increases varied for the 2 donors and for agg and col2. 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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P114. Mass Effect versus Biologic Inhibition of rhBMP-2 Activity by Cellular Environment (Inorganic Polyethylene Beads versus Fibroblasts) – Implications on Use of BMP for Salvage of Fusion or Devices

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BACKGROUND CONTEXT: Previous work has revealed that certain cells in the fusion environment can inhibit rhBMP-2. These findings emphasize the need for thorough cleaning of the fusion bed to optimize osteoinductivity. It is unknown whether the inhibition is due to cellular mass (structural) or biologic. BMP is often used in the setting of failed prior fusion, so scar cells (fibroblasts) between the bony margins should be cleared. With the advent of artificial discs, BMP may be called upon to help salvage (fuse) a failed disc replacement segment. Such an environment, in addition to loose cells, may contain inorganic wear products from the device material.

PURPOSE: This study explores whether non-organic particles (such as polyethylene wear beads) can inhibit rhBMP-2, and whether known inhibitory cells need to be viable (alive) to impart their inhibitory effect.

STUDY DESIGN/SETTING: A rat model for lumbar pseudarthrosis has been developed in our laboratory to study osteoinductive substances in vivo.

OUTCOME MEASURES: Radiographs and manual testing.

METHODS: A minimal effective dose of rhBMP-2 to rescue fusion in this model was determined. Other substances can be added into this environment to study their effect on osteoinduction. In an effort to investigate whether this is a purely biologic phenomenon or perhaps a mass-related structural barrier effect, fibroblasts were devitalized and tested. Also, inorganic polyethylene beads roughly the same size as fibroblast cells (20–30 microns) were used. Creating beads of this size served several purposes. First, by mimicking the size of cells previously tested, the study will help determine how much of the inhibitory effect of the cells was due to a mass barrier effect. Secondly, smaller particles that are easily phagocytosed by macrophages have been implicated in spurring an inflammatory reaction, which may inhibit fusion by a secondary pathway.

RESULTS: 30 female Lewis rats underwent L4-5 posterolateral fusion. Rats received 0.14 ml of 0.032 mg/ml rhBMP2 alone (n=8), rhBMP2 with 125 mic-l of DMEM (medium) (n=4), or rhBMP-2 mixed with either 5×10^6 inorganic particles (size 20–30 microns) (n=6), 5×10^6 Lewis skin fibroblast devitalized cells (n=6), or 5×10^6 Lewis skin fibroblast cells (not devitalized) (n=6).

Table 1
Treatments

Treatment Cells (added to rhBMP-2)	L4-5 Fusion	No of Rats	% Fused
Lewis Skin Fibroblast Devitalized Cells	0	6	0.0%
Inorganic Particles	0	6	0.0%
Lewis Fibroblast Cells	0	6	0.0%
None (control)	0	6	100.0%
DMEM only (medium)	4	4	100.0%

CONCLUSIONS: The results indicate that microscopic inorganic particles in the environment can inhibit rhBMP-2 osteoinductivity in vivo. This implies that it would be as important to perform a thorough debridement of the fusion environment that may contain wear debris from a prosthesis. A barrier effect may be the cause of inhibition. (Note that osteogenic cells, eg nonselective bone marrow, still overcome this mass effect.)

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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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