The Use of Osteotech Surface-activated Cortical Lordotic Allograft in Anterior Cervical Discectomy and Fusion

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Abstract: The Osteotech OsteoActive cortical lordotic spacer is an allograft interbody graft that is surface demineralized to a standard depth to allow exposure of growth factors. The availability of growth factors on the surface of the allograft purportedly creates a biologically active surface capable of stimulating bone growth while preserving implant strength without adding any additional bone graft or osteoinductive agents (including demineralized bone matrix). However, no scientific articles exist demonstrating the fusion rate in anterior cervical discectomy and fusion (ACDF) procedures using this allograft. This study is a prospective, cohort study with 38 consecutive patients who underwent ACDF with Osteotech surface demineralized cortical, lordotic allograft, and anterior cervical plating via modified Smith-Robinson technique. Radiographic fusion was determined with plain radiographs and complications were assessed. Average follow-up was 29.6 months, with a minimum of 2-year follow-up (range, 24 to 46 mo). The average age was 51.3 years (range, 32 to 68 y) and the comorbidities included 13 smokers, 1 diabetic, and 8 patients with prior surgeries. Three frank nonunions with radiolucent lines and/or motion on flexion/extension radiographs were noted, and 3 additional levels were suspicious for delayed union with evidence of incomplete incorporation. The fusion rate was 92.3% (72/78) of levels, including three 3-level fusions that had not gone to arthrodesis. Four out of 6 patients with nonunions or delayed unions were smokers. There was no evidence of graft fracture even in the face of surface treatment of the allograft with the demineralization process. Two patients who underwent revision ACDF for previous pseudarthrosis fused with the revision procedure using the Osteotech cortical allograft. There were no instances of hardware failure or reoperation for graft failure, pseudarthrosis, or nonunion. Two patients had plate subsidence with encroachment of the hardware on the adjacent level. Complications occurred in 3 patients (7.9%) with 2 urgent irrigation and debridements for evacuation of postoperative seroma/hematoma and 1 patient with significant dysphagia and dysphonia. The fusion rate and lack of reoperations in this prospective cohort study establishes that the surface activated allograft used in this study is an excellent interbody device. The surface activation of the cortical allograft allows incorporation in the anterior cervical interspace without additional demineralized bone graft or autograft. Future studies could elucidate if the rate of fusion may be hastened by the surface-activated graft due to the exposed demineralized bone matrix and resultant osteoinductivity.

Key Words: cervical, pseudarthrosis, allograft, Osteotech

Anterior cervical discectomy and fusion (ACDF) is a widely accepted procedure for treating various cervical spine disorders including spondylosis, disc herniation, and trauma. The type of interbody graft used and the quality of fusion can predict outcomes.1–2 Single-level, instrumented ACDF has enjoyed a high rate of successful fusion using either allograft or autograft3–4 with reports ranging from 82% to 94% and 83% to 99%, respectively. However, morbidity associated with the harvesting of iliac crest autograft, including persistent pain, may be seen in as many as one-quarter of patients.5–9 Therefore, increased focus on the use of allograft for ACDF has garnered much interest. The use of allograft alone has historically led to inferior results.10 The application of anterior plating has improved overall clinical results and radiographic fusion.11 The combination of plating with allograft placement theoretically diminishes the risk of kyphosis, increases rigidity, and may obviate the need for postoperative bracing.12,13 Furthermore, graft site harvest complications are virtually eliminated.

A recent study demonstrated an excellent radiographic fusion rate using allograft and plating even with multilevel constructs.14 Schlosser et al demonstrated a 94.5% fusion rate across all patients. Also, when they specifically addressed multilevel constructs, they found a 94% fusion rate with 3-level constructs and an 86% fusion rate with a 4-level ACDF. However, 3 types of commercially available allografts were used in this study: Medtronic Cornerstone, Depuy VG3, and Synthes MTF. This study accords with another report15 that demonstrated a 95.6% fusion rate in 3-level ACDF with anterior plating. Once again, different interbody grafts were used, including autograft, fibular ring allograft, and titanium cages.
In our present study, we evaluated one interbody spacer, the Osteotech OsteoActive cortical lordotic spacer, which is a graft that is surface demineralized to a standard depth to allow exposure of growth factors. The technique of surface activation purportedly creates a biologically active surface capable of stimulating bone growth while preserving implant strength. Furthermore, the surface-activated allograft does not require the addition of bone graft or osteoinductive agents (including demineralized bone matrix) to promote interbody fusion. We specifically sought to examine the radiographic fusion rate in not only single-level ACDF but also in multilevel constructs that also underwent concomitant anterior cervical instrumentation. Our experience demonstrates the first study to specifically assess the radiographic fusion rate of the Osteotech OsteoActive cortical lordotic spacer.

METHODS

A prospective, cohort study with 38 consecutive patients underwent ACDF with Osteotech surface demineralized cortical, lordotic allograft, and anterior cervical plating via modified Smith-Robinson technique. Patients included in the study were refractory to conservative methods including anti-inflammatory medications, physical therapy, and epidural steroids. All of the operations were performed by the senior author (R.F.D.) between January 2003 and December 2004. Three types of anterior plates were used: Medtronic Premier, Synthes CSLP, and the SpineVision plate. Patients wore a soft external orthosis for 6 weeks. Radiographic fusion was determined with plain radiographs obtained at consistent follow-up intervals of 6 weeks, 3 months, 6 months, 1 year, 2 years, and biannually thereafter. Fusion was defined as the absence of radiolucent lines surrounding the allograft/host bone interface and no evidence of hardware failure. Hardware failure was determined by migration of instrumentation, fracture of any screw or plate, and radiolucency around screw tracts. Patient charts were also reviewed for fracture of any screw or plate, and radiolucency around screw tracts. Patient charts were also reviewed for potential postoperative complications, including hematoma, respiratory distress, infection, dysphagia, dysphonia, new symptoms or neurologic deficits, major vessel injury, and adjacent segment degeneration.

To obtain a consistent fusion bed for the Osteotech interbody graft, a similar surgical algorithm was followed for each ACDF. The process hinged on 3 principles integral to ACDF: (1) “fit and fill” of the interbody space, (2) compression of the interbody graft, (3) restoration of the sagittal cervical lordosis. Appropriate preparation of the disc space included complete anterior and lateral osteophyte removal to facilitate complete discectomy and restore sagittal lordosis; precise contouring of the interbody space was completed with a high-speed burr to remove the anterior aspect of the superior vertebral body. A broach, the same size as the final implant, was used to maximize fit and fill. Slight distraction of the graft space by a Cloward intervertebral distractor or a Caspar distractor allows easy insertion of the lordotic Osteotech allograft. The distraction was released to allow compression before anterior cervical plating.

RESULTS

A total of 38 patients underwent ACDF with the Osteotech OsteoActive cortical lordotic spacer. There were 14 males and 24 females, and the average age was 51.7 years old (range 32 to 68). The average follow-up was 29.6 months, with a minimum of 2-year follow-up (range, 24 to 46 mo). Comorbidities included 13 smokers, 1 diabetic, and 8 patients with prior surgeries. A total of 78 levels underwent the index procedure. Two of the surgeries included using the Osteotech allograft spacer to repair a previous nonunion from a prior ACDF. Eight of the patients were operated on for adjacent level degeneration, and 2 of these patients had a pseudarthrosis at the attempted initial fusion level. The number of levels operated upon and the distribution of cervical levels are demonstrated in Tables 1 and 2.

Three nonunions (frank lucent lines at the graft/host bone interface) were noted and 3 additional levels were suspicious for delayed union (incomplete incorporation of the allograft in the interbody space). The fusion rate was 92.3% (72/78) of levels, including three 3-level fusions that had not gone to arthrodesis. Interestingly, all three 4-level ACDF procedures went on to union whereas 50% (3/6) of 3-level ACDF cases went on to nonunion. Figure 1 identifies the quality of the fusion that was obtained with the Osteotech cortical allograft and concomitant ACDF. Four out of 6 patients (66.7%) with nonunions or delayed unions were smokers (Fig. 2). There was no evidence of graft fracture even in the face of surface treatment of the allograft with the demineralization process. Two patients had plate subsidence with encroachment of the hardware on the adjacent level. Two patients who underwent revision ACDF for previous pseudarthrosis fused with the revision procedure using the

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### TABLE 1. The Rate of Fusion by Number of Levels Fused

<table>
<thead>
<tr>
<th>No. Levels</th>
<th>No. Patients</th>
<th>Fusion Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>10 (26%)</td>
<td>9/10 (90%)</td>
</tr>
<tr>
<td>2</td>
<td>19 (50%)</td>
<td>17/19 (89%)</td>
</tr>
<tr>
<td>3</td>
<td>6 (16%)</td>
<td>3/6 (50%)</td>
</tr>
<tr>
<td>4</td>
<td>3 (8%)</td>
<td>3/3 (100%)</td>
</tr>
<tr>
<td>Total</td>
<td>38</td>
<td>Average = 92.3%</td>
</tr>
</tbody>
</table>

### TABLE 2. The Distribution of Cervical Levels Fused

<table>
<thead>
<tr>
<th>Level</th>
<th>No. Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>C 2/3</td>
<td>0</td>
</tr>
<tr>
<td>C 3/4</td>
<td>12</td>
</tr>
<tr>
<td>C 4/5</td>
<td>18</td>
</tr>
<tr>
<td>C 5/6</td>
<td>28</td>
</tr>
<tr>
<td>C 6/7</td>
<td>20</td>
</tr>
<tr>
<td>C 7/T1</td>
<td>0</td>
</tr>
</tbody>
</table>
Osteotech cortical allograft to promote a fusion at the previous pseudarthrosis level. There were no instances of hardware failure or reoperation for graft failure or nonunion. Of the 3 frank nonunions and the 3 additional probable nonunions, only one of the patients had persistent neck and left arm pain. This same patient also had subjacent segment degeneration but at present has not undergone a revision operation. One of the 8 patients (12.5%) who had a prior ACDF underwent a revision ACDF for adjacent level degeneration went on to a nonunion.

An overall complication rate of 7.9% (3/38) occurred in the present study. Two patients required urgent irrigation and debridements for evacuation of postoperative seroma/hematoma, and 1 patient sustained significant, prolonged dysphagia and dysphonia. There were no new neurologic deficits and no superficial or deep wound infections.

**DISCUSSION**

Long-term studies have shown that allograft does not compromise the overall radiographic and clinical results in ACDF with anterior instrumentation.\(^{11,17}\) Furthermore, donor site morbidity is eliminated and restoration of the segmental alignment is achieved. Still, some authors have shown the superiority of autograft over allograft especially in patients who are smokers.\(^ {18,19}\) Other studies have also purported the benefit of autograft in multilevel constructs due to the multiple interfaces that are required to fuse to the interbody graft.\(^ {20,21}\) Some authors believe that multilevel corpectomies and strut grafting decreases the nonunion rate because it decreases the number of interfaces required for the fusion.\(^ {22,23}\) The use of strut allografts for long fusions brings about a different set of complications including loss of lordosis, graft dislodgement, and the need for posterior augmentation.\(^ {24,25}\) With the advent of a variety of nonbiologic...
interbody cages made of various materials, a comparison basis with allograft will be mandatory to establish safety and efficacy.36

In our study, we used a single allograft type to obtain fusion in the interbody space in the anterior cervical spine. Strict attention was paid to the “carpentry” of the interbody space so that endplates were drilled to match the contour of the allograft spacer. Meticulous endplate preparation was also created with the use of a high-speed burr. Burring of the endplates, which exposes the subchondral bone, has been shown to decrease the pseudarthrosis rate by 4.4% per level.28 By adhering to the principles of precise contouring of the interbody space, restoration of sagittal alignment, and compression across the interspaces, the reduction of the rate of pseudarthrosis may be achieved even in difficult multilevel procedures. Further evidence that host bone and graft mismatch may play a role in pseudarthrosis formation was shown by Farey et al29 because a higher propensity for nonunion was found at the caudal interface of a graft with the native endplate. This could be a result of the surface concavity of the endplate that must be drilled to match the overall contour of the graft.

Many studies have shown the lower rate of fusion with multilevel constructs. Bohman et al30 demonstrated a rate of 89% and 73% for 2 and 3-level ACDF, respectively. Hilibrand et al31 recently noted an even lower rate of fusion for multilevel interbody cervical fusions. Their fusion rate of 66% prompted these authors to espouse multilevel corpectomies and strut grafting to lower the pseudarthrosis rate. In our study, 2, 3, and 4-level fusions had an arthrodesis rate of 89%, 50%, and 100%, respectively. Cumulatively, the arthrodesis rate for multilevel procedures in our study was 82.1% (23/28). With the use of the Osteotech surface-activated graft, an improvement in the historical fusion rate was observed. Further investigation may help elucidate the role of smoking in patients who undergo multilevel ACDF. Even though smokers have characteristically suffered from lower fusion rates (66.7% of our nonunions were patients who smoked), matched cohorts comparing multilevel ACDF with multilevel corpectomies and strut grafting may help clarify the role of a surface-activated allograft in anterior cervical spine surgery. Most likely, the crucial tenets in obtaining an arthrodesed level, regardless of surgical modality, will be to follow the 3 principles of anterior cervical spine surgery: (1) fit and fill, (2) restore alignment, and (3) compression with instrumentation.

The promotion of arthrodesis in the cervical spine is not new. Anterior cervical instrumentation was initially developed in the 1960s by Bohler and Gaudernak32 and soon followed by Caspar et al33 in the 1980s. These techniques continue to evolve with new developments in plate fixation and dynamic and variable locking screws.34 Novel interbody devices continue to be tested and produced in hopes of producing a more consistent and expeditious fusion biology.35 However, cost containment must be considered when combining allograft with instrumentation. Angevine et al36 demonstrated the cost-effectiveness of allograft when used with anterior instrumentation. They stated that the benefit of allograft when compared with autograft was at a cost of $496 per quality-adjusted life years. Furthermore, if the Osteotech OsteoActive lordotic allograft spacer could enhance the rate of fusion and hasten the date of return to work for postoperative patients, the cost-effectiveness of ACDF with Osteotech surface-activated graft could be even greater.

CONCLUSIONS

Our study demonstrates the efficacy and safety of the Osteotech surface-activated lordotic allograft spacer when used in single-level and multilevel ACDF. The single-level, multilevel, and overall fusion rate was 90%, 82.1%, and 92.3% which compares favorably with the historical cohort that forms the comparison group for this study. The number of previously operated patients in this series of patients from a mature practice likely indicates the fusion rate is conservative. It is important to note that although pseudarthrosis were determined by radiologic analysis, there have been to date no revisions for pseudarthrosis. Furthermore, the ability of the Osteotech graft to enhance fusion in a previous pseudarthrosis level is manifested by the 2 successful revision ACDF procedures for previous nonunions that went on to arthrodesis with the revision procedure using the OsteoActive allograft. The surgical algorithm outlined in this study is critical to the success of the overall procedure. Further studies would help elicit the role of the Osteotech surface-activated allograft in smokers and whether the rate of the fusion is hastened by an allograft that has exposed growth factors due to the processing of the allograft. The OsteoActive allograft has proven its clinical utility and we have also shown that the processing of the allograft does not lead to graft fracture or subsidence. Therefore, we believe the use of this Osteotech product is effective in promoting arthrodesis in the anterior cervical spine when combined with anterior cervical instrumentation.

REFERENCES