



## Clinical Study

# Difference in canal encroachment by the fusion mass between anterior cervical discectomy and fusion with bone autograft and anterior plating, and stand-alone cage



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## ABSTRACT

We conducted a prospective randomized study comparing stand-alone cage and bone autograft and plate implants in anterior cervical discectomy and fusion ([www.clinicaltrials.gov](http://www.clinicaltrials.gov), NCT01011569). Our interim analysis showed autologous bone graft with plating was superior to a stand-alone cage for segmental lordosis. During this analysis, we noted a difference in canal encroachment by the fusion mass between the two fusion groups. A narrow cervical spinal canal is an important factor in the development of cervical spondylotic myelopathy, therefore this unexpected potential risk of spinal cord compression necessitated another interim analysis to investigate whether there was a difference in canal encroachment by the fusion mass between the two groups. Patients had a minimum 1 year of follow-up. The Neck Disability Index, neck and arm pain Visual Analog Scales and lateral radiographs, including bone fusion patterns, were evaluated. Twenty-seven (16 males, 11 females, mean age 54.8 years) and 31 (24 males, seven females, mean age 54.5 years) patients were in the cage and plate group, respectively. Both groups improved after surgery. Fusion began at 2.6 months and 1.3 months and finished at 6.7 months and 4.0 months in 24 (88.9%) and 28 (90.3%) patients in the cage and plate group, respectively. Encroachment into the spinal canal by the fusion mass was significantly different between the fusion types, occurring in 21 (77.8%) patients in the cage group versus six (19.4%) in the plate group ( $p = 0.003$ ). There was a high incidence of spinal canal encroachment by the fusion mass in the stand-alone cage group, possibly limiting use in narrow spinal canals.

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## 1. Introduction

Anterior cervical discectomy and fusion (ACDF) with autologous bone graft is currently the gold standard for the surgical treatment of degenerative disc disease of the cervical spine [1,2]. However, this procedure may have complications, including collapse of the graft bone, graft donor site morbidity, screw breakage and pullout and screw/plate migration [1,3–6]. To avoid these complications, the cervical cage was developed and is currently widely used [4,7–11]. The cervical cage is biomechanically more rigid than iliac graft bone, thereby producing good clinical results. Controversy remains, however, regarding its own complications, including cage subsidence, kyphotic deformity, and pseudarthrosis [5,7,8,12].

The authors have been conducting a prospective randomized study comparing stand-alone cage and iliac bone graft with anterior plating, and reported an interim analysis revealing that the segmen-

tal angle at the operated segment was significantly more lordotic in the iliac bone graft with plate group at 12 months postoperatively, compared to the stand-alone cage group [13]. During the interim analysis, the authors noted that there was a difference in canal encroachment by the fusion mass between the two groups. Therefore, this unexpected potential risk of spinal cord compression necessitated an interim analysis to investigate whether there was a difference in canal encroachment by the fusion mass between the two groups.

## 2. Materials and methods

## 2.1. Study design

This study has been conducted after informed patient consent was obtained and the Institutional Review Board of our institute approved the study protocol (H-0804-044-004). The prospective randomized study recruited patients who underwent single-level ACDF between 2008 and 2010 ([www.clinicaltrials.gov](http://www.clinicaltrials.gov),

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NCT01011569). The inclusion criteria were radiculopathy or myelopathy due to cervical disc herniation, spinal stenosis, or hypertrophy of the posterior longitudinal ligaments. We excluded patients who had ossification of the posterior longitudinal ligament, cervical trauma, previous cervical spine surgery, severe osteoporosis, or systemic infection or malignancy. The operative method for single-level ACDF was determined using a random number table after informed consent was obtained, and the surgeon was informed on the day of the operation as to what operative method was to be used by the study coordinator. Enrollment commenced in July 2008 and concluded in December 2010.

During this period, 75 patients consented to participate in the study and these patients were prospectively randomly assigned to one of two groups. A total of 58 patients (ACDF-cage group, 27 patients; ACDF-bone/plate group, 31 patients) were followed for more than 1 year and qualified for the present interim analysis.

## 2.2. Operative technique

As described in our previous report, a standard left-sided Smith-Robinson anteromedial approach to the cervical spine was performed [13]. Briefly, a complete intervertebral discectomy was performed and the cartilaginous end plates were removed by curettage. The posterior longitudinal ligament was removed, and decompression of the spinal cord and nerve root was confirmed.

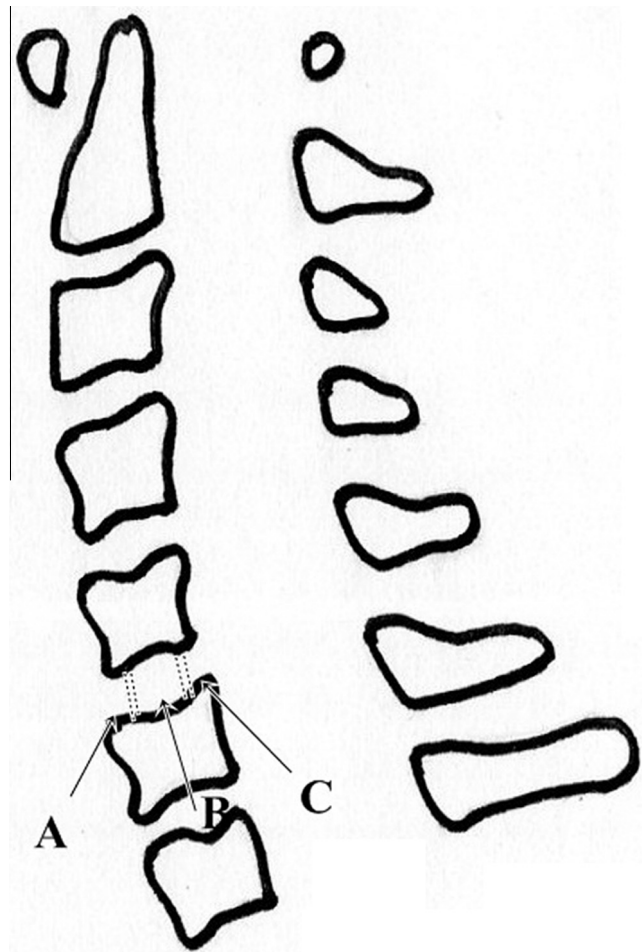
For fusion with the stand-alone cage, the size of the cage was determined after inserting a trial cage with reference to the predetermined height before incising the anterior longitudinal ligament under fluoroscopic control. Two types of cages were used; MC1+ (LDR Medical, France) was used in 13 patients and Solis (Stryker, South Allendale, NJ, USA) was used in 14 patients. The cage was filled with allomaterial (a type 1 collagen/hydroxyapatite matrix; Healos, Depuy Spine, Raynham, MA, USA) soaked with autologous bone marrow aspirated from the iliac crest. An adequate-sized implant was inserted into the disc space by gentle tapping under fluoroscopic control. For fusion with autologous bone graft with anterior plating, all patients received tricortical iliac crest autografts and the grafts were inserted with the cortical surface positioned anteriorly under fluoroscopic control. Two types of semiconstrained anterior plate were applied with variable angled screws; Blackstone (Blackstone Medical, Springfield, MA, USA) was used in 16 patients, and Atlantis (Medtronic Sofamor Danek, Memphis, TN, USA) was used in 15 patients.

## 2.3. Clinical evaluation

The patients filled out an evaluation form which contained a Neck Disability Index (NDI) and both neck and arm pain Visual Analog Scales (VAS) before surgery and at each postoperative follow-up at 1, 3, 6, and 12 months and yearly thereafter. Postoperatively, surgical site pain at the cervical and iliac wounds were evaluated. Clinical and radiological assessments were evaluated by a third party consisting of physician assistants and research nurses blinded to the purpose of this study.

## 2.4. Radiologic evaluation

Preoperative evaluations included plain radiographs (standing anterior-posterior, lateral neutral, and lateral flexion and extension views), CT scans, and MRI. After the operation, plain radiographs were taken at every scheduled follow-up. The fusion initiation area was divided into anterior, interface/internal, and posterior to the inserted cage or iliac bone graft (Fig. 1). Fusion was observed based on the presence of a bony bridge incorporating the graft and the adjacent end plates, and pseudarthrosis was diagnosed if bony bridging was absent [9]. Completion of fusion was defined when



**Fig. 1.** Diagram defining the area where fusion began, defined as anterior (A), interface/internal (B), and posterior (C) to the inserted cage or iliac bone graft.

a bony bridge was seen on the lateral radiograph. To assess encroachment into the spinal canal by the fusion mass, a line was drawn along the middle of the posterior margin of the vertebral body at the operated level on the lateral radiographs (Fig. 2). If the bone mass was found to extend beyond the posterior wall, it was defined as encroaching the canal. Bone fusion initiation time and area, completion of fusion and canal encroachment at the operated level were examined on lateral radiographs at every follow-up in both groups.

## 2.5. Statistical analysis

The  $\chi^2$  test and Fisher's exact test were used for analysis of binary values and the Mann-Whitney U test was used for continuous values. The odds ratio was calculated using logistic regression analysis. All statistical analyses were done with the Statistical Package for the Social Sciences (version 17.0, IBM, Armonk, NY, USA), and statistical significance was defined as  $p < 0.05$ . Results are reported as mean  $\pm$  standard deviation.

## 3. Results

### 3.1. Demographics

A total of 58 patients were analyzed in the present study. Twenty-seven patients were in the stand-alone cage group (16 males, 11 females, mean age  $54.8 \pm 13.2$  years) and 31 patients in the iliac bone graft and plate group (24 males, seven females, mean

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