New, Prospective Data for a Uniquely Processed Allograft

Uniquely Processed
OSTEOAMP is a differentiated allograft that is uniquely processed with bone and bone marrow to retain a wide array of growth factors which support each phase of the bone healing cascade.¹

Multiple Formats
OSTEOAMP is currently offered in putty, granule, sponge and fiber formats. In July, a new Flowable format will be available, adding to the comprehensive Bioventus portfolio.

Existing Clinical Evidence
OSTEOAMP is backed by multiple, peer reviewed, clinical publications which demonstrate positive fusion assessments in a variety of surgical settings. In a large, multicenter, retrospective study of 321 patients that received TLIF or LLIF, it was reported that OSTEOAMP is a viable alternative to Infuse based on fusion rates.²

New Clinical Evidence
Two abstracts were presented at the North American Spine Society (NASS) 2020 virtual annual meeting featuring OSTEOAMP in a prospective, posterolateral lumbar fusion study.³⁻⁵ A summary of one of the abstracts is listed below.⁵

Clinical Study Design:
• Prospective (level II evidence)⁶
• 1- and 2-level instrumented posterolateral lumbar fusion (PLF) from L1-S1
• No interbody fusion
• 42 patients enrolled (26 for 1-level, 16 for 2-level)
• Multicenter (9 sites)
• Radiographic (X-ray, CT)
• Clinical outcomes (ODI, VAS, SF-36)

Overview of the Abstract:⁵
• Title: A Novel Bone Graft Has Higher Fusion Rate Than Local Autologous Bone in Stand-alone Posteriorlateral Fusion: A Propensity Score Adjusted Analysis
• OSTEOAMP Group: 12-month outcomes for 1- and 2-level PLF patients (N = 38)
• Local Autologous Bone (LAB) Group: 12-month outcomes for 1-level PLF patients (N = 82) that received local bone only from a large, previously published, randomized controlled trial
• Propensity Scoring: Investigators chose the most clinically relevant patient baseline characteristics, including gender, age, BMI, tobacco use, ODI, and VAS back and leg pain.
• Results: Fusion, assessed with CTs by two independent and blinded radiologists, was significantly higher for OSTEOAMP (84%) compared to local autologous bone (61%). OSTEOAMP demonstrated high rates of improved patient outcomes, with no product related serious adverse events.

<table>
<thead>
<tr>
<th>12-MONTH OUTCOMES</th>
<th>OSTEOAMP</th>
<th>LAB</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fusion</td>
<td>84%</td>
<td>61%</td>
<td>0.028 (RR 1.4)</td>
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<tr>
<td>ODI Score (Improvement)</td>
<td>20.3 (31.5)</td>
<td>18.8 (30.5)</td>
<td>0.7585</td>
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<tr>
<td>SF-36 PCS Improvement</td>
<td>15.4</td>
<td>13.1</td>
<td>0.1642</td>
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<tr>
<td>SF-36 MCS Improvement</td>
<td>7.1</td>
<td>7.6</td>
<td>0.175</td>
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</tbody>
</table>

CI = 95%  p-value < 0.05 = statistical significance


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