

# A Prospective Randomized Study of Posterolateral Lumbar Fusion Using Osteogenic Protein-1 (OP-1) Versus Local Autograft With Ceramic Bone Substitute

## Emphasis of Surgical Exploration and Histologic Assessment

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**Study Design.** A prospective, randomized and controlled study.

**Objectives.** To evaluate the osteoinductive property of Osteogenic Protein-1 (OP-1 or BMP-7) and fusion rate in human instrumented posterolateral lumbar fusion through radiographic examination, surgical exploration, and histologic assessment.

**Summary of Background Data.** The use of osteoinductive agents is a current topic in spinal fusion. Numerous preclinical investigations have demonstrated efficacy of osteoinductive proteins in spinal fusion, but few human clinical studies have been reported.

**Methods.** Nineteen patients with L3–L4 or L4–L5 degenerative spondylolisthesis underwent posterolateral lumbar fusion using pedicle screw instrumentation. The patients were randomized to receive either OP-1 Putty (3.5 mg OP-1/g of collagen matrix per side) alone (n = 9), or local autograft with HA-TCP granules (n = 10). Fusion status was evaluated using plain radiography and CT scan. Radiographic fusion criteria included less than 5° of angular motion, less than 2 mm of translation, and evidence of bridging bone in the posterolateral lumbar area in which the graft materials were placed following decortication. After a minimum 1-year follow-up, the patients who showed radiographic evidence of fusion underwent instrumentation removal and surgical exploration of the fusion site. Biopsy specimens were taken from the fusion mass and evaluated histologically.

**Results.** Radiographic fusion rate was 7 of 9 OP-1 patients and 9 of 10 control patients. Based on surgical exploration of these 16 patients, new bone formation was macroscopically observed in the posterolateral lumbar region in all cases; however, solid fusion was observed in 4 of 7

OP-1 and 7 of 9 HA-TCP/autograft patients. Histologic assessment demonstrated viable bone in 6 of 7 OP-1 patients. All the control (HA-TCP/autograft) specimens contained viable bone and fibrous tissue surrounding ceramic granules, suggesting slow incorporation of the graft material.

**Conclusions.** In a human posterolateral lumbar spine trial, OP-1 reliably induced viable amounts of new bone formation, but the fusion success rate evaluated by surgical exploration was only 4 of 7.

**Key words:** Osteogenic Protein-1 (OP-1), bone morphogenetic protein, posterolateral lumbar fusion, surgical exploration, histology. **Spine 2006;31:1067–1074**

Posterolateral spinal fusion serves as an established method for surgical management of selective degenerative lumbar pathologies. Although achieving a solid fusion often leads to successful surgical outcomes, it is estimated that 10% to 55% of all posterolateral lumbar fusions fail, at times necessitating reoperation and/or resulting in continued symptoms and loss of function.<sup>1–5</sup> Many variables influence the healing response of the spinal fusion, including host site conditions (local blood supply, decortication procedure, level of fusion),<sup>6</sup> mechanical environment (instability, instrumentation, bracing),<sup>7–9</sup> and other factors (age, nutrition, smoking).<sup>10,11</sup> Graft bone conditions (source, type, amount of bone) also influence the healing process of spinal fusion. Currently, autogenous cancellous bone is the gold standard bone grafting material for spinal fu-