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SYMPOSIUM: CURRENT CONCEPTS IN CERVICAL SPINE SURGERY

# A New Zero-profile Implant for Stand-alone Anterior Cervical Interbody Fusion

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**Abstract**

*Background* Several studies suggest fusion rates are higher with anterior cervical discectomy and fusion procedures if supplemented with a plate. However, plates may be associated with higher postoperative morbidity and higher rates of dysphagia. This led to the development of a cervical stand-alone cage with integrated fixation for zero-profile segmental stabilization.

*Questions/purposes* We asked whether this new implant would be associated with a low rate of dysphagia and other short-term complications in patients having anterior cervical discectomy and fusion and would be able to achieve solid fusion and maintain postoperative reduction in pain.

*Methods* We prospectively followed 38 patients with radiculopathy/myelopathy undergoing anterior cervical discectomy and fusion using the new implant. Intraoperative parameters, clinical features (Neck Pain Disability Index, visual analog scale score for neck/arm pain, Odom's criteria), and dysphagia scores were recorded. Radiographs were taken to assess implant failure. Thirty-four patients had a minimum 6 months' followup (mean, 8 months; range, 6–11 months).

*Results* Three patients at 6 weeks and one patient at 6 months complained about minor dysphagia-related symptoms. There was no hardware failure recordable and all patients had evidence of fusion. Compared to preoperatively, visual analog scale pain score and Neck Pain Disability Index were reduced at 6 weeks' followup without change during further followup.

*Conclusions* The new cervical stand-alone anterior fusion device allows decompression and fusion with low complication rates. The incidence of chronic postoperative dysphagia was infrequent in comparison to published data. Prospective randomized trials with more patients and longer followup are necessary to confirm these observations.

*Level of Evidence* Level IV, therapeutic study. See Guidelines for Authors for a complete description of levels of evidence.

The authors (MS, FK) certify they have or may receive payments or benefits from a commercial entity (Synthes GmbH Switzerland, Oberdorf, Switzerland) related to this work.
Each author certifies that his or her institution approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research.

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## Introduction

Degenerative conditions of the cervical spine (eg, degenerative disc disease or cervical spondylotic myelopathy) are a major cause of radicular arm pain with or without neurologic deficits. When nonoperative treatment fails, surgery may be considered. There are two different philosophies to treat a diseased motion segment after cervical spine anterior decompression: an interbody fusion [13, 19] or a disc prosthesis [16]. Anterior cervical discectomy and

fusion (ACDF) is considered the "gold standard" surgical treatment for elderly patients or for patients with contraindications for the use of a cervical disc prosthesis [17]. Many surgeons prefer to add an anterior plate in fusion procedures for enhancing stabilizing properties, as several studies suggest this leads to increased fusion rates and reduced failure rates, particularly in multilevel procedures [5, 14, 32].

The addition of a plate is, however, not without side effects. Although the profile of current anterior plates is thinner than that of earlier designs, the plates are still somewhat bulky. In the early postoperative period, 2% to 67% of the patients may complain of dysphagia [33]. Mostly these symptoms disappear during the first 3 months after surgery [3, 18], but not all patients recover completely from swallowing problems. The incidence of chronic dysphagia-related symptoms after ACDF ranges from 3% to 21% in the current literature [10, 15, 24, 38], whereas the pathophysiologic cause still remains unclear. Additionally, the screw-plate interface might lead to postoperative complications. Cases of migrating screws and subsequent soft tissue damage are reported [6, 25]. Further, Park et al. [22] demonstrated a higher incidence of adjacent-level degenerations if an additional plate was used. The authors stated this finding is consistent with inappropriate sized or misaligned plates interfering with the adjacent-level disc space. Yang et al. [37] supported this thesis, demonstrating lower rates of adjacent-level degeneration performing ACDF without plates.

Based on these results, a radiolucent implant (Fig. 1) for stand-alone anterior interbody fusion procedures of the cervical spine (Zero-P; Synthes GmbH Switzerland, Oberdorf, Switzerland) was developed to potentially avoid these complications. This implant was based on an anterior stand-alone stabilization implant of the lumbar spine described previously [7, 29]. One in vitro biomechanical study [30] showed similar stability using the cervical implant with integrated screws in comparison to already established cervical cage and plate constructs. In 2007 the implant received the CE mark. In February 2008, the US Food and Drug Administration approved the clinical use of this implant for degenerative cervical spine conditions.

**Fig. 1** An image shows the Zero-P implant. Reprinted with permission from Synthes GmbH Switzerland (Oberdorf, Switzerland).

We asked (1) whether this new implant is associated with a low rate of dysphagia and other short-term complications in patients having ACDF; (2) whether this implant is able to achieve solid fusion; (3) whether this implant is able to maintain the postoperative reduction in pain; and (4) whether a learning curve using the implant is detectable.

## Patients and Methods

We enrolled 38 selected patients (24 male, 14 female) who underwent ACDF between May 2008 and May 2009. All patients had symptomatic cervical spine disc disease between C3/C4 and C7/Th1 and failed nonoperative treatment. The indications for surgery were radicular arm pain with or without neck pain and/or functional/neurologic deficit confirmed by MRI or CT. The displayed patient example shows a typical two segmental cervical spinal stenosis in sagittal MRI (Fig. 2A). Axial MRI plain revealed that the spinal canal stenosis was caused by (Fig. 2B) soft disc stenosis C4/C5 and (Fig. 2C) C5/C6 resulting in (Fig. 2D) radiculopathy of C5 and C6 and myelopathic changes in C5/C6. Patient selection was based on inclusion and exclusion criteria (Table 1). We operated on 15 patients with monosegmental, 20 patients with bisegmental, and three patients with trisegmental disease (Table 2). All 38 selected patients were treated by anterior decompression and stabilization with the Zero-P device in the target levels, with a total of 64 levels operated on.

In the operation theater, patients were placed with a head extension in supine position. To obtain the target disc space, a standard left side approach to the cervical spine was performed. After anterior decompression, trial spacers were used to determine which implant shape would be used. After the trial spacer was correctly fitted into the disc space, a corresponding Zero-P implant filled with β-tricalcium phosphate (chronOS cylinder; Synthes GmbH, Oberdorf, Switzerland) was inserted with an implant holder/aiming device. Correct position of the cage was controlled by using an image intensifier in lateral and AP views. The device should be placed 2 mm behind the anterior column in the lateral view (Fig. 2E) and in the center of the disc space in the AP view (Fig. 2F). The three different implant configurations offered are with a parallel-shaped endplate (Fig. 3A), a convex-shaped endplate

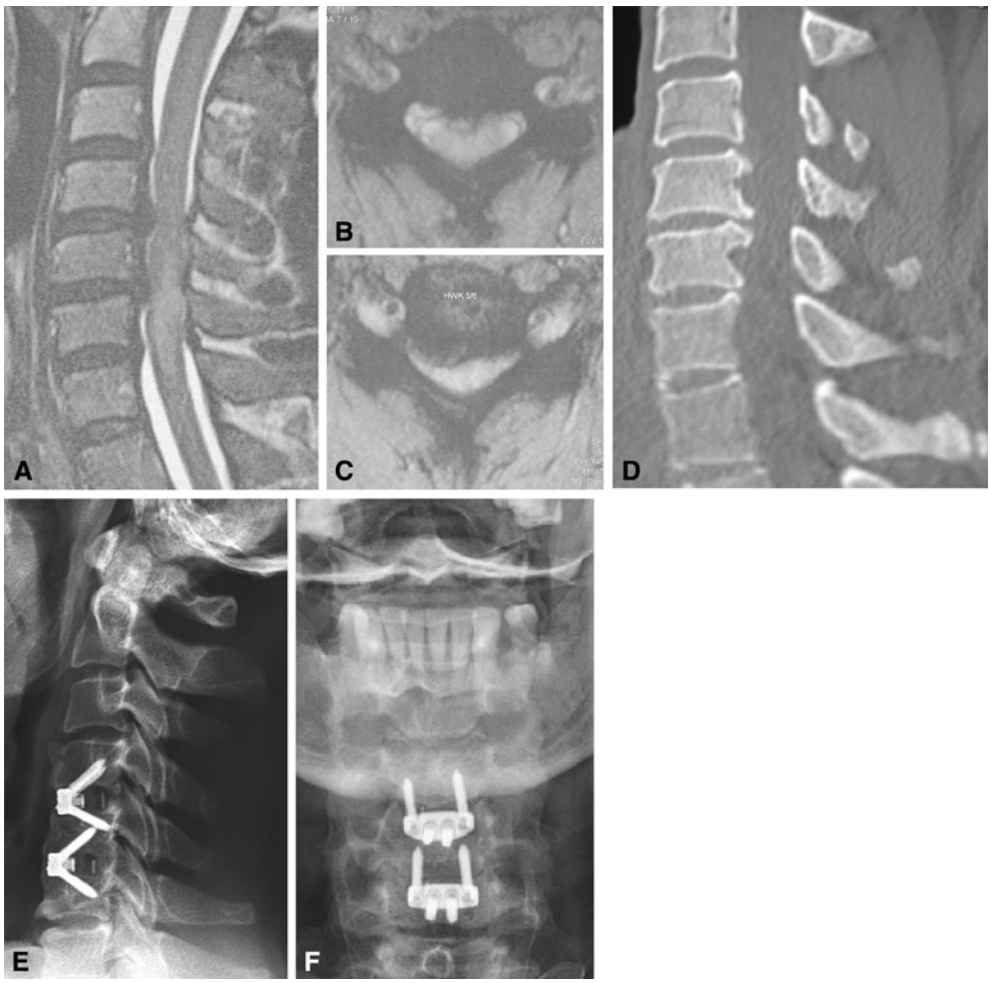


**Fig. 2A–F** (**A**) T2-weighted MRI in sagittal plain, (**B**) MRI in axial plain of C4/5, (**C**) MRI in axial plain of C5/6 and (**D**) CT in 2D-sagittal reconstruction show a cervical spinal stenosis C4/C5 + C5/C6 resulting in radiculopathy of C5 and C6 and myelopathic changes in C5/C6. (**E**) Lateral and (**F**) AP plain radiographs show the patient 6 months after decompression and fusion with Zero-P.

(Fig. 3B), and a lordotic-shaped endplate (Fig. 3C). The Zero-P device contains a polyether ether ketone body with tantalum markers to control the position during insertion. Included is a small plate containing four holes with internal screw treads. After drilling the pilot hole through the aiming device, the first locking screw was inserted. The implant system contains screws of 14- and 16-mm lengths. In most of the cases described in this report, screws of 16-mm length were used. Subsequently, the other three holes were drilled using the guidance of the aiming device. The aiming device was then removed and the three remaining screws were inserted using torque limitation (1.2 Nm). When the Zero-P implant is completely inserted, its zero-profile characteristic can be seen (Fig. 4). Angled instruments for drilling and inserting screws in the upper (C3/C4) and lower (C6/C7/Th1) cervical spine are also available.

To assess a potential learning curve with the implant, the operation time and radiation time were recorded. The average operation time for a monosegmental decompression and stabilization lasted 114 ± 24 minutes and the radiation time was calculated as 88 ± 54 seconds. For the bisegmental operation, the average operation time increased by 31% to 150 ± 30 minutes and the average radiation time increased by 21% to 107 ± 77 seconds. In comparison to a monosegmental operation, the average operation time of a trisegmental stabilization increased by 68% to 192 ± 50 minutes and the average radiation time by 92% to 169 ± 56 seconds.

Postoperatively, we used no collars regardless of the number of operated levels. All patients received standardized pain medication containing metamizole and an oral muscle relaxant. Supervised by a physiotherapist, the patients were mobilized on the first day after the operation and received physical treatment with heat and/or massages for the dorsal neck. No active physiotherapy for the neck was allowed within 6 weeks postoperatively. The average hospitalization time was 6 days (range, 4–11 days).

During followup, clinical and radiographic data were collected on the last day of hospital stay, at 6 weeks, at 3 months, and at 6 months. Complications were recorded as implant-related, surgery-related, or general (not directly implant or surgery related). Four of the 38 patients (11%) did not appear for one of the followup examinations. These patients were excluded from the study. The remaining 34 patients were included in the clinical and radiographic evaluations at each followup time. The minimum followup was 6 months (mean, 8 months; range, 6–11 months).

**Table 1.** Patient selection criteria

| Criteria |
|---|
| Inclusion |
| Age 18–70 years |
| Symptomatic cervical disc disease between C3/C4 and C7/Th1 with |
| Neck or arm (radicular) pain and/or |
| Functional/neurologic deficit confirmed by imaging (CT or MRI) |
| Exclusion |
| Previous surgery at the index level |
| Fused level adjacent to the index level |
| Patients having no contraindication for total disc replacement and wanting to be treated with total disc replacement after informed consent |
| Systemic or local infection |
| Active rheumatoid arthritis, noncontrolled diabetes mellitus, or any other medical condition(s) that would represent an increase in surgical risk or interfere with normal healing |
| Known history of osteoporosis |
| Previous known allergy to the materials contained in the device, such as polyether ether ketone or titanium alloy |
| History of any invasive malignancy (except nonmelanoma skin cancer) unless treated with curative intent and there has been no clinical signs or symptoms of the malignancy for more than 5 years |
| Pregnant or planning to become pregnant during study period |

Clinical examination included measurement of neck and radicular arm pain on a visual analog scale (VAS) of 0 to 100, with 0 representing no pain and 100 representing severe pain [4, 8], and assessment of functional outcome using the validated German translation of the Neck Pain and Disability Scale (NPAD-D), expressed as a percentage ranging between 0% and 100% [12, 28]. Dysphagia-related symptoms were graded by the physician depending on the patient's state as none (no episodes of swallowing problems), mild (rare episodes of dysphagia), moderate (occasional swallowing difficulty with specific food), and severe (frequent difficult swallowing with majority of food) according to Bazaz et al. [3]. Additionally, the amount of pain (VAS 0–100) and the duration of dysphagia-related symptoms were recorded.

Three of us (MS, AP, FK) independently evaluated all images including plain radiographs and lateral flexion/extension radiographs. At the day of discharge and at each followup visit, plain radiographs (AP and lateral views) were used to detect implant failure, including segmental collapse, caused by implant subsidence. An implant penetration into the adjacent endplates of more than 2 mm was defined as segmental collapse [39]. According to Pitzen et al. [23], fusion was defined as an absence of radiolucencies, absence of bone sclerosis, and evidence of bridging trabecular bone within the fusion area.

We computed means and SDs for continuous data (VAS, NPAD-D scores). We determined differences in VAS and NPAD-D scores between preoperative and postoperative time points and during further followup using the t test for paired samples if a normality test was passed or a Wilcoxon signed-rank test if a normality test was failed. Intraobserver variability for radiographic evaluation was determined using kappa statistics. SPSS® software (Version 15.0; SPSS Inc, Chicago, IL) was used for all analyses.

**Table 2.** Preoperative patient data and operated level(s)

| Variable | All patients (n = 38) | Monosegmental ACDF (n = 15) | Bisegmental ACDF (n = 20) | Trisegmental ACDF (n = 3) |
|---|---|---|---|---|
| Age (years)* | 53.7 ± 9 | 52.8 ± 8 | 54.2 ± 10 | 55.7 ± 3.5 |
| Number of women | 15 | 5 | 8 | 2 |
| Number of men | 23 | 10 | 12 | 1 |
| NPAD-D (%)* | 55.8 ± 18.3 | 49.6 ± 19.1 | 59.5 ± 18.9 | 64.1 ± 12.3 |
| Level C3/C4 | 3 | 0 | 2 | 1 |
| Level C4/C5 | 14 | 2 | 9 | 3 |
| Level C5/C6 | 23 | 6 | 14 | 3 |
| Level C6/C7 | 23 | 6 | 15 | 2 |
| Level C7/Th1 | 1 | 1 | 0 | 0 |
| Total implants | 64 | 15 | 40 | 9 |

* Values are expressed as mean ± SD; ACDF = anterior cervical discectomy and fusion; NPAD-D = German translation of the Neck Pain and Disability Scale.

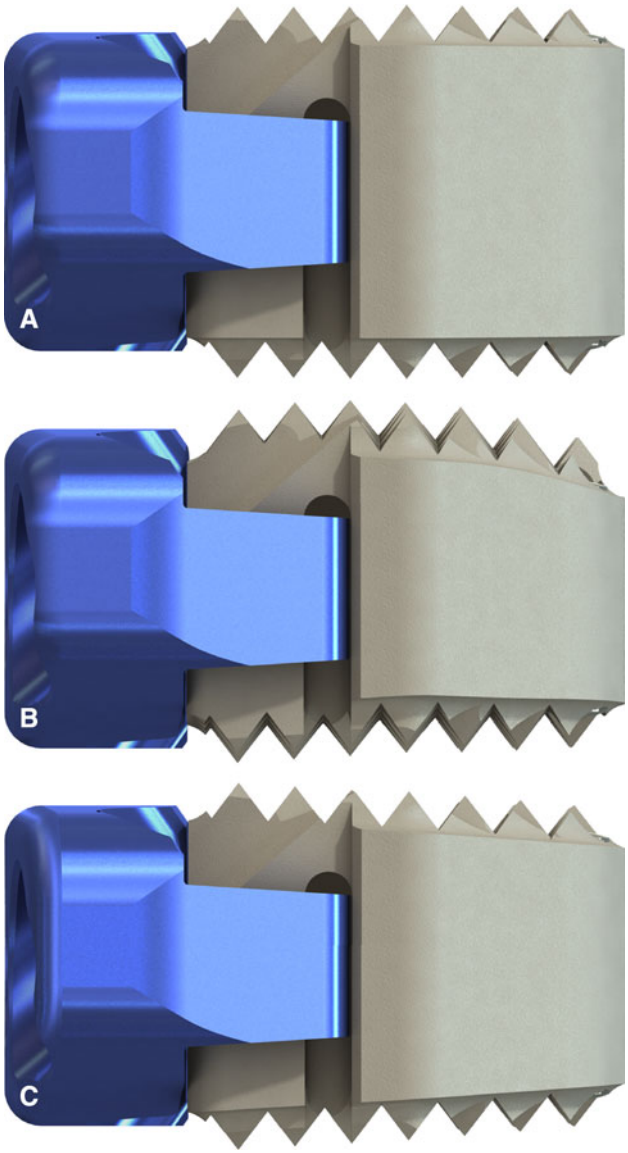


**Fig. 3A–C** Images show different implant configurations: (**A**) parallel-shaped endplate, (**B**) convex-shaped endplate, and (**C**) lordotic-shaped endplate. Reprinted with permission from Synthes GmbH Switzerland (Oberdorf, Switzerland).

## Results

Before surgery, four of 38 patients complained of minor dysphagia (VAS score, 1.7 ± 0.9). In the early postoperative period, 21 of 34 patients (62%) complained about minor dysphagia (VAS score, 2.1 ± 1.2) with symptom duration of 21 ± 16 days. At 6 weeks' followup, the number of patients complaining of minor dysphagia was reduced to three of 34 patients. Only one female patient complained about minor dysphagia (VAS score, 1.6) at 3 and 6 months followup (Fig. 5). According to the Bazaz score [3], there was no moderate or severe dysphagia detectable during followup.

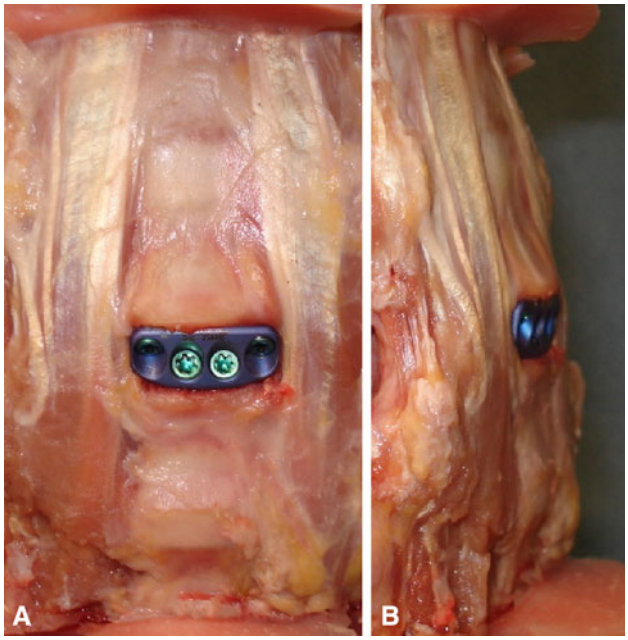


**Fig. 4A–B** (**A**) Lateral and (**B**) AP views show the zero-profile of the Zero-P device implanted in a cadaveric specimen.

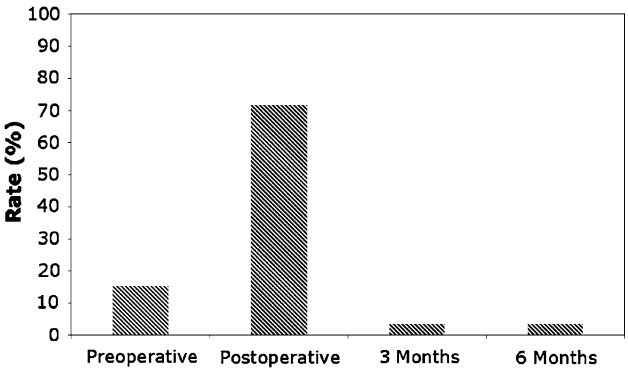


**Fig. 5** A graph shows incidence (percentage) and duration of dysphagia-related symptoms.

Intraobserver agreement for radiographic evaluation was almost perfect. We observed no implant subsidence or segmental collapse by 6 months; there were no radiolucent lines or detectable implant/screw loosening. All patients showed evidence of fusion in each operated segment according to the criteria of Pitzen et al. [23]. We observed no implant-related complications. In two patients, a temporarily swelling of the neck without airway problems caused by a prevertebral hematoma occurred. No patient had revision surgery. One patient developed an allergy to metamizole.

All patients had a reduction in VAS neck pain ($p < 0.001$) (Fig. 6), VAS radicular arm pain ($p < 0.001$) (Fig. 6), and NPAD-D ($p < 0.001$) (Fig. 7) within the first 3 months. We observed no change in VAS neck pain

($p = 0.306$), VAS radicular arm pain ($p = 0.889$), and NPAD-D score ($p = 0.189$) comparing 3 and 6 months' followup.

Comparing the duration of the monosegmental operations, related to a supposed learning curve, there was a longer operation time for the first three monosegmental operations (143 ± 15 minutes) than for the last three monosegmental operations (93 ± 11 minutes) recordable.

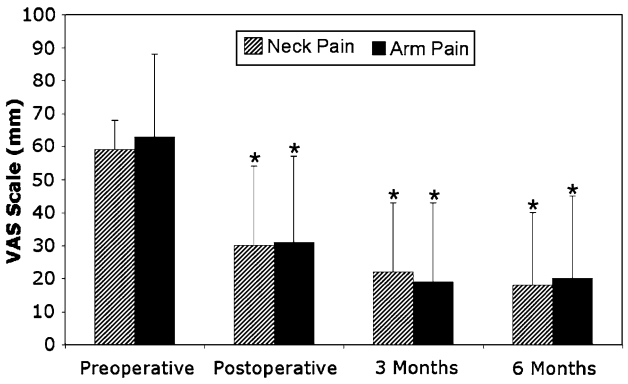


**Fig. 6** A graph shows neck pain and radicular arm pain (0–100 VAS score) preoperatively and during followup. *$p < 0.001$ versus preoperative time point.

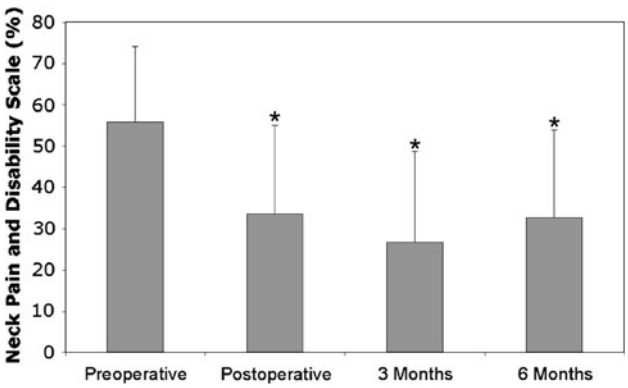


**Fig. 7** A graph shows Neck Pain and Disability Scale (NPAD-D) preoperatively and during follow-up. *$p < 0.001$ versus preoperative time point.

## Discussion

If nonoperative treatment of cervical spine disc disease fails, ACDF or cervical arthroplasty are two possible operative techniques [20, 27, 36]. There are more potential candidates for a cervical total disc arthroplasty than a lumbar total disc arthroplasty, but according to the retrospective study of Auerbach et al. [2], only 43% of patients met their inclusion criteria and were candidates for cervical total disc arthroplasty. If there are contraindications for using an artificial disc, ACDF is still the gold standard for surgical treatment. In cases where ACDF was performed, numerous reports have documented the effective use of additional plating to treat degenerative spine conditions and avoid pseudarthrosis, especially in multilevel procedures [1, 11, 32, 34]. However, the use of an additional anterior plate is associated with various intraoperative and postoperative complications. In this study, we described the first clinical and radiographic results of a new ACDF technique using a cage with an integrated zero-profile plate and angle-stable screws. We asked whether this new implant would be associated with a low rate of dysphagia and other short-term complications in patients having this ACDF procedure, would be able to achieve solid fusion and maintain postoperative reduction in pain, and is associated with a learning curve.

We note several limitations to this study. First, the study was performed as an observational study without a control group. Second, the number of patients was small, and third, the followup time was short at only 6 months. Due to the short-term followup, we were not able to compare adjacent-segment degenerations using the zero-profile implant with those of cage and plate constructs.

Chronic dysphagia is a well-known phenomenon after ACDF and plating, with a wide variability from 3% up to 21% [15, 24, 26, 33, 35]. For the early postoperative period, the rate of dysphagia in our study is similar to that in the current literature [3, 18, 38]. However, in comparison to published data [3, 18, 38], the incidence of chronic dysphagia in our patients was low (Table 3). Only one of 34 patients complained about mild symptoms of dysphagia. According to Fountas et al. [10], postoperative soft tissue

**Table 3.** Comparison of dysphagia rates in the current literature

| Study | Number of patients | Dysphagia short term (< 2 months) | Dysphagia medium term (3–6 months) | Dysphagia long term (> 6 months) |
|---|---|---|---|---|
| Bazaz et al. [3] | 249 | 50.2% | 17.8% (4.8% moderate–severe) | 12.5% |
| Lee et al. [18] | 310 | 54.0% | 18.6% | 15.2% |
| Smith-Hammond et al. [31] | 38 | 47.0% | | 23.0% |
| Yue et al. [38] | 74 | | | 35.1% |
| Scholz et al. [current study] | 34 | 62.0% | 2.9% | |

edema, esophageal injury, postoperative hematoma, and adhesive formations around implanted cervical plates might be possible explanations for dysphagia-related symptoms, although the exact pathophysiologic mechanism remains unknown. According to Lee et al. [18], there is a correlation between plate thickness and dysphagia rate, with decreased dysphagia incidence when thinner plates were used. Several patients with isolated anterior cervical hyperostosis or "diffuse idiopathic skeletal hyperostosis" have revealed symptoms of chronic dysphagia after anterior osteophyte resection [9, 21, 24]. This might suggest why plates are sometimes associated with chronic dysphagia. The zero-profile design of Zero-P avoids an implant contact to the soft tissue in front of the cervical spine. This might avoid any mechanical irritation of the esophagus and may explain the low dysphagia rate in our patients.

Regardless of the number of operated levels in this study, there were no implant-related complications during followup. This finding is contrary to literature data where, especially for multilevel plate reconstructions, a failure rate of up to 71% was reported [26]. In a recent literature review, Vaccaro et al. [35] reported an incidence of screw and plate loosening between 0% and 15.4%, screw breakage between 0% and 13.3%, plate breakage between 0% and 6.7%, plate and graft displacement (with or without graft fracture) between 0% and 21.4%, and implant malposition (screws in discs, plating of unfused segments, etc) between 0% and 12.5% for long segmental anterior plate fixation. Newer implants are designed with different screw-locking mechanisms to avoid these mechanical complications. It should be noted balancing between preferably small plate dimensions (low profile) and the necessity of thicker plates to have a secure constrained screw fixation is challenging from an engineering standpoint. Nevertheless, the problem of screw and plate malposition during surgery still exists. Specifically, the lack of implant migration or screw loosening in this study might be related to the design of the locking plate-screw interface. The plate with an internal screw thread engages with the outer screw thread located in the head of the screw providing a safe, constrained, and angle-stable screw fixation.

Zero-P was able to maintain the postoperative reached level of VAS and NPAD-D pain scores. Comparing these outcome data (VAS and NPAD-D) to those of previously described outcome data of cage and plate constructs [1, 11, 14, 16, 20, 23, 27], no differences could be detected. Due to the short-term followup and the lack of CT evaluation, which is necessary to grade the fusion status, we were not able to compare fusion results with those in the literature.

Using the Zero-P device, especially in the upper and lower cervical spine, was associated with a learning curve. In the first cases, a longer operation time was recorded. It was easy to use the implant in the levels C4/C5, C5/C6, and C6/C7. Below and above, especially in patients with a short neck or high sternum, the screw insertion might be challenging due to the angulation of the screws.

Our observations suggest this new cervical stand-alone anterior fusion device with integrated screw fixation allows anterior cervical decompression and stabilization with low rates of dysphagia. No implant-related complications were observed. We believe the incidence of chronic postoperative dysphagia was infrequent in comparison to published data owing to the "zero" implant profile. A randomized trial with longer followup, comparing the zero-profile fusion technique with established fusion techniques, should be performed to confirm our observations.

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