

VESUVIUS® Demineralized Fibers Osteobiologic System Plus Passively Concentrated Bone Marrow Aspirate as an Alternative to Iliac Crest Autograft in Posterolateral Fusion Procedures

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Abstract:

Fusion masses in 75 consecutive posterolateral fusion patients receiving VESUVIUS® Demineralized Fibers demineralized cortical allograft perfused with BMA were assessed via A/P-view & F/E X-rays, and/or CT scans, and rated as absent, mild, moderate, or extensive (0, 1, 2, or 3). Fusion masses in all patients were rated as extensive or moderate, with 69 of 75 rated as extensive (92%), and 6 of 75 rated as moderate (8%).

Introduction:

Posterolateral fusion (PLF) with pedicle screw fixation is a commonly used procedure in the operative management of lumbar spine diseases. Iliac-crest autologous bone is long considered to be the “gold standard” due to its inherent osteoconductivity, osteoinductive potential, and osteogenicity; unfortunately, numerous published reports document substantial occurrences of morbidity associated with the harvest procedure.¹ While allografts provide an alternative source of bone graft for PLF, most processed allografts possess no osteogenic, or cellular, component.

In addition to osteoinductive proteins and growth factors, bone marrow aspirate (BMA) obtained from the iliac crest, as well as from vertebral bodies, is a primary storehouse for mesenchymal stem cells, and has been shown to enhance not only the osteoinductive potential of bone grafts, but also bestow a functional osteogenic component to bone grafts.² The concept of concentrated BMA is to manually increase the number of MSCs per unit draw of BMA.³

The aim of this study is to assess fusion results achieved in PLF patients receiving VESUVIUS Demineralized Fibers demineralized cortical allograft perfused with passively concentrated BMA in the treatment of spinal disorders for patients undergoing PLF.

Materials & Methods:

Radiographs from 75 consecutive patients with radiculopathy with or without mild myelopathy due to lumbar degenerative disc disease were studied. Patients received PLF and instrumentation (bilateral rod-and-screw construct), and lateral gutters of each fusion level were filled with VESUVIUS Demineralized Fibers (K2M, Leesburg, VA) plus passively concentrated BMA, which was aspirated from either the vertebral body or posterior wing of the iliac crest of each patient via the passive-concentration technique first described by Muschler et al.³ Patients received an average of 15 cc VESUVIUS Demineralized Fibers plus Per10–15 mL BMA per level. Patient follow-up comprised clinical examinations in addition to radiographic documentation evaluated at regular and standard time points (e.g., preoperatively, intraoperatively, immediately postoperative, and at six months, 12 months, and 18 months post-surgery).

Radiographic imagery to document and determine fusion status, as well as status of implant constructs, was obtained at follow-up visits. Radiographic evaluation was completed by the primary investigator, and all patient identifiers were removed prior to reading. Results were recorded and used to assess fusion, fusion mass, and implant integrity. Fusion masses were assessed from A/P view X-rays (obtained at six-, 12-, and 18-month follow-up visits). Additionally, flexion/extension X-ray imaging and/or CT scans obtained at follow-up visits were also utilized to verify fusion masses and assess spinal and implant stability.

Mineralization of fusion masses was rated separately as absent, mild, moderate, or extensive (0, 1, 2, or 3) using previously published definitions.^{4,5}

Data Category	n	0	1	2	3	Avg Fusion Rating
All Patients	75	0 (0%)	0 (0%)	6 (8%)	69 (92%)	2.92
Levels Treated						
One Level	51	0 (0%)	0 (0%)	4 (8%)	47 (92%)	2.92
Two Level	23	0 (0%)	0 (0%)	2 (9%)	21 (91%)	2.91
Two Level	1	0 (0%)	0 (0%)	0 (0%)	1 (100%)	3.00
Latest Follow Up						
6–7 mos.	12	0 (0%)	0 (0%)	3 (25%)	9 (75%)	2.75
8–10 mos.	7	0 (0%)	0 (0%)	1 (14%)	6 (86%)	2.86
12 mos.	52	0 (0%)	0 (0%)	1 (2%)	51 (98%)	2.98
15–18 mos.	4	0 (0%)	0 (0%)	1 (25%)	3 (75%)	2.75
Age						
≥65 yrs.	40	0 (0%)	0 (0%)	3 (7%)	37 (93%)	2.93
<65 yrs.	35	0 (0%)	0 (0%)	3 (9%)	32 (91%)	2.91

Table 1: Clinical Data

Results:

Representative X-ray and CT images are presented in Figures 1–2. X-ray films demonstrating mineralization of VESUVIUS Demineralized Fibers are presented in Figures 3–5.

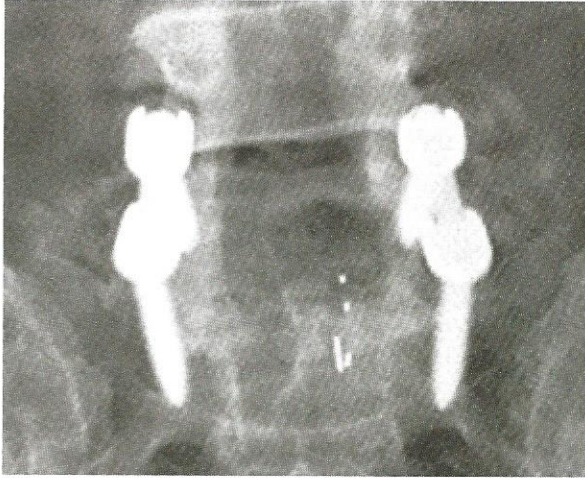


Figure 1: Representative six-month X-ray



Figure 2: Representative six-month CT Scan



Figure 3: Six-week X-ray demonstrating initial mineral deposition within VESUVIUS Fibers graft material

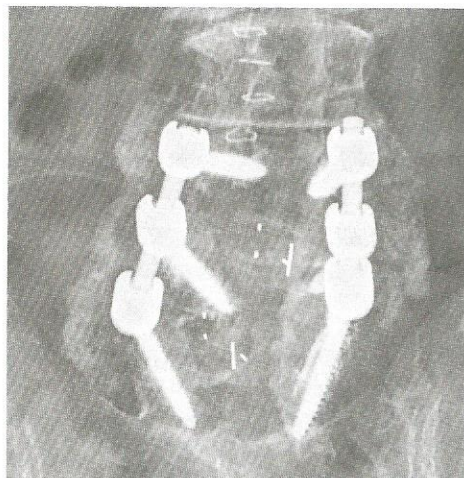


Figure 4: Three-month X-ray showing expansion of mineralization process within VESUVIUS Fibers allograft



Figure 5: Six-month X-ray indicating mineralization & consolidation of VESUVIUS Fibers graft bed

Conclusions:

In this retrospective consecutive-patient study, fusion masses in all 75 PLF patients receiving VESUVIUS Demineralized Fibers perfused with BMA were rated as extensive or moderate, with 69 of 75 rated as extensive (92%), and 6 of 75 rated as moderate (8%).

References:

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