Anterior Cervical Fusion with Stand-alone Trabecular Metal Cages to Treat Cervical Myelopathy Caused by Degenerative Disk Disease. Observations in 88 Cases with Minimum 12-month Follow-up

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J Neurol Surg A 2018;00:1–6.

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Abstract

Background Anterior cervical fusion (ACF) with autologous bone was reported > 50 years ago. The continuous development of materials with elastic properties close to that of the cortical bone improves induction of osteogenesis and simplifies the technique of interbody fusion. To determine the safety and efficiency of stand-alone trabecular metal (TM) (or porous tantalum) cages for ACF, we performed a retrospective analysis of 88 consecutive patients with one-level or two-level degenerative disk disease (DDD) causing cervical myelopathy treated by interbody fusion with stand-alone TM cages.

Materials and Methods During a 65-month period, 88 consecutive patients had ACF at 105 levels between C3 and C7. All surgeries involved one- or two-segmental DDD producing mild or severe cervical spine myelopathy, in 31 patients (35.2%), associated with unilateral or bilateral radiculopathy. We implanted all disk spaces with unfilled TM trapezoidal cages (Zimmer Biomet Spine, Broomfield, Colorado, United States).

Results At a mean follow-up of 31 months (range: 12–65 months), 95.4% of patients had a good to excellent outcome, with subjective and objective improvement of myelopathy; the result was fair in two and poor in two other patients. Radicular pain and/or any deficits disappeared in 84 patients (95.4%) complaining of preoperative myeloradiculopathy. The fusion rate was 68.2% at 6 months and 100% at 1 year. Device fragmentation was never observed. In two cases, a second operation with removal of TM cages, corpectomy, expansion cages, and plating was necessary.

Conclusions TM cages appear to be safe and efficient for ACF in DDD patients with myelopathy. To confirm our preliminary impressions, larger studies with long-term follow-up are necessary.

Keywords

- anterior cervical fusion
- anterior cervical diskectomy
- cervical myelopathy trabecular metal cages
- porus tantalum

Introduction

Anterior cervical microdiskectomy is usually performed for degenerative disk disease (DDD) that causes radiculopathy and/or myelopathy. Surgical intervention is indicated after failure of adequate conservative treatment.[1,2] When spinal cord compression for cervical DDD at one or more disk levels causes myelopathy with or without brachialgia, anterior cervical microdiskectomy and osteophytectomy followed by anterior cervical fusion (ACF) are accepted as standard

received
December 4, 2017
accepted after revision
March 12, 2018

DOI https://doi.org/10.1055/s-0038-1642008.
ISSN 2193-6315.

procedures, although several authors maintain that a fusion following anterior cervical diskectomy is not necessary.[3–6]

The reasons for using bone substitutes for ACF are biomechanical support, restoring foraminal height, and maintaining cervical lordosis, reducing donor site complications, and realize a shorter hospital stay.[7–12] Optimal osteointegration, is warranted. During the last 2 decades, stand-alone cages of various materials, allowing immediate stability without plates and screws, have been developed.

The ideal cage for ACF should ensure immediate structural support and subsequently adequate osteointegration and stability. A determining factor is the capacity of the material to be elastically deformed by external forces, returning to its initial shape or position once the load is removed.[13,14] This capacity is defined by the elastic modulus (EM): Higher EM requires higher forces for deforming the material temporarily. Among several metals, trabecular metal (TM) (porous tantalum) is an open-cell porous biomaterial with a structure similar to trabecular bone. The structure of porous tantalum affords a high volumetric porosity, a low EM, and relatively high frictional characteristics.[15–17] Moreover, TM is inert and resistant to acid corrosion.[18] All these characteristics make tantalum ideal for implants[17] and therefore an excellent biomaterial for ACF cages.

On the basis of these considerations, we investigated the bony incorporation of TM cages inserted in the interspace after anterior cervical microdiskectomy and osteophytectomy. Outcomes, fusion rates, and complications were assessed in 88 consecutive patients operated on for cervical DDD causing one- or two-level spondylotic myelopathy after a minimum follow-up of 12 months.

Material and Methods

Patient Population

From July 2010 to December 2015, a consecutive series of 88 patients were enrolled in the study: 37 men and 51 women, with an average age of 58.8 years (median: 59 years; range: 44–83 years). Only patients requiring one- or two-level surgery at contiguous disk spaces between C3–C4 and C6–C7 for DDD were considered eligible. Patients with multisegmental cervical stenosis, diffuse and severe arthrosis, previous surgery, traumatic disc herniation, and poor general health conditions (American Society of Anesthesiologists IV) were excluded. Therefore, only patients with cervical myelopathy caused by one- or two-level spinal cord compression that was treatable with microdiskectomy, osteophytectomy, and subsequent ACF were included.

A total of 47 patients (53.4%) had a smoking history (minimum 10 cigarettes daily). Presenting symptoms included mild to severe myelopathic symptoms in the legs only in 19 patients (21.6%), in arms and legs in 69 patients (78.4%), and associated with radiculopathy in 23 patients (26.1%.) The mean preoperative Nurick grade was 1.53 ± 0.5; the mean preoperative modified Japanese Orthopaedic Association (mJOA) score was 12.5 ± 1.5.

Preoperative diagnosis was confirmed by magnetic resonance imaging (MRI) in all cases. It showed various alterations of the intramedullary signal in 79 cases (89.8%). In 21 both hypointensity on T1-weighted MR images and hyperintensity on T2-weighted MR images were observed, whereas in 58 cases, only hyperintensity on T2-weighted MR imaging was present.

Surgical Procedure

Single-level (71 cases) and two-level (17 cases) procedures accounted for 105 inserted implants. Under general anesthesia, a microsurgical anterior approach was performed. With adequate distraction, the vertebral end plates were drilled symmetrically; complete diskectomy and osteophytectomy was accomplished. In all cases, adequate exposure and decompression of dura and origin of nerve roots was achieved. The single- or two-level arthrodesis was performed with TM cages of various sizes (Zimmer Biomet Spine, Broomfield, Colorado, United States). The cage is a trapezoidal-shaped and slightly wedged implant.

Intraoperative lateral fluoroscopic control confirmed the position of the implant: in three cases it was necessary to replace the cage before closure because of a suboptimal position (too anterior, too posterior, oblique). After surgery, all patients wore a soft cervical collar for 3 to 4 weeks.

Outcome Measures

Clinic and radiographic controls (including standard and flexion-extension radiographs) were conducted on postoperative day 1, 1 week (only clinic evaluation), 3 months, 6 months, and 12 months after surgery in all cases. Cervical radiographs were reviewed by an independent radiologist blinded to the study. The fusion was considered complete when (1) trabecular bone across the interfaces and trabecular bridging bone formation at the anterior and/or posterior surface of involved vertebral bodies appeared (the so-called sentinel signs), (2) lucencies between cage and vertebral plates disappeared, (3) the flexion-extension range of motion was ≤ 5 degrees at the fusion site, and (4) disk height was preserved without collapse-induced kyphosis.[19]

Postoperative MRI was performed in those patients with incomplete recovery or with a reappraisal of pain or other neurologic symptoms after surgery.

The level of patient satisfaction was assessed by two questions at each clinical visit: (1) Are the symptoms the same, better, or worse after surgery? and (2) Are you satisfied with the results of surgical treatment? Following hospital discharge, patients were also asked to record requirement of postoperative analgesics (monitored by the patient response yes/no to the daily question: Have you used pain medications prescribed to relieve pain for which you underwent surgery?), and postoperative work-time loss (number of days lost from work after surgery).

Statistical Analysis

The smokers' group was matched to the nonsmokers, and the chi-square test was used to calculate differences in fusion rates. A paired sample t test was performed for differences in the preoperative and postoperative Nurick grade. The p values > 0.05 were considered not significant (NS).

Results

Mean operative time was 75 minutes (range: 55–80 minutes) for one-level and 93 minutes (range: 75–105 minutes) for two-level procedures. Overall hospital stay after surgery averaged 1.43 days (range: 1–3 days) with a low requirement for analgesics. In particular, during the first 48 postoperative hours, seven patients (7.9%) still complained of slight neck and radicular pain, requiring oral or parenteral analgesics.

Mortality was 0%. Worsening of myelopathy associated with fixation failure, needing reoperation, occurred in two patients (2.3%), worsening of myelopathy without fixation failure in another two (2.3%), and superficial wound infection in one patient (1.1%) resolved with antibiotics and daily medications on an outpatient basis. Permanent hoarseness or swallowing complaints were never observed; transient hoarseness was found in four patients (4.5%: from 4 to 7 weeks) and transient swallowing in other four (4.5%: from 3 to 24 days).

Implant-related complications requiring further surgical treatment were observed in two patients (2.3%), who had a failure of fixation and needed a second operation for late worsening of myelopathy after a first period of improvement. Both patients were treated with removal of TM cages, corpectomy, expansion cages, and anterior plating, 3 and 8 months after the first operation, respectively.

Follow-up evaluation data $\leq$ 12 months were available for all patients. At a mean clinical follow-up of 35.8 months (median: 37 months; range: 12–65 months), radicular and neck pain resolved in all cases, and patients' perception of outcome was generally good (16 cases [18.2%]) or excellent (68 cases [77.3%]) (p = NS). Regarding the subjective level of patients' satisfaction rate, the result was referred to as "good" only from those patients who experienced transient postoperative complications and from patients who still complained of slight pain during the first postoperative days (►**Table 1**). Four patients without any improvement or with slight worsening of myelopathic complaints described their result as fair. The satisfaction rate was excellent in all the others including smokers. All working-active patients returned to work within 4 to 6 weeks, especially if activities were not too arduous and the preoperative myelopathy not too severe.

Objectively, neurologic improvement was confirmed by the mean postoperative Nurick grade of 0.92 $\pm$ 0.3, better than the preoperative one ($p < 0.05$). The mean preoperative mJOA score was 14.7 $\pm$ 1.3 ($p < 0.05$). For both scales, the percentage of improvement was + 39.8% (Nurick scale) and 17.6% (mJOA scale).

Cervical radiographs performed during the follow-up period never showed breaking, collapsing, angular deformation, subsidence, pseudoarthrosis, fragmentation, or protruding at the level of the TM cages, except for the two patients reoperated for failure of the implant. In particular, in the first case, a male 68-year-old smoker with severe C5–C6 and C6–C7 preoperative myelopathy, we observed a small fracture of the inferior vertebral end plate of C6 and bone fragment dislocation (with new "osteophyte-like" compression) 15 days after discharge. In a second nonsmoking patient, a posterior dislocation of the TM cage occurred after a mild head/cervical trauma 8 months after surgery. Signs of pathologic reabsorption and necrosis were not found in the contiguous vertebral bodies, and inflammatory reactions were never seen around cages. In nine cases a slight or moderate kyphosis was observed at the 3-month radiograph control, was improved at the 6-month control, and was not completely gone at the 12-month follow-up.

Fusion was observed after 3 months in 17 of 41 nonsmoking patients (41.5%) and in 2 of 47 smokers (4.2%) ($p < 0.05$); the overall fusion rate at 3 months was 21.6%. Six months after surgery, fusion was seen in 36 nonsmokers (87.8%) and in 23 smokers (48.9%), respectively ($p < 0.05$); overall fusion rate at 6 months was 68.2%. Overall fusion rate at 12 months after surgery was 97.7% (97.9% in nonsmokers versus 97.5% in smokers). ►**Table 2** summarizes the fusion rate at different intervals of radiographic follow-up.

During this period of follow-up, we did not observe any case with clinical and MRI features of degeneration changes of adjacent disk levels.

Discussion

Cervical myelopathy caused by DDD at one or more disk levels is the most common cause of spinal dysfunction and nontraumatic spastic paraparesis and quadriparesis in the elderly.[20] It is a chronic devastating disease that may be improved by surgical decompression and fusion in many patients, although in a minority surgery does not change the neurologic condition or the natural course of disease. Many authors have discussed the factors affecting prognosis and results of decompressive surgeries for myelopathy caused by cervical DDD.[21–23] The most important factors are age,

Table 1 Level of satisfaction rate[a]

	Nonsmokers: 41 (%)	Smokers: 47 (%)	Overall: 88 cases (%)
Fair	2 (4.9)	2 (4.2)	4 (4.5)
Good	7 (17.1)	9 (19.1)	16 (18.2)
Excellent	32 (78.0)	36 (76.6)	68 (77.3)

[a]Median follow-up: 37 months; p = not significant.

Table 2 Fusion rates at radiographic follow-up

Follow-up interval	Nonsmokers: 41 (%)	Smokers: 47 (%)	p	Overall: 88 cases (%)
3 mo	17 (41.5)	2 (4.2)	< 0.05	19 (21.6)
6 mo	36 (87.8)	23 (48.9)	< 0.05	59 (68.2)
12 mo	40 (97.9)	46 (97.5)	Not significant	86 (97.7)

duration of symptoms, preoperative transverse diameter of spinal cord at the site of maximal compression, and signal intensity changes on preoperative MRI.[21,24–30]

Intramedullary changes of the spinal cord signal in spondylotic myelopathy can be reversible (hyperintensity on T2-weighted imaging) or not reversible (hypointensity on T1-weighted imaging).The regression of hyperintensity on T2-weighted imaging is associated with a better prognosis.[20,22,26–32]

Not enough information is available regarding the possible different outcome in relation to the early or late regression of T2 hyperintensity. Our preliminary experience seemed to exclude a relationship between time of signal recovery, amount of reexpansion of the spinal cord at the level of maximal compression, and long-term outcome.[26]

During the last 2 decades, the use of bone autograft has gradually decreased, mainly because of the high rate of local side effects (pain, hematoma, scarring, infection, visible iliac crest defect). It has been replaced by allografts and by several types of interbody spacers (cages) made of synthetic materials,[8–12,19,33–35] with or without anterior plating.[36] Even if the mean fusion time is shorter with bone autograft, the current implants used for arthrodesis and fusion allow an immediate biomechanical support, restore the height of disk space and intervertebral foramina, restrict mobility, and prevent collapse of disk space, thus reducing the incidence of subsequent kyphotic deformity.[8,10–12,19] This structural support and the subsequent successful osteointegration and fusion allow reabsorption of residual osteophytes. This consideration justifies the lesser invasive surgical approach, both in terms of interspace drilling and consequently in terms of cage dimension.

The ideal device for ACF following anterior cervical diskectomy has not yet been identified and is related to several variables (age, quality of bone, preexisting adjacent disease).[37,38] In a previous article, we investigated the bony incorporation of a composite implant made by a carbon fiber cage containing coralline hydroxylapatite, reporting a low complication rate and good fusion and clinical outcome.[38] In a second article,[37] we reported our retrospective analysis of 36 cases of DDD treated by interbody fusion with polyetheretherketone (PEEK) cages. About 97% of patients had a good outcome, and cervical fusion rate was 61.1% at 6 months and 100% at 1 year. PEEK cages appeared to be safe and efficient for ACF, and the result was fair in only one myelopathic patient.[37] Even if this and other composite implants seem to ensure good or excellent results,[8,10–12,19,37–39] in the selection of cages of increasing relevance is the concept of EM, that is, the capacity of a material to be elastically deformed by an external force, returning to its initial shape or position removing the load.[13,14] A lower EM results in a more natural compatibility with respect to bone material.

This concept is strictly connected to the possible accelerated DDD of adjacent levels due to increased stress induced by ACF.[40–51] Symptomatic adjacent-segment disease occurs at a mean incidence of 2.9% per year (range: 0–4.8%) during the 10 years after ACF with autogenous bone graft, especially at the C5–C6 and C6–C7 interspaces ($p < 0.0001$).[47] Therefore, 25.6% of patients with ACF with an autogenous bone graft would have new DDD at an adjacent level within 10 years after surgery and $\sim$ 70% of them need additional operative procedures.[47] The lower the EM, the lower seems to be the stress induced by ACF and the lower should be the adjacent-level disease,[41,48,49] and the higher the bony growth in and around the cage.[52] Therefore, to approximate the rate of adjacent-level disease to that of autologous bone graft,[47] the biomateral used for realizing cages should have an EM close to the bone.

Experimental studies demonstrated that the EM of TM corresponds to a mixture of bone obtained from human subchondral and cancellous bone,[13,53] leading to better load transfer and minimizing the stress-shielding phenomenon. Also for these reasons TM cages appear highly suitable for ACF after cervical microdiskectomy.[53–57]

Porous tantalum or TM is an open-cell porous biomaterial with a structure similar to human trabecular cancellous bone, having three-dimensional dodecahedron repeats. It has an average porosity of up to 80% with a consistent open-pore structure designed to resemble the physical and mechanical properties of cancellous bone. The coefficient of friction of TM cages is one of the highest among biomaterials, allowing for sufficient primary stabilization of implants.[53] Different fusion rates and results have been achieved in ACF using porous tantalum cages, which has led to contradictory views among spine surgeons.[53–59] Even if in the lumbar spine TM has been demonstrated to be effective in obtaining fusion and improving patient outcomes after anterior and posterior lumbar interbody fusion,[53] in a prospective randomized controlled study of 80 patients, Löfgren et al[59] reported that TM showed a statistically significant lower single-level ACF fusion rate than the group treated with tricortical autograft (69% versus 92%, respectively). In accordance with them, Kasliwal et al[58] concluded their prospective randomized clinical study on 39 patients treated for a single-level degenerative cervical disk disease considering porous tantalum not ideal for ACF. Anyway, the number of cases enrolled in every single arm of the study is quite low for statistical validation.[58]

In contrast with these two articles, many other authors reported very encouraging results using TM cages for ACF in DDD. More than 10 years ago, Vicario et al[57] reported good clinical and radiologic results with tantalum cages in a series of 24 consecutive patients. Fernández-Fairen et al,[56] in a series of 61 cases (28 treated with TM cages), evaluated if ACF with porus tantalum implants could be considered a cost-effective method to treat cervical disk disease with radiculopathy. They concluded that this device can be safely used as a stand-alone cage and is less costly and more effective compared with bone autograft with plating.[56] In the international literature there was recently a reappraisal of this topic, with several articles confirming the effectiveness of TM cages for ACF in DDD.[53–55] On a consecutive series of 99 patients with a mean follow-up $\geq$ 5 years, Papacci et al[55] reported long-term statistically significant clinical good results and a low rate of complications. At the same time, King et al[54]

reported their preliminary experience on fusion 6, 12, and 24 months postoperatively in a series of 10 cases treated with TM cages after anterior cervical corpectomy, reporting a 100% fusion rate and a low rate of subsidence 2 years after surgery.

On the basis of this literature analysis, we report the largest series (88 cases and 105 implants) of ACF performed with porus tantalum cages on a series of myelopathic patients, with or without radiculopathy, obtaining encouraging preliminary results. In particular, our overall rate of complications was quite low (5.7%). Worsening of myelopathy associated with failure of the implant occurred in two patients, and worsening of myelopathy without fixation failure occurred in another two. At a mean follow-up of 35.8 months, patients' perception of clinical outcome was referred to as good (17%) or excellent (78.4%). Four patients without improvement or with a slight worsening of myelopathy considered their result as fair. In particular, two of four patients had reoperations. In the first, a small fracture of the inferior vertebral end plate of C6 and bone fragment dislocation created after some weeks a new "osteophyte-like" compression; in the second, a posterior dislocation of TM cage occurred after mild head-cervical trauma 8 months after surgery.

Regarding radiologic results, overall fusion was observed after 3 months in 21.6% of patients: 41.5% nonsmokers and 4.2% smokers. Six months after surgery, fusion was achieved in 87.8% of nonsmokers and in 48.9% of smokers (overall fusion rate was 68.2%). After 12 months the fusion rate was 100% in both groups. A slight or moderate kyphosis was observed in nine cases at 3-month radiographic control, improved at the 6-month control but had not disappeared after 12 months; we did not observe any case with clinical and MRI features of degeneration changes of adjacent disk levels.

Conclusions

Our preliminary observations suggest that porous tantalum cages can be considered excellent bone substitutes for ACF after anterior cervical microdiskectomy and osteophytectomy at one or two levels for the treatment of patients with cervical spondylotic myelopathy. In our series, TM standalone cages ensured a high fusion rate with a low rate of complications. To confirm our encouraging results and the possible role of porous tantalum in reducing the incidence of symptomatic adjacent-segment disease, larger series are warranted.

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