



## Clinical Study

# Application of a stand-alone anchored spacer in noncontiguous anterior cervical arthrodesis with radiologic analysis of the intermediate segment



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## ABSTRACT

The purpose of this study was to describe the clinical features of noncontiguous cervical degenerative disc disease (cDDD), investigate the efficacy and complications of a stand-alone anchored spacer (SAAS) for patients with noncontiguous cDDD, and present radiologic analysis of the intermediate segment (IS) after skip-level fusion. Nineteen consecutive patients with noncontiguous cDDD who underwent skip-level anterior cervical discectomy and fusion (ACDF) with SAAS from January 2010 to December 2012 were enrolled in this study. Clinical outcomes were assessed preoperatively and at 24 months postoperatively using the Japanese Orthopaedic Association score, Neck Disability Index, and Visual Analog Scale. Overall cervical alignment (OCA) of the cervical spine, and the range of motion (ROM), intervertebral disc height (IDH), disc signal intensity and disc protrusion of IS were measured and compared before and after surgery. Clinical outcomes significantly improved compared to preoperative scores. The OCA was corrected and maintained at 24 months postoperatively compared with preoperative values ( $p < 0.05$ ). There were no significant differences in the ROM and IDH of the IS at each follow-up ( $p > 0.05$ ). However, decreased signal intensity on T2-weighted MRI was evidenced in three mobile IS at final follow-up (20.0%). Skip-level ACDF with SAAS may be an efficacious option for the treatment of noncontiguous cDDD.

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## 1. Introduction

Noncontiguous cervical degenerative disc disease (cDDD) is an uncommon age-related neurological disorder, substantially impairing the quality of life. There is no consensus on the optimal choice of surgical technique or management of the intermediate segment (IS) for this disease. When the topic is limited to preserving the normal IS, noncontiguous arthroplasty seems to theoretically be the best surgical procedure for patients with two noncontiguous symptomatic levels [1]. However, cervical artificial disc replacement is also associated with prosthesis-related complications and adjacent segment disease (ASD) [2–4]. Moreover, non-adjacent disease is often accompanied by severe spondylosis, advanced age or congenital fusion of IS, which may restrict the application of artificial discs in noncontiguous arthroplasty.

In view of the limitations of arthroplasty, anterior cervical discectomy and fusion (ACDF) is a common treatment for patients with noncontiguous cDDD when conservative treatment fails.

Considering the additive biomechanical forces on the IS, some surgeons sacrifice the IS to apply an anterior plate for anterior contiguous fusion. Finn et al. [5] demonstrated that the range of motion (ROM) was only modestly increased in the IS after insertion of a skip-level fusion construct in a cadaveric study and recommended considering skip-level fusion when confronted with non-adjacent disease. Some surgeons may choose noncontiguous ACDF with two anterior cervical plates. Although this method keeps the IS disc intact, there is the risk of adjacent level ossification, dysphagia and additional expense [6–8].

The Zero-P implant (Synthes, Oberdorf, Switzerland), a new stand-alone anchored spacer (SAAS) with zero-profile, has been reported to facilitate neurological improvement and decrease the incidence of postoperative dysphagia, and to provide a similar biomechanical stability to a plate-cage construct [9]. Skip-level ACDF with SAAS, which fuses the involved levels without plates, may be the optimal treatment choice for intractable noncontiguous cDDD. This stand-alone technique without obvious contraindications theoretically preserves the intermediate level disc, and also avoids plate-related complications. However, there are concerns regarding degeneration of the IS after skip-level fusion with SAAS.

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Thus, degeneration of the IS should be evaluated by radiographic measurements and MRI.

The purpose of this study was to describe the clinical features of noncontiguous cDDD, investigate the efficacy and complications of the Zero-P cage for patients with noncontiguous cDDD, and present a radiologic analysis of the IS after skip-level fusion. It is hoped that the information will provide surgeons with a better understanding of this therapeutic option for noncontiguous cDDD.

## 2. Materials and methods

### 2.1. Patient demographics

This is a prospective clinical study approved by the Institutional Ethics Committee of our center. All patients provided written informed consent. All patients suffered from noncontiguous cDDD with myelopathy, radiculopathy, or both, with radiologic diagnosis. The inclusion criteria were noncontiguous cDDD with radiculopathy or/and myelopathy refractory to conservative treatment for at least 6 weeks. The exclusion criteria included noncontiguous cDDD due to ossification of the posterior longitudinal ligament, a requirement of posterior surgery, cervical canal stenosis, cervical trauma, deformity, metabolic bone disease, tumor, cervical instability, active infection, and fracture of the cervical spine.

From January 2010 to December 2012, 21 patients with noncontiguous cDDD underwent skip-level ACDF with the Zero-P device. As two patients were lost to follow-up, 19 (eight men, 11 women) were included in the study. The average age at operation was 58.0 years (range 37–75 years).

### 2.2. Surgical procedure

All surgical procedures were performed by a single senior spine surgeon. After general anesthesia, the patients were placed in the supine position with head extension. An anterior cervical approach and exposure was performed through an oblique right-sided incision. Targeted levels were confirmed by C-arm fluoroscopy. After anterior decompression, trial spacers were used to determine the proper implant shape and size. Then, the corresponding Zero-P implant filled with excised local bone fragments from decompression was inserted into the prepared intervertebral space. When the Zero-P implant was satisfactorily inserted, screws were inserted cranially and caudally to fix the implant. Postoperatively, a soft collar was used for 4 weeks.

### 2.3. Clinical evaluation

The clinical evaluations included the Japanese Orthopaedic Association (JOA) score, Neck Disability Index (NDI), and Visual Analog Scale (VAS). These outcomes were recorded by a blinded physician. The clinical outcomes were collected preoperatively and at 24 months postoperatively. The diagnosis of symptomatic ASD was based on the presence of new symptoms referable to ACDF. Other complications including dysphagia, cerebrospinal fluid leak, hematoma, and instrument failure were also recorded at follow-up visits.

### 2.4. Radiologic evaluation

All patients had preoperative plain radiographs, CT scan, and MRI of the cervical spine. Static and dynamic radiographs were taken immediately postoperatively, and at 3, 6 and 24 months postoperatively. The overall cervical alignment (OCA) was analyzed, determined by tangential lines on the posterior edge of the C2 and C7 bodies on lateral radiographs. The ROM of the IS from

dynamic flexion–extension lateral radiographs and the intervertebral disc height (IDH) of the IS on lateral radiographs were measured and recorded to evaluate degeneration of the IS. IDH was measured using a perpendicular line from the middle of the inferior endplate to the superior endplate in the same disc space (Fig. 1). Bony fusion was defined as  $<2^\circ$  movement on extension–flexion radiographs and the absence of a radiolucent gap between the graft and the endplate [10]. The radiographic parameters were collected preoperatively, and at 3 and 24 months postoperatively. The radiographs were independently measured by two senior neuroradiologists unrelated to the surgical procedures. To correct the intraobserver and interobserver reliability of the radiographic measurements, each observer recorded the measurements twice for each radiograph, and mean values were used for statistical analysis.

Additionally, MRI at 24 months postoperatively was compared with preoperative MRI to evaluate degeneration of the IS. The following MRI findings were investigated: (1) decreased signal intensity (DSI), and (2) disc protrusion. For the assessment of MRI findings, the classification of Matsumoto et al. was used after a minor modification (Table 1) [11]. Increase by at least one grade was considered as progression of degeneration. The pre- and post-operative MRI were independently analyzed by the aforementioned neuroradiologists. The final results were determined by one neuroradiologist. The interobserver reliability of MRI grading by the two neuroradiologists was assessed using the kappa score. The kappa score ranges from 0 to 1, with a higher value indicating better reliability. We considered  $<0.40$  as poor,  $0.40$ – $0.74$  as fair to good, and  $0.75$ – $1.00$  as excellent. All radiographic and MRI measurements were obtained using the Picture Archiving and Communication System (GE Healthcare, Chalfont St Giles, UK).

### 2.5. Statistical analysis

The mean  $\pm$  standard deviation were determined for quantitative data. All statistical analyses were performed using the Statistical Package for the Social Sciences version 17.0 (IBM, Armonk, NY, USA). All continuous data were normalized with the Shapiro–Wilk model. Repeated measures analysis of variance or paired *t*-test was used to assess continuous data between time points.  $p < 0.05$  was considered statistically significant.

## 3. Results

### 3.1. Clinical features

A total of 19 symptomatic noncontiguous cDDD patients received surgical treatment. There were eight men and 11 women (men:women 1:1.4), with a mean age of 58.0 years (range 37–75 years) at operation; 68.4% of these patients were older than 50 years. Of these patients, 52.6% presented with myeloradiculopathy, 26.3% with myelopathy, and 21.1% with radiculopathy. Most (78.9%) patients suffered two noncontiguous levels of cDDD while 21.1% suffered three noncontiguous levels of cDDD. The majority (78.9%) had a mobile IS, while immobile IS (21.1%) was due to congenital fusion or ossification of prevertebral tissue. The vast majority of patients (94.7%) presented with a single IS, while 5.3% had double contiguous IS (fused). Of the total 20 IS, the most common location was C4/C5 (75%), and 75% of the IS (15/20) were mobile. General characteristics including preoperative neurological condition, IS condition and operative variables are shown in Table 2.

### 3.2. Clinical outcomes

The VAS and NDI scores significantly reduced and the JOA score increased compared with baseline values (Fig. 2). The JOA score

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