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Comparative analysis of clinical outcomes between zero-profile implant and cages with plate fixation in treating multilevel cervical spondilotic myelopathy: A three-year follow-up

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ABSTRACT

Objectives: This study aimed to figure out three-year clinical outcomes and complications of ACDF with Zero-p in treating multilevel cervical spondylotic myelopathy (MCSM) by comparing with plate fixation.
Clinical materials and methods: Patients with MCSM caused by degenerative disc herniation only were recruited from April 2010 to December 2010. According to the surgical procedures, the patients were divided into two groups at random, the plate group and Zero-P group. The data was collected before surgery and at three-year follow-up. Clinical parameters, including Japanese orthopedic association (JOA) score, neck disabled index (NDI) were evaluated. Cervical segmental lordosis was calculated and fusion in each level was assessed on lateral radiographs. The Bazaz's criterion and the short Swallowing and Quality of Life (SQOL) questionnaires were used to evaluate the dysphagia incidence and severity respectively. The presence of ALOD was observed and recorded on lateral radiographs.
Results: A total of 72 patients (46 men and 26 women) were recruited. The mean age at operation was 52.9 ± 7.9 years, ranged from 43 to 69 years. There was no significant difference between two groups preoperatively in age, sex, operative levels, JOA, NDI, cervical lordosis, dysphagia incidence, SQOL and ALOD incidence. JOA, NDI and cervical lordosis improved postoperatively and postoperative SQOL got restitution in both groups. However, no difference was detected. There were 7 patients with ALOD in the plate group after surgeries while there was only 1 patient in Zero-P group. The difference of AOLD incidence between them was significant. Of the 7 patients with ALOD in the plate group, 4 patients developed ALOD in cranial level, 2 in caudal level and 1 in both levels. The patient in Zero-P group developed ALOD in caudal level.
Conclusion: Based on the three-year follow-up, we could not conclude that Zero-P was superior to plate fixation in clinical outcomes such as neurological results, cervical lordosis, fusion rate and the incidence and severity of dysphagia in treating MCSM. However, it had the advantage of reducing ALOD incidence which tended to happen in ACDF with plate fixation.

1. Introduction

The surgical choices in treating multilevel (three- or four-level) cervical spondilotic myelopathy (MCSM) are still controversial. Anterior, posterior and combined anterior and posterior approach for MCSM have been reported [1,2]. Recent studies have showed that multilevel anterior cervical discectomy and fusion (ACDF) with plate fixation is safe and effective for treating MCSM [3,4]. However, the complications of multilevel fusion are accompanied by cervical plate including post-op dysphagia and adjacent level ossification development (ALOD) [5,6].

Zero-P, a new kind of cervical interbody cage, consists of titanium alloy plate and PEEK interbody spacer with locking head screws. This design is supposed to decrease the complications such as dysphagia and ALOD caused by plate fixation. So far, some scholars [7–15] have performed some prospective studies and they reported short-term (two or less than two years) clinical outcomes and complications in treating one- or two-level cervical spondilotic myelopathy (CSM). However, few prospective articles have been reported after long-term follow-up (three or more than three years)

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in treating MCSM. In this study, we try to demonstrate three-year clinical outcomes and complications of ACDF with Zero-p in treating MCSM by comparing with plate fixation.

2. Clinical materials and methods

The study was approved by the Committee on Ethics of Biomedicine, Second Military Medical University. Patients with MCSM caused by degenerative disc herniation only were recruited from April 2010 to December 2010 and patients with any one of the following criteria were excluded: the presence of ossification of the posterior longitudinal ligament (OPLL), a history of previous cervical spine surgery, spasmodic torticollis, myasthenia gravis, motor neuron disease, ankylosing spondylitis, scoliosis, cervical spine trauma or tumors and adjacent level ossification. All the surgeries were performed by the same senior surgeon. All patients had typical symptoms and radiographic evidences of cervical spondylosis myelopathy for longer than 1 year and had failed in conservative treatments. According to the surgical procedures, the patients were divided into two groups randomly, the plate group and Zero-P group.

All the patients received tracheal traction exercise 2 days before surgeries. The basic techniques for exposure, discectomy and decompression were performed using a right-sided skin incision. Extensive decompression was performed including removal of the osteophytes, herniated nucleus pulposus and discectomy. Milled autograft was used in both groups. For the plate group, PEEK cages (Solis, Stryker, USA) and plating systems (Atlantic, Medtronic Sofamor, USA) were used. For Zero-P (Depuy Syncage; Depuy Synthes, USA) group, Zero-P cages were used. A soft collar was given to all the patients after surgery with the fixation from 6 to 8 weeks.

Data collection was informed to all the patients orally and all the patients consented to use their clinical materials. The data was collected before surgery and at three-year follow-up. Clinical outcomes, including Japanese orthopedic association (JOA) scores and neck disabled index (NDI) scores were evaluated. The Bazaz's [16] criterion and the short Swallowing and Quality of Life (SQOL) questionnaires [17] were used to evaluate the dysphagia incidence and severity respectively. Anteroposterior, lateral and flexion-extension lateral radiographs before surgery and at three-year follow-up. Three-dimensional CT scan were performed on symptomatic patients or those with other abnormal X-ray imaging postoperatively. Cervical segmental lordosis was calculated by measuring the angle between the superior endplate of the upper most involved vertebra and the inferior endplate of the lower most involved vertebra on lateral radiographs. Fusion in each level was assessed by all the criteria below: (1) the absence of motion >2 mm between the spinous processes on flexion–extension lateral radiographs; (2) the absence of a radiolucent gap between the graft and the endplate; (3) the presence of continuous bridging trabeculae at the graft and endplate junction [18]. ALOD was defined as heterotopic ossification which developed along the cranial or/and caudal part of anterior longitudinal ligament following ACDF while decreased disc height or vertebral slip was not detected in the adjacent levels. Its presence was observed and recorded on lateral radiographs. Two senior radiologists performed all the measurements and calculated the mean value of each parameter was obtained.

The SPSS for Windows Version 17.0 K (SPSS, Chicago, IL) was used for the analysis. Intergroup comparisons were made using T test, Wilcoxon Singed-rank test, or Pearson's X^2 test (Fisher's Exact test). Comparisons of pre- and postoperative clinical and radiologic outcomes were made using Wilcoxon Singed-rank test or paired *t*-test. $P < 0.05$ was considered statistically significant.

Table 1
Comparison of parameters between patients with plate fixation and Zero-P.

	The plate group	Zero-P group	P
No. Of C3-6/C4-7 operative levels	16/22	12/22	0.551
Sex, Male/Female	25/13	21/13	0.724
Age (range), y	56.2 ± 5.7 (43–67)	56.9 ± 5.9 (44–69)	0.616

Table indicating no significant difference was detected between two groups before surgery in the operative levels, sex and age.

Table 2
Comparison between patients with plate fixation and Zero-P in JOA, NDI, lordosis, dysphagia incidence and SQOL.

		The plate group	Zero-P group	P
JOA	Preop	10.16 ± 2.11	10.29 ± 2.15	0.790
	Postop	12.34 ± 1.84	12.15 ± 1.88	0.663
NDI	Preop	13.58 ± 3.17	13.62 ± 3.19	0.960
	Postop	5.63 ± 2.33	5.74 ± 2.53	0.857
Lordosis	Preop	11.08 ± 2.46	11.35 ± 2.58	0.651
	Postop	17.79 ± 1.72	17.53 ± 1.96	0.556
Dysphagia incidence(NO.)	Preop	5.3%(2)	5.8%(2)	0.910
	Postop	5.3%(2)	8.8%(3)	0.555
SQOL	Preop	66.47 ± 1.89	66.59 ± 1.93	0.803
	Postop	66.79 ± 1.99	66.32 ± 2.32	0.480

Table showing no significant difference was found between two groups in JOA, NDI, lordosis, dysphagia incidence and SQOL either before surgery or at three-year follow-up.

3. Results

A total of 72 patients (46 men and 26 women) were recruited. The mean age at operation was 52.9 ± 7.9 years, ranged from 43 to 69 years. The demographics and group distribution was shown in Table 1. There was no significant difference between two groups preoperatively in age, sex and operative levels.

For the neurological results, increased JOA scores and decreased NDI scores were observed in both groups postoperatively. But no significant intergroup difference in any of scoring system was found. The evidence of solid fusion was detected in all the patients in both groups at three-year follow-up. For the cervical lordosis, there was no significant difference in both groups preoperatively. No significant intergroup difference existed at three-year follow-up (Table 2).

Preoperatively there was no difference in dysphagia incidence and SQOL scores between two groups. 2(5.3%) patients in the plate group and 3(8.8%) patients in Zero-p group complained mild dysphagia postoperatively. Decreased SQOL scores were detected in both group. There was no significant intergroup difference between two groups either in dysphagia incidence or in SQOL at the last follow-up (Table 2).

All the adjacent level could be observed on the lateral radiographs. There was no patient with AOLD before surgeries either in the plate group or in Zero-P group. There were 7 patients with ALOD in the plate group after surgeries while there was only 1 patient in Zero-P group. The difference of AOLD incidence between them was significant. However, no patient developed new symptoms or more severe symptoms and needed reoperation at the last follow-up in both groups. Of the 7 patients with ALOD in the plate group, 4 patients developed ALOD in cranial level, 2 in caudal level and 1 in both levels. The patient in Zero-P group developed ALOD in caudal level (Table 3) (Fig. 1).

4. Discussion

ACDF with plate fixation is recommended because of the direct decompression, the restoration of the height of interbody space and the restruction of the cervical lordosis [19]. But the use of an