V92™ Cellular Bone Matrix in Spine Fusion:
Safety Profile and Early Clinical Outcomes

William C. Tally, MD
Athens Orthopaedic Clinic
Athens, GA

V92™
CELLULAR BONE MATRIX

V92™ Cellular Bone Matrix In Spine Fusion

Early clinical results demonstrate progression toward bony fusion and improved patient outcomes following surgery with V92™ cellular bone matrix. The cellular bone matrix used in the study has been subjected to a number of laboratory tests in order to ensure that the allograft cellular matrix does not stimulate an immune response, including a mixed lymphocyte reaction assay. These studies combined with the early clinical results demonstrate that the cellular scaffold is safe and effective for spinal fusion. Further follow up will be required to assess the lasting benefit and long term safety of the product in these applications.

Introduction

Spinal fusion procedures are reliant on a bony fusion substrate in addition to the fixation hardware. Many grafting options are available including autogeneous, allogeneic and synthetic materials. Recently an allograft cellular bone matrix (ACBM) has been developed with viable cells and a novel cryopreservative (V92™ cellular bone matrix).

The ACBM used in this study consists of a cell/scaffold combination in a dimethlyl sulfoxide (DMSO) free cryopreservative. Bone marrow derived cells are combined with demineralized bone matrix (DBM) and mineralized bone particulate at surgery prior to graft placement.

Methods

A retrospective chart review was conducted to identify all patients receiving the V92™ cellular bone matrix material in lumbar spinal fusion with a minimum of 3 month follow up. Any adverse events including infection, revisions and evidence of immune response were noted.

Clinical outcome was assessed using SRS 22, Oswestry Disability Index (ODI) and Visual Analog Scale (VAS) patient outcome measures. These were recorded pre-op and at 2 weeks, 6 weeks and 3 months.

Fusion status was assessed using CT scanning. Patients were deemed fused if CT scans demonstrated evidence of bridging bone at the fusion site without evidence of motion on flexion-extension x-ray films.

Results

A total of 29 patients underwent spinal fusion with interbody implant and posterior fixation at a total of 34 spinal levels. Patients received 5 cc of the V92™ cellular bone matrix in the disc space in combination with cancellous allograft and/or tricalcium phosphate bone graft substitute in the interbody implant and posterolateral spinal region.

The average fusion rate was 82.7% at 3 months. Bone healing was seen as progressing toward homogeneous graft appearance and robust mineralization at the graft site, with an absence of subchondral cyst formation or heterotopic bone.

Clinical outcomes measures were available for 18 patients.

Functional outcomes demonstrated improvements at 3 months in pain, disability and quality of life.

The SRS 22 assessment tool showed a scoring mean value increase of 23% (PreOP = 2.76, 3 mo = 3.40). [Figure 1]

A decrease was seen in mean values for Oswestry Disability Index (-28%: PreOP = 47%, 3 mo = 34%). [Figure 2]

The VAS Back Pain (-58%: PreOP = 7.22, 3 mo = 3.03) and VAS Leg Pain (-60%: PreOP = 6.53, 3 mo = 2.59) also decreased with time. [Figure 3]

No complications that could be attributed to the cellular bone matrix were noted, including osteolysis, graft site inflammation or immune response.

Figure 1 *- SRS 22 Score*

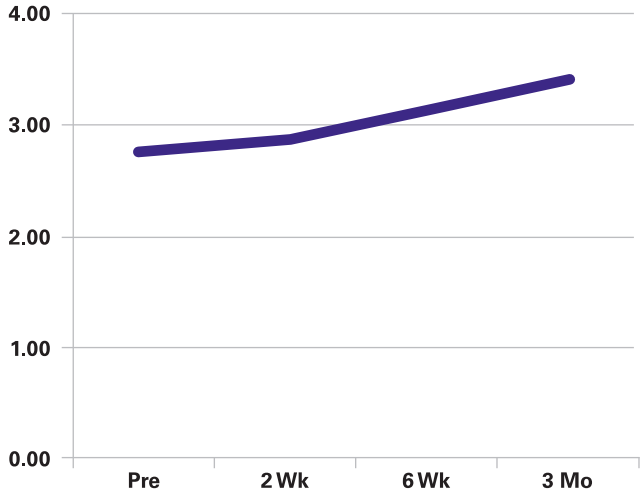


Figure 2 *- Oswestry Disability Index Score*

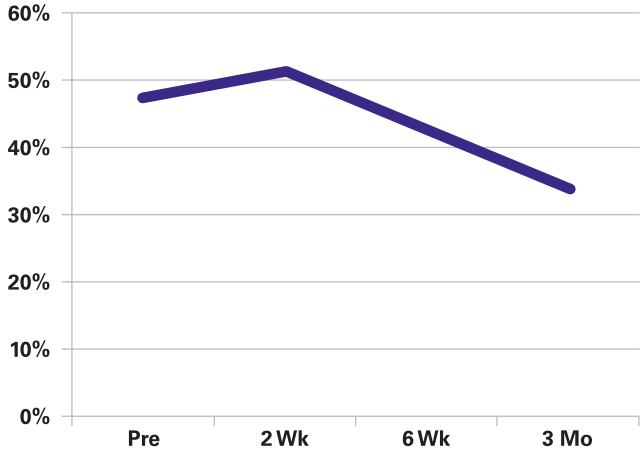
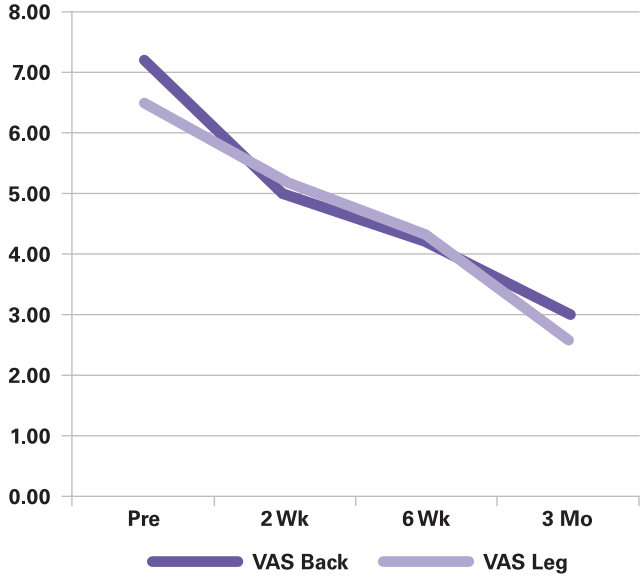


Figure 3 *- Visual Analog Scale scores*



For more information on V92™, please contact:

Exclusively foot & ankle Paragon 28®

4B Inverness Ct. E, Ste. 280
Englewood, CO 80112, U.S.A.
855.786.2828 | www.paragon28.com

Processed by: UMTB Biomedical, Inc.
An AATB Accredited Tisue Bank
P01-WP-0003 RevA
© Copyright 2016 Paragon 28, Inc.
™ Trademarks and ® Registered Marks of Paragon 28, Inc. All rights reserved.
Caution: U.S. Federal Law restricts this device to sale by or on order of a physician.