Anterior Cervical Spine Fusion Rates Using a Frozen Laminated Composite Allograft and Plating

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Abstract

Cervical disc herniation and cervical spondylosis presenting with radiculopathy, myelopathy or both are common conditions treated by spine surgeons. Anterior cervical discectomy and fusion (ACDF) provides for direct decompression of the involved neural elements and stabilization of the involved vertebral segments. Autologous cortico-cancellous bone graft, harvested from the iliac crest is considered the "gold standard" for grafting material. Bone graft donor site pain and morbidity, as well as increased operative time have led to a trend toward alternatives to iliac crest bone graft harvesting. The most commonly used substitute for autologous bone graft is human cadaveric allograft bone. This multicenter study retrospectively reviewed a cohort of patients who underwent anterior cervical discectomy and fusion using a machined, frozen, cortico-cancellous allograft and anterior plating. Observed fusion rates compared favorably with published results for single-level ACDF. For multi-level ACDF fusion rate was substantially higher than that of most published series.

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INTRODUCTION

Cervical disc herniation and cervical spondylosis presenting with radiculopathy, myelopathy or both are common conditions treated by spine surgeons. These conditions, when treated surgically, may be approached anteriorly or posteriorly. Anterior cervical discectomy and fusion (ACDF) provides for direct decompression of the involved neural elements and stabilization of the involved vertebral segments. Autologous cortico-cancellous bone graft, harvested from the iliac crest, has traditionally been the most common graft material used in ACDF. It possesses osteogenic, osteoinductive and osteoconductive properties. The cortical portion of the graft, with its greater mechanical strength, provides structural support, while the cancellous portion provides a favorable environment for vascular ingrowth. While the use of autologous iliac crest bone graft has long been regarded the “gold standard”, increasing numbers of spine surgeons are abandoning its use in favor of non-autologous fusion materials. Bone graft donor site pain and morbidity, as well as increased operative time are factors cited by surgeons for this trend([6]). The ideal autologous bone graft substitute would be stable in axial compression, thus resisting displacement and excess subsidence. In addition, it would possess osteogenic, osteoinductive and osteoconductive properties. There are presently a number of different options available for use in anterior cervical spine fusions; however, none possess all of the above properties. They include titanium spacers and cages, hydroxyapatite, biocompatible osteoinductive polymers, ceramics, demineralized bone matrix and BMP. The most commonly used substitute for autologous bone graft however, is human cadaveric allogeneic bone.

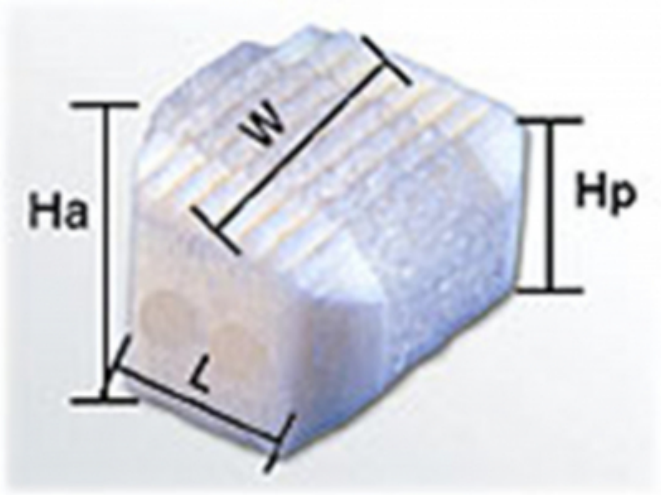
Allograft bone products are considered highly osteoconductive, weakly osteoinductive and non-osteogenic. Freeze-dried allografts may be stored at room temperature and have an indefinite shelf life, making them a convenient alternative. However, the process of freeze-drying can reduce mechanical strength by 50% compared with frozen grafts([9,22]). Most studies reporting on the use of freeze-dried iliac crest allografts cite a high graft collapse rate. Allogeneic fibula has also been used as an effective substitute for autologous iliac crest in ACDF. Despite their successful use, all freeze-dried grafts are subject to breakage, collapse and wide anatomical variation. Frozen allografts that are kept at -20°C do not have decreased mechanical strength and can be stored for up to 1 year([22]). An increasing

number of proprietary machined or milled frozen allografts are becoming available from a number of commercial distributors. The purpose of this study was to evaluate the fusion rate in single and multilevel ACDF using a proprietary frozen laminated composite allograft.

METHODS

This multicenter study retrospectively reviewed a cohort of patients who underwent anterior cervical discectomy and fusion using VG2™ Cervical Allograft (DePuy Spine/LifeNet) and anterior plating. VG2™ Cervical Allograft is a machined, frozen, cortico-cancellous allograft comprised of two cortical planks of bone surrounding a cancellous center (Figure 1).

Figure 1



The cortical planks provide strength for anterior column support. The cancellous bone provides a lattice for remodeling, thus ensuring an osteoconductive environment. 92 patients with 146 fusion levels were included and followed for two years. All patients underwent either a single-level or multi-level ACDF by one of the two spine surgeon authors, using the Smith-Robinson technique. A rigid plate was used on all single-level cases. Multi-level cases were instrumented with either a rigid plate or dynamic plate depending upon surgeon preference. Follow-up radiographs were obtained at six weeks and three months postoperatively. Additional interval studies were obtained as clinically or radiographically indicated for up to two years or until fusion was observed. Lateral cervical spine radiographs were presented in a random fashion with regard to patient identity and examination date and assessed by three evaluators, an orthopaedic spine surgeon, a musculoskeletal radiologist and a senior orthopaedic surgery resident.

Evaluators were blinded with regard to surgery date, outcome and all other clinical and patient data. Fusion was identified by the absence of a radiolucent gap between the graft and the endplate; and the presence of continuous, bridging, bony trabeculae at the graft-endplate junction. A pseudarthrosis was identified radiographically by the absence of bridging, osseous, trabecular bone from the vertebral bodies to the graft and the presence of a lucent line at the graft-vertebral body junction. Fusion was assumed if at least two of the three evaluators identified a given level as such.

Figure 2

Figure 2: A 40-year-old male with a C6-7 disc herniation. A) Preoperative lateral radiograph demonstrates mild disc space narrowing. B) 1-month postoperative radiograph after ACDF with VG2 Cervical Allograft and DOCÂ™ Ventral Cervical Plating System at C6-7. C) 6-month postoperative radiograph showing solid fusion at C6-7.

Figure 3

Figure 4

RESULTS

Of the 146 attempted fusion levels, 138 (94.5%) were identified as having a solid fusion. Of the 51 patients with single-level ACDF 48 (94.1%) had a solid fusion. The numbers of fused and non-fused segments per vertebral level are shown in Table 1. No statistical significance was found with regards to fusion rate and vertebral level (p=0.276).

Figure 5

Table 1: Attempted Single Level Fusions By Cervical Level

Vertebral Level	C3-C4	C4-C5	C5-C6	C6-C7	C7-T1
# Fused	1	7	23	16	1
# Non-fused	0	0	1	2	0

In patients who underwent multi-level ACDF, 90 of 95 levels (94.7%) attained a solid fusion, with a solid fusion rate by patient (fusion at all operative levels) of 90.2% (37/41). One (1) patient in the non-fused group failed to fuse at both attempted levels (C5-C6 and C6-C7), the other three patients failed at the uppermost operative level (C3-C4 or C4-C5). Table 2 outlines the number of fused and non-fused segments per vertebral level. No statistical significance was found with regards to fusion rate and vertebral level (p=0.505).

Figure 6

Table 2: Attempted Multiple Level Fusions By Cervical Level

Vertebral Level	C3-C4	C4-C5	C5-C6	C6-C7	C7-T1
# Fused	7	22	37	24	0
# Non-fused	2	1	1	1	0

DISCUSSION

Despite being considered the “gold standard”, there is a trend away from using autologous iliac crest bone graft that is supported by reports that outline a variety of acute and chronic complications related to the donor site([6,21,23,27,34]). Complications including pain, difficulty with ambulation, infection, wound drainage and impairment of work and recreational activities have been reported. A variety of materials have been tried as fusion substrates with variable results. One of the most widely used materials is freeze dried fibular allograft. It has a fusion rate of 70% to 92% when used in ACDF. Its use is complicated by the reduction in strength that comes from freeze-drying([7,9,22]), and the inconsistency in size and quality that is inherent in non-machined allograft bone. Freeze dried allografts have also been shown to have a higher rate of subsidence and collapse([24]). Recently the pursuit of the ideal ACDF fusion substrate has led many manufacturers to produce machined allografts that attempt to incorporate structural stability while maintaining osteoinductive and osteoconductive properties. Most of these products are fresh frozen to avoid the complications associated with freeze-drying.

The VG2™ Cervical Allograft tested here is a fresh frozen machined composite allograft that addresses the concerns

mentioned above. It generates strength through its outer cortical planks and maintains the ostoeconductive properties of the cancellous bone that comprises its inner lamina. Implant specific rasps, sizing guides and insertion tools allow for easy insertion and implant size selection. We are unaware of any previous studies that evaluate fusion rates of machined cortico-cancellous allografts.

The reported fusion rate for unplated single-level ACDF using autologous iliac crest bone graft is 83% to 100%([1,2,10,11,13,16,17,18,19,20,22,24,30,31,33]) depending on the series cited. Fusion rates for multi-level ACDF are generally lower. Published studies report a fusion rate for unplated two-level ACDF using autologous iliac crest bone graft of 50% to 75%([1,2,10,11,13,16,18,20,22,33,35]). Recent reports of multi level ACDF utilizing an anterior plate have shown improved fusion rates when compared to unplated multilevel fusions. Fusion rates from 47% to 100% have been reported utilizing autologous iliac crest or cortical allograft with an anterior plate([3,4,5,8,14,15,25,26,28,29]). Our results compare favorably with published results for single-level ACDF. For multi-level ACDF our fusion rate was substantially higher than that of most published series and as high as the best reported results. VG2™ Cervical Allograft demonstrates fusion rates similar to or better than those reported for autologous iliac crest and freeze-dried iliac crest or fibular allografts. The reported data did not take into account lower fusion rates seen in smokers.

Figure 7

Figure 3: A 39-year-old male with cervical spondylosis ar C5-C7. A) Preoperative lateral radiograph. B) An immediate postoperative radiograph after ACDF vith VG2 Cervical Allograft and DOCÂ™ Rod Plating at C5-C7. C) Lateral radiograph at 1 year postop showing solid fusion at both levels.

Figure 8

Figure 9

References

1. An HS, Simpson JM, Glover JM, et al: Comparison between allograft plus demineralized bone matrix versus autograft in anterior cervical fusion: A prospective multicenter study. Spine 20:2211-16, 1995.
2. Bishop RC, Moore KA, Hadley MN: Anterior cervical interbody fusion using autogeneic and allogenic bone graft substrate: a prospective comparative analysis. J Neurosurgery 85(2):206-10, 1996.
3. Bolesta MJ, Rechtime GR 2nd, Chrin AM: Three- and four-level anterior cervical discectomy and fusion plate fixation: a prospective study. Spine 25(16):2040-4; discussion 2045-6, 2000.
4. Bose B: Anterior cervical fusion using Caspar plating: Analysis of results and review of the literature. Surg Neurol 49:25-31, 1998.
5. Bose B: Anterior cervical instrumentation enhances rates in multilevel reconstruction in smokers. J Spinal Disorders 14(1):3-9, 2001.
6. Brown C, Eismont F: Complications in spinal fusion. Orthop clin North Am 29:679-99, 1998.
7. Buttermann GR, Glazer PA, Bradford DS: The use of bone allografts in the spine. Clincical Orthopaedics and Related Research (324):75-85, 1996.
8. Connolly PJ, Esses SI, Kostuik JP: Anterior cervical fusion: Outcome analysis of patients fused with and without anterior cervical plates. J Spinal Disorders 9:202-6, 1996.
9. Cornu O, Banse X, Docquier PL, Luyckx S, Delloye C: Effect of Freeze drying and gamma irradiation on the mechanical properties of human cancellous bone. J Orthop Res 18(3):426-31, 2000
10. Epstein NE: Anterior cervical diskectomy and fusion without plate instrumentation in 178 patients. J Spinal Disorders 13(1):1-8, 2000.
11. Fernybough JC, White JI, LaRocca H: Fusion rates in multilevel cervical spondylosis comparing allograft fibula with autograft fibula in 126 patients. Spine 16(10 Suppl):S561-4, 1991.
12. Gore DR, Sepic SB: Anterior cervical fusion for degenerated or protruded discs: A review of one hundred forty-six patients. Spine 9:667-671, 1984.
13. Grossman W, Peppelman WC, Baum JA, Kraus DR: The use of freeze-dried fibular allograft in anterior cervical fusion. Spine 17(5):565-9, 1992.
14. Heidecke V, Rainov NG, Burkert W: Anterior cervical fusion with the Orion locking plate system. Spine 23:1796-1802, 1998.
15. Kaiser MG, Haid RW Jr, Subach BR, Barnes B, Rodts GE Jr: Anterior cervical plating enhances arthrodesis after discectomy and fusion with cortical allograft. Neurosurgery 50(2):229-36; discussion 236-8, 2002.
16. Krag MH, Robertson PA, Johnson CC, et al: Anterior cervical fusion a modified tricortical bone graft: A radiographic analysis of outcome. J Spinal Disorders 10:420-30, 1997.
17. Malloy KM, Hilibrand AS: Autograft versus allograft in degenerative cervical disease. Clinical Orthopaedics and Related Research (394):27-38, 2002.
18. Martin GJ, Haid RW Jr, MacMillan M, Rodts GE Jr, Berkman R, Wetzel FT: Anterior cervical discectomy with freeze-dried fibula allograft. Spine 24:852-859, 1999.
19. McGuire RA, St. John K: Comparison of anterior cervical fusions using autogenous bone graft obtained from the cervical vertebrae to the modified Smith-Robinson technique. J Spinal Disorders 7:499-503, 1994.
20. Mutoh N, Shinomiya K, Furuya K, et al: Pseudoarthrosis and delayed union after anterior cervical fusion. Int Orthop

17:286-9, 1993.
21. Rawlinson J: Morbidity after anterior cervical decompression and fusion: The influence of the donor site on recovery, and the results of a trial of surgibone compared to autologous bone. Acta Neurochir (Wien) 131:106-18, 1994.
22. Sandhu HS, Grewal BS, Parvataneni H: Bone graft substitutes: Clinical applications. Orthopedic Clinics of North America Vol 30 Num 4, 1999.
23. Schnee CL, Freese A, Weil RJ, Marcotte PJ: Analysis of harvest morbidity and radiographic outcome using autograft for anterior cervical fusion. Spine 22:2222-7, 1997.
24. Segal HD, Harway RA: The use of fibular grafts with anterior cervical fusion. Orthopaedic Review 21:367-9, 1992.
25. Shapiro S: Banked fibula and the locking anterior cervical plate in anterior cervical fusions following cervical discectomy. J Neurosurgery 85(4):736-7, 1996.
26. Shapiro S, Connolly P, Donnaldson J, Abel T: Cadaveric fibula, locking plate, and allogenic bone matrix for anterior cervical fusions after cervical discectomy for radiculopathy or myelopathy. J Neurosurgery 95(1 Suppl):43-50, 2001.
27. Silber JS, Anderson DG, Daffner SD, Brislin BT, Leland JM, Hilibrand AS, Vaccaro AR, Albert TJ: Donor site morbidity after anterior iliac crest bone harvest for single-level anterior cervical discectomy and fusion. Spine 28(2):134-9, 2003.
28. Wang JC, McDonough PW, Endow KK, Delamarter RB: Increased fusion rates with cervical plating for two-level anterior cervical discectomy and fusion. Spine 25(1):41-5, 2000.
29. Wang JC, McDonough PW, Kanim LE, Endow KK, Delamarter RB: Increased fusion rates with cervical plating for three-level anterior cervical discectomy and fusion. Spine 26(6):643-6; discussion 646-7, 2001.
30. Wigfield CC, Nelson RJ: Nonautologous interbody fusion materials in cervical spine surgery. How strong is the evidence to justify their use? Spine 26(6):687-694, 2001.
31. Young WF, Rosenwasser RH: An early comparative analysis of the use of fibular allograft versus autologous iliac crest graft for interbody fusion after anterior cervical discectomy. Spine 18(9): 1123-4, 1993.
32. Younger EM, Chapman MW: Morbidity at bone graft donor sites. J Orthop Trauma;3:192-5, 1989.
33. Zdeblick TA, Ducker TB: The use of freeze-dried allograft bone for anterior cervical fusions. Spine 16:726-9, 1976.
34. Zeidman S, Ducker T, Raycroft J: Trends and complications in cervical spinal surgery: 1989-1993. J Spinal Disorders 10:523-6, 1997.
35. Zhang ZH, Yin H, Yang K, et al: Anterior intervertebral disc excision and bone grafting in cervical spondylitic myelopathy. Spine 8:16, 1983.

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