Use of Stand-Alone Intersomatic Titanium Interbody Cage Cespaces for Cervical Anterior Arthrodesis and Fusion in Cervical Degenerative Diseases

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Research article

Keywords: Anterior cervical decompression, Arthrodesis, Cervical degenerative diseases, Cespace, Interbody fusion

Posted Date: February 17th, 2021

DOI: <https://doi.org/10.21203/rs.3.rs-241618/v1>

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Abstract

Background: Cespace is a solid titanium spacer used for arthrodesis and fusion between vertebral cervical bodies in the treatment of degenerative diseases of cervical spine.

Methods: We present our clinical experience in a group of 180 patients, affected by cervical myelopathy due to spondylosis or cervical disc herniation and undergone surgical operation. All patients underwent an anterior discectomy and interbody fusion through positioning of one or more levels Cespace device. Patients were evaluated by clinical and radiological assessment pre-operatively, immediately post-operatively and at follow-up. We assess clinical outcome using visual analogue scale for pain and a modified Japanese Orthopedic Association scale for myelopathy. We also considered functional outcome, using Odom classification.

Results: After surgical treatment we report a significant relief of pain and clinical improvement. Radiological evaluations showed no change in cervical lordosis. No case of junctional syndrome was observed over all follow-up period.

Conclusion: Cespace is a safety and efficacious orientated solution for cervical interbody fusion.

Background

Anterior cervical spine surgery represents a consolidated and widely accepted procedure for cervical degenerative diseases such as spondylosis, disc herniation, ossified posterior longitudinal ligament, spinal cord tumors, and vascular diseases. This surgery aims the advantage to directly visualize and treat the lesions anteriorly to the spinal cord and spinal nerves. The use of novel spinal implants during this surgical procedure has enhanced the fusion rates, reduced postoperative immobilization, and improved clinical therapeutic effects [1]. The aim of ACDF is to obtain an optimal decompression of the myelofascicular structures, the restoration of the height of disc, immediate load support to the anterior column and arthrodesis [2]. Fusion devices include autologous or different allograft materials, including artificial disc, bone cement, polymers, ceramics, PEEK cages and titanium cages.

Anterior cervical discectomy and inter-body fusion with stand-alone cages represents a valid treatment option for symptomatic cervical degenerative disease. Stand-alone intersomatic cages permit a physiologic metameric alignment and fusion both in one- and two-level procedures, and recently also in a multi-levels surgery [3–5]. In recent years a stand-alone intersomatic titanium cage has been designed. This cage is sprayed with pure titanium powder onto the oxide-free surface to form a rough, microporous surface with high stability that facilitates bone growth, and can be successfully used for joints replacement arthroplasty.

Aim of this study is to describe our 4-year experience in 180 consecutive cases of degenerative cervical diseases treated at our Institution with ACDF and implant of Plasmapore® (CeSpace®, Aesculap AG,

Tuttlingen, Germany)-coated titanium cage. We also described the long-term clinical and functional outcome.

Methods

Patients selection and data collection

A retrospective analyses of medical records of 180 patients, affected by cervical degenerative diseases, undergone ACDF with a stand-alone intersomatic titanium cage implant, from 2012 to 2016, was conducted. The epidemiological information, clinical presentation, duration of symptoms, radiological findings, and the clinical outcome were evaluated. Indication for surgery was cervical pain associated with intractable radiculopathy that did not respond to conservative and medical treatment for a period of at least five weeks, or evidence of progressive neurologic deficit. Patients previously treated by another cervical surgical procedure, affected by traumatic injuries and with other concomitant spinal diseases (tumors, infections) were excluded from the study. Pre-operative full neurological examination was performed. The VAS was used for neck and radicular pain and the JOA score for myelopathy. All patients underwent to pre-operative radiological studies of the cervical spine included X-rays in lateral, anteroposterior and flexion/extension views, CT scan and MRI with T1 and T2-weighted sequences in transverse and sagittal planes (Fig. 1). All patients signed an informed consent with description of surgical procedure, alternative proposed methods of treatment, and possible complications.

Surgical technique

In all patients we performed a standard anterior cervical discectomy through a right-sided anterolateral retropharyngeal approach. All patients received general anesthesia and ceftriaxone 2 g I.V. 30 min before incision. All patients were monitored in terms of blood pressure, pulse rate, oxygen saturation and electrocardiographic signals. The patients were placed in a supine position with the head slightly reclined. Horizontal skin incision for one or two levels was performed in right paramedian cervical area. The surgical exposure involving access to the operating site and retraction of the tissues using minimal instrumentation. The trachea and esophagus were retracted in order to better see the vertebral bodies. After fluoroscopic control, we performed the decompression of the spinal cord and/or nerve roots including complete discectomy, removal of the posterior longitudinal ligament, removal of osteophytes that were in contact and / or compressed the neural elements. Optimal decompression of neural structures was verified using a blunt probe. The bony surface of both vertebral end-plates has been preserved as possible during discectomy. Implant selection and Cespace positioning was obtained under lateral fluoroscopy. The implant design correlates with the anatomy of the cervical spine. Cespace device is coated by microporous Plasmapore® which permits bony ingrowth into the surface of the implant during bone remodeling period (fusion).

Follow-up and outcomes

Patients' clinical examination were compared with their preoperative examinations in the first, sixth, and twelfth month after surgery. At the last follow-up, the outcomes were rated according to Odom's criteria as excellent, good, fair, or poor, depending on the resolution, improvement, or persistence of preoperative symptoms. All patients underwent radiographic control two days after surgery, in order to allow for early mobilization.

Radiological evaluation

All patients underwent antero-posterior, lateral and flexion/extension X-rays within two post-operative days. Radiographs were also taken at 6 weeks, 3 and 6 months after surgery (Fig. 2), and compared during the follow-up. We looked for radiological evidence of a) subsidence, as defined as cage migration of more than 2 mm into the adjacent vertebral body; b) migration along the superior and/or inferior endplates; c) settling of the implant; d) degree of spinal curvature. We also checked the preservation of cervical lordosis, distance between adjacent endplates, ratio between height of the spinal unit and height of cage, and ratio between the surface of the endplate and surface of the cage.

Results

The study included 180 patients, 97 (53.8%) male and 83 (46.1%) female, aged between 39 and 72 years (mean age 56.6 years). There were 135 (75%) single-level and 45 (25%) double-levels of disease. The preoperative clinical evaluation revealed the presence of cervical pain in 82 patients (45.5%), of radicular pain in 65 (36.1%), both in 91 (50.5%). The C3-C4 level was affected in 22 patients (12.2%), C4-C5 in 63 patients (35%), C5-C6 in 70 patients (38.8%), and C6-C7 in 25 patients (13.8%). In the preoperative period, the mean VAS score for neck pain was 7.8 (range 4–10), while it was 8.06 (range 5–10) for radicular pain. We recorded a clear improvement in these parameters at the 12-month follow-up. At this point, the mean VAS score for neck pain was 2.8 (range 0–6), while it was 2.1 (range 0–6) for radicular pain. Clinical and neurological status of patients was evaluated with the JOA scale. The average pre-operative score was 9. In the follow-up the score improved to 15.3. During the last clinical evaluation, the Odom criteria were also applied. Ninety-seven patients (53.8%) showed an excellent outcome, sixty-three (35%) a good outcome. No patient had a poor outcome, while only 20 (11.1%) had a fair outcome. Overall, we have documented a clear progressive resolution of the symptoms, highlighted in the preoperative phase, in 160 patients (88.8%).

We reported 8 (4.4%) cases of subsidence. In 4 (2.2%) cases migration was less than 2 mm. In 2 cases we documented a kyphotic reduction less than 4°. We did not note cases of cage migration both in immediate post-operative period and within the follow-up. A rate of 97% of fusion between adjacent vertebral bodies has been documented. MRI evaluation was performed during follow up (Fig. 2) with detection of 12 cases of adjacent segment disease.

Discussion

Cervical degenerative diseases are chronic, progressive conditions evolving to ankyloses of the motion segment. These pathological conditions are characterized by an initial loss of elasticity of the disc and its progressive alteration of the ability to reduce and distribute the pressure forces on the vertebral endplates. The loss of compactness of the disc also causes the decrease of vertebral heights and thickening of the ligamentum flavum. The process of bone rearrangement due to an incorrect alignment can cause the formation of osteophytes too. Consequence of these structural alterations can be hypo and/or hypermobility of the cervical spine, spondylolisthesis and spinal stenosis. The frequent injuries to which the spinal cord is subject, can cause inflammatory and/or ischemic phenomena and, finally yield myelopathy. Although in the early stages these alterations can also be asymptomatic, however the presence of disc herniation, osteophytes and hypertrophied ligaments may compress the spinal cord with the result of onset of cervical pain, radiculopathy, or myelopathy [6].

The surgical treatment must aim to decompress the nerve structures, to restore the correct alignment of the vertebrae and, if necessary, allow the stabilization of the vertebral spine. In planning surgical treatment, neuro-radiological studies are extremely important. The radiographic study with dynamic tests of the cervical spine allows us to evaluate the degree of movement of the affected segment. As a result, in our cases history, we observed in all patients a significant reduction of the degree of movement of the concerning segment. Finally, the MRI provides information on the extent of compression, on the presence of any malacic areas and if the discopathy is soft or hard.

Many procedures have been proposed for the surgical treatment of cervical degenerative diseases such as anterior decompression, laminectomy, laminoplasty and instrumented anterior and posterior fusion by plates or screws. Anterior approaches are effective for neural decompression, showing better clinical outcomes with less surgical trauma compared to posterior approaches. Anterior plating has been used to increase fusion rates and reduce subsidence and postoperative kyphosis. Husag et al., reported in our series of patients undergone anterior cervical discectomy, an excellent overall benefit in 95% of cases. However, at the same time, the merger rate of 70%, after the procedure, led to an increase segmental motion, subsidence and cervical kyphosis leading to instability and degenerative disc disease in adjacent levels [7].

The microsurgical ACDF through placement of auto or hetero graft in the intersomatic space represents the operative procedure of choice for degenerative disc disease and cervical spondylosis associated with radiculopathy or myelopathy. The term "total removal" means that disc must be taken away up to the cortex of the vertebral body, paying special care to the preparation of the endplates for the lodging of the cage. With this procedure it is possible to overcome the limitations associated with anterior plates and screws [8]. This procedure has the potential to improve fusion, correct vertebral alignment and significantly reduce the incidence of subsidence. The objective of ACDF is to eliminate motion between adjacent vertebrae by forming a bony amalgamation which is obtained by minimizing intervertebral motion during the fusion phase. The position of any interbody spacer should be maintained to prevent its extrusion, irritation of surrounding tissues, and to allow union with the adjacent vertebrae. Nevertheless, ACDF is burdened by a series of possible complications such as dysphagia and, especially in multilevel

procedures. Breakage, loosening of screws, screw penetration to endplate and fractures are possible complication too [9].

Although ACDF represents a well-established technique in the treatment of degenerative cervical pathology, to date, there are still doubts about the most suitable technique of fusion to adopt. The use of autologous grafts from the iliac crest represented the ideal treatment for many years. However, this technique is burdened by a series of complications such as graft collapse, disc space height loss, kyphosis and possible morbidity of the donor site such as pain, hematoma, and infections [10–11]. In order to overcome these limitations, intersomatic fusion cages of various shapes and compositions have been developed. Cages are characterized as cubical implants that are thought to restore physiological disc height and allow bone growth through the implant with osseous fusion [12]. Thus structured the cages favor a faster fusion allowing the correct realignment of the cervical spine. Moreover, the presence of dislocation and subsidence appears significantly reduced [13]. Different types of cages, of various shapes and materials, are available to perform ACDF, including titanium cages, carbon fiber reinforced polymer cages, PEEK cages, and cages integrated with and without synthetic bone grafts [13–16]. However, Meier et al., in 2004 comparing six different spacers for spondylosis of the cervical spine in a series of 267 patients, reported a higher tendency of dislocation of PEEK cages as compared to other implants such as plasmaphore coated titanium cages [17].

The Plasmapore® pore sizes range from 50 to 200 micrometers with a microporosity of 35% and thickness of 0.35 mm, leading to a large surface area and providing an optimal surface for bone growth. Moreover, Plasmapore® is a very rough surface and should support the primary stability of the cage, consequently, the cages are not filled with any form of bone or other form of material. At the end of the discectomy, the choice of cage dimensions must be made by means of a special measuring device which is housed in the now empty interbody space of the disc. It is necessary to choose the right height measurement, to avoid both the over-size, which would risk stretching the nerve roots causing iatrogenic damage, and the down-size, which could result in a kyphosis of the motion segment with loss of the spinal balance.

Krayenbuhl et al., in their series of patients affected by cervical myelo-radiculopathies, described a 98% fusion rate with only 2% of subsidence [18]. Arregui et al., implanted Cespace in a series of 104 patients. Bone fusion rate was 66.3% six months after the surgical procedure, while it was 91% at the end of the first year of follow-up [14]. Recently, Takeuchi et al., have shown that the use of PPC promotes faster bone formation after ACDF. In this study, the bone fusion defined as the formation of bone bridges between the fixed vertebral bodies was total [19]. Our data appear in line with reported literature. Bone fusion rate was 97% while subsidence cases were only 8 (4.4%).

Conclusions

Anterior discectomy and interbody fusion by positioning the Cespace device is a safe and valid alternative to the conventional methods of treatment for cervical degenerative disc disease such as

anterior decompression, laminectomy, laminoplasty and instrumented anterior and posterior fusion by plates or screws. It constitutes an effective method for the treatment of cervical disc herniation in terms of improving the neurological deficits, reducing post-operative pain and improving the quality of life. Furthermore, the stand-alone intersomatic titanium cage implant have proven to be effective and safe for the restoration of the physiological height of the disc, to allow bone growth aimed at obtaining fusion and to allow the correct realignment of the cervical spine, preserving cervical lordosis.

Abbreviations

ACDF

anterior cervical decompression and fusion

PEEK

polyether- ether- ketone

CT

computed tomography

MRI

magnetic resonance imaging

VAS

Visual Analog Scale

JOA

Japanese Orthopedic Association

Declarations

Ethics approval and consent to participate: This study was approved by Medical Ethics Committee of University of Messina. Written informed consent was obtained from each patient.

Consent for publication: All applicable consents for publication were acquired. All Patients gave written consent to participate.

Availability of data and materials: Data and materials used in this study can be made available upon reasonable request.

Competing Interests: All authors declare that they have no conflict of interest.

Funding: No funding was received for this work.

Authors' contributions: FC and GC made a substantial contribution to the conception of the work;

GC, MC and IG made a substantial contribution to data acquisition; GC, MC, MSC, SF, and GLF made a substantial contribution to the analysis and interpretation of the data; GC and MC drafted and critically reviewed the work; AG approved the final version. All authors read and approved the final manuscript.

Acknowledgements: Not applicable.

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Figures

Figure 1

Preoperative T2-weighted sagittal magnetic resonance imaging revealing disc prolapse and spinal cord compression at the C5-C6 level.

Figure 2

On the left we can observe postoperative lateral plain X-ray at 6 months presenting the implant. On the right, of the same case, we see the control T2-weighted sagittal magnetic resonance imaging.