

# A Modern Biomaterial for Adhesion Prevention

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Received 24 October 2005; revised 1 June 2006; accepted 6 June 2006

Published online 12 September 2006 in Wiley InterScience (www.interscience.wiley.com). DOI: 10.1002/jbm.b.30659

**Abstract:** A biomaterial composed of carboxymethylcellulose, poly(ethylene oxide), and calcium can be prepared in a variety of ways to reduce fibrin deposition and adhesion formation. This biomaterial platform can be formulated into a flowable gel with tissue adherence appropriate for use in minimally invasive surgery. The device remains at the site of placement even in gravitationally dependent areas. A peridural formulation was shown in preclinical studies to be safe and effective in reducing adhesions to dura following spinal surgery. A peritoneal formulation used on pelvic organs following peritoneal cavity surgery was also shown to be safe and effective. A clinical feasibility study showed that patients with severe back pain and lower extremity weakness treated with the peridural formulation, applied over their nerve roots following laminectomy or laminotomy, experienced significantly reduced symptoms when compared with surgery-only controls. The peritoneal formulation was shown in two multicenter feasibility studies of women undergoing pelvic surgery to significantly reduce adhesion formation when compared with surgery-only controls. Confirmation of the feasibility studies awaits results from pivotal clinical trials. These formulations were safe, effective, and easy to use. This biomaterial provided a benefit to patients undergoing surgery where postsurgical adhesion formation is a concern. © 2006 Wiley Periodicals, Inc. *J Biomed Mater Res Part B: Appl Biomater* 81B: 239–250, 2007

**Keywords:** absorbable; viscoelastic; fibrin; bioresorbable; adhesion

## INTRODUCTION

Postoperative adhesion formation is the single greatest complication of surgery.<sup>1–5</sup> Fibrous adhesions form after surgery to peritoneum, central nervous system, pericardium, pleura, and synovium. Pelvic adhesions have been found in 56–100% of patients by second-look laparoscopy after primary gynecological surgery.<sup>6</sup> Diamond et al.,<sup>7</sup> as well as DeCherney and Mezer,<sup>8</sup> demonstrated that gynecologic pelvic surgery typically causes adhesions to the adnexa, leading to infertility and pelvic pain. Menzies and Ellis<sup>9</sup> showed that adhesion formation follows general surgical procedures, especially those involving bowel. Clinical consequences of adhesions after peritoneal cavity surgery include increased rates of reoperation,<sup>3</sup> postoperative bowel obstruction,<sup>10</sup> infertility,<sup>11</sup> and chronic pelvic pain,<sup>12,13</sup> all of which markedly increase healthcare costs.<sup>14,15</sup>

The clinical consequences of adhesions are not limited to abdominal-pelvic operations. Fibrosis can form between

spinal dura mater and interposing structures as a result of hematoma or residual necrotic tissue, including fat.<sup>16–18</sup> It was reported that fewer than one-third of patients who undergo a repeated operation after lumbar disc surgery show persistent improvement of their symptoms; the chance of long-term surgical success after a repeated operation may be diminished in cases in which epidural fibrosis is prevalent.<sup>18,19</sup> Repeat surgery for epidural fibrosis is often less successful and may require prolonged operating time and increased risks of adhesive arachnoiditis and dural tears from surgery to treat fibrosis at the surgical site.<sup>20–22</sup> 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.<sup>23–25</sup>

## ADHESION PREVENTION ADJUVANT TECHNOLOGY

### Gynecologic Surgery

Use of adhesion prevention adjuvants has become the standard of practice following conservative gynecologic sur-

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