increases varied for the 2 donors and for agg and col.2. Rabbit NP cell gene expression was not affected by rhGDF-5.

**CONCLUSIONS:** To our knowledge, this is the first report on the relative dose-dependent effects of rhGDF-5 on human and rabbit IVD cells and the first to investigate the effects of rhGDF-5 on rabbit IVD cell gene expression. Indicators of anabolic activity for human and rabbit AF cells and human NP cells increased with rhGDF-5 over the entire dose range, but rabbit NP cells were not responsive to any dose of rhGDF-5. In considering these differences, however, it is important to note that cell populations of human and rabbit NP are different (more notochordal cells in the rabbit NP) and that cells were at various stages of dedifferentiation, due to monolayer expansion, prior to alginate bead encapsulation.

**FDA DEVICE/DRUG STATUS:** This abstract does not discuss or include any applicable devices or drugs.


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**Table 1**

<table>
<thead>
<tr>
<th>Treatment Cells (added to rhBMP-2)</th>
<th>L4-5 Fusion No of Rats % Fused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lewis Skin Fibroblast Devitalized Cells</td>
<td>0 6 0.0%</td>
</tr>
<tr>
<td>Inorganic Particles</td>
<td>0 6 0.0%</td>
</tr>
<tr>
<td>Lewis Fibroblast Cells</td>
<td>0 6 0.0%</td>
</tr>
<tr>
<td>None (control)</td>
<td>0 6 100.0%</td>
</tr>
<tr>
<td>DMEM only (medium)</td>
<td>4 4 100.0%</td>
</tr>
</tbody>
</table>

**FDA DEVICE/DRUG STATUS:** This abstract does not discuss or include any applicable devices or drugs.

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**P115. Up to 5-year Prospective Results of 1, 2, and 3-Level Lumbar Arthroplasty with the ProDisc-L Device at a Single Institute**

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**BACKGROUND CONTEXT:** Artificial discs have been approved by the US FDA as an alternative to fusion in intractable degenerative disc disease. The ProDisc-L is the only device designed and tested in the US clinical trials for multi-level (1 and 2) degenerative disc disease. Understanding the benefits of arthroplasty, it is even more advantageous over fusion when it comes to treating multiple levels, since multi-level fusion can be considerably more morbid and stiffening. 3-level lumbar arthroplasties have also been performed under a “compassionate use” allowance by the FDA.

**PURPOSE:** Longer term follow-up of multi-level lumbar disc replacement.

**STUDY DESIGN/SETTING:** Prospective single-center study.

**PATIENT SAMPLE:** Patients with lumbar arthroplasty at a single institute with the ProDisc-L device.

**OUTCOME MEASURES:** Oswestry Disability Index, Visual Analog Scale for pain, Visual Analog Scale for patient satisfaction, and flexion-extension range of motion.

**METHODS:** This is a prospective study of 252 patients with lumbar arthroplasty at a single institute with the ProDisc-L device. There were 116 1-level, 109 2-level, and 27 3-level implantations. Follow-up is up to 5 years now, and the results are reported in terms of Oswestry Disability Index, Visual Analog Scale for pain, Visual Analog Scale for patient satisfaction, and flexion-extension range of motion.

**RESULTS:** As reported in the past for earlier follow-up, the improvements in disability, pain, and patient satisfaction continue to be maintained at final follow-up for 1, 2 or 3-level disc replacements. VAS and ODI scores are 50% or lower from preoperative values at 3 years and beyond for 1, 2 and 3-level ADRs. There is actually a trend to increased benefit after multi-level arthroplasty, which correlates to increased preoperative disability. There have been no device-related complications, although there have been a handful of reoperations which will be illustrated. No adjacent segment problems have been detected yet at 5 years.

**CONCLUSIONS:** The results indicate that lumbar arthroplasty with the ProDisc-L device has shown significant benefits in pain and disability reduction, is holding up to the test of the rigorous USFDA standards, and holding up to the test of time thus far at about 5 years. Multi-level arthroplasty has obvious advantages to multi-level fusion, and DDD is unfortunately often not isolated to a single level at L4-5 or L5-S1. This device appears to be well-suited for this scenario.

**FDA DEVICE/DRUG STATUS:** ProDisc-L: Approved for this indication.

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