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Review Article

Dynamic cervical implant in treating cervical degenerative disc disease: a systematic review and meta-analysis

Junfeng Zeng*, Yuchen Duan*, Hao Liu, Beiyu Wang, Quan Gong, Yi Yang, Hua Chen, Xin Rong

*Department of Orthopaedic Surgery, West China Hospital, Sichuan University, Chengdu, China. *Equal contributors.*

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Abstract: To systematically compare the safety and efficacy of dynamic cervical implant (DCI) with anterior cervical discectomy and fusion (ACDF) and cervical total disc replacement (CTDR) in treating cervical degenerative disc disease (CDDD). Electronic searches were conducted using PubMed, Embase, CBM, CNKI, VIP, and Wan Fang database (update to October 19, 2016). The relevant published literatures were screened by two independent reviewers according to the inclusion criteria. No language restriction was applied. Two prospective and four retrospective studies were enrolled with a total of 491 patients. No statistical difference was observed with regard to operative time, intraoperative blood loss and Japanese Orthopedic Association (JOA) score between DCI and ACDF group or DCI and CTDR group. No statistical difference was identified between DCI and ACDF group in Visual Analog Score (VAS) for neck and arm and between DCI and CTDR group in Neck Disability Index (NDI). Compared with ACDF group, DCI group presented higher treated segmental ROM, lower cephalad segmental ROM and caudal segmental ROM, but equal in overall range of motion (ROM). No significant difference in cephalad, treated and caudal segmental ROM was seen between DCI group and CTDR group. Based on our study, the limited evidence indicated that DCI is as effective and safe as ACDF and CTDR for patients with CDDD. DCI may maintain the ROM of treated segment and delay the occurrence of adjacent segment disease. However, insufficient evidence supports that DCI may decrease the stress of facet joints.

Keywords: Anterior cervical discectomy and fusion, cervical total disc replacement, dynamic cervical implant, cervical degenerative disc disease, meta-analysis, cervical spine

Introduction

Symptomatic cervical degenerative disc disease (CDDD) is the main cause of radiculopathy and myelopathy in cervical spine. These patients always present with symptoms like neck and arm pain, sensory changes and gait instability. Anterior cervical discectomy and fusion (ACDF) has been an effective surgical method of alleviating these symptoms since 1950s [1]. However, adjacent segment disease (ASD) is a well-known complication after ACDF [2-4]. Biomechanical studies suggested that fusion of surgical segments increases the stress of adjacent levels [5, 6].

With the aim of restoring or preserving the physiological motion of the spine as well as achieving equivalent or slightly superior clinical outcome compared with the traditional fusion surgery, cervical total disc replacement (CTDR) has become a substitute for fusion in recent years [7-9]. The results of a meta-analysis indicated that CTDR surpassed ACDF with regard to the lower rate of ASD [10]. Though the heterotopic ossification (HO) after CTDR was not associated with clinical outcomes, the reported occurrence rate was unexpectedly high, differ from 17.8% to 94.1% [11-15]. Furthermore, it had been suggested that hyper-mobility occurred to the operated segments after TDR, which may lead to increased stress on facet joints [16, 17].

Dynamic cervical implant (DCI) was originally developed by Dr. Guy Matgé *et al.* in 2002, which is a U-shaped titanium stabilizing device, and was introduced to clinical use in 2004. The

current second degeneration was developed by Paradigm Spine (New York, NY, USA) in 2005. The DCI implant stabilization was designed to combine the advantages of ACDF and CTDR [18]. DCI is a non-fusion surgical technique that allows limited flexion and extension of cervical spine, whereas the motion of cervical spine in rotation and lateral bending were limited [19]. The previous biomechanical study found that the DCI could spare the overload of facet joints which had been found in unconstrained TDR [16].

In order to identify and summarize the best available evidence, we conduct this meta-analysis to: (1) compare the safety and efficacy among DCI, ACDF and CTDR in treating patients with CDDD; (2) find out whether DCI may maintain the treated segmental ROM compared to ACDF; (3) find out whether DCI may decrease the stress of facet joints compared to CTDR.

Materials and methods

Search strategy

This meta-analysis was conducted under PRISMA Statement [20]. And all relevant published studies were searched from PubMed, Embase, CBM, CNKI, VIP, and Wan Fang database (update to October 19, 2016) using the combination of the following keywords: dynamic cervical implant, DCI, u-shaped disc implant, dynamic cervical stabilization and cervical. No language restriction was applied. The reference lists of eligible studies were reviewed for possibly relevant studies.

Inclusion and exclusion criteria

The relevant published studies were systematically reviewed. Literature that were included should meet the following criteria: (1) original articles; (2) studies comparing the clinical and radiological outcomes between the dynamic cervical implant with ACDF or CTDR; (3) patients were medically confirmed of CDDD who needed surgical intervention; (4) patients were followed up more than twelve months; (5) studies reported at least one needed outcome. Excluded criteria included: (1) unrelated studies; (2) conference abstracts; (3) biomechanical studies; (4) case reports; (5) systematic review; (6) letter to editor or comment.

Data extraction

Two authors independently reviewed the full text of included studies and extracted the information we need into Excel, including basic characteristics of studies and patients, surgical outcomes, clinical outcomes and radiological outcomes. Any disagreement between the two authors was settled through further discussions.

Risk of bias assessment

The quality of included six cohort studies were independently appraised by two authors using the Newcastle-Ottawa quality assessment scale (NOS) [21]. Any disagreement between the two authors was resolved through further discussions. The NOS uses a score system (range from 0 to 9) to evaluate the methodological quality of case-control studies and cohort studies. Studies with a score of 0 to 3, 4 to 6 and 7 to 9 were classified as low quality, medium quality and high quality, respectively.

Statistical analysis

This meta-analysis was conducted using Review Manager software (RevMan 5.3; Cochrane Collaboration). Weighted mean difference (WMD) and 95% confidence intervals (CI) were assessed for continuous data (intraoperative blood loss, operation time, overall ROM, segmental ROM). Standardized mean difference (SMD) and 95% CI were assessed for continuous data (clinical outcomes, intervertebral disc height) when the same continuous outcomes are measured according to different scales. Probability of $P<0.05$ was considered as statistically significant. I^2 statistic (ranging from 0 to 100%) was calculated to assess the heterogeneity among included studies. I^2 statistic >50% with P-value <0.10 was considered to represent substantial heterogeneity, under which circumstance, random effects analysis was performed, otherwise, fixed effects analysis was performed [22].

Result

Identification of relevant studies

We systematically searched the PubMed, Embase, CBM, CNKI, VIP, and Wan Fang data-

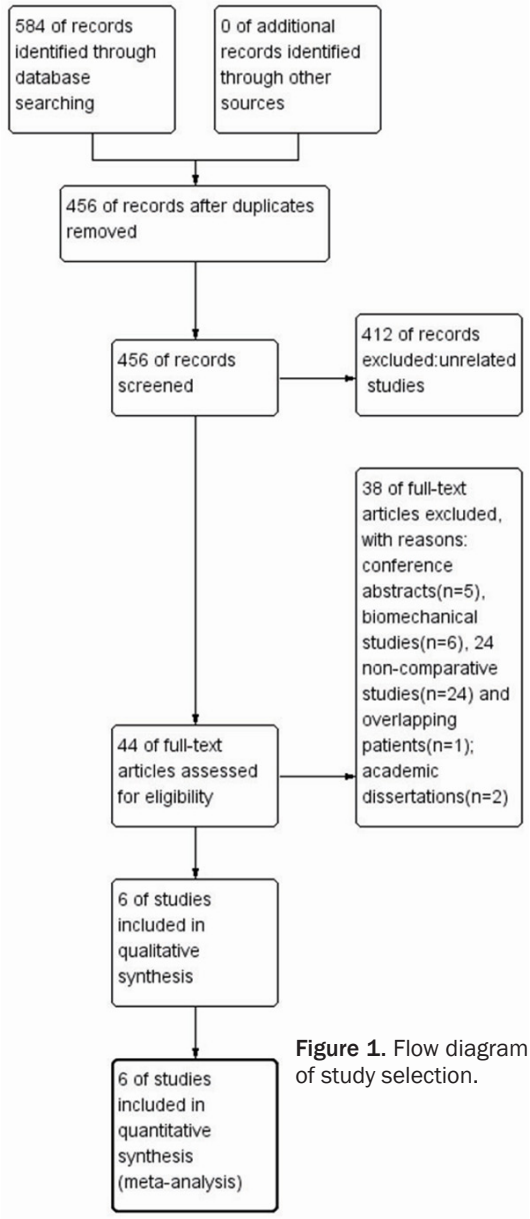

Figure 1. Flow diagram of study selection.

base for relevant studies and 584 studies that has been yielded. Four hundred and fifty-six articles were retrieved after removing duplicate studies. Four hundred and twelve unrelated studies, 5 conference abstracts, 6 biomechanical studies, 2 academic dissertations and 24 non-comparative studies were eliminated. Two studies [23, 24] were conducted by the same research team and the patients may have overlapped. One article [23] was eliminated. Eventually, six studies [24-29] were qualified. A flow diagram of search strategy of relevant studies is illustrated in **Figure 1**.

Characteristics of eligible studies and quality assessment

Two prospective studies and four retrospective studies were identified in our study. The information of eligible studies was listed in **Table 1**. There were 190 patients treated with dynamic cervical implant, 168 patients treated with ACDF and 133 patients treated with CTDR. Each included study was evaluated in accordance with NOS, which is presented in **Table 2**. The mean score (ranging from 8 to 9) of included studies was 8.5. All included studies were regarded as high quality.

Meta-analysis of outcomes

Surgical outcomes: Four studies with 141 patients treated with DCI, 94 patients treated with ACDF and 133 patients treated with CTDR were eligible for the meta-analysis of surgical outcomes. No statistical difference was identified between the DCI and ACDF group in operative time and intraoperative blood loss (operative time: WMD: -3.34, 95% CI: [-21.23, 14.54], P≤0.0001, I^2=91%, **Figure 2**; intraoperative blood loss: WMD: -32.04, 95% CI: [-84.94, 20.86], P≤0.00001, I^2=100%, **Figure 2**). Statistical heterogeneity was detected. There was no statistical difference in that between the DCI and CTDR group (operative time: WMD: 0.20, 95% CI: [-7.07, 7.48], P=0.13, I^2=51%, **Figure 2**; intraoperative blood loss: WMD: 2.27, 95% CI: [-6.88, 11.41], P=0.0005, I^2=87%, **Figure 2**). Substantial heterogeneity was found among these studies.

Clinical outcomes: Six studies with 190 patients treated with DCI, 168 patients treated with ACDF and 133 patients treated with CTDR were included in the meta-analysis of clinical outcomes. We found no significant difference in JOA score between the DCI and ACDF group (SMD: 0.58, 95% CI: [-0.27, 1.44], P<0.00001, I^2=89%, **Figure 3**), the DCI and CTDR group (SMD: -0.01, 95% CI: [-0.27, 0.25], P=0.94, I^2=0%, **Figure 3**), respectively. However, obvious heterogeneity was detected between the DCI and ACDF group. We found no statistical difference between the DCI and ACDF group in VAS for neck (SMD: 0.07, 95% CI: [-0.24, 0.39], P=0.39, I^2=0%, **Figure 3**) and arm (SMD: -0.17, 95% CI: [-0.51, 0.17], P=0.33, I^2=0%, **Figure 3**). No significant difference was identified in NDI

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

References	Year	Country	Study design	Sample size			Mean age			Male (%)			Follow-up		
				ACDF	DCI	CTDR	ACDF	DCI	CTDR	ACDF	DCI	CTDR	ACDF	DCI	CTDR
Li et al. [26]	2013	China	P	42	39	-	49.5±9.3	45.3±8.6	-	54.8	53.8	-	35.4	26.7	-
Richter et al. [27]	2015	Switzerland	P	27	26	-	46±7.3	44.1±8.8	-	40.7	61.5	-	12.8±1.5	13.0±1.8	-
Jia et al. [25]	2015	China	R	47	23	-	50.3	47.5	-	66.0	65.2	-	44.0	44.0	-
Liu et al. [29]	2016	China	R	-	67	85	-	42.6±9.6	46.3±8.2		56.7	43.5	-	42.7	46.1
Zhu et al. [28]	2014	China	R	34	25	32	49.5	47.1	48	53.0	56.0	45.4	20.3	20.0	20.1
Guan et al. [24]	2016	China	R	18	10	16	51.3±7.2	44.5±5.6	44.0±4.5	50.0	60.0	50.0	35.8	36.5	36.7

Note: R, retrospective, P, prospective.

Table 2. Methodological quality assessment of studies included in the meta-analysis based on Newcastle-Ottawa quality assessment scale (NOS)

References	Selection			Comparability			Outcome			Total
	Representativeness of the exposed cohort	Selection of the non-exposed cohort	Ascertainment of exposure	Demonstration that outcome of interest was not present at the start of study	Study controls for age or gender	Study controls for any additional factor	Assessment of outcome	Follow-up long enough for outcomes to occur	Adequacy of follow-up of cohort	
Li et al. [26]	1	1	1	1	1	0	1	1	1	8
Richter et al. [27]	1	1	1	1	1	1	1	1	1	9
Jia et al. [25]	1	0	1	1	1	1	1	1	1	8
Liu et al. [29]	1	1	1	1	1	1	1	1	1	9
Zhu et al. [28]	1	1	1	1	1	0	1	1	1	8
Guan et al. [24]	1	1	1	1	1	1	1	1	1	9

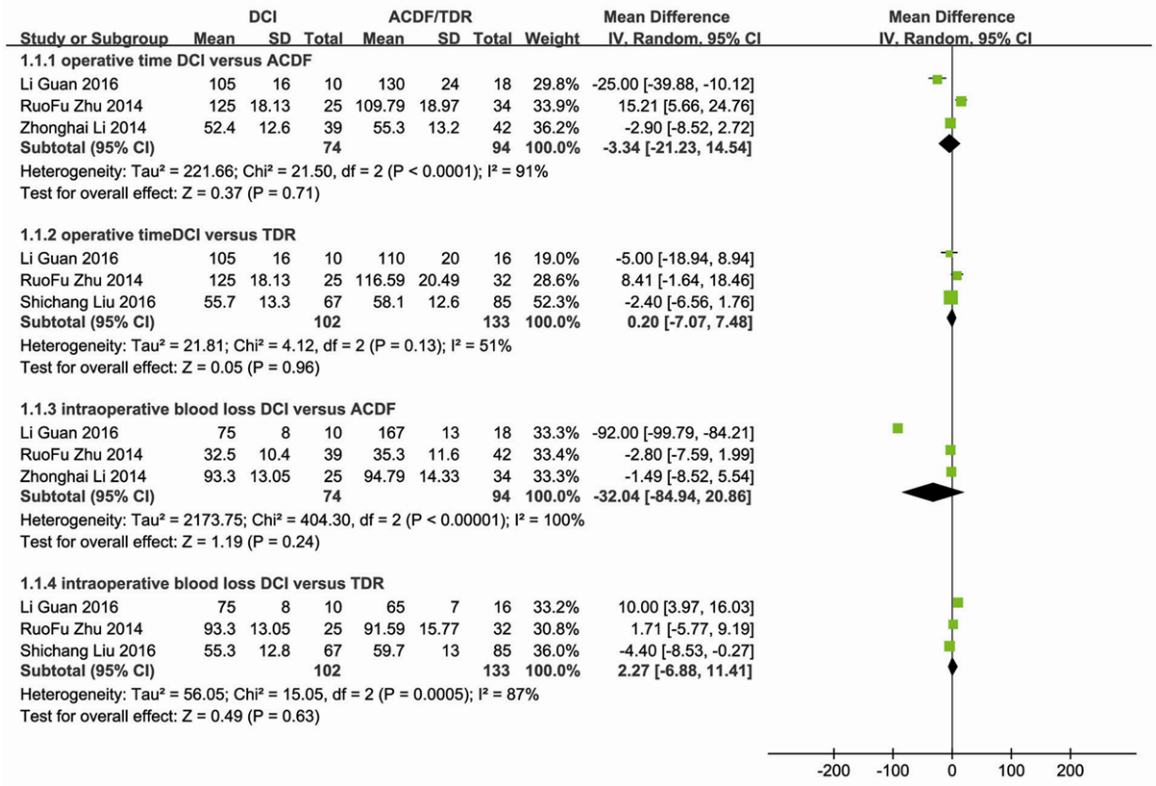

Figure 2. Comparison of operation time and intraoperative blood loss.

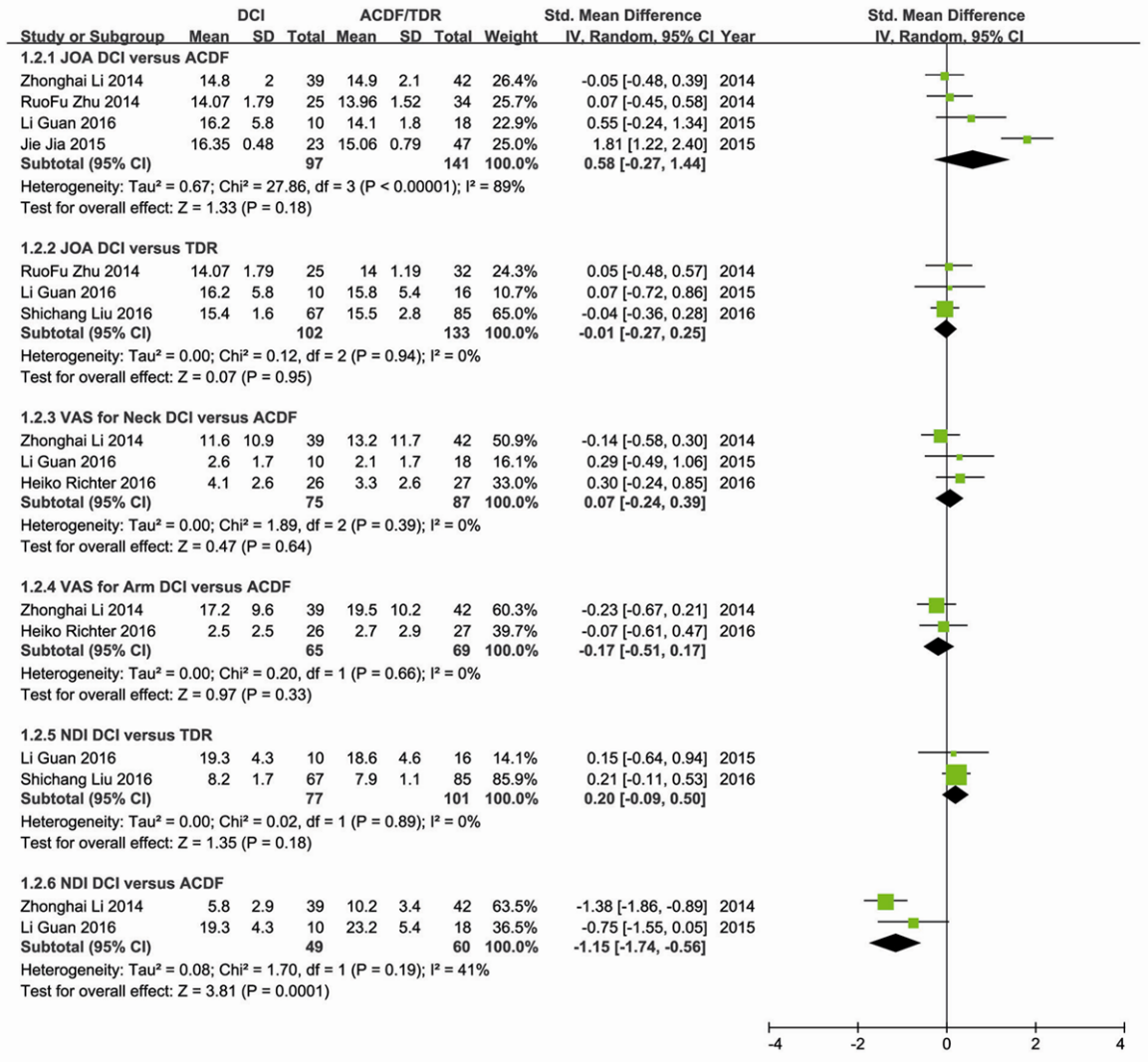

Figure 3. Comparison of clinical outcome.

between the DCI and CTDR group (SMD: 0.20, 95% CI: [-0.09, 0.50], P=0.89, I^2=0%, **Figure 3**). Significant difference was identified in NDI between the DCI and ACDF group (SMD: -1.15, 95% CI: [-1.74, -0.56], P=0.19, I^2=41%, **Figure 3**).

Radiological outcomes: Six studies with 164 patients treated with DCI, 141 patients treated with ACDF and 133 patients treated with CTDR were included in the meta-analysis of radiological outcomes. We found no statistical difference between DCI and ACDF group in overall ROM (WMD: 6.75, 95% CI: [-0.93, 14.43], P=0.08, I^2=69%, **Figure 4**). The overall ROM of CTDR group was significantly higher compared with DCI group (WMD: -2.65, 95% CI: [-4.53, -0.78], P=0.006, I^2=0%, **Figure 4**). Significant heterogeneity was identified between the DCI and ACDF group in overall ROM. The DCI group had significant higher treated segmental ROM than that of ACDF group (WMD: 8.04, 95% CI: [7.19, 8.88], P=0.91, I^2=0%, **Figure 5**). The DCI group presented significant lower cephalad segmental ROM than that of ACDF group (WMD: -1.56, 95% CI: [-1.82, -1.31], P=0.71, I^2=0%, **Figure 5**), as well as the caudal segmental ROM (WMD: -1.44, 95% CI: [-1.71, -1.18], P=0.37, I^2=4%, **Figure 5**). No significant difference was identified in cephalad segmental ROM (WMD: -0.34, 95% CI: [-0.91, 0.23], P=0.29, I^2=20%, **Figure 5**), treated segmental ROM (WMD: 0.03, 95% CI: [-1.63, 1.68], P<0.00001, I^2=91%, **Figure 5**) and caudal segmental ROM (WMD:

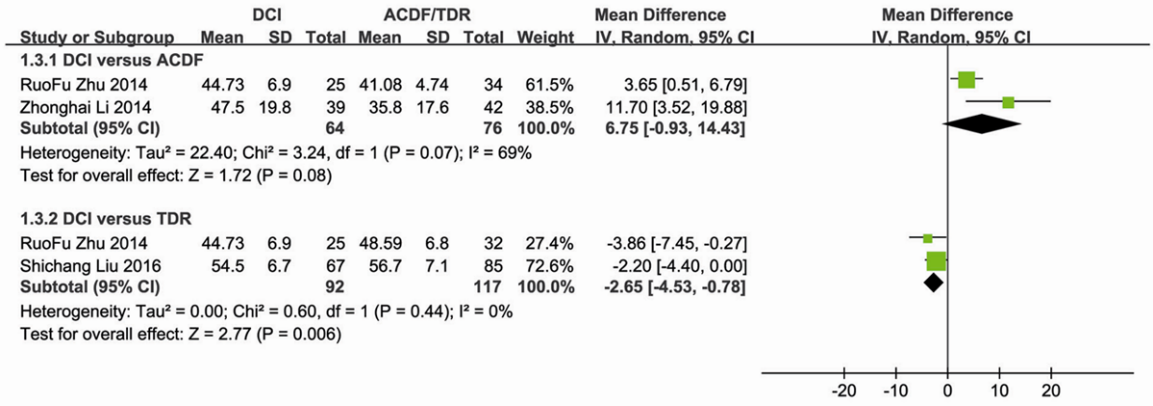

Figure 4. Comparison of overall ROM.

0.34, 95% CI: [-0.17, 0.86], P=0.99, I^2=0%, **Figure 5**) between DCI group and CTDR group. However, obvious heterogeneity was detected between DCI group and CTDR group in treated segmental ROM.

Discussion

ACDF is considered as the "gold standard" technique for symptomatic CDDD and has achieved satisfactory outcomes [30, 31]. Although ACDF is successful, Hilibrand *et al.* reported that the occurrence of symptomatic ASD was 2.9% per year after operation, and 25.6% of the patients might developed ASD within 10 years [2]. Besides, biomechanical studies indicated that fusion of the treated segment increased the stress faced by the adjacent segment, which theoretically accelerates the occurrence of ASD [5, 6]. The concern for ASD, and to mimic the native physiological activity of the cervical spine had led to the development of motion preserving technique CTDR. Previous studies demonstrated the safety and efficacy of CTDR as a feasible alternative to ACDF in the treatment of symptomatic CDDD [7-9]. Furthermore, CTDR has been found to have a lower rate of ASD compared with ACDF [10]. However, the development of HO is considered to be one of the major complications following CTDR [11-15]. In addition, biomechanical researches indicated that the sliding articulation of artificial cervical disc might not satisfactorily control the motion. Consequently, hyper-mobility would occur to the operated segment, as well as an increase of the facet joint stress [16, 17]. These may accelerate the degeneration of the facet joint and affect the outcome of long-term follow-up of CTDR.

DCI is a newly emerged U-shaped implant that represents a completely new cervical implant philosophy. It was originally designed to combine the advantages of arthrodesis and CTDR. Compare with CTDR, DCI has the following characteristics: (1) the U-shaped structure functions as a shock absorber which may protect the adjacent segments from excessive stresses [19]; (2) it restricts excessive flexion and extension, and can nearly blocks rotation and lateral bending, thus, theoretically protecting the facet joint from excessive stress; (3) it can be used in a wider scope, such as patients with serious degeneration of facet joint; (4) without a metal-polyethylene articulating surface, local or systemic reaction to the wear debris will decrease.

Our meta-analysis indicated that no significant difference was identified between DCI and CTDR group in operative time, intraoperative blood loss, JOA, and NDI scores. Our study also shown that there was no difference between DCI group and ACDF group in operative time, intraoperative blood loss, VAS neck and arm and JOA scores, except NDI scores. In fact, only two studies compared the NDI scores between DCI and ACDF in the included studies. The small sample size may be responsible for the surprising result. In other words, DCI is as safe and effective as ACDF and CTDR in the treatment of CDDD. Based on our results, we believe that most of the relief of clinical symptoms after cervical spine surgery depends on a successful and complete decompression rather than the type of the implant device.

Regarding the radiology outcome, our study indicated that the treated segmental ROM of

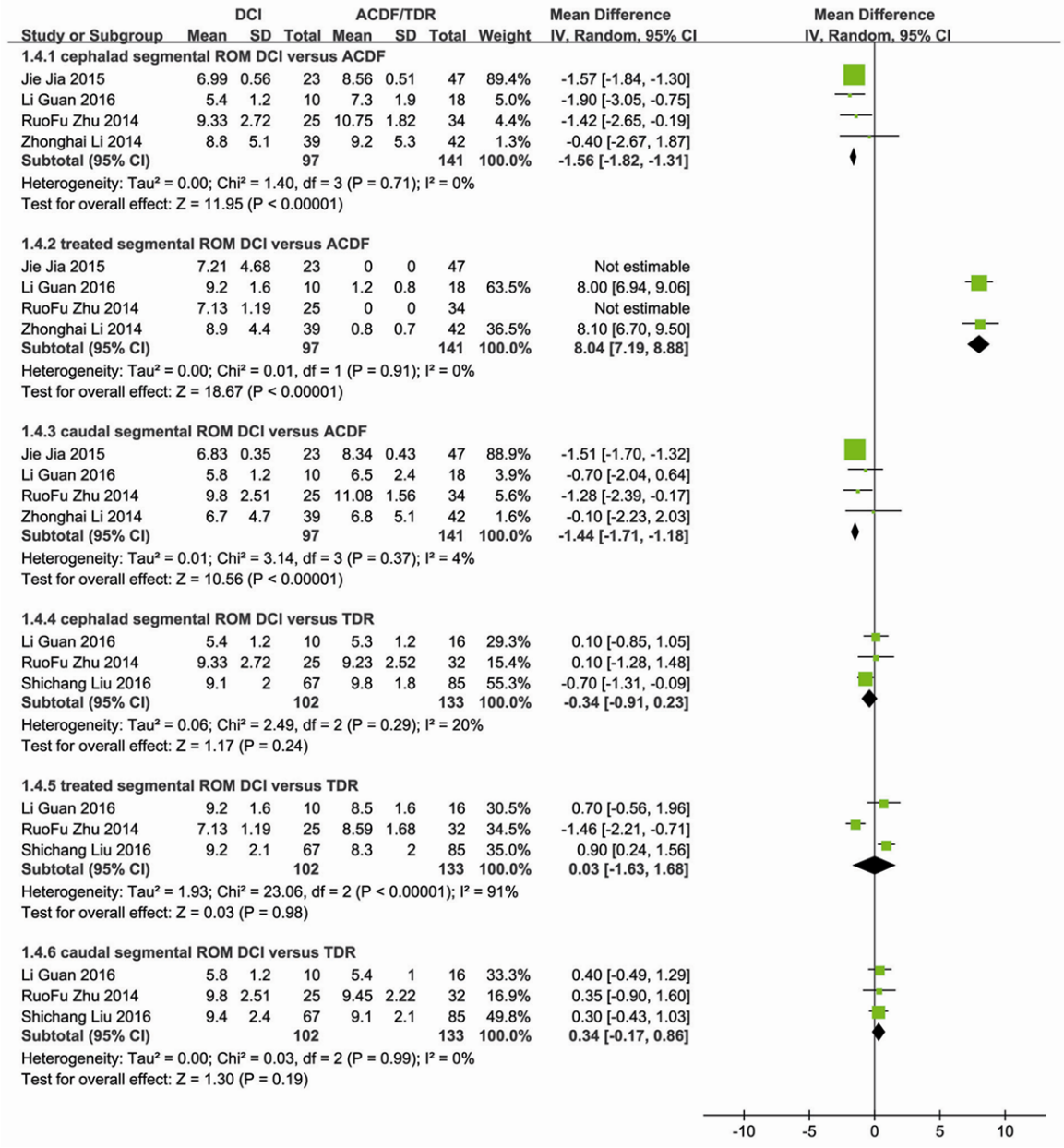

Figure 5. Comparison of segmental ROM.

DCI group was higher than ACDF group, while both cephalad and caudal segmental ROM of DCI group were lower than ACDF group. This was similar to the conclusion proposed by Mo et al. [16]. Due to the fusion of the treated segment, the ROM of the treated segment is 0° theoretically. In order to compensate the loss motion, the motion of the adjacent segments increased. It may accelerate the degeneration of the adjacent segment or increase the incidence of ASD. Compared with ACDF, DCI may retain a certain motion of the treated segment, thus reducing the stress of the adjacent segment, and theoretically slowing down the degeneration of the adjacent segment or decreasing the incidence of ASD. Our study suggested that there was no difference between DCI group and ACDF group in overall ROM. We think the increased motion of adjacent segments compensated the loss motion of the treated segment in ACDF.

Mo *et al.* [16] conducted a biomechanical model and finite element analysis in 2014, found that the ROM of treated segment of CTDR was increased while that was slightly reduced

in DCI. They concluded that the hypermobility of the treated segment increased the stress of the facet joints in CTDR; the semi-restrictive activity of DCI maintained the ROM of the treated segment as well as prevented excursive movement of the corresponding facet joints. Zhu *et al.* [28] reported a reduced postoperative treated segment ROM and an equal postoperative adjacent segment ROM compared with the preoperative ones in DCI group. However, we found no significant difference in cephalad, treated, and caudal segmental ROM between DCI group and CTDR group. The results of the present meta-analysis are consistent with the study conducted by Liu *et al.* [29]. They reported that the ROMs in treated, cephalad, and caudal segments were of no significant difference at final follow-up in both DCI and CTDR group compared with the preoperative ones. In another word, our meta-analysis indicated that insufficient evidence to support that DCI may decrease the stress of facet joints compared to CTDR.

First, because of the lack of related RCTs, the level of the evidence is relatively low. Second, because only six studies were included, the sample size was small. Due to these limitations, the results of our study should be interpreted with caution and high-quality RCTs with long-term follow-up are needed to confirm these results.

This meta-analysis indicates that DCI is an effective and safe surgical procedure compared with ACDF and CTDR for the treatment of CDDD. DCI may possibly maintain the ROM of treated segment and delay the occurrence of ASD. However, there is a lack of evidence support that DCI may decrease the stress of facet joints compared to CTDR. Further studies with long-term follow-up are needed.

Disclosure of conflict of interest

None.

Address correspondence to: Hao Liu, Department of Orthopaedic Surgery, West China Hospital, Sichuan University, 37 Guoxue Lane, Chengdu 610041, Sichuan Province, China. Tel: +86 18980601369; E-mail: liuhao6304@126.com

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