Outcome Evaluation of Zero-Profile Device Used for Single-Level Anterior Cervical Discectomy and Fusion with Osteoporosis Compared without Osteoporosis: A Minimum Three-Year Follow-Up Study

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OBJECTIVE: **We compared the mid-term efficacy and safety of anterior cervical discectomy and fusion (ACDF) using a Zero-Profile device for cervical degenerative disc disease (CDDD) with and without osteoporosis.**

METHODS: **We performed a retrospective study of elderly patients with CDDD treated by single-level ACDF with a Zero-Profile device. The patients were divided into group A (osteoporosis) and group B (no osteoporosis) according to the bone mineral density. The clinical outcomes (Japanese Orthopaedic Association, neck disability index, visual analog scale, and short-form 36 scores), radiological outcomes (cervical lordosis and fusion rate), and complications were reviewed at each follow-up examination.**

RESULTS: **All procedures were successfully performed in all patients. The Japanese Orthopaedic Association, neck disability index, visual analog scale, and short-form 36 scores and cervical lordosis were significantly improved postoperatively in both groups ($P < 0.05$). However, no significant difference was found between the 2 groups at each follow-up point ($P > 0.05$). No significant difference was found in the fusion rate at 3 months postoperatively (group A, 88.9%; group B, 90.0%), dysphagia rate at 1 month postoperatively (group A, 11.1%; group B, 15.0%), or cage subsidence rate at the final follow-up visit (group A, 11.1%; group B, 10.0%; $P > 0.05$). All patients achieved solid fusion, and no patient had dysphagia at the final follow-up examination.**

CONCLUSIONS: **ACDF with the Zero-Profile device can be used as an effective and reliable treatment for single-level CDDD with osteoporosis.**

INTRODUCTION

Anterior cervical discectomy and fusion (ACDF) was first described by Smith and Robinson[1] in the 1950s and has been considered as the reference standard for the treatment of symptomatic cervical degenerative disc disease (CDDD) refractory to conservative management.[2] It has been reported that 2% of all patients with CDDD were identified as having osteoporosis and of which ACDF accounted for 63.35%.[3] Of spine surgery patients aged >50 years, 51.3% of women and 14.5% of men will have osteoporosis.[4] The prevalence of osteoporosis has been ~34.1%–37% among women aged >50 years, significantly greater than that in men (7%) in China.[5] With an increasing life expectancy, the prevalence of osteoporosis among patients with CDDD who require ACDF will continue to increase.

Osteoporosis is a condition in which bone strength is compromised owing to deterioration in bone mass and quality.[6] A multivariate regression analysis showed that osteoporosis was

Key words
- Anterior cervical discectomy and fusion
- Cervical degenerative disc disease
- Dysphagia
- Fusion
- Osteoporosis
- Subsidence
- Zero-Profile device

Abbreviations and Acronyms
ACDF: Anterior cervical discectomy and fusion
CDDD: Cervical degenerative disc disease
JOA: Japanese Orthopaedic Association
NDI: Neck disability index
SF-36: Short-form 36
VAS: Visual analog scale

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1 of major factors for an increased risk of revision surgery after cervical spine surgery.[3] Management of CDDD with osteoporosis is challenging. The inherent poor bone stock increases the risk of failure of the instrumentation, including screw pull out and interbody cage subsidence.[7,8] Moreover, it has been demonstrated that patients with osteoporosis experience slower and less reliable bone healing,[9-11] which could increase the complications such as pseudoarthrosis, adjacent level degeneration, and progressive junctional kyphosis and, thus, the revision surgery rate.[3] Consequently, patients with CDDD plus osteoporosis require, not only appropriate osteoporosis treatment, but also effective and rigid instrumentation.

The conventional autologous iliac bone graft or interbody cage with anterior locking plate has the advantages of immediate postoperative stability, a greater fusion rate, and a lower incidence of pseudarthrosis.[12,13] However, anterior plating has been associated with a number of potential disadvantages such as a greater incidence of dysphagia and soft tissue injury and a greater incidence of adjacent level disease.[14-16] A new Zero-Profile device was recently developed to reduce the complications of traditional cervical plate construct and maintain the benefits of an interbody cage with a plate construct.[17,18] Many studies, including our previous study documenting the use of the Zero-Profile device for single- and multilevel ACDF, have shown a lower incidence rate of complications, especially dysphasia, and equivalent radiographic and clinical results.[19-21]

It has been reported that cancellous bone is more affected by osteoporosis than cortical bone; therefore, osteoporosis has been a major factor in poor screw fixation, screw or plate dislodgement, and fixation failure.[22,23] Only 56% of lumbar interbody fusion procedures in patients with osteoporosis had achieved solid fusion at the 2-year follow-up point, with a rate of pedicle screw loosening of 45% and cage subsidence of 54%.[24] However, solid fusion was achieved in all 75 patients with moderate to severe osteoporosis who had undergone anterior corpectomy and reconstruction with titanium mesh cage and dynamic cervical plate in the study reported by Yan et al.[25] Although an average of 2.8–4.2-mm cage subsidence had occurred at the 11-month follow-up visit, no anterior implant failure was reported.[25] It is reasonable to assume that the options for adequate fixation will be limited when patients with severe osteoporosis present for surgical consultation.[7]

We found that the Zero-Profile device used in ACDF could lead to similar clinical and radiological outcomes compared with use of the cage and plate and a lower incidence and shorter duration of dysphagia than in our pervious study.[21] Whether the Zero-Profile device is appropriate for single-level ACDF with osteoporosis is still unknown. Few studies have reported on the efficacy of the Zero-Profile device for ACDF with a focus on patients with osteoporosis. The aim of the present study was to compare the mid-term efficacy and safety of the Zero-Profile device in the treatment of single-level CDDD in patients with and without osteoporosis and determine whether the Zero-Profile device is suitable for single-level CDDD in the presence of osteoporosis.

METHODS

Study Design and Patient Population

The institutional ethics committee of Clinical College of Yangzhou University approved the present retrospective cohort study. From December 2010 to December 2014, 42 patients with single-level CDDD who had undergone ACDF with the Zero-Profile device were included in the present study. All the patients provided written informed consent to participate in the study. All patients had undergone preoperative radiographs (anteroposterior, lateral, and flexion-extension), multiplanar reconstructed computed tomography, magnetic resonance imaging, and a dual-energy X-ray absorptiometry bone mineral density assessment (**Figure 1**). The bone mineral density of the lumbar spine (L2–L4; in g/cm^2) was assessed, and T $\leq$ −2.5 standard deviation was defined as osteoporosis.[6]

The inclusion criteria were as follows: 1) males aged >70 years and females aged >60 years; 2) a diagnosis of osteoporosis without osteoporosis treatment; 3) radiculopathy and/or myelopathy refractory to conservative treatment of ≥6 weeks' duration; 4) a diagnosis of single-level CDDD treated by ACDF with the Zero-Profile device; 5) operative level at C3-C4 to C6-C7; and 6) a follow-up period >36 months. The exclusion criteria were as follows: 1) males aged <70 years and females aged <60 years; 2) multilevel CDDD; 3) a requirement for posterior surgery; 4) the presence of other cervical diseases, including cervical trauma, deformity, infection, tumor, or instability; 5) metabolic bone disease; 6) active infection or uncorrectable bleeding diatheses; and 7) severe comorbidity in the heart, liver, kidney, or lung, causing intolerance to surgery.

Using the T score, the patients were divided into 2 groups: the osteoporosis group (group A; T $\leq$ −2.5 standard deviation) and no-osteoporosis group (group B; T > −2.5 standard deviation). Forty-two patients initially fulfilled the study criteria; however, 4 patients were lost to follow-up. Of the remaining 38 patients available for analysis, 18 were in group A (3 men and 15 women; age range, 60–76 years; mean age, 66.9), and 20 were in group B (8 men and 12 women; age range, 60–78 years; mean age, 67.3 years). No statistically significant differences were found in age, gender, treated levels, and follow-up period between the 2 groups ($P > 0.05$; **Table 1**).

Surgical Management

All surgical procedures were performed as described previously[21] and were performed by the same senior surgeon. The patients were positioned supine with head extension on the operating table after the induction of general anesthesia. An anterior cervical approach was performed through a right-sided Smith–Robinson approach, and the targeted level was confirmed by C-arm fluoroscopy. After complete decompression and endplate preparations had been performed (avoiding excessive removal of the subchondral bone), trial spacers were used to determine the most suitable implant shape and size. Next, an appropriate Zero-Profile device filled with excised local bone fragments from decompression was implanted into the prepared intervertebral space. When the Zero-Profile implant had been satisfactorily inserted, screws were inserted into the superior and inferior

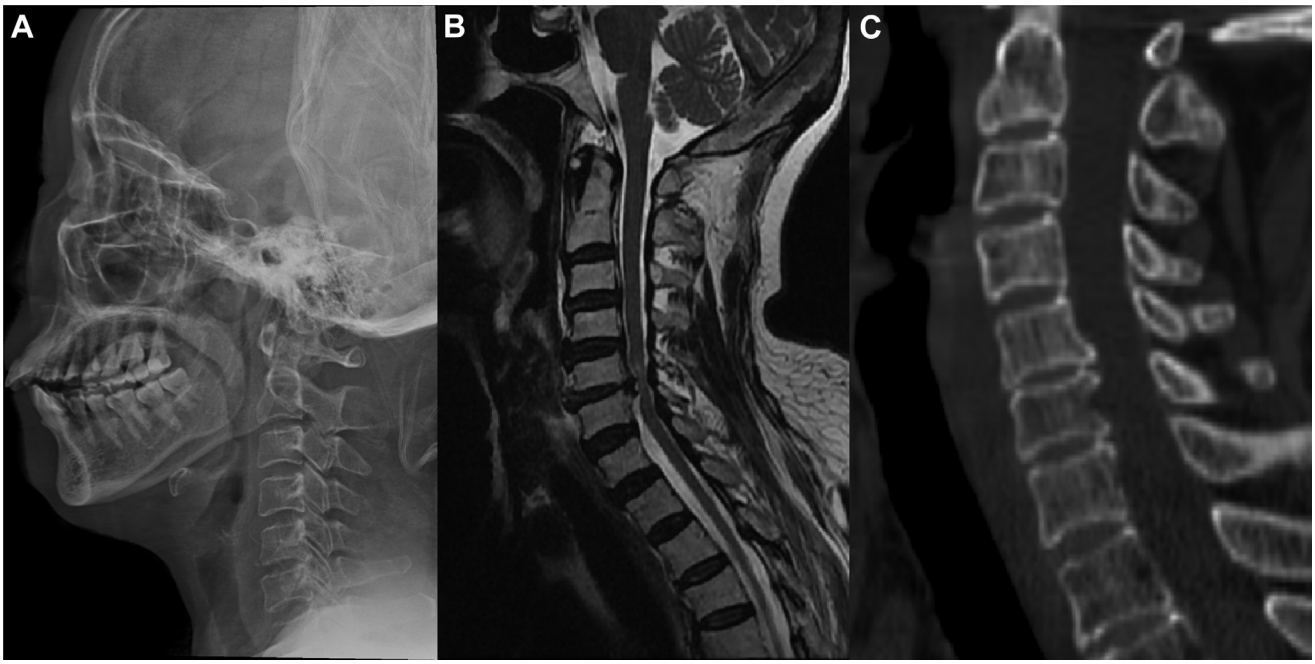

Figure 1. Preoperative (**A**) lateral radiographs and (**B**) T2-weighted magnetic resonance image from a patient in group A showing cervical spondylosis with spinal cord compression at the C5-C6 level. (**C**) Preoperative sagittal computed tomography reconstruction showing osteoporosis.

vertebrae to fix the implant. The operative time and intraoperative blood loss in the 2 groups were recorded.

All the patients wore a Philadelphia collar for 3 months postoperatively. Osteoporosis treatment, including oral activated vitamin D 800 IU/day, calcium 1200 mg/day, and bisphosphonates, were taken by all patients in group A after they had undergone ACDF.[26] Their serum calcium level was checked monthly.

Table 1. Comparison of Baseline Characteristics of Assessed Patients

Characteristic	Group A	Group B	*P* Value
Gender			0.16
Male	3	8	
Female	15	12	
Average age (years)	66.9 ± 4.5	67.3 ± 7.0	0.62
Operated levels			0.74
C3-C4 and C4-C5	9	8	
C5-C6 and C6-C7	9	12	
Operative time (minutes)	73.6 ± 12.3	75.5 ± 9.0	0.67
Blood loss (mL)	70.1 ± 12.0	74.1 ± 10.8	0.60
Hospitalization time (days)	5.2 ± 0.6	5.1 ± 0.8	0.68
Cost of index surgery (US$)	7075.0 ± 263.4	6387.5 ± 257.1	<0.0001
Follow-up period (months)	40.1 ± 3.2	41.5 ± 3.1	0.18

Data presented as number of patients or mean ± standard deviation.

Evaluation Criteria

The total cost of the procedure, including the cost of osteoporosis treatment, was recorded. The clinical evaluations, including the Japanese Orthopaedic Association (JOA) score for neurological function, neck disability index (NDI) score for neck pain, visual analog scale (VAS) for neck and arm pain, and the short-form 36 (SF-36) for the general quality of life were performed preoperatively and at 3 months and the final follow-up visit postoperatively. The incidence of dysphagia was evaluated using the grading system reported by Bazaz et al.,[27] defined as none, mild, moderate, and severe at 1 and 3 months and the final follow-up visit postoperatively. Other complications, including cervical soft tissue swelling, cerebrospinal fluid leak, hematoma, infection, and implant failure, were also recorded.

Plain radiographs (anteroposterior and lateral views) were performed at 2 days and 3 months postoperatively and at the final follow-up examination after surgery. The parameters were measured by 2 independent radiologists. Cervical lordosis was defined using the Cobb angle formed between the upper vertebral body of C3 and the lower vertebral body of C7 on standing lateral plain radiographs. Successful fusion was defined as follows: 1) changes in the interspinous distance of the fused segments <2 mm on extension-flexion radiographs; 2) the presence of continuous bridging bony trabeculae across the intervertebral space; 3) no transparent belt between the fusion cage and the interfaces of

the upper and lower endplate; and 4) no evidence of pull out of the device.[19,28] The occurrence of cage subsidence was defined as the loss of anterior intervertebral disc height or posterior intervertebral disc height >2 mm.[28]

Statistical Analysis

Data are presented as the mean ± standard deviation. SPSS for Windows, version 13.0 (IBM Corp., Armonk, New York, USA), was used for analysis. Comparisons between pre- and postoperatively were performed using the Student paired *t* test. Independent sample *t* tests were used to compare the surgical parameters, clinical outcomes, and radiographic parameters between the 2 groups. Differences in the rate of dysphagia and cage subsidence between the 2 groups were assessed using the χ^2 test. $P < 0.05$ was considered to indicate statistical significance.

RESULTS

Surgical Parameters

All procedures were performed successfully in all patients. The operated levels were C3-C4 and C4-C5 (group A, $n = 9$; group B, $n = 9$) and C5-C6 and C6-C7 (group A, $n = 9$; group B, $n = 11$), and these differences were not statistically significant ($P > 0.05$; Table 1). The mean operative time and blood loss was 73.6 ± 12.3 minutes and 70.1 ± 12.0 mL in group A and 75.5 ± 9.0 minutes and 74.1 ± 10.8 mL in group B, respectively. These differences were also not statistically significant ($P > 0.05$; Table 1). The mean cost of the procedure in group A ($7075.00 ± $263.40) was significantly greater than that in group B ($6387.50 ± $257.10; $P < 0.001$; Table 1). The mean hospitalization time was 5.2 ± 0.6 days in group A and 5.1 ± 0.8 days in group B. This difference was also not statistically significant ($P > 0.05$; Table 1).

Clinical Outcomes

The mean follow-up time was 40.1 ± 3.2 months in group A and 41.5 ± 3.1 months in group B, and this difference was not statistically significant ($P > 0.05$; Table 1). The JOA score, NDI score, and VAS score for the neck and arm were significantly improved postoperatively compared with the preoperative values in both groups ($P < 0.05$; Figures 2 and 3 and Table 2). Similarly, the SF-36 score, including the physical component summary and mental component summary scores, had significantly increased postoperatively compared with the preoperative values in both groups ($P < 0.05$; Figure 4 and Table 3). All the improvements were maintained over time, and no statistically significant differences were found between the immediate postoperative and last follow-up examination results ($P > 0.05$; Tables 2 and 3). In addition, we found no significant differences between the 2 groups in any of the clinical parameters at each follow-up point.

Radiological Outcomes

The cervical lordosis had been significantly corrected from 9.8° ± 1.1° preoperatively to 16.9° ± 1.3° at 3 months postoperatively and 16.1° ± 1.3° at the final follow-up visit in group A (Figure 5). The cervical lordosis had also been corrected in group B: from 10.4° ± 1.2° preoperatively to 17.2° ± 1.6° at 3 months postoperatively and 16.6° ± 1.4° at the final follow-up visit. No statistically significant differences in cervical lordosis were found between the 2 groups at each follow-up point ($P > 0.05$; Figure 6 and Table 3). The fusion rate at 3 months postoperatively was 88.9% (16 of 18) in group A and 90.0% (18 of 20) in group B, which was not significantly different ($P > 0.05$). All the patients had achieved solid fusion at the final follow-up visit.

Complication Outcomes

All the patients tolerated the procedure well, and no implant failure occurred during the follow-up period. Cervical soft tissue swelling occurred during the postoperative period in 2 patients in group A and 2 patients in group B; however, no statistically significant difference was found ($P > 0.05$). Using the Bazaz criteria, 2 patients (11.1%) complained of dysphagia (1 moderate and 1 mild) in group A and 3 patients (15.0%) had dysphagia (1 moderate and 2 mild) in group B at 1 month postoperatively.

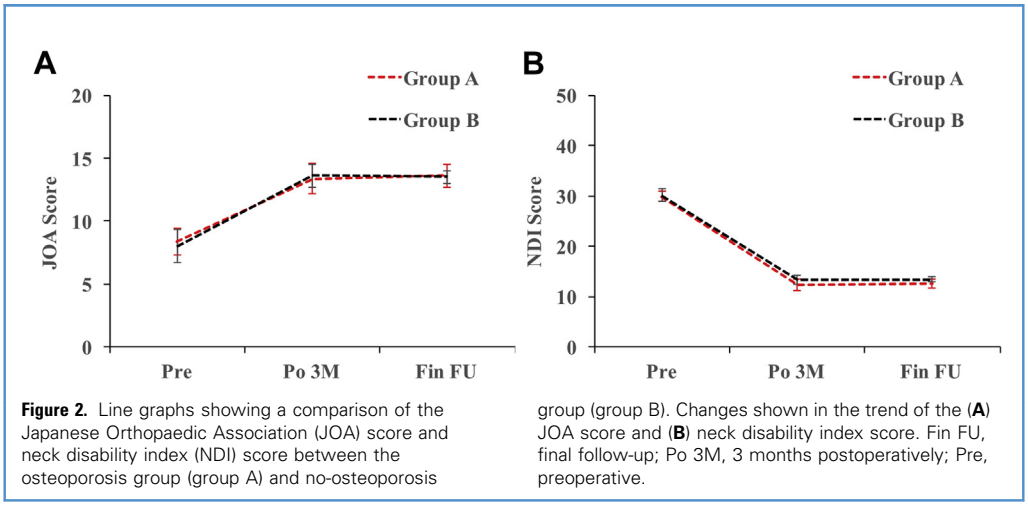

Figure 2. Line graphs showing a comparison of the Japanese Orthopaedic Association (JOA) score and neck disability index (NDI) score between the osteoporosis group (group A) and no-osteoporosis group (group B). Changes shown in the trend of the (**A**) JOA score and (**B**) neck disability index score. Fin FU, final follow-up; Po 3M, 3 months postoperatively; Pre, preoperative.

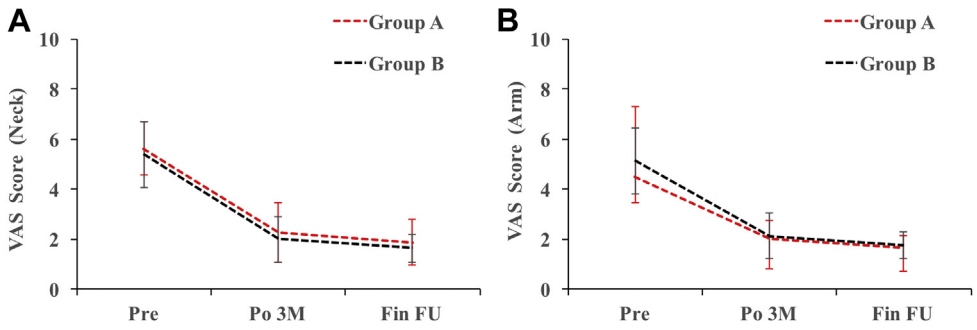

Figure 3. Line graphs showing a comparison of the visual analog scale (VAS) score between the osteoporosis group (group A) and no-osteoporosis group (group B). Changes shown in trend of the VAS score for the (**A**) neck and (**B**) arm. Fin FU, final follow-up; Po 3M, 3 months postoperatively; Pre, preoperative.

However, none of these patients complained of dysphagia at 3 months postoperatively. Statistically significant differences were found in the presence of dysphagia between the 2 groups at all follow-up points ($P > 0.05$; Table 4). In addition, no statistically significant difference was found between group A (2 of 18) and group B (2 of 20) in the cage subsidence rate at the final follow-up visit ($P > 0.05$; Table 4).

Table 2. Preoperative and Postoperative Scale Scores in Both Groups

Scale	Group A	Group B	*P* Value
JOA score			
Preoperative	8.4 ± 1.0	8.0 ± 1.2	0.40
Postoperative 3 months	13.4 ± 1.1*	13.6 ± 0.8*	0.60
Final follow-up	13.6 ± 0.9*	13.5 ± 0.5*	0.68
NDI score			
Preoperative	29.9 ± 3.5	30.1 ± 3.4	0.87
Postoperative 3 months	12.4 ± 1.2*	13.2 ± 1.8*	0.13
Final follow-up	12.6 ± 0.9*	13.4 ± 1.7*	0.20
VAS score (neck)			
Preoperative	5.6 ± 0.9	5.3 ± 1.1	0.67
Postoperative 3 months	2.3 ± 0.7*	2.0 ± 0.9*	0.56
Final follow-up	1.8 ± 0.3*	1.6 ± 0.5*	0.35
VAS score (arm)			
Preoperative	4.5 ± 2.6	5.1 ± 2.4	0.76
Postoperative 3 months	2.0 ± 0.7*	2.1 ± 0.6*	0.68
Final follow-up	1.6 ± 0.5*	1.8 ± 0.4*	0.35

Data presented as mean ± standard deviation.
JOA, Japanese Orthopaedic Association; NDI, neck disability index; VAS, visual analog scale.
*Statistically significant difference with preoperative value ($P < 0.05$).

DISCUSSION

Influence of Osteoporosis on the Efficacy of ACDF

ACDF is a well-established procedure for symptomatic CDDD because of the direct neural compression and reconstruction of spinal stability by fusion of the affected segments.[29] The number of elderly patients who require ACDF will increase, and the prevalence of osteoporosis in elderly patients is high.[3,7] ACDF in the presence of osteoporosis remains a challenge for physicians owing to the poor bone strength.

Data from our previous study indicated that the presence of osteoporosis is important in the outcomes of ACDF.[26] Patients with osteoporosis were more likely to require revision surgery and longer hospitalization and to incur greater hospitalization costs compared with their counterparts without osteoporosis who had undergone ACDF.[3] Chen et al.[30] demonstrated that osteoporosis treatment with zoledronic acid in patients with osteoporosis with single-level lumbar fusion resulted in shorter fusion times, greater fusion rates, and better clinical outcomes. It has been further confirmed that osteoporosis treatment can improve the radiological and functional results of ACDF in patients with osteoporosis.[26] Our study has demonstrated that all clinical and radiological parameters had significantly improved after surgery, and no statistically significant differences were observed between the 2 groups, suggesting that patients with osteoporosis receiving osteoporosis treatment, including vitamin D 800 IU/day, calcium 1200 mg/day, and bisphosphonates, can achieve similar satisfactory results compared with patients without osteoporosis.

Safety and Efficacy of Zero-Profile Device in ACDF with Osteoporosis

Elderly patients with osteoporosis have less dense bone and osteoblast activity, which will result in negative bone remodeling and reduced pull-out strength of the implanted device.[8] Anterior

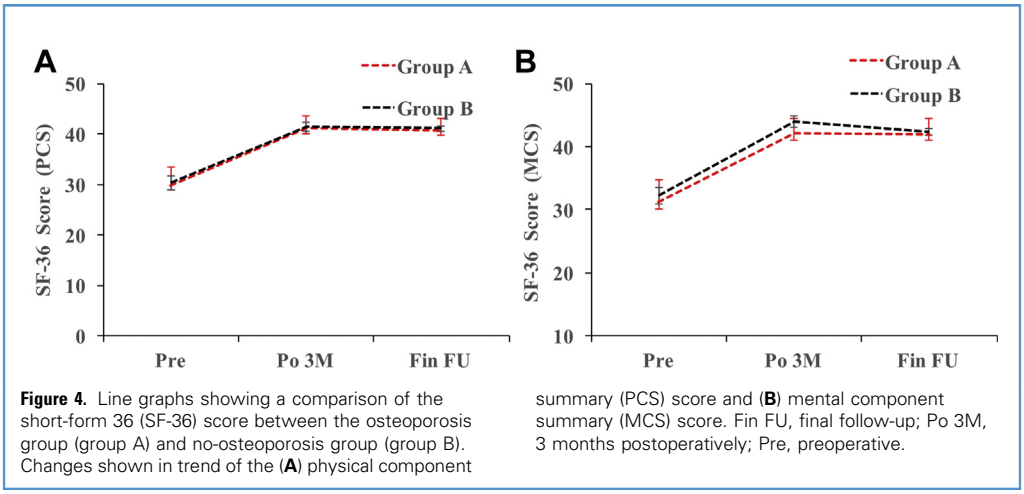

Figure 4. Line graphs showing a comparison of the short-form 36 (SF-36) score between the osteoporosis group (group A) and no-osteoporosis group (group B). Changes shown in trend of the (**A**) physical component summary (PCS) score and (**B**) mental component summary (MCS) score. Fin FU, final follow-up; Po 3M, 3 months postoperatively; Pre, preoperative.

cervical implants tend to dislocate, especially in cases of severe osteoporosis or a significant reduction of bone quality.[22] Although osteoporosis treatment could benefit the outcome of ACDF in the treatment of CDDD in patients with osteoporosis,[26] rigid fixation instrumentation and techniques can increase the fusion rate.[8]

In the osteoporotic spine, bone–implant failure is most commonly the result of screw pullout or cutout; thus, optimizing the bone–screw interface is paramount for achieving fixation.[22,31] Thus, to improve the fixation and fatigue strength of instrumentation, cement-augmented anterior cervical screw fixation after cervical corpectomy and multilevel ACDF with cage and plate has yielded favorable outcomes in patients with osteoporosis.[32,33] With the development of titanium mesh cage and its wide use in ACDF, Yan et al.[25] have shown acceptable clinical results after cervical multilevel fusion with titanium mesh cage and dynamic cervical plate after cervical corpectomy in patients with osteoporosis.

Table 3. Preoperative and Postoperative Short-Form 36 Score and Cervical Lordosis in Both Groups

Variable	Group A	Group B	*P* Value
SF-36 PCS score			
Preoperative	29.9 ± 3.4	30.2 ± 2.9	0.85
Postoperative 3 months	41.2 ± 2.2*	41.4 ± 2.3*	0.92
Final follow-up	40.6 ± 2.4*	41.1 ± 2.5*	0.68
SF-36 MCS score			
Preoperative	31.1 ± 2.7	32.2 ± 2.3	0.47
Postoperative 3 months	42.1 ± 2.6*	43.9 ± 3.8*	0.33
Final follow-up	42.0 ± 2.0*	42.4 ± 3.0*	0.75
Cobb angle (°)			
Preoperative	9.8 ± 1.1	10.4 ± 1.2	0.67
Postoperative 3 months	16.9 ± 1.3*	17.2 ± 1.6*	0.56
Final follow-up	16.1 ± 1.3*	16.6 ± 1.4*	0.35

Data presented as mean ± standard deviation.
SF-36, Short-Form 36; PCS, physical component summary; MCS, mental component summary.
*Statistically significant difference with preoperative values ($P < 0.05$).

The Zero-Profile device, a new type of cervical interbody cage, consists of a small titanium alloy plate, a polyether ether ketone polymer cage, and 4 screws for internal fixation to reduce the morbidity associated with the traditional cervical anterior plate and maintain the benefits of interbody cages with an anterior plate.[17,18] In addition, the titanium alloy plate has an internal screw thread that engages with the outer screw thread in the head of the screw, making the implant constrained and gives an angle-stable screw fixation to further reduce implant failure in patients with osteoporosis.[7,8] Previous studies have confirmed that the application of the Zero-Profile device in ACDF can achieve, not only similar clinical and radiological improvement compared with traditional plate and cage, but also reduce the related complications such as dysphagia and adjacent segment degeneration.[19-21]

To the best of our knowledge, data on the safety and efficacy of the Zero-Profile device in single-level ACDF with osteoporosis are not available. However, previous studies have confirmed a high fusion rate and low incidence of cage subsidence in older female patients (mean age, 55 years) who had undergone ACDF with a Zero-Profile device.[20,34] Albanese et al.[35] further confirmed that the Zero-Profile device was still effective and safe for 4-level ACDF in the treatment of elderly patients (mean age, 61.7 years) with CDDD. In our series, the JOA, NDI, VAS, and SF-36 scores and cervical lordosis in all patients in both groups were improved significantly after surgery at the final follow-up visit, and the postoperative clinical outcomes were well maintained. In addition, all patients had achieved solid bony fusion at the final follow-up visit. No statistically significant differences were found in the clinical outcomes and radiological outcomes between the 2 groups, suggesting that single-level ACDF with the Zero-Profile device can achieve satisfactory therapeutic effects in patients both with and without osteoporosis and CDDD at the mid-term

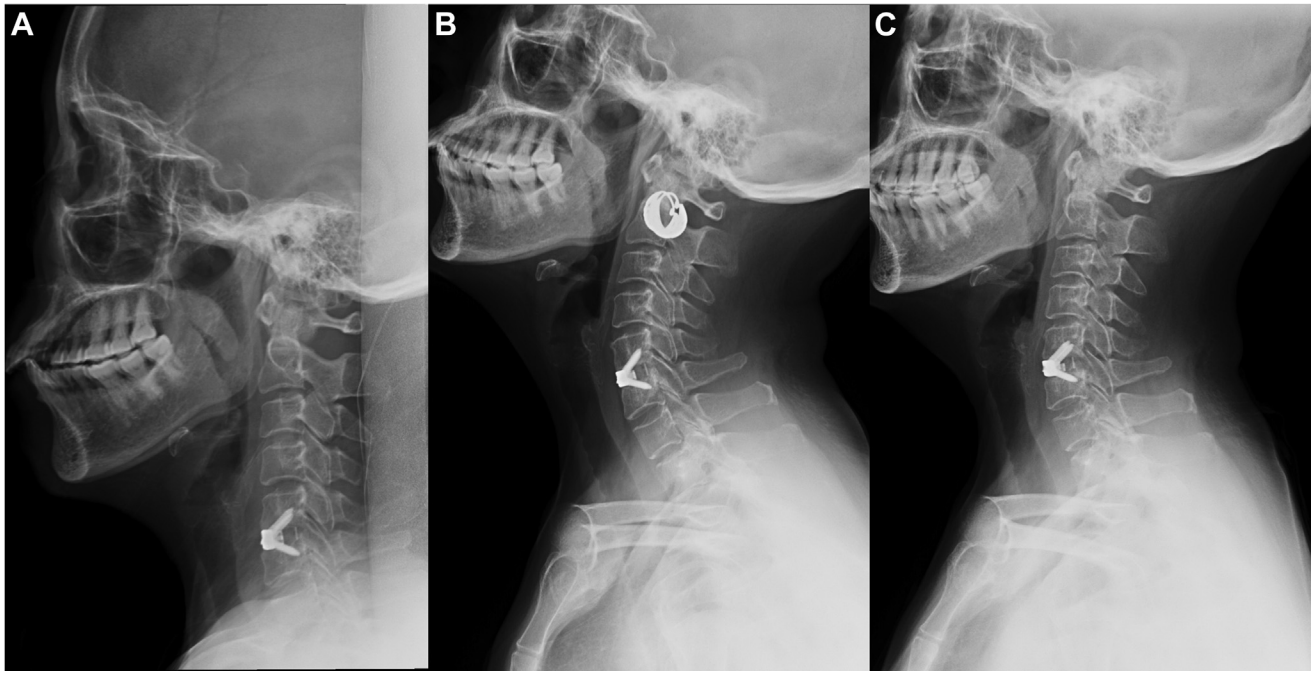

Figure 5. Lateral radiographs of the cervical spine with osteoporosis in group A at (**A**) 2 days postoperatively, (**B**) 3 months postoperatively, and (**C**) final follow-up visit showing improvement of cervical lordosis and solid fusion.

follow-up visit. Although 2 cases of cage subsidence were observed in group A, the long-term clinical outcomes and bony fusion of the patients with cage subsidence remained satisfactory. Therefore, ACDF with the Zero-Profile device was still safe and effective in the treatment of single-level CDDD with osteoporosis.

Advantages of Zero-Profile Device in ACDF

Dysphagia is 1 of the most frequently reported complications after ACDF with plate fixation, with an incidence of 38.85% at 1 month, 31.65% at 3 months, and 10.0%–12.1% at the final follow-up examination.[36,37] The thickness of the plate and the adhesions attaching to the esophagus to the prevertebral plate are considered

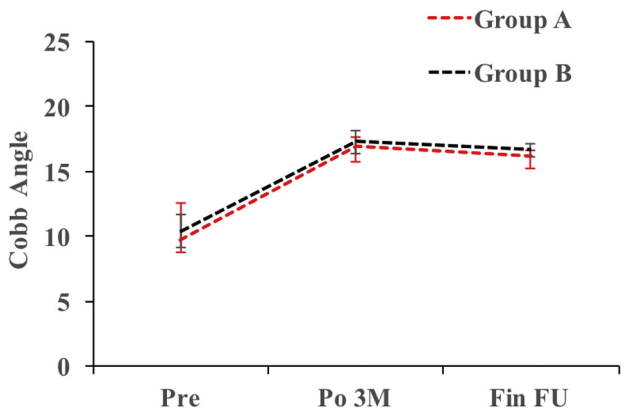

Figure 6. Line graphs showing a comparison of the Cobb angle between the osteoporosis group (group A) and no-osteoporosis group (group B). Fin FU, final follow-up; Po 3M, 3 months postoperatively; Pre, preoperative.

Table 4. Comparison of Dysphagia Rate and Cage Subsidence Rate in Both Groups

Variable	Group A	Group B	*P* Value
Dysphagia rate			0.85
Postoperative 1 months	11.1 (2/18)	15.0 (3/20)	
Postoperative 3 months	0 (0/0)	0 (0/0)	
Final follow-up	0 (0/0)	0 (0/0)	
Cage subsidence rate			1.00
Postoperative 3 months	11.1 (2/18)	10.0 (2/20)	
Final follow-up	0 (0/0)	0 (0/0)	
Fusion rate	0 (0/0)		1.00
Postoperative 3 months	88.9 (16/18)	90.0 (18/20)	
Final follow-up	100 (18/18)	100 (18/18)	

Data presented as % (*n*/*N*).

major causes of dysphagia.[38] The Zero-Profile device is completely contained in the decompressed intervertebral space and can avoid mechanical irritation of the esophagus and other prevertebral soft tissues.[17] A meta-analysis study confirmed the low incidence of both transient and persistent dysphagia after ACDF using the Zero-Profile device.[39] In the present study, a significantly lower incidence of postoperative dysphagia (11.1%–15.0% at 1 month postoperatively and 0% at 3 months postoperatively) was observed in both groups compared with the incidence reported by others using the cage and plate.[36,37]

Because osteoporosis is mainly present in elderly patients, the osteophytes in the front of the vertebral body is often more obvious than that of the young patient. Exposure of too much of the affected vertebral body is not necessary for Zero-Profile device fixation, which could reduce the surgical trauma and operative time, especially in multilevel ACDF.[20,35] In addition, it is not necessary to remove the original titanium plate in the symptomatic adjacent segment disease after ACDF for Zero-Profile device fixation, which can also significantly shorten the operative time and reduce the risk of removing original implant.[19] In our study, 2 patients in group A and 3 patients in group B, who had undergone ACDF in the adjacent segment of previous fusion segment, achieved satisfactory results postoperatively. Furthermore, Shi et al.[40,41] found that the Zero-Profile device provided safe and effective treatment of 2 noncontiguous levels of CDDD, which can keep the intermediate segment intact and have a low effect on the intermediate segment.

However, the present study still had some limitations. First, it was a single-center retrospective cohort study, and no method was adopted to ensure unbiased randomization. Moreover, the sample size was small. Further multicenter prospective randomized studies and larger patient samples are needed to confirm the results.

CONCLUSIONS

The Zero-Profile device for single-level ACDF could significantly improve the clinical and radiological outcomes in the treatment of CDDD. In patients with osteoporosis, ACDF with the Zero-Profile device can obtain the same surgical effects compared with patients without osteoporosis in the treatment of single-level CDDD. Therefore, we suggest that ACDF with the Zero-Profile device can be used as an effective and reliable treatment of single-level CDDD in the presence of osteoporosis.

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