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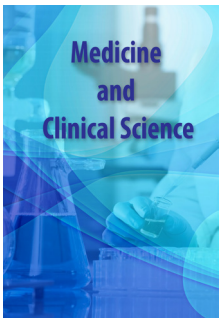
Original Article



Retrospective analysis of complications in anterior cervical discectomy and fusion using cage

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Anterior Cervical Discectomy and Fusion, Cervical Fusion, Cervical Cage, Retrospective Study

Abstract

Introduction: Anterior cervical discectomy and fusion (ACDF) is often performed surgery for single and multi-level cervical disc pathology. The purpose of the present study was to evaluate retrospectively the performance of TiPEEK cages, by assessing fusion rate and intra-operative and post-operative complications in patients who underwent ACDF with Mecta-C cervical cage.

Materials and methods: Seventy-eight patients who underwent ACDF using Mecta-C cervical cage alone or combined with plates were reviewed retrospectively for clinical and radiological outcomes. Bone substitute was used in all the cases.

Results: At the time of surgery the mean age of the patients was 48.2±10.1 years (range 26.7 – 75.5). After one year 76 patients underwent a CT scan which proved a complete fusion. At the follow up of 46.5 months±13.7 (range 29 – 70) the clinical outcome was reported to be "excellent", "very good" or "good" in 47.4%, 29.5% or 14.1% of patients, respectively. Only 7% of the patients reported a "poor" outcome. No adverse effects, neither intra-operative nor post-operative, were observed.

Conclusions: ACDF using Mecta-C cervical cage filled with a bone substitute as a stand-alone device or combined with the Mecta-C cervical plate leads to a complete fusion in all patients one year after surgery. Furthermore, 75% of patients reported satisfying clinical outcomes without any complications or adverse events.

Introduction

More than 80 per 100,000 people are affected by cervical disc disease (CDD) [1]. Radicular pain, myelopathy and spinal joint instability are among the main clinical manifestations secondary to degenerative changes in the cervical spine. After failure of first-line conservative therapies such as physiotherapy, oral drugs or injections of epidural cortisone, or in presence of myelopathy, surgical approaches are indicated [2].

As outlined in pioneering works [3,4] anterior cervical discectomy and fusion (ACDF) was developed as a less invasive alternative to the traditional posterior approach for the treatment of CDD and cervical disc herniation [5]. Nowadays, ACDF has been established as the gold standard treatment for both single and multi-level CDD, with an average of 130,000 procedures performed yearly in the USA [6]. It is speculated that this procedure reduces local mobility while simultaneously driving significant adjacent disease/degeneration [7]. When compared to discectomy alone ACDF has several advantages [8]. During ACDF, the disc is removed and replaced by a cage, and additional plate and screws, if indicated [9]. Cages, with or without plating, rapidly became the most commonly used intervertebral implants [10,11] as an alternative to autografts and allografts [12-14]. In fact, the introduction and application of anterior plate fixation was demonstrated to enhance stabilization allowing an improvement in fusion rate, cervical alignment, implant subsidence and a reduction of failure rates [15-17].

Several types of intervertebral cages are nowadays available for the treatment of cervical fusion. They are mainly made of titanium, carbon fiber and polyetheretherketone (PEEK). In particular, PEEK has an elastic modulus similar to cortical bone, despite being a bioinert material [18]. On the other hand, a titanium interface for PEEK was shown to enhance cellular attachment and osteoblastic phenotype expression by in vitro reports [18-20], together with osteoconductive activity and increased shear strength in an in silico model [21]. Under these premises, titanium coated PEEK cages (TiPEEK) were demonstrated to lead to a more robust intervertebral fusion in comparison to a standard PEEK device in animal models [22]. Moreover, human clinical studies showed that TiPEEK are safe and efficacious, and exhibit similar fusion rates and clinical outcomes with respect to traditional implants [23]. Recent clinical evidences also indicated an improved radiographic fusion of TiPEEK, although the differences were not significant [23].

The purpose of this study was to evaluate retrospectively the performance of TiPEEK cages, assessing the fusion ratio and intra-operative and post-operative complications in patients who underwent a cervical fusion with TiPeek Mecta-C cervical cage, with 75% of them also implanted with a cervical plate.

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Methods

All the patients were retrospectively reviewed for clinical and radiological outcome after approval of the Institutional Review Board (Retrospective review of the Mecta-C cage in cervical fusion: AZ Monica Ethische Commissie, OG 106). All the data were processed and analyzed after anonymization

Study design and patients selection

Between March 2015 and January 2017, 78 patients underwent a cervical fusion by the same surgeon at the Spine Clinic at Monica Hospital, Antwerp, Belgium, for a total of 114 cages implanted. Seventy-five (75.6) percent of them (n=59) were also implanted with an intervertebral cervical plate. The patients were of both sexes, over 18 years, and able to participate to the study. They were asked to sign the ethics committee-reviewed and approved informed consent form before being enrolled in the retrospective study.

Surgical procedures

All 78 patients received a standard ACDF using the Smith-Robinson technique (3) with implantation of a TiPeek Mecta-C cage (Medacta, Switzerland), combined with the use of Mecta-C cervical plate (Medacta). The same experienced spine surgeon performed all surgical procedures by anterolateral left sided approach. After the disc was removed, an intervertebral cage was placed with additional plating when indicated, with the addition of bone substitute, Mectagel® (βTCP+HA) (Teknimed, l'Union, France) [3]. The cages were both wedged and convex, with height sizes ranging from 4 to 8 mm (Figure 1).

The patients followed the standard rehabilitation procedures used at the Spine Clinic at Monica Hospital consisting in wearing a soft collar for two weeks followed by physiotherapy for 6 weeks.

Outcome measures

Demographic data including age at surgery, diagnosis, follow-up time after surgery and gender were collected for each patient. During the pre-operative planning, magnetic resonance imaging (MRI) was used to evaluate indication and diagnosis and to choose the most appropriate implant type/size matching the patient's anatomy. At 1-year follow up after surgery, computed tomography (CT) scan was used to assess the bone fusion. At follow-up all patients were reached out by phone and asked to fill in a questionnaire to express their satisfaction after the surgical treatment.

Statistical analysis

For this observational retrospective study no sample size calculation was performed. Data were reported as observations.

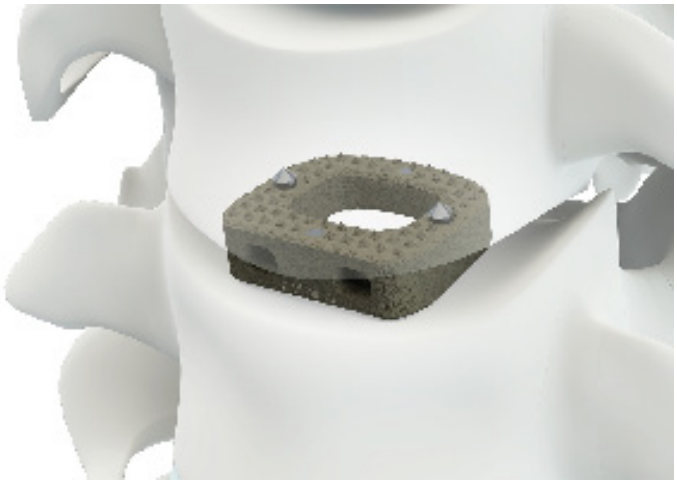

Figure 1. Detail of a Mecta-C cage

Results

Patient demographics

A total of 78 patients were included in this retrospective study. The mean age of patients was 48.2 years (range 26.7 – 75.5, SD 10.06), with a male/female ratio of 39.7% vs 60.3% (31 vs 47). The mean follow-up was 46.5 months (range 29 – 70, SD 13.7). Only 2 patients were lost at follow up for CT scan, but they expressed their satisfaction level when reached out by phone. Fourty-seven (47) patients received a single level, 26 patients a double level and 5 patient a triple level fusion (Table 1). All patients were operated on levels between C3 and C7 (Table 2).

No patient died, neither peri-operatively nor until the last follow-up.

A total of 114 Mecta-C cages were placed (Table 3). In 59 patients (75.6%) the cage was used in association with Mecta-C cervical plate, in the remaining 19 patients (24.4%) as a stand-alone cage.

Different clinical indications were identified, including brachialgia, cervicalgia, cervicobrachialgia and myelopathy (Table 4).

The overall clinical indications were divided into the following and more narrowing technical indications after reviewing the pre-operative MRI (Table 5).

Radiographic fusion

At 1-year follow-up, 2 patients (2.6%) were lost whereas all other patients (n=76, 97.4%) reached a proven fusion on CT scan according to Bridwell et al's criteria [24] (Figure 2).

Clinical outcomes

At a mean follow-up of almost 4 years (46.5 months), the patients' clinical outcome was very satisfactory. In fact, 76.9% of them reported an outcome ranging from excellent (47.4%) to "very good" (29.5%), 14.1% reported "good", and only 9% reported a "poor" outcome (Table 6).

Adverse events and complications

No adverse effects or complication were associated with all the cages implanted in the study.

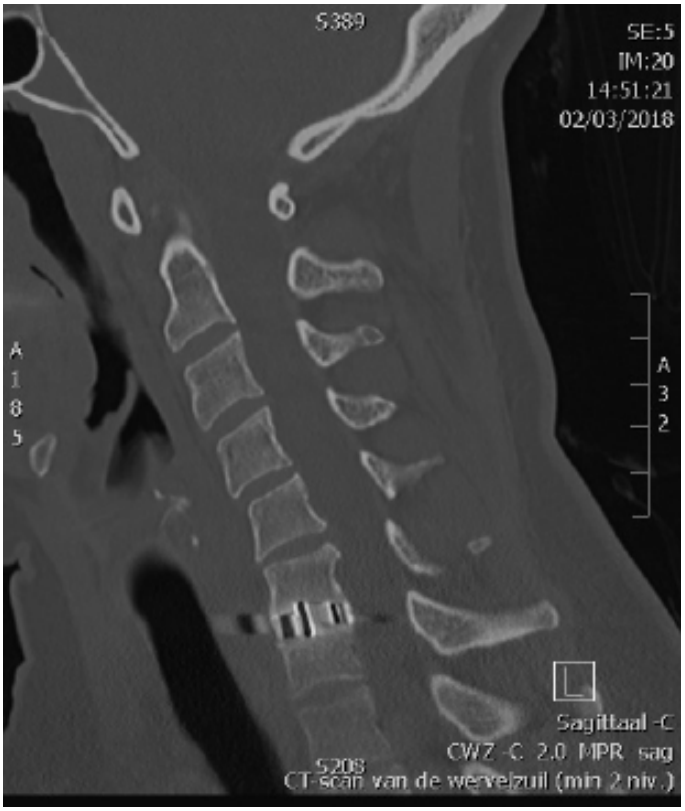

Figure 2. DTC scan of a patient included in the study proving fusion according to Bridwell et al's criteria

Number of levels	Frequency (%)
1	47 (60.3)
2	26 (33.3)
3	5 (6.4)
Total	78 (100.0)

Table 1. Number of surgical levels involved by surgery

Level	Frequency (%)
C3-4	2 (2.6)
C3-4, C4-5	2 (2.6)
C4-5	3 (3.8)
C4-5, C5-6	8 (10.3)
C4-5, C5-6, C6-7	3 (3.8)
C5-6	29 (37.2)
C5-6, C6-7	16 (20.5)
C6-7	14 (17.9)
C6-7, C7-T1	1 (1.3)
Total	78 (100.0)

Table 2. Distribution of surgically treated levels.

Cage (height)	Frequency (%)
Wedged (4 mm)	4 (3.5)
Convex (5 mm)	66 (57.9)
Wedged (5 mm)	15 (13.1)
Convex (6 mm)	23 (20.2)
Wedged (6 mm)	4 (3.5)
Convex (7 mm)	1 (0.9)
Convex (8 mm)	1 (0.9)
Total	114 (100.0)

Table 3. Types of Mecta-C cervical cages used in cervical fusion.

Clinical Indication	Frequency (%)
Cervicobrachialgia	52 (66.7)
Brachialgia	13 (16.7)
Cervicalgia	10 (12.8)
Myelopathy	3 (3.8)

Table 4. Clinical indications for Mecta-C cervical cages in the study.

Technical indication	Frequency (%)	Total frequency (%)
Disc herniation – and myelopathy	34 (43.6) 1 (1.3)	35 (44.9)
Foraminal stenosis – and discopathy	5 6.4) 8 (10.3)	13 (16.7)
Spinal stenosis – and disc herniation – and discopathy – and myelomalacy	4 (5.1) 1 (1.3) 2 (2.6) 3 (3.8)	10 (12.8)
Discopathy – and myelum compression	7 (9.0) 1 (1.3)	8 (10.3)
ADD (Anterior Disc Degeneration) – above and under previous fusion – above previous fusion – under previous fusion – and pseudarthrosis	1 (1.3) 2 (2.6) 3 (3.8) 1 (1.3)	7 (9.0)
Instability	2 (2.6)	2 (2.6)
Pseudoarthrosis	2 (2.6)	2 (2.6)
Fracture	1 (1.3)	1 (1.3)
Total	78 (100.0)	78 (100.0)

Table 5. Technical indications for cervical cages used in the study.

Clinical outcome	Frequency (%)
Excellent	37 (47.4)
Very good	23 (29.5)
Good	11 (14.1)
Poor	7 (9.0)
Total	78 (100.0)

Table 6. Satisfaction level expressed by the patients.

Discussion

Patients undergoing ACDF with the TiPeek Mecta-C cervical cage of Medacta, as stand-alone cage or combined with the Mecta-C cervical plate, reported a satisfactory clinical outcome in 91% of cases, with no adverse events associated with the procedure and a complete intervertebral body fusion in all patients. The efficacy of the device was assessed mainly on cervicobrachialgia as the main symptom and for disc herniation/discopathy and spinal/foraminal stenosis as the main diagnosis.

ACDF has been accepted as a relatively safe, effective and common procedure for the management of the degenerative spinal cervical diseases, resulting in cervical radiculopathy [25]. The main goal of this surgical treatment is to obtain a valid nerve decompression and a long lasting successful fusion. The use of a cage in ACDF allows reducing the operation time while maintaining the intervertebral disc height and lordosis. Nevertheless, subsidence and cage migration of stand-alone cervical cages, resulting in a delayed fusion, nonunion, kyphosis and loss of lordosis have been reported [26].

In the present work analyzing the performance of the ACDF a fusion proven by CT scan has been observed in all patients at one year of follow-up, suggesting that the combination of TiPeek Mecta-C cervical cage is an effective technique. These positive results may be credited to the use of an osteoconductive titanium coated PEEK cage, having similar rigidity to the normal bone, and the practical advantage to enable the surgeon to radiographically monitor the progression to bony fusion [27-29]. The combination with synthetic bone, consisting of nanoparticular hydroxyapatite graft and substituting the autograft, reduced the donor site morbidity related to the use of autologous bone [30], conferring a further advantage to this procedure. Moreover, the TiPeek Mecta-C cervical cage represents a mechanical structure providing good load-bearing capacity, with a lordotic design restoring the anatomic sagittal alignment of the cervical spine. More importantly it showed to be a versatile device. Its physiological design, the multitude of available sizes and either the dome-shaped or flat superior endplate allow the surgeon to respect the patient's unique individual anatomy towards a personalized clinical approach.

The main limitation of this study is the small size of the population and the retrospective nature of the analysis.

Conclusion

Taken together these findings showed that ACDF using TiPeek Mecta-C cervical cage of Medacta, as stand-alone cage or combined with the Mecta-C cervical plate filled with bone substitute Mectagel® leads to a high union rate and satisfactory clinical results without peri- and post-operative complications or adverse events. The clinical and radiological outcomes showed that the TiPeek Mecta-C cervical cage for ACDF is an effective, reliable, and safe alternative to the conventional method for the treatment of cervical CDD.

Conflicts of interest

None to declare.

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