:** Systematic review and meta-analysis.

**Objective:** To perform a systematic review of clinical outcomes between stand-alone anchored spacers and traditional cages with plate fixation for dysphagia and pseudoarthrosis using data from clinical trials.

**Methods:** Our search protocol was added to PROSPERO register and systematic review using PRISMA method was performed. Then, we systematically searched for studies addressing stand-alone anchored spacers in patients who underwent ACDF. Mean Neck Disability Index (NDI), dysphagia incidence % (Dinc%), and Swallowing–Quality of Life (SQOL) scores during preoperative, immediate postoperative and last follow-up visits were extracted. Chi-square and analysis of variance (ANOVA) tests were used for statistical comparisons ( $P \leq .05$ ).

**Results:** The initial search generated 506 articles in CENTRAL and 40 articles in MEDLINE. Finally, 14 articles were included. Total number of patients was 1173 (583 anchored stand-alone and 590 plate). Dinc% scores were statistically significantly lower in the stand-alone anchored spacer compared to the plate-screw construct ( $P \leq .05$ ). ANOVA showed no statistically significant difference in the comparisons of SQOL. On the other hand, NDI scores were statistically significantly lower in baseline of stand-alone anchored spacer and the plate-screw construct compared with both immediate postoperative and last follow-up visits ( $P \leq .05$ ).

**Conclusions:** Our study results revealed that the stand-alone anchored spacers were associated with less dysphagia in the immediate and last follow-up.

## Keywords

anterior cervical discectomy and fusion (ACDF), zero-p, stand-alone, plate-screw

## Introduction

Anterior cervical discectomy and fusion (ACDF), a surgical procedure first introduced in 1958 is one of the most commonly performed spinal procedures.<sup>1,2</sup> More than 500 000 procedures were performed from 1990 and 1999 in the United States alone.<sup>3</sup> ACDF is primarily used for the treatment of patients with indications of disc herniation, degenerative disc disease, spondylosis, and cervical spondylotic myelopathy (CSM).<sup>4</sup>

ACDF surgery can be divided into distinct steps. The first involves anterior exposure to the affected disc spaces, the

second involves decompression of the neural structures, and the last step involves placement of an interbody spacer. Over the past 50 years, there has been very little change in the first

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2 steps of the operation, but there has been an evolution of techniques to facilitate the fusion.

Originally, the interbody spacer consisted of autologous bone harvested from the patient's iliac crest of various shapes.<sup>5</sup> However, iliac crest bone graft (ICBG) is associated with serious morbidities, including pain, infection, hematoma, and iliac crest fractures.<sup>6</sup> Subsequently, there was a push toward the design of various structural autografts that would allow for bone growth. These structural autografts, made from different materials such as titanium and polyetheretherketone (PEEK) were often placed alone (stand-alone). The results of these stand-alone systems were good overall, with excellent results in single-level fusions in terms of fusion rates and patient outcomes. However, the rates of nonunion (pseudoarthrosis) for multilevel constructs was alarmingly high, in excess of 30%.<sup>7,8</sup>

Performing an ACDF with plating, which involves the use of a plate that is fastened to the anterior surface of the intravertebral discs with screws (plate-screw construct) was originally developed in the 1970s for use in cervical spine trauma. The addition of a plate has been shown to increase fusion rates in multilevel fusion. The mechanism of this improvement in fusion rates has been hypothesized to be due to decreased micromotion and increased stability.<sup>9,10</sup> These plate-screws systems have been widely accepted as the gold standard in performing ACDFs.

The plate-screw system is not without its problems, however. The most important of these complications is dysphagia, which can be temporary, but at times may progress to chronic dysphagia. The reported rates of early postoperative dysphagia varies from 1% to 50%<sup>11-13</sup> and long-term dysphagia has been shown to vary from 13% to 20%.<sup>14,15</sup> It has been hypothesized that the mechanisms behind reported higher rates of dysphagia due to the plate-screw system are due to the increased dissection that is needed above and below the construct as well as the plate being immediately posterior to the esophagus.<sup>14-16</sup> Other complications related to the plate-screw system are screw pull-out, plate breakage, and adjacent level ossification.<sup>17-19</sup>

Because of these concerns, anchored spacers have now been developed, which consist of an allograft cage with screws or shims that can be directly inserted into the vertebral bodies above and below.<sup>20,21</sup> Because of the fact that these anchored spacers do not protrude past the vertebral bodies and the anchoring systems can be deployed completely within the spacer, it is hypothesized that these anchored cage systems will have advantage of the increased fusion rates seen in plate-screw systems, yet not have the same rates of dysphagia and other plate-related morbidities.

There have been some recent articles comparing stand-alone anchored spacers and ACDF with plate-screw constructs.<sup>22-28</sup> There have been attempts to extract this data in a meta-analysis and systematic review.<sup>29-32</sup> Some of the limitations of these systematic reviews and meta-analyses include the fact that these studies did not include randomized clinical trials in their meta-analysis data.<sup>29</sup> Other limitations include that some of these reviews only looked at the use of these implants for limited indications such as CSM<sup>29</sup> or cervical degenerative disc disease.<sup>31</sup> The aim of our study was to perform a search in both the CENTRAL (Cochrane central register of clinical trials) and

MEDLINE clinical trials databases in order to determine if using only randomized clinical trials will affect the primary outcomes of dysphagia incidence (Dinc%) and Swallowing-Quality of Life (SQOL) and to include all indications for ACDF. We also looked at Neck Disability Index (NDI) as a secondary outcome when comparing stand-alone anchored spacers and the plate-screw constructs.

## Methods

### PRISMA Guidelines

For our systematic review, we followed the guidelines of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).<sup>33</sup> The protocol for the online research was submitted and accepted by the international prospective register for systematic reviews (PROSPERO).<sup>34</sup>

### Inclusion and Exclusion Criteria

We included only randomized controlled trials that directly compared the use of stand-alone anchored spacers versus plate-screw constructs in patients who underwent ACDF. In addition, all studies addressed functional outcomes, including NDI, SQOL metric measured by the Bazaz method,<sup>14,16</sup> and dysphagia incidence. We excluded any articles in language other than English.

### Online Search

CENTRAL: Using the Cochrane clinical trials database, we systematically searched for studies addressing stand-alone anchored spacer in patients who underwent ACDF. MEDLINE: The same process was repeated using the Medline clinical trial database. All stages of this research were conducted independently by 2 investigators.

### Keywords

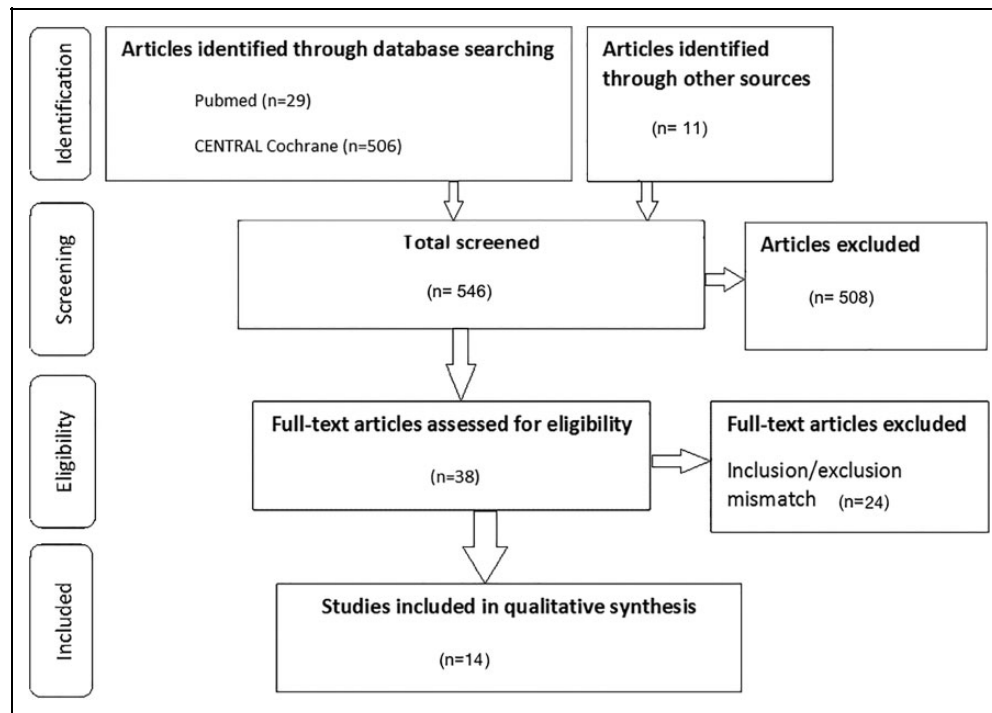
We used the following keywords in our search in both CENTRAL and MEDLINE databases: “zero-profile” OR “zero profile” OR “zero-p” OR “stand-alone” OR “anchored spacer” OR “anchored cage” OR “anchored fusion” OR “no-profile” AND “cervical.”

### Risk of Bias

The risk of bias of the selected works was estimated according to guidelines in Cochrane Handbook for Systematic Reviews of Intervention,<sup>35</sup> which assess the risk of bias in 7 domains, each sorted subjectively as high risk, low risk, or uncertain risk.

### Statistical Analysis

All statistical analysis was performed with R-Studio software (version 1.1.423, Richmond Hill, Ontario, Canada). Chi-square test was used for comparison of stand-alone cage and plate-screw construct demographic data preoperative, and intraoperative and postoperative values. Mean dysphagia incidence



**Figure 1.** PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram for selection of articles.

% (Dinc% = [incidence of dysphagia/ total number of patients] × 100), SQOL and NDI scores during preoperative, immediate postoperative (<3 months) and last follow-up (3 months to 3 years) visits were extracted and combined. Analysis of variance (ANOVA) test was used for comparison of the functional outcome scores in the stand-alone anchored spacers and plate-screw constructs. Post hoc Tukey test was used for inter-group comparisons. Statistical significance was set at  $P \leq 0.05$ . All data will be presented as means ± standard deviation, unless otherwise noted.

**Results**

**Literature Search**

The initial search generated 506 articles in CENTRAL. We selected 20 articles because they directly compared the use of stand-alone anchored spacers versus plate-screw construct in patients who underwent ACDF. Out of the 20 selected articles, only 8 were included in the study because they addressed NDI and dysphagia scores. On the other hand, the search generated 29 articles in MEDLINE (in addition to 11 by manual hand search). The same inclusion criteria were applied and 18 articles were selected. Out of the 18 selected articles, only 12 were included in the study because they addressed NDI and dysphagia scores. Out of 20 resulting studies, 6 studies did not address functional outcomes, including SQOL metric measured by the Bazaz method<sup>14,16</sup> and dysphagia incidence; and 7 studies did not address NDI. Finally, a total of 14 articles were analyzed (Figure 1).

**Table 1.** Patient Demographic Data—Preoperative.

Demographic	Anchored Cage (n = 583)	Plate-Screw (n = 590)	P
Age (years) (mean ± SD)	50.84 ± 4.91	50.87 ± 4.79	.92
Gender n(%)			.81
Male	301	295	
Female	236	240	
NR <sup>a</sup>	46	55	
Body mass index (kg/m <sup>2</sup> ) (mean ± SD)	27.60 ± 2.36	28.08 ± 2.56	.036
Smokers	21 ± 12	19 ± 11	
Diagnosis			
Degenerative disc			<.0001
Yes	79	117	
No	4	467	
NR <sup>a</sup>	5	6	
Herniation			.66
Yes	65	60	
No	513	524	
NR <sup>a</sup>	5	6	
Other			.051
Yes	439	413	
No	139	171	
NR <sup>a</sup>	5	6	
Fusion vertebrae			.66
1-level	239	245	
2-level	174	161	
3-level	110	120	
4-level	11	15	
NR <sup>a</sup>	49	49	

<sup>a</sup>Not reported (NR) values were not used for significance testing.

**Table 2.** Demographic Data: Intraoperative and Postoperative.

Preoperative	Anchored Cage (n = 583)	Plate-Screw (n = 590)	P
Operative time (min) (mean $\pm$ SD)	95.92 $\pm$ 26.05	105.62 $\pm$ 19.79	<.0001
1-level	80.4 $\pm$ 12.1	108.7 $\pm$ 22.8	.000
2-level	124.3 $\pm$ 19.3	143.3 $\pm$ 22.4	.017
Estimated blood loss (mL) (mean $\pm$ SD)	71.73 $\pm$ 29.33	99.47 $\pm$ 38.50	<.0001
1-level	56.8 $\pm$ 19.0	89.4 $\pm$ 29.7	.001
2-level	78.8 $\pm$ 22.5	102.3 $\pm$ 36.6	.038
Hospital days	2.95 $\pm$ 3.06	3.29 $\pm$ 3.44	.48
Fusion rate % (2 years)	93.99 $\pm$ 4.41	95.11 $\pm$ 3.55	.019
Cost of index surgery (\$)	\$6478.20 $\pm$ 836.6	\$7510.80 $\pm$ 899.9	.001
Complications, n			
Infection			1.00
Yes	1	1	
No	181	186	
NR <sup>a</sup>	401	403	
Hoarseness			.50
Yes	3	6	
No	179	181	
NR <sup>a</sup>	401	403	
ALO			.24
Yes	2	0	
No	180	187	
NR <sup>a</sup>	401	403	
CSF leak			.62
Yes	1	3	
No	181	184	
NR <sup>a</sup>	401	403	
Instrument fail			.015
Yes	0	7	
No	182	180	
NR <sup>a</sup>	401	403	
Hematoma			1.00
Yes	1	2	
No	181	185	
NR <sup>a</sup>	401	403	
New neuro deficit			.37
Yes	1	4	
No	181	183	
NR <sup>a</sup>	401	403	
Pseudoarthrosis			1.00
Yes	1	2	
No	181	185	
NR <sup>a</sup>	401	403	
Subsidence	12/123 (9.8%)	9/122 (7.4%)	

Abbreviations: ALO, adjacent level ossification; CSF, cerebrospinal fluid.

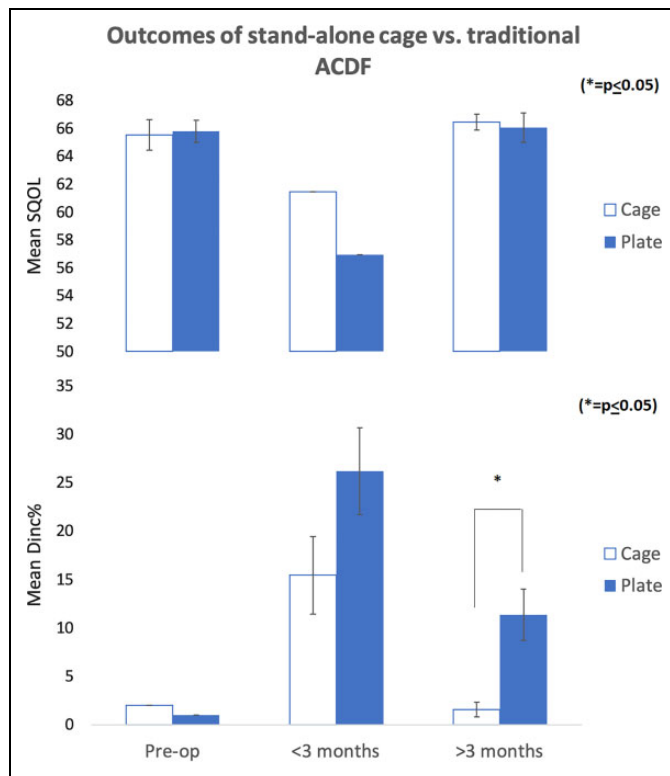
<sup>a</sup>Not reported (NR) values were not used for significance testing.

### Patient Population

Total number of patients was 1173. The number of patients receiving the anchored-cage systems was 583 (50%), while 590 (50%) patients received the plate-screw systems. Table 1 summarizes the demographics of both groups. Average age at time of surgery was 51 years old in both groups. Average body mass index was 27.6 kg/m<sup>2</sup> in anchored-cage groups and was statistically significantly lower than plate-screw patients ( $P = .04$ ). Listed males were 596 (51%) while females were 476 (41%), with no difference between treatment groups. There was an equal proportion of smokers in both groups.

Degenerative disc disease patients received statistically significantly more ACDF with plate screw systems as compared to anchored-cage systems (20% vs 14%;  $P = .004$ ). In all, 45% of all patients received single level fusion (Table 1).

The average operative time for the plate-screw systems was 105.62  $\pm$  19.79 minutes, which was longer than the anchored-cage systems that was 95.92  $\pm$  26.05 minutes ( $P = .0001$ ). The average blood loss for the plate-screw systems was 99.47  $\pm$  38.5 mL, which was higher than in the anchored-cage cases (71.73  $\pm$  29.33 mL;  $P = .0001$ ). Both groups had similar stay in the hospital (3 days; Table 2). One article compared



**Figure 2.** Bar graph demonstrating the difference in mean Dinc% (dysphagia incidence %) and SQOL (Swallowing–Quality of Life) scores between stand-alone anchored spacer and plate-screw constructs, during preoperative, immediate postoperative (<3 months), and last follow-up (3 months to 3 years) visits (ACDF = anterior cervical discectomy and fusion; cage= stand-alone anchored spacers, plate = plate-screw constructs, \*P < .05, error bars are standard deviations).

operative times for 1-level cases in anchored-cage systems ( $80.4 \pm 12.1$  minutes) versus plate-screw systems ( $108.7 \pm 22.8$  minutes;  $P = .00$ ) and showed that the anchored cage systems had a significantly reduced operative time. They also found significant improvement in the operative times for anchored-cage systems in 2-level cases ( $124.3 \pm 19.3$  vs  $143.3 \pm 22.4$  minutes;  $P = .02$ ) compared with plate-screw systems. For estimated blood loss, the article compared 1-level cases in anchored-cage systems ( $56.8 \pm 19.0$  mL) versus plate-screw systems ( $89.4 \pm 29.7$  mL;  $P = .00$ ) and showed that the anchored-cage systems had a significantly reduced blood loss. They also found significant improvement in the estimated blood loss for anchored-cage systems in 2-level cases ( $78.8 \pm 22.5$  vs  $102.3 \pm 36.6$  mL;  $P = .04$ ) compared with plate-screw systems.<sup>28</sup>

Plate-screw systems demonstrated significantly higher levels of instrumentation failure (7 vs 0;  $P = .01$ ). In addition, the plate-screw systems were associated with elevated rate of adjacent level ossification, hoarseness, cerebrospinal fluid (CSF) leak, hematomas, new neurological deficits, and pseudoarthrosis compared with the anchored-cage systems, though these findings were not statistically significant. The cost of index surgery of stand-alone cage in one study was

lower than plate-screw construct (\$6478 vs \$7511, respectively). Both fusion rate and infection rate were similar in both groups (Table 2).

### Primary Outcomes

**Dysphagia Incidence.** Mean Dinc% scores from each of the 12 out of 14 resulting studies (508 patients with cage and 513 with plate) was extracted and calculated. Then, the scores were plotted (Figure 2) (Table 3). There was a statistically significant difference between the anchored-cage constructs immediate visits (<3 months) and last follow-up visits ( $P = .005$ ). Also, there was statistically significant difference between the plate-screw constructs immediate visits (<3 months) and last follow-up visits (>3 months;  $P = .001$ ). Finally, the anchored-cage system was associated with statistically significant lower incidence of dysphagia compared with the plate-screw system at the last follow-up visits (3 months to 3 years;  $P = .008$ ; Figure 2) (Table 3).

**Swallowing–Quality of Life.** Mean SQOL scores from each of the 3 out of 14 resulting studies (140 patients with cage and 173 with plate) during immediate postoperative (<3 months) and last follow-up (3 months to 3 years) visits were extracted and combined (Figure 2) (Table 3). There were no statistically significant differences between the anchored-cage constructs baseline and last follow-up visits ( $P = .32$ ). Also, there was no statistically significant difference between the plate-screw constructs baseline and last follow-up visits (>3 months;  $P = .39$ ). Finally, there was no statistically significant difference between cage and plate groups during last follow-up visits ( $P = .59$ ).

### Secondary Outcome

**Neck Disability Index.** Mean NDI scores from each of the 8 out of 14 resulting studies (309 patients with cage and 328 with plate) after using a stand-alone cage in comparison to ACDF with plate were extracted and combined (Figure 3) (Table 3). There was statistically significant difference in the NDI scores between baseline cage versus immediate cage postoperatively ( $P = .01$ ) and last cage follow-up ( $P = .01$ ); and baseline plate versus immediate plate postoperatively ( $P = .03$ ) and last plate follow-up ( $P = .004$ ). Finally, there was no statistically significant difference between cage and plate groups during last follow-up visits ( $P = .37$ ).

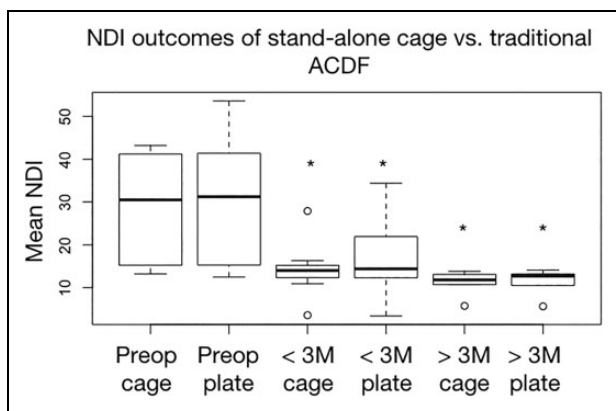
### Risk of Bias

Eight (40%) studies used appropriate methods of randomization (Figure 4). The remaining articles did not describe the randomization methods and as such, they were all considered unclear risk. Fourteen articles described and used appropriate methods of outcome data blinding and reporting and thus were considered low risk. The remaining articles did not describe their methods and were considered unclear risk. Only 2 articles utilized high-risk methods for patient

**Table 3.** Outcome Data From all 14 Studies.

Cage	C1	C2	C3	C4	C5	C6	C7	C8	C9	C10	C11	C12	C13	C14
No. of patients	49	27	68	22	30	83	35	52	34	23	26	69	44	21
Dinc% preoperative	—	—	—	—	—	2	—	—	—	—	—	—	—	—
<3 mo	—	4	6	5	20	45	31	0	6	4	—	28	23	14
>3 mo	—	0	2	0	0	0	3	—	9	0	—	2	2	0
SQOL preoperative	—	—	—	—	—	63	—	—	67	67	—	—	—	—
<3 mo	—	—	—	—	—	4	—	—	—	4	—	1	—	—
>3 mo	—	—	—	—	—	-2	—	—	0	-1	—	0.1	—	—
NDI preoperative	40	24	17	—	37	—	—	43	14	13	43	—	—	—
<3 mo	26	10	6	—	23	—	—	27	—	10	15	—	—	—
>3 mo	—	10	6	—	25	—	—	30	8	—	—	—	—	—
Plate	P1	P2	P3	P4	P5	P6	P7	P8	P9	P10	P11	P12	P13	P14
No. of patients	49	30	70	25	33	107	35	52	38	28	28	35	33	27
Dinc% preoperative	—	—	—	—	—	1	—	—	—	—	—	—	—	—
<3 mo	—	13	13	24	42	48	40	6	5	25	—	20	30	48
>3 mo	—	3	6	8	27	5	20	—	5	0	—	20	9	22
SQOL preoperative	—	—	—	—	—	64	—	—	66	67	—	—	—	—
<3 mo	—	—	—	—	—	10	—	—	—	7	—	0	—	—
>3 mo	—	—	—	—	—	0	—	—	0	-1	—	0	—	—
NDI preoperative	40	25	17	—	38	—	—	43	14	12	54	—	—	—
<3 mo	12	11	6	—	24	—	—	27	—	9	19	—	—	—
>3 mo	—	11	7	—	25	—	—	30	8	—	—	—	—	—

Abbreviations: SQOL, Swallowing-Quality of Life; NDI, Neck Disability Index.<sup>38-46</sup>

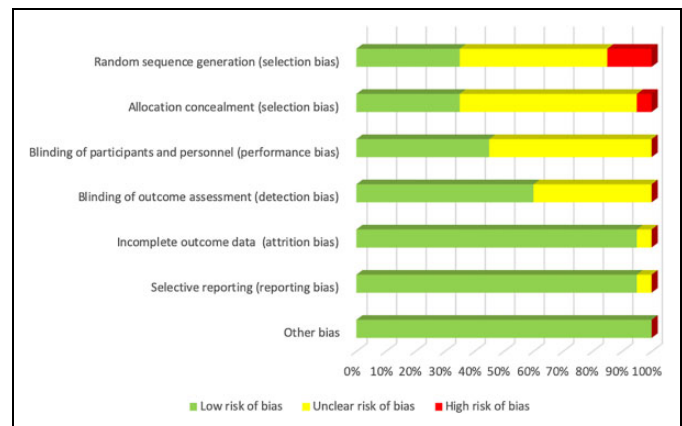


**Figure 3.** Box plot demonstrating the difference of Neck Disability Index (NDI) between stand-alone anchored spacer and plate-screw constructs, during preoperative, immediate postoperative (<3 months) and last follow-up (3 months to 3 years) visits (ACDF = anterior cervical discectomy and fusion; cage= stand-alone anchored spacers, plate= plate-screw constructs, \*P < .05).

randomization (patients chose their surgical procedure) and so were considered high risk (excluded from data extraction).<sup>22,36</sup>

**Discussion**

ACDF continues to be a well-utilized surgery with excellent results and one that is well tolerated by patients. As techniques have evolved, the use of a plate and screw system has become increasingly popular among surgeons as it has been shown to



**Figure 4.** Risk of bias assessment. Figure is available in color online only.

have good fusion rates and more robust biomechanical properties compared with stand-alone allograft and autograft spacers.<sup>1-3</sup> A disadvantage, however, is a potential association with increased incidence of dysphagia.<sup>16</sup> Thus, the use of stand-alone spacers with screws or shims that can be directly inserted into the vertebral bodies above and below has shown some promise. In this study, we aimed to compare the plate-screw systems to the anchored systems in terms of functional outcomes, fusion rates, dysphagia, and quality of life.

Our patient population did not include tumors, trauma, or infection, which may affect the rates of dysphagia. We found that intraoperatively, estimated blood loss and operative times

were reduced in stand-alone anchored spacers in comparison with plate-screw constructs (overall and based on number of levels). This likely represents the fact with the anchored-cage constructs, one does not have to dissect as much soft tissue off the vertebral bodies as compared to the plate-screw systems. During multilevel fusions, the placement of the cage can be difficult as one has to expose the extreme ends of the fusion. This is not required in the anchored-cage systems as each level can be treated individually and at no point does it require one to have the extreme levels of the fusion exposed at the same time.

One of the major complications, instrument failure, was noted to be higher in the ACDF with plate-screw constructs compared with the anchored-cage constructs. In addition, the cost of surgery was higher in one of the studies in ACDF with plate-screw systems.

One concern of the earlier stand-alone systems without the anchoring shims or screws was the reduced rate of fusion, especially in multilevel fusions.<sup>7,8</sup> With the plate-screw systems, fusion occurs at a higher rate due to the rigidity. The anchored-cage systems appear to mitigate these concerns for pseudoarthrosis, as evidenced by the equal rates of fusion in the anchored-cage constructs and the plate-screw constructs.

In our study, we focused on the functional outcomes, including NDI, dysphagia incidence, and swallowing difficulty measured by the Bazaz method (assessment of severity of dysphagia based on frequency of episodes of swallowing difficulty for liquid or solid food).<sup>14,16</sup> Occurrence of dysphagia is believed to be due to soft tissue swelling, esophageal injury, or adhesive formations.<sup>18</sup> By not requiring as much soft tissue and esophageal retraction, it is not surprising that anchored-cage systems were found to be associated with lower early incidence of postoperative dysphagia compared with the plate-screw systems. The fact that this improvement in dysphagia incidence persisted to the longer time period may be related to the fact that the plate-screw systems may act as an irritant to the esophagus, despite newer, very slim designs of the plate.

In general, our results are similar to other meta-analyses and systematic reviews. Tong et al<sup>29</sup> showed that the anchored spacers had a decreased rate of dysphagia than the plate-screw systems at all time points. Their study included both randomized controlled studies and retrospective reviews but was limited to only multilevel CSM. Dong et al<sup>30</sup> showed that anchored systems had a lower incidence of dysphagia at early and later time points, but only had 10 studies. Similar to our results, they found that the anchored systems had a statistically significant lower blood loss compared to the plate-screw systems.<sup>30</sup> Duan et al<sup>31</sup> showed that the anchored systems had lower incidence of dysphagia in both the early and late postoperative time points. Liu et al<sup>32</sup> showed that the anchored systems had lower dysphagia, but higher rates of subsidence than the plate-screw systems. It should be noted that our meta-analysis included all the data of the above meta-analysis as long as they came from randomized control studies and thus represents a larger pool of data and with less risk of bias.<sup>37</sup> Limitations to our study include that 14 of the resulting articles

included only primary outcomes, while 13 only included secondary outcomes.

Based on our findings, ACDF with stand-alone anchored spacers may be a good alternative to traditional plate-screw constructs in that it affords less postoperative dysphagia without compromising fusion rates.

### Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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