*Acta Orthop. Belg.*, 2022, **88**, 285-291

*ORIGINAL STUDY*

*doi.org/ 10.52628/88.2.7727*

# Zero-profile implant versus integrated cage-plate implant in treatment of single level cervical disc disease

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**The aim of this retrospective study is to evaluate and compare the clinical and radiological results of the use of Zero-P implant and the integrated cage-plate implant in surgical treatment of single level cervical disc disease. It includes 54 consecutive patients who underwent single level anterior cervical discectomy and fusion. The patients were divided into 2 groups. Group (A) including 28 patients operated with zero-profile implant and group (B) including 26 patients operated with integrated cage-plate implant. Mean operative time, blood loss, incidence of dysphagia and any other complications related to the procedure were recorded and compared. Patients were assessed radiologically by measuring cervical lordosis using the Cobb angle and the segmental angle. Patients were assessed clinically by the Japanese orthopedic association score and the neck disability index. These values were also compared. The mean age of the patients in group (A) was 49.5±11 years, and in group (B) it was 49.8±11.6 years. Mean blood loss and operative time in group (A) were 77.3±9.4 ml and 72.1±7.9 minutes, while in group B, they were 80.7±9.5 ml and 74.8±8.4 minutes with no statistically significant difference between both groups. There were also no statistically significant difference between both groups as regards incidence of dysphagia, clinical scores nor radiological parameters. In conclusion, both zero-profile implant and integrated cage-plate implant have comparable satisfactory clinical and radiological results in treatment of single level cervical disc diseases with little complications.**

**Keywords**: Anterior cervical discectomy; cervical fusion; zero-profile implant; plate cage Benezech; integrated cage-plate implant.

## INTRODUCTION

Anterior cervical discectomy and fusion is considered the standard in surgical treatment of cervical disc diseases *(1)*. Interbody cages were introduced to overcome the disadvantages of using structural autogenous bone grafts *(2)*. Furthermore, use of stand-alone interbody cages without fixation was occasionally associated with some complications such as subsidence into the end plate or cage migration. To overcome such complications, combined anterior plate is advocated by some, providing more stability and enhancing the fusion rate *(3)*. Anterior plates are not without their own problems such as dysphagia, plate dislodgement, and adjacent segment affection especially with

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*No benefits or funds were received in support of this study.*
*None of the authors have a conflict of interest.*

inappropriate plate length *(4)*. Newer implants have been introduced in a trial to avoid the above mentioned complications. Zero-profile implant (Zero-P, Synthes GmbH Switzerland, Oberdorf, Switzerland) is a cage inserted in the intervertebral disc space fixed to the adjacent vertebral bodies with screws passing through the endplate. It has the mechanical advantages of the cage-plate construct while avoiding contact with the soft tissues anterior to cervical spine, thus decreasing the incidence of dysphagia *(5)*. Another relatively new implant, is the integrated cage-plate implant (the plate cage Benezech, PCB, SCIENT'X, Paris, France).

The aim of this study is to evaluate and compare the clinical and radiological results of the use of Zero-P implant and the integrated cage-plate implant in surgical treatment of single level cervical disc disease.

## MATERIALS AND METHODS

This retrospective study included 54 consecutive patients who underwent single level anterior cervical discectomy and fusion between August 2015 and March 2018 by the authors. The study included patients suffering from cervical radicular pain and/or axial neck pain after failure of conservative measures for at least 6 weeks, or patients with moderate to severe cervical myelopathy. Their radiological images revealed etiological pathology at a single disc level requiring surgery at that level only. Patients with other cervical pathologies such as fractures, infections or tumors, those requiring multiple level disc surgeries and patients who had previous cervical surgeries were excluded from the study. The patients were divided into 2 groups. Group (A) included 28 patients operated with Zero-P implant and group (B) included 26 patients operated with PCB. Minimum follow up in both groups was 24 months. Detailed preoperative medical history taking, physical and neurological examination were performed and recorded for each patient. Preoperative cervical spine plain radiographs were obtained from all, with anterior-posterior and lateral views as well as oblique views, along with preoperative cervical spine CT scan and MRI. Postoperative cervical spine plain radiograph was performed within few days after surgery and after 1, 3, 6, 12 and 24 months. Radiological evaluation included measurement of cervical lordosis using the Cobb angle between the lower endplate of C2 and the lower endplate of C7. The segmental angle was measured between the 2 adjacent vertebrae of the fusion level (upper endplate of the cephalad vertebra and lower endplate of the caudal vertebra) *(6)*. As regards clinical evaluation, Japanese Orthopaedic Association score (JOA score) was used to assess the neurological function *(7)*. Functional level was assessed via neck disability index (NDI) *(8)*. Incidence of dysphagia was recorded using Bazaz et al system *(9)*. Statistical analysis was done using the SPSS program. P scores $< 0.05$ was considered as statistically significant and $P < 0.001$ as highly significant.

All patients were operated in supine position under general anesthesia. Right sided Smith-Robinson approach through transverse skin incision was used. The required intervertebral disc space was identified by fluoroscopy. Under surgical microscope, discectomy was done with positioning of the Caspar distracter and removal of the cartilaginous endplates with a curette to promote fusion. A high-speed burr was used to remove the posterior osteophytes, then, dissection of the posterior longitudinal ligament and widening of the neural foramina were performed. Trial spacers were applied to decide the appropriate size of the cage. Zero-P implant filled with synthetic bone graft was used in patients of group (A) with 4 screws inserted through the adjacent endplates. The cage should be 2 mm behind the anterior margin of the vertebral body *(10)*. PCB (with PEEK cage filled with synthetic bone graft) was applied in patients of group (B) with fixation of the plate with one screw up and one screw down. The appropriate position of the implant in both groups was checked with intraoperative fluoroscopy. Postoperative semi-rigid collar was applied for 6 weeks.

## RESULTS

Fifteen females and 13 males were in Group (A). In group (B) there were 15 females and 11 males. The mean age of the patients in group (A) was 49.5±11 years, and in group (B) it was 49.8±11.6

years. Fusion level was C5-6 in 25 patients, C6-7 in 14 patients, C4-5 in 9 patients, and C3-4 in 6 patients. 11 patients were preoperatively diagnosed as cervical myelopathy, of which 6 patients were included in group (A) and 5 patients were in group (B). The rest suffered from cervical radiculopathy with or without axial neck pain. There was no statistical difference between the 2 groups as regards age, sex and diagnosis. Mean blood loss in group (A) was 77.3±9.4 ml, while in group B, it was 80.7±9.5 ml. Mean operative time in group (A) was 72.1±7.9 minutes, and it was 74.8±8.4 in group (B). There was no statistically significant difference between both groups as regard operative time and blood loss (Tables 1 & 2).

As regards JOA score, it improved from 8.7±3.8 preoperatively in group (A) to 13.5±4.2 at the last follow up, while in group (B), it improved from 8.8±3.6 preoperatively to 13.7±3.8 at the final follow up. NDI score improved in group (A) from 39.1±3.9

Table 1. — Group (A) demographic data, diagnosis and operative data

| | Age (yrs) | Sex | Operative time (min) | Blood loss (ml) | Main complaint | Level of fusion |
|---|---|---|---|---|---|---|
| **1** | 49 | F | 70 | 70 | Neck pain+ Radiculopathy | C5-6 |
| **2** | 42 | M | 75 | 95 | Neck pain+ Radiculopathy | C6-7 |
| **3** | 55 | F | 60 | 80 | Neck pain+ Radiculopathy | C5-6 |
| **4** | 51 | M | 65 | 80 | Myelopathy | C4-5 |
| **5** | 62 | F | 70 | 70 | Neck pain+ Radiculopathy | C5-6 |
| **6** | 34 | F | 80 | 70 | Neck pain+ Radiculopathy | C3-4 |
| **7** | 45 | M | 65 | 90 | Neck pain+ Radiculopathy | C6-7 |
| **8** | 39 | F | 80 | 90 | Neck pain+ Radiculopathy | C5-6 |
| **9** | 58 | M | 65 | 80 | Myelopathy | C6-7 |
| **10** | 46 | M | 65 | 85 | Neck pain+ Radiculopathy | C3-4 |
| **11** | 60 | F | 85 | 90 | Neck pain+ Radiculopathy | C5-6 |
| **12** | 48 | F | 70 | 65 | Neck pain+ Radiculopathy | C4-5 |
| **13** | 33 | M | 60 | 70 | Neck pain+ Radiculopathy | C5-6 |
| **14** | 35 | F | 75 | 65 | Neck pain+ Radiculopathy | C4-5 |
| **15** | 47 | M | 75 | 70 | Myelopathy | C5-6 |
| **16** | 38 | F | 65 | 85 | Neck pain+ Radiculopathy | C5-6 |
| **17** | 45 | M | 70 | 75 | Neck pain+ Radiculopathy | C5-6 |
| **18** | 47 | F | 85 | 80 | Neck pain+ Radiculopathy | C5-6 |
| **19** | 66 | F | 65 | 80 | Myelopathy | C6-7 |
| **20** | 74 | M | 85 | 85 | Myelopathy | C5-6 |
| **21** | 35 | F | 70 | 85 | Neck pain+ Radiculopathy | C4-5 |
| **22** | 46 | F | 75 | 70 | Neck pain+ Radiculopathy | C6-7 |
| **23** | 40 | M | 65 | 75 | Neck pain+ Radiculopathy | C5-6 |
| **24** | 46 | M | 90 | 90 | Neck pain+ Radiculopathy | C6-7 |
| **25** | 57 | F | 80 | 60 | Neck pain+ Radiculopathy | C4-5 |
| **26** | 68 | M | 75 | 80 | Myelopathy | C6-7 |
| **27** | 53 | F | 65 | 65 | Neck pain+ Radiculopathy | C5-6 |
| **28** | 69 | M | 70 | 65 | Neck pain+ Radiculopathy | C5-6 |

Table 2. — Group (B) demographic data, diagnosis and operative data

| | Age (yrs) | Sex | Operative time (min) | Blood loss (ml) | Main complaint | Level of fusion |
|---|---|---|---|---|---|---|
| **1** | 33 | F | 80 | 95 | Neck pain+ Radiculopathy | C6-7 |
| **2** | 58 | F | 65 | 75 | Neck pain+ Radiculopathy | C5-6 |
| **3** | 39 | F | 90 | 90 | Neck pain+ Radiculopathy | C6-7 |
| **4** | 67 | M | 75 | 85 | Myelopathy | C5-6 |
| **5** | 55 | F | 70 | 65 | Neck pain+ Radiculopathy | C4-5 |
| **6** | 76 | M | 65 | 80 | Myelopathy | C5-6 |
| **7** | 38 | F | 75 | 95 | Neck pain+ Radiculopathy | C5-6 |
| **8** | 61 | F | 80 | 80 | Neck pain+ Radiculopathy | C3-4 |
| **9** | 45 | M | 75 | 70 | Neck pain+ Radiculopathy | C6-7 |
| **10** | 48 | F | 85 | 90 | Neck pain+ Radiculopathy | C3-4 |
| **11** | 41 | F | 75 | 75 | Neck pain+ Radiculopathy | C5-6 |
| **12** | 56 | M | 85 | 70 | Myelopathy | C4-5 |
| **13** | 44 | F | 85 | 95 | Neck pain+ Radiculopathy | C5-6 |
| **14** | 51 | F | 80 | 65 | Neck pain+ Radiculopathy | C5-6 |
| **15** | 53 | M | 80 | 95 | Neck pain+ Radiculopathy | C5-6 |
| **16** | 60 | M | 90 | 80 | Myelopathy | C4-5 |
| **17** | 56 | F | 70 | 80 | Neck pain+ Radiculopathy | C5-6 |
| **18** | 62 | M | 70 | 85 | Neck pain+ Radiculopathy | C5-6 |
| **19** | 45 | F | 80 | 70 | Neck pain+ Radiculopathy | C3-4 |
| **20** | 33 | F | 65 | 75 | Neck pain+ Radiculopathy | C6-7 |
| **21** | 36 | M | 80 | 70 | Neck pain+ Radiculopathy | C6-7 |
| **22** | 40 | F | 60 | 90 | Neck pain+ Radiculopathy | C4-5 |
| **23** | 37 | M | 70 | 90 | Neck pain+ Radiculopathy | C6-7 |
| **24** | 57 | M | 60 | 70 | Neck pain+ Radiculopathy | C5-6 |
| **25** | 32 | F | 70 | 85 | Neck pain+ Radiculopathy | C3-4 |
| **26** | 68 | M | 65 | 80 | Myelopathy | C6-7 |

preoperatively to 12.6 ±3.1 at the final follow up, while in group (B), it improved from 38.7±4.1 preoperatively to 12.4±3.8 at the final follow up. The improvement of JOA score and NDI score was statistically significant in both groups between the preoperative score and final follow up score, but there was no statistically significant difference between the two groups when comparing JOA score or NDI score in both groups preoperatively or at the final follow up. As regards dysphagia, 3 patients in group (A) (10.7%) had immediate postoperative dysphagia (all of them were moderate, 2 performed surgery at C5/6 level and 1 at C6/7), but no patient had persistent dysphagia beyond the first postoperative month. In group (B), 4 patients (15.3%) experienced postoperative dysphagia, 2 of them were mild (both C6/7 fusion) and 2 were moderate (1 patient at C4/5 and the other at C5/6). As in the other group, none of them had persistent dysphagia after one month. The difference in incidence of dysphagia between both groups was not statistically significant. Incidence of dysphagia was not statistically higher following particular level of fusion. Radiologically, the cervical lordosis improved from 10.9±4.8° preoperatively

to 16.8±3.9° at the final follow up in group (A), while in group (B), it improved from 11.3±4.1° preoperatively to 17.1±4.3° at the final follow up. The correction was statistically significant in both groups, but when comparing both groups, there was no significant difference as regards the preoperative values or the last follow up values. The segmental angle improved from 4.8±3.9° preoperatively to 6.1±3.7° at the final follow up in Group (A), while in group (B), it improved from 5.1±3.9° preoperatively to 6.2±4.1° at the last follow up. Again, there was no significant difference between both groups as regards correction of segmental angle. All patients showed signs of fusion at the final follow up with no case of pseudoarthrosis or implant failure (Figures 1 & 2).

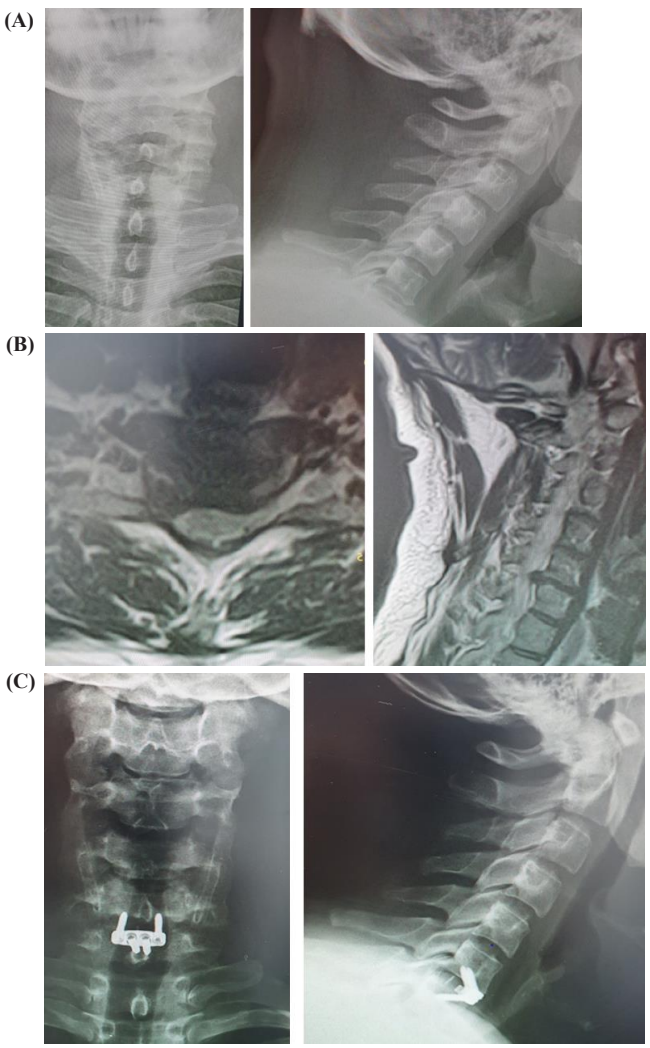


***Figure 1.*** — Forty five years old male C/O neck pain and brachialgia due to C6-7 disc herniation, C6-7 anterior cervical discectomy and fusion was done with Zero-P implant. **(A)** Preoperative plain radiographs **(B)** Preoperative MRI **(C)** Postoperative plain radiograph at final follow up.

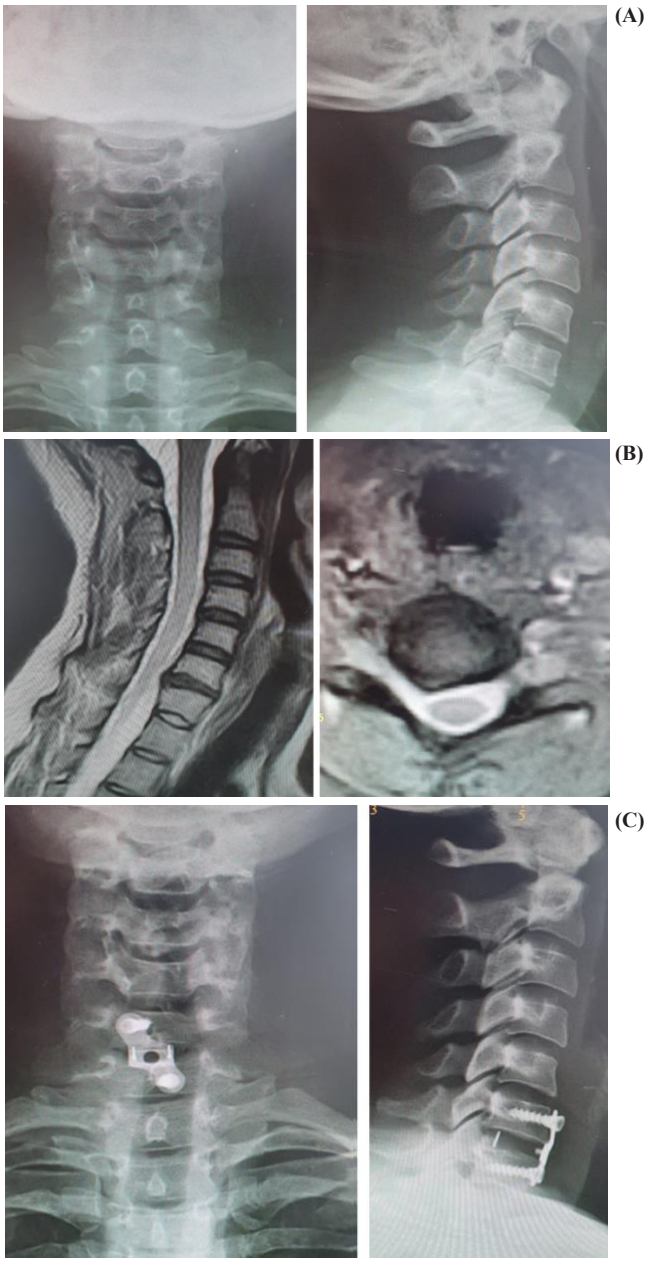


***Figure 2.*** — Thirty three years old female C/O neck pain and right brachialgia due to C6-7 disc herniation. Anterior cervical discectomy with PCB implant was performed. **(A)** Preoperative plain radiographs **(B)** Preoperative MRI **(C)** Postoperative plain radiograph at final follow up.

## DISCUSSION

Cervical disc disease is a common condition with clinical presentation ranging between neck pain, radiculopathy or cervical myelopathy *(11)*. Anterior cervical discectomy and fusion which was introduced by Cloward et al, is a well-known modality of its treatment *(12,13)*. Adding anterior plate usually enhances the stability of the spinal segment intended to be fused and helps avoiding the complications of using stand-alone bone graft or interbody cage *(3,14)*. Complications related to the anterior cervical plate include screws loosening and pullout as well as postoperative dysphagia *(11)*. The incidence of dysphagia in the first 3 months after surgery ranged in previous studies between 4 and 57% with the use of anterior plate while the incidence of persistent dysphagia for more than 3 months ranged between 12 and 39% *(15,16)*. According to a study by Lee et al, postoperative dysphagia is related to the thickness of the titanium plate. Irritation of the prevertebral soft tissue and consequently dysphagia, is less with thinner plates *(17)*. Zero-P which consists of interbody fusion cage and intervertebral screws provides adequate stability and at the same time less postoperative dysphagia *(18)*. The lower rate of dysphagia compared to the conventional cage and anterior plate may be due to containment of Zero-p totally within the intervertebral disc space resulting in less prevertebral soft tissue irritation. It may also be due to less soft tissue traction during surgery as there is no need to do excessive traction to control the angle of the screws or the length of the plate *(19)*.

Only few studies have compared the effectiveness and the complications of the Zero-p implant and PCB implant in anterior cervical fusion. In a study conducted by Wang et al, the operation time and intraoperative blood loss were significantly lower in Zero-p group than in PCB group *(20)*. This was consistent with the results of Xiao et al and Yan et al. *(11,13)*. In our study, the operation time and intraoperative blood loss were lower in Zero-P group without being significantly different. The difference in improvement of JOA and NDI scores between both groups was not significant in our study. This was consistent with the results of Wang et al. *(20)*. However, in the studies of Xiao et al and Yan et al., the postoperative JOA and NDI scores were significantly better in Zero-p group than in PCB group *(11,13)*. Incidence of dysphagia in the study of Wang et al was 13.7% in the Zero-P group and 13.3% in the PCB group without statistically significant difference between both groups *(20)*. Similarly in our study, incidence of dysphagia was 10.7% in Zero-P group and 15.3% in PCB group with no significant difference. However, in the study of Xiao et al, incidence of dysphagia was 18.3% in Zero-P group and 28.3% in PCB group after 6 months follow up and in the study of Yan et al, incidence of dysphagia was 16.33% in Zero-P group and 26.53% in PCB group after 6 months. These differences between the 2 groups were statistically significant in both studies *(11,13)*.

As regards the cervical curvature, there was statistically significant correction in both groups in our study without any significant difference when comparing the 2 groups. These results are consistent with that of Xiao et al, Yan et al., and Wang et al. *(11,13,20)*.

## CONCLUSION

Both Zero-P implant and PCB implant have satisfactory clinical and radiological results in treatment of single level cervical disc diseases with little complications. The results of the Zero-P implant are slightly better than PCB, along with some reduction in the operative time and blood loss and less incidence of postoperative dysphagia. However these differences were not statistically significant.

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