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# Retrospective evaluation of cervical fusion with DTRAX (R) cervical cage

## ABSTRACT

**Background:** Cervical radiculopathy is a relatively common problem that often affects individuals in their 5<sup>th</sup> decade. Most cases resolve with conservative treatment, but when unsuccessful, many opt for surgical intervention. Anterior cervical discectomy and fusion is currently considered the gold standard for the surgical management of cervical radiculopathy. One promising alternative, the DTRAX facet system is minimally invasive and may significantly reduce or eliminate cervical radicular symptoms. This case series and literature review looks to investigate the safety and efficacy of the DTRAX facet system in treating cervical radiculopathy.

**Methods:** This retrospective analysis was performed by chart review of patients who underwent posterior cervical fusion and received the DTRAX spinal implant at University of California, Los Angeles within the last 8 years. Patient charts were located using the surgical cases report function of Epic electronic medical record, and patients were included in the study if they received a DTRAX implant during the stated time period. Data were compiled and analyzed using Microsoft Excel.

**Results:** A total of 14 patient charts were reviewed. Of the 14, there were no immediate postoperative complications. One international patient was subsequently lost to follow-up, and of the remaining 13, mean follow-up duration was 273 days, with a range of 15–660 days. All but one reported improvement of symptoms postoperatively, there were no device failures, and no reoperations were required. There were similar outcomes in patients who received single versus multilevel operations.

**Conclusion:** The findings of this retrospective study of 14 patients who received the DTRAX facet system over the last 8 years support the conclusions of previous studies that DTRAX is safe and effective. In addition, this is the first study to look for differences in outcomes between single and multi-level DTRAX operations, of which there were none. Further investigation with larger cohorts should be conducted as DTRAX becomes more widely adopted in order to verify its safety and efficacy in various clinical scenarios.

**Keywords:** Cervical radiculopathy, cervical stenosis, DTRAX

## INTRODUCTION

Cervical radiculopathy refers to a condition in which cervical spinal nerve roots become impinged within the neural foramina, resulting in a radiating neuropathy throughout the ipsilateral arm. Cervical disc herniation is the most common cause of this impingement, with another cause being cervical spondylosis.<sup>[1,2]</sup> Cervical radiculopathy is a relatively common problem with an incidence of 1.79 per 1000 person-years that peaks in the 5<sup>th</sup> decade of life.<sup>[3-5]</sup> Most cases of cervical radiculopathy resolve with conservative management, which can include immobilization, physical therapy, cervical traction, nonsteroidal anti-inflammatory drugs, and epidural

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corticosteroid injections.<sup>[2,6]</sup> When conservative treatment is unsuccessful, many patients opt for surgical intervention, such as anterior cervical discectomy and fusion (ACDF), total disc replacement (TDR), and more recently, the DTRAX facet system.

For many years, ACDF has been considered the gold standard for surgical management of pain and/or neurological symptoms of the cervical spine.<sup>[7-9]</sup> Studies have shown ACDF to be effective in alleviating the pain and suffering caused by cervical radiculopathy. One such study, which examined 242 cases, reported a fusion rate above 90% for ACDF with and without plating, with around 90% of patients experiencing either good or excellent clinical outcomes.<sup>[8]</sup> This is supported by large literature reviews, one of which found an overall fusion rate of 90.1%, and another that found an improvement in pain of 81.7%.<sup>[10,11]</sup>

ACDF is effective but is not without risk of complications. These include postoperative recurrent laryngeal nerve palsy, wound hematoma, Horner syndrome, pharyngeal or esophageal laceration, thoracic duct injury, pneumothorax, vertebral artery laceration, carotid artery or jugular vein injury, among others. Of these, the most common complication is postoperative dysphagia.<sup>[7]</sup> The procedure also requires the removal of bone and various tissues, which can result in complications such as angulation deformity, bone graft or instrumentation extrusion, and mechanical instability of the cervical spine.<sup>[7]</sup> TDR, which involves full removal of the native disc and replacement with an artificial device, has been shown to have comparable outcomes and complications to those of ACDF.<sup>[9,12,13]</sup>

One promising alternative to ACDF and TDR is the DTRAX facet system. DTRAX is a titanium screw and cage that is inserted between the cervical facets through a minimally invasive procedure. Placement of the cage between the facet joints takes advantage of the inclination of the cervical facets in the transverse plane to open the neural foramina.<sup>[12,14]</sup> Opening the neural foramina can relieve some of the pressure placed on the nerve roots by cervical spondylosis and stenosis. This procedure has been shown to significantly reduce or eliminate cervical radicular symptoms. A prospective study with 60 participants showed significant improvement in neck disability index (NDI), Short Form-12 version 2, and Visual Analog Scale scores (VAS) at 2 weeks postoperation, with sustained significant improvement up to 1 year. In addition, there were no significant perioperative complications such as vertebral artery injuries, nerve root injuries, spinal cord injuries, or reoperations.<sup>[12]</sup> Another retrospective study showed immediate and sustained improvement in NDI and

VAS scores after DTRAX implantation, and there were no nerve root palsies, reoperations, or vertebral artery injuries reported.<sup>[14]</sup>

While the results of these studies are promising, it is imperative that the safety and efficacy of the DTRAX facet system continue to be elucidated. It has been shown that DTRAX can reasonably be used as an alternative to ACDF and TDR for radicular pain; however, more research must be done to determine if it is safe and effective enough to 1 day replace ACDF as the gold standard for surgical treatment of cervical radiculopathy. This retrospective case series and literature review looks to add to the existing literature by investigating the outcomes of DTRAX facet system procedures performed by two experienced surgeons operating in the University of California, Los Angeles (UCLA) health system over the last 8 years. We hypothesize that our study findings will mirror previous studies in showing that the DTRAX facet system significantly reduces cervical radicular symptoms with minimal complications.

## METHODS

The data collection for this retrospective analysis was performed by chart review of patients who underwent posterior cervical fusion and received the DTRAX spinal implant at UCLA since January 1, 2010. Patients were included in the study if they received a DTRAX implant during the stated time period. Information pertinent to the study was collected including demographic information, past medical and social history, intra-, peri-, and postoperative data, radiographic data, and follow-up information. Institutional Review Board approval was obtained before initiation of any study activities.

The study variables included demographic information such as age, sex, weight, height, and body mass index (BMI). Past medical history obtained included indication for surgery, comorbidities, psychiatric history, medications, prior conservative treatments, and duration of pain/radiculopathy. Social history variables such as tobacco and alcohol use, highest education, and work status were also collected. Intraoperative data collected included spinal level of surgery, laterality, estimated blood loss, blood transfusion, duration of operation, and graft material. Perioperative data included length of hospital stay, disposition, complications, and need for readmission. At follow-up, data collected included postoperative pain, symptoms, and need for reintervention.

The chart review for this study was conducted using CareConnect, the UCLA Health electronic medical record

program that is powered by Epic. Within Epic, the surgical cases report function was used to search for individuals who received the DTRAX spinal implant. More specifically, “DTRAX spinal implant surgery (4021)” within the “procedures” search option was used to locate cases that took place between January 1, 2010 and December 10, 2020. Each resulting patient chart was then reviewed, and the study variables were searched for in the chart and input into Microsoft Excel. If a certain variable could not be found in their chart, “NA” was entered to indicate that information was not available for that patient. The data were collected and analyzed using Microsoft Excel. Formulas embedded in the software were used to perform all calculations. The data was then organized into figures to summarize the pertinent findings.

In order to be eligible for surgical intervention, all patients were diagnosed with cervical foraminal stenosis with radicular symptoms by clinical exam, radiographic imaging, and/or electrical studies. Patients who initially opted for conservative treatment prior to surgery trialed some combination of nonsteroidal anti-inflammatory drugs, activity modifications, exercise, acupuncture, physical therapy, epidural steroid injection, and facet blocks with insufficient relief. Surgical intervention was recommended for patients with persistent radicular pain, numbness/tingling, or reduced reflexes who had signs of foraminal stenosis on imaging. Initial imaging included cervical X-ray, magnetic resonance imaging, and/or computed tomography, and all images were read by the lead surgeon to determine patient eligibility for surgical intervention. All patients received cervical X-rays at each follow-up visit to assess implant positioning.

All surgeries were performed by one of two lead surgeons, a board-certified orthopedic surgeon or a board-certified neurosurgeon, both of whom are familiar with the procedure. The procedures were performed as follows, with only slight variation depending on specific patient needs or intraoperative situations. The patient is identified and taken to the operating room after proper anesthesia is induced with endotracheal tube placement. After routine intubation, the patient is placed in a prone position with the head in a neutral position on a foam donut. The posterior neck is prepped and draped in the usual sterile fashion. An incision is made one and a half finger breaths off of midline, and carried through the subcutaneous tissue and the fascia. Identification of the level is confirmed via Steinman pin and lateral view on fluoroscopy and a hemostat is used to spread the fascia and muscle and deepen the incision to directly visualize the surgical site. A probe is advanced to gain access to the bony elements and then a decorticator is introduced to strip the muscle from the posterior lamina out to the mid-portion

of the facet joint at the spinal level bilaterally. Once the lateral mass is decorticated the device is removed. A tube is advanced over the probe and the probe is removed. A rasp is then advanced and used for additional decortication. The DTRAX Cervical Cage is now inserted into the joint. Graft material is placed over the lateral masses for purposes of fusion. If necessary, a screw fixation is then placed into the implants bilaterally for further fixation of the implant to the vertebra. The incision is then reapproximated with sutures and a sterile dressing and a collar are applied. The patient is then transferred to a supine position maintaining the head-torso alignment stable, and a C-collar is applied. The patient is then extubated and transferred to postanesthesia recovery.

## RESULTS

A total of 14 patient charts were reviewed, with 9 male patients and 5 female patients. The mean age was 58 years with a range of 46–71 years. The mean duration of radicular symptoms was 5.7 years with a median of 6 years and a range of 1–13 years [Table 1].

A total of 36 DTRAX implants were placed ranging from spinal level C2-C3 to C7-T1, with C5-C6 being most common. The majority of surgeries were bilateral, with only two being done unilaterally, and single level, with more than half performed on a single level [Table 2].

The operations were relatively brief with low morbidity, lasting an average of 94 min with minimal blood loss and an average hospital stay of 16.6 h once in recovery. There were no intra-operative complications, and all implants were appropriately positioned on X-ray immediately after the procedure [Table 3].

Postoperatively, only one patient was completely lost to follow up, and this was an international patient who returned to her home country. Mean follow up was

**Table 1: Patient demographics/baseline characteristics**

Patients	n = 14
Age (years)	
Mean	57.8
Range	46-71
Gender (n)	
Male	9
Female	5
Duration of radicular symptoms (years)	
Mean	5.7
Median	6
Range	1-13+

**Table 2: Summary of procedures**

Total numbers of DTRAX implants	n=36
Type of procedure	
Unilateral, single level	2
Bilateral, single level	8
Bilateral, two level	3
Bilateral, three level	1
Level of implant	
C2-C3	2
C3-C4	9
C4-C5	6
C5-C6	11
C6-C7	6
C7-T1	2

**Table 3: Intra- and peri-operative data**

Variables	Results
Mean estimated blood loss	Minimal
Duration of operation (min), mean±SD	94±75
Mean length of hospital stay (h)	16.6±15.2
Complication rate (%)	0
Implant appropriately placed on X-ray (%)	100

273 days, with a range of 15–660 days. There were no device failures in any patients and no patients required surgical reintervention. All patients who presented for follow up had an appropriately placed implant on X-ray, as read by a radiologist. Of the 13 patients who presented for initial follow up, 12 (92%) reported improvement or resolution in their radicular symptoms. One patient reported no improvement in the radicular symptoms at all three follow up visits [Table 4].

The key characteristics, operative information, and outcomes of each individual patient are summarized in Table 5.

In this study, patients who received single and multi-level operations as well as patients with unilateral versus bilateral operations had similar outcomes. Six patients had previously undergone cervical operations, one of which reported continued radicular symptoms after receiving the DTRAX implant. That patient received an implant at a single level after previously undergoing C3-5 ACDF and C2-3 foraminotomy.

## DISCUSSION

This retrospective case series a literature review presents the outcomes of DTRAX facet system procedures performed by two experienced UCLA surgeons since January 1, 2010. The results of the study provide further evidence for the safety and efficacy of the DTRAX facet system in reducing cervical radicular symptoms. The rationale for intra-articular cervical

facet distraction and arthrodesis for cervical spondylosis was first described by Goel *et al.*<sup>[15]</sup> Goel *et al.* hypothesized that the observed sequela of cervical spondylosis, such as disc degeneration, buckling of the posterior longitudinal ligament, osteophyte formation, and central and foraminal stenosis, occurred secondary to facet instability. Goel *et al.* proposed an alternative method of treating cervical spondylosis using intra-articular facet spacers, with the goal of restoring facet stability. The efficacy and safety of this technique was first described by Goel and Shah, who reported successful results using the Goel cervical facet spacer on patients with single-or mutlti-level cervical spondylotic radiculopathy and/or myelopathy.<sup>[16]</sup> The study reported an increase in foraminal height, disc height, and canal size, as well as symptomatic improvement of pain, radiculopathy, and myelopathy. These results have formed the basis for newer intra-articular cervical facet distraction devices, such as the DTRAX facet system in this study.

Compared to ACDF, which is currently considered the gold standard, DTRAX is less invasive, requires a shorter hospital stay, and has fewer potential complications.<sup>[17,17]</sup> Efficacy data thus far has shown DTRAX to be comparable to ACDF for radicular pain, with multiple studies demonstrating significant improvement in symptoms in 90%–100% of patients.<sup>[12,14]</sup> The favorable outcomes of this study add to the growing literature supporting DTRAX as a low-morbidity, high-efficacy alternative for cervical radicular symptoms.

This study included a diverse population of patients. There were patients from various ethnic groups, from the normal, overweight, and obese BMI categories, respectively, their symptoms ranged from mild to severe with and without numbness and tingling, and the duration of symptoms varied from 1 to 13 + years, with a wide range and combination of prior treatments and interventions.

The findings of this study provide evidence for the safety of DTRAX, and its potential as a low-morbidity alternative to ACDF for radiculopathy. Blood loss in all procedures was reported as minimal, and the procedures took an average of 94 ± 75 min and on average required a 17 ± 15-hour hospital stay. Those values include two patients who had additional injuries and whose surgeries involved more than just DTRAX placement. If those patients are excluded from the calculations, the procedures took an average of 70 ± 21 min with an average hospital stay of 12 ± 9 h. In comparison, one study looking at ACDF found an average blood loss of 87.4 ± 99.6 mL, average length of procedure of 204 ± 59 min and an average length of stay of 47.5 ± 38.4 h with ACDF.<sup>[17]</sup> The clinical significance of the difference in

blood loss between DTRAX and ACDF is questionable, as 87 mL of blood loss is not concerning in most cases. However, a longer average hospital stay of nearly a day and a half intuitively has important implications, such as increased cost to the patient and the healthcare system, as well as increased risk of nosocomial infection.

In this study, no significant complications were reported with DTRAX, such as vertebral artery injuries, nerve root injuries, spinal cord injuries, or reoperations. This is comparable to previous DTRAX studies which also reported no significant complications.<sup>[12,14]</sup> In contrast, a 2019 review

found ACDF to have a complication rate of 13.2%–19.3%, and readmission rates ranging from 5.1% (30 days) to 7.7% (90 days postoperatively). Complications included dysphagia, hematoma, worsening myelopathy, recurrent laryngeal nerve palsy, cerebrospinal fluid leaks, wound infection, increased radiculopathy, Horner’s syndrome, respiratory insufficiency, esophageal perforation, and instrument failure.<sup>[18]</sup> This demonstrates the significantly higher morbidity with ACDF, with most of these complications being completely avoided with DTRAX given the minimally invasive posterior approach.

Outcomes from single and multi-level DTRAX operations were examined in this study. This differs from previous studies which have primarily looked at the efficacy of DTRAX in treating single-level radiculopathy. Both unilateral and bilateral procedures were performed, 2 of which were unilateral and occurred at a single level. The remainder of the procedures were bilateral, 4 of which were multi-level–3 at two-levels and 1 at three-levels. The outcomes of the multilevel procedures were favorable, with each patient reporting postoperative improvement in

**Table 4: Postoperative data**

Variables	Results
Mean follow-up in days (range)	273 (15-660)
Number of patients who presented for follow up visit	13
Number of patients reporting improvement in symptoms	12
Number of patients reporting no improvement in symptoms at each follow-up visit	1
Device failures	0
Surgical reinterventions	0

**Table 5: Summary of individual patient characteristics, operative information, and outcomes**

Case	Age	Sex	BMI	Indication	Spinal level	Laterality	Graft material	Hospital stay (h)	Postoperative reduction in pain
1	50	Male	22.6	C6-C7 foraminal stenosis, cervical disc herniation, cervical stenosis, cervical radiculopathy	C6/C7	Bilateral	Osteotech Grafton Putty	1.5	Yes
2	67	Male	30.8	C5-C6 and C6-C7 foraminal stenosis with degenerative disc disease	C5/C6, C6/C7	Bilateral	Osteotech Grafton Gel	21	Yes
3	54	Male	29.6	C5-C6 radiculopathy R confirmed by EMG	C5/C6	Right	MTF DBX putty	18	Yes
4	52	Female	20.5	C5-C6 radiculopathy due to foraminal stenosis right > left	C5/C6	Bilateral	Osteotech Grafton Gel	19.5	Yes
5	56	Female	20.0	C5-C6 persistent cervical stenosis s/p C5-C6 ACDF	C5/C6	Bilateral	NA	48	Yes
6	70	Male	32.5	Left C3-4 cervical foraminal stenosis with radiculopathy	C3/C4	Left	NA	2.5	Yes
7	71	Female	36.1	C3-4 radiculitis from foraminal stenosis and facet joint collapse	C3/C4	Bilateral	NA	3.5	Yes
8	55	Male	27.5	Right C4-5 cervical foraminal stenosis with radiculopathy	C4/C5	Bilateral	Osteotech Grafton Putty	3.5	Yes
9	46	Female	31.2	Revision of C5-6 TDR due to ongoing neck pain and C5-6 cervical foraminal stenosis with radiculopathy	C5/C6	Bilateral	Osteotech Grafton Putty	15	NA
10	55	Male	32.4	Severe neck pain, status postartificial disc replacement C3-4, C4-5, w/confirmed facet-generated pain at these two levels	C3/C4, C4/C5	Bilateral	NA	8	Yes
11	62	Female	20.3	Foraminal stenosis on the left at C5-6, C6-7 and C7-T1. Severe degenerative collapse of the disk at C5-6 with major osteophytes, slightly less so at C6-7 and anterior subluxation of C7 on T1, slightly less so at C6-7 and anterior subluxation of C7 on T1	C5/C6, C6/C7, C7-T1	Bilateral	NA	45.5	Yes
12	50	Male	30.9	C3-4 cervical foraminal stenosis with radiculopathy in bilateral shoulders	C3/C4	Bilateral	NA	1.5	Yes
13	71	Male	27.4	C4-5 cervical foraminal stenosis with radiculopathy	C3/C4, C4/C5	Bilateral	NA	22	Yes
14	50	Male	24.3	C2-3 cervical foraminal stenosis with radiculopathy from adjacent level disease of prior fusion	C2/C3	Bilateral	Osteotech Grafton Putty	23.5	No

NA - Not applicable; TDR - Total disc replacement; BMI - Body mass index; MTF - Musculoskeletal transplant foundation; DBX - Demineralized bone matrix



pain with no complications postoperatively or at follow up. Of the remaining patients, only 1 reported no significant improvement in pain. This patient was a 50-year-old Caucasian male with a BMI of 24.3 and a 7-year history of radicular symptoms that he rated an 8/10 with associated numbness and tingling. He had previously trialed physical therapy, C3-5 ACDF, and C2-3 foraminotomy, with no improvement. He received a C2/C3 DTRAX implant bilaterally but continued to have preoperative levels of neck and shoulder pain at 9 months postoperation, without any associated numbness and tingling, that he managed with 50 mg pregabalin and 2–3 5/325 mg hydrocodone/acetaminophen. He opted to trial physical therapy before attempting any further surgical intervention.

Three other patients reported pain at a follow-up visit, however they were all documented by the surgeon as unrelated to the DTRAX procedure. One developed new neck pain 19 months postoperation that differed from the preoperation pain. The surgeon determined the pain to be unassociated with the DTRAX procedure and prescribed physical therapy for treatment. Another developed bilateral occipital neuralgia. This patient has a congenitally fused C2-3 segment and an iatrogenically fused C3-6 segment. This resulted in a C2-6 fused immobile segment that is thought to be causing hypermobility of the C1-2 junction and C2 neuralgia, leading to greater occipital neuralgia. The third patient with postoperative pain developed bilateral shoulder and medial scapular pain at 1-year postoperation. He was diagnosed with scapular dyskinesia and right elbow medial epicondylitis and prescribed physical therapy.

Though this study has promising findings, it also has some limitations that warrant cautious interpretation of the results. As with all retrospective studies, data was collected by reviewing and analyzing completed cases and attempting to draw conclusions from the results. This introduces the possibility for errors such as selection bias and confirmation bias. The authors attempted to avoid these issues by using the care connect algorithm previously mentioned in the methods section to search for patients, and including all the resulting patients who met the inclusion criteria. Another limitation of this study is the low total number of patients. Without a larger cohort, it is difficult to extrapolate the generalizability and transferability of the results. Surgical complications can be rare, and as such require a large cohort in order to reveal whether or not a procedure can be associated with a particular negative outcome. A large prospective study would be ideal to add credibility to the validity of the results of this and previous retrospective studies.

## CONCLUSION

The findings of this retrospective case series of 14 patients who received the DTRAX facet system over the last 8 years support the conclusions of previous studies that DTRAX is safe and effective. Further investigation with larger cohorts should be conducted as DTRAX becomes more widely adopted in order to verify its potential as a less invasive alternative for the treatment of cervical radiculopathy.

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Nil.

## Conflicts of interest

Dr. Shamie- Stock Options with Providence Medical Tech.

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