

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.^{1–5} Many variables influence the healing response of the spinal fusion, including host site conditions (local blood supply, decortication procedure, level of fusion),⁶ mechanical environment (instability, instrumentation, bracing),^{7–9} and other factors (age, nutrition, smoking).^{10,11} 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-