A cervical “zero-profile” cage with integrated angle-stable fixation: 24-months results

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INTRODUCTION

Whenever conservative treatment of degenerative cervical spine conditions (radiculopathy or myelopathy) fails an operative intervention may become necessary. Anterior Cervical Discectomy and Fusion (ACDF) is the current gold standard, however in cases where there are no contraindications a disc prosthesis may be a viable alternative.

Studies have demonstrated a reduced time to achieve fusion and a higher fusion rate, especially in multilevel ACDF procedures, where supplemental plate fixation has been used (7). However, the use of this accompanying plate may be associated with more complications and a higher post-operative morbidity (13,16).

The purpose of this prospective mono-centric case series study is to investigate the mid-term (minimum follow-up 24 months) safety and efficacy using a new “zero-profile” stand-alone cage with integrated angle-stable fixation in single- and multilevel anterior cervical fusions.

53 consecutive patients with radiculopathy/myelopathy at one to three levels underwent an anterior cervical discectomy and fusion procedure using the “zero-profile” implant (97 levels operated). A CT-scan at 12-months was taken to assess fusion status, implant failure, subsidence and migration.

The overall fusion rate was 97%. 3 out of 45 patients (6.6%) complained about mild dysphagia related symptoms at 24 months follow-up. There was no recorded incidence of hardware failure.

The new cervical stand-alone anterior fusion device allows a safe anterior cervical decompression and stabilisation, a low rate of chronic dysphagia and achieves a high fusion rate. Prospective randomised trials are necessary to confirm these results.

Keywords: anterior cervical fusion; stand alone cage; ACDF; Zero-P.

A cervical stand-alone implant with integrated fixation and locking screws (Zero-P, Synthes GmbH, Switzerland) has been developed to potentially minimise the disadvantages of conventional cage and plate constructs. Preliminary clinical and radiographic 6 months results demonstrated safe usage of the implant and a reduced rate of dysphagia compared to values found in literature. Vanek et al. described a significantly higher fusion rate using the Zero-P implant when compared to a cage combined with a dynamic plate at 9 months follow-up. There is a lack of mid term clinical and radiological evidence for Zero-P, while there is only one study with 24 months FU currently available. However this study does not assess fusion rate by computed tomography. Therefore, it is the purpose of this prospective case series to investigate the mid-term safety (minimum FU 24 months) and efficacy using Zero-P in single- and multilevel procedures. The primary objectives of this study were to determine the percentage of patients with (1) evidence of fusion based on CT-scans at 12 months and (2) clinical absence of dysphagia. Secondary objectives were to evaluate the amount of subsidence/migration of the device, the ability to maintain postoperative lordosis and the incidence of adjacent level degeneration at 24 months after implantation.

### PATIENTS AND METHODS

#### Patient Population

From May 2008 to May 2010, 53 selected patients (28 male and 25 female) with symptomatic cervical spine Degenerative Disc Disease (cDDD) were enrolled in this prospective mono-centric study and underwent an ACDF procedure. Patient selection was based on the inclusion and exclusion criteria described in Table I. Indication for surgery was radicular arm pain with or without neck pain and/or functional/neurological deficit confirmed by MR- or CT-imaging after conservative treatment had failed. Preoperative demographic data and clinical pattern of the patients are depicted in Table II. Treatment for all selected patients comprised anterior decompression and stabilisation with Zero-P in the target levels (total of 97 operated levels).

#### Surgical technique and Postoperative Care

The surgical technique was performed in the same manner as previously described and a standard left side approach was used. All cages were filled with a β-Tricalcium Phosphate cylinder (B-TCP) (chronOS, Synthes GmbH, Switzerland) and no additional autologous bone graft was used. Implant size was intraoperatively measured using probe implants and an appropriate screw length was determined based on the dimensions of the

### Table I. — Patient selection criteria

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<tr>
<th>Inclusion criteria</th>
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<tr>
<td>• Age 18-70 years</td>
<td>• Previous surgery at the index level</td>
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<td>• Symptomatic cervical disc disease (SCDD) between C3/4-C7/T1 with:</td>
<td>• Fused level adjacent to the index level</td>
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<td>– Neck or arm (radicular) pain and/or</td>
<td>• Patients who had no contraindication for TDR and wanted to be treated with TDR after informed consent</td>
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<td>– Functional/neurological deficit confirmed by imaging (CT or MRI)</td>
<td>• Systemic or local infection</td>
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<td>• Active rheumatoid arthritis, non-controlled diabetes mellitus, or any other medical condition(s) that would represent a significant increase in surgical risk or interfere with normal healing</td>
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<td>• Known history of osteoporosis</td>
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<td>• Previous known allergy to the materials contained in the device, such as polyetheretherketone (PEEK) or titanium alloy (TAN)</td>
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<td>• Active malignancy. A patient with a history of any invasive malignancy (except non-melanoma skin cancer), unless treated with curative intent and there has been no clinical signs or symptoms of the malignancy for more than 5 years</td>
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<td>• Pregnant or planning to become pregnant during study period</td>
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vertebral body. Patients were fully mobilised from the first day after surgery without a cervical collar.

**Clinical Evaluation**

Operation time and radiation time were documented intra-operatively. Clinical examinations including measurement of neck pain and radicular arm pain (VAS 0-10) were performed preoperatively and at 3, 6, 12 and 24 months FU. A numeric scale from 0 to 10 was applied to assess the pain experienced, where “0” represents “no pain” and “10” indicates “severe pain”. Similarly, the validated German version of the Neck Pain Disability Index (NPDI-G) expressed as a percentage was used to assess the functional outcome. According to Bazaz et al (2), patient self reported dysphagia related symptoms were graded as “None”, “Mild”, “Moderate” and “Severe”. Additionally, the amount of dysphagia associated pain (VAS 0-10) and the duration of dysphagia related symptoms were recorded.

**Radiologic Assessment**

Plain X-rays with anteroposterior and lateral view in standing position, along with computed tomography films in axial view as well as 2D-reconstructions in sagittal and coronal view were evaluated by three experienced spine surgeons. Radiographs were taken before and after surgery and during FU at 3, 6, 12 and 24 months. A computed tomography with 2D-reconstructions was performed at 12 months FU.

Fusion was evaluated on sagittal and coronal two-dimensional CT reconstructions. If continuous trabecular bone bridges could be confirmed at 12 months FU (at any one of the following locations : anterior, posterior, lateral or within the cage) the segment was classified as fused (Fig. 1A-C). In case of absence of any bony bridge or confirmation of a complete bony discontinuity within the disc space (Fig. 1D) the segment was classified as non-fused (4).

Cage migration and subsidence was evaluated on lateral plain X-rays. To assess cage subsidence and migration the method proposed by Gercek et al (6) was used. Accordingly, anterior and posterior disc space height as well as the distance between the posterior titanium alloy marker pin of the implant and the posterior wall of the lower endplate was measured postoperatively and at 24 months FU. Subsidence was stated as present, if one or both disc space height parameters changed by at least 3 mm (6). Cage migration was stated, if the distance between the posterior cage marker and the posterior wall changed by 3 mm or more (6).

To evaluate changes of the lordotic cervical alignment, measurements were taken preoperatively, postoperatively and at 24 months FU on lateral plain radiographs using a modification of the method described by Faldini et al (3). Global Cervical Lordosis (GCL) was measured between the upper border of C3 and the lower border of C7 ; this is due to fact that the upper boarder of the C3 endplate can be more accurately visualised than that of C2. Fusion Site Lordosis (FSL) was measured between the upper endplate of the cranial fusion site vertebra and the lower endplate of the caudal fusion site vertebra (mono-segmental, bi-segmental or tri-segmental FSL). For cervical alignment, positive values represent lordosis while negative values indicate kyphotic alignment.
To assess adjacent level degeneration the scoring system described by Kellgren and Lawrence (8) was used on lateral plain X-rays at 24 months FU. According to Kellgren and Lawrence, Grade 0 indicates a definite absence of radiographic degenerative changes; Grade 1 indicates a doubtful presence of degeneration; Grade 2 indicates degeneration is definitely present though of minimal severity; Grade 3 indicates moderate degeneration and Grade 4 indicates severe degeneration. Formation of osteophytes, periarticular ossicles, cartilage narrowing with subchondral bone sclerosis, pseudocystic areas and altered bone shape were considered as evidence of degeneration (8).

Statistical evaluation

Data relating to measurements at the different time points were statistically compared using a t-test for paired samples. Statistical differences were defined at a 95% confidence level. The values are given as mean ± standard deviation. SPSS (SPSS 16.0.1, SPSS Inc. Chicago, Illinois, USA) software supported the statistical evaluation.

RESULTS

The patient data of the mono-, bi- and trisegmental treatment groups are depicted in Table II. Of the 53 patients, three patients (6%) did not appear for one of the follow-up examinations within the 12 months after surgery (all three were treated bi-segmentally). Therefore, these patients were excluded from further analysis. The remaining 50 patients (94%) passed the 12 months FU time-point. There was a further loss between 12 and 24 months FU. From the original cohort of 53 patients, 45 patients (85%) passed the 24 months FU time point. The overall loss of patients during FU was 15%.

Intra- and perioperative parameters

Due to the good visibility of the posterior marker it was easy to assess the implant position intraoperative. The implant was inserted adequately deep such that the plate was set back from the anterior tension band and the whole implant resided within the disc space (Fig. 2). Due to the screw angulation it was difficult to insert the implant at level C7/T1 and C3/4 because of possible interference with the sternum or chin. In most of the cases a cage of 6 mm height with convex shape and 16 mm locking crews was implanted.

The average operation time for the 17 mono-segmental ACDF procedures was 116 ± 25 minutes and the radiation time was calculated to be 90 ± 53 seconds. For the 28 bi-segmental operations the average operation time increased by approximately 27 minutes (31%) to 143 ± 32 minutes and the average radiation time increased by approximately 20 seconds (18%) to 110 ± 69 seconds. In comparison to a mono-segmental procedure, the average operation time of the 8 tri-segmental ACDF

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patients was graded as mild and 1 patient complained about moderate dysphagia. On average, the duration of the preoperative swallowing difficulties was 4 years. Postoperatively, none of these 5 patients complained about long-term dysphagia.

Overall 36 out of 50 patients complained about mild dysphagia (VAS 2.4 ± 1.7) with average symptom duration of 31 ± 51 days within the early postoperative period. At 24 months FU, 42 out of 45 patients were free from swallowing difficulties. Only three patients (6.6%) complained about throat pain (VAS 1.8 ± 0.4) at 24 months FU. According to Bazaz et al (2), the dysphagia of these three patients was graded as mild.

**Clinical outcome**

All patient outcomes improved resulting from the surgical procedure confirmed by a significant (p < 0.05) reduction of neck pain, radicular arm pain and NPDI-G within the first 3 months compared to the preoperative values. There was no statistical difference comparing the VAS-values of neck pain (Fig. 2) and radicular arm pain (Fig. 2) and NPDI-G (Fig. 3) during further follow-up. However, a slightly increased average VAS score for neck pain and average NPDI-G value was detectable at 12 months and 24 months without statistical significance.

Prior to surgery 5 out of 53 patients complained about minor swallowing difficulties. 4 out of the 5 patients showed anterior spondylophytes in plain lateral radiographs. According to the Bazaz-Score (2) the preoperative dysphagia from 4 of these 5 patients was graded as mild and 1 patient complained about moderate dysphagia. On average, the duration of the preoperative swallowing difficulties was 4 years. Postoperatively, none of these 5 patients complained about long-term dysphagia.

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**Radiographic outcome**

No anterior or posterior implant migration was recorded during FU. According to the criteria of Gereck et al (6), one female patient, operated in the levels C5/6 and C6/7 showed cage subsidence (Fig. 4) of the uppermost cage into the C6 vertebra without clinical effect (Neck Pain VAS 0, Arm Pain VAS 0 and NPDI-G 2.5%).
Complications

There were two patients with an approach related oedema without airway problems and without indication for revision surgery. Two patients suffered temporary hoarseness probably due to a recurrent laryngeal nerve irritation. One patient developed an allergy against metamizole (general complication).

DISCUSSION

Additional plating, especially in multilevel ACDF procedures, achieves a higher fusion rate and less cage subsidence (4,5,6,9,20). However, this accompanying plate involves a further risk of hardware-related operative and postoperative complications (13,16). Great care must be taken during surgery to avoid plate malpositioning. Plates are sometimes associated with chronic dysphagia, especially if bulky plates are used (10). Placing of an oversized plate close to the adjacent level may increase the rate of adjacent level ossification (13). Vaccaro et al (24) reported a ratio of screw and plate loosening up to 15% and an incidence of screw breakage up to 13.3% in a literature review.
this study the effect of bone mineral density was, at least partially, managed by the exclusion of patients with a history of osteoporosis.

Sugawara et al (21) recommended the use of ß-TCP as bone substitute in combination with titanium cages. The combination of ß-TCP cylinders and Zero-P leads to an excellent fusion rate of 97% in this study. Most notably, all tri-segmentally treated patients showed complete bony fusion after one year.

The general cause of ASD (adjacent level degeneration) is currently not completely understood. There is an increased incidence of adjacent level degeneration if a plate with an inappropriate size is used. Park et al (13) recommended a minimum distance between the end of the plate to the adjoining, untreated disc space of 5mm to avoid plate related adjacent level degeneration. Using Zero-P might avoid the mechanical causes of ASD because all implant material is located inside the treated disc space. However, in our study cohort an increase of ASD of approximately 10% cranially and 13% caudally (Grade 0 to 1) was observed. Furthermore, most of the patients with preoperative evidence of ASD showed an average increase of 1 grade from

A zero-profile device with integrated locking screw fixation, such as Zero-P, might be a potential solution to avoid the majority of plate related complications. In vitro comparison of Zero-P with cage-plate constructs showed equivalent biomechanical stability (18). Clinical and radiographic 6 and 12 months results demonstrated safe usage of the implant and a reduced rate of dysphagia when compared to literature (1,19). Vanek et al (25) reported similar biomechanical stability of Zero-P compared to cage and dynamic plate constructs with 12 months FU. The purpose of this prospective case series was to investigate the mid-term safety and fusion status of a zero-profile device with integrated fixation in single-, two- and three level procedures.

There was no implant related complication recorded, regardless of the number of operated levels, but there was one female patient with radiological evidence of cage subsidence. Different factors have been shown to influence the occurrence of subsidence such as the condition of the vertebral body and the interaction between implant and endplate. The effects of endplate preparation, bone density and loading distribution on the failure of cervical and thoracic endplates have been investigated (11,23). In this study the effect of bone mineral density was, at least partially, managed by the exclusion of patients with a history of osteoporosis.

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the pre-existing state. Another potential reason for ASD is the misalignment of the cervical sagittal profile. It is important to restore and maintain cervical spine lordosis to decrease the degree of ASD as was reported by Faldini et al (3). An increase of GCL angle and FSL angle was observed in our study when comparing the preoperative condition with the postoperative and 24 months FU conditions.

Dysphagia is a well-known phenomenon after ACDF, with a wide range of chronic dysphagia (3% up to 21%) being reported (4,17,22). Regardless of the kind of implant used, up to 71% of patients suffering from approach related dysphagia in the early postoperative period (16). Similar findings were observed in the present study, with 72% of the patients reporting dysphagia with symptoms lasting an average of 31 days.

Our patients with preoperative dysphagia were free of long-term dysphagia in the postoperative course after intraoperative osteophyte resection. This finding is supported by reports of resolved chronic dysphagia after anterior resection of osteophytes in patients with isolated anterior cervical hyperostosis or “Diffuse Idiopathic Skeletal Hyperostosis (DISH)” (12). The prevalence of chronic dysphagia in the present study was low in comparison to published data using cages and additional plates. Only 3 out of 45 patients (6.6%) complained about mild dysphagia symptoms. The presented low rate of dysphagia was comparable to the published data from Azab et al (1) and Qi et al (15) who were using Zero-P for single- and double-level ACDF. These findings might be associated with the design of Zero-P, which avoids protrusion of the implant past the anterior wall of the vertebral body and hence eliminates contact between implant material and soft tissue in front of the cervical spine.

There are limitations associated with a study of this nature given that the study was performed as an observational study without a control group and no randomisation of patients was performed.

**CONCLUSION**

The new “zero-profile” stand-alone cage with integrated angle-stable fixation allows a safe anterior cervical decompression and stabilisation, the maintenance of postoperative achieved cervical lordosis, a low rate of chronic dysphagia and attains a high fusion rate. A randomised trial, comparing this “zero-profile” cervical fusion device with establish-
ed plating techniques, should be performed to prove the encouraging results of this study.

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REFERENCES