MLTJ
Muscles, Ligaments and Tendons Journal

ORIGINAL ARTICLE

TITANIUM TRABECULAR 3D ELECTRON BEAM MELTING (EBM) PRINTED CERVICAL CAGES TO PROMOTE RAPID HEALING IN CERVICAL FUSION. A PROSPECTIVE STUDY

Nermine Habib[1], Renato Gondar[1,2], Adrien May[1], Julien Galley[3], Daniele Valsecchi[1], Vera Maren Stetzelberger[1], Gianluca Maestretti[1]

[1] Neurospinal Unit, Department of Orthopaedics and Traumatology, Fribourg Hospital (HFR), University of Fribourg, Fribourg, Switzerland
[2] Department of Neurosurgery, Geneva University Hospitals, Geneva, Switzerland
[3] Department of Radiology, Fribourg Hospital (HFR), University of Fribourg, Fribourg, Switzerland

Corresponding author's e-mail: nermine.emad@gmail.com

Received: 17/06/2026
Accepted: 15/09/2026
Published: 21/10/2026

Conflict of interests: Drs Habib, Gondar, May, Galley, Valsecchi, Stetzelberger have no relevant financial relationships to disclose. Prof Maestretti holds a patent related to the cage in collaboration with MT Ortho and serves as a member of its advisory board.
Fundings: No external funding was received for this study.
Data availability: The datasets generated and analyzed during the study are available from the corresponding author upon reasonable request.
Contributions: NH conceived the study, collected data, performed analysis and drafted the manuscript. RG participated in data collection, radiological assessment and fusion grading and manuscript revision. AM participated in data collection radiological assessment and fusion grading and manuscript revision. JG participated in radiological assessment and fusion grading and manuscript revision. DV participated in data collection, radiological assessment and fusion grading and manuscript revision. VMS participated in statistical analysis, interpretation of data and manuscript revision. GM supervised and conceived the study and revised the manuscript.
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LEVEL OF EVIDENCE: 2b

ABSTRACT

Background: Anterior cervical discectomy and fusion (ACDF) is widely used for treating degenerative cervical disc disease. Porous trabecular titanium (PTT), manufactured by electron beam melting (EBM) technology, has demonstrated excellent osteogenic and osteoinductive potential *in vitro*, but *in vivo* performance remains unclear.

Methods: This level IIb, prospective cohort study included 26 patients undergoing one- to three-level ACDF using patented 3D EBM-printed PTT cages modelled by CAD/CAM technology. Primary outcome was fusion rate at 3 months, assessed by CT. Secondary outcomes included VAS pain scores and the Neck Disability Index (NDI) at 3, 6, 12, and 24 months.

Results: Single-level fusion was performed in 14 patients (54%), two-level fusion in 9 patients (35%), and three-level fusion in 3 patients (11%). At the 3-month CT scan 18 (72%) patients showed radiographic signs of new bone formation (Goldschlager grade ≥1), of these, 8 patients (32%) had continuous bridging bone (grade 2) meeting the study's pre-specified definition of fusion, while 10 patients (40%) showed non-continuous new bone (grade 1), At the 6-month follow-up, plain radiographs suggested fusion in 96% of patients. Mean radicular and axial VAS pain scores improved by 83% and 81%, respectively. Mean NDI scores improved by 76%. Fusion rates and clinical outcomes did not differ between patients undergoing different numbers of operated levels.

Conclusions: 3D-EBM-printed porous trabecular titanium cages in ACDF were associated with early radiographic signs of osseointegration on CT at 3 months, and with apparent fusion on plain radiographs in the large majority of patients by 6 months, together with significant improvements in disability and pain scores. Larger, controlled studies are needed to confirm these early findings.

Publisher smc media srl

KEYWORDS
Anterior cervical discectomy, degenerative disc disease, arthrodesis, cervical radiculopathy, interbody cage, osteointegration, spinal fusion, trabecular titanium

INTRODUCTION

Degenerative cervical disc disease is increasingly prevalent, causing significant pain and reduced quality of life. It may be associated with myelopathy and radiculopathy. After the failure of adequate conservative treatment, surgical intervention is indicated[1-3]. Surgical standard procedures include anterior cervical discectomy and fusion (ACDF) or anterior cervical corpectomy and fusion (ACCF).

Structural autografts were initially used for spinal fusion, however, donor-site complications, such as infection, hematoma, and chronic pain, have promoted the use of allografts, osteoconductive materials, as well as cages of different materials.

Bone substitutes for ACCF offer biomechanical support, restoration of foraminal height, maintaining cervical lordosis, reduction of donor-site complications, and shorter hospital stays[4,5]. Optimal osteointegration is therefore essential. Stand-alone cages of various materials have been developed to allow immediate stability without plates and screws. An ideal cage design must maintain disc height and the correct alignment while achieving sufficient primary stability to permit osteointegration and long-term fixation.

Cages are typically small implants with lateral, upper, and/or lower windows and a central cavity filled with bone or osteoinductive materials. They can also act as carriers for osteoinductive- or osteoconductive agents to promote long-term stability through biologic integration[6].

An important property of implant materials is their ability to deform elastically under load and return to their original shape once unloaded[5]. This property is defined by the elastic modulus (EM). The EM is a measure of a material's stiffness; materials with a higher EM deform less under the same applied load. Cage materials with an EM closer to that of native bone are thought to reduce stress-shielding and subsidence[7]. Particularly, cages made of highly porous materials have been used in the last years in order to treat lumbar degenerative disease with sagittal imbalance[8].

Trabecular metal (TM), a porous tantalum biomaterial, has structural and mechanical properties similar to trabecular bone, combining high volumetric porosity, a low EM, and favorable frictional characteristics[9–11]. TM is also inert, corrosion-resistant, more osteoconductive than other commercially available biomaterial, and produces only minor artefact on MRI[12]. These properties have made tantalum a widely used biomaterial for ACDF cages[3,5,9,13–17]. However, porous tantalum and EBM-printed trabecular titanium differ substantially in base material, manufacturing process, and resulting pore architecture; consequently, clinical and biological data obtained with trabecular tantalum implants cannot be directly extrapolated to EBM-printed trabecular titanium cages, which therefore require independent in vivo validation.

The cage used in this study incorporates trabecular titanium (TT) endplates designed to promote bone ingrowth. The scaffold has a lateral oval window allowing bone-graft insertion *(Fig. 1)*. No bone graft was used in this study, so that the implant could be evaluated without this confounding factor. Custom-made trabecular titanium cages have previously been used in patients with spinal deformity and sagittal imbalance, improving deformity correction and restoration of patient-specific sagittal alignment[18].

In vitro, highly porous trabecular titanium cages manufactured by EBM, allowed human adipose stem cells (hASCs) to adhere, migrate, and proliferate without any surface modifications, while also promoting osteogenic differentiation, suggesting an intrinsic osteoinductive potential[13].

Despite this preclinical trial, to our knowledge, no in vivo study has yet evaluated the osteointegration and osteoinductive behavior of this specific EBM-printed trabecular titanium design.

We report a prospective series, with a minimal follow-up of 1 year, of patients undergoing ACDF with specially designed 3D printed cages made of PTT and modelled by CAD/CAM technology by means of EBM.

The objectives of this study were to evaluate: (i) radiological fusion grade at three months by CT scan, (ii) clinical outcome in terms of visual analogue scale (VAS)



Figure 1. *Cage of porous trabecular titanium made by EBM® (Patent MT Ortho design).*

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pain score and Neck Disability Index (NDI) preoperatively and postoperatively, (iii) differences in fusion rates and clinical scores according to the number of operated levels (one, two, or three).

MATERIALS AND METHODS

Patient population

In this prospective level IIb study from February 2019 to October 2021, a consecutive series of 26 patients were enrolled in the study. A total of 14 men and 12 women, with an average age of 53 years (range: 39–75 years), were included. Two patients were lost to follow-up after the 3-month CT scan, while one dropped out of the study for personal reasons.

The remaining 23 patients had a minimum clinical and/or radiological follow-up of 1 year. The mean follow-up was 28 months (range: 12-36 months).

All patients received patented and specially designed 3D printed PTT cages modelled by CAD/CAM technology by means of EBM (MT Ortho, Aci Sant'Antonio Sicily, Italy).

Of the 26 patients, an anterior plate was positioned in 16 patients (61.5%) with clinical and/or radiological signs of myelopathy. Bone grafts were not used.

Single-level fusion was performed in 14 patients (54%), two-level fusion in 9 patients (35%), and three-level fusion in 3 patients (11%). Forty-one-disc levels were addressed in total, of which 10% (n = 4) involved C3-4, 17% (n = 7) C4-C5, 44% (n = 18) C5-C6, 27% (n = 11) C6-C7, and 2% (n = 1) C7-D1 *(Table 1)*.

All patients underwent preoperatively a cervical spine X-ray and magnetic resonance imaging (MRI). Postoperative cervical spine X-rays with anterior-posterior and lateral neutral projections were performed in all patients. The follow-up (both clinical and radiological) was at 6 weeks postoperatively, 3 months, 6 months, and at 1, 2, and 3 years. At 3 months, all patients underwent an additional cervical CT scan.

Inclusion criteria:

1) Patients requiring one- to three-level surgery by ACDF at contiguous disk spaces between C3 and D1;
2) Degenerative cervical spine conditions with myelopathy or radiculopathy;
3) Unsuccessful conservative treatment;
4) No previous surgery at the involved level;
5) Over 18 years old at the time of surgery;
6) Willingness to comply with the study plan and sign the consent form.

Exclusion criteria:

1) Previous cervical spine surgery;
2) Traumatic disc herniation;
3) Minors (under 18 years old);
4) Cognitive impairment precluding informed consent.

The study was conducted in accordance with the ethical standards of research as described by Padulo et al. (2016)[25] and in accordance with the Declaration of Helsinki. The Ethics Cantonal Committee in Human Research of Canton Vaud, Switzerland (CER-VD Project-ID (ID 2019-02303) has approved the study.

Patients (total)	**26**
Male	14
Female	12
Single level fusion	14
2-level fusion	9
3-level fusion	3
Disc levels fused (total)	**41**
C3-4	4
C4-C5	7
C5-C6	18
C6-C7	11
C7-D1	1

Table 1. *Demographics.*

Implant design and additive manufacturing

The cages used in this study were given by MT Ortho company (MT Ortho s.r.l., Aci Sant'Antonio, CT, Italy). The cages featured two trabecular titanium endplates (Ti6Al4V), modeled by CAD/CAM technology by means of EBM technology with a porosity of 87% and a pore size of 650 µm, providing sufficient surface roughness to allow hASC attachment, migration, and proliferation without any surface treatments. The hASCs seeded on TT have been shown to produce a secretome enriched with molecules that promote a shift towards osteogenic differentiation[13]. EBM processing occurs at a high build-chamber temperature (approximately 700°C) and under vacuum, with helium introduced into the build chamber. This process requires fewer support structures and produces surfaces with greater inherent roughness which is considered favorable for osseointegration. Other authors demonstrated that highly porous Ti, without any surface treatment, was able to trigger cellular proliferation, colonization and differentiation towards the osteoblastic lineage. Trabecular titanium has also been shown to support adhesion and proliferation of endothelial progenitor cells, favoring vascularization and osteointegration.

Outcome measures

Radiological evaluation

Fusion was assessed by a multi slice thin-cut (0.6 mm) CT and defined by continuous bridging of trabecular bone and the absence of radiolucent lines at 3 months on CT. Continuous bridging was further subdivided as involving less than or more than 30% of the interbody cage area.

Fusion was assessed independently by a radiologist, an orthopaedic surgeon, and a neurosurgeon none of whom was involved in the patients' surgery. The semiquantitative

cular titanium endplates with a porosity of 87%

score described by Goldschlager et al.[19] was used in this study:

Grade 0: No new bone formation

Grade 1: New bone formation but not continuous between C3 and C4 (cleft of discontinuity);

Grade 2: Continuous bridging new bone but comprises <30% of fusion area;

Grade 3: Continuous bridging new bone formation of >30% of fusion area.

Each observer was blinded to the assessments of the other two; questionable cases were resolved by discussion.

Multiplanar images were acquired with the Revolution™ Apex Platform | GE Healthcare CT scan and reconstructed in the sagittal, axial, and coronal planes.

Cage or graft subsidence was defined as the sinking of the cage or graft into the upper or lower endplates, with a decrease of ≥2 mm in disc height compared with the immediate postoperative radiograph. Any loss of graft height was regarded as graft collapse[14,20-23].

Clinical evaluation

Pain levels were recorded preoperatively and at 3 months, 6 months, 1 and 2 years postoperatively using the Visual Analogue Scale (VAS).

Patients were also evaluated preoperatively and at 3 months, 6 months, 1 and 2 years. Disability was assessed at the same time points using the Neck Disability Index (NDI).

Statistical analysis

Continuous variables were tested for normal distribution using the Kolmogorov-Smirnov test. As the data were not normally distributed, the pre- and postoperative VAS (for radicular and axial pain) and NDI, were compared using the Wilcoxon test for paired samples. Improvement was calculated by subtracting the follow-up value from the preoperative value. Data is presented as median with range in parenthesis. P values equal to or >0.05 were considered statistically not significant (NS). The different groups were compared using the Kruskal-Wallis test[24].

RESULTS

Radiological evaluation

At the 3-month CT scan, 25 patients were evaluable. Eighteen patients (72%) showed radiographic signs of new bone formation (Goldschlager grade ≥1): 10 patients (40%) showed grade 1 (non-continuous) new bone, and 8 patients (32%) showed grade 2 fusion (continuous bridging bone) thereby meeting the study's pre-specified definition of fusion. No patient reached grade 3 at this time point. The remaining 7 patients (28%) showed no new bone formation (grade 0) *(Fig. 2)*.

Six of these 7 patients subsequently showed radiographic signs of fusion on plain radiographs at 6 months, corresponding to an overall radiograph-based apparent fusion rate of 96% at 6 months. Because this later assessment relied on plain radiographs rather than CT, it is not directly comparable to the stricter, CT-based 3-month grading *(Table 2)*.

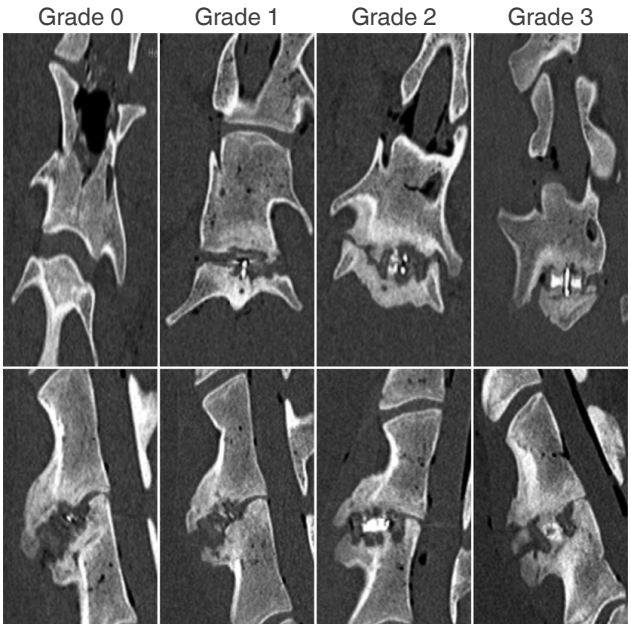


Figure 2. *Computed tomography, in the coronal plane above and sagittal plane below, giving an example of each scoring grade (from Goldschlager et al.[19]).*

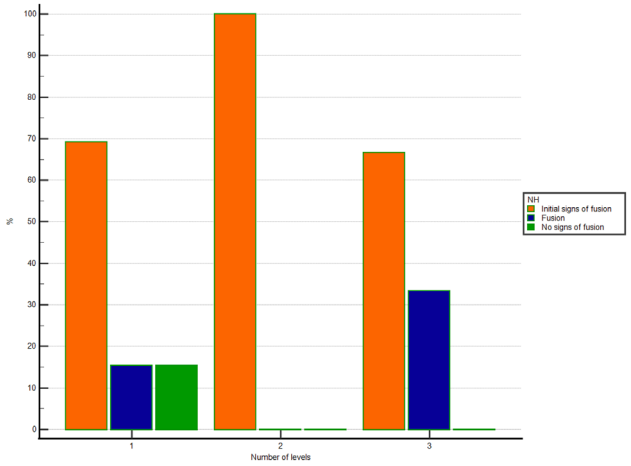


Figure 3. *Comparison of fusion rates in patients with 1,2 or 3 level fusions.*

Total patients with CT scan	25
No signs of fusion (grade 0)	7
Fusion grade 1	10
Fusion grade 2	8

Table 2. *Fusion in 3-month CT scan.*

Fusion rate did not differ significantly between patients undergoing one-, two-, or three-level fusion *(Fig. 3)*.

Clinical evaluation

All clinical scores improved significantly after surgery: the radicular and axial VAS improved by 83% and 81%,

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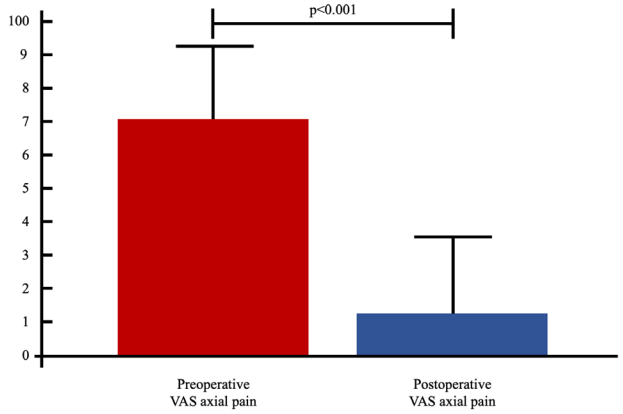


Figure 4. *Comparison of the pre- to postoperative VAS axial pain.*

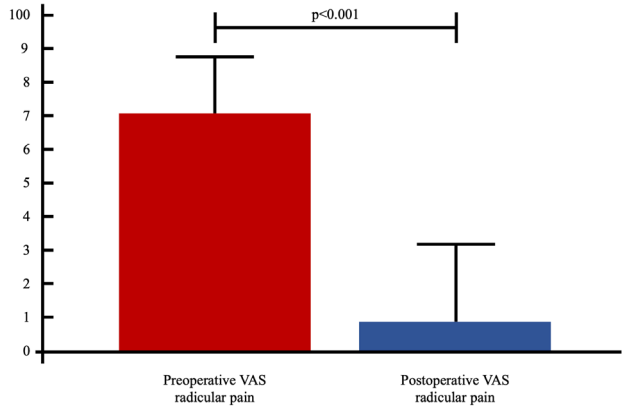


Figure 5. *Comparison of the pre- to postoperative VAS radicular pain.*

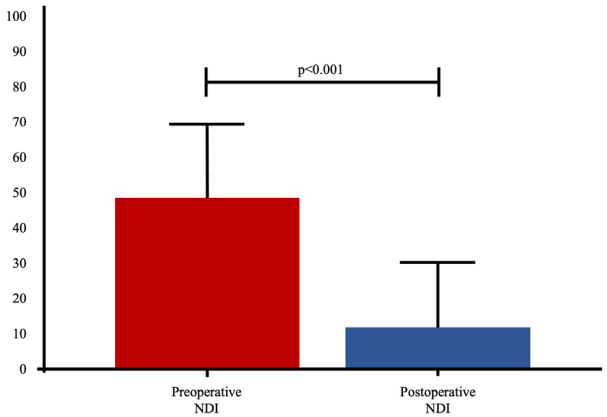


Figure 6. *Comparison of the pre- to postoperative neck disability index.*

while the NDI improved by 76%. Axial VAS improved from preoperatively 7.0 ± 2 to 1.3 ± 2 at follow-up (p <0.0001) *(Fig. 4)*. Radicular VAS from preoperatively 5.4 ± 4 to 0.9 ± 2 at follow-up (p <0.0001) *(Fig. 5)*. NDI improved from preoperatively 48.1 ± 21 to 11.7 ± 19 at follow-up (p <0.0001) *(Fig. 6)*.

The change in axial and radicular VAS did not differ significantly by number of operated levels (%; pre-operative 7.3 ± 2 and 6.1 ± 4 consecutively and FU 0.7 ± 2 both axial and radicular AS; p = 0.670 and 0.706). NDI improvement likewise did not differ significantly between patients undergoing one-, two-, or three-level surgery (%; pre-operative 52.3 ± 20, at FU 10.8 ± 23; P = 0.486) *(Table 3)*.

Complications

One patient did not acquire fusion and, despite being symptomatic, declined further surgery.

One patient in the grade 2 group showed signs of subsidence in one of the two cages implanted at the 3-month CT scan. This patient was lost to follow-up after choosing treatment at another institution.

One patient developed adjacent-segment disease at 30 months, not requiring surgery at the latest follow-up.

There were no surgical complications in our series, with no cases of infection, cord injury, dysphagia, or hoarseness.

DISCUSSION

Radiological evaluation

This prospective study evaluated early fusion following ACDF using patented trabecular titanium 3D EBM-printed cervical cages. To our knowledge, this is the first in vivo study to assess fusion as early as three months postoperatively using CT imaging in patients treated with these implants. At 3 months, 72% of patients showed radiographic signs of new bone formation, of which 32% already met the study's definition of fusion (continuous bridging bone). At the 6 months radiographic follow-up 96% of the patients showed apparent fusion. These rates are broadly consistent with fusion rates reported in the literature for other cage materials, although direct comparison is limited by differences in grading systems and imaging modality[3,9,15,23,26–30].

The early radiographic signs of bone formation observed in this study may be related to the biological properties of the trabecular titanium cages, which have two trabecular titanium endplates with a porosity of 87% and a pore size of 650 µm. These titanium cages have previously been shown in vitro to support hASC attachment, migration, and proliferation without surface treatment, together with a secretome favoring osteogenic differentiation[13]. Other authors demonstrated that highly porous Ti, without any

Parameters	One level	Two levels	Three levels	p value
NDI improvement	32 (-4–70)	42 (-24–72)	34 (32–92)	0.49
VAS axial pain improvement	5 (-1–10)	7 (1–10)	8 (3–8)	0.67
VAS radicular pain improvement	4 (-1–10)	7 (-2–10)	7 (0–10)	0.71

Table 3. *Improvement in different clinical scores according to the number of levels fused.*

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surface treatment, could trigger cellular proliferation, colonization, and differentiation toward the osteoblastic lineage[31,32]. Moreover, TT also allows the adhesion and proliferation of endothelial progenitor cells and, consequently, by permitting vascularization, promotes osteointegration[33].

Interestingly, no significant differences in fusion rate were found between one-, two-, and three level procedures, which contrasts with the current literature, reporting increasing pseudarthrosis rates with increasing the number of fused cervical levels[34,35]. However, these results should be interpreted cautiously, given the limited sample size in our cohort, particularly the small three-level subgroup.

Clinical evaluation

Clinically, this study showed substantial improvement in disability and pain scores after surgery, with the NDI score improving by 76% and VAS radicular and axial scores by 83 and 81%, consecutively.

Several studies have reported comparable clinical outcomes with other cage designs. Löfgren et al.[29] reported improvement in axial and radicular symptoms in 79% of patients undergoing single-level ACDF with an unfilled porous tantalum ring at 2-year follow-up. Fernández-Fairen et al.[30] also reported a good/excellent outcome in 78.7% of patients using unfilled porous tantalum rings at 24-month, confirmed at 11-year follow-up[23].

Bell et al.[36] similarly reported postoperative NDI improvement across one- to four-level ACDF, with all groups reaching the mild-disability category.

Furthermore, we could not show significant differences in clinical outcomes between patients undergoing one-, two-, and three-level procedures.

Complication rates

As donor-site morbidity associated with autograft harvesting remains a significant concern, stand-alone tantalum cages have emerged as an alternative. Previous studies have reported lower pain levels and fewer donor-site complications such as hematoma formation and infections[37]. In this study, in which autografts were not used, no hematoma or infection occured.

Patel et al.[37] described radiographic fragmentation and deformation in some tantalum implants, neither was encountered in this study. Also, no cases of infection, hoarseness, or dysphagia were documented. One case of subsidence and one case of non-union occurred, both requiring further surgery. This complication was graded as level III according to Sink et al.[38]. One patient developed adjacent-segment disease at 30 months, managed conservatively with analgesics (grade II).

Strengths

A major strength of this study is its prospective design as well as the novel radiological evaluation using CT imaging at 3 months postoperatively, allowing more detailed early assessment of fusion and implant stability than the plain radiographs used in most prior series of porous cages. Independent, blinded grading by a radiologist, an orthopaedic surgeon, and a neurosurgeon further supports the reliability of the fusion assessment.

Limitations

Several limitations should be acknowledged. First, the sample size was relatively small, limiting the statistical power of subgroup analysis, particularly for the three-level group. Second, Goldschlager grade 1 was challenging to evaluate and recognize. This was mitigated by independent, blinded assessment by three observers, but residual inter-observer variability cannot be excluded. Because grade 1 reflects non-continuous new bone rather than true bridging fusion, this should be interpreted as an indicator of early osteogenic activity rather than of structural fusion. Third, the absence of a control group treated with alternative cage materials limited direct comparisons of implant performance. Finally, comparisons with prior studies are limited by the use of different classification systems across literature, including the Brantigan-Steffee-Fraser (BSF) classification for anterior lumbar interbody fusion (ALIF) and the Lenke classification for posterolateral fusion (PLF). Although less frequently mentioned, we found the classification proposed by Goldschlager et al.[19] to be most suitable for our cohort[39,40]. Fourth, formal mechanical testing data for the cage used in this study, including elastic modulus, compressive stiffness, and yield behavior were not available for inclusion in this manuscript.

Meaning of the study

These findings suggest that trabecular titanium 3D EBM-printed cages may promote rapid early osteogenic activity and, in a subset of patients, early bony bridging following ACDF. To our knowledge, this is the first in vivo study to report these results for this implant design.

Unanswered questions and future research

Larger, multicenter, and ideally controlled studies are needed to confirm the early radiographic findings observed in this cohort and to clarify whether the higher 3-month grade 1 rate translates into higher longer-term fusion rates. Randomized comparative studies evaluating trabecular titanium cages against structural autografts, allografts, osteoconductive materials, as well as cages of different materials would help clarify whether the observed advantages are specific to this implant design.

CONCLUSION

The use of patented 3D EBM-printed porous trabecular titanium cages in ACDF was associated with early radiographic signs of osseointegration on CT at 3 months, and with apparent fusion on plain radiographs in the large

majority of patients by 6 months, together with significant improvements in disability and pain scores. These findings support the potential of trabecular titanium cages to promote early osseointegration and provide a promising option for cervical interbody fusion.

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