



Safety and Effectiveness of Bone Allografts in Anterior Cervical Discectomy and Fusion Surgery

By Larry E. Miller, Ph.D. and Jon E. Block, Ph.D.

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INTRODUCTION

Most patients with symptomatic and radiographically confirmed cervical radiculopathy who are unresponsive to at least 6 weeks of conservative medical care realize immediate and sustained clinical benefit from surgical treatment that includes *en masse* disc excision coupled with osteophyte removal to decompress the nerve roots at the affected level.^{1,2} However, this procedure results in structural alterations that are less than optimal from an anatomic and biomechanical standpoint. Consequently, despite satisfactory clinical outcomes, cervical discectomy and neural decompression alone almost always results in disc space collapse.^{3,4}

In order to maintain disc height and stability after discectomy, an interbody instrumented fusion procedure is commonly performed. In fact, anterior cervical discectomy and fusion (ACDF) remains the standard of care for patients presenting with recalcitrant radiculopathy or myelopathy due to cervical disc herniation or cervical spondylosis. Following surgical disc removal, the residual empty space is typically filled with a structural bone graft, synthetic cage, or other interbody spacer. In many cases, external fixation devices such as plates and screws are also used for additional support to promote fusion. Two types of supplemental bone grafts are traditionally used in ACDF surgery—autograft and allograft.

Historically, autologous bone harvested from the patient's iliac crest has been used as the interbody spacer, thereby requiring a separate surgical site. The use of bone autografts in ACDF has several well documented shortcomings including extended operative duration, lingering chronic pain at the donor site, and interference with daily activities caused by this secondary surgical procedure.⁵

In contrast, allogeneic bone grafts (Figure 1) avoid the complications associated with harvesting bone from a patient. Allograft material is obtained from deceased human donors, undergoes rigorous safety screening, and is transplanted into the patient at the time of surgery. Allografts have an excellent safety and effectiveness profile and have been used with increasing frequency in ACDF surgery.

Figure 1: VG2® Cervical Allograft



An alternative to using autologous or allogeneic bone grafts during ACDF is the use of cages that are often filled with morselized autologous bone from the surrounding area supplemented with bone graft substitutes (such as crushed allograft, demineralized bone matrix, or synthetics such as calcium phosphate and/or hydroxyapatite). The purpose of cages is to support the segment while bony fusion is promoted through the central void filled with grafting material.

In an effort to preserve natural motion at the affected level and to reduce the likelihood of purported adjacent segment degeneration, there has been a concerted effort to develop artificial disc replacement devices for treatment of patients with symptomatic compressive neuropathies.⁶ Indeed, clinical trials of cervical disc arthroplasty versus the current “gold standard”, ACDF with allograft, have demonstrated similar short-term clinical benefit in patients with symptomatic cervical disease.⁷⁻⁹ However, despite recent marketing approvals by US regulators of several artificial cervical discs, arthroplasty is a new technique with limited long-term patient data available.¹⁰

The primary objective of this systematic review is to provide an evaluation of published studies that directly compared clinical and radiographic outcomes with ACDF using allograft versus ACDF with autograft, ACDF using cages with or without bone graft substitute, and cervical disc arthroplasty for the treatment of symptomatic cervical disc disease.

METHODS

Study Selection

An initial search of MEDLINE was conducted for articles using the following keywords:

- 1) Anterior cervical discectomy,
AND
- 2) Fusion, spondylodesis, or spondylosyndesis,
AND
- 3) Allograft, or allogeneic, or homograft

The reference lists of relevant review articles were also screened for possible study inclusion. In total, we identified and reviewed titles and abstracts of over 500 studies.

We then applied the following study selection criteria: (1) comparative studies of ACDF using bone allograft versus ACDF with autograft, ACDF using cages with or without bone graft substitute, and/or cervical disc arthroplasty, (2) published in an English

language journal between August 1990 and August 2009, (3) sample size of more than 10 subjects in each treatment group, (4) study reported at least one of the following outcomes: neck and/or arm pain using a visual analogue scale (VAS), neck disability index (NDI), quality of life with PCS (Physical Component Summary) and/or MCS (Mental Component Summary) scores of the SF-36, radiographic fusion rate, wound infection, dysphagia, and adjacent segment degeneration, and (5) if multiple studies used common patients, only the most recent study was chosen for analysis.

Using these criteria, we refined our search to 47 potential studies for inclusion in this systematic review. After reviewing the full-text of these manuscripts, we excluded 27 additional trials for the following reasons: common patients from other studies (n=9), unable to differentiate outcomes between groups (n=8), no relevant outcomes reported (n=6), sample size of less than 10 subjects in at least one study group (n=2), and other (n=2). Ultimately, 21 comparisons from 20 studies^{7-9,11-27} formed the basis for this systematic review. One study reported outcomes of allograft versus three comparison groups¹³ and outcomes from two manuscripts on discectomy were combined into a single comparison for data analyses because the patients and follow-up period were identical, but different variables were reported in each paper.^{7,12}

Data Collection

Study data were entered using a pre-designed database. The following data were abstracted from each article: first author's name, journal name, publication year, study design, surgical technique, sample size, age, gender, length of clinical and radiographic follow-up, neck and arm pain using a VAS, NDI, PCS, MCS, radiographic fusion rate, and clinically relevant adverse events (e.g., wound infection, dysphagia, adjacent segment degeneration) for each group. For studies that reported multiple observations over time, we recorded patient outcomes from the latest follow-up period.

RESULTS

This report includes data from four distinct treatment groups: ACDF with allograft (Allograft, n=1,341), ACDF with autograft (Autograft, n=568), ACDF using cages with or without bone graft substitute (Cage, n=87) and cervical disc arthroplasty (Arthroplasty, n=603). Four trials, all studies of Arthroplasty vs. Allograft, were prospective randomized studies.^{8,9,12,20} The remainder were prospective and nonrandomized^{11,13,14,16,21,22,24,26} or retrospective^{15,17-19,23,25,27} in nature. Eight Allograft studies used bone allografts without the use of instrumentation^{11,14,15,17,19,23,24,26} while the remainder utilized allograft with plate,^{8,9,12,18,21,22,25,27} allograft with plate and cage,^{13,20} and allograft with bone morphogenetic protein and variable instrumentation.¹⁶

Baseline Characteristics

Baseline patient characteristics were well balanced among the four study groups (Table 1). The median radiographic follow-up time was notably shorter in the Autograft group (12 months) compared to the other groups (19-24 months).

Table 1: Baseline Characteristics

Characteristic	Allograft (n=1,341)	Autograft (n=568)	Cage (n=87)	Arthroplasty (n=603)
Number of Studies	20	12	4	5
Study Sample Size	35 (10-292)	34 (13-148)	19 (13-37)	103 (15-242)
Males, %	50 (41-63)	54 (33-67)	48 (32-69)	46 (45-60)
Age, y	45 (35-56)	45 (35-48)	47 (38-64)	43 (34-44)
Radiographic Follow-up, mos	19 (3-48)	12 (3-83)	21 (6-24)	24 (12-24)
Clinical Follow-up, mos	24 (3-48)	29 (3-83)	21 (6-31)	24 (12-31)

All data presented as median values (range).

Neck and Arm Pain

Neck and/or arm pain were reported in 8 studies.^{8,9,12,13,16,20,25,27} Neck pain measured with a VAS was reduced by 63-69% in all groups post-treatment (Figure 2). All studies reported neck pain improvement of at least 50% except for the Arthroplasty cohort of the Bhadra study.¹³ Arm pain improved 75% in the Allograft group and

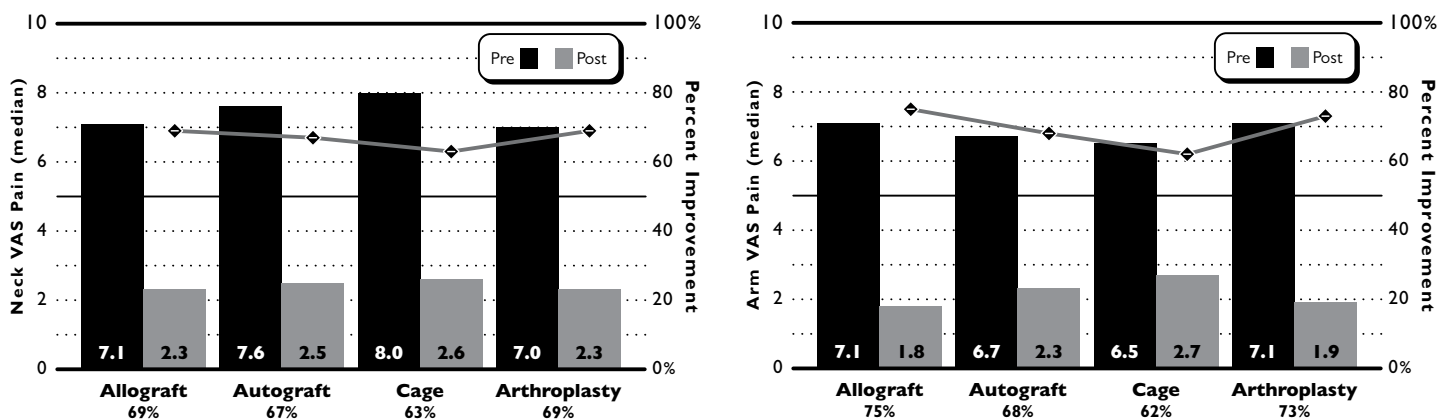


Figure 2. Median absolute and percent improvement in VAS neck (left) and arm (right) pain following treatment with Allograft, Autograft, Instrumentation, and Arthroplasty.

was notably greater than Autograft (68%) and Cage (62%). All studies reported at least a 50% reduction in arm pain following treatment.

Neck Disability Index

Patient outcomes on the NDI were reported in 5 studies.^{8,9,12,16,27} There was notable improvement in neck disability (61-65%) in the Allograft and Arthroplasty groups following treatment (Figure 3). Although Autograft improved by 76%, this outcome was reported in only 1 study of 36 patients.¹⁶ Similarly, the 46% improvement with Cage was reported in only a single trial of 22 patients.²⁷

Quality of Life

Quality of life outcomes were not reported in any study using Autograft or Cage and in only 2 studies overall, representing 2 Allograft groups and 2 Arthroplasty groups.^{8,12} PCS scores similarly improved in Allograft (42%) and Arthroplasty (44%) groups (Figure 4). MCS scores improved modestly (16-21%) in the Allograft and Arthroplasty groups.

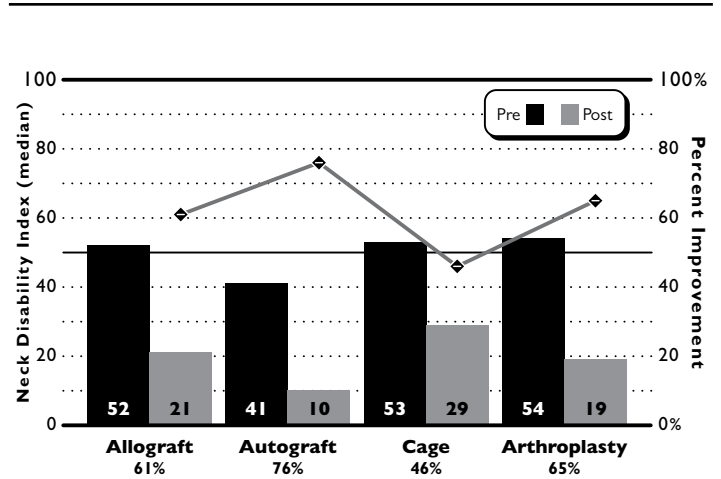


Figure 3: Median absolute and percent improvement in Neck Disability Index (NDI) following treatment with Allograft, Autograft, Instrumentation, and Arthroplasty.

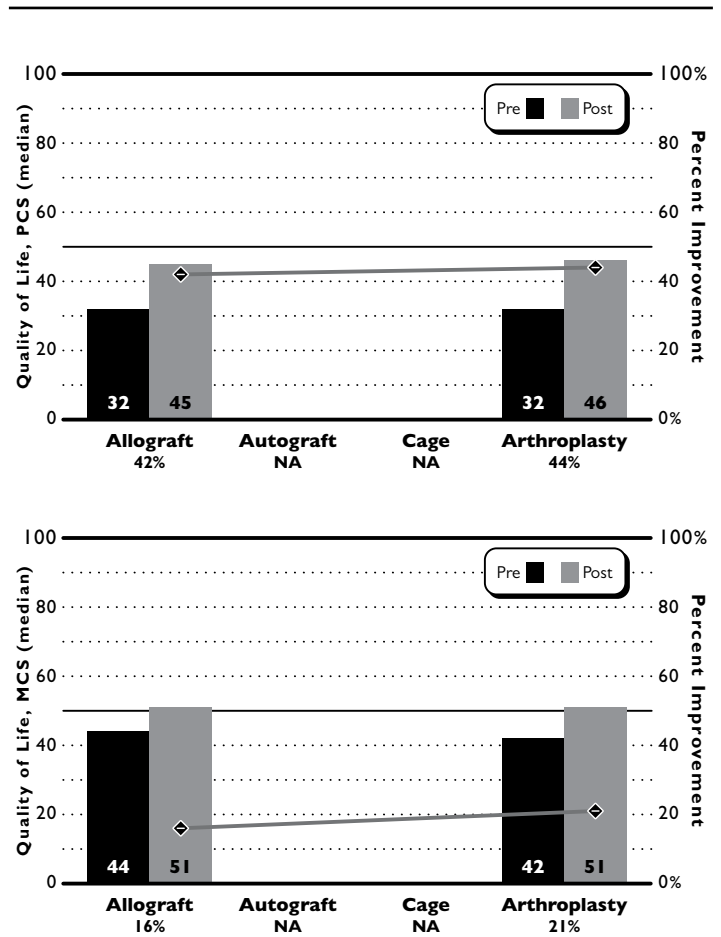


Figure 4: Median absolute and percent improvement in the Physical Component Summary (PCS) scores (top) and Mental Component Summary (MCS) scores (bottom) of the SF-36 following treatment with Allograft and Arthroplasty.

Radiographic Fusion Rates

Fusion rates were reported in 14 studies of Allograft, Autograft, and Cage.^{11,13-19,21-25,27} The fusion rates, analyzed by number of treated levels, were 91% in the Allograft group and Autograft groups (Table 2). Although fusion rates of 97% were observed with Cage, the small number of reported levels (n=69) makes this analysis somewhat unreliable.

Table 2: Radiographic Fusion Success

Variable	Allograft	Autograft	Cage
Fusion Success / Levels, (%)	949/1042 (91)	751/826 (91)	67/69 (97)

Adverse Events

Wound infection at the surgical site was reported in 7 studies^{9,12,13,19,25-27} and was uncommon (0.9% overall), regardless of treatment type (Table 3). Dysphagia was reported in 8 studies^{8,9,12,13,19,25-27} and was notably higher in the Cage group (19.5%) vs. other groups (0-4.8%). The study of Vaidya and colleagues²⁷ reported dysphagia in 85% of Cage patients, thereby heavily influencing the outcomes in the Cage group because of the smaller sample size. Adjacent segment degeneration was reported in 6 studies^{8,13,16,25-27} with no notable differences among groups.

Table 3: Adverse Events

Event	Allograft	Autograft	Cage	Arthroplasty
Wound Infection, (%)	2/505 (0.4)	0/26 (0)	0/87 (0)	7/345 (2.0)
Dysphagia, (%)	30/703 (4.3)	0/26 (0)	17/87 (19.5)	27/568 (4.8)
Adjacent Segment Degeneration, (%)	10/377 (2.7)	2/58 (3.4)	0/87 (0)	3/223 (1.3)

Supplementary Cage Study Outcomes

Due to the paucity of comparative data for subjects who underwent ACDF using cages with or without bone graft substitute, we identified additional studies that reported at least 2-year patient outcomes to corroborate the results identified in our literature review. Debusscher and colleagues²⁸ treated 20 patients with ACDF using a composite resorbable cage and plating and followed all patients through a mean of 27 months post-treatment. Improvements were observed in neck pain (55%), arm pain (83%), and NDI (65%) while fusion success was 96%. Chiang et al.²⁹ treated 56 patients with ACDF and a cage with bovine xenograft bone graft substitute. At 3-5 years of follow-up, radiographic fusion was 100% and no reoperations were required. Dai and coworkers demonstrated that 2-year patient outcomes were similar following ACDF utilizing a cage containing tricalcium phosphate with (n=33) or without (n=29) plating.³⁰ Neck pain declined ~70% and arm pain decreased ~60% in each group. Overall, these study outcomes are supportive of those identified in the systematic review.

DISCUSSION

The results of this systematic review demonstrate that ACDF, regardless of bone graft material or instrumentation, and cervical disc arthroplasty each result in successful mid-term clinical and radiographic outcomes. Despite the similarities in outcomes found in this systematic review, there are a number of advantages to using allografts instead of autografts, cages with or without bone graft substitute, or artificial discs.

No Risk of Donor Site Morbidity

The use of allografts avoids the common complication of donor site morbidity that occurs with autogenic bone grafting.^{5,31-33} Autograft bone harvest is responsible for a protracted return to normal activities,^{34,35} ambulation difficulty in over 50% of patients,³⁵ chronic pain in 26% of cases (almost half of which require pain medication),³⁵ and poor long-term graft site appearance in 1 of 6 patients.³⁶ Most spine surgeons now use allograft materials for ACDF surgery to avoid these complications.

Safety and Sterility

Allograft donor tissue may be obtained from a variety of sources. While generally considered a safe material for use as a biological implant, not all processors treat tissues the same way. Many of the leading tissue processors provide tissues using a process that has been validated to achieve the same sterility level as synthetic medical devices and has been shown to eliminate viruses. Allograft donors must have no history of HIV, hepatitis, and autoimmune disorder. The allograft bone grafts available from bone banks should undergo strict screening and recovery processes that conform to Food and Drug Administration (FDA) and American Association of Tissue Banks (AATB) standards. The recovered bone tissue, as well as other tissues, are then tested for microbiological contamination. Tissue is then subjected to a cleaning regimen, and sometimes a sterilization process is performed. It is important for the clinician to understand the source and processing method of allograft tissues for use in their practice.

Cost Effectiveness

There are distinct cost advantages associated with allogeneic bone grafting versus autograft or synthetic cages. It is well established that bone allografts are cost effective and offer significant gains in quality-adjusted life years in the setting of lumbar fusion.³⁷ For cervical fusion procedures, autografts cost almost twice that of allografts¹³; these additional costs are primarily attributable to harvest site morbidity. Synthetic cages, which in recent years have begun to match allograft costs, must still be filled with additional material thereby raising the total cost of the implant by 50% or more. Arthroplasty is the most expensive of the four options (largely due to the significantly more complicated surgical technique, longer operation time, and premium cost of the implant) but offers no proven long-term clinical advantages.

Excellent Patient Outcomes

Numerous studies have concluded that ACDF with allograft results in clinically satisfactory outcomes for patients with recalcitrant cervical radiculopathy and myelopathy. The results of this systematic review corroborate this conclusion. Allograft with ACDF results in dramatic pain relief, improvements in disability and quality of life, high fusion rates, and a low incidence of adverse events. No distinct differences in clinical or radiographic mid-term outcomes were observed among the Allograft, Autograft, Cage, and Arthroplasty groups.

Long-Term Clinical Data

Bone allograft materials have been used in cervical surgery for decades.^{17,24} Conversely, synthetic cages and cervical disc arthroplasty devices are more recent additions to the market. In fact, the first cervical disc arthroplasty device was approved by the FDA in 2007. Obviously, a major limitation of cages and cervical disc arthroplasty devices is that long-term patient outcomes with these synthetic devices are unknown.¹⁰

CONCLUSIONS

Based on a systematic review of the peer-reviewed literature, we conclude that bone allograft material is a safe and effective adjunct to ACDF for the treatment of patients with recalcitrant cervical radiculopathy and myelopathy. Furthermore, when considering additional factors such as donor site morbidity and the higher cost of ACDF with autograft, the high cost and alarmingly high dysphagia rates associated with cages, and the high cost and unknown long-term outcomes of arthroplasty (Table 4), ACDF surgery with allograft offers distinct advantages. It is clear that with recent advances in sterilization and in virus reduction technologies, allograft material is a superior adjunct to ACDF procedures.

Table 4: Overall Evaluation of ACDF with Allograft, ACDF with Autograft, ACDF with Cage, and Cervical Disc Arthroplasty

Evaluation	Allograft	Autograft	Cage	Arthroplasty
Procedural Safety	★★★	★★★	★★★	★★★
Performance	★★★	★★★	★★★	★★★
Post-operative Morbidity	★★★	★○○	★○○	★★★
Cost Effectiveness	★★★	★○○	★★○	★○○
Long-term Patient Outcome	★★★	★★○	★★○	??

★★★ Excellent ★★○ Average ★○○ Poor ?? Unknown

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