

Posterior Lumbar Fusion using EVEREST® Spinal Stabilization System plus VESUVIUS® Demineralized Cortical Allograft Fibers Perfused with Bone-Marrow Aspirate: A Prospective Study with Interim 12-month Results

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Introduction

Posterolateral fusion(PLF)is commonly used in the management of lumbar-spine diseases. Autogenous iliac-crest bone graft (ICBG) is considered to be the "gold standard" however, numerous reports show instances of morbidity associated with ICBG harvest.

Autogenous bone-marrow aspirate (BMA) is a storehouse for osteoprogenitor cells, in addition to osteoinductive proteins, growth factors, and bestow a functional osteogenic component to bone grafts. The goal of behind passively concentrated autogenous BMA is to increase numbers of osteoprogenitor cells, such as mesenchymal stem cells (MSCs), per unit draw of BMA.

Methods

The purpose of this multi-center prospective study was to evaluate fusion rates, outcomes, and complications from use of VESUVIUS Demineralized Cortical Fibers perfused with passively concentrated BMA in patients undergoing PLF for one- or two-level lumbar degenerative disease.

Diagnostic images (CT scan) were obtained at 12 months to assess fusion. Robustness of fusion was rated separately as absent, partial consolidation, or bridging fusion (0, 1, or 2). Patient-outcome data(ODI, VAS, and Patient Satisfaction) were collected for analysis. Patients were assessed at 3, 6, 12, and 24 months. To date, 47 patients have available one-year data.

There were 35 single-level PLFs (11 implanted interbodies) and 12 two-level PLFs (14 implanted interbodies), for a total of 59 levels treated.

Learning Objectives

Knowledge of bone graft options

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Results

38 patients (64%) with bridging fusion masses in left lateral gutters, and 37 patients (63%) in right lateral gutters; 7 patients (12%) with partial consolidation in left lateral gutters, and 10 patients (17%) in right lateral gutters; fusion masses were absent in left lateral gutters of 14 patients (24%), and in right lateral gutters of 12 patients (20%).

VAS back decreased 42.6 points; VAS hip/buttock decreased 34.8; VAS leg decreased 34.2. ODI decreased 26.6 points, and 88.1% of patients were surgically satisfied.

Conclusions

This study shows 78% bridging fusion rates at 12 months using VESUVIUS Demineralized Fibers perfused with concentrated BMA in treatment of spinal disorders.