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ORIGINAL STUDY

Anterior cervical discectomy and fusion with Scarlet AC-Y cervical secured cage. Safety evaluation and 6 months radiological follow up

Patrick Fransen

From IM2S – Clinique Médico-chirurgicale orthopédique de Monaco, Monaco

Fusion rates in ACDF procedures with classical cages are higher if supplemented with a plate. However, the use of plates has been associated with increased morbidity and dysphagia. As an alternative, we studied the ACDF approach using, a secured titanium cage with integrated fixation screws, which allows for "Zero Profile" segmental stabilization.

We performed a retrospective analysis of prospectively collected data on a group of 32 patients which had been subjected to ACDF using the Scarlet AC-T (*) secured titanium cage. The studied population comprised 13 males (40.6%) and 19 females (59.4%), aged between 36 and 76 years, (mean 56.5 y) and operated between October 1st 2014 and June 1st 2016. A total of 39 cages were implanted (25 in one-level surgery and 14 in two-levels). The most frequently operated levels were C5C6 (22), C6C7 (13), C4C5 (2) and C3C4 (2).

All the operated patients initially presented with neck and arm pain. 17 had signs of myelopathy. The predominant diagnosed etiologies were: soft disc herniation (9 patients), disco-osteophytic compression (22) and pseudarthrosis (1).

The patients were evaluated for immediate post-operative complications. After 6 months, screw loosening, device subsidence/migration and fusion were assessed by ROM measurement on dynamic lateral Xrays.

We observed 2 cases of minimal subsidence, 2 mild transient dysphagias, 1 superficial infection, no screw loosening, and no migration. Bridging bone around the cage was observed in 27 levels (69.2 %). 30 levels (77,0 %) showed signs of solid fusion, 7 leve1s (4.9 %) signs of incomplete or ongoing fusion, and 2 levels (5.1 %) radiological signs of failed fusion.

ACDF with the Scarlet AC-T cervical secured cage is safe. No implant failure or implant related complication could be observed. Solid or ongoing fusion was observed in 94,9 % of the operated levels after 6 months.

(*)Produced by Spineart SA, Switzerland

Keywords : ACDF ; Scarlet AC-T ; Cervical disc degeneration ; Stand-alone cage ; Zero-profile spacer, Radiographic fusion.

INTRODUCTION

Anterior cervical discectomy and fusion (ACDF) has been performed successfully using various techniques. The most common one relies on the use of a cage and plate system, which guaranties a high fusion proportion. However, the use of a plate may lead to specific, technique-related complications: nerve root irritation by oblique plating, screw malpositioning, plate loosening or breakage. A

■ Patrick Fransen.
IM2S – Clinique Médico-chirurgicale orthopédique de Monaco, Monaco.
Correspondence : Patrick Fransen, IM2S - Clinique Médico-chirurgicale orthopédique de Monaco, 10 Avenue d'Ostende, 98000 Monaco.
E-mail : fransenp@yahoo.fr

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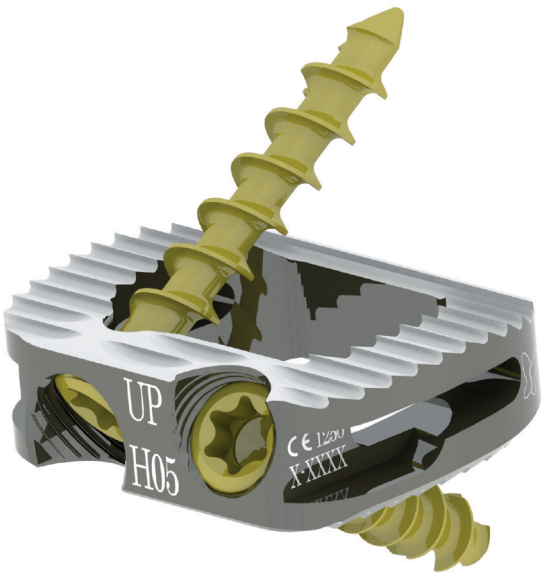

Fig. 1. — We used an anatomic zero-profile titanium cage secured by integrated screws with an incorporated locking system (Scarlet AC-T® Spineart, Switzerland)

frequency of 10.7% of such complications has been reported by Ning et al. *(9)*, although rarely requiring reoperations. Recently more attention has been focused on dysphagia, a significant discomfort that may be more significant when anterior plating is performed *(1,3,10,14)*.

Over the time and to prevent these complications, unsecured stand-alone cage systems have first been used. Although titanium and poly-ethyl-ether-ketone (PEEK) cages behave in similar fashion when augmented with an anterior plate system *(15)*, there seem to be slight differences when used as stand-alone implants.

PEEK cages have a reputation of poor bony integration. Indeed, in their study with stand-alone unsecured PEEK or Carbon fiber cages, Yoo et al. *(22)* observed a mere 74.1% rate of fusion and a 31% rate of subsidence, with no difference between the two materials. This confirmed previous results by Cabraia et al. *(2)*, who compared PEEK and titanium cages, finding a better fusion rate with titanium. On the other hand, titanium stand-alone cages, despite their possible advantage of better bony integration *(8)* but may show an increased rate of subsidence and subsequent kyphotic malalignment (up to 19%), particularly if the cage is inserted under high distraction *(2,6,19,20)*.

Recently, Yin et al. *(21)* reported that "Zero Profile"cervical cages had results similar to those of cage and plate systems, both in terms of intraoperative time and intraoperative blood loss, but scored better for dysphagia. Hofstetter et al. *(3)* found that, when compared to "Zero Profile" implants, the use of a plate leads to an increased swelling of the prevertebral space. In addition, "Zero Profile" implants may lead to a reduced occurrence of plate-induced ossification, which has been observed when the distance between the plate and the adjacent disc is less than 5mm *(11,12)*.

The present study is a first report on a series of patients subjected to ACDF with a "Zero Profile", full titanium, secured cage, which could have better bone integration than PEEK cages, avoid the subsidence seen with stand-alone titanium cages, and allow simple surgery with minimal postoperative dysphagia.

MATERIAL AND METHODS

Study population: We performed a retrospective analysis of prospectively collected data on a group of 32 patients which had been subjected to ACDF using the Scarlet AC-T secured titanium cage. The studied population comprised 13 males (40.6%) and 19 females (59.4%), aged between 36 and 76 years, (mean 56.5 y).

Time span covered: All members of the study group were operated between October 1st 2014 and June 1st 2016.

Number of operated levels and implanted cages:

25 patients had one-level surgery, 7 patients had two-level surgery.

39 cages were implanted, the most frequently operated levels being C5C6 (22 cages), C6C7 (13 cages), C4C5 (2 cages) and C3C4 (2 cages).

Surgery: All patients were operated in the supine position, under general anaesthesia and with preoperative fluoroscopic control. A Caspar retractor was used systematically. The compressive osteophytes and disc material were completely resected under the microscope and the posterior longitudinal ligament was opened until the anterior

aspect of the dura could be seen, allowing complete decompression of the neurological structures and exploration of both neuroforamina. The Scarlet AC-T cage, which is prefilled with a bone substitute (**) was then positioned in the intersomatic space and secured to the vertebrae adjacent to the operated level, using the two oblique screws featured by each cage.
(**)"B-Gel" (Spineart, Switzerland)

Pre-op symptoms and aetiologies: All 32 patients presented with neck and arm pain. Amongst theses patients, 17 presented with clinical and/or radiological signs of myelopathy. Nine patients presented with predominant compression by soft disc herniation, whereas in 22 patients, the compression was more disco-osteophytic. One patient presented with pseudarthrosis on an existing stand-alone PEEK cage.

Study endpoints: The primary endpoint of the study was the short term safety of the Scarlet AC-T cervical cage, with attention to immediate post-operative complications, subsidence, screw loosening, and anterior or posterior migration.

The secondary endpoint was the evaluation of postoperative fusion by assessment of the range of motion on flexion-extension lateral cervical spine Xrays at the operated level after 6 months FU.

RESULTS

Short term safety:

Immediate postoperative AP and Lateral cervical spine Xrays were available for all patients.

Immediate postoperative complications:

- Two patients presented with mild transient dysphagia, one of them with hoarseness.
- There was one case of superficial wound infection, treated conservatively.
- In one patient, the upper screw could not be implanted due to the extreme obesity of the patient.

Medium term (6 months PO) safety:

Postoperative radiological evaluation after 6 months was available for 25 patients (78.1%) and 29 levels (74.3%).

We observed the following complications:

- Two cases of minimal subsidence
- No screw loosening.
- No anterior or posterior migration of the cage.

Bridging bone around the cages at 6 months PO:

This was observed in 27 of the 29 evaluated levels (93.1%).

Assessment of fusion at 6 months PO by ROM measurement:

22 patients (or 68,7% of the initial total) had usable dynamic X rays.

Fig. 2. (a, b, c) — Lateral cervical spine X-ray in neutral (a), flexion (b) and extension (c) posture, showing stable fusion 6 months after surgery

Flexion /extension instability was assessed comparing the interspinous process distance between the flexion and the extension lateral cervical spine Xray:

- a difference of less than 2mm was considered equivalent to solid fusion.
- a difference of between 2 and 6mm was considered as incomplete or ongoing fusion.
- a difference of more than 6 mm failed fusion (Figure 2 a,b,c).

Of these 22 patients with usable images:

- 17 patients (77.3%) showed signs of solid fusion,
- 4 patients (18.2%) showed signs of incomplete or ongoing fusion, and
- 1 patient (4,5%) presented with radiological signs of failed fusion.

DISCUSSION

The new trend towards "Zero-profile" cages in cervical surgery is supported by several studies reporting good results, with a 92.6% to 99% fusion rate and no hardware failure *(1,3,5,10,13).* Usually, the dysphagia rate was reported as low as 1.8 to 6 % *(1,3,13,14,18)* but Njoku et al. *(10)*, with a study focused on a thorough assessment of dysphagia reported a probably more realistic 12.2% rate of dysphagia, although not necessarily debilitating. Shin et al. *(16)* compared zero-profile secured cages, stand-alone cages and graft plate systems in their study, showing that not only was there less dysphagia without plate, but also that secured cages presented with less postoperative kyphotic changes than stand-alone cages.

For these reasons, the choice of a low profile implant seems reasonable, leaving us with the question about how to avoid the subsidence observed with unsecured titanium stand-alone cages, and the poor osteo-integration observed with unsecured PEEK stand-alone cages.

Kotsias et al. *(4)* recently published that partially coating a PEEK cage with titanium does not confer to the cage the fusion induction qualities of titanium, as these hybrid cages behaved the same way as plain PEEK cages, showing only limited osteo-integration. Opting for a full-titanium cage seems therefore to be the only way to take advantage of the fusion induction qualities of titanium.

Stein et al. *(17)* showed in a cadaver study that integrating a screw fixation system in the cage conferred to it a biomechanical stability comparable to that of a cage-plate system. This was later clinically confirmed, as secured "Zero-profile" implants were shown to allow for improvement and preservation of cervical lordosis and disc height *(7,5)*.

Our results support the theory that using titanium, secured, zero-profile cages for ACDF could provide the benefits of titanium-induced osteointegration, without the subsidence or kyphotic changes seen with unsecured stand-alone cages, without any donor site morbidity, and could avoid mechanically induced dysphagia. Prospective randomised trials are necessary for confirmation.

CONCLUSION

Anterior cervical discectomy and fusion with the Scarlet AC-T cervical secured cage is a safe procedure. No implant failure or implant related complication could be observed. Solid or ongoing fusion was observed in 95,5 % of the operated levels after 6 months.

REFERENCES

1. **Bucci MN, Oh D, Cowan RS, Davis RJ, Jackson RJ, Tyndall DS, Nehls D.** The ROI-C zero-profile anchored spacer for anterior cervical discectomy and fusion: biomechanical profile and clinical outcomes. *Med Devices* (Auckl). 2017; 10 : 61-69.
2. **Cabraja M, Oezdemir S, Koeppen D, Kroppenstedt S.** Anterior cervical discectomy and fusion: comparison of titanium and polyetheretherketone cages. *BMC Musculoskelet Disord*. 2012 ; 14 ; 13 : 172.
3. **Hofstetter CP, Kesavabhotla K, Boockvar JA.** Zero-profile Anchored Spacer Reduces Rate of Dysphagia Compared With ACDF With Anterior Plating. *J Spinal Disord Tech* 2015 ; 28 : E284-90.
4. **Kotsias A, Mularski S, Kühn B, Hanna M, Suess O.** Does partial coating with titanium improve the radiographic fusion rate of empty PEEK cages incervical spine surgery? A comparative analysis of clinical data. *Patient Saf Surg* 2017 ; 28 ; 11 : 13.
5. **Lane PD, Cox JL, Gaskins RB, Santoni BG, Billys JB, Castellvi AE.** Early Radiographic and Clinical Outcomes Study Evaluating an Integrated Screw and

Interbody Spacer for One- and Two-Level ACDF. *Int J Spine Surg* 2015 ; 17 ; 9 : 39.

6. **Li ZJ, Wang Y, Xu GJ, Tian P.** Is PEEK cage better than titanium cage in anterior cervical discectomy and fusion surgery? A meta-analysis. *BMC Musculoskelet Disord* 2016 ; 17 : 379.
7. **Miao J, Shen Y, Kuang Y, Yang L, Wang X, Chen Y, Chen D.** Early follow-up outcomes of a new zero-profile implant used in anterior cervical discectomy and fusion. *J Spinal Disord Tech* 2013 ; 26 : E193-7.
8. **Nemoto O, Asazuma T, Yato Y, Imabayashi H, Yasuoka H, Fujikawa A.** Comparison of fusion rates following transforaminal lumbar interbody fusion using polyetheretherketone cages or titanium cages with transpedicular instrumentation. *Eur Spine J* 2014 ; 23 : 2150-5.
9. **Ning X, Wen Y, Xiao-Jian Y, Bin N, De-Yu C, Jian-Ru X, Lian-Shun J.** Anterior cervical locking plate-related complications; prevention and treatment recommendations. *Int Orthop* 2008 ; 32 : 649-55.
10. **Njoku I Jr, Alimi M, Leng LZ.** *et al.* Anterior cervical discectomy and fusion with a zero-profile integrated plate and spacer device: a clinical and radiological study: Clinical article. *J Neurosurg Spine* 2014 ; 21 : 529-37.
11. **Park JB, Cho YS, Riew KD.** Development of adjacent-level ossification in patients with an anterior cervical plate. *J Bone Joint Surg Am* 2005 ; 87 : 558-63.
12. **Park JB, Watthanaaphisit T, Riew KD.** Timing of development of adjacent-level ossification after anterior cervical arthrodesis with plates. *Spine J* 2007 ; 7 : 633-6.
13. **Scholz M, Schnake KJ, Pingel A, Hoffmann R, Kandziora F.** A new zero-profile implant for stand-alone anterior cervical interbody fusion. *Clin Orthop Relat Res* 2011 ; 469 : 666-73.
14. **Scholz M, Schelfaut S, Pingel A, Schleicher P, Kandziora F.** A cervical "zero-profile" cage with integrated angle-stable fixation: 24-months results. *Acta Orthop Belg* 2014 ; 80 : 558-66.
15. **Schulz C, Mauer UM, Mathieu R.** [Clinical and Radiological Results after Anterior Cervical Corpectomy with Cage Fusion - a Retrospective Comparison of PEEK vs. Titanium Cages]. *Z Orthop Unfall* 2017 ; 155 : 201-208.
16. **Shin JS, Oh SH, Cho PG.** Surgical Outcome of a Zero-profile Device Comparing with Stand-alone Cage and Anterior Cervical Plate with Iliac Bone Graft in the Anterior Cervical Discectomy and Fusion. Korean *J Spine* 2014 ; 11 : 169-77.
17. **Stein MI, Nayak AN, Gaskins RB, Cabezas AF, Santoni BG, Castellvi AE.** Biomechanics of an integrated interbody device versus ACDF anterior locking plate in a single-level cervical spine fusion construct. *Spine J* 2014 ; 14 : 128-36.
18. **Wang Z, Jiang W, Li X, Wang H, Shi J, Chen J, Meng B, Yang H.** The application of zero-profile anchored spacer in anterior cervical discectomy and fusion. *Eur Spine J* 2015 ; 24 : 148-54.
19. **Yamagata T, Takami T, Uda T** *et al.* Outcomes of contemporary use of rectangular titanium stand-alone cages in anterior cervical discectomy and fusion: cage subsidence and cervical alignment. *J Clin Neurosci* 2012 ; 19 : 1673-8.
20. **Yamagata T, Naito K, Arima H, Yoshimura M, Ohata K, Takami T.** A minimum 2-year comparative study of autologous cancellous bone grafting versus beta-tricalcium phosphate in anterior cervical discectomy and fusion using a rectangular titaniumstand-alone cage. *Neurosurg Rev.* 2016 ; 39 : 475-82.
21. **Yin M, Ma J, Huang Q** *et al.* The new Zero-P implant can effectively reduce the risk of postoperative dysphagia and complications compared with the traditional anterior cage and plate: a systematic review and meta-analysis. *BMC Musculoskelet Disord* 2016 ; 18 ; 17 : 430.
22. **Yoo M, Kim WH, Hyun SJ, Kim KJ, Jahng TA, Kim HJ.** Comparison between Two Different Cervical Interbody Fusion Cages in One Level Stand-alone ACDF: Carbon Fiber Composite Frame Cage Versus Polyetheretherketone Cage. *Korean J Spine* 2014 ; 11 : 127-35.