

Oxiplex Reduces the Incidence of Back Pain, Leg Pain, and Associated Symptoms 6 Months Following Single Level Lumbar Laminectomy for Removal of a Herniated Disc

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Wednesday, October 15, 2008, 1:06 PM
General Session: Lumbar New Technology Podium
Presentation

"Oxiplex Reduces the Incidence of Back Pain, Leg Pain, and Associated Symptoms 6 Months Following Single Level Lumbar Laminectomy for Removal of a Herniated Disc"

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Background: Oxiplex gel (carboxymethylcellulose, polyethylene oxide and calcium) was developed to coat and protect nerve roots for reduction of pain and symptoms following lumbar disc surgery.

Purpose: To evaluate the safety and effectiveness of Oxiplex gel for reduction of pain and associated symptoms following lumbar disc surgery.

Study Design: The study was a randomized, third-party blinded, multicenter, pivotal clinical trial to evaluate the safety and effectiveness of Oxiplex gel to reduce postoperative back and leg pain as well as related symptoms following surgery for removal of a herniated lumbar disc at L4-L5 or L5-S1.

Patients: Patients undergoing single-level lumbar laminectomy or laminotomy, and a discectomy randomized to receive either surgery plus Oxiplex (n = 177) or surgery alone (n = 175).

Outcome Measures: At baseline and following surgery at 1, 3, and 6 months patients were evaluated using 1) quality of life measures (Lumbar Spine Outcomes Questionnaire: LSOQ, BenDebba et. al., Spine J. 7:118-132), and 2) clinical evaluations were performed at 1 and 6 months.

Methods: Patients undergoing single-level lumbar laminectomy, laminotomy, or discectomy were intraoperatively randomized to receive either surgery plus Oxiplex or surgery alone. Patients were assessed 1, 3 and 6 months following surgery using 1) the LSOQ, and 2) clinical evaluations. Safety was evaluated by analyzing adverse events and clinical symptoms. Effectiveness was evaluated by scoring the LSOQ to produce composite scores for leg pain, back pain, and patient satisfaction.

Results: Baseline demographics, surgical procedures, LSOQ scores and clinical evaluations were balanced between Oxiplex (N=177) and surgery-only (N=175) groups. All subjects did well following surgery. There were no cases of CSF leaks in the Oxiplex-treated group and no differences in laboratory values or vital signs. There were no differences in adverse events, laboratory values or physical findings between Oxiplex-treated patients and controls. Oxiplex patients in the challenging patient population having severe back pain at baseline showed greater reductions in pain and symptoms from baseline across all LSOQ variables compared to surgery-only controls. In that population, there was a statistically significant reduction of back pain [P=0.013] and leg pain [P=0.012] in the Oxiplex group compared to controls at 6 months following surgery. More Oxiplex patients were satisfied with the outcome of their surgical treatment than control patients (P=0.045). Fewer patients in the Oxiplex group had abnormal musculoskeletal physical exams at 6 months compared to controls. Patients in the Oxiplex group had less hypoaesthesias, paraesthesias, and sensory loss compared to controls. Patients in the Oxiplex group had fewer re-operations during the 6-month follow-up than controls (1 vs. 6).

Conclusion: Taken together, these data demonstrate a consistent clinically significant improvement in outcomes resulting from the use of Oxiplex gel in lumbar spine surgery.

NASS ABSTRACT