Spine

SPINE Volume 38, Number 13, pp E792–E797




# Anterior Interbody Fusion of the Cervical Spine With Zero-P Spacer

*Prospective Comparative Study—Clinical and Radiological Results at a Minimum 2 Years After Surgery*

Petr Vanek, MD,* Ondrej Bradac, MD,* Patricia DeLacy, MD,† Jiri Lacman, MD,‡ and Vladimir Benes, MD, PhD*

**Study Design.** A prospective study.

**Objective.** The aim of this study was to compare clinical and radiological efficacy of anterior cervical microdiscectomy and fusion done by the newly designed low-profile interbody spacer in cases of symptomatic cervical spine spondylosis.

**Summary of Background Data.** There are basically 2 ways to provide interbody fusion in the degenerative cervical spine; the first is by way of an unanchored "stand-alone" bone graft or cage, and the second is with bone graft or a cage anchored with a plate. Both concepts have their own benefits as well as potential drawbacks. Low-profile angle-stable spacer Zero-P is an implant that can potentially limit the drawbacks of both these procedures.

**Methods.** Prospective study collecting clinical and radiological data of 77 patients undergoing anterior cervical interbody fusion of 1 or 2 motion segments from C3–C7 was performed. Zero-P spacer was used in 44 patients (55 segments) and in 33 cases (41 segments), stabilization was done using interbody spacer and dynamic anterior cervical plate. Patients were followed a minimum of 2 years after surgery.

**Results.** There was no significant difference in neck disability index values, presence of dysphagia ($P = 0.308$), and Cobb C values during follow-up ($P = 0.051$) between both groups. A significant difference in the first 2 values of Cobb S was found ($P < 0.001$), but the next course of Cobb S changes showed no difference in either group. No difference was found in the radiological stability during follow-up, and no revision surgery was done.

**Conclusion.** The results of this study confirm biomechanical assumptions associated with the Zero-P spacer. Implantation of this new cage results in setting required biomechanical conditions in the treated segment that are comparable with those when the segment is treated with a dynamic plate. However, the potential of the mentioned implant to reduce the incidence of postoperative dysphagia was not proven on this sample of patients.

**Key words:** cervical spine, degenerative disc disease, dynamic plate, Zero-P, technique.

**Level of Evidence:** 3

**Spine 2013;38:E792–E797**

Anterior cervical discectomy or microdiscectomy is a common surgical procedure given the high incidence of degenerative disease of the cervical spine. Despite significant technological progress represented by new dynamic technologies, interbody fusion is still indicated in the overwhelming majority of cases. Although the fusion established through the anterior approach has been used in the treatment of degenerative diseases of the cervical spine for more than 50 years, there is no generally accepted procedure to achieve it to date.[1] Recent systematic review of randomized controlled trials based on 33 studies included 2267 patients demonstrated very low-quality evidence of little or no difference in the pain relief and the fusion rate between the performed techniques.[2] Today, there are 2 ways to provide interbody fusion; the first is by way of an unanchored "stand-alone" cage and the second is with bone graft or a cage anchored with a plate. Both concepts have their own benefits as well as potential drawbacks. The most often mentioned drawbacks of these techniques are the postoperative dysphagia for a plate constructs and lower immediate stability with cage sinking for a stand-alone technique.[3–7]

Low-profile angle-stable spacer Zero-P (Synthes, Zuchwil, Switzerland) is an implant that declare potential to limit the drawbacks of both these procedures. In particular, it can increase immediate stability of a treated segment as compared with the stand-alone concept, even in the absence of an implant on the anterior cervical spine as in the case of cervical plating.

From the *Department of Neurosurgery, Charles University, 1st Faculty of Medicine, Military University Hospital, Prague, Czech Republic; †Department of Neurosurgery, Royal Hallamshire Hospital, Sheffield, United Kingdom; and ‡Department of Radiology, Military University Hospital, Prague, Czech Republic.

Acknowledgment date: December 18, 2012. First revision date: February 5, 2013. Second revision date: February 27, 2013. Acceptance date: March 8, 2013.

The manuscript submitted does not contain information about medical device(s)/drug(s).

No funds were received in support of this work.

No relevant financial activities outside the submitted work.

Address correspondence and reprint requests to Petr Vanek, MD, Department of Neurosurgery, Charles University, 1st Faculty of Medicine, Military University Hospital, U vojenske nemocnice 1200, Prague 6, 169 00 Czech Republic; E-mail: petr.vane@uvn.cz

DOI: 10.1097/BRS.0b013e3182913400

The objective of this work is to compare clinical and radiological results of cervical spine procedures using a new device (Zero-P) with those using a cage and dynamic locking plate.

## MATERIALS AND METHODS

Seventy-seven patients enrolled in this study from December 2008 to June 2010. Prospectively, with informed consent, each patient underwent a minimum 6-week period of a conservative treatment for radicular irritation caused by degenerative changes in the cervical spine. Patients with a radicular power deficit or cervical myelopathy were not enrolled in this group. In all cases, the conservative therapy was found to be ineffective. Indication for surgery was made on the basis of a correlating clinical picture and the evidence of root or spinal cord compression on recent magnetic resonance imaging. Patients with symptomatic findings in 1 or a maximum of 2 levels of the cervical spine were included in this study.

All patients underwent surgery under general anesthesia. Once the clinical segment had been targeted, the anterior cervical spine was prepared in a supine position through a collar incision, using a standard Smith-Robinson approach.[1] Then, using a surgical microscope and a microdrill, the intervertebral disc was extirpated, dorsal osteophytes were removed, and posterior longitudinal ligament was intersected, allowing the spinal cord and nerve roots at that level to be decompressed.

Prior to surgery, it was decided to perform interbody spondylodesis either in the usual way using an interbody polyethyl-ether-ketone cage device Cornerstone (Medtronic, Minneapolis, MN) with a locking dynamic plate Premier (Medtronic), or by way of the new implant Zero-P (Synthes, Zuchwil, Switzerland, made of PEEK cage and integrated titanium plate, which is fixed using 4 titanium screws, 2 into each vertebral body endplate). In both groups, the cages were filled with bone graft substitute ChronOS (Synthes, Zuchwil, Switzerland). These 2 described techniques were alternated regularly between each consecutive week. Therefore, each consecutive week patients received only one from the described techniques. All surgical procedures were performed by 2 senior spinal surgeons from our team.

Patients were allowed to sit up and mobilize on the first postoperative day. Anteroposterior and lateral check radiographs of the cervical spine were obtained on the first postoperative day as well. The cervical collar was removed the same day after these radiographs were deemed satisfactory. Physiotherapy for rehabilitation of the cervical muscles by way of isometric contraction was initiated on the first day. Patients were observed for any sign of dysphagia (no special scale—only dichotomized evaluation of "yes" or "no" was used). Patients were discharged home on the third or fourth postoperative day.

Patients received regular follow-up in the outpatient clinic; at 6 weeks then 3, 6, 12, and 24 months after surgery. Before surgery, and at every postoperative outpatient visit, the study patients were asked to complete the neck disability index questionnaire[8] to assess the overall amount of disability caused by their cervical spine pathology with regards to their activities

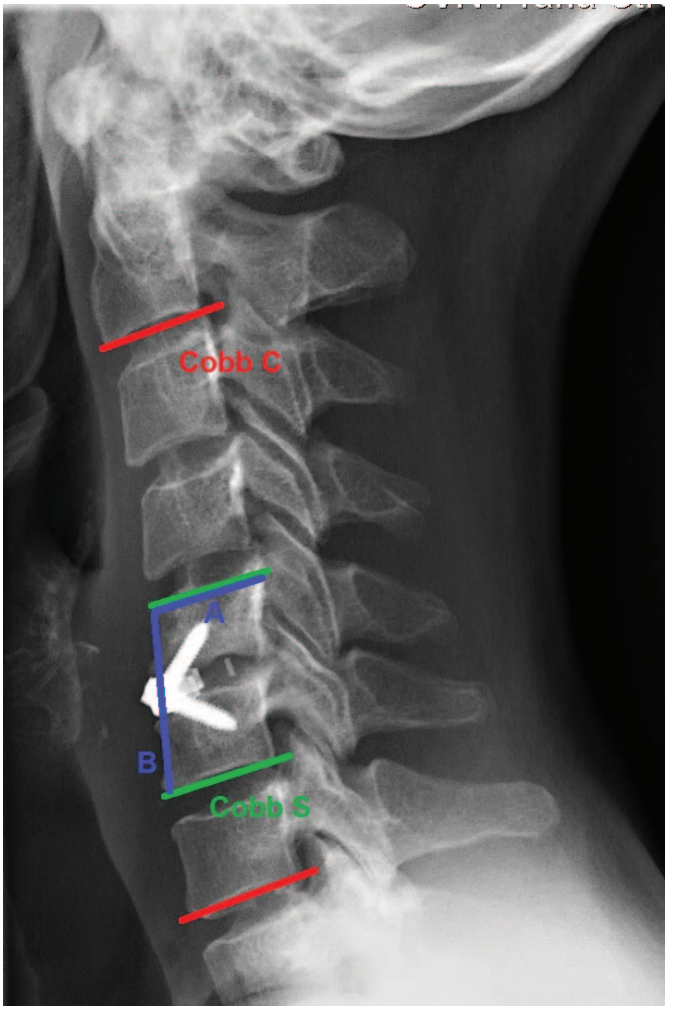


**Figure 1.** Technique of Cobb C, Cobb S, and relative height of segment measurement.

of daily living. Patients were asked about any symptoms of dysphagia immediately and during the follow-up control. The patients' overall satisfaction regarding the result of surgery was monitored by the modified criteria proposed by Odom, at the end of the follow-up period (1 − excellent + good × 2 − fair + poor).[9] New anteroposterior and lateral radiographic images of the cervical spine were obtained within the course of each follow-up control; additional dynamic imaging was performed at 6, 12, and 24 months after surgery. Before the surgery and during the postoperative follow-up, the sagittal profile of the cervical spine was assessed from the radiographs using the Cobb angle measured between the lower endplate of the second cervical vertebra and the lower endplate of the seventh cervical vertebra (if visible). Otherwise the lower endplate of the most caudal visible cervical vertebra was, always carried out in the same way for each patient (Cobb C). Similarly, the Cobb angle (Cobb S) of the treated segments was measured and monitored. The change in height of the treated segment(s) was measured at the same time. With respect to a standardized measurement of the segment Height. This was calculated as a ratio of the upper endplate size to the segment height measured in parallel to the anterior spine

**TABLE 1. Baseline Characteristic of Study Groups**

| | Zero-P | Cage + Plate | *P* |
|---|---|---|---|
| Sex | | | |
| Male | 26 | 19 | 1.000 |
| Female | 18 | 14 | |
| Age | 33–77 yr | 35–74 yr | |
| Mean | 50.2 ± 10.3 | 51.8 ± 12.9 | 0.290 |
| Number of treated segments | | | |
| One | 33 | 25 | 1.000 |
| Two | 11 | 8 | |
| Level | | | |
| C3–C4 | 4 | 7 | |
| C4–C5 | 10 | 6 | |
| C5–C6 | 25 | 18 | |
| C6–C7 | 16 | 10 | |
| Cage height | | | |
| 4 mm | 0 | 2 | |
| 5 mm | 7 | 8 | |
| 6 mm | 11 | 12 | |
| 7 mm | 23 | 15 | |
| 8 mm | 14 | 3 | |
| 9 mm | 0 | 1 | |

(in mm) (Figure 1). The computed tomography was not used for fusion assessment to minimize patient irradiation. Long-term radiological stability was assessed after 2 years using dynamic radiographic images and bony bridging counting over the treated segments: (1) stable—2 or more bony trabecular bridging over the treated segment together with a change no more than 2° on flexion-extension radiograph; (2) probably stable—at least one bony bridge and the same finding on flexion-extension radiograph such as in grade 1; and (3) unstable—no sign of bony healing or more extensive movement than 2° on flexion-extension radiograph. An independent observer, radiologist who was not a member of the team, recorded these data and added them into a database.

Follow-up data of Cobb S and Cobb C angles and relative height of the treated segments were processed statistically using ANOVA for repeated measures. Effects of time (treatment), group (Zero-P *vs.* interbody cage and plate) and their interaction were studied. Comparison of categorical variables was done using the Fisher test.

## RESULTS

The implant Zero-P spacer was implanted in 44 patients, giving a total of 55 treated segments. The control group consisted of 33 patients treated with a plate and a cage for stabilization in a total of 41 segments. Surgical procedures covered the whole extent of the subaxial cervical spine from C3 to C7 and both groups were comparable with respect to the number of treated segments in each level. Both groups were also comparable regarding the ratio of patients in which mono- or bisegmental surgery was indicated (Table 1). No adverse events relating to the surgical treatment were recorded.

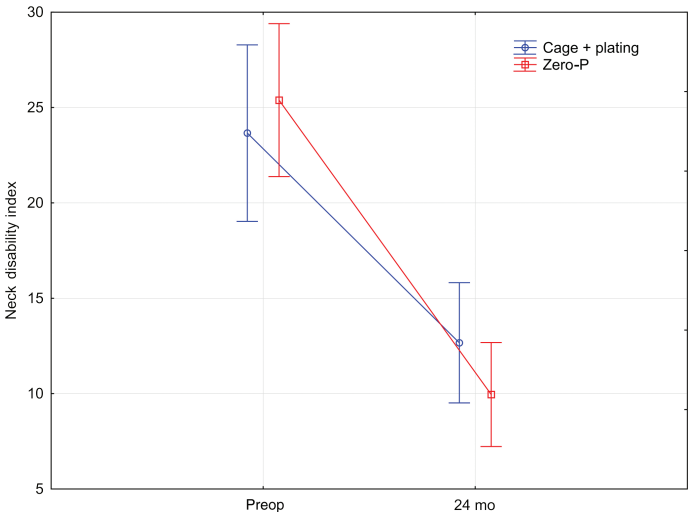


**Figure 2.** Course of neck disability index values during follow-up. Preop indicates preoperative.

Preoperative values of neck disability index and values after follow-up are depicted in Figure 2. Significant effect of treatment ($P < 0.001$) was shown. The percentage of overall improvement achieved reached 61. No group or interaction effect was found. Any degree of dysphagia in early postoperative course was encountered in 10 patients in Zero-P group and in 10 patients in cage and plate group ($P = 0.600$). At completed follow-up, dysphagia was still present in 1 patient in the Zero-P group and in 3 patients in the cage and plate group ($P = 0.308$).

The measured Cobb C values showed lower values prior to surgery, as well as during the postoperative follow-up, in the Zero-P group compared with patients with a cage and plate; however, the impact of the group variable was not proven ($P = 0.051$). Time effect was not shown to be significant either ($P = 0.075$). Cobb C values for the whole patient group in the postoperative period increased to a maximum in the follow-up visit at 6 weeks, and these values decreased again slightly in later follow-up visits. Interaction between the group and time was not proven ($P = 0.082$); Cobb C progress can be considered as comparable in both monitored groups (Figure 3). In the study of Cobb S variable progress, the time effect was proven ($P < 0.001$). A significant increase of Cobb S value was evident in the first postoperative visit, and these values decreased gradually again in further periods. Interaction between the group and time was also proven ($P < 0.001$). The maximum Cobb S value in the Zero-P group was achieved in the first postoperative control, and in the other group it was measured in the second postoperative control. Cobb S values measured later on

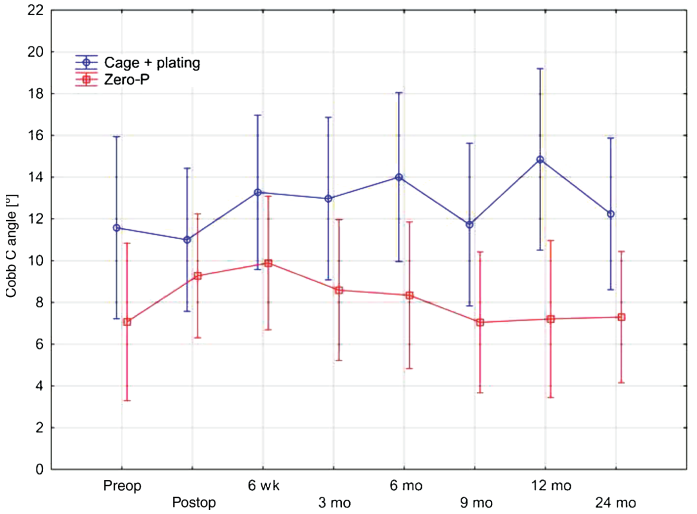


**Figure 3.** Development of radiological parameter Cobb C during follow-up. Preop indicates preoperative; postop, postoperative.

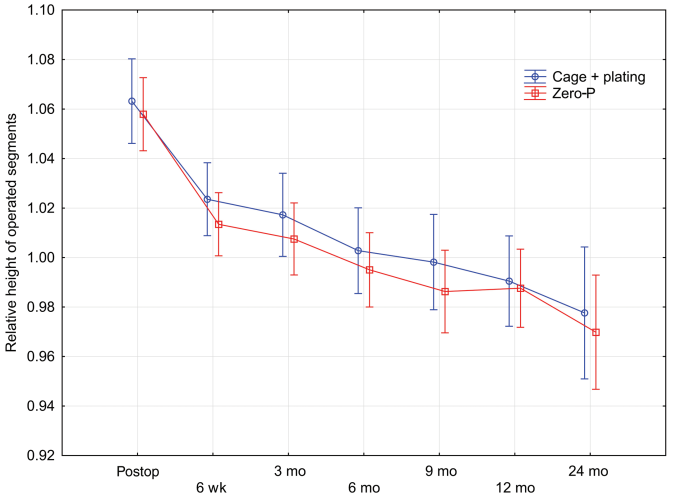


**Figure 5.** Development of radiological parameter relative height during follow-up. Postop indicates postoperative.

are comparable in both groups (Figure 4). The relative height of treated segments in respect of preoperative state in both groups is depicted in Figure 5. Interaction has not been recorded here, and the progress was comparable in both groups. When assessing the whole patient group, the time effect was significant ($P < 0.001$). Mean increase in the height of the treated segments was 6% in the first postoperative visit. This value then decreased gradually with time reaching 97% of preoperative state by the 24-month follow-up visit. Group effect or interaction between the group and time was not proven here.

Two years after surgery, long-term radiological stability was comparable in both groups (Table 2). During the follow-up, no patient underwent repeated surgery as a consequence of implant failure.

## DISCUSSION

The requirement to increase the immediate postoperative stability after bone grafting between vertebral bodies led to the development of an anterior plating system. Originally, these systems were unstable in respect to the angle and had no locking screws. They were shortly followed by a second generation of angle-stable plates with screws anchored in the plate, and subsequent third generation type of dynamic plating systems where the screws are rigidly anchored in a plate, which also allows for controlled reduction of the treated segment and thus offering better conditions for bony fusion.[3,10,11] However, neither plating system is free from complications. Complications in the sense of hardware failure are reported in up to 35% of cases when all generations of plating systems are assessed together. Analysis of angle-stable systems showed up to 18% of mentioned failures, although most of the series refer to the incidence of these complications being of a lower percentage.[4,5,11,12] The presence of a plate itself in the anterior cervical spine and its contact with the esophagus is considered to be a possible cause of postoperative dysphagia; the incidence of which is reported as being up to 30% during the first 3 months after surgery that plateaus at 1 year at a rate of 13% to 21%.[13] This theory might also be confirmed by the significantly lower incidence of postoperative dysphagia in patients after simple cervical arthroplasty as compared with those treated with the addition of a cervical plate.[5] The presence of a plate is also likely to accelerate degenerative changes in adjacent segments.[4]

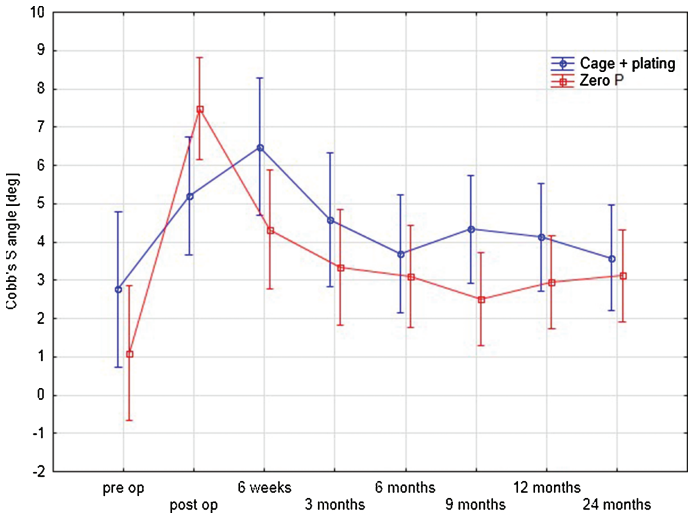


**Figure 4.** Development of radiological parameter Cobb S during follow-up. Preop indicates preoperative; postop, postoperative.

Interbody cages are designed to be implanted without additional anchoring in the segment—stand-alone technique.[14,15] Despite this method of treatment being widely accepted,[16–18] it also has a number of drawbacks. The main disadvantage is lower extension stability of the unanchored cage that is probably responsible for the cage sinking in, or for the later segmental kyphosis in the treated segment.[19,20] Immediate biomechanical stability achieved in a segment treated with the Zero-P spacer was tested within an *in vitro* study conducted by Scholz *et al*.[21] There was a lower stability of the Zero-P device in flexion and extension compared with cages with a locking plate. However, the difference was not found to be significant. No difference in lateral flexion and

**TABLE 2. Long-term Radiological Stability After 2 Years of Follow-up**

| | Zero-P | Cage + Plating |
|---|---|---|
| Stable | 41 | 29 |
| Probably stable | 3 | 4 |
| Unstable | 0 | 0 |

*Stable—2 or more bony trabecular bridging over the treated segment together with a change no more than 2° on flexion-extension radiograph; probably stable—at least one bony bridge and the same finding on flexion-extension radiograph such as in grade 1; unstable—no sign of bony healing or more extensive movement than 2° on flexion-extension radiograph.*

rotation was found between the groups.[21] An integral part of the Zero-P spacer is a plate and screw system, eliminating the basic disadvantage of stand-alone cages, which is extension instability.[14,18,19]

Zero-P spacer implantation may result in a certain distraction in the anterior part of the surgical site and may be responsible for development of a larger lordosis, higher Cobb S values, of the treated segment in comparison with the technique of a cage with a locking plate. On the contrary, if the implanted cage is anchored with a plate, the plate implantation then leads to segmental compression through the cage. An anterior compression of the treated segment results in the reduction of segmental lordosis, achieved within the previous cage implantation. However, at the 6-week follow-up visit, the physiological load shows a significant decline of Cobb S values in the group with the Zero-P spacer. Apart from axial load, it is probably due to the mentioned lower biomechanical stability of the implant in flexion and extension. On the contrary, the same mechanism leads to an increase of Cobb S values in patients with plate stabilization where the physiological load of the segment works against tension on the anterior spine produced by the plate, which corresponds to maximum Cobb S values measured 6 weeks after surgery. A decline in Cobb S values was reported in both groups from the sixth week; there were no significant differences between both monitored groups for the remaining follow-up period. It was published that mono- or bisegmental cervical surgery does not affect the complex sagittal profile of the cervical spine, even in cases of cage sinking followed by progressive segmental kyphosis.[22] This also applies to our patient group—the complex sagittal profile of the cervical spine expressed by the measured Cobb C value did not show any significant changes in comparison of both groups as well as in the whole postoperative progress.

Sinking in of the stand-alone cages with or without subsequent segmental kyphosis is considered to be one of the major disadvantages of this type of cervical stabilization.[19] Song *et al*[23] compared the stand-alone cage technique and the technique of the cage with a locking plate and reported 32.3% of sinking with unanchored cages against 9.7% in the group with the locking plate. We assessed relative height reduction of treated segments, and we found no significant difference in relative height reduction between both studied groups.

Because we did not obtain follow-up CT scan, we were not able to assess fusion of treated segments. Therefore we were able to assess only radiological stability from plain radiographs. In our patient group, we found radiological stable or probable stable situation in all segments in both study groups 24 months after surgery.

In contradiction to the study published ahead of print by Miao *et al*,[24] we did not find a significant difference in the incidence of dysphagia during the follow-up. Although a lower incidence of dysphagia was found in those patients treated with Zero-P implant, this study lacks sufficient power to statistically demonstrate superiority of Zero-P group over cage and plate group for dysphagia. Both techniques led to a significant reduction in pain in our patients, as assessed by neck disability index and this data corresponds to early published ones. The same results were found in the patients' overall satisfaction with follow-up at 2 years according to the criteria proposed by Odom.

## CONCLUSION

The results of this study confirm biomechanical assumptions associated with the Zero-P spacer. Implantation of this new cage results in setting required biomechanical conditions in the treated segment are comparable with those when the segment is treated with a dynamic plate. However, the potential of the mentioned implant to reduce the incidence of postoperative dysphagia was not proven on this sample of patients. Further observation to monitor potential reduction of adjacent segment degeneration is mandatory and planned.

### ➢ Key Points

- ❑ Anterior cervical discectomy or microdiscectomy is a common surgical procedure given the high incidence of degenerative disease of the cervical spine. Despite significant technological progress represented by new dynamic technologies, interbody fusion is still indicated in the overwhelming majority of cases.
- ❑ There are basically 2 ways to provide interbody fusion; the first is by way of an unanchored stand-alone bone graft or cage, and the second is with bone graft or a cage anchored with a plate. Both concepts have their own benefits as well as potential drawbacks.
- ❑ Low-profile angle-stable spacer Zero-P is an implant that can potentially limit the drawbacks of both these procedures.
- ❑ The results of this study confirm biomechanical assumptions associated with the Zero-P spacer. Implantation of this new cage results in setting required biomechanical conditions in the treated segment are comparable with those when the segment is treated with a dynamic plate. On the other hand the potential of the mentioned implant to reduce the incidence of postoperative dysphagia was not proven on this sample of patients.

## References


1. Smith GW, Robinson RA. The treatment of certain cervical spine disorders by anterior removal of the intervertebral disc and interbody fusion. *J Bone Joint Surg Am* 1958;40:607–24.
2. Jacobs W, Willems PC, Kruyt M, et al. The Cochrane Collaboration: systematic review of anterior interbody fusion techniques for single and double level cervical degenerative disc disease. *Spine* 2011;14:E950–60.
3. Vanek P, Bradac O, DeLacy P, et al. Comparison of three fusion techniques in the treatment of the degenerative cervical spine. Is autograft really "the golden standard"? *Spine* 2012;37:1645–51.
4. Kao FC, Niu CC, Chen LH. Maintenance of interbody space in one- and two-level anterior cervical interbody fusion: comparison of the effectiveness of autograft, allograft and cage. *Clin Orthop Relat Res* 2005;430:108–16.
5. McAfee PC, Capuccino A, Cunningham BW, et al. Lower incidence of dysphagia with cervical arthroplasty compared with ACDF in a prospective randomized clinical trial. *J Spinal Disord Tech* 2010;23:1–7.
6. Pitzen TR, Chrobok J, Stulik J, et al. Implant complications, Psion, loss of lordosis and outcome after anterior cervical plating with dynamic or rigid plates. *Spine* 2009;34:641–46.
7. Shimamoto N, Cunningham BW, Dmitriev AE, et al. Biomechanical evaluation of stand-alone interbody fusion cage in the cervical spine. *Spine* 2001;26:432–36.
8. Vermon H, Mior S. The neck disability index: a study of reliability and validity. *J Manip Physiol Ther* 1991;14:409–15.
9. Odom GL, Finney W, Woodhall B. Cervical disc lesions. *J Am Med Assoc* 1958;166:23–8.
10. Bohler J, Gaudernak T. Anterior plate stabilization for fracture dislocations of Loir cervical spine. *J Trauma* 1980;20:203–5.
11. Lowery GI, McDonough RF. The significance of hardware failure in anterior cervical plate fixation. Patient with two to seven-year follow-up. *Spine* 1998;23:181–86.
12. Suchomel P, Barsa P, Buchvald P, et al. Autologous versus allogenic bone grafts in instrumented anterior discectomy and fusion: a prospective study with respekt to bone union patern. *Eur Spine J* 2004;13:510–5.
13. Riley LH, Skolasky MA, Albert TA. Dysphagia after anterior cervical decompression and fusion: prevalence and risk factors from a longitudinal cohort study. *Spine* 2005;30:2564–69.
14. Matge G. Cervical cage fusion with five different implants: 250 cases. *Acta Neurochirurg* 2002;144:539–49.
15. Vavruch L, Hedlund R, Javid D, et al. A prospective randomized comparison between the Cloward procedure and a carbon fibre cage in the cervical spine: a clinical and radiologic study. *Spine* 2002;27:1694–01.
16. Fernández-Fairen M, Sala P, Dufoo M Jr, et al. Anterior cervical fusion with tantalum implant: a prospective randomized controlled study. *Spine* 2008;33:465–72.
17. Hacker RJ. A randomised prospective study of an anterior cervical fusion device with minimum two years follow-up results. *J Neurosurg* 2000;93:222–6.
18. Peolsson A, Vavruch L, Hedlund R. Long-term randomised comparison between a carbon fibre cage and the Cloward procedure in the cervical spine. *Eur Spine J* 2007;16:173–78.
19. Kadziora F, Pflugmacher R, Schafer J, et al. Biomechanical comparison of the cervical spine interbody fusion cages. *Spine* 2001;26:1850–57.
20. Kolstad F, Nygaard OP, Andersen H, et al. Anterior cervical arthrodesis a "stand-alone" cylindrical titanium cage. Prospective analysis of radiographic parameters. *Spine* 2010;35:1545–50.
21. Scholz M, Reyes PM, Schleicher P, et al. A new stand-alone cervical anterior interbody fusion. Biomechanical comparison with established anterior cervical fixation device. *Spine* 2009;34:156–60.
22. Barsa P, Suchomel P. Factor affecting sagittal malalignment due to cage subsidence in stand-alone cage assisted anterior cervical fusion. *Eur Spine J* 2007;16:1395–400.
23. Song KJ, Teghavi CE, Lee KB, et al. The efficacy of plate construct augmentative versus stand-alone in anterior cervical Psion. *Spine* 2009;34:2886–92.
24. Miao J, Shen Y, Kuang Y, et al. Early follow-up outcomes of new Zero-profile implant used in anterior cervical discectomy and fusion. *J Spinal Disord Tech* 2012; Nov 16 ahead of print.