Reduction in leg pain and lower-extremity weakness with Oxiplex/SP Gel for 1 year after laminectomy, laminotomy, and discectomy

Kee D. Kim, M.D., Jeffrey C. Wang, M.D., Daniel P. Robertson, M.D., Darrel S. Brodke, M.D., Mohammed BenDebba, Ph.D., Kathleen M. Block, B.S.N., M.A., and Gere S. diZerega, M.D.

Department of Orthopedic Surgery, University of California, Los Angeles, School of Medicine; Livingston Reproductive Biology Laboratories; University of Southern California Keck School of Medicine, Los Angeles; FzioMed, Inc., San Luis Obispo; Department of Neurological Surgery, University of California Davis Medical Center, Davis, California; Lee Neurosurgery, Fort Myers, Florida; Division of Orthopedic Surgery, University of Utah, Salt Lake City, Utah; and Department of Neurosurgery, Johns Hopkins University Medical Center, Baltimore, Maryland

Object. Although good surgical technique is effective in reducing postoperative epidural fibrosis, compression or tethering of the nerve root may cause recurrent radicular pain and physical impairment. The implantation of a bioresorbable gel on the dura may further decrease the amount of scar formation after surgery and thus improve the patient's ability to perform activities of daily living (ADL). This study is a 12-month evaluation of the safety and effectiveness of Oxiplex/SP Gel (FzioMed, Inc., San Luis Obispo, CA) in the reduction of pain and radiculopathy after lumbar discectomy.

Methods. A pilot randomized single-blind multicenter clinical trial was conducted to evaluate the performance of Oxiplex/SP Gel in patients who underwent surgery for unilateral herniation of the lumbar disc at L4–5 or L5–S1. Eighteen patients with severe leg pain and lower-extremity weakness (11 women and seven men) were randomly assigned intraoperatively to receive the gel at the conclusion of surgery (treatment group) or to undergo surgery alone (control group). Self-assessment questionnaires (Lumbar Spine Outcomes Questionnaire) to assess pain, symptoms, and ADL were completed preoperatively and at scheduled postoperative intervals (30 days, 90 days, 6 months, and 12 months).

The authors examined the spine and lower extremities of patients scheduled for discectomy to assess neurological function and pain. Treated patients received sufficient Oxiplex/SP Gel (1–3 ml) to coat the nerve root and fill the epidural space. Postoperative clinical evaluations were performed at 30 and 90 days. Patients completed the self-assessment questionnaires at baseline and were contacted by telephone or mail for the completion of the postoperative self-assessment questionnaires.

Surgical procedures were well tolerated; no device-related adverse events and no clinically significant laboratory results were reported. The 11 patients with severe leg pain and lower-extremity weakness who were treated with Oxiplex/SP Gel had a reduction in those symptoms at 30 days, 90 days, 6 months, and 12 months after discectomy, compared with the seven control patients who underwent surgery only.

Conclusions. Oxiplex/SP Gel was easy to use and safe in patients who underwent unilateral discectomy. A greater benefit in clinical outcome measures was seen over the 12-month follow-up period in gel-treated patients.

Key Words • herniated disc • laminectomy • lumbar discectomy • failed-back surgery • Oxiplex/SP Gel • Lumbar Spine Outcomes Questionnaire

Epidural fibrosis occurring after lumbar surgery may contribute to failed-back surgery syndrome, which is characterized by recurrent radiculopathy with symptoms including weakness and pain in the lower extremity.[17,20,27] Compression or tethering of spinal nerve roots and dorsal root ganglia often causes recurrent radicular pain and physical impairment.[2,23,27,31] In addition to the application of good surgical techniques,[13] many kinds of materials have been implanted in the epidural space in an effort to reduce scar formation.[1,8,14,28] One formulation, ADCON-L (Gliatech, Cleveland, OH), received FDA approval for scar reduction following lumbar surgery.[28,31] Nevertheless, widespread use of ADCON-L was limited by reports of late-onset headaches and associated leakage of cerebrospinal fluid from dural injuries; these adverse events were potentially related to delayed healing and foreign body reaction.[16,22]

Abbreviations used in this paper: ADL = activities of daily living; CMC = carboxymethylcellulose; FDA = Food and Drug Administration; LSOQ = Lumbar Spine Outcomes Questionnaire; MR = magnetic resonance; PEO = polyethylene oxide.