CLINICAL EXPERIENCES OF SINGLE AND MULTI-LEVEL LUMBAR SPINE FUSIONS USING A DBM/CALCIUM SULFATE/BMA COMPOSITE GRAFT TO EXTEND LOCAL BONE

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INTRODUCTION

Spinal fusion requires the formation of stable, healthy bone. There are three components of bone formation: osteoconduction, osteoinduction, and osteogenesis. Osteoconduction, a passive process, provides a physical pathway for osteoprogenitor cell migration. Osteoinduction is the process of mesenchymal stem cell recruitment and differentiation. Osteogenesis is the production of bone by recruited cells, and includes osteoconduction, osteoinduction, and angiogenesis.

Iliac crest autograft has long been the gold standard for bone fusion and healing. The advantage of utilizing iliac crest autograft for spinal fusions includes lack of potential immune response, and a history of solid fusion potential, with success rates reported from 65-95%. Negatives associated with utilizing iliac crest bone graft include pseudoarthrosis rates of 5-35%, limited quantity, added surgical time, separate operative site to manage, postoperative pain, potential infection, and blood loss. Associated morbidity rates have been reported as high as 30% in some series. These complications can translate to additional costs including longer operating room times, additional operative site care, antibiotics for the treatment of infection, blood transfusions, re-operation, and others.

EDGE™ Spine Graft Extender Allograft DBM Composite with Large Cancellous Chips product (Wright Medical Technology, Arlington, TN) contain the osteoinductive properties of demineralized bone matrix (DBM) derived from demineralization of ground cortical bone. This process of demineralization exposes multiple bone morphogenetic proteins (BMPs) and growth factors. These factors serve as a signal to induce bone formation by signaling mesenchymal cells to differentiate. Growth factors also regulate the rate and type of bone growth. EDGE™ Spine Graft Extender Allograft DBM Composite with Large Cancellous Chips has the added benefit of large cancellous chips (4-10mm) that enable the graft to carry up to 130% of its volume in bone marrow, if desired.

In combination with a surgical grade calcium sulfate, these composite materials can provide all three components of bone formation. The purpose of this review is to report clinical results using EDGE™ Spine Graft Extender Allograft DBM Composite with Large Cancellous Chips in single and multi-level fusions of the lumbar spine as an extender to local bone.
MATERIALS AND METHODS
In a two and a half year period, 79 patients with instrumented lumbar spinal fusions using EDGE™ Spine Graft Extender Allograft DBM Composite with Large Cancellous Chips Custom grafts were evaluated at one clinical site. In all cases, autograft bone consisted solely of decortication and laminectomy local bone. There were no additional harvests for autologous bone in this patient series.

Posterior approaches were carried out utilizing both open and minimally invasive (MIS) techniques. Preoperative medical clearance and informed consent were obtained from all patients. General endotracheal anesthesia was used in all cases. Foley catheters were inserted for all cases, and were removed on postoperative day 1. Jackson-Pratt drains were used on traditional open lumbar fusions for an average of 2 days. No drains were utilized in MIS lumbar and lumbosacral interbody fusions. All patients were immediately mobilized on the day of surgery for MIS cases. Fusions were instrumented in every case using standard techniques. Postoperative physical therapy was provided for all patients.

Decortication of facet joints and posterolateral elements including transverse processes, where appropriate, was performed. In all cases the custom graft was reconstituted with iliac crest bone marrow aspirate (BMA), approximately 10cc of BMA per 10cc EDGE™ Spine Graft Extender Allograft DBM Composite with Large Cancellous Chips. The posterior superior iliac spine (PSIS) was cannulated with a Jamshidi needle and 2-3cc of BMA was taken before relocating the needle to aspirate more BMA. This technique minimizes the risk of peripheral blood contamination. This process was completed 3-4 times depending on the quantity of BMA required. Local bone obtained from laminectomies, facetectomies and osteotomies was stripped of its soft tissue, morselized and then added to this mixture. The composite graft was placed posterolaterally over the decorticated bone. Lateral mass and pedicle screws were placed at appropriate and indicated segments and joined by contoured rods.

For interbody fusions, PEEK grafts were filled with local bone and the custom graft reconstituted with BMA. The remainder of the disc space was also packed with this mixture. A posterolateral fusion was also employed in these cases with the remainder of the graft material. Pedicle screws were placed at appropriate and indicated segments and joined by contoured rods. For MIS cases percutaneous techniques were utilized to place cannulated pedicle screws using the PathFinder™ system (Abbott Spine, Inc, Austin, TX). The senior author determined fusion by evaluating radiograph views to assess bridging bone or dense posterolateral bone at a minimum of 6 months postoperatively.

RESULTS
The average patient age was 53 years (22-85 years, SD 12.4 years). Comorbidities in the cohort included history of smoking (39.2%) and diabetes (17.7%) | TABLE 1. Neither smoking nor diabetes showed a statistically significant relationship with achievement of complete fusion within six months when using EDGE™ Spine Graft

![Figure 1: Fusion Rates by Smokers and Non-Smokers](image1.png)

**FIGURE 1** FUSION RATES BY SMOKERS AND NON-SMOKERS (p>0.05)

![Figure 2: Fusion Rates by Diabetics and Non-Diabetics](image2.png)

**FIGURE 2** FUSION RATES BY DIABETICS AND NON-DIABETICS (p>0.05)

Extender Allograft DBM Composite with Large Cancellous Chips BMA, and local bone as the fusion substrate (smoking: p=0.73; diabetes: p=1.00) | FIGURES 1 AND 2.

Thirty four percent of patients underwent these procedures subsequent to previous spinal surgeries. Bone cement augmentation of pedicle screws using the Pedestal Fenestrated Tap System™ (Abbott Spine, Inc, Austin, TX) in the lumbar spine was performed in patients with significant osteoporosis or tumor involvement of the operated segments. Posterolateral lumbar fusion (94.9%) was used more often than interbody fusion (24.1%) and 57% of the patients had only one level fused.
Overall, 87.3% of fusions were successful. The custom graft reconstituted with BMA and local bone was utilized in both posterolateral and interbody fusions of the lumbosacral region. These posterolateral and interbody procedures demonstrated fusion rates of 86.6% (65/75) and 89.5% (17/19) respectively. **FIGURE 3.** Images of successful fusion are demonstrated in **FIGURES 4A-E.**

**TABLE 1 | BASIC PATIENT AND SURGICAL INFORMATION**

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<thead>
<tr>
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<th>(N = 79)</th>
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<td>SMOKING</td>
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<td>(39.2%)</td>
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<td>DIABETES</td>
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<td>(17.7%)</td>
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<td>PRIOR OPERATION</td>
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<tr>
<td>BONE CEMENT AUGMENTATION</td>
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<tr>
<td>INTERBODY FUSION</td>
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<td>(24.1%)</td>
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<td>POSTEROLATERAL LUMBAR FUSION</td>
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<td>LEVELS FUSED</td>
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<tr>
<td>6</td>
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**FIGURE 4A-E: DEGENERATIVE DISC**

A) PRE-OPERATIVE.
B) POST-OPERATIVE.
C) 1 MONTH POST-OPERATIVE.
D) 3 MONTHS POST-OPERATIVE.
E) 6 MONTHS POST-OPERATIVE.

**FIGURE 3 | SUCCESS RATES BY FUSION TYPE**

- Overall PLLF
- Interbody
DISCUSSION

Relieving a patient’s pain by stabilizing the aggravated motion segments is the goal of spinal fusions. Autologous iliac crest bone graft is commonly reported as the most successful material for bone grafting because it contains all the key components necessary for bone formation; however it is typically associated with significant limitations including donor site morbidity, increased costs and operative time. Alternatives to autologous bone graft would ideally demonstrate four critical components: osteoinductive, osteoconductive, osteogenic, and structural integrity to provide mechanical support to the spinal fusion. The custom graft provides three of these components necessary for good bone formation through the combination of the calcium sulfate carrier, DBM, and high volume of large cancellous bone chips. This combination provides an ideal carrier for high volumes of bone marrow aspirate.

Calcium sulfate has been used for years as a bone void filler and as a bone graft substitute with favorable results. In a two year study, Alexander, et al. compared surgical grade calcium sulfate and local decompression bone to autologous posterior iliac crest bone in spinal fusion. Results showed the calcium sulfate plus local bone provided equivalent bone formation to the autologous iliac crest group and may be considered a viable alternative. Likewise, Chen, et al. compared iliac crest bone graft to autograft laminec-tomy bone with calcium sulfate and found no significant difference between the fusion rate and sizes of the fusion bone mass. Kelly, et al. also demonstrated excellent results using calcium sulfate alone and in conjunction with a variety of materials (DBM, BMA, autograft) in a variety of applications.

DBM is a form of allograft that has been demonstrated to be osteoinductive, or capable of inducing bone formation in heterotopic sites. All lots of DBM used in EDGE Spine Graft Extender Allograft DBM Composite with Large Cancellous Chips are tested for inductivity prior to release. The testing methods have been correlated with new bone formation in athymic rat models, which is widely considered the gold standard for assessing osteoiductivity of a material.

Similar to autograft, the combination of BMA and DBM provides osteoinductive, osteoconductive, and potential osteogenic capacity. The synergy between these two compositions has been well documented. Tiedeman et al. concluded in his study on the composition of BMA and DBM that the two together produced a response greater than the sum of either marrow or DBM alone. Connolly has also published extensively on the bone regenerative properties of BMA and DBM, finding that these composite grafts are at least equivalent to autologous grafting in the management of arthrodesis, fracture defects, and other bone loss problems.

In a quest to find a substitute for iliac crest autograft, it is important to emphasize that EDGE Spine Graft Extender Allograft DBM Composite with Large Cancellous Chips may provide the surgeon a means to “reverse engineer” or closely mimic autologous bone graft on the back table by combining fresh marrow with an off-the-shelf blend of large cancellous chips and bioassayed proteins. This surgeon-blended composite graft very closely mimics the physical and biochemical properties of harvested iliac crest bone by combining a protein-rich cancellous scaffold with high volumes of cell rich autologous marrow.

CONCLUSION

This patient series demonstrates the benefits of a composite DBM/BMA/calcium sulfate graft with local bone in treatment of lumbar spinal fusions. Excellent fusion rates were documented with an overall average of 87.3%. This is comparable to published reports with iliac crest graft. The morbidity associated with harvesting marrow aspirate is significantly less than that associated with bone graft harvest, and also offers decreased surgical time and costs.
REFERENCES


EDGETM Spine Graft Extender Allograft DBM Composite with Large Cancellous Chips has also been marketed under the tradename ALLOMATRIX® Custom graft.

For more information, please visit www.edge-spine.com

Many variables including patient pathology, anatomy, and surgical techniques may influence procedural outcomes. Before use, physicians should review all risk information and the Instructions for Use provided with the product.

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