Anterior Cervical Corpectomy and Fusion with the C-VBR

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Abstract

Introduction: Anterior Cervical Corpectomy and Fusion (ACCF) procedures are increasing as the population ages and cancer treatments improve. Currently, one expandable and one non-expandable cervical Vertebral Body Replacement (VBR) devices have been FDA 510(k) approved. Cervical VBR device specific data has yet to be established.

Object: To present the efficacy and safety data of the first non-expandable cervical VBR device to receive FDA 510(k) approval.

Methods: A retrospective consecutive series of 56 female and 41 male ACCF patients, from a single institution, were followed for an average of 30 months. ACCF patients were, on average, taking 11 different daily medications, 40 (41%) were smokers and 39 (40%) were on anticoagulation therapy that required pre- and post-operation management. Eighty-nine percent were American Society of Anesthesiologists (ASA) class III or IV. Sixty-six patients had pre-operative C2-7 Cobb angles of five degrees or less.

Fusion was determined by CT scan, flexion/extension X-rays or both. Complications of dysphagia, subsidence, non-union and additional surgery were recorded. Demographic pre-operative patient characteristics and post-operative fusion rates were presented with descriptive statistics. Complication rates were tabulated during the follow-up period.

Results: Fusion was documented in 89 of 93 patients (96%). To be statistically conservative, the three patients with inadequate radiographic follow-up were counted as non-unions. Twenty-three patients (25%) had additional surgery during the follow-up period, 5 (5%) planned, 18 (19%) unplanned.

Conclusion: The fusion rate was 96% and consistent with previous ACCF reports. Three cases of C-VBR subsidence resulted in dysphagia and subsequent anterior plate removal. Incidentally, the ACCF rate was noted to be higher than the ACDF rate in this cohort of patients at high risk for surgical morbidity and mortality.

The C-VBR was found to be a safe and effective device for ACCF surgery.

Introduction

Successful multi-level anterior cervical decompression and fusion (ACDF) and anterior cervical corpectomy and fusion (ACCF) are strongly influenced by the bone graft source[1], the smoking addiction[2,3], the number of levels fused[4-9] and the construct stability[10-15]. Patient satisfaction can be maximized when the non-union and complication rates are minimized[16]. For multilevel cervical disorders, the surgeon often determines the bone graft source, the number of levels fused, the surgical technique and the construct stability.

The initial ACCF experience with fibular allografts had unacceptably high expulsion, fracture, non-union and revision rates[17-20]. Supplemental halo fixation was not as successful as the addition of posterior cervical fixation for reducing fibular allograft associated complications [12,19,20]. Cylindrical titanium mesh technology anchored implants to end-plates better than fibular

allografts reducing the expulsion rate[21]. Polyetheretherketone (PEEK) spacers were introduced with the “benefit” of having a modulus of elasticity (15 GPa) closer to bone than titanium (110 GPa)[22]. However, PEEK spacers behaved similar to fibular allografts demonstrating unacceptably high rates of expulsion, fracture, subsidence and non-union[23,24].

In January 2016 the C-VBR (PALO ALTO SPINE, Louisville, KY K152568) received 510(k) approval as the first non-expandable VBR device for use in the cervical spine (Figure 1). The C-VBR is trapezoidal in all three planes. Anterolateral “brakes” and anterior-superior “spikes” are two additional design features which deter spinal cord injury. The large end-plate surface areas and anterior windows allow for better graft packing and contact of the graft with the host bone. The FDA approved the C-VBR for use for the following indications: replacement of a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e. fracture), for immediate use in myelopathic patients with conditions that do not respond to non-operative interventions

(including Ossification of the Posterior Longitudinal Ligament [OPLL], kyphosis, or masses resulting in stenosis), and for treatment of multilevel degenerative disk disease or contiguous disk herniations that result in neck and arm radicular pain. This article presents the cohort of patients that was submitted to the FDA to determine the safety and efficacy of the C-VBR for use as a cervical vertebral body replacement (VBR) device.

Methods

The study group was composed of 56 female and 41 male patients. The average patient was 56 years of age with 19 (22%) being 65 or older. The body mass index (BMI) average of 30.5 (kg/m^2) was indicative of obesity. On average, ACCF patients were taking 11 different daily medications with 84 (88%) of the patients taking at least four different medications on a daily basis. Forty patients (41%) were smokers and 39 (40%) were on anticoagulation therapy that required pre- and post-operation management. Sixty-three of the 96 patients (69%) were American Society of Anesthesiologists (ASA) class IV, 19 class III, 9 class II and 5 class I. Thus, this cohort with an ASA average of

3.5 was at high risk for peri-operative morbidity and non-union (40% smokers). Sixty-six patients had pre-operative C2-7 Cobb angles of five degrees or less.

All patients had surgery at a single institution by one of the two authors. ACCF cases were performed between February 2013 and January 2015. All patients had a C-VBR implanted along with supplemental FDA approved anterior plate (n = 88), posterior cervical fixation (n = 5) or both (n = 4). The average follow-up was 30 months (range 1 - 50 months). Two patients were lost to follow-up and were classified as non-unions. Five patients died from unrelated causes, three of these patients had radiographic documentation of a solid fusion prior to their death. Heart attacks claimed two patients four and 24 months post-op; cancer led to one death nine months post-op; and strokes captured two patients 19 and 27 months post-operation.

Ninety patients (93%) had a primary diagnosis of stenosis with 30 (31%) having myelopathy. Four patients (4%) presented with OPLL

and three (3%) with metastatic cancer. Eighty-three ACCF patients (86%) had a single corpectomy. The authors recognize that 70 of the 97 patients (72%) may have been adequately treated by a multi-level ACDF or a posterior decompression and fusion (PCDF). These 70 patients were given the multi-level ACDF or PCDF options during the informed consent discussion. Their decision for ACCF may have been influenced by the authors' technique bias for ACCF versus multi-level ACDF or PCDF. This technique bias has been present since 1999[21]. This technique bias led to the development of the C-VBR and the authors' financial bias, which was disclosed to all patients prior to surgery. The C-VBR was developed because the "off label" devices previously used for cervical VBR were associated with unacceptably high complication rates. The 15 patients between February 2013 and January 2015 opting for multilevel allograft ACDFs or PCDF alone were excluded from this study and not included in the data sent to the FDA for C-VBR safety and efficacy evaluation.

Twenty-six of the 83 (31%) single level ACCF patients also had an interbody fusion performed at a level adjacent to the corpectomy. Autologous bone graft from the corpectomy was used as graft at these adjacent levels. Hybrid constructs were performed in lieu of additional corpectomy level(s) in order to increase the number of fixation screws placed into intermediary vertebral bodies. The autologous bone graft from the corpectomy trough was used in over 90% of these interbody fusion levels. Ten of the 83 (12%) single level ACCF patients had two additional interbody fusions at levels adjacent to the corpectomy. Eleven of the 13 (85%) two-level corpectomy patients also had an adjacent level interbody fusion (see table 1). Autologous bone from the corpectomy was used at all levels in these 13 patients. Five patients (5%) had simultaneous anterior-posterior procedures. Four patients (4%) had a staged posterior procedure after a fall (3 cases) or non-union from recurrent cerebral spinal leak (1 patient). Posterior cervical decompression and fusion (PCDF) was included when four anterior levels were decompressed, a severe kyphotic deformity existed, or a posterior decompression was indicated. Three unplanned PCDFs were also performed: two after trauma and one

for non-unions at the two IBF levels. The average pre-operative cervical lordosis (C2-7) was -0.4 degrees (range 20 to -20 degrees).

Fusion was determined by CT scan, flexion/extension X-rays or both. All imaging studies were interpreted by an independent Board Certified Radiologist and confirmed by the Attending Physician. Patients with inadequate radiographic follow-up were counted as non-unions to provide the most conservative statistical estimate of successful fusion.

Complications monitored included dysphagia, instrumentation migration, revision surgery, and non-union. Pre- and post-operative Cobb measurements were used to detect progressive kyphosis. Anterior migration of the cervical plate or a change in the angulation of the fixation screws was used to identify subsidence (see figure 2).

Results

Fusion was documented in 89 of 93 (96%) patients. Fusion was documented by CT scan alone (8 patients; 9%), flexion/extension X-rays alone (44 patients; 47%) or both (37 patients 40%; see figure 2). Fusion could not be assessed in four ACCF patients due to inadequate radiographic follow-up. All 219 corpectomy interfaces visualized resulted in radiographic fusion. Three non-unions at 57 IBF levels (5%) were documented by CT scan. Autologous graft was used inside the two PEEK IBF cages and the one carbon fiber IBF cage that resulted in non-unions. Complications included: dysphagia (8; 9%), subsidence (3; 3%), re-exploration for possible hematoma (3; 3%), adjacent level disease (3; 3%), non-unions at IBF levels (2; 2%) progressive kyphosis (3; 3%) and explantation (2; 2%). The first explantation occurred three weeks after surgery when the patient had a seizure and fell down a flight of stairs. The incident required removal of the device, extension of the fusion and supplemental posterior fixation. The second explantation occurred in a known Methicillin Resistant Staphylococcus Aureus (MRSA) carrier who seeded his implants six weeks after surgery. In all, 23 patients

(24%) required an additional surgical procedure: two for suspected anterior epidural hematomas, one posterior hematoma; two devices were explanted; three patients had an adjacent level disk herniation; four had delayed and unplanned posterior cervical decompressions and fusions; eight required anterior plate or screw removal for instrumentation migration or prominence; and two required posterior instrumentation removal. One patient underwent a PCDF and revision for a malpositioned DTrax cage.

Discussion

Majd et al., were the first to report a 97% fusion rate with the cage/plate technique in 1999[21]. The exceptionally high fusion rate, non-existent anterior approach infection rate compared to the posterior approach's infection rate, and high risk patient population all contributed to the authors ACCF technique bias. Since 1999 we have been developing a cervical VBR device with safety features in order to reduce the expulsion, fracture, non-union and revision rates (see figure 1). Both authors also

acknowledge a financial interest associated with the C-VBR use. Both surgeons also had the luxury of adding a simultaneous or staged posterior construct in order to increase construct stability and fusion probability.

High ACCF fusion rates have also been reported by other investigators[25,26]. Castellvi et al., reported that the ACCF technique overcame the negative effects of smoking, pending litigation and workers' compensation status[26]. If patients with inadequate radiographic follow-up were not counted as failures, the fusion rate in the current study would closer to 100%. Still, the 96% ACCF fusion rate remains impressive as the current sample group was composed of older, medically complex, smokers, many of which required anti-coagulation management.

The current 96% ACCF fusion rate compares favorably to previously reported one- and two-level ACDF fusion rates, especially when allograft was used[1,5,27-29]. It also compares favorably to the 95% fusion rate for ACDFs seen in this cohort.

When compared to three or four level ACDFs, the ACCF technique consistently achieves a superior fusion rate[30]. We attribute the high fusion rate to: the use of autologous bone graft[1], the large surface area exposing autologous graft to host bone, and the construct stability[10-15]. Autologous bone graft optimizes the osteoinductive, osteoconductive and osteogenic potentials within the fusion mass. Harvesting local bone from the cervical corpectomy channel also eliminates the possibility of prolonged iliac crest bone graft harvest site pain and its associated complications[31-33].

The large anterior and end-plate C-VBR windows allow for efficient packing of the bone graft with elimination of “air gaps”. The trapezoidal design of the C-VBR has two distinct advantages when compared to all cylindrical devices. The snug fit between the C-VBR and the corpectomy walls increases the construct stability and maximizes the volume of graft bone within three millimeters of the host bone and its blood supply.

The trapezoidal shape, anteriorly placed spikes and anterolateral brakes of the C-VBR provide increased resistance during surgical implantation. Lack of resistance during implantation of cylindrical devices may result in paralysis[34]. These design features also increase the post-operative **safety** profile. Biomechanical testing demonstrated a 12-fold preference for anterior expulsion, rather than retropulsion. Cylindrical cages demonstrate no directional expulsion preference. To date, no C-VBRs have demonstrated horizontal migration.

Dysphagia (9%) and plate instrumentation related complications in the current series were comparable to previous ACCF reports[,25,26,35-37,]. Eight patients (9%) required cervical plate and or screw removal (see Figure 2). No patients required PEG tube placement for dysphagia. One patient requiring esophageal dilation for chronic dysphagia pre-operatively underwent another esophageal dilation during follow-up.

Vertical migration or subsidence of the C-VBR was documented in three cases (3%; see Figure 2). The trapezoidal platform was designed to reduce subsidence by approximating the hard subcortical end-plate bone in the periphery. Fixation spikes provide an initial resistance to subsidence with the platforms providing 2.5X more resistance once the spikes are fully engaged. The technique of placing a non-expandable device passively into the corpectomy trough also decreases the risk for post-operative subsidence[38-40]. Expandable devices, on the other hand, require active engagement of the end-plates during surgical deployment. Engagement of the bony end-plates for device stabilization and/or indirect decompression of the neuroforamen increase the compressive forces on expandable devices. As such, expandable devices mandate smaller surface areas for graft-host bone contact at the end-plates (see figure 3). This subsidence prevention feature of expandable devices reduces the probability of fusion and increases the risk of device collapse[41].

In sum, the FDA provided 510(k) approval for the C-VBR when used with bone graft and supplemental fixation. The patients receiving ACCFs were high risk for perioperative morbidity. Despite adverse patient characteristics such as, poor health, the smoking habit and obesity, the fusion rate was 96% and the complication profile for the C-VBR was limited to three cases of subsidence.

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