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Use of Carboxymethylcellulose/Polyethylene Oxide Gel in Microdiscectomy With Interlaminectomy

A Case Series Comparison With Long-term Follow-up

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Study Design. A consecutive, case series comparison.

Objective. To compare safety, long-term pain, and disability scores with and without use of carboxymethylcellulose/polyethylene oxide (CMC/PEO) gel after microdiscectomy with interlaminectomy.

Summary of Background Data. Patient outcomes after microdiscectomy for lumbar disc herniation are frequently complicated by adhesions and fibrotic scars. Present management is controlled by good surgical technique as adhesion-reduction agents to date, have either proved ineffective or toxic. In 2002 a 100% synthetic combination of CMC/PEO, which reduces adhesions and fibrosis, became available across Europe as a gel application, (OXIPLEX/SP adhesion barrier gel FzioMed, Inc., San Luis Obispo, CA) and distributed under the trade names OXIPLEX/SP adhesion barrier gel (DePuy International, Ltd., Leeds, United Kingdom) and MEDISHIELD adhesion barrier gel (Medtronic International Trading SARL, Tolochenaz, Switzerland).

Methods. A consecutive series of 70 patients with lumbar disc herniation undergoing microdiscectomy with interlaminectomy by the same surgeon were treated at the end of surgery with either CMC/PEO gel (N = 35) or no gel (N = 35). Treatments were allocated by an independent investigator. At presurgery and regular intervals over 3 years postsurgery, Oswestry disability index (ODI) and leg and back pain scores determined by visual analog scales (VAS), were assessed by a member of the surgical team blinded to the initial treatment allocation.

Results. Three years postsurgery reduction in disability as measured by the decrease in ODI compared with presurgery (mean ± SD) was significantly ($P < 0.05$) greater with CMC/PEO than controls (−49.4 ± 12.7 *vs.* −41 ± 17.8). CMC/PEO treatment also resulted in significantly more patients having no disability as measured by reaching 0% ODI scores (15 CMC/PEO [43%] *vs.* 0 control group [0%]) ($P < 0.01$). Leg and back pain as measured by the decrease in VAS scores 3 years postsurgery were reduced with CMC/PEO compared with controls (leg −6.8 ± 1.7 *vs.* −5.6 ± 1.6, back −0.4 ± 1.5 *vs.* −0.1 ± 2.0), $P < 0.05$ for leg pain. Importantly there were no safety issues and no differences in complications between the 2 treatment groups during the 30 day postoperative period.

Conclusion. CMC/PEO gel after microdiscectomy with interlaminectomy appears safe to use and in a 3-year follow-up significantly reduces disability and leg pain scores compared with our conventional treatment.

Key words: microdiscectomy, laminectomy, adhesions, fibrosis, pain, carboxymethylcellulose, polyethylene. **Spine 2008;33:1762–1765**

Microdiscectomy with laminectomy are the most common surgical treatments for lumbar disc herniation and spinal stenosis, but it is estimated that between 3% and 19%[1–3] of cases result in recurrent lumbar disc herniation and instability and pain. The cause of postlaminectomy pain has been controversial,[4,5] but it is now recognized that reduction of epidural adhesions and fibrosis at the attendant spinal nerve and nerve root, as demonstrated by postoperative magnetic resonance imaging (MRI) or computed tomography (CT), can lead to improved outcomes. To date, methods to reduce adhesions and fibrosis have primarily focused on improved surgical technique rather than use of devices which have either proved limited in their effectiveness or toxicity.

More recently the development of modern technologies such as carboxymethylcellulose (CMC) and polyethylene oxide (PEO), which have respectively been shown to reduce adhesions[6–8] and to interact with the proteins causing fibrosis[9] has given surgeons hope that postlaminectomy outcomes can be improved. However, a practical problem with CMC is that it is rapidly resorbed and consequently does not reside at the site of surgery long enough to take effect. This issue has been overcome by development of a 100% synthetic combination of CMC/PEO stabilized with calcium chloride that became available across Europe in 2002 as a gel application, OXIPLEX/SP adhesion barrier gel (FzioMed, Inc., San Luis Obispo, CA) – distributed under the trade names OXIPLEX/SP adhesion barrier gel (DePuy International Ltd., Leeds, United Kingdom) and MEDISHIELD adhesion barrier gel (Medtronic International Trading SARL, Tolochenaz, Switzerland). Assessment of the CMC/PEO in an animal model demonstrated a reduction in epidural fibrosis.[10] A pilot clinical study indicated safety profiles similar to surgery alone and in patients with significant leg pain and lower extremity weakness at baseline, those treated with

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The device(s)/drug(s) is/are FDA-approved or approved by a corresponding national agency for this indication.

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