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Use of temporary tissue separating devices to improve post-surgical outcomes in cardiac and spine surgery. The Preclinical and Clinical Development Teams of REPEL CV and Oxiplex Gel. Gere diZerega MD on behalf of REPEL CV and Oxiplex Gel Development Teams, Keck School of Medicine, University of Southern California, Los Angeles, California, USA

Local reduction of post surgical tissue reaction to improve medical outcomes by use of bioresorbable materials to temporarily isolate surgical sites has been led by the development and use of intraperitoneal devices following gynecologic and general surgery. Recently, additional benefits to patient outcomes have been demonstrated by this therapeutic strategy with the use of REPEL CV (SyntheMed, Iselin, NJ) in neonates undergoing staged, planned cardiac reconstructions via sternotomy and Oxiplex Gel (FzioMed, San Luis Obispo, CA) in patients with severe leg and back pain undergoing decompression of a lumbar herniated disc. **REPEL CV:** Adhesions encountered in reoperative cardiac surgery can prolong operating time and increase risk. REPEL CV, a novel bioresorbable barrier film, was designed to reduce epicardial fibrosis and adhesion formation following surgical injury to the heart and mediastinal space. A comparative, evaluator-masked, randomized, multicenter study design was performed in infants undergoing multiple stage repair via sternotomy. Before chest closure, infants were randomized to REPEL CV film placement (n=54) or Control (no treatment, n=49) at 15 centers in the USA. At repeat sternotomy 2-13 months later, the extent and severity of adhesions at the investigative surgical site (ISS) were assessed. A four grade adhesion severity scoring system was standardized as follows: None, Mild (filmy, non-cohesive, requiring blunt dissection), Moderate (filmy, non-cohesive, requiring sharp and blunt dissection), and Severe (dense, cohesive, requiring extensive sharp dissection).

There were significantly fewer patients with Severe adhesions (29.6% vs. 71.4%, $p < 0.0001$), and a significantly lower percentage of the ISS had Severe adhesions (21.19% vs. 49.57%, $p = 0.0005$) in the Barrier group compared to the Control group at the second sternotomy. There were no significant differences in adverse events between the groups. No adverse events were definitely attributed to REPEL CV. In conclusion, use of REPEL CV was safe and effective in reducing the extent and severity of postoperative adhesions in infants undergoing repeat median sternotomy (Lodge et al., *Ann Thorac Surg* 86:614-21, 2008). **Oxiplex Gel:** A prospective, randomized, blinded, parallel group clinical study of 352 patients (Oxiplex treated, N = 177 and surgery only, N = 175) was performed to assess the safety and effectiveness of Oxiplex, a novel bioresorbable gel (FzioMed, San Luis Obispo, CA), to reduce postsurgical pain and neurological symptoms in patients undergoing their first single-level laminotomy, laminectomy, or discectomy at L4-L5 or L5-S1. Patients were randomly selected to receive surgery only or surgery plus Oxiplex placed on and around the dura and nerve root prior to wound closure. The effectiveness of Oxiplex for the reduction of pain and associated symptoms was assessed 6 months following surgery using quality of life measure (Lumbar Spine Outcomes Questionnaire: LSOQ) and clinical evaluations. Subjects treated with Oxiplex were shown to experience greater reductions in back pain ($P = 0.0193$) and leg pain ($P = 0.0123$) at 6 months compared to control subjects, in the challenging group with severe back pain at baseline. More subjects in the Oxiplex group were satisfied with the outcome of their surgical treatment than subjects in the control group ($P = 0.0456$). Neurologic dysfunction was less commonly reported in the Oxiplex subjects compared with control subjects. Hypoesthesia was reported in 10.2 % (n = 18) of the Oxiplex subjects vs. 14.9 % (n = 26) in control subjects. Subjects in the Oxiplex group had fewer reoperations during the 6-month follow-up than subjects in the control group (1 vs. 6), as well as fewer abnormal musculoskeletal physical exams (15% vs 24%, respectively). **Conclusion:** Protecting the dura and nerve root at the laminotomy site with Oxiplex following lumbar spine surgery is associated with a greater improvement in neurological function and less postoperative pain compared to patients undergoing surgery only (Rhyne et al., *Spine*, in press). **Overall Conclusion:** Use of temporary tissue separating devices to reduce local tissue reaction following surgery provides a useful strategy to improve postoperative outcomes in peritoneal, cardiac, and spinal disc surgery. Continued application of this strategy should lead to further improvement in patient care across multiple surgical disciplines.