

Reduction of postoperative adhesions after laparoscopic gynecological surgery with Oxiplex/AP Gel*: a pilot study

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Objective: To determine whether Oxiplex/AP Gel (FzBioMed, San Luis Obispo, CA) was safe and preliminarily effective in reducing postsurgical adhesions after adnexal surgery by laparoscopy.

Design: Prospective, multicenter, double-blind, randomized, U.S. Food and Drug Administration-monitored feasibility study.

Setting: University and private clinics.

Patient(s): Patients undergoing laparoscopic surgery with pelvic adhesions, tubal occlusion, endometriosis, and/or dermoids were randomized to receive Oxiplex/AP Gel or no further treatment after surgery.

Intervention(s): A blinded, parallel-group design was conducted at six centers. Patients (aged 18–46 years) underwent laparoscopic surgery, with second-look surgery 6–10 weeks later. Surgeries were videotaped. Oxiplex/AP Gel was used to cover adnexa and adjacent tissue.

Main Outcome Measure(s): Blinded reviews of videotapes were quantitated with the American Fertility Society adhesion score (AFS score).

Result(s): In 18 treatment patients, surgery was performed on 29 adnexa. Application of Oxiplex/AP Gel required approximately 90 seconds. In 10 control patients, surgery was performed on 18 adnexa. The mean baseline AFS score for each group was 8.0. At second look, treated adnexa had the same score (8.1), whereas in control adnexa the score increased (from 8.0 to 11.6). Thirty-four percent of treated adnexa increased in adhesion score, in contrast to 67% of control adnexa. There were no device-related adverse events.

Conclusion(s): In this pilot study, Oxiplex/AP Gel was safe, easy to use with laparoscopy, and produced a reduction in the increase of adnexal adhesion scores. (Fertil Steril® 2005;84:1450–6. ©2005 by American Society for Reproductive Medicine.)

Key Words: Adhesions, Oxiplex/AP Gel, surgery

Postoperative adhesion formation is the single greatest complication of gynecological surgery (1–3). Pelvic adhesions have been found in 56%–100% of patients undergoing second-look laparoscopy after primary gynecological surgery (4). Diamond

et al. (5) and DeCherney and Mezer (6) demonstrated that gynecological pelvic surgery typically causes adhesions to the adnexa. Rosen and Sutton (7) and Howard et al. (8) recently summarized the contribution of adnexal adhesions to infertility and pain. Although most conservative gynecological surgery is performed by laparoscopy, there are no adhesion prevention devices that can be easily delivered with laparoscopy.

Oxiplex/AP Gel (FzBioMed, San Luis Obispo, CA) was specifically formulated for laparoscopic application, with tissue adherence and persistence sufficient to prevent adhesion formation. A similar preparation of Oxiplex (Oxiplex/SP Gel) was shown to reduce back pain and leg weakness from epidural adhesions after lumbar surgery (9, 10).

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