Adept®

ADHESION REDUCTION SOLUTION [4% ICODEXTRIN]

This is a summary of some of the key findings from the following paper:
Adept® (icodextrin 4% solution) reduces adhesions after laparoscopic surgery for adhesiolysis: a double-blind, randomized, controlled study
Authors: Brown, Colin B, et al. Fertility and Sterility® Vol. 88, No. 5, November 2007

BACKGROUND

The formation of adhesions following abdominopelvic procedures is nearly unavoidable. Adhesions can lead to infertility and post-operative pain. Adept® solution works as an instillate and forms a fluid reservoir in the peritoneal cavity with a prolonged residence time of up to 4 days and is slowly absorbed by the lymphatic system. Because of this, a large pivotal trial to confirm Adept's clinical efficacy and safety was performed.

STUDY OBJECTIVES

To evaluate the efficacy and safety of Adept® in reducing adhesions after laparoscopic gynecological surgery involving adhesiolysis while comparing it to Lactated Ringer's Solution (LRS).

STUDY DESIGN

Double-blind, randomized multicenter study consisting of four visits and conducted at 16 referral centers. Patients consisted of women ≥ 18 years old in general good health. Laparoscopic surgery was planned for a gynecological procedure that included adhesiolysis followed by a second follow-up laparoscopy 4-8 weeks later. Details of each visit are as follows:

Visit 1 (Up to 4 weeks prior to surgery)	Visit 2 (First lap procedure)	Visit 3 (1-3 weeks after initial surgery)	Visit 4 (Final lap procedure 4-8 weeks after initial surgery)
Patient underwent physical exam and samples were taken for lab tests	Presence/absence of adhesions, extent & severity, and AFS* scores recorded	Patients underwent clinical laboratory tests and a physical examination	Videotaping and scoring of all available anatomical sites were performed, including AFS scores
Patient's medical history was recorded	Abdomen irrigated with minimum of 100 ml of study solution every 30 min.	Concomitant medications and any adverse events were recorded	All adverse events and concomitant medications were recorded
Degree of pain assessed at baseline using a visual analog scale (VAS)	A minimum of three adhesions had to be lysed and recorded at initial surgery		Degree of pain assessed at final visit using VAS
	Any remaining study solution was aspirated, and 1000 ml of study solution instilled		

Adhesions were scored at all 23 or all available anatomical sites. The presence or absence and severity of the adhesions were recorded. Extent was defined as one of the following:

Localized	Moderate	Extensive
< 1/3 of the adhesion site covered	1/3-2/3 of the adhesion site covered	>2/3 of the adhesion site covered

* American Fertility Society

Baxter

Severity was defined as:

Mild: filmy and avascular **Severe:** dense, cohesive, or vascular

Study efficacy measures included: clinical success, incidence, extent, and severity of adhesions and adhesion scoring using the AFS classification for adnexal adhesions. During a discussion with the FDA, the clinical success of adhesion reduction for a patient was determined as a reduction in adhesions of at least three or 30% of sites lysed (depending on which is greater) between initial surgery and the follow-up laparoscopy.

Safety was assessed by serious adverse events (SAEs), adverse events and changes in lab values. Patients also recorded their well-being and all concomitant meds.

RESULTS

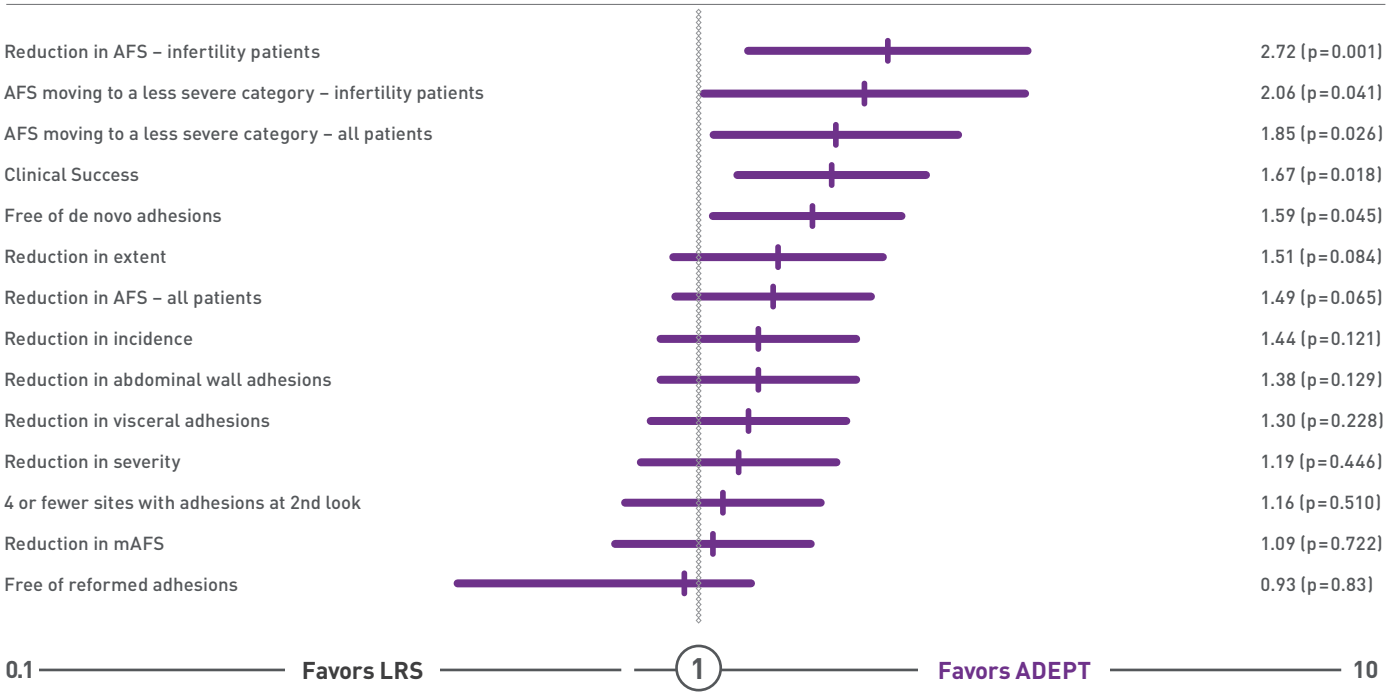
The study began with 203 patients in the Adept® group and 199 patients in the LRS group. More Adept® patients achieved clinical success than did LRS patients (49% vs. 38%). Of the 57 patients treated with Adept® and the 55 patients treated with LRS who showed moderate/severe AFS scores at initial surgery, 29 patients (51%) and 19 (35%) patients, respectively, moved to a minimal/mild AFS category due to improvements in their AFS score. Safety was comparable with both groups. The frequency of adverse events and the number of patients who reported them were similar in both treatment groups.

Patients treated with Adept® had more favorable outcomes than those receiving LRS. In patients with infertility and in the subgroups with diagnoses of endometriosis or pain, the parameters of clinical success and AFS score also showed more favorable outcomes with Adept® compared with LRS.

CLINICALLY PROVEN RESULTS

PAMELA study Double-blind randomized controlled trial comparing ADEPT (n=203) and Lactated Ringer's Solution (n=199) during laparoscopic gynecological surgery

In 13 out of 14 study parameters ADEPT had a positive outcome compared with LRS



Adept®

ADHESION REDUCTION SOLUTION [4% ICODEXTRIN]

CONCLUSIONS

Based on this study, Adept® is easy-to-apply, safe, and effective as an adhesion reduction agent in laparoscopy.

Using Adept® as an irrigant and postoperative instillate reduces adhesions after laparoscopic gynecologic adhesiolysis more than LRS. Although both Adept®- and LRS-treated patients showed a reduction in AFS score from their baseline score, the Adept® patients displayed a more significant reduction in AFS score of 2.5-3.0 units beyond that of the LRS patients. A reduction of this amount is considered clinically significant since a patient can now be placed in a better prognostic category (minimal, mild) for pregnancy as opposed to what would have occurred otherwise (moderate, severe).

ADEPT® Adhesion Reduction Solution [4% Icodextrin] Indications

Important Risk Information for ADEPT®

ADEPT® is intended for use as an intraperitoneal instillate for the reduction of adhesions following gynecological laparoscopic surgery, and should be used as the irrigant during the course of that surgery.

ADEPT® is indicated to be used in gynecological laparoscopic surgery of the abdominal-pelvic cavity in adults.

Contraindications

ADEPT® is contraindicated:

- In patients with known or suspected allergy to cornstarch based polymers, icodextrin, maltose or isomaltose intolerance, or in patients with glycogen storage disease.
- In the presence of frank infection (e.g. peritonitis) in the abdomino-pelvic cavity.
- In procedures with laparotomy incision. Serious post-operative wound complications including dehiscence and cutaneous fistula formation have been reported from clinical experience when ADEPT® was used in surgical cases with laparotomy incision.
- In procedures involving bowel resection or repair, or appendectomy. Anastomotic failure, ileus, peritonitis and rare cases of serosal fibrosis following procedures involving bowel resection and instillation of ADEPT® have been reported from clinical experience.

There are rare reports of pleural effusion from clinical experience with ADEPT®. As a possible relationship to the use of ADEPT®, in conjunction with inappropriate fluid monitoring during surgical procedure cannot be ruled out, the volume of ADEPT® instilled should always follow the recommendations of the Instructions for Use.

Self-limited vulvar swelling is a known side-effect of instilling large volumes of fluid into the abdomino-pelvic cavity. Most cases resolve within one week of surgery. When swelling is associated with urinary retention, catheterization may be necessary effects).

Maltose metabolites of icodextrin may interfere with blood glucose measurement in diabetic patients who use rapid blood glucose systems that are not glucose specific.

For safe and proper use of this device, please refer to full Instructions For Use.

CE 0123

GLBL/41/19-0007 01/2020

Baxter