

Tissue Sparing Posterior Fixation as a Treatment Option for Degenerative Disc Disease

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Background on Cervical Spondylosis

Cervical spondylosis is the age-related degeneration of cervical discs that results in symptoms of neck pain, radiculopathy and/or myelopathy. The chemical composition of the nucleus pulposus and annulus fibrosus changes and is associated with a progressive loss of the disc's viscoelastic properties. Disc height decreases, the disc bulges posteriorly, and the adjacent vertebral bodies collapse onto one another. Failure of the disc causes secondary changes: buckling of the ligamentum flavum, thickening of the facet joint capsules, osteophyte formation, and vertebral subluxations. These secondary changes contribute to a decrease in size of the central

canal and neuroforamina. The above events are collectively described as degenerative disc disease and result in spinal stenosis. Spinal stenosis causes direct mechanical pressure on the nerve roots and/or spinal cord. The exact pathogenesis of cervical radicular pain is multifactorial. It is understood to be a result of a combination of direct nerve root compression, movement at the stenotic level, and an inflammatory response [1, 2]. Intrinsic blood vessels of the compressed nerve have been shown to demonstrate increased permeability, which results in nerve root edema. As the edema becomes chronic, fibrosis and scar ring ensue, contributing to an altered response threshold and increased sensitivity of the nerve root to pain. Pain mediators released from the nerve cell bodies, intervertebral disc, and surrounding tissue play a role in initiating and perpetuating the inflammatory response [3].

Age related degenerative disc changes often lead to symptoms of neck pain, arm pain, shoulder pain, numbness, weakness, and changes in gait. When degenerative changes result in pinched nerves in the cervical spine, the resulting painful condition is commonly referred to as cervical radiculopathy. Globally, the reported annual incidence of cervical radiculopathy is 83.2/100,000 persons [4], while the reported prevalence is believed to be 3.5/1000 persons [5].

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Posterior Microendoscopic Foraminotomy

Posterior cervical foraminotomy has been indicated in patients with unilateral radiculopathy, absent significant neck pain with maintained cervical lordosis [6–8]. Further, it is a desirable option in cases presenting with laterally herniated disc and lateral stenosis [6]. The surgical objective of a foraminotomy is to decompress the nerve roots while maintaining motion at the affected level. Fessler and Adamson were among the first to describe clinical outcomes utilizing a microendoscopic approach [6, 9]. A meta-analysis of posterior cervical foraminotomies performed by McAnany et al. and a clinical study by Kim et al. showed a significant improvement in pain and return to normal life [10, 11]. In some cases, axial neck pain, and less commonly, instability may ensue because the motion segment is not stabilized [12].

Decompression and Fusion

A surgeon may prefer to decompress and fuse the spine when there is instability, bilateral radicular symptoms, and/or symptomatic spinal cord compression. Anterior cervical discectomy and fusion (ACDF) is currently the most common approach for decompressing and stabilizing the spine, accounting for 68% of all cervical spinal surgeries [13].

Despite the numerous benefits associated with ACDF, there are risks that could lead to a surgeon recommending against it. The most well-documented post-operative complication tied to ACDF is dysphagia, a serious complication that has been reported to be as high as 31% following multi-level ACDF [14]. Access to the upper anterior cervical spine can be challenging due to position of the jaw, while exposure of C6–T1 is variable and may be problematic in some cases. Injury to the esophagus or vertebral and carotid arteries are rare but can be life threatening. Another concern with ACDF is the risk of pseudoarthrosis. When treating multiple levels with an ACDF procedure, Bolesta et al. reported rates of solid arthrodesis to be as low as 47% [15].

A surgeon may consider a posterior (PCF) or a combined anterior and posterior (circumferential,

CCF) option. Of the three common methods of cervical fusion, CCF is currently the least commonly performed [16, 17] however the frequency of CCF has been increasing at a greater rate than ACDF or PCF (CCF:182%, ACDF:139%, PCF:177%, between years 2001 and 2010) [16]. One contribution to the increase in CCF is that surgeons are opting to perform fusion and decompression procedures in patients previously deemed high-risk for revision following ACDF or PCF procedures alone.

The inclusion of supplemental posterior fixation most commonly involves lateral mass screw and rod fixation, laminectomy, and fusion of the posterior lateral mass [18]. This approach is preferred when there is posterior neural compression, a congenitally narrowed canal, or pathology at three or more levels. Posterior instrumentation increases rigidity of the construct and improves fusion rates [19]. Accessing the spine with this method comes with a cost via extensive paraspinal muscle dissection, retraction, and retraction. The combined trauma to muscle, increased incision size, and prolonged surgical retraction are a few explanations for why posterior fusion surgeries are associated with a longer surgery time, greater blood loss, and longer hospital stays compared to ACDF [20].

A tissue-sparing approach for posterior cervical fusion was developed [21] that preserves the normal muscular and ligamentous attachments to the posterior cervical spine. This technique has been shown to reduce the length of stay, blood loss, and operative duration to be comparable to that typically seen following ACDF [22] and shorter than that typically seen following PCF with lateral mass fixation [23].

When decompression is deemed necessary, which co-morbidities or risk factors are most relevant in determining approach? We briefly highlight some of the most prevalent risk factors for revision: nicotine use and advanced age.

Nicotine Use

Smoking has been shown to negatively affect the cervical spine by contributing to the onset of osteoporosis, reducing osteoblast activity, increasing cortisol levels, decreasing vascular oxygen

supply to bone, and decreasing calcium absorption [24]. This altered bone metabolism contributes to the increased risk of pseudarthrosis, infection, dysphagia, and adjacent segment disease, as well as decreases the rate of fusion observed in smokers [24–27]. Smokers receiving multi-level treatment exhibited lower rates of fusion and higher rates of complications, particularly postoperative wound infection [24, 25, 27]. A circumferential approach may benefit patients who use nicotine through improved stability during fusion.

Advanced Age

The majority of ACDF procedures are performed on people over the age of 45 [28]. Advanced age at time of cervical spinal fusion has been well documented as a predictor of complications [29–31], poorer surgical outcomes [29, 32], and increased length of stay [30]. Moreover, the prevalence of comorbidities such as diabetes and cardiovascular diseases significantly increase with advancing age

[33], with these individuals now representing a greater population of patients being treated with surgery [34]. Patients with an average age over 54 that have opted for circumferential fusion have shown high fusion rates and comparable complication rates to ACDF [35, 36]. Thus, we can conclude that advanced age increases possibility of postoperative complications or disease progression following ACDF, but these risks can be mitigated with the inclusion of supplemental posterior fixation.

DTRAX System

Tissue sparing posterior fixation can be performed using instrumentation available on the market. One such system is the DTRAX® Spinal System (Providence Medical Technology, Inc.). The spinal system is composed of specialized instruments that carry out the novel technique and placement of the cervical facet implants and decortication/fusion of the lateral mass (Fig. 12.1). In the U.S., the spinal system and



Fig. 12.1 (a) Instruments of DTRAX/CORUS Spinal System. (b) Detailed views of instrument tips. (1) Access Chisel (2) Trepine Decorticator (3) Guide Tube (4) Rasp Decorticator (5) Rotary Decorticator (T) Bone Graft Tamp

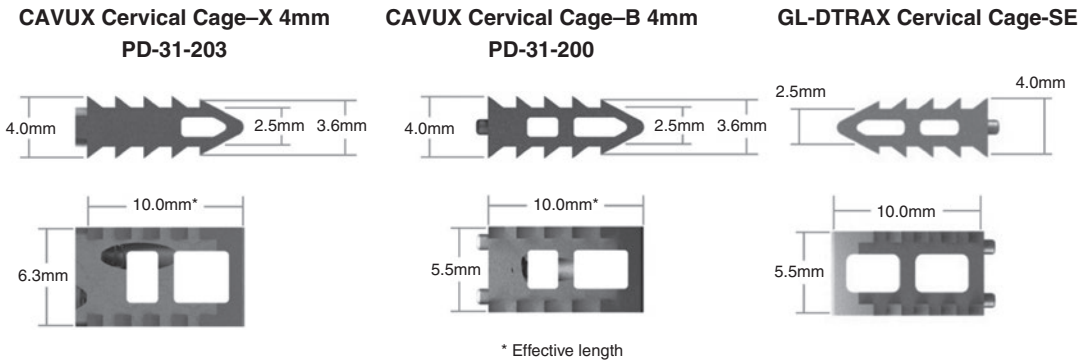


Fig. 12.2 Cervical cage configurations

cages are referenced under separate product names; the CORUS Spinal System and CAVUX Cervical Cages.

DTRAX Cervical Cages are manufactured from implant grade titanium alloy. They are available in three configurations (Fig. 12.2): the DTRAX Cage-SE, CAVUX Cage-B, and CAVUX Cage-X. A hollow design in all cages enables packing of bone graft. The teeth on superior and inferior surfaces are designed to resist expulsion. The surfaces of the cages are acid-etched and textured at the cellular level to facilitate osseous integration. The CAVUX Cages -B and -X are not available in CE approved markets, but are available in the U.S.

Indications and Contraindications

The indications differ between the U.S. and EEA markets and are therefore both presented below.

EEA Market

Indications The DTRAX System is indicated for use in skeletally mature patients for posterior cervical treatment at C3–C7 (inclusive) spinal levels for patients with single level radiculopathy due to degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies and/or degenerative disease of the facets.

US Market

Indications The CORUS Spinal System is a set of instruments indicated to be used to perform posterior cervical fusion in patients with cervical degenerative disc disease.

The CAVUX Cervical Cage is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine (C3–C7) with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. Patients should have received at least 6 weeks of non-operative treatment prior to treatment with the device. Devices are intended to be used with autogenous bone graft and supplemental fixation, such as an anterior plating system.

Surgical Technique

Operating Room and Patient Preparation

After routine intubation, place the patient in a prone position on bolsters with face supported by a donut or foam support, holding the neck in a neutral position. Use tape or a cervical visualization harness to pull the patient's shoulders inferiorly (Fig. 12.3). Rotate the table to allow positioning of the two C-arm machines.

Fig. 12.3 Patient preparation involves prone positioning, head support and pull-down of shoulders



Fig. 12.4 The use of two C-arms for lateral and AP views concurrently is recommended



C-Arm Preparation and Tips

Set up the C-Arm at the side of the table in AP with the arm fully retracted. Find a clear AP view. Advance the C-Arm while rotating the detector back to find the lateral view. A fully retracted C-Arm allows for finding the lateral view by advancing the arm of C-Arm instead of moving the whole machine. Returning to the AP position only requires rotating the detector forward while fully retracting the C-Arm. This C-Arm set up allows clear imaging to be retained while rapidly switching between views.

The use of two C-Arms is recommended for ease of imaging which can improve safety and significantly reduce the time length of the procedure. If a second C-Arm is used, leave the first C-Arm in the lateral position. Rotate the first C-Arm 20°–30° so that the arm is under the patient's shoulders. This provides room for the second C-Arm under the patient's neck. Place the

second C-Arm at the head of the table and with the arm fully advanced to find the AP view.

Finding the AP view with the arm of the second C-Arm fully advanced allows the arm portion to be retracted during the procedure to create working space for tools, then fully advanced to quickly restore AP imaging. On the second C-Arm add approximately 25–30° caudal/cranial inclination; this adjustment, along with the flexion of the head, allows an en face or near en face view of the target facet joint (Fig. 12.4).

Skin Markings and Sterile Field

Images clearly demonstrating facet joint anatomy are essential for proper preoperative skin markings. Use fluoroscopic guidance to identify surgical border and level to be treated. Identify and mark the medial and lateral borders of the facets using AP view on fluoroscopy, a slender, straight

metallic instrument (e.g., K-wire or Steinman pin), and surgical pen (Fig. 12.5). Identify the target facet joint level using the same method and mark it with a transverse line (Fig. 12.6). Mark the approximate skin incision and entry point by measuring two finger widths caudally from the target level.

Prepare and drape the patient's posterior neck in a routine sterile fashion. It is recommended the C-Arm(s) remain in place during this portion so

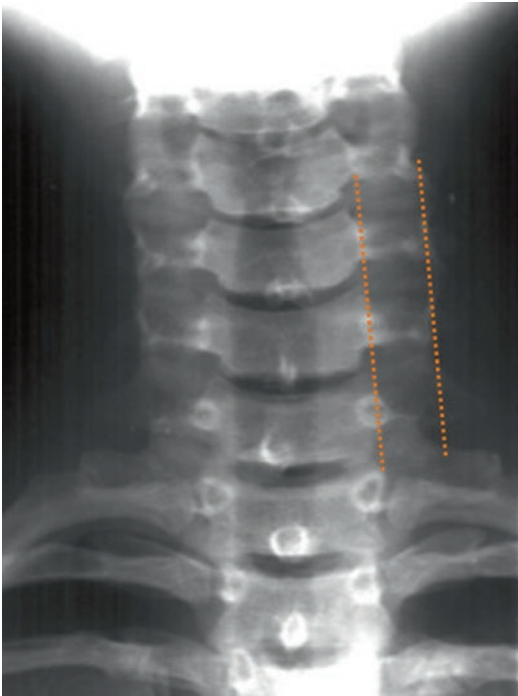


Fig. 12.5 The medial and lateral borders of the facets are identified using AP view



Fig. 12.6 The operative level is identified and marked on the patient

that the radiological markers are not lost. Open the sterile-packaged tray containing the surgical instruments and the sterile-packaged pouches containing the implants and their delivery instruments.

Establish Trajectory and Access the Facet Joint

Use a spinal needle to confirm the trajectory under fluoroscopic guidance. Due to the acute angle of the facet joint the trajectory often results in the entry point being located approximately two finger widths below the target level. Reinsert or reposition the spinal needle as needed until the correct entry point and trajectory is confirmed. The correct trajectory will match the angle of the facet joint (Fig. 12.7). Repeat this process for the contralateral side. If desired the needles may be used to administer local anesthesia and/or epinephrine for pain or bleeding control. Remove the first spinal needle while leaving the contralateral needle in place to provide a guidance reference. Make initial longitudinal incision by the confirmed entry points and carry through the subcutaneous tissue and the fascia. Use a hemostat to



Fig. 12.7 The spinal needle confirms trajectory under fluoroscopic guidance and is positioned to match the angle of the facet joint

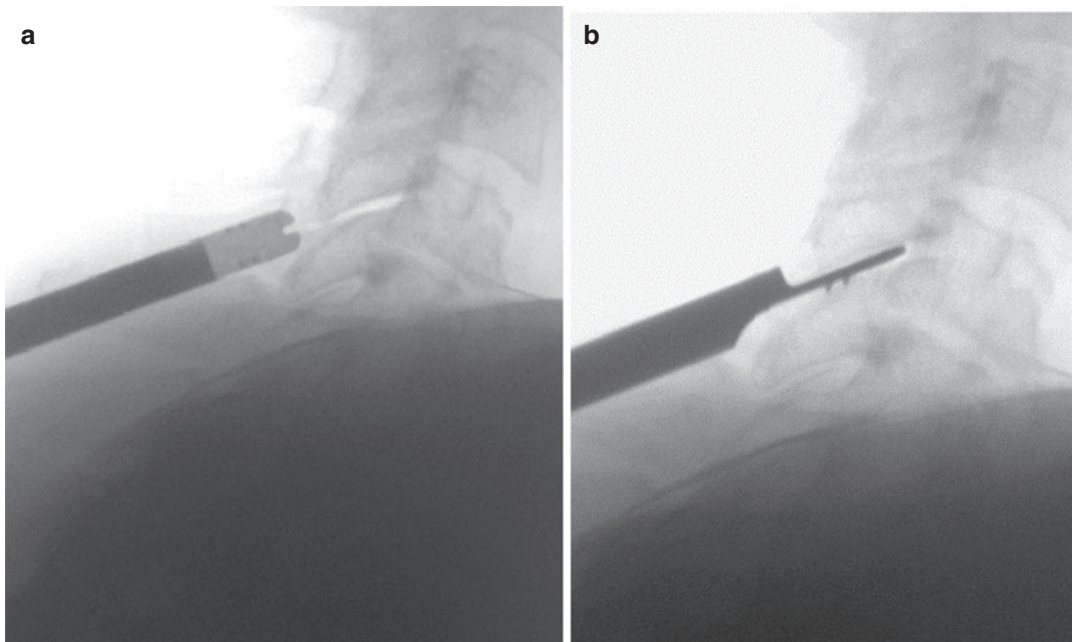


Fig. 12.8 (a) The Access Chisel is advanced with a flat end in a cranial/caudal orientation until bone is reached. (b) Upon reaching bone, the chisel is rotated 90 degrees

and advanced into the facet joint. The positive stop should be facing the inferior articular process of the level above

spread the fascia laterally. Carry the dissection down as needed to achieve desired level of direct visualization.

Under AP fluoroscopic guidance, advance the Access Chisel through the incision using a slight medial to lateral trajectory in AP view with its distal tip in the cranial-caudal orientation until bone is reached (Fig. 12.8a). Confirm the Access Chisel is centered medial to lateral on the lateral mass. Rotate the Access Chisel 90° so that its positive stop feature is oriented cranially, i.e., towards the inferior articular process of the level above. Orientation markers on the Access Chisel indicate the orientation of the instrument. Using control in AP and lateral fluoroscopy, find the superior portion of the facet joint, lower Access Chisel tip to find and cut the capsule of the joint. Use the Multi-Tool to lightly mallet the Access Chisel to advance it into the facet joint (Fig. 12.8b). Advance the Access Chisel until its positive stop feature abuts the inferior articular process of the level above. Once positioned, pull back on the Access Chisel handle's orange trig-

ger to release the Access Chisel handle. Remove the handle. Maintain gentle downward pressure on the Access Chisel to retain its placement within the facet joint.

Decorticate the Lateral Masses and Establish Working Channel

Advance the Decortication Trepine over the Access Chisel while rotating in an alternating clockwise/counterclockwise motion to aid its advancement through soft tissue until its distal tip contacts bone (Fig. 12.9). Align the Trepine Decorticator so that its teeth are positioned against the superior lateral mass. Decorticate the superior lateral mass and the medial portion of the lamina by moving the Trepine Decorticator in a windshield wiper motion of 10° rotations. This action will strip the muscle subperiosteally and create bleeding from the bone. Do not apply excessive pressure while decorticating as over decortication may compromise the biomechanical

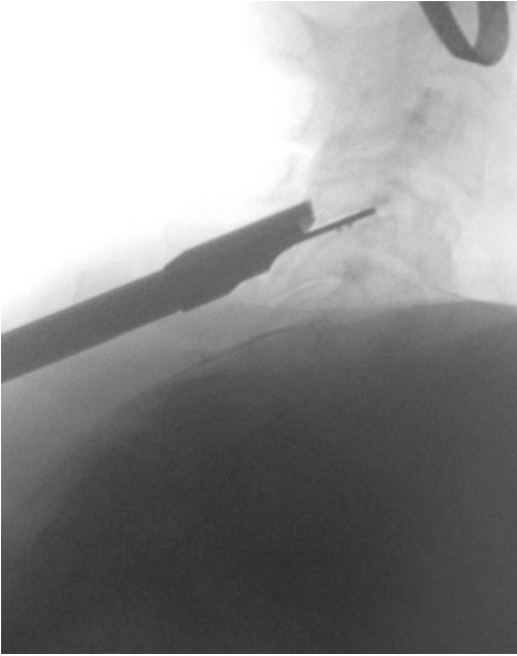


Fig. 12.9 The Trepine Decorticator is advanced over the Access Chisel until the distal tip contacts bone

cal integrity of the inferior articular process of the level above. Remove Trepine Decorticator while applying gentle downward pressure on the Access Chisel to prevent the Access Chisel from dislodging from the facet joint.

To establish the working channel, slide the Guide Tube over the Access Chisel with the tines of the Guide Tube in a cranial/caudal orientation to ease insertion over the proximal end of Access Chisel. Then rotate the Guide Tube 90° to align its tines with facet joint. Because the Guide Tube is a unidirectional tool ensure its correct orientation in the facet joint. Align the head arrow icon on Guide Tube handle with the orientation markers on Access Chisel shaft. The head arrow icon and orientation markers should be facing cranially.

Confirm the distal tines are aligned with the facet joint. Place the Multi-Tool over the Access Chisel. The Multi-Tool should be placed with its pry feature faced down. Lightly impact the Multi-Tool to advance the Guide Tube into the facet

joint. Advance the Guide Tube until its positive stop feature abuts the inferior articular process of the level above (Fig. 12.10). Verify Guide Tube placement on both lateral and AP views. Proper and final Guide Tube depth is achieved when its positive stop feature abuts the inferior articular process of the level above. Center the Guide Tube between the medial and lateral borders of the facet joint on AP view. Remove the Access Chisel while maintaining downward pressure on the Guide Tube.

Decorticate the Facet Joint

Insert the Rasp Decorticator through the Guide Tube and advance using the Fork Mallet until the upper handle of the Rasp Decorticator is flush with the handle of the Guide Tube. Lightly mallet the Rasp Decorticator with the Multi-Tool to decorticate the interarticular surfaces of the facet. Retract the Rasp Decorticator by inserting the Multi-Tool into the Rasp Decorticator notch and rotating the Multi-Tool to release the Rasp Decorticator handle. This allows for the controlled removal of the Rasp Decorticator while maintaining the position of the Guide Tube in the facet joint. Lift the Rasp Decorticator, rotate it 180°, then lightly impact it to advance it and further decorticate, achieve bleeding of the bone, and remove joint material. Repeat this step until the Rasp Decorticator can be retracted out without resistance. Remove the Rasp Decorticator while maintaining downward pressure on the Guide Tube.

Insert and advance the Rotary Decorticator through the Guide Tube by hand while rotating its handle in a clockwise motion until it reaches a hard stop against the Guide Tube. Once the Rotary Decorticator is fully inserted in the Guide Tube, apply caudal pressure to the Guide Tube and rotate the Rotary Decorticator clockwise 360°. Caudal pressure on the Guide Tube helps the Rotary Decorticator decorticate the inferior facet. Remove the Rotary Decorticator while continuing to rotate it clockwise.

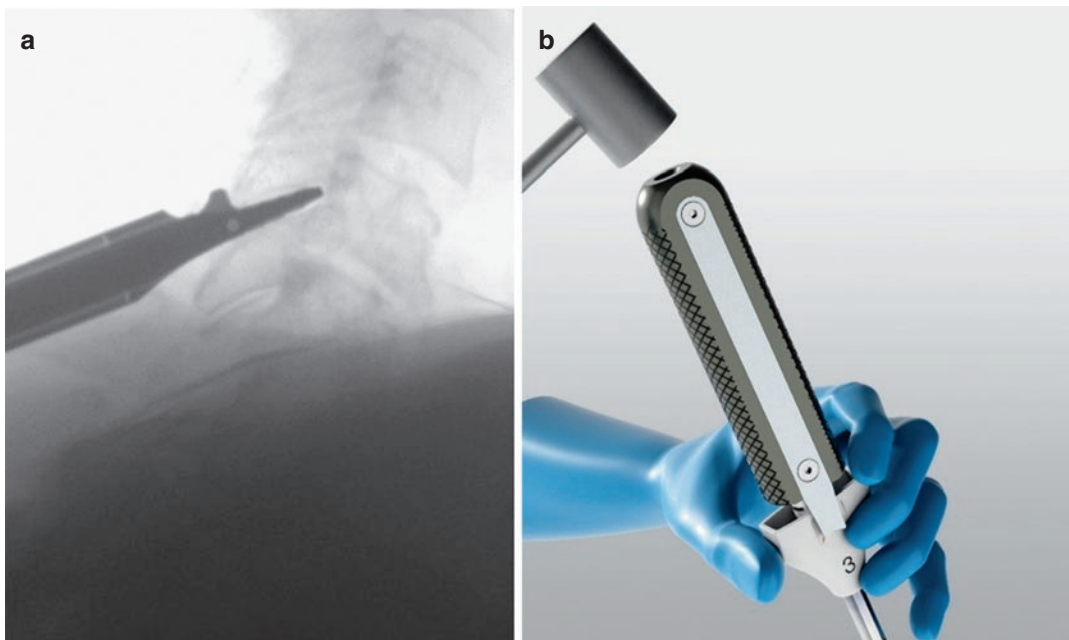


Fig. 12.10 (a) The Guide Tube is advanced into the facet joint using the (b) Multi-Tool

Implant the Cervical Cage

Prepare the Cervical Cage by packing it with autogenous and/or allogenic bone graft prior to placement. The Cervical Cage is preloaded on its delivery instrument (Cage Delivery Instrument). Align the Cage with the facet joint by orientating the head arrow icon on the handle of the Delivery Instrument cephalad, i.e., toward the patient's head. Under AP and lateral fluoroscopic control, mallet the Cage Delivery Instrument through the Guide Tube until its handle locks with the handle of the Guide Tube in order to advance the Cage into the facet joint.

Use AP & Lateral fluoroscopy to confirm proper placement of the Cage. The Cage should be in the middle of the facet joint, centered between the medial and lateral borders of the facet joint as identified by fluoroscopic views (Fig. 12.11). The anterior margin of the Cage should be aligned with the anterior margin of the lateral mass.

Deploy the Inferior Bone Screw (Cage-B and Cage-X Only)

Once proper cage position is confirmed, introduce, and advance the bone screw into the hole at the top of the handle of the Cage Delivery Instrument while maintaining downward pressure on the Cage Delivery Instrument. When resistance is encountered, rotate the Bone Screw Handle clockwise while applying downward pressure to advance it into the Cage. The laser-mark line on Bone Screw Shaft indicates the screw position relative to the Cage. When the laser-mark line is visible above the Cage Delivery Instrument the Bone Screw is contained within the Cage Delivery Instrument. When the laser-mark is no longer visible above the Cage Delivery Instrument the Bone Screw Tip has reached the Cage. Continue to rotate the Bone Screw Handle until a snapping sound is heard and there is no resistance rotating the handle (Fig. 12.12). This indicates full Bone Screw

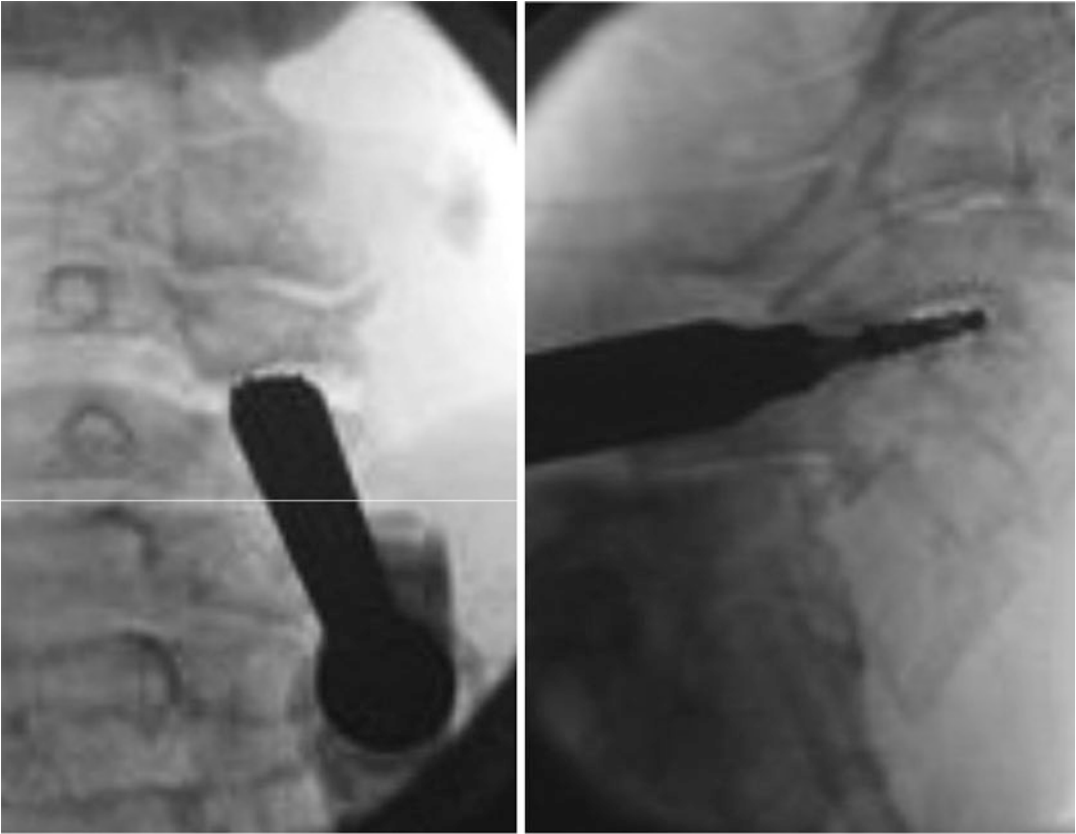


Fig. 12.11 AP and lateral fluoroscopy is used to position cage in facet



Fig. 12.12 The screw will break away from the delivery mechanism after enough resistance from advancing into the bone

deployment and that the release feature of the Bone Screw has been activated. Once deployed, remove the Bone Screw Shaft and Handle by pulling it out of the Cage Delivery Instrument. Turn the gray Release Knob on the Cage Delivery Instrument counterclockwise until the Cage is fully released.

Deploy the Superior Bone Screw (Cage-X Only)

Remove the Release Knob and Retention Wire Assembly from the Cage Delivery Instrument to reveal the superior bone screw hole. This is the larger hole on the handle of the Cage

Delivery Instrument. While maintaining downward pressure on the Cage Delivery Instrument, introduce and advance the Bone Screw into the Superior Fixation Screw Hole until the black marker line is no longer visible above the handle of the Cage Delivery Instrument. Deploy and release the Fixation Screw by repeating the process described in the section above. Remove the Release Knob and Retention Wire Assembly from the Cage Delivery Instrument, then remove the Cage Delivery Instrument. Use AP and lateral fluoroscopic views to verify the correct placement of the Cage and Bone Screws.

Apply Bone Graft Material to Decortication Bed

Insert bone graft material such as demineralized bone matrix, into the top of the Guide Tube (Fig. 12.13). Introduce the Bone Graft Tamp into the Guide Tube and advance to push the bone graft material into the prepared bony surfaces, i.e., the decorticated lateral masses. Final control and verification of Cage positioning using AP and lateral fluoroscopy is recommended (Fig. 12.14).

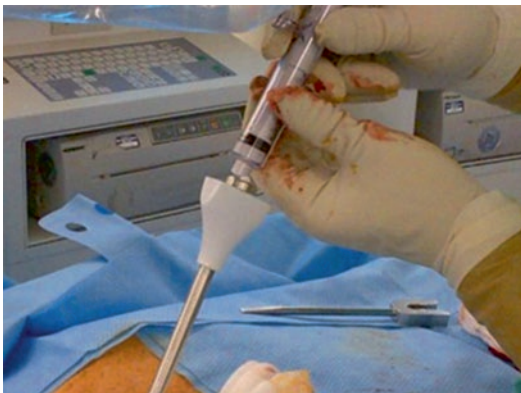


Fig. 12.13 Bone graft material is placed into the top of the Guide Tube

Sutures, Contralateral Procedure, and Final Patient Preparation

Close the paraspinal muscles, approximate tissues, and skin in layers with sutures. Repeat the full procedure for the contralateral facet joint of the target level. Apply a sterile dressing. Apply external immobilizing collar according to surgeons' post-operative protocol.

Clinical Evidence for Decompression and Fusion When Using Posterior Cervical Stabilizers

The capability of the DTRAX system to provide decompression and fusion at the cervical spine has been described both when performed as a stand-alone posterior procedure as well as when used as supplemental fixation as part of a circumferential procedure.

A prospective, multi-center, single arm clinical study was performed to assess clinical and radiographic outcomes of patients with cervical radiculopathy treated with DTRAX cages using a tissue sparing decompression and fusion posterior procedure at one level. The patients were followed over a period of 2 years following surgery [37]. The study hypothesis was that indirect root decompression with the DTRAX Cage would provide clinical relief of radiculopathy in patients with spondylosis with straight or lordotic cervical spines that do not present with symptomatic central canal stenosis necessitating an anterior approach.

Sixty patients were initially enrolled into the study, and 53 of them (88%) were available at 2-year follow-up. The mean age at the time of surgery was 52.8 years (range: 40–75 years). The treated level was C3–C4 in three patients (5.7%), C4–C5 in 6 (11.3%), C5–C6 in 36 (67.9%) and C6–C7 in 8 patients (15.1%). A significant decrease was reported in the mean values of Neck

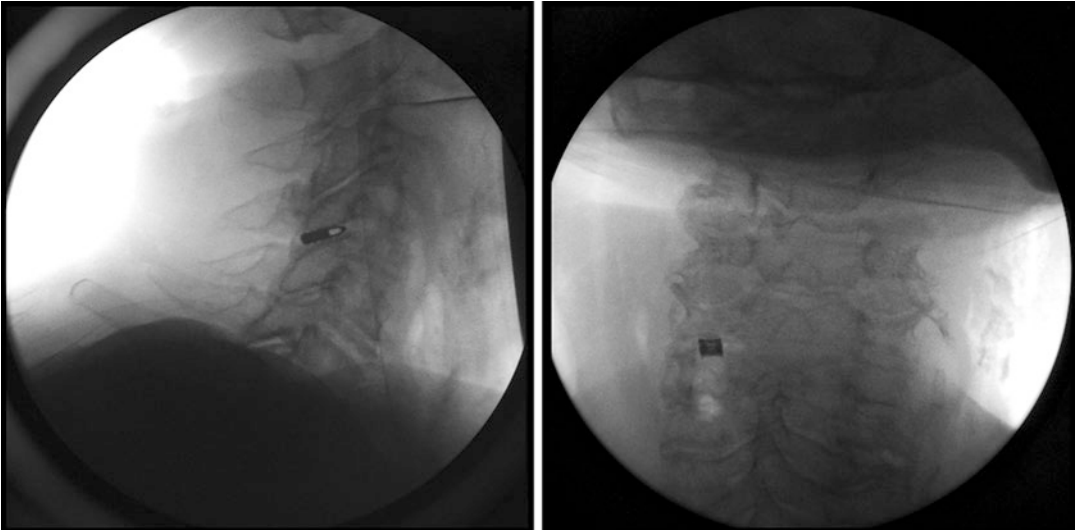


Fig. 12.14 Final cage positioning is confirmed in AP and lateral fluoroscopy

Disability Index (NDI) and Visual Analogue Scale (VAS) for the neck and arm pain as well as an increase in SF-12v2 physical and mental scores at each follow-up out to 2 years comparing to the preoperative values. There were no significant differences in clinical outcomes between 1-year and 2-year follow-up.

All patients showed improvement in the NDI when compared to preoperative and this improvement was maintained at 2 years. Of the 53 patients, 2 patients had an increase in arm pain and 2 had an increase in neck and arm pain that was reflected in VAS scores. Three patients had no change in neck pain and one had no change in neck and arm pain scores for VAS.

The most common device-related adverse events were shoulder pain and paresthesia. The most common procedure-related adverse events were postoperative pain, nausea, pain from bone graft harvest site, and shoulder pain. Severe adverse events included shoulder pain, shoulder/elbow weakness, bilateral sciatica, flank pain, mid-back pain, recurrence of neck pain, recurrence of arm pain, and acute exacerbation of osteoarthritis in the knee. No procedure or device-related serious adverse events were noted during the 2-year follow-up. One patient reporting right shoulder pain was noted as a severe

adverse event, which was reported as procedure-related. No revision surgeries were reported at the index level or at adjacent levels. Finally, there were no device migrations, expulsions, or breakages at the 2-year follow-up.

The radiographic fusion rate was reported in 52 of 53 patients (98.1%). Radiographic fusion was defined by less than a 2 mm change in interspinous distance measured on flexion extension radiographs taken at 24 months. The overall change in interspinous distance was 0.78 ± 0.58 mm with a range of 0.04–2.16 mm. Translational motion at the treated level of less than 2 mm were noted for all 53 patients. There were no radiographic signs of implant loosening, breakage, migration, or screw back-out. CT scans revealed evidence of bridging bone in 93.3% of patients at 12 months.

In the United States, the DTRAX system is commonly used in conjunction with ACDF to improve fusion rates. Good clinical outcomes were observed by Kramer et al. [38] when using DTRAX Cages to augment an ACDF procedure in 35 high-risk patients (mean age, 55 years). In their report, they defined high-risk as either addressing three or more levels, two or more levels with concomitant comorbidities (osteoporosis, nicotine use, arthritis), or two or more levels

with history of pseudarthrosis. Of their cohort, 16 were smokers and 27 had three or more levels treated.

Including both anterior and posterior procedures, average blood loss was 70 ml and the average length of stay was 1.03 days. As of last follow up (range 102–836 days), VAS scores improved on average 4.86 points or 64.70%. Two patients were treated for complications consisting of superficial wound infections and resolved with antibiotics. There were no reoperations or readmissions nor were there any recorded neurological or vascular complications.

A multi-site prospective randomized clinical trial is currently underway in the United States to evaluate the safety and efficacy of the DTRAX system when used as supplemental posterior fixation to an ACDF in patients treated at three levels.

Biomechanical Performance of DTRAX Cervical Cages Alone and When Integrated with Anterior Constructs

The efficacy of the DTRAX facet cage is due to a decreased range of motion at the instrumented level, foraminal distraction, and maintenance of its deployment position during repeated bending motion and loading.

A study by Leasure and Buckley was conducted to evaluate the biomechanical efficacy of the DTRAX cervical cage in vitro [39]. Three aspects of device performance were addressed, including acute stabilization, neuroforaminal distraction, and migration of the implant over time due to repeated loading. The results of this study indicate that a stand-alone cage substantially increases intervertebral stability, does not loosen within the cervical facet joint during repeated bending loads, and maintains decompression of the cervical nerve roots through extension.

The biomechanical performance of the DTRAX Cages were further tested by Voronov et al. [40]. In their study they measured flexion-extension range of motion, lateral bending, and axial rotation across three conditions; intact, with

anterior plate, with anterior plate and DTRAX Cages. This progression of constructs was tested for one level (C6–C7) and two levels (C3–C5). As expected, adding an anterior construct stabilized the cervical spine. When the anterior plate was supplemented with posterior stabilizers, all three measures of stability further improved significantly. By the authors estimation, the addition of facet cages to a ACDF increased stiffness six-fold compared to the anterior construct alone. Havey et al. [41] observed similar changes on stability using a zero-profile anterior cage with DTRAX Cages. In addition, their results showed that when both anterior and posterior constructs were used together, there was no change in lordosis observed when compared to the intact condition. Conservation of lordosis in the absence of an anterior construct was summarized by Laratta et al. [42], who in their review of DTRAX literature, found no evidence of kyphosis at follow-up visits ranging from 12 to 24 months.

Conclusion

Technological advancements in tissue sparing PCF have shown this technique can improve outcomes when compared to a traditional open approach in select patients with symptomatic radiculopathy, particularly when used as an adjunct to ACDF. The presented clinical, radiographic, and biomechanical evidence for minimally invasive posterior cervical facet cages should encourage surgeons to consider their full armamentarium when designing a treatment plan for patients presenting with increased risk for non-union. Moreover, we call for future work to determine which additional risk factors increase chance of revision and to establish subsequent treatments to best mitigate these risks, providing better outcomes for this growing pool of patients.

Disclaimer This Chapter contains information about DTRAX® Spinal System and the CORUS Spinal System and CAVUX Cervical Cage product lines, manufactured by Providence Medical Technology, Inc. Other manufacturers' products may be available to treat or degenerative disc disease. One of the contributing authors of this Chapter, Erik Summerside, is an employee of Providence

Medical Technology, Inc. Information about the DTRAX Spinal System is provided herein for educational purposes and is not to be construed as promotional in any manner. Prescribing decisions should be made based on DTRAX Spinal System indications and labeling by trained medical professionals. This Chapter may contain information that is not in the labeling approved by the U.S. Food and Drug Administration or another applicable regulatory body.

Conflicts of Interest Dr. Heller has acted as a consultant for Convatec, Nuvasive, Providence Medical Technology, SI Bone, Stryker, Zimmer Biomet, and RTI. He receives royalties from Nuvasive, has personal investments in Portola, ATEC, and SpineBiopharma, and provides research support for Ethicon. Dr. Glenn has consulted for Providence Medical Technology. Bruce McCormack and Erik Summerside have an ownership stake in Providence Medical Technology (see disclaimer).

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