Comprehensive Analysis of Hybrid Surgery and Anterior Cervical Discectomy and Fusion in Cervical Diseases
A Meta-Analysis

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Abstract
To investigate the outcomes and reliability of hybrid surgery (HS) versus anterior cervical discectomy and fusion (ACDF) for the treatment of multilevel cervical spondylosis and disc diseases.

Hybrid surgery, combining cervical disc arthroplasty (CDA) with fusion, is a novel treatment to multilevel cervical degenerated disc disease in recent years. However, the effect and reliability of HS are still unclear compared with ACDF.

To investigate the studies of HS versus ACDF in patients with multilevel cervical disease, electronic databases (Medline, Embase, Pubmed, Cochrane library, and Cochrane Central Register of Controlled Trials) were searched. Studies were included when they compared HS with ACDF and reported at least one of the following outcomes: functionality, neck pain, arm pain, cervical range of motion (ROM), quality of life, and incidence of complications. No language restrictions were used. Two authors independently assessed the methodological quality of included studies and extracted the relevant data.

Seven clinical controlled trials were included in this study. Two trials were prospective and the other 5 were retrospective. The results of the meta-analysis indicated that HS achieved better recovery of NDI score (P=0.038) and similar recovery of VAS score (P = 0.058) compared with ACDF at 2 years follow-up. Moreover, the total cervical ROM (C2–C7) after HS was preserved significantly more than the cervical ROM after ACDF (P = 0.000) at 2 years follow-up. Notably, the compensatory increase of the ROM of superior and inferior adjacent segments was significant in ACDF groups at 2-year follow-up (P < 0.01), compared with HS.

The results demonstrate that HS provides equivalent outcomes and functional recovery for cervical disc diseases, and significantly better preservation of cervical ROM compared with ACDF in 2-year follow-up. This suggests the HS is an effective alternative invention for the treatment of multilevel cervical spondylosis to preserve cervical ROM and reduce the risk of adjacent disc degeneration. Nonetheless, more well-designed studies with large groups of patients are required to provide further evidence for the benefit and reliability of HS for the treatment of cervical disk diseases.

Abbreviations: ACDF, anterior cervical discectomy and fusion; ASD, adjacent segment disease; CDA, cervical disc arthroplasty; CI, confidence interval; HO, heterotopic ossification; HS, hybrid surgery; NDI, neck disability index; NOS, Newcastle–Ottawa Scale; RCT, randomized controlled trial; ROM, range of motion; RR, risk ratio; VAS, visual analog scale

Key Points:
1. Hybrid surgery achieved better recovery of NDI score and similar recovery of VAS score compared with ACDF in 2 years follow-up.
2. Hybrid surgery showed more preservation of cervical ROM (C2–C7) than ACDF in 2 years follow-up.
3. The compensatory increase of the ROM of adjacent segments after ACDF was significantly higher than HS.

1. INTRODUCTION
Anterior cervical discectomy and fusion (ACDF) has been the standard surgical treatment for cervical spondylosis and disc diseases for decades. It is proved to achieve neural decompression, segmental stabilization, and excellent clinical outcomes.1–3 However, ACDF results in a loss of mobility at the treated segment and increases the stress on adjacent segments, which may
cause more rapid disc degeneration and lead to adjacent segment diseases (ASD).\textsuperscript{5–6} In recent years, cervical disc arthroplasty (CDA) was developed as an alternative procedure to preserve segmental motion and theoretically prevent adjacent segment degeneration.\textsuperscript{7,8} An accumulation of short- and intermediate-term follow-up studies\textsuperscript{9} and a few long-term studies\textsuperscript{10,11} demonstrate the legitimacy of CDA. The theoretical advantages of CDA include: preservation of the motion patterns and the range of motion (ROM), reconstitution of disc height and spinal alignment, and earlier recovery of cervical function. However, in cases of multilevel cervical spondylosis and disc diseases, the affected discs may show different types and degrees of degeneration at each level. Consequently, CDA may not be suitable for all the affected levels, for instance, the levels with no motion, a collapsed intervertebral space, facet degeneration, or bony spurs.\textsuperscript{12} Meanwhile, there is no need to fuse all the affected levels if an alternative, safe, and effective surgery can be performed, because longer fusion may cause larger loss of ROM and greater stress at adjacent levels.

The hybrid surgery (HS), combining CDA with fusion, is a novel treatment for patients with multilevel cervical degenerated disc disease in recent years. The rationale of HS comes from the notion that the most suitable treatment should be utilized at each cervical disc, respectively, based on the deferent status of cervical levels.\textsuperscript{13} Previous meta-analysis reviews focus on the comparison between single-level CDA and ACDF; however, the clinical and radiologic outcomes of HS compared with ACDF in patients with multilevel degenerated disc disease are less clear. The purpose of this meta-analysis is to compare outcomes of HS with ACDF in multilevel cervical disc diseases to evaluate the safety, efficiency, and reliability of HS.

2. MATERIALS AND METHODS

2.1. Search Strategy

To search all of the relevant literature, we conducted a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)-compliant search of Medline, Embase, Pubmed, Cochrane library, and Cochrane Central Register of Controlled Trials (CENTRAL) by using combinations of the following keywords “hybrid surgery,” “cervical disc arthroplasty,” “cervical artificial disc replacement,” “cervical prosthesis,” “anterior-cervical disectomy and fusion,” “cervical disc arthroplasty combined with fusion,” “artificial disc replacement combined with fusion,” and “total disc replacement combined with ACDF.” We searched for randomized controlled trials (RCTs), prospective and retrospective clinical controlled trials published between January, 1990 and December, 2015 that compared HS with ACDF. We placed no restrictions on the language of the publication. References cited in the relevant articles were also reviewed. All researches were carefully estimated to identify repeated data. Criteria used to define duplicate data included study centers, treatment information, and any additional inclusion criteria.

2.2. Inclusion and Exclusion Criteria

Clinical trials that conformed to the following criteria were eligible for inclusion in this study: original clinical trials; studies that include HS compared with ACDF; and studies with follow-up more than 1 year. We excluded in vitro human cadaveric biomechanical studies, articles that were duplicate reports of an earlier trial, reviews, and case-reports.

2.3. Data Extraction

Two of the authors extracted the data from eligible studies independently, discussed discrepancies, and reached conformity for all items. The indispensable information extracted from all primary researches included the titles, author names, year of publication, original country, study design, sample size, type of arthroplasty prosthesis, duration of follow-up, and outcome parameters. The corresponding author of each study was contacted to obtain any missing information if it was required. This study included 7 clinical controlled trials from different countries, in each trial the comparison of these 2 different surgical methods was studied in the same center. The extracted data were rechecked for accuracy or against the inclusion criteria by the corresponding author.

2.4. Outcomes

The following outcomes were extracted from the included publications.

1. Disability was assessed postoperatively using the neck disability index (NDI).
2. Pain was assessed using the arm and neck visual analog scale (VAS).
3. Total cervical ROM (C2–C7) was assessed by dynamic flexion and extension lateral cervical radiographs.
4. ROM of superior and inferior adjacent levels was also obtained.
5. Complications: heterotopic ossification (HO), adjacent disc degeneration, implant subsidence, dysphagia, dysphonia, limb symptoms, dural/spinal cord injury, and infections.
6. Quality of life: health score, SF-36 score, and EQ-5D.

2.5. Quality Assessment

The quality of each study was independently assessed by the authors according to the Newcastle–Ottawa Scale (NOS). The manual was downloaded from Ottawa Hospital Research Institute online. The NOS uses a pentagram symbol “*” rating system (a pentagram symbol stands for 1 score) to judge quality of cohorts based on 3 aspects of the cohort studies: selection, comparability, and outcomes. Scores were ranged from 0 to 9. Studies with a score ≥ 7 were regarded to be of high quality.

2.6. Statistical Analysis

We performed all meta-analyses with the STATA 12.0 (StataCorp LP, College Station, TX). For continuous outcomes, means and standard deviations were pooled to generate a mean difference, and 95% confidence intervals (CIs) were generated. For dichotomous outcomes, the risk ratio or the odds ratio and 95% CI were assessed. A probability of $P < 0.05$ was considered to be statistically significant. Assessment for statistical heterogeneity was calculated using the $I^2$ tests, which described the proportion of the total variation in meta-analysis assessments from 0% to 100%.\textsuperscript{13} The random effects model was used for the analysis when an obvious heterogeneity was observed among the included studies ($I^2 > 50\%$). The fixed-effects model was used
when there was no significant heterogeneity between the included studies ($I^2 \leq 50\%$). The possibility of publishing bias was not evaluated because there were less than 10 studies assessed.

We performed this article based on the methods recommended by Cochrane collaboration and reported the summarized results according to PRISMA statement. As our study was performed based on previous studies, so the ethical approval and informed consent were not required.

3. RESULTS

2.7. Study Characteristics

By searching in PubMed, Embase, Medline, Cochrane library, and CENTRAL, 87 studies were initially identified. A total of 74 studies were excluded because they did not meet the inclusion criteria. A flow diagram of the selection process for relative articles is shown in Figure 1. Finally, 7 studies were included into our meta-analysis and the characteristics are presented in Table 1. Out of the 7 studies, 2 are designed as prospective trials and the other 5 are retrospective. Totally, 109 patients were undergone HS and 127 patients were undergone ACDF for multilevel cervical disc diseases.

2.8. Quality Assessment

Assessment of the study specific quality scores from NOS system is shown in Table 2. The median score of included studies was 7.43, with a range from 6 to 8, and 6 of the 7 studies were identified as relatively high-quality.
Table 1
Patient and Study Characteristics of the 4 Included Studies in the Meta-Analysis.

| Source       | Study Location | Trials Design | Sample Size | Mean Age, years (Range) | Gender (M/F) | Follow-Up, month (Range) |
|--------------|----------------|---------------|-------------|-------------------------|--------------|--------------------------|
| Giovanni 2015 | Italy          | Retrospective | 20          | 44.2 ± 9.8              | 11/9         | 6.12 - 24                |
| Mei 2015     | China          | Retrospective | 20          | 47.3 ± 9.8              | 10/10        | 6.12 - 24                |
| Ding 2014    | China          | Retrospective | 13          | 55.4 ± 4.7              | 76           | 9.70 - 12/11             |
| Kang 2013    | China          | Prospective   | 12          | 50.2 ± 7.5              | 9/6          | 24                       |
| Hey 2013     | Singapore      | Retrospective | 7           | 78 ± 6.5                | 24 - 25      | 24 - 25                  |
| Shen 2013    | China          | Retrospective | 18          | 54.2 ± 35               | 11/17        | 24.1 - 34                |
| Shin 2009    | Korea          | Prospective   | 20          | 46.8 ± 28               | 22/18        | 24                       |

ACDF = anterior cervical discectomy and fusion.

2.9. Outcomes Analysis

Comparison between the HS and ACDF was based on usual clinical outcomes and functional recovery, including NDI, VAS, total cervical ROM, superior segmental ROM, inferior segmental ROM, reoperation rate, HO, and quality of life satisfaction (EQ-5D, SF-36 score, and health score). The age, gender, affected levels, NDI, and VAS score were comparable preoperatively between the 2 groups (P > 0.05) in these studies.15-21

2.10. NDI

Seven studies reported a postoperative NDI score of HS and ACDF. All of the 7 trails completed 2-year follow-up. The meta-analysis showed that the between-study heterogeneity was high (I² = 72.8%), in this case a random effects model was used to calculate the summary risk ratio with corresponding 95% CI. The standardized mean difference (SMD) was −0.532 for the NDI (95% CI = −1.074 to −0.030; z = 2.07, P = 0.038), indicating that HS showed lower NDI than ACDF at 2-year follow-up (the diamond located on the left of the null line) (Figure 2). Through analyzing the data, we found out the high heterogeneity comes from the study of Shin et al.18 After exclusion of this study, the heterogeneity was apparently reduced (I² = 48.6%). A fixed effects model was used to show that the SMD was −0.245 for the NDI (95% CI = −0.330 to 0.041; z = 1.68, P = 0.093), indicating there was no significant difference in NDI between the 2 groups at 2-year follow-up (Figure 3). In the forest plots, the overall effect estimate was showed by the diamond of total or subtotal 95% CI, when overlapped the vertical line of no effect (P ≥ 0.05), indicating there was no statistically significant difference in NDI score between the 2 treatment groups.

2.11. VAS

Seven studies reported neck VAS score postoperatively at 2-year follow-up and the data were pooled to be analyzed. The fixed effects model was used because the heterogeneity was not significant (I² = 5.3% in 2-year follow-up). The data at 2-year follow-up showed no significant difference in VAS score between HS and ACDF (SMD = −0.254, 95% CI = −0.517 to 0.006; z = 1.89, P = 0.058) (Figure 4).

2.12. ROM of C2–C7

The total cervical ROM (C2–C7) was reported postoperatively in the 7 included studies at 2-year follow-up. Three studies15,17,18 stated there was no significant difference of cervical ROM in hybrid groups at 2-year postoperatively compared with preoperative ROM (P > 0.05), indicating HS could preserve cervical ROM effectively. On the contrary, the ROM was significantly lost postoperatively in ACDF groups at 2-year follow-up (P < 0.05). Only 1 study16 reported no significant difference of the total ROM 2 years postoperatively between HS and ACDF (P > 0.05). Our meta-analysis of the pooled data showed that HS significantly preserved more ROM of C2–C7 than ACDF at 2-year follow-up (SMD = 0.700, 95% CI = 0.332–1.068; z = 3.73, P = 0.000) (Figure 5).

Table 2
Methodological Quality of Studies Included in the Meta-Analysis Assessed by the Newcastle–Ottawa Scale.

| Studies      | Selection | Comparability | Outcome | Total score |
|--------------|-----------|---------------|---------|-------------|
| Giovanni 2015 | ★★        | ★★            | ★★      | 7           |
| Mei 2015     | ★★        | ★★            | ★★      | 8           |
| Ding 2014    | ★★        | ★★            | ★★      | 8           |
| Kang 2013    | ★★        | ★★            | ★★      | 7           |
| Hey 2013     | ★★        | ★★            | ★★      | 8           |
| Shen 2013    | ★★        | ★★            | ★★      | 8           |
| Shin 2009    | ★★        | ★★            | ★★      | 6           |

The Newcastle–Ottawa scale contains 8 items that are divided into 3 categories: selection (4 items, 1 star each), comparability (1 item, up to 2 stars), and exposure/outcome (4 items, 1 star each). A ★★★ presents a “high-quality” choice of individual study.

Figure 2. Forest plot of the meta-analysis of the NDI score comparing hybrid surgery with ACDF by a random effects model. Seven studies with high heterogeneity (I² = 72.8%) were analyzed to calculate the summary risk ratio with corresponding 95% CI. The SMD was −0.552 for the NDI (P = 0.038, the diamond locates on the left of the null line), indicating that hybrid surgery showed lower NDI than ACDF at 2-year follow-up. ACDF = anterior cervical discectomy and fusion, CI = confidence interval, NDI = neck disability index, SMD = standardized mean difference.
2.13. ROM of Adjacent Segments

Four studies reported ROM of the superior and inferior adjacent segments at 2-year follow-up and 2 studies reported 1-year follow-up. They reported that the ROM of adjacent segments at 1 or 2 years after HS did not differ significantly from that preoperatively (P > 0.05). However, the superior and inferior adjacent segments in ACDF group displayed a significantly increased ROM at 2 years postoperatively when compared with preoperative ROM (P < 0.05), which was considered as a cause to the long-term cervical disc degeneration at the adjacent levels. Also the difference between the 2 groups was significant at 2-year follow-up.\(^\text{15,17,18}\) The meta-analysis showed that ACDF significantly increased ROM of the superior and inferior adjacent segments at 2 years postoperatively compared with HS. ROM of the superior segment: (2-year follow-up: SMD = -0.875, 95% CI = -1.228 to -0.521; \(z = 4.85, P = 0.000\); the diamond located on the left of the null line) (Figure 6). ROM of the inferior segment: (2-year follow-up: SMD = -0.720, 95% CI = -1.067 to -0.373; \(z = 4.07, P = 0.000\); the diamond located on the left of the null line) (Figure 7).

2.14. Adverse Events

The included studies did not report significant difference of the complications between the HS and ACDF. Kang et al\(^\text{15}\) reported that 1 patient developed HO without the need of further intervention in HS. In ACDF group, 1 patient developed ASD with another surgical intervention after 27 months, and 1 patient with asymptomatic implant subsidence was reported. Hey et al\(^\text{16}\) reported 3 patients had residual limb symptoms that improved 6 weeks postoperatively, and 1 patient had dysphagia which resolved at 2 weeks after surgery. No significant complication was reported in the other 2 studies. Longer-term follow-up and more data were required to analyze the incidence of adverse events after HS and ACDF.

2.15. Quality of Life

Hey et al\(^\text{15}\) reported no significant difference in the quality of life between the patients with HS and ACDF. The value of EQ-5D was 0.264 ± 0.175 in HS group versus 0.689 ± 0.327 in ACDF group (\(P = 0.275\)). The health score was 80 ± 49.33 in HS group versus 70 ± 15.28 in ACDF group (\(P = 0.658\)).
for the treatment of single-level cervical diseases. However, arthroplasty are equivalent or superior to the outcomes of ACDF meta-analysis reports that the clinical outcomes of cervical disc degeneration. However, as a relatively novel treatment, the cervical disc segmental ROM, and prevent long-term adjacent disease, aiming to treat each cervical level with the most suitable combination CDA with fusion to treat multilevel degenerative disc motions and the higher risk of ASD. The design of HS is to be appropriate to perform CDA because the cervical stability may not be compensated for cervical ROM and increase the stress of adjacent cervical levels, which may accelerate the degeneration of cervical disc degeneration combined with instability of cervical spine may not be effective to perform HS because the cervical stability should be reconstructed by ACDF.

The meta-analysis demonstrated that HS preserved similar cervical ROM 2 years postoperatively, compared with preoperative ROM, whereas, the total cervical ROM was significantly decreased postoperatively at 2 years after ACDF. Furthermore, the compensatory increased ROM of the superior and inferior adjacent segments was significant at 2 years after ACDF compared with HS. Therefore, the HS, combining artificial disc replacement and fusion, largely maintains total cervical ROM and the physiological status of adjacent levels. Based on the above data, HS may provide a better alternative treatment for multilevel cervical disc diseases, decreasing the stress on adjacent segments, reducing the risk of adjacent disc degeneration, and averting the drawbacks of multilevel ACDF.

The present study is the first meta-analysis on this topic to investigate the outcomes and efficiency of HS versus ACDF for multilevel cervical disc diseases. There are several strengths and limitations of this study. The strengths include rigorous search strategy, no language limitations, articles screening and methodological assessments performed in duplicate, abstracted data verified by 2nd reviewer, and utilization of the NOS system to judge the quality of the evidence. However, several limitations of this study should be acknowledged. First, there was no RCT comparing the outcomes between HS and ACDF. The studies included were composed of 7 clinical controlled trials, the statistic quality of which was inferior to RCTs. Second, the statistical power could be improved in the future by including more studies. Owing to the small number of included studies, some parameters could not be analyzed by subgroups to avoid a high heterogeneity which may exert instability on the consistency of the outcomes. Third, the follow-up was up to 2 years, which was not enough to observe the long-term recovery and complications. In addition,
the clinical heterogeneity might be caused by the different indications for surgery, various implants, and surgical technologies used at different treatment centers.

In summary, this meta-analysis indicates that the novel HS, combining CDA and fusion, provides equivalent outcomes and functional recovery for cervical disc diseases, even better recovery of NDI and preservation of cervical ROM, reducing the risk of adjacent disc degeneration. However, more well-designed studies with large groups of patients and long-term follow-up are required to provide further evidence for the benefit and reliability of HS in the treatment of multilevel cervical disc diseases.

This article is a republished version of the retracted article “Hybrid Surgery Versus Anterior Cervical Discisectomy and Fusion in Multilevel Cervical Disc Diseases: A Meta-Analysis”, which appears in Volume 95, Issue 21 of Medicine. No other changes have been made to the republished article aside from the title.

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