

Iliac crest autograft versus alternative constructs for anterior cervical spine surgery: Pros, cons, and costs

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Abstract

Background: Grafting choices available for performing anterior cervical discectomy/fusion (ACDF) procedures have become a major concern for spinal surgeons, and their institutions. The "gold standard", iliac crest autograft, may still be the best and least expensive grafting option; it deserves to be reassessed along with the pros, cons, and costs for alternative grafts/spacers.

Methods: Although single or multilevel ACDF have utilized iliac crest autograft for decades, the implant industry now offers multiple alternative grafting and spacer devices; (allografts, cages, polyether-etherketone (PEEK) amongst others). While most studies have focused on fusion rates and clinical outcomes following ACDF, few have analyzed the "value-added" of these various constructs (e.g. safety/efficacy, risks/complications, costs).

Results: The majority of studies document 95%-100% fusion rates when iliac crest autograft is utilized to perform single level ACDF (X-ray or CT confirmed at 6-12 postoperative months). Although many allograft studies similarly quote 90%-100% fusion rates (X-ray alone confirmed at 6-12 postoperative months), a recent "post hoc analysis of data from a prospective multicenter trial" (Riew KD *et al.*, CSRS Abstract Dec. 2011; unpublished) revealed a much higher delayed fusion rate using allografts at one year 55.7%, 2 years 87%, and four years 92%.

Conclusion: Iliac crest autograft utilized for single or multilevel ACDF is associated with the highest fusion, lowest complication rates, and significantly lower costs compared with allograft, cages, PEEK, or other grafts. As spinal surgeons and institutions become more cost conscious, we will have to account for the "value added" of these increasingly expensive graft constructs.

Key Words: Allograft, cages, anterior cervical spine surgery, costs, efficacy, explantation, iliac crest autograft, polyether-etherketone, single-level discectomy/fusion (1-level ACDF)

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INTRODUCTION

Grafting choices available for single level (1-level

ACDF) or multilevel anterior cervical discectomy/fusion (multilevel ACDF) procedures have been increasingly impacted by the manufacturing industry. The author

reviews the pros, cons, and lower costs for utilizing iliac crest autograft, considered the “gold standard”, and compares this to alternative spacers and grafts (allograft, cages, PEEK (polyether-etherketone), and others).^[6] Previous studies document up to 100% (CT and dynamic X-ray confirmed) fusion rates utilizing iliac autograft (within one postoperative year) for performing 1-level ACDF.^[13] The majority of other studies, particularly those utilizing allograft, document similarly high fusion rates based on X-ray analysis alone [Table 1]. Riew, Heller, and Sasso *et al.*, presented “The fate of delayed union following anterior cervical discectomy and fusion (1-level ACDF): A Post-Hoc analysis of data from a prospective multicenter trial” (Cervical Spine Research Society Abstract Dec. 2011, Phoenix, AZ, unpublished) that had originally compared single-level allograft/plated ACDF versus artificial disc replacements. Therein they documented significantly delayed fusion rates for allograft/plated fusions: 55.7% at 1 year, 87% at 2 years, and 92% at 4 years. Reevaluation of fusion data for autograft, allograft, cages, PEEK, and other spacers/constructs needs further assessment. Furthermore,

although the value of these constructs is typically expressed in terms of fusion rates, clinical outcomes, and risks/complications, the inherent costs or the “value added” should now be factored in.

FUSION RATES FOR NON-PLATED 1-LEVEL ANTERIOR DISKECTOMY WITH (ACDF) OR WITHOUT FUSION (ACD)

Previous to plating, 1-level anterior discectomies were performed with or without fusion with varying levels of success. In 2007, Xie and Hurlbert evaluated the necessity for interbody fusion for patients with radiculopathy following 1-level ACD (anterior discectomy).^[47] Randomizing 42 patients to one of three treatment groups, ACD alone, ACDF, and ACDF with instrumentation, they evaluated radiographic and clinical outcomes (Short Form 36). Both clinical and SF-36 scores comparably improved in all 3 groups. However, radiographic fusion occurred in only 67% with ACD (undergoing no fusion), but in 93% of those with ACDF, and 100% with ACDF and plates. Nevertheless, for those undergoing ACD without fusion, preoperative segmental kyphosis, present in 17% of patients, increased to 75% postoperatively, while those undergoing fusion exhibited “...no change in sagittal balance...” They concluded that although ACD resulted in adequate clinical outcomes, stating that “within a 2-year follow-up period, the technique of reconstruction plays no role in clinical results”, but that the absence of fusion resulted in an increased rate of kyphotic deformity.^[47]

Also in 2007, Nandoe, Tewarie, Bartels *et. al.* evaluated the long-term outcomes for ACD and compared these with published data regarding long-term outcomes for those undergoing ACDF.^[34] They identified 551 patients, 90.1% of whom were satisfied with the outcomes of surgery 2 months later. They also randomly selected 102 patients and interviewed them with the neck disability index regarding persistent problems up to 18 years following ACD operations. However, when this survey was performed the percentage of satisfaction had decreased to 67.6%; complaints involved neck and radicular pain to the arm. They concluded that “...there is no superiority of any fusion technique compared with ACD alone...”^[34]

In an additional 2007 study, Wright and Eisenstein evaluated 97 consecutive patients one year following ACDF performed at one or two levels utilizing iliac autograft (tricortical-Smith Robinson technique) without instrumentation; patients were immobilized in semi-rigid collars for two postoperative months.^[46] For the 54 patients having 1-level ACDF, 6 exhibited pseudarthrosis (11%); for the 43 patients having 2-level ACDF, 12 (28%) exhibited pseudarthroses. Noting the latter high pseudarthrosis rate, the authors were “...inclined to change their practice to include internal fixation in the form of anterior plating for fusions carried out at more

Table 1: Fusion rates for single-level anterior discectomy with fusion utilizing X-ray and/or 2D-CT studies

Authors	1-AD alone fusion rates (X-ray) (2D-CT)	1-ADF no plates fusion rates (X-ray) (2D-CT)	1-ADF with plates fusion rates (X-ray) (2D-CT)	Years fusion rates (X-ray) (2D-CT)
Riew (CSRS [2011])				1 year 55.7 2 years 87 4 years 92 X-ray (all) Allograft (all)
Fraser ^[17]	84.9 X-ray	92.1 X-ray	97.1 Meta-analysis (Mixed Grafts) X-ray	
Kaiser ^[23]		90 X-ray	96 Allograft X-ray	
Samartzis ^[32]			100 Allograft X-ray 90.3 Autograft X-ray	
Balabhdra ^[11]			96 Allograft X-ray	
Miller ^[29]			91 Allograft X-ray 97 Cages X-ray	
Epstein ^[13]			100 Autograft X-ray and 2D-CT	

1-AD Alone: Single level anterior discectomy without fusion, 1-ADF: Anterior discectomy with fusion, CSRS: Cervical Spine Research Society Meeting, Phoenix, Az 2011), All numbers are in percentages

than one level". Note, that this opinion did not include plating the 1-level ACDF.^[46]

Again in 2007, Nabhan, Pape, Pitzen et. al. performed a randomized, controlled, prospective study, utilizing radiographic assessment (1, 6, and 12 weeks, 6 mos, 1 and 2 years postoperatively) of fusion following 1-level ACD fused with a stand-alone cage (19 patients) or with cage and plate fixation (18 patients).^[33] There were no significant statistical difference regarding range of motion, nor any differences in quality of outcomes measured by the Visual Analogue Scale (VAS). Here the authors conclude that "anterior plate fixation did not demonstrate an improvement in the progress of fusion in one-level ACDF".^[33]

An additional 2007 study performed by Lind, Zoega, and Rosen, 24 patients with radiculopathy were randomized to undergo ACDF without plates utilizing either a fusion cage or autograft.^[29] They observe no significant differences for the two groups two years postoperatively with respect to: loss of disc space height, deformation in flexion, however, the cage group appeared to have a "significantly better clinical outcome" largely attributed to the "lack of deformation of the fused segments" particularly for multilevel procedures.^[29]

Subsequently, in 2009, Konduru and Findlay reexamined the various studies regarding the relative efficacy of ACD or ACDF.^[27] They observed that even in the multiple randomized prospective trials comparing ACF with ACDF, there was "no significant difference" in the relief of arm or neck pain. Differences included for the ADF patients, "...a temporary increase in postoperative axial neck pain", while the ACDF patients required longer operative times, prolonged lengths of stay, and more time to return to work. They did observe "There is some evidence to suggest that plate fixation can lead to increased fusion rates".

Summary: *Multiple studies involving ACD or ACDF performed without plates for 1-level anterior cervical disease, particularly addressing radiculopathy, have yielded comparable clinical outcomes. However, ACD were associated with higher rates of kyphosis, a complication avoided by ACDF.*

FUSION RATES FOR 1-LEVEL ACDF UTILIZING MULTIPLE SPACERS AND PLATING SYSTEMS

High fusion rates, often ranging up to 100%, have been variously reported for 1-level ACDF utilizing different grafts (autograft/allograft/cages/polyether-etherketone [PEEK]) and plate designs (constrained or fixed/semi-constrained/ dynamic plates) [Table 1].

Constrained, Semi-constrained, and dynamic plates

The three major types of anterior cervical plates,

constrained, semi-constrained, and dynamic, allow for differing degrees of motion that impact graft settling, graft shielding (prevention of compression on graft/vertebral interfaces), and ultimately, fusion.

Constrained (fixed) plates (e.g. Orion, Medtronic, Memphis, TN, USA), consist of a plate with screws firmly fixed to the plate so that there is no "toggle" or motion; this most severely limits or "constrains" graft settling, and provides the greatest degree of graft shielding, thus decreasing fusion rates. The semi-constrained plates (e.g. Atlantis, Medtronic, Memphis, TN, USA) consist of a plate with a screw that toggles 17 degrees cephalad/caudad: the "toggling" fosters some motion, thereby allowing for mild graft settling, while also mildly limiting stress shielding. Alternatively, dynamic plates (e.g. ABC, Aesculap, Tuttingen, Germany) allow for the most motion, thereby maximizing graft settling and minimizing stress shielding. To attain "dynamization", the ABC plate utilizes a slotted design which allows the screw heads to migrate (up to 10 mm in the largest plates) in both the cephalad (screws placed maximally superiorly and migrating inferiorly) and caudad (screw placed maximally inferiorly and migrating superiorly) directions.

Summary: There is increasing evidence that points to the superiority of dynamic plates over constrained and semi-constrained plates. As the screws are able to migrate within the slotted plate design, stress shielding is limited while graft compression is maximized.

I-LEVEL ANTERIOR CERVICAL DISCECTOMY WITHOUT FUSION; I-LEVEL ANTERIOR CERVICAL DISCECTOMY WITH FUSION; I-LEVEL ACDF WITH FUSION AND PLATING

In Fraser and Hartl's meta-analysis involving 21 papers with a minimum of 25 cases/paper, and 1-year follow-up, the overall fusion rate was 89.5% [2682 patients]: the fusion rate for 1-level anterior discectomy without fusion (ACD) 84.9%, 1-level anterior discectomy with fusion (ACDF) 92.1%, and plated 1-level ACDF was 97.1%.^[17]

NON-PLATED VERSUS PLATED ACDF

In Kaiser, Haid, Subach *et al.*, series, for 1-level plated ACDF utilizing constrained Orion, semi-constrained Atlantis Plates (both Medtronic, Memphis, TN, USA), and constrained Codman Plates (Codman and Shurtless, Inc., Raynham, MA, USA)], the fusion rate utilizing cortical allograft (for both groups) was 96% compared with 90% fusion rates for non-plated 1-level ACDF.^[23]

In Samartzis, Shen, Goldberg *et al.*, series, patients underwent 1-level ACDF utilizing either allograft or autograft and constrained Orion plates (Medtronic,

Memphis, TN, USA).^[37] They found that 100% of patients undergoing 1-level ACDF fused utilizing Orion plate/allograft compared with a 90.3% fusion rate for 1-level ACDF utilizing Orion plate/autograft; these data failed to clearly demonstrate a significant difference.^[37]

Summary: *Although plated 1-level ACDF correlated with higher fusion rates versus non-plated 1-ACDF, these differences were not significant: 96% vs. 90%. Nevertheless, one must consider the “value added” of the plates, which includes a reduction in the risk of anterior graft extrusion. Therefore, the evidence supports the ACDF as the procedure of choice with the added use of plates to prevent graft extrusion.*

CONSTRAINED (FIXED) VERSUS DYNAMIC PLATING

In Nunley, Jawahar, Kerr *et al.*, prospective randomized study 1-level ACDF were performed in 28 patients while 2-3 level ADF were completed in 38 patients, 50% of patients received dynamic, and 50% received static/fixed plates.^[35] Although the types (static versus dynamic) did not alter 1-level ACDF fusion rates, dynamic plates appeared to modestly contribute to higher fusion rates for the multilevel group.^[35]

DYNAMIC PLATES AND ALLOGRAFT OR AUTOGRAFT

Several series now document how dynamic plates maximize graft compression, minimize graft shielding, and increase fusion rates compared with constrained or semi-constrained plates.^[1,9,13]

DYNAMIC PLATES AND ALLOGRAFT

In Balabhdra, Kim and Zhang series of 1-level ACDF performed utilizing dense cancellous allograft and dynamic ABC plates (Aesculap, Tuttlingen, Germany), a 96% fusion rate was achieved in 66 patients.^[1]

DYNAMIC PLATING WITH AUTOGRAFTS

In 2011, Epstein cited 100% fusion rate for 60 patients undergoing 1-level ACDF utilizing iliac autograft and dynamic plates (ABC; Aesculap, Tuttlingen, Germany) [Figures 1-7].^[13] Fusion occurred an average of 3.8 months [range 2.5-8 mos] postoperatively, while 5 heavy smokers exhibited delayed fusions occurring between 6-8 months postoperatively.^[13]

In Epstein's study of 116 patients undergoing single level anterior corpectomy (e.g. corpectomy defined as for example, C5-C7 with removal of both the C5/C6 and C6/C7 disc and intervening vertebral body of C6) and fusion utilizing iliac autograft and dynamic plates, 3 developed

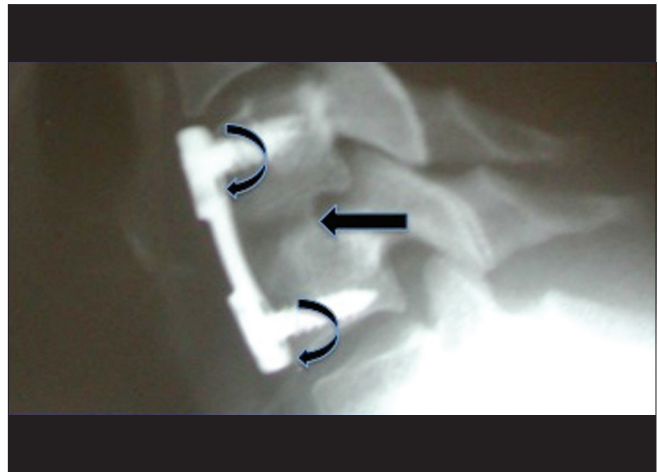


Figure 1: Three months following a single-level anterior discectomy and fusion, the lateral X-ray shows an iliac autograft (single arrow) within the anterior 2/3 of the interspace. Note the clear lack of lucency between the cephalad and caudad graft/vertebral end plate junctions, but the difficulty directly visualizing bony trabeculation that is better defined on CT. Additionally, the dynamic ABC plate (Aesculap, Tuttlingen, Germany) is adequately placed, while the screws have migrated (curved arrows), approximately 2-3 mm both cephalad and caudad, in the slotted design of the plates

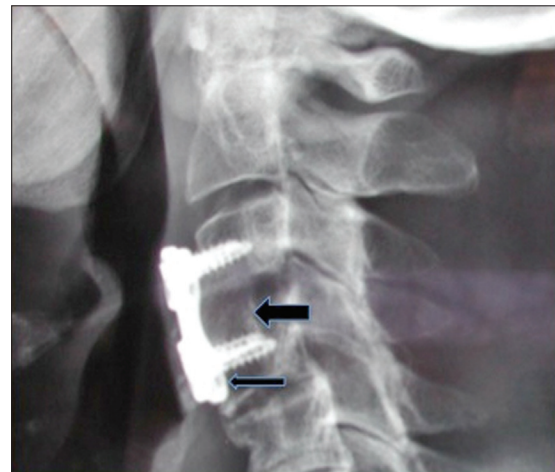


Figure 2: In another lateral radiograph obtained 3.5 months following a single-level anterior discectomy and fusion, the posterior margin of the iliac crest autograft within the disc space (single large arrow) is visualized and the lack of lucency of the cephalad graft/vertebral body interface is noted. Here, the screws within the plate have migrated 3-4 mm inferiorly, while superiorly there has been only 2 mm of migration

plate/graft extrusion or pseudarthrosis.^[9]

Summary: *Evidence supports the use of Dynamic Plates for performing ACDF as they appear to increase fusion rates by decreasing graft shielding and increasing graft compression while also preventing graft extrusion.*

SAFETY AND EFFICACY OF ALLOGRAFT, AUTOGRAFT, CAGES, ARTHROPLASTY

Miller and Block evaluated results of four different

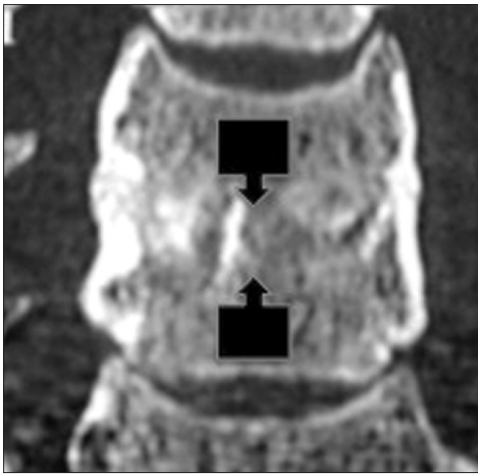


Figure 3: The coronal 2D-CT scan, obtained 3 months following a single-level anterior discectomy and fusion without plating, confirmed fusion. Observe the bony bridging and trabeculation crossing the disc space (large arrow), accompanied by the total lack of lucency at the cephalad and caudad graft/vertebral junctions

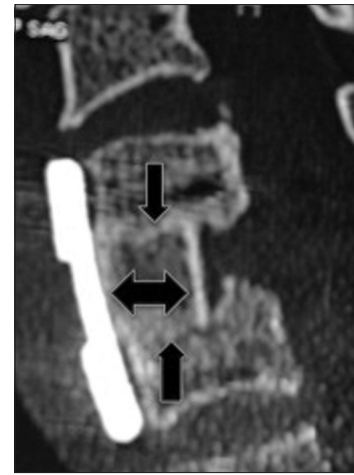


Figure 4: The sagittal 2D-CT scan obtained 6 months following a single-level anterior discectomy and fusion readily demonstrates adequate placement of the graft within the anterior 2/3 of the disc space (double tipped arrow), accompanied by cephalad and caudad fusion (absence of lucency and presence of bony trabeculation: single arrows) of the graft/vertebral body interfaces

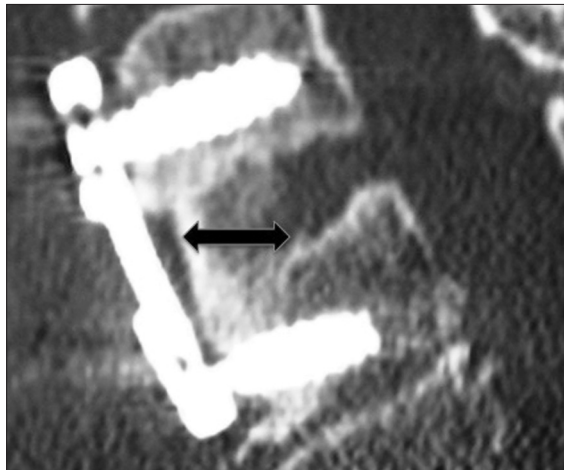


Figure 5: This sagittal 2D-CT study documents adequate placement of the graft (double tipped arrow) and fusion 3 months following a single-level anterior discectomy and fusion. The 2D-CT readily confirms the absence of lucency and presence of bony trabeculation at the cephalad and caudad graft/vertebral end plates

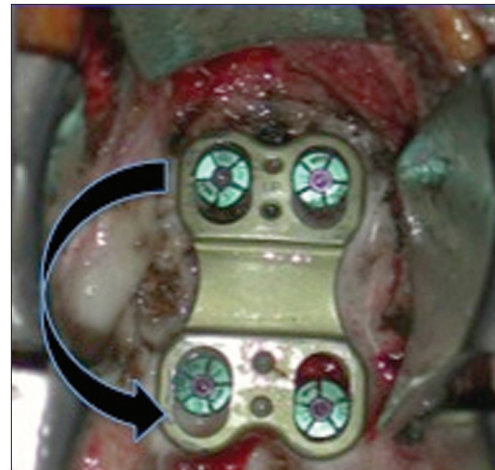


Figure 6: Intraoperative photograph showing the anterior exposure for a single-level anterior discectomy and fusion. A dynamic ABC plate (Aesculap, Tuttlingen, Germany) is seen, with the four screws in place (large curved arrow). Note that when applying these plates, the width of the central plate is typically that of the graft itself

ACDF constructs (allograft, autograft, a cage, and disc arthroplasty) obtained from 20 studies.^[31] They found comparable outcomes for all groups with 91% fusion rates for allograft and autograft, and 97% for cages.^[31] There was no clear explanation as to why the result for cages was higher. In another study by Lind, Zoega, and Rosen, one-level ACDF utilized autograft versus a fusion cage (both without plates).^[29] At two years, no significant differences were found regarding disc heights or kyphosis at the fusion levels, but they too noted that the cage groups “had significantly better clinical outcomes”; there was again, no explanation for the latter findings. When Moreland, Asch, Clabeaux et. al evaluated ACDF

utilizing an implantable titanium cage (50 cages; 37 patients) versus allograft (28 concurrent patients; 66 historical data), comparable fusion rates and outcomes were “clinically and statistically indistinguishable” at 6 postoperative months. Cages resulted in an 84% fusion rate at 3 months and 95% fusion rate at 6 months.^[32]

Summary: *The data do not clearly indicate that cages are superior to allograft or autograft fusions. Rather they appear to demonstrate that results are at least comparable. Further evaluation of these fusion rates utilizing CT and not just X-ray alone would likely indicate a higher failure rate for cages than has previously been reported.*



Figure 7: Typically following surgery for a single-level anterior discectomy and fusion, a cervical thoracic orthosis is worn rather than a collar alone as this affords greater immobility. Here we show a Miami J CTO Orthosis (Ossur Americas Trauma and Spine, Paulsboro NJ, USA)

Furthermore, the quality of these studies and their ties to industry warrant further consideration.

ARTHROPLASTY VERSUS 1-LEVEL ACDF WITH ALLOGRAFT AND PLATES

In 2011, Riew, Heller, Sasso, *et al.*, presented (Cervical Spine Research Society Abstract, Dec. 2011, Phoenix, AZ, unpublished) a post-hoc analysis of their data obtained from a prospective, randomized, multicenter study originally designed to compare cervical disc arthroplasty with 1-level ACDF (allograft/plates). Utilizing X-rays alone (AP, lateral, flexion/extension films reviewed by radiologists blinded to the study design at 6, 12, 24, and 48 months postoperatively), they discovered a much lower initial fusion rate, but a high delayed fusion rate for the single-level allograft/plated fusions than had previously been reported. The fusion rate at one year was only 55.7% while it increased to, 87% at 2 years, and 92.3% at 4 years. Their interpretation of these data was not that the value/safety/efficacy of these allograft constructs should be revisited, but rather, that if patients failed to fuse early (typically defined as within the first 6 postoperative months, otherwise they were deemed pseudarthroses), they would not necessarily require additional surgery as the majority would go on to eventually fuse. This meant that patients with pseudarthrosis did not require additional surgery, but rather would go on to spontaneously fuse without bracing or further treatment.

Summary: Recent evidence showed much lower 1-year fusion rates for allograft/plated 1-ACDF than had previously been reported. As a result of this low fusion rate the authors should have reevaluated their use of allograft for the 1-level ACDF constructs.

EXAMINATION OF CAGES

Animal studies with cages

An *in-vivo* goat model was utilized by Sinclair, Konz, Dawson *et al.*, to assess host-bone response and fusion rates for PEEK versus porous tantalum interbody cervical fusion devices both of which contained iliac crest autograft.^[41] They found better bone attachment, ingrowth, and bridging for the tantalum implants, and attributed this to its “open cell porous structure”.

In another goat model (caprine model), Cunningham, Seftor, Hu *et al.*, looked at four different models for performing ACDF; autograft alone, autograft with a cage, autologous growth factors with a cage, or autograft and a plate.^[7] They found comparable volumes of trabecular bone formation utilizing autogenous bone and the concentrated extract, while the use of cages better maintained the disc space distraction than autograft alone.

Good results were also achieved in Steffen, Voss, and Morgan’s study of a canine model in which single-level intervertebral cages were applied with hollow centers containing autograft; the 9 dogs who survived 12 months exhibited early radiographic subsidence (defined as the penetration of the cages past the vertebral end plates), but uniform fusion.^[44]

In a sheep model, Scholz, Schleicher, Eindorf, *et al.*, evaluated cages “augmented with mineralized collagen matrix (MCM) and platelet-rich plasma as an osteoconductive/inductive construct” for ACDF by examining three groups: titanium cage with cancellous autograft, titanium cage with MCM, and titanium cage with MCM and platelet-rich plasma.^[38] The lower fusion rate was documented radiographically and histopathologically for the MCM group, and adding plasma rich protein did not enhance fusion.

Summary: In these animal studies, none of the other constructs was superior to autograft. Additionally, cages were not superior to other constructs.

HUMAN STUDIES WITH CAGES

Cages with autograft

Although some of the animal-based data were promising, the clinical fusion data utilizing tantalum cages and porous blocks for 1-level ACDF typically were not. Kepler and Rawlins authored one of the few studies citing success utilizing mesh cages with autologous cancellous bone graft (from the manubrium or iliac crest); they observed a 98.4% fusion rate.^[26]

In Kasliwai, Baskin, and Traynelis study, 39 patients undergoing 1-level ACDF were divided into three treatment groups; 11 received autograft, 13 had porous

tantalum ring devices with the central cavity packed with cancellous iliac crest autograft, and 15 received a porous tantalum block.^[25] Two patients in the porous tantalum block group failed to fuse, 5 patients with the porous tantalum cages demonstrated device fragmentation and a sixth patient showed erosion of the adjacent vertebrae.

Similarly, Song, Taghavi, Hsu *et al.*, observed higher fusion rates for ACDF utilizing autograft compared with fusion cages which were associated with both lower and slower fusion rates. At 6 weeks, early fusion was observed between bone chips, at 3 months initial bridging between graft/host was documented, at 3-6 months anterior spur formation occurred, at 12 months "kissing" lesions were noted and finally, at 1-2 postoperative years, bony incorporation was documented.^[42]

Summary: *Clinically, cage constructs were associated with "both lower and slower fusion rates". Furthermore the cages were associated with device fragmentation and erosion (pistoning) into the adjacent vertebrae (more severe than simply subsidence). Thus it appears that ACDF with a dynamic plate and autograft was superior to cages for anterior cervical fusion.*

Outcomes of 1-level ACDF

Comparable outcomes have been reported utilizing various permutations and combinations of grafts and/or plating systems for 1-level ACDF.^[2,23,37,45]

Samartzis, Shen, Goldberg, *et al.*, observed good/excellent outcomes in 91.3% of patients undergoing 1-level ACDF performed with plates (31 patients) or without plates (38 patients) (fixed/semi-constrained).^[37]

Bhadra, Raman, Casey, *et al.*, reported on the outcomes for 4 different 1-level ADF constructs: (1) fixed-plates and autograft, (2) fixed-plate, cage, and bone substitute, (3) cage alone, and (4) disc arthroplasty.^[2] They found comparable 1-year postoperative outcomes, including the VAS (Visual Analog Scale) and SF-12 (12-Physical and Mental Health Scales of the Short Form-36) scores.

In Epstein's study of 60 patients undergoing autograft/dynamic-plated 1-level ACDF, outcomes were measured utilizing Odom's Criteria, Nurick Grades, and the SF-36 outcomes questionnaire (obtained up to 24 months postoperatively).^[13] The average preoperative Nurick Grade was 3.3, but improved to 0.3 (mild radiculopathy) postoperatively (2 years). Odom's Criteria revealed 52 excellent, 6 good, and 2 fair outcomes; all of the latter 8 (good to fair outcomes) were heavy smokers. Postoperatively, the SF-36 questionnaire demonstrated marked improvement [>10.0 point gain] on 5 of 8 Health Scales at 6 months, 7 of 8 within 1 year, and all 8 within 2 years. The greatest increase in the SF-36 Health Scales occurred in Bodily Pain within the first 6 postoperative weeks, and increased further at 1 year; preoperatively Bodily Pain (BP) Health Scale was 25.9, it increased to

52.5 by the 6th postoperative week, was 56.6 at 3 months, 58.0 at 6 months, 70.5 at 1 year, and 76.7 at 2 years.

In Jacobs, Willems, Kruyt *et al.*, when outcomes were compared across 33 studies involving 2267 patients undergoing one or two-level anterior discectomy alone (ACD) or with fusion (ACDF): graft, cement, cage, and plates), there was "... little or no difference in pain relief between the techniques".^[20] Although Odom's criteria were similar whether iliac crest autograft or metal cages had been utilized, iliac autograft was still considered the "gold standard" contributing to higher rates of fusion. The results of Jacobs, Willems, van Limbeek *et al.*, confirmed these data.^[21] Reid, Johnson, and Wang further observed that despite the development of these multiple adjuncts for fusion, "they successfully reproduce the enhancement of fusion rates observed with tricortical autograft".^[36]

Summary: *Comparable outcomes are largely being reported for 1-level ACDF utilizing a multitude of grafting (autograft, allograft, PEEK, cages) and plating techniques (constrained, semi-constrained, dynamic). Nevertheless, iliac crest autograft remains the "gold standard", and in many instances, still produced the highest fusion rates.*

Complications attributed to rhBMP-2 (Infuse: Medtronic, Memphis, TN, USA)

In Vaidya, Carp, Sethi *et al.*, despite comparable long-term outcomes following 1-level ACDF performed utilizing rhBMP-2 (Infuse: Medtronic, Memphis, TN, USA), and PEEK cages (Polyether-etherketone (Depuy Spine, Raynham, MA, USA) in 22 patients versus allograft spacers/DBM (demineralized bone matrix) in 24 patients, the three fold greater cost and incidence of severe postoperative dysphagia (1-6 postoperative weeks) associated with rhBMP-2 and PEEK cages led the authors to choose only allograft in the future.^[45] Of interest, most spine surgeons no longer use "off-label" rhBMP-2 in anterior cervical surgery as it has been associated not only with dysphagia but with multiple other complications also seen at other locations including "exuberant/ectopic bone formation, paralysis (cord/nerve damage), dural tears, bowel-bladder and sexual dysfunction, respiratory failure, inflammation of adjacent tissues, fetal developmental complications, scar, excessive bleeding and even death".^[12]

Furthermore, Carragee, Hurwitz, and Weiner noted that there were "increasingly, reports of frequent and occasionally catastrophic complications associated with the use of recombinant human bone morphogenic protein (rhBMP-2) in spinal fusion surgeries".^[4] The morbidity associated with utilizing rhBMP-2 for anterior cervical fusions, was associated with an estimated 40% greater risk of adverse events with rhBMP-2 in the early postoperative period, including some life-threatening events".^[4] They also questioned the complete lack of complications reported in the initial 13 industry-

supported articles (780 patients) associated with using rhBMP-2 for a wide variety of spinal fusions, the majority of which were "off-label". They observed, "adverse events of these types and frequency were either not reported at all or not reported to be associated with the use of rhBMP-2." Of major concern was why peer review and spine journal editors did not expose or disclose these "oversights". Shimer, Oner, and Vaccaro similarly raise the issue of complications utilizing INFUSE with anterior cervical surgery, particularly referring to the concerns regarding "...vertebral osteolysis, ectopic bone formation, radiculitis, and cervical soft tissue swelling".^[40]

Other complications of ACDF

The frequency of complications attributed to anterior cervical surgery vary. In Epstein's 2007 study involving graft/plate extrusions and pseudarthroses (dynamic X-ray/2D-CT confirmed) following 116 dynamic-plated single level anterior corpectomy (removal of single vertebral body, not just a one-level disc removal) and fusions, there were 2 major, and 3 minor complications.^[9,13] Major complications in 2 patients with ossification of the posterior longitudinal ligament (OPLL) included one vertebral artery injury (embolized without sequelae), and 1 cerebrospinal fluid fistula (repaired with microfibrillar collagen/fibrin sealant). Three minor complications included 1 plate revision (C6-C7 level in obese patient with inability to perform adequate intraoperative X-ray), 1 transient deltoid paresis (resolved in 3 months), and 1 nearly asymptomatic pulmonary embolism (treated with an inferior vena cava [IVC] filter).

In Fehlings, Smith, Kopjar *et al.*, comprehensive prospective, multicenter study, the risks and frequency of perioperative (within 30 days) and delayed (31 days to 2 years following surgery) complications attributed to spondylotic myelopathy (CSM) requiring 302 cervical operations (anterior only, posterior only, and combined 360-degree procedures) were evaluated.^[15] There were 332 complications. Of these, 15.6% occurred perioperatively (25 were major and 48 were minor in 47 patients). These included minor cardiopulmonary events (3.0%), dysphagia (3.0%), superficial wound infection (2.3%), and increased myelopathy (1.3%). For the 275 patients followed for 2 years, 14 delayed complications occurred in 12 patients (8 minor and 6 major). For patients undergoing anterior cervical surgery only, 1 or more perioperative complications were observed in 11% of 176 patients, while there was a 9% complication rate observed for those having posterior surgery alone (n = 107). Interestingly, the wound infection rate for anterior surgery alone was 0.6% compared with 4.7% for posterior surgery alone. The incidence of dysphagia was highest for the 360-degree procedures (21.1%), was a lesser 2.3% for anterior surgery alone, but was further reduced to 0.9% for isolated posterior surgery alone. Furthermore, a higher perioperative complication rate positively correlated with

older age, 360-degree procedures, longer operative times, and greater intraoperative blood loss.

Summary: *Complications of 1-level ACDF include neurological deficits, vertebral artery injury, cerebrospinal fluid fistula, graft or plate extrusion, pseudarthrosis, and infection.*

Complications of iliac crest autograft: Typically overestimated

High complication rates (some approaching 90%) are often reported for autograft harvesting for anterior cervical surgery related to donor site morbidity.

In Konduru and Findaly's 2009 review of multiple "prospective randomized trials", they noted that "if a fusion procedure is undertaken, the use of interbody spacers does have the advantage of avoiding donor site complications" which included pain amongst other factors.^[27]

In Dimitriou, Mataliotakis, Angoules *et al.*, the overall complication rate of 19.37% was cited for harvesting iliac crest bone graft (1249 complications in 6449 patients), and included infection, hematoma, fracture, and hypertrophic scar.^[8] In Heneghan and McCabe's study, 53 patients had ACDF with and without iliac autograft over 4 years.^[18] The morbidity associated with iliac autograft was 90% for pain at the donor site, 7% for infection, 1 jejunal perforation, and longer operative duration (285 minutes versus 238 minutes).^[18] In Lied, Roenning, Sundseth *et al.*, study, they performed 1-3 level ACDF utilizing autograft in 181 patients versus PEEK in 77 patients; although both constructs resulted in comparable outcomes, they preferred PEEK due to the "lack of donor site morbidity".^[28] In Kepler and Rawlins study of 38 patients undergoing ACDF with cages and cancellous autograft harvested through "... a cortical window with limited subperiosteal stripping"; 35 of 38 patients had no pain at 6 weeks, and all pain resolved by 12 weeks.^[26]

Nevertheless, some studies cite a much lower morbidity rate for autograft harvesting, while others question whether "industrial bias" impacts the reporting of high donor site morbidity. When Wright and Eisenstein reviewed the results of ACDF utilizing iliac crest autograft, 51 at 1-level, and 43 at 2-levels, they noted that "only 2 of the 97 patients had pain related to the donor site".^[46]

In 2011, when Carragee, Hurwitz and Weiner reported on the "... frequent and occasionally catastrophic complications associated with use of recombinant human bone morphogenetic protein-2 (rhBMP-2) in spinal fusion surgeries", they also noted that, "the reported morbidity of iliac crest donor site pain was found to have serious potential design bias".^[4]

Summary: *Carragee et al. have questioned whether "bias"*

introduced by industry contributed to the over reporting of morbidity associated with iliac crest autograft harvesting.

DISTRIBUTION AND COSTS OF SINGLE LEVEL ANTERIOR DISKECTOMY AND FUSION

Changing frequency of 1-level ACDF in the USA

Single-level anterior cervical discectomy and fusion (1-level ACDF) is one of the most frequently performed cervical operations in the United States.^[30,46] Between 1992-2005, utilizing Medicare Beneficiary Data (Medicare Part A; ICD-9-CM codes), a 206% increase in the frequency of 1-level ACDF surgeries for degenerative cervical spine pathology was documented.^[46]

More surgeons, more operations, more variations: Where are the data to prove the “Value Added”

In 2012, McGuire, Harrast, Herkowitz *et al.*, studied the geographic variation for cervical surgery.^[30] From 1998-2004, they noted historically by 2004, cervical fusions comprised 41% of all fusions, that the number of orthopedic spine surgeons increased by 24%, and the number of cervical fusions increased by 67%.^[30] Operative choices also changed; interbody devices increased from 0-31%, anterior cervical plates from 39%-79%, allograft from 14%-59%, while autograft decreased from 86% to 10%. More interbody devices were used in the Southeast and Southwest versus the Midwest, while the Southwest and Northwest used more autograft. Their conclusion was that “...surgeons are performing more fusions and utilizing more structural allografts, interbody devices, and/or anterior cervical plates.”

Summary: *There are more 1-ACDF being performed by more surgeons in the USA. Furthermore, the marked differences in the frequencies of these procedures depend in part upon where you live.*

Cost comparisons of various approaches to 1-Level ACDF

Although most 1-level ACDF studies focus on outcomes and fusion rates, few compare costs of less expensive and more expensive combinations of spacers, plates/instruments, and supplies. The “value-added” of different plates (constrained, semi-constrained, dynamic), spacers (autograft, allograft, cages (wire mesh), and polyether-etherketone [PEEK], among others), and bone graft supplements, bone morphogenetic protein [BMP], demineralized bone matrix [DBM], and beta tri-calcium phosphate [B-TCP]) is typically not explored.

One study documented comparable costs for 3 different spacers/constructs for 1-level ACDF; (1) plate/cage/bone substitute, (2) cage alone, and (3) disc arthroplasty.^[2] However, for the fourth plate/iliac autograft construct, less costly instrumentation, was deemed less cost-effective due

to the patients’ longer hospitalization [LOS=5 days].^[2]

In a second study, the costs/effectiveness of autograft spacer/cervical spine locking plates [CSLP; Synthes-North America, West Chester, PA, USA] in 26 patients versus the Syncage C [Titanium Box, Synthes, Paoli, PA, USA] filled with autograft cancellous bone in 27 patients were compared.^[24] Notably, the higher cost for the cages was negated by shorter operative time and shorter length of stay [LOS], advantages that were tempered by a tendency for a longer time to fusion.

A third study utilized cage/mesh/autograft cancellous bone/plate in 27 patients versus iliac autograft spacer/plate in 27 patients, determining that surgical costs were comparable.^[5] The operative time saved by avoiding iliac crest bone harvesting (perioperative morbidity/increased LOS associated with the donor graft site) was negated by the increased cage cost.

In a fourth study, Epstein’s series of 60 patients undergoing 1-ACDF utilizing iliac autograft with plates, the autograft construct cost \$0.00 when compared to allograft (up to \$2,552/graft), or to cages (range up to \$7,928), and simply incurred an additional 45 minutes of operative time (total average 3.4 hours) for the grafting procedure, and average additional LOS.^[13]

Summary: *Iliac autograft, utilized to perform 1-level ACDF costs \$0.00, while other spacers like allograft may cost (without overhead; what the hospital actually pays) up to \$2,552 for grafts, with cages costing up to \$7,928. Nevertheless, the different constructs have other pros and cons, and in many instances, actual hospital costs may equalize as long as BMP/INFUSE is not utilized.*

Cost benefit using more complex approaches

Cost-benefit analyses were performed in two other studies that compared the least expensive (e.g. autograft spacer) versus the more expensive (e.g. allograft spacer/BMP, PEEK/rhBMP-2, allograft spacer/DBM) instruments and supplies for performing 1-3 level ADF.^[3,45] In Buttermann’s study, comparable outcomes and fusion rates were observed for autograft spacer versus allograft/BMP.^[3] The allograft/BMP, however, significantly increased neck swelling/dysphagia (50%) versus autograft (14%), and was considered more expensive as it prolonged the LOS. This complication and its costs, therefore, outweighed the benefit of shorter operative time for allograft/BMP. In Vaidya, Carp, Sethi *et al.*, study comparing rhBMP-2/PEEK cages in 22 patients to allograft spacers/DBM in 24 patients, comparable outcomes (Oswestry, Visual Analog Scale, Arm/Neck Pain Scores) were observed for the two constructs, and higher fusion rates were observed for rhBMP-2/PEEK.^[45] Nevertheless, the greater frequency of postoperative dysphagia utilizing rhBMP-2/PEEK, and its 3 times greater cost prompted the authors to return to utilizing allograft/DBM.

Summary: *It appears that utilization of PEEK with BMP*

have a higher cost and complication rate. In Carragee et al. study, they reported a 40% incidence of complications following the use of rhBMP-2 /Infuse for anterior cervical surgery, resulting in postoperative neck swelling, seroma, and hematoma.^[4]

Thus, it appears that ACDF using dynamic plates and autografts are the most cost effective treatment for anterior cervical discectomy. Where feasible, Scoville’s posterior laminotomy approach to lateral cervical discs should be considered a viable alternative as this avoids the multiple unique risks of anterior cervical surgery, and critically, the necessity for simultaneous fusion.

1-level ACDF performed at a single institution

In a 2008 study involving 102 single-level ACDF performed at a single institution, Epstein et al., analyzed the variations in surgical/hospital costs and the extent to which surgeons choices affected these costs [Table 2].^[10] Cases were taken from a single DRG category (473: cervical spine fusion), and utilized a single Principle ICD Procedure Code (81.02); 22 patients had single-level disc disease with myelopathy (ICD-9 diagnosis code 722.71), while 80 patients had single-level disc disease without myelopathy (ICD-9 diagnosis code 722.0). The average age was 46.7 (range 20-79 years). The total cost of hospitalization (Total Costs) was defined as the individual patient costs divided into In-Patient Hospitalization (room costs/length of stay [LOS], diagnostic and laboratory studies, and other in-patient expenditures), and Surgical Costs.^[10] The latter included: (1) Operative Costs (operating room charges, the costs for anesthesia, and recovery room costs); (2) Instrumentation Costs (plates, screws, and spacers [autograft, allograft, PEEK, mesh]); and (3) Supply Costs (supplements to spacers including demineralized bone matrix [DBM], Beta TriCalcium Phosphate [B-TCP: Vitoss, OrthoVita, Malvern, PA, USA], and bone morphogenetic protein [rhBMP-2 or BMP/INFUSE]. All Instrument and Supply

Costs were the actual costs to the hospital without overhead; this is differentiated from hospital charges that typically include a 3-4-fold mark-up/increase to cover overhead costs.

Total Costs associated with individual patients ranged widely from a minimum of \$21,626 to a maximum of \$97,086 (difference of \$75,460: factor of 4.8) [Table 2].^[10] The upper and lower 95% limits were \$81,392 and \$30,692 (difference of \$50,609, factor of 2.6). Total Costs were broken down into In-patient Hospital Costs and Surgical Costs. In-patient Hospital Costs ranged from \$15,113 to \$76,687 (difference of \$61,574, factor of over 5); most of the variability was attributed to the length of stay [LOS], (range 1-11 days). The difference in Surgical Costs, although not as large, indicated the impact of the individual surgeon’s decisions or choices effecting costs.

The decision or choices [e.g. instrumentation] made by surgeons directly impacted the Surgical Costs.^[10] Dividing Surgical Costs into 3 subcategories revealed that Instrumentation Costs showed a nearly 10-fold variation from \$1,098 to \$10,921 (difference of \$9,824)! The instrumentation costs (cost to the hospital without overhead) for the author’s one patient was \$1,015 for autograft, a dynamic plate, and 4 screws, while other combinations of plates and spacers [allograft, PEEK, cages] contributed to the near 10-fold difference in operative costs incurred by other surgeons. Plate cost ranged from \$1,015-\$3,601, allograft spacers from \$1,220-\$3,640, PEEK spacers from \$4,930-\$5,246, and cages from \$1,942-\$4,347. Interestingly, Supply Costs contributed relatively little to the total (variance) of the Surgical Costs and the Operative Costs showed less variability than instrumentation costs.

Fifteen spinal surgeons performed all 102 cases in this series.^[10] However, when number of cases and costs were separately analyzed, the first 6 surgeons (A-F) were found to have performed 79% of the operations (T=81 cases, each surgeon performing 8-20 operations apiece), and their decisions and choices clearly impacted costs.^[10] For instance, the Total Costs for Surgeon A were greater than for the other 5 surgeons (B-F). Surgeon A had an average Total Cost of \$64,887 that was 32% higher than the average Total Cost of \$49,094 noted for the other 5 surgeons (B-F). Surgeon A also had the highest average cost in all categories except Surgical Supplies. Surgeon A’s patients also spent more time in the operating room (avg. 4.6 (surgeon A) versus 4.2 hours (surgeons B-F)), in the recovery room (12.8 versus 8.4 hours), and were hospitalized longer (LOS 4.6 versus 1.7 days) when compared with the other 5 surgeons (B-F). Furthermore, surgeon A’s Total Costs for performing 8 operations (avg. \$64,887, range \$43,422-\$84,281) exceeded the Total Costs of Surgeons E and F, who collectively performed 37 operations (avg. \$44,513 and \$44,509); the range for

Table 2: Costs (Without overhead) of anterior discectomy and fusion grafts, plates, screws, cages performed at one institution (Epstein^[10])

Variable	Minimum	Maximum	Difference	Approximate factor (X)
Total Costs	\$21,626	\$97,086	\$75,460	4.8 X
In-patient Costs	\$15,113	\$76,460	\$61,547	5 X
Range of Costs: Plates	\$1,015	\$3,601		
Range of Costs: Allograft	\$1,220	\$3,640		
Range of Costs: Cages	\$1,942	\$4,347		
Range of Costs: PEEK	\$4,930	\$5,246		

PEEK: Polyether-etherketone

Surgeon E was \$31,698 to \$69,645, and for surgeon F \$21,626 to \$65,077.

Summary Surgeons choices and the choice of surgeons impact the Total Hospital Costs. They influence In-patient Costs as their individual postoperative results utilize different amounts of hospital materials (e.g. studies, tests), and longer lengths of stay. The Surgical Costs, on the other hand, are largely influenced by the individual surgeon's choice of implants; we unfortunately do not yet know the "value added" of these more expensive alternatives.

Operative waste

The concept of operative waste is relatively new to spine surgery, but has been considered in other medical/surgical studies aimed at cost saving.^[16,19,22,39,43]

In a series analyzing patients undergoing elective major colorectal surgery, few patients required perioperative transfusions; therefore, the authors stopped requesting routine preoperative cross matching of blood.^[39] In Heuer, Kaiser, Lendeman et. al. study evaluating patients with acute liver injuries, they determined that liver transplants in carefully selected patients were both cost-effective and life saving.^[19] In another study, the original working hypothesis that 20-30% of Medicare expenditures were wasted for hospitalized patients with multiple medical/surgical disorders was discounted; rather, an overall 10% increase in expenditures resulted in a 3.1%-11.3% decrease in 30-day mortality rates.^[22] An additional study examined the value of obtaining intraoperative cultures for patients with acute appendicitis; it was not cost effective as the 6.4% who developed postoperative infections were symptomatic from different organisms than those isolated during the original surgery.^[16] In Soroceanu, Canacari, Brown et. al., the authors quantified intraoperative waste during spinal surgery, and examined whether an educational program for spinal surgeons would reduce that waste.^[43] Operative waste occurring during the 15 months prior to surgeon education was 20.2%, and was reduced to 10.3% in the 10-month period following surgeon education. The percentage of the operative budget attributed to operative waste prior to surgeon education was 4.3%, and this was reduced following surgeon education to 1.2%.

Summary: Operative waste or explantation, defined as the implantation of a device, its alteration, and removal prior to closing, is an extremely underreported problem. Although there should be a reasonable/anticipated "cost of doing business", it likely should not exceed 5%.

Costs of permanently implanted versus explanted devices following 1-ACDF

Little is known about the costs of permanently implanted devices utilized to perform 1-ACDF while even less has been documented about the costs of explanted devices, defined as those devices that are

initially implanted but are removed and discarded prior to wound closure (altered, bent, screwed in, or otherwise changed so that they must be discarded).^[11,14] In 2009 Epstein, Schwall, and Hood analyzed the cost of implanted versus explanted devices utilized to perform 87 1-ACDF at a single institution [Table 3].^[11] They included patients from all relative DRG categories, and were primarily interested in assessing the cost to the hospital (without overhead) of all implanted and explanted instrumentation (i.e. screws, plates, and spacers [allograft, cages, autograft]). The total cost to the hospital for permanently implanted plates, screws, and spacers was \$355,863; 85 plates=\$120,694 (range \$441 to \$2,025), screws at 4 per 85 cases=\$103,572, allograft spacers 64=\$92,776 (range \$843 to \$2,552), cages (including top/bottom attachments=\$38,821 (range \$1,720 to \$7,928), while there was no device cost associated with 14 iliac crest autografts [Table 3]. The total cost for explantation, defined as the implantation, alteration, and removal of devices prior to closing 1-ADF, was \$32,850, and comprised 9.2% of the cost of implanted devices.^[11] Explantation occurred with the following frequency and associated cost; 7 plates explanted in 5 cases cost \$12,743, 37 screws explanted in 17 cases (range 1-10 per case) cost \$11,014, 8 explanted allograft spacers utilized in 7 cases cost \$9,093, while there were no explanted cages.

Six surgeons performed 76 (87.3%) of 87 cases in this series (7-25 cases each), and all surgeons explanted devices in 12.5% to 46.2% of their cases. The 5 remaining surgeons who performed 4 or fewer operations per surgeon also demonstrated high explantation rates.^[11]

Table 3: Costs of permanently implanted versus explanted devices utilized to perform 87 single-level anterior cervical discectomy and fusion in 2009 at a single institution (Epstein^[11])

Variable for 2009 Study Epstein ^[11]	Total Cost for all Implants	Cost for Plates	Cost for Screws	Cost for Allograft Spacers	Cost for Cages
2009 Implanted Device Costs*	\$355,863	\$120,694	\$103,572	\$92,776	\$38,821
2009 Explanted Device Costs**	\$32,850	\$12,743 (7 plates)	\$11,014 (37 screws)	\$9,093 (8 spacers)	0 (0 cages)
Range of Costs for Items		\$441-\$2,025	\$304/screw (average)	\$843-\$2,552	\$1,720-\$7,928

*Implanted Device Costs= Costs (without overhead) for permanent implants, **Explanted device Costs=Costs (without overhead) for implants placed, revised, and removed prior to closing

Table 4: Summaries of sections

Section	Summary
Fusion Rates For Non-Plated 1-level Anterior Discectomy With (ACDF) or Without Fusion (ACD)	Summary: Multiple studies performing ACD or ACDF without plates for 1-level anterior cervical disease, particularly radiculopathy, have yielded comparable clinical outcomes, but ACD were associated with higher rates of kyphosis, a complication avoided by ACDF.
Non-Plated versus Plated ACDF	Summary: Although plated 1-level ACDF correlated with higher fusion rates versus non-plated 1-ACDF, these differences were not great: 96% vs. 90%. Nevertheless, one must consider the "value added" of the plates, which includes a reduction in the risk of anterior graft extrusion.
Plates and Allograft or Autograft	Summary: Dynamic plates increase fusion rates for 1-level ACDF, as plate migration decreases graft shielding and increases graft compression. Furthermore, like the other plates, the dynamic plate adds the benefit of reducing anterior graft extrusion.
Safety and Efficacy of Allograft, Autograft, Cages, Arthroplasty	Summary of Cages: The data do not clearly indicate that cages are superior to allograft fusions, but seem to show they are at least comparable. Further evaluation of these fusion rates utilizing CT and not just X-ray alone would likely indicate a higher failure rate than has previously been reported. Additionally, the quality of these studies and their ties to industry warrant further assessment.
Arthroplasty versus 1-level ACDF with Allograft and Plates:	Summary: Logically, Riew <i>et al.</i> after reassessing their data for 1-level allograft/plated fusions, should not have just concluded that "its OK, they eventually go on to fuse", but rather that these fusions rates are initially very low for a long period of time, and that, therefore, alternative constructs should be sought.
Animal Studies with Cages:	Summary: To summarize the latter study, neither supplement was superior to autograft. Additionally, in the other studies, cages did not demonstrate clear superiority to other constructs.
Human studies with Cages	Summary: Clinically, cage constructs were associated with "both lower and slower fusion rates". Furthermore the cages were associated with device fragmentation and erosion into the adjacent vertebrae (more severe than simply subsidence).
Outcomes of 1-level ACDF	Summary: Comparable outcomes are largely being reported for 1-level ACDF utilizing a multitude of grafting (autograft, allograft, PEEK, cages, other) and plating techniques (constrained, semi-constrained, dynamic). Nevertheless, iliac crest autograft remains the "gold standard", and in many instances, still produced the highest fusion rates.
Complications of ACDF:	Summary: Complications of 1-level ACDF include the small potential for vertebral artery injury, cerebrospinal fluid fistula, graft or plate extrusion/revision, pseudarthrosis, and infection (appears to be more likely with posterior cervical and/or circumferential surgical procedures). Additionally noted are medical complications, particularly pulmonary embolism.
Complications of Iliac Crest Autograft: Typically Overestimated	Summary: Complication rates for iliac crest autograft harvesting, including pain, are often grossly overestimated and exaggerated. Subsequent studies such as that by Carraggee <i>et al.</i> have questioned whether "bias" introduced by industry-supported studies had led to the over reporting of the risks and complications of harvesting autograft.
More Surgeons, More Operations, More Variations: Where are the data to prove the "Value Added"	Summary: There are more 1-ACDF being performed by more surgeons with marked differences in frequencies of these procedures depending upon where you live in the USA.
Cost Comparisons of Various Approaches to 1-Level ACDF	Summary: Iliac autograft, utilized to perform 1-level ACDF costs \$0.00, while other spacers like allograft may cost (without overhead; what the hospital actually pays) up to \$2,552 for grafts, with cages costing up to \$7,928. Nevertheless, the different constructs have other pros and cons, and in many instances, actual hospital costs may equalize so long as BMP/INFUSE is not utilized.
Cost Benefit using more complex approaches	Summary: It appears that utilization of PEEK, BMP, etc have a higher cost and complication rate. In Carragge <i>et al.</i> study, they reported a 40% incidence of complications following the use of rhBMP-2 / Infuse for anterior cervical surgery, resulting in postoperative neck swelling, seroma, and hematoma.
1-level ACDF Performed at a Single Institution	Summary: Surgeons choices and the choice of surgeons impact the Total Hospital Costs. They influence In-patient Costs as their individual postoperative results utilize different amounts of hospital materials (e.g. studies, tests), and longer lengths of stay. The Surgical Costs, on the other hand, are largely influence by the individual surgeon's choice of implants; we unfortunately do not yet know the "value added" of these more expensive alternatives.
Operative Waste	Summary: Operative waste or explantation, defined as the implantation of a device, its alteration, and removal prior to closing, is an extremely underreported problem. Although there should be a reasonable/ anticipated "cost of doing business", it likely should not exceed 5%.
Costs of Permanently Implanted Versus Explanted Devices Following 1-ACDF	Summary: Explantation, the implantation (alteration so it cannot be used again) but removal of instrumentation prior to closing, occurs during spinal surgery; but at what cost? In 2009, the total costs of explantation added to the total budget for all implanted devices utilized to perform 87 1-ACDF; this substantial operative waste must be curtailed.
Education Measures to Reduce Explantation for Single-Level ADF	Summary: At one institution in 2010, educating surgeons (two meetings) regarding the need to avoid explanting devices utilized for 1-level ACDF surgery, substantially reduced the cost of explanted devices from 20.0% to 5.8%.

Summary: *Explantation, the implantation (alteration so it cannot be used again) but removal of instrumentation prior to closing, occurs during spinal surgery; but at what cost? In 2009, the total costs of explantation added to the total budget for all implanted devices utilized to perform 87 1-ACDF; this substantial operative waste must be curtailed.*

Education measures to reduce explantation for Single-level ADF

Determining in 2009, that explantation of instrumentation substantially added to the costs of performing 1-ACDF, Epstein *et al.*, prospectively evaluated the costs/frequency of explanting instrumentation in 1-ACDF in 2010 at the same single institution before and after surgeon-education.^[14] During the first 4 months of 2010 (Jan.-Apr.), spine surgeons were unaware of concerns regarding explantation. At the end of April 2010, spinal surgeons underwent two educational sessions regarding the inherent explantation costs and their frequency. Explantation rates were then tracked for the remaining 8 months (May-Dec.) of 2010. The educational impact on explanation costs and frequency for these two periods were then compared, and contrasted with the prior results from 2009.^[11,14] The total explantation rate for 2009 was 24 (27.6%) in the 87 1-ACDF performed at one institution.^[11] In 2010, prior to surgeon education, instrumentation was explanted in 45.5% of the cases. Following surgeon education, explanation occurred in 16% of cases.^[14] The individual device-related explanation rates were also reduced following surgeon education: screws (12.5% before education versus 7.7% after education), plates (9.4% versus 0%), and allograft spacers (7.1% versus 2.9%). In 2010, the overall cost of explanted devices presented as a percent of implanted devices was lower after surgeon-education (5.8%), than before surgeon-education in 2010 (20.0%) or 2009 (9.2%). It appeared that the frequency and cost of explanted instrumentation utilized to perform 1-ADF were significantly reduced through surgeon education.

Summary: *At one institution in 2010, educating surgeons (two meetings) regarding the need to avoid explanting devices utilized for 1-level ACDF surgery, substantially reduced the cost of explanted devices from 20.0% to 5.8%*

CONCLUSIONS

More spinal surgeons and greater interest from industry in promoting spinal instrumentation has led to an overuse of many spinal implants [Table 4]. Although there are many published reports about the pros and cons of these different constructs, design flaws, and “bias” have led to the questioning of the validity of some of the reported results/outcomes.

Furthermore, little attention has been paid to the

“value added” of these constructs, much less their costs. However, with the escalating cost of medical care, spine surgeons in the future must participate in correlating fusion rates and outcomes with relative costs of different instrumentation systems utilized to perform 1-ACDF [Table 4]. This review reaffirms the value of iliac crest autograft and dynamic plates in performing 1-level ACDF producing predominantly good/excellent outcomes and high fusion rates, at lower cost. Despite the manufacturing industry looking after major economic interests and promoting instrumentation, spine surgeons should focus on the “value added” of iliac crest autograft, quality of outcomes, fusion rates, and cost containment.

Opportunities for cost saving should also extend to minimizing the rate of explantation, the placement, adjustment (no longer reusable), and removal of a device, prior to closure. Should there be an acceptable explantation rate for spinal procedures allocated to the cost of doing business? Although the spine literature has not readily addressed this issue, a hypothetical 5%-10% explantation rate for spinal procedures may be appropriate. Establishing an acceptable rate alone could substantially reduce the present added costs of “explantation” incurred during anterior cervical surgery as discussed in this series.

Furthermore, the costs and frequency of explantation involving 1-ACDF may represent only the “tip of the iceberg” as it is likely that much higher costs will be identified for more extensive spinal procedures. These findings should encourage more institutions to develop and institute “surgeon-education” and “enhanced practices” to reduce the costs/frequency of such explantation during all spine operations.

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