

Anterior Cervical Interbody Fusion Using a Polyetheretherketone (PEEK) Cage Device and Local Autograft Bone

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In a population of patients with high rates of tobacco use, diabetes mellitus, obesity, and other factors that negatively affect fusion rates, local autograft may be a good choice for efficacy and cost savings.

Anterior cervical discectomy and fusion (ACDF) has been performed with various techniques and devices for many years. Autologous iliac crest grafts were initially used for the Cloward^{1,2} and Robinson and Smith³ techniques, but because of iliac crest graft site complications (eg, pain, infection, fracture, dystrophic scarring^{4,5}), the procedure was generally superseded by allograft implants. These implants were then supplemented with anterior locking plate devices. More recently, unitary devices combining a polyetheretherketone (PEEK) spacer with screw or blade fixation have been developed, such as the Zero P (Synthes, Inc.) and the ROI-C cervical cage (LDR). Bone graft is required to fill the cavity of these devices and to promote osseous union. Demineralized bone matrix,⁶ tricalcium phosphate,^{7,8} and bone morphogenetic

protein (BMP) have been used for these purposes, but they add expense to the procedure and have been associated with several complications (eg, neck swelling, dysphagia associated with BMP).⁹

Although multiple studies have demonstrated effective fusion rates and good outcomes for both iliac crest autograft and grafting/spacer constructs, the debate over cost and “added value” remains unresolved. One institution, which has published articles reviewing the spine literature and its own data, concluded that iliac crest autograft was the most cost-effective and consistently successful ACDF procedure.^{5,10}

The VA Portland Health Care System (VAPORHCS) has analyzed the use of local autograft sources at the surgical site to circumvent the need to make a second incision at the iliac crest and, theoretically, to decrease risks and expenses associated with iliac crest autograft, allograft bone, and artificial constructs. Given the paucity of data on this method, the case series presented here represents one of a few studies that analyze local autograft

for promotion of arthrodesis in a PEEK spacer device.

This article will report on the prospectively collected results of consecutive cases performed by Dr. Ross using a ROI-C cervical cage for 1-level anterior cervical discectomy between August 2011 and November 2014. This study received institutional review board approval.

METHODS

Neck disability index (NDI) forms were used to assess the impact of neck pain on patients' ability to manage in everyday life. The NDI form was completed before surgery and 3 and 9 months after surgery.

Dr. Ross preferred to perform minimally invasive posterior cervical foraminotomy for unilateral radiculopathy. Therefore, all patients with radiculopathy had bilateral symptoms or a symptomatic midline disc protrusion not accessible from a posterior approach. Standard techniques were used to make a left-side approach to the anterior cervical spine except in cases in which a previous right-side approach could be reused. Under the microscope, the anterior longitudinal

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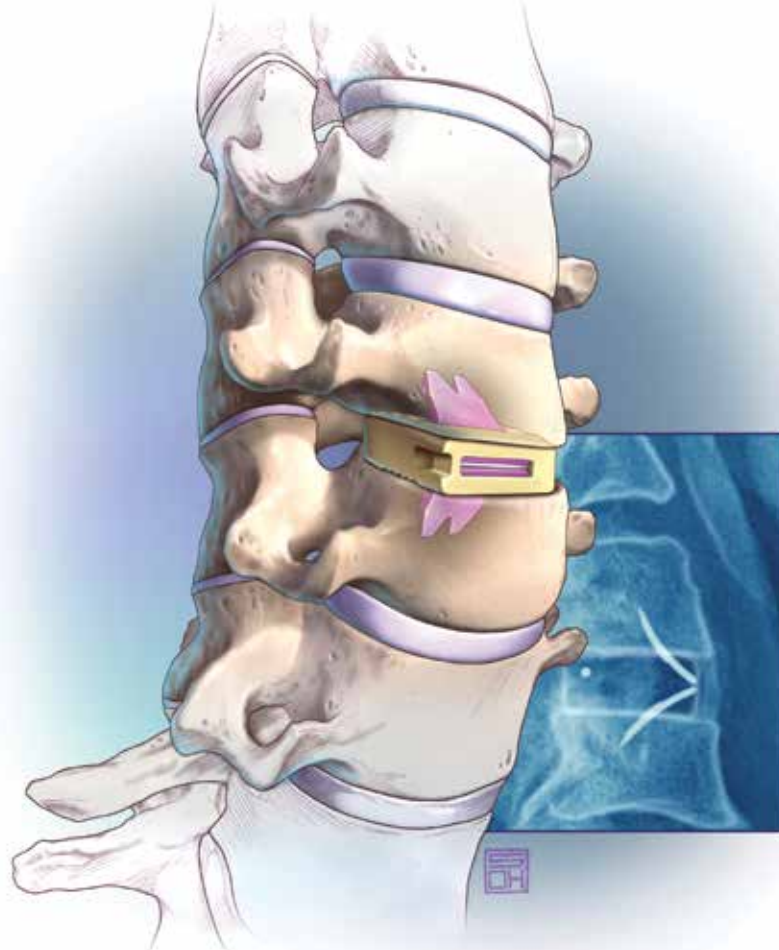
ligament and annulus were incised, and the anterior contents of the disc space were removed with curettes and pituitary rongeurs. Care was taken to remove all cartilage from beneath the anterior inferior lip of the rostral vertebral body and to remove a few millimeters of the anterior longitudinal ligament from the rostral vertebral body without use of monopolar cautery (Figure 1). A 2 mm Kerrison punch then was used to remove the anterior inferior lip of the rostral vertebral body, and this bone was saved for grafting. No bone wax was used within the disc space.

After all disc space cartilage was removed from the endplates, additional bone was obtained from the uncovertebral joints and posterior vertebral bodies as the decompression proceeded posteriorly. Occasionally, distraction posts were used if the disc space was too narrow for optimal visualization posteriorly. After decompression was achieved, a lordotic ROI-C cervical cage was packed in its lumen with the bone chips and impacted into the disc space under fluoroscopic guidance. The blades were impacted under fluoroscopic guidance as well. The wound was closed with absorbable suture.

Antibiotics were given for no more than 24 hours after surgery. Ketorolac was used for analgesia the night of the surgery, and patients were asked to not use nonsteroidal anti-inflammatory drugs for 3 months after surgery. Lateral radiographs were obtained 3 and 9 months after surgery and every 6 months thereafter until arthrodesis was detected.

RESULTS

Seventy-seven consecutive patients underwent 1-level anterior cervical discectomy (Table 1). Twenty-four procedures were performed for radiculopathy, 52 for myelopathy, and



1 for central cord injury sustained in a fall by a patient with preexisting spinal stenosis. Surgery was performed at C3-C4 (25 cases), C4-C5 (11 cases), C5-C6 (15 cases), and C6-C7 (1 case) for patients with myelopathy. Surgery was performed at C3-C4 (2 cases), C4-C5 (3 cases), C5-C6 (9 cases), and C6-C7 (10 cases) for patients with radiculopathy.

Twenty-eight patients reported presurgery tobacco use. Although all tobacco-using patients agreed to cease use in the perioperative period, at least 9 admitted to resuming tobacco use immediately after surgery. Eighteen patients had diabetes mellitus. In 2 patients, a diagnosis of osteoporosis was made with dual-energy X-ray absorptiometry. One patient was a chronic user of steroids before and after surgery. Mean body mass index (BMI) was 30.6, and 13 patients were morbidly obese (BMI > 34).

In 2 cases, only a single blade was placed. The second blade could not

be placed because of broken adjacent screws (1 case) or undetermined reason (1 case).

The mean time for follow-up was 17 months (range 3-34). Four patients were lost to follow-up: 3 after the 1-month postoperative visit and 1 with severe psychiatric problems after hospital discharge.

There were no new neurologic deficits, no wound infections, and no recurrent laryngeal nerve palsies in the 77 patients. Eight months after surgery, 1 patient with radiculopathy underwent foraminotomy at the index level for persisting foraminal stenosis. Two patients whose myelopathic symptoms persisted after surgery returned for minimally invasive posterior laminotomy to remove infolded ligamentum flavum. The presurgery and 3- and 9-month post-surgery NDI scores were available for 52 patients (Table 2). Before surgery the mean NDI score was 24 (range 8-40). Three months postsurgery the mean NDI score was 15 (range

Table 1. Patient Demographics and Surgical Indications

Patients	77 (65 males)
Mean age, y (range)	58 (38-89)
Mean body mass index (range)	30.6 (24 to ≥ 70)
Indication	
Radiculopathy	
C3-C4	2
C4-C5	3
C5-C6	9
C6-C7	10
Total	24
Myelopathy	
C3-C4	25
C4-C5	11
C5-C6	15
C6-C7	1
Total	52
Central cord injury	1

2-27) for patients with myelopathy and 13 (range 2-28) for patients with radiculopathy. The patient with the highest NDI score (28) stated that though all his symptoms were relieved, he had gauged his responses to protect his disability claim. Nine months after surgery, the mean NDI scores were 9.5 (range 5-17) for patients with myelopathy and 6 (range 2-13) for patients with radiculopathy. No NDI score was higher postsurgery than presurgery.

Arthrodesis was defined as bony bridging between the adjacent vertebral bodies and the bone graft within the lumen of the device, anterior to the device, or posterior to the device. In Dr. Ross' protocol, computed tomography (CT) scans or flexion-extension radiographs were obtained only if pseudarthrosis was suspected to avoid unnecessary radiation exposure. Sixty-six patients had at least the 3-month radiography

follow-up available. All 52 patients with 9-month follow-up data achieved complete arthrodesis, as determined by plain film radiography. Bridging ossification was found anterior to the device in all but 9 patients. Trabeculated bone was growing through the lumen of the device in all cases (Figure 2). A broken blade without clinical correlation was noted on imaging for 1 patient.

The total cost of the ROI-C cervical cage (LDR) for VAPORHCS was \$3,498, or \$1,749 for the PEEK spacer plus \$1,749 for 2 metal blades. In comparison, the total cost of a typical anterior locking plate would have been \$6,700, or \$3,200 for the plate plus \$2,000 for 4 screws and \$1,500 for an allograft fibular spacer. Demineralized bone matrix (1 mL) as used in cervical arthrodesis by other surgeons at VAPORHCS cost \$279, or about \$500 including shipping.

DISCUSSION

Anterior cervical discectomy with fusion is a very common and successful surgical procedure for cervical myelopathy, radiculopathy, and degenerative disease that has failed to be corrected with conservative therapy.¹⁰ Medicare data documented a 206% increase in 1-level fusion procedures for degenerative spine pathology performed between 1992 and 2005.¹¹ When a procedure is performed so often, it is appropriate to review methods and analyze efficacy, cost, and cost-effectiveness.

According to a 2007 meta-analysis, the fusion rates of 1-level ACDF arthrodesis at 1-year follow-up are 97.1% in patients treated with anterior plates and 92.1% in patients treated with noninstrumented fusion.¹² The rate disparity was larger for multiple-level fusion: 50% to 82.5% for instrumented cases^{12,13} vs 3% to 42% for nonin-

strumented cases.¹⁴⁻¹⁶ Given the higher fusion rates achieved with instrumentation, surgeons have favored its use in ACDF.

Computed Tomography Use

Computed tomography has long been considered the gold standard for assessing arthrodesis outcomes (eg, Siambanes and Mather).¹⁷ However, recent data on potential harm caused by CT-related ionizing radiation suggest a need for caution with routine CT use.^{18,19} For cervical spine CT, Schonfeld and colleagues found that the risk for excess thyroid cancers ranged from 1 to 33 cases per 10,000 CT scans.²⁰ According to another report, “limiting neck CT scanning to a higher risk group would increase the gap between benefit and harm, whereas performing CT routinely on low-risk cases approaches a point where its harm equals or exceeds its benefit.”¹⁹ As some have questioned even routine postoperative use of radiation in patients with unremarkable clinical courses— patients should be spared unnecessary exposure — CT scans or flexion-extension radiographs were obtained at VAPORHCS only if clinical symptoms or radiographs were suggestive of pseudarthrosis.²¹ As none of the VAPORHCS patients had those symptoms, none underwent postoperative CT.

For anterior cervical arthrodesis, surgeon preference determines which of many different bone substrates can be used with instrumentation, which impacts the costs. Fusion substrates include structural autografts, structural allografts, morselized autografts, morselized allografts, demineralized allografts, porous ceramics and metals, and BMP. Given these many options, studies comparing the

constructs are lacking, especially with regard to the cost of alternative fusion constructs that produce similar outcomes. The Centers for Disease Control and Prevention defines cost-benefit analysis as a “type of economic evaluation that measures both costs and benefits (ie, negative and positive consequences) associated with an intervention in dollar terms.”²² It has been reported that using iliac crest autografts with anterior plate instrumentation is the most cost-effective method, yet alternatives remain in use.^{5,10}

For ACDF, iliac crest bone is an ideal and widely used construct substrate. Structural grafts harvested from the crest provide significant stability due to their bicortical or tricortical configuration with interposed osteoinductive and osteogenic cancellous bone. Few graft complications (eg, graft resorption) and no immunogenic or infectious complications have been reported for iliac crest bone. However, autologous iliac crest increases operative time, and donor-site morbidity has been reported.^{23,24} A retrospective questionnaire-based investigation by Silber and colleagues, who evaluated iliac crest bone graft site morbidity in 1-level ACDF, found that 26.1% of patients had pain at the iliac crest harvest site, and 15.7% had numbness.²⁴ Other complications, which occurred at lower rates, were bruising, hematoma, pelvic fracture, and poor cosmesis.^{23,25} In addition, osteoporosis and comorbid conditions have made it a challenge to acquire iliac crest autograft, contributing to the popularity of alternative substrates.²⁵

Allografts

An alternative to autografts, allografts have the advantages of reduced operative time and reduced donor-site

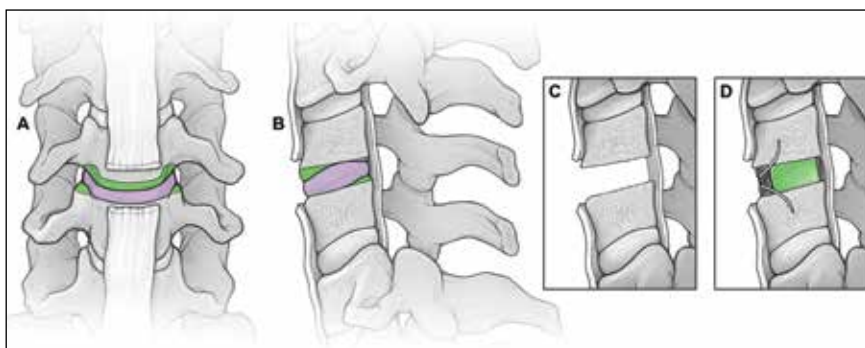


Figure 1. A, Anterior depiction of cervical spine shows resection of anterior longitudinal ligamentum from rostral vertebral body, cartilaginous disc (purple), and available-for-harvest autologous bone (green). B, Lateral depiction. C, Lateral view of prepared disc space. D, Lateral view shows fusion device in place with contained autologous bone (green).

morbidity.²⁶ Major historical concerns with allografts have included risk for disease transmission, costs associated with sterilization and serologic screening of grafts, and lack of oversight, leading to human allografts being acquired from dubious sources and ending up in the operating room.^{27,28} Two major types of allografts are available: mineralized and demineralized.

Arthrodesis rates are inferior for mineralized (structural) allografts with instrumentation than for autografts with instrumentation.²⁹ In addition, smoking and other comorbidities have influenced fusion rates more in allograft than autograft fusions.³⁰⁻³³ However, allografts are being widely used because they avoid the donor-site morbidity associated with autografts and because they are load bearing, can provide structural stability and an osteoconductive matrix, and can be used off the shelf without adding much time to surgery.

Demineralized matrix substrates are commercial osteoconductive and osteoinductive biomaterials approved for filling bone gaps and extending graft when combined with autograft.^{7,8} Despite their osteoinductive properties, these substrates have had

Table 2. Neck Disability Index (n = 52)

Time Frame	Mean (range)
Before surgery	24 (8-40)
3 months after surgery	
Myelopathy	15 (2-27)
Radiculopathy	24 (2-28)
9 months after surgery	
Myelopathy	9.5 (5-17)
Radiculopathy	6 (2-13)
Mean follow-up (range), mo	17 (3-34)

a high degree of product inconsistency, in some cases leading to poor outcomes.³⁴ The lack of randomized studies with these constructs has made the determination of clear indications a challenge.

The initial enthusiasm over use of BMP, another bone-graft substitute for cervical fusion, was curtailed by reports of adverse events (AEs). Effective in anterior lumbar spine fusions, BMP was adapted to off-label use in the cervical spine a few years ago.³⁵ Initial studies by Baskin and colleagues and Bishop and colleagues showed its fusion

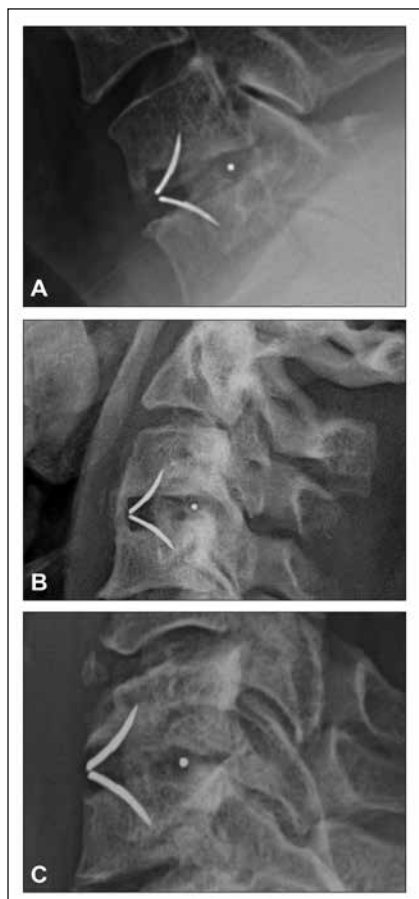


Figure 2. A, Lateral cervical radiograph 3 months after surgery shows persisting autograft bone within lumen of ROI-C cervical cage (LDR) and early osseous bridging anterior to device. B, Lateral cervical radiograph 3 months after surgery shows persisting autograft bone within lumen of ROI-C cervical cage and complete osseous bridging anterior to device. C, Lateral cervical radiograph 4 months after surgery shows persisting bridging bone within lumen of device and little anterior ossification.

rates superior to those of allograft.^{31,32} Both studies reported no significant AEs. However, studies by Dickerman and colleagues and Smucker and colleagues demonstrated increased soft-tissue swelling leading to dysphagia and prolonged hospitalization, which were attributed to higher dosage (no study has identified a precise dose

for individual patients).^{36,37} In addition, the cost of BMP is higher than that of any other bone-graft option for ACDF.³ Osteolysis has also been reported with BMP use.³⁸⁻⁴⁰ Carragee and colleagues highlighted the potential carcinogenicity of BMP, but this finding was not corroborated by Lad and colleagues.^{41,42}

Cost Considerations

In addition to surgical effectiveness, spine surgical device costs have come under increased scrutiny.⁴³⁻⁴⁵ In 2012, plates were reported to cost (without overhead or profit margin to hospitals) between \$1,015 and \$3,601, and allograft spacers were estimated to cost between \$1,220 and \$3,640, cage costs ranged from \$1,942 to \$4,347, and PEEK spacers cost from \$4,930 to \$5,246.⁵ Individual surgeon instrumentation costs varied 10-fold based on the fusion constructs used.⁵

In a cost-effectiveness review of anterior cervical techniques, cage alone was the least expensive technique, disc arthroplasty or cage/plate/bone substitute groups were the next most expensive, and autograft alone was the most expensive option due to hip graft site morbidity.⁴³ In another study, operative time associated with harvesting an iliac crest graft was equivalent in cost to that of an interbody cage.⁴⁴ Other studies have compared the costs of various anterior cervical fusion constructs.^{9,10,45,46} A limitation of these studies is that autologous bone often refers to iliac crest grafts rather than local autograft. Epstein reviewed data from these studies and concluded, “ACDF using dynamic plates and autografts are the most cost effective treatment for anterior cervical discectomy,” citing a cost of \$1,015 for this construct.⁵ Although Epstein demonstrated the cost-effectiveness

of autograft in an individual surgeon’s hands, the results also are significant in that the studies identified areas in which improvements can be made at other institutions. The ROI-C cervical cage and local autograft bone cost that the authors report is at the lower end of the range reported by Epstein.⁵

Device explant rates also can be a concern. Operative waste was well described in a retrospective analysis of 87 ACDF procedures.⁴⁷ The study found that the cost of explanting devices implanted during the same intraoperative period was equivalent to 9.2% of the cost of permanently implanted constructs. Epstein addressed operative waste by using educational modules to evaluate spine surgeons’ decision making before and after education. After the intervention, the institution noted a marked decline in costs related to explanted devices—from 20% in 2010 (before education) to 5.8% of the total cost of implanted devices in 2010 (after education).⁵

In the present study, the authors demonstrated that use of local morselized autograft with a PEEK spacer for 1-level ACDF had excellent arthrodesis rates and minimal complications. Of the 52 patients with 9 month postoperative data, all achieved arthrodesis regardless of tobacco use. This method compares favorably with other fusion options in terms of radiographic arthrodesis rates. In addition, it avoids the donor-site morbidity associated with autografts from an iliac site but maintains the benefits of the osteogenic, osteoconductive, and osteoinductive properties of autograft bone. Use of local autograft avoids the costs associated with iliac crest autograft, including increased operating and anesthesia time, additional operating room supplies (drapes, sutures, etc) needed for operating at a

second site, and prolonged hospital stay due to pain at the donor site. Use of local autograft also obviates complications at a second surgical site; purchase, storage, and sterilization of allograft; and the neck swelling, possible carcinogenicity, and cost of purchase of BMP. Other than the occasional reuse of distraction posts, this method involves no other expensive explant supplies.

Autografts have osteogenic, osteoconductive, and osteoinductive properties, and autograft fusion rates are generally superior to allograft fusion rates. Bone morphogenetic protein fusion rates may be comparable to autograft fusion rates.^{9,26,32} Shortcomings of iliac crest autografts include increased operative time, blood loss, and donor-site morbidity. Allografts are osteoconductive and osteoinductive, but their fusion rates are inferior to those of iliac crest autografts. Other shortcomings are infection transmission and immunogenicity risks, higher graft resorption and collapse rates, cost, and previous issues relating to provenance. Bone morphogenetic protein is the most osteoinductive material with fusion rates similar to those of autograft, but its use is associated with neck swelling, dysphagia, osteolysis, potential carcinogenicity, and high cost.⁹

CONCLUSION

Overall, use of local autograft with a PEEK spacer has all the advantages of iliac crest autograft along with the benefit of working within the same operative window as the ACDF, thus reducing the infection, bleeding, and pain risks that may be encountered with a second incision. This procedure is effective, inexpensive, and cost-effective compared with alternatives and may be preferable for 1-level ACDF. In a population of patients with high rates

of tobacco use, diabetes mellitus, obesity, and other factors that negatively affect fusion rates, local autograft may be a good choice for efficacy and cost savings. ●

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ANTERIOR CERVICAL DISCECTOMY FUSION

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