Radiographic Fusion Rates for Anterior Cervical Discectomy and Fusion Using Frozen Laminated Composite Allograft and Plating

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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 is the "gold standard" in grafting materials used for 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 yielded consistently high rates of solid fusion for ACDF procedures, increasing numbers of spine surgeons are abandoning its use in favor of other fusion materials. Bone graft donor site pain and morbidity, as well as increased operative time are factors cited by surgeons for this trend[6,21,23,27,34]. The ideal bone graft substitute would be stable in axial compression, resisting displacement and excess subsidence, and possess osteogenic, osteoinductive, and osteoconductive properties. There are presently a number of different bone grafting options available for use in anterior cervical spine fusion. Yet none possess all of the properties of an ideal replacement for iliac crest bone graft. These options include titanium spacers and cages, hydroxyapatite matrices, biocompatible osteoinductive polymers, ceramics, demineralized bone matrix and bone morphogenetic protein (BMP). The most commonly used substitute for autologous bone graft however, is human cadaveric allograft bone.

Allograft bone products are considered highly osteoconductive, weakly osteoinductive, and non-osteogenic. Freeze-dried allografts may be stored at room temperature for a long period of time, making them a convenient alternative. However, the process of freeze-drying can reduce mechanical strength compared with frozen grafts[9,22]. Allogenic fibula has been used as an effective substitute for autologous iliac crest in ACDF. Despite their successful use, freeze-dried fibular grafts are subject to breakage, a high collapse rate, and wide anatomical variation. Frozen allografts that are kept at -20C, do not have decreased mechanical strength and can be stored for up to one 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, VG2™ Cervical Allograft (DePuy Spine/LifeNet), with anterior plating.

Figure 1A) A 39 year old male with cervical spondylosis at C5-C7. Preoperative lateral radiograph.

Figure 1B) An immediate postoperative radiograph after ACDF with the VG2 Cervical Allograft and the DOC™ Ventral Cervical Stabilization System constructed at C5-C7.

METHODS

This multicenter retrospective study reviewed a cohort of patients who underwent anterior cervical discectomy and fusion using VG2 Cervical Allograft and anterior plating. VG2 Cervical Allograft is a machined, frozen, cortico-cancellous allograft comprised of two cortical planks of bone surrounding a cancellous center. The cortical planks provide strength for anterior column support. The cancellous bone provides an osteoconductive lattice for remodeling. A total of 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. An anterior plate was used in all patients. 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 solid 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, clinical outcome and all other clinical information including smoking status. Fusion was identified as the absence of a radiolucent gap between the graft and the endplate; and the presence of continuous, bridging, bony trabeculae at the graft-endplate interface. A pseudoarthrosis 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-endplate interface. A solid fusion was assumed if at least two of the three evaluators identified a given level as fused.

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 number 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).

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 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). The number of fused and non-fused segments per vertebral level in patients undergoing multi-level ACDF are shown in Table 2. No statistical significance was found with regards to fusion rate and vertebral level (p=0.505).

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

Figure 1C) Lateral radiograft at one year postop showing solid fusion at both levels.

DISCUSSION

As discussed previously, despite being considered the "gold standard", there is a current trend away from the use of autologous iliac crest bone graft due to postoperative bone graft donor site pain and morbidity. Prior authors have reported complications including donor site pain, difficulty with ambulation, infection, wound drainage, and impairment of work and recreational activities. A variety of materials have been used as fusion substrates in the cervical spine with variable results. One of the most widely used materials is freeze-dried fibular allograft. It has a fusion rate of 70% to 92%[13,31] 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 in the cervical spine[24]. Recently the pursuit of an improved ACDF fusion substrate has led many manufacturers to process machined allografts that attempt to incorporate structural stability while maintaining osteoinductive and osteoconductive properties.

The reported fusion rate for unplated single-level ACDF using autologous iliac crest bone graft is 83% to 100%[1,2,10,11,13,16-20,22,24,30,31,33]. 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[3-5,8,14,15,25,26,28,29]. 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. We are unaware of any previous studies that evaluate fusion rates of machined cortico-cancellous allografts in the cervical spine.

The VG2 Cervical Allograft is a frozen machined composite allograft that generates strength through its outer cortical planks and maintains the osteoconductive 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. VG2 Cervical Allograft demonstrates fusion rates similar to, or better than, those reported for autologous iliac crest, freeze-dried iliac crest, or fibular allografts for single- or multi-level ACDF.

The views expressed in this article are those of the author(s) and do not reflect the official policy or position of the Department of the Navy, Department of Defense, or the United States Government.

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