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Anterior Approaches for Two-Level Cervical Degenerative Disease: A Comparative Study of at least 6-Year Follow-Up

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Conflict of Interest
The authors have no financial conflicts of interest.

ABSTRACT

Objective: To compare the clinical and radiogrincaphic results of a hybrid surgery (HS) and cervical artificial disc replacement (ADR) for contiguous two-level cervical spondylosis.
Methods: A total of 56 patients with contiguous two-level degenerative cervical spondylosis who underwent cervical HS and ADR via an anterior approach and completed at least 6 years of follow-up were included in this study. Patients were divided into two groups: group I, comprising 22 patients who underwent ADR, and group II, comprising 34 patients who underwent HS combined ADR and anterior cervical discectomy and fusion using a cage. Clinical outcomes were evaluated based on the visual analog scale (VAS) scores for arm pain, neck disability index (NDI), and modified MacNab criteria. Radiological parameters were assessed by measuring the bone fusion status, cervical range of motion (ROM C2-C7), heterotopic ossification (HO), adjacent segment disease (ASD) incidence, and fused segment height (FSH).
Results: The VAS scores and NDI significantly improved in both groups, without significant differences between the groups. The incidences of HO, ROM C2–C7, and FSH were similar between groups, without significant differences. New osteophyte formation and osteophyte enlargement at adjacent segments were more frequently found in the HS group; however, the difference was not significant.
Conclusion: Clinical results of this study showed that the clinical efficacy and radiological changes in HS were similar to those of ADR. HS can be an alternative procedure for the treatment of two-level cervical spondylosis.

Keywords: Cervical vertebrae; Arthroplasty; Hybrid

INTRODUCTION

Anterior cervical discectomy and fusion (ACDF) has become the standard surgical treatment for degenerative cervical spine disease, allowing for direct decompression and improving the nerve function.[5] However, ACDF affects the segmental motion at adjacent discs, influencing spinal biomechanics and making abnormal loads that may put additional stress on adjacent discs and accelerate their degeneration.[10]

An artificial disc replacement (ADR) was created as a motion-preserving alternative technique to ACDF for the treatment of degenerative cervical disease at one or two levels, despite the higher costs.[3] Because the spondylotic cervical spine is often related to contiguous two levels, cervical ADR is a desirable alternative to ACDF due to its theoretical advantages, such as motion preservation and reduction of adjacent segment degeneration. However, surgical indications for ADR are relatively narrow compared to ACDF, and not all affected levels may meet acceptable indications for ADR. Furthermore, multilevel ADR may increase the possibility of disqualification of the health insurance coverage with increased medical costs.

For these reasons, the hybrid surgery (HS), combined fusion and non-fusion technique, can provide a balance between ACDF and ADR. Shin et al.[7] reported that two-level HS consisting of ADR combined with ACDF showed better clinical and radiological outcomes in comparison with two-level ACDF. However, as far as the authors' knowledge, few studies have evaluated the clinical and radiological results of a long-term follow-up of ADR and hybrid surgery in contiguous two-level degenerative cervical disease.[11]

Therefore, this study aimed to compare the clinical outcomes with radiological data and procedure-related complications between ADR and hybrid surgery for two-level cervical spondylosis.

MATERIALS AND METHODS

After obtaining approval from the institutional review of our institute, a retrospective review of patients who underwent anterior surgical treatment for contiguous two-level cervical degenerative disease from January 2007 to December 2012 was conducted. The study was approved by the Institutional Review Board (IRB) Institutes and Life Research Committee of the Hospital (IRB No. 2020-06-019-001).

The inclusion criteria were as follows: patients who 1) had signs and symptoms of radiculopathy or myelopathy resistant to conservative treatment, 2) underwent an adjacent two-level anterior surgical procedure for degenerative cervical spondylosis, and 3) had complete clinical and imaging data at least 6 years postoperatively. The exclusion criteria of the patients were as follows: with 1) severe osteoporosis and aged ≥80 years at surgery; 2) active infection, ankylosing spondylitis, or severe ossification of the posterior longitudinal ligament; and 3) a history of definite traumatic injury.

The patients were divided into two groups based on the anterior surgical techniques: Group I, comprised 22 patients who underwent two-level ADR, and Group II, comprised 34 patients who underwent HS of ADR combined with stand-alone cage (**FIGURE 1**).

In the ADR group, all patients had arthroplasties using Mobi-C disc prostheses (LDR, Troyes, France). In Group II (hybrid surgery), cage insertion was performed at the site with more severe degenerative change. For fused segments, a polyetheretherketone cage (Solis®; Stryker, Kalamazoo, MI, USA) or (Impix® cage; Medicrea, Lyon, France) with a demineralized bone matrix (CGDBM®; CGBIO, Seoul, Korea) was used. The cage was filled with a mixture of demineralized bone matrix, and a local osteophyte-derived bone dust was obtained intraoperatively. A Philadelphia neck collar was worn constantly for 3 weeks in group I (ADR)

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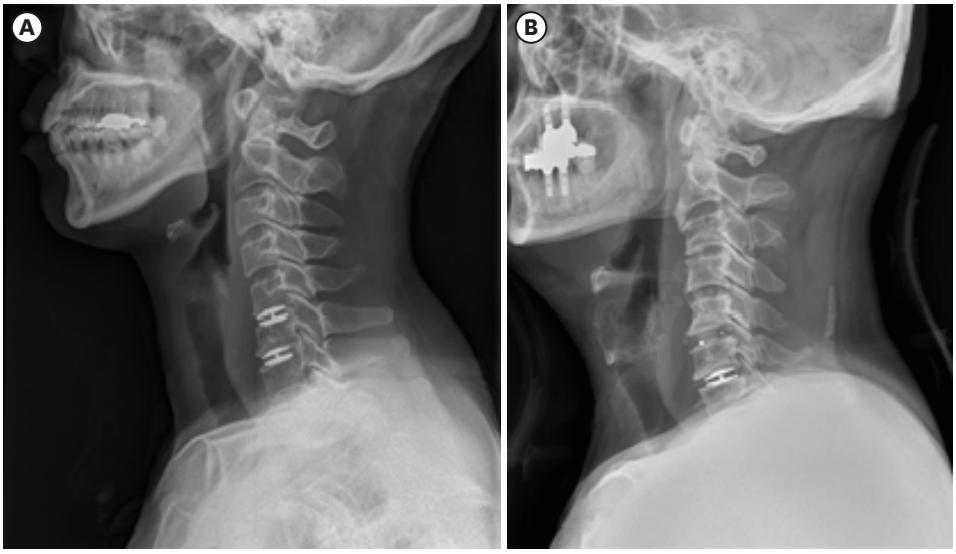

FIGURE 1. Representative cases of each group. (A) Group I (ADR). (B) Group II (Hybrid surgery: combined ADR and anterior cervical discectomy and fusion).
ADR: artificial disc replacement.

and for 3 months in group II. In Group II, 19 patients underwent higher-level fusion and lower-level ADR, and 15 patients underwent higher-level ADR and lower-level fusion surgery.

Serial radiographs obtained preoperatively, at 3 months postoperatively, and at the final follow-up of >6 years were independently analyzed for radiological evaluation. Radiological parameters were assessed by measuring bone fusion status, cervical range of motion (ROM), heterotopic ossification (HO), and incidence of adjacent segment disease (ASD).

Clinical outcomes were evaluated based on the visual analog scale (VAS) for arm pain and neck disability index (NDI). Graft- and instrument-related complications, including dysphagia and hoarseness, were also evaluated. The HO severity or unexpected bone formation after ADR was assessed by identifying anterior osteophytes according to McAfee's classification.[6]

Fusion was defined as the presence of trabecular bone bridging on simple radiographs and the absence of radiolucency between the adjacent vertebral body and graft, as well as the absence of motion at the fused segment.[8] Global cervical lordosis (GCL) was defined as the angle subtended by a line drawn parallel to the inferior endplate of the C2 vertebral body and a line drawn parallel to the inferior endplate of the C7 vertebral body. Cervical ROM was measured as the difference between the GCL in the extended neck position and the GCL in the flexed position. Fused segment height (FSH) was defined as the mean value of the anterior and posterior vertebral heights at the operated levels.

Statistical analysis

All data are presented as means ± standard deviations. All statistical analyses were performed by the SPSS version 12. Statistical significance was set at p of <0.05. Student's t-test was used to evaluate changes between the preoperative and final parameters. The Pearson χ^2 method was also applied to evaluate results between groups.

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TABLE 1. Preoperative demographic data and surgical outcome

Variables	Group I (ADR) (n=22)	Group II (Hybrid) (n=34)	*p* between groups
Age (years)	50±12.2	52±8.4	>0.05
Mean follow-up periods (years)	6.5±1.7	6.3±1.0	>0.05
Sex ratio (M:F)	11:11	18:16	>0.05
Smokers	5 (22.8)	10 (29.4)	>0.05
Obesity (BMI) 25	8 (36.3)	13 (38.2)	>0.05
Symptom			
Radiculopathy	17 (77.3)	24 (70.6)	>0.05
Myelopathy (cord signal change)	5 (22.7)	10 (29.4)	>0.05
Surgical level			
C3-4-5	2	3	
C4-5-6	9	15	
C5-6-7	11	16	

Data are mean±standard deviation or number (%) of patients.
ADR: artificial disc replacement, BMI: body mass index.

RESULTS

A total of 56 patients treated with ADR or hybrid surgery for contiguous two-level cervical spondylosis from 2007 to 2012 were included in this study. No statistically significant differences were observed in the demographic data (**TABLE 1**).

Significant arm pain relief was achieved in both groups at the last follow-up compared to the preoperative values ($p<0.05$). The mean NDI scores were significantly decreased in both groups as compared to preoperative values ($p<0.05$). No significant differences were observed between the groups at the final follow-up (**TABLE 2**). The evaluation using modified MacNab criteria revealed that the percentages of the excellent or good outcomes were 86.3% and 88.2%, respectively, and no significant difference between the two groups was observed.

The mean ROM was slightly decreased in the ADR group (from 42.3°±10.2° to 41.6±8.3) and more decreased in HS group (from 42.2°±6.9° to 35.1°±5.8); however, cervical ROM was maintained in both groups without significant differences between them ($p>0.05$).

The FSHs were slightly increased in the ADR and HS groups (from 56.5 mm±5.3 to 57.3 mm±8.5 and from 56.3 mm±4.3 to 57.8 mm±8.8, respectively). However, no significant difference was observed between the pre- and postoperative FSH levels between the groups ($p>0.05$) (**TABLE 3**). At the final follow-up of more than 6 years, fusion rates at the ACDF level in the HS (group II) showed 100% bone fusion. New osteophyte formation at adjacent segments was observed in three patients (13.6%) in the ADR group and six patients in the HS group (**FIGURE 2**). Enlargement of osteophytes was observed in two and three patients in the ADR and HS groups, respectively. Moreover, prominent disc space narrowing was observed in one patient in the HS group. Although radiographic changes at adjacent segments

TABLE 2. Surgical and clinical outcomes

Outcomes	Group I (ADR)	Group II (Hybrid)	*p* between groups
Operative time (minutes)	80.5±10.3	78.2±10.2	>0.05
Preoperative VAS (arm pain)	6.5±2.0	6.4±1.8	>0.05
Final follow-up VAS	2.1±1.2	2.1±1.3	>0.05
p within groups	<0.05	<0.05	
Preoperative NDI	42.3±10.2	40.5±9.9	>0.05
Final follow-up NDI	20.6±7.5	21.4±8.2	>0.05
p within groups	<0.05	<0.05	

ADR: artificial disc replacement, VAS: visual analogue scale, NDI: neck disability index.

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TABLE 3. Radiographic outcomes

Outcomes	Group I (ADR)	Group II (Hybrid)	*p* between groups
Preoperative ROM (C2–C7)	42.3±10.2	42.2±6.9	>0.05
Final follow-up ROM (C2–C7)	41.6±8.3	35.1±5.8	>0.05
p within groups	>0.05	>0.05	
Preoperative FSH (mm)	56.5±5.3	56.3±4.3	>0.05
Final follow-up FSH	57.3±8.5	57.8±8.8	>0.05
p within groups	>0.05	>0.05	

ADR: artificial disc replacement, ROM: range of motion, FSH: fused segment height.

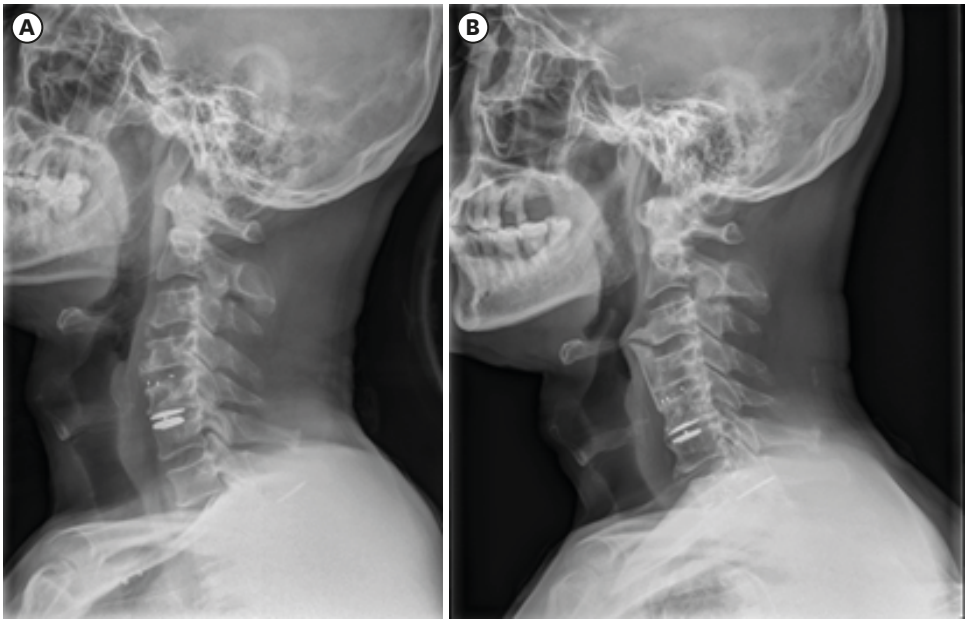

FIGURE 2. A 50-year-old male patient underwent hybrid surgery at the C4-5 and C5-6 levels. (A) A simple lateral radiograph taken 3 months postoperatively shows the good position of the cage at C4-5 and artificial disc at the C5-6 level. (B) Simple lateral radiograph taken 6 years postoperatively reveals severe anterior osteophyte at the C3-4 level and even at the artificial disc replacement level.

TABLE 4. Postoperative complications and radiographic changes

Variables	Group I (ADR)	Group II (Hybrid)	*p* between groups
Operation-related complications			
Dysphagia	0	0	
Hoarseness	0	1	
Subsidence or dislodgement	0	0	
Heterotopic ossification	14	23	
Total	14 (64%)	24 (70%)	>0.05
Radiographic changes at adjacent segments			
New osteophyte formation	3	6	
Osteophyte enlargement	2	3	
Disc space narrowing	0	1	
Total	5 (23%)	10 (29%)	>0.05

ADR: artificial disc replacement.

seemed to be found more frequently in group II, no significant difference was observed in radiographic changes at adjacent segments using the Pearson χ^2 test (p>0.05). Heterotopic bone formation was similarly observed in both groups (**TABLE 4**).

No significant difference was observed in surgery-related complications. Device-related complications, such as cage or artificial disc migration, were also not found.

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DISCUSSION

ACDF for the surgical management of degenerative cervical spondylosis, radiculopathy, and myelopathy is a well-recognized classic and standard procedure.[5]

The degenerative cervical spine occasionally involves contiguous two-level lesions, and interbody fusion using only cages or cages with plate fixation is performed as the primary fusion technique. However, a two-level ACDF may result in much more stress to adjacent discs and a higher rate of pseudoarthrosis and revision than the single-level ACDF.[9]

Several studies have reported that multilevel ACDF increases biomechanical stress, which may accelerate degeneration in adjacent segments and eventually lead to ASD.[3]

An ADR was designed to compensate for the disadvantages of ACDF and has been used as a surgical alternative to replace the cage. However, not all affected levels of degenerative cervical spine could satisfy the acceptable ADR criteria, and health insurance usually does not cover multilevel ADR in Korea. Auerbach et al.[1] reported that just 43% of patients with cervical spine disease could meet the strict ADR criteria. Although surgical criteria were expanded to include the ASD treatment, the percentage of qualifiers increased to just 47%.

In the two-level degenerative cervical spondylosis, studies on the two-level ADR and biomechanics affecting the normal cervical spine motion are limited. HS was devised to overcome shortcomings associated with multilevel ACDF or ADR. The theoretical background of HS is that not all diseased disc levels show the same degree of degeneration. Therefore, the procedure should be tailored based on the degeneration status.

Shin et al.[7] and Kang et al.[4] reported that HS, which consisted of fusion and non-fusion, had better clinical outcomes than two or three ACDF levels in early clinical effects.

In this study, comparison of the clinical and radiological results in the ADR and HS groups with at least 6 years is presented.

Clinical outcomes of the VAS for arm pain and NDI for neck discomfort showed significant improvement in both groups at the last follow-up. According to the radiological results, cervical ROM was maintained in both groups at the final follow-up. This may be related to the ROM preservation at the operated level and may be the ground for better clinical and radiological outcomes, even in the long follow-up period. This maintained ROM in the ADR and HS can help prevent ASD. Although no symptomatic ASD and no revision surgery were observed in this study, the incidence of radiographic ASD increased to 23% in the ADR group and 29% in the HS group. The HS group seemed to have higher frequency of ASD than the ADR group, despite the lack of significant differences. Occurrence of HO and spontaneous bone fusion following implantation are inevitable postoperative adverse events after ADR and decrease the ROM of the operated level, which is contrary to the main goal of artificial discs. In past studies, various results on the occurrence of HO after the cervical ADR were reported.[2,13] In a very long-term follow-up study by Yang et al.[12], the incidence rate of HO was up to 90% in their 30-year follow-up.

In this study, the HO prevalence, a common complication after ADR and HS, was higher in the HS group, with no significance. Similarly, Wang et al.[11] reported no significant

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differences in complications related to surgery and radiological changes at adjacent segments for the treatment of two-level cervical spondylosis. For these reasons, degeneration of the cervical spine should be considered before HS.

This study has some limitations, despite a minimum of 6-year follow-up study. First, selection bias may be inevitable in this retrospective study. Second, a relatively small number of patients were associated with limited power of statistical evaluation. Results should be interpreted with caution, and large-scale, long-term follow-up studies are recommended.

CONCLUSION

The efficacy of HS was similar to that of a two-level ADR in terms of clinical and radiological results. HS can be an alternative procedure for two-level cervical spine diseases.

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