

Length of stay associated with posterior cervical fusion with intervertebral cages: experience from a device registry

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Background: Using a multi-center medical device registry, we prospectively collected a set of perioperative and clinical outcomes among patients treated with tissue-sparing, posteriorly-placed intervertebral cage fusion used in the management of symptomatic, degenerative neural compressive disorders of the cervical spine.

Methods: Cervical fusion utilizing posteriorly-placed intervertebral cages offers a tissue-sparing alternative to traditional instrumentation for the treatment of symptomatic cervical radiculopathy. A registry was established to prospectively collect perioperative and clinical data in a real-world clinical practice setting for patients treated via this approach. This study evaluated length of stay as well as estimated blood loss and procedural time in 271 registry patients.

Results: The median length of stay was 1.1, 1.1 and 1.2 days for patients having a stand-alone arthrodesis, revision of a pseudoarthrosis, and circumferential fusion (360°), respectively, and was not related to number of levels treated. Historical comparison to published literature demonstrated that average lengths of stay associated with open, posterior lateral mass fixation were consistently ≥ 4 days. Average blood loss (range: 32–75 mL) and procedural time (range: 51–88 min) were also diminished in patients having tissue-sparing, cervical intervertebral cage fusion compared to open posterior lateral mass fixation.

Conclusions: Adoption of this tissue-sparing procedure may offer substantial cost-constraining benefits by reducing the length of post-operative hospitalization by, at least, 3 days compared to traditional lateral mass fixation.

Keywords: Cervical fusion; cervical radiculopathy; length of stay; DTRAX; CAVUX; cages; minimally invasive surgery

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Introduction

Spine-related healthcare expenditures have risen dramatically over the past several decades (1). In fact, spinal fusion remains among the costliest operating room procedures performed in the United States (US) (2). Thus, it is imperative to initiate

and adopt methods to constrain costs associated with spinal procedures without compromising patient care. Despite technical advances in the diagnosis and treatment of spinal disorders, the length of hospital stay has not improved over time (3). Thus, diminishing length of stay, if accomplished, can be a valuable step in curtailing healthcare expenditures.

When conservative medical management fails to ameliorate chronic symptoms of cervical myeloradiculopathy, operative decompression and fusion is indicated. Although it provides satisfactory clinical results, posterior cervical laminectomy and lateral mass fixation with instrumentation requires wide operative dissection with disruption of musculo-ligamentous and neural structures, resulting in higher blood loss, longer operating time and lengthier hospital stays than anterior fusion approaches (4,5).

An alternative, tissue-sparing posterior fusion procedure has been developed that utilizes a unique set of posterior cervical fusion instruments and intervertebral cages placed posteriorly in the facet joint space to provide indirect neural decompression, stabilization, and promotion of cervical fusion (6,7). Biomechanical investigations of this device have demonstrated similar segmental stability to posterior lateral mass fixation and anterior cervical discectomy and fusion (ACDF) (8,9). Additionally, cadaveric and radiographic studies have confirmed facet distraction with enlargement of foraminal area and width following implantation (10-12). Patients have realized improvements in pain, function and quality of life with this procedure and clinical results have been durable (7,13-15).

The tissue-sparing posterior fusion procedure involves the use of devices that prepare the joint for fusion as well as use of the posteriorly-placed cages. The DTRAX[®] Spinal System is a set of instruments intended and indicated for access and preparation of a spinal joint to aid in fusion and the CAVUX[®] cervical cages are indicated for use in skeletally mature patients with degenerative disc disease of the cervical spine with accompanying radicular symptoms. The cages are intended to be used with autogenous bone graft and supplemental fixation. The supplemental fixation may be achieved either with an anterior plating system or ALLY[™] bone screw. These products have been available commercially in the US since 2013. A medical device registry was established at several clinical sites in the US to track the ongoing performance and clinical utility of this tissue-sparing spinal fusion approach in a real-world clinical practice setting. Herein, we provide characterization of patients enrolled in the registry with respect to length of stay, estimated blood loss, and procedural time.

Methods

This is a multi-center medical device registry, initiated at 13 clinical sites in the US, to evaluate the ongoing utilization of the CAVUX[®] cervical cages (Providence Medical

Technology, Pleasanton, CA, USA) in the management of symptomatic, degenerative neural compressive disorders of the cervical spine. The primary aim of the registry is to prospectively collect a set of perioperative and clinical outcomes among patients treated with tissue-sparing, posteriorly-placed intervertebral cage fusion.

Characterization and description of the device system, procedural details and surgical technique have been published previously (16). Briefly, using a tissue-sparing posterior approach, the system employs titanium posterior cervical cages that are positioned between the facet joints and supplemented with bone graft to facilitate fusion. The device provides joint distraction and indirect foraminal decompression to alleviate radicular symptoms (11).

The primary aim of this review was to evaluate the data collected relative to the length of hospital stay following posteriorly-placed cervical cage fusion as well as related perioperative characteristics including estimated blood loss and procedural time. Patients were included if they supplied at least one of these three variables and did not undergo any other concomitant procedures in addition to those involving posterior fusion cages at other levels. Under the aegis of the device registry, this study was granted an exemption by an independent central IRB (Ethical and Independent Review Services, Corte Madera, CA, ID #16140-01, #15146-01). All data were de-identified and anonymous, and thus did not require patient informed consent.

Patients were sub-categorized by the type of procedure performed. Three study groups included (I) posteriorly-placed cervical cage fusion as a primary, stand-alone procedure; (II) revision using posteriorly-placed cage fusion for pseudoarthrosis due to non-union after ACDF; and (III) circumferential (360°) fusion consisting of ACDF plus posteriorly-placed cage fusion.

Length of stay data are presented as median and range to assure independence against extreme values. Estimated blood loss and procedural time are shown as mean \pm standard deviation. For all variables, data are presented for type of procedure overall and by number of levels treated.

Results

Table 1 provides demographics and background characteristics for 271 patients that were eligible for inclusion in this analysis. In majority of cases (54%), the procedure was performed as a stand-alone intervention and most cases involved the implantation of bilateral, posteriorly-placed cervical cages (87%). Length of stay data were available

Table 1 Patient demographic and baseline characteristics

Characteristics	Value (n=271)
Demographics	
Age (years), median [range]	58 [28-87]
Female, n [%]	139 [51]
Procedure performed, n [%]	
Stand-alone	147 [54]
Pseudoarthrosis	38 [14]
Circumferential (360°)	86 [32]
Cage placement, n [%]	
Unilateral	6 [2]
Bilateral	235 [87]
Indeterminate	30 [11]

for 97% (264 of 271) of patients. Estimated blood loss and procedural time were available for 64% (173 of 271) and 62% (167 of 271) of patients, respectively.

Overall, median length of stay values indicated a brief hospitalization and did not vary notably by type of procedure (range: 26–28 hours). Additionally, length of stay was similarly short and consistent across number of treated levels (Table 2).

To the contrary, mean estimated blood loss and procedural time values varied widely depending on the type of procedure performed (Tables 3,4). Operative blood loss, however, was extremely low for all patients irrespective of procedure or number of levels treated. Notably, estimated blood loss and corresponding procedural time were uniformly lower in patients undergoing surgery for pseudoarthrosis compared to patients having stand-alone or circumferential procedures. For example, patient undergoing surgery for pseudoarthrosis had less than half the average blood loss as patients having a stand-alone fusion (31.5 vs. 74.8 mL) (Table 3). The mean operative duration was correspondingly lowest among patients having revision surgery for pseudoarthrosis as well (51.0 min) (Table 4). Additionally, procedural time was approximately 20% longer for circumferential fusion compared to stand-alone arthrodesis (88.1 vs. 73.5 min).

Discussion

This medical device registry was initiated to capture real world, pragmatic experience regarding the clinical

utilization and performance of a novel, cervical cage fusion system for patients with recalcitrant radicular symptoms refractory to conservative management. It expands and compliments other ongoing studies of this device.

We found that tissue-sparing, posteriorly-placed cage fusion was associated with a brief period of hospitalization of approximately 1.2 days irrespective of type of procedure performed or number of levels treated. Commensurately, this procedure also resulted in minimal blood loss and short operative time. Our average length of stay compares favorably with studies employing open posterior lateral mass fixation and instrumented fusion. Numerous single-center studies have reported average lengths of stay following posterior cervical fusion ranging from 4.0 to 7.3 days (3,4,17-22). Several other studies reporting length of stay following posterior cervical fusion are of note due to their large sample sizes. For example, using the Nationwide Inpatient Sample (NIS) from 1,000 randomly selected US hospitals, Shamji *et al.* (5) reported an average length of stay of 4.1 days in 2,457 posterior cervical fusion procedures. Similarly, in a matched cohort analysis of the American College of Surgeons National Surgical Quality Improvement Program (ACS-NSQIP, 2011–2014) database, 264 patient treated with posterior cervical fusion had a mean length of stay of 4.2 days (23). Finally, Myhre *et al.* (24) examined the Medicare database and identified 46,171 patients treated with posterior cervical fusion between 2005 and 2012. Their average post-operative length of hospitalization was 6.0 days.

Adding posteriorly-placed cervical cage fusion to ACDF (i.e., circumferential fusion) did not result in increased length of stay among our registry patients. In fact, the median length of stay among this subgroup was 1.2 days which is somewhat shorter than the well-documented average 2-day hospitalization for ACDF patients (5,23,25,26). Based on the findings of this analysis we hypothesize that the major contributor to length of stay is the type of posterior approach performed, open versus tissue-sparing, with the tissue sparing approach having a more favorable length of stay profile.

Our findings for estimated blood loss and procedural time also compare quite favorably with the published literature on posterior lateral mass fixation. Estimated blood loss during an open, posterior cervical fusion range from 225 to 480 mL (4,17-19,22,27), which is substantially greater than our highest average blood loss of 75 mL among stand-alone patients. For procedural time, our highest

Table 2 Length of stay (hours) by type of procedure and number of levels treated

Levels	Stand-alone			Pseudoarthrosis			Circumferential (360°)		
	N	Median	Range	N	Median	Range	N	Median	Range
All Levels	143	26.0	6–336	37	27.0	8–240	84	28.0	12–123
1 Level	55	24.0	9–144	18	25.5	12–60	28	24.0	23–123
2 Levels	57	27.0	6–156	15	29.0	8–240	23	24.0	18.5–96.0
3 Levels	26	28.5	22–336	3	12.0	12–48	30	29.0	12–96
4 Levels	3	26.0	23–49	1	24.0	24–24	3	61.5	42–81

Table 3 Estimated blood loss (mL) by type of procedure and number of levels treated

Levels	Stand-alone			Pseudoarthrosis			Circumferential (360°)		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
All levels	64	74.8	76.1	25	31.5	35.9	84	58.1	70.1
1 Level	23	87.5	82.7	12	28.3	40.3	29	41.9	44.6
2 levels	23	62.6	85.5	9	28.8	30.6	21	69.3	114.9
3 levels	16	78.0	54.0	3	46.7	46.2	31	64.4	48.9
4 levels	2	42.5	10.6	1	50.0	–	3	74.5	34.6

Table 4 Procedural time (min) by type of procedure and number of levels treated

Levels	Stand-alone			Pseudoarthrosis			Circumferential (360°)		
	N	Mean	SD	N	Mean	SD	N	Mean	SD
All levels	62	73.5	32.7	23	51.0	35.5	82	88.1	53.7
1 level	22	74.9	38.1	11	48.7	43.5	28	70.9	45.5
2 levels	22	75.1	36.9	9	50.1	27.8	21	72.2	49.7
3 levels	16	66.6	16.7	3	62.3	33.6	30	111.5	55.9
4 levels	2	94.5	6.4	0	–	–	3	133.5	19.1

average estimate in patients having a circumferential fusion, 88 min, was also lower than the range of 110–270 min for posterior cervical fusion (4,17,22,27,28).

Adopting tissue-sparing procedures for treating common degenerative disorders of the lumbar spine has resulted in substantial reductions in length of stay and, correspondingly, in lower costs (29,30). It would seem logical that similar adoption of tissue-sparing, posteriorly-placed cervical cage fusion over the traditional open posterior procedure that involves lateral mass fixation with instrumentation would yield similar cost-constraining

benefits. It has been argued that attempts to reduce length of stay do not necessarily translate to lower costs as the bulk of healthcare expenditures takes the form of overhead, or is incurred early in the patients' hospital stay (31). However, most of the patients treated in this registry required only a single day of hospitalization which is, at minimum, a 3-day reduction in length of stay over posterior lateral mass fixation. Even if only a small percentage of overall costs are incurred during the final hospital day, the difference noted in our comparison remains noteworthy and very likely cost-beneficial.

Conclusions

Patients undergoing posteriorly-placed, cervical cage fusion required brief post-operative hospitalization that was substantially shorter than length of stay associated with open, posterior lateral mass fixation and comparable to ACDF.

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Footnote

Conflicts of Interest: Drs. Siemionow and McCormack have a financial interest in Providence Medical Technology. Drs. Smith, Gillespy, McCormack and Gundanna received remuneration for medical chart review and data collection. Dr. Block received support from Providence Medical Technology to assist in manuscript development.

Ethical Statement: This study was granted an exemption from patient informed consent by an independent central IRB (Ethical and Independent Review Services, Corte Madera, CA, ID #16140-01, #15146-01).

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