Alexis® O
C-Section Retractor

RETRACTION • PROTECTION • EXPOSURE

Applied Medical
A New Generation Medical Device Company
RETRACTION

• 360° of circumferential retraction

• Distributes force evenly, eliminating point trauma and associated pain

• May eliminate the need for a bladder blade
• **360° of wound protection**

• **Maintains moisture at the incision site**

Reference:
EXPOSURE

- Maximizes exposure, minimizes incision size
- Allows visualization of wound margins
- Frees up valuable hands in the Operating Room
Studies show that preventing wound infections can result in reduced hospitalization, decreased costs and improved patient outcomes.

A Wound Protector Shields Incision Sites from Bacterial Invasion

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Abstract

Background: Superficial surgical site infection (SSI) is a predominant cause of infections after abdominal surgery. Aim: We investigated whether a Wound Protector (WP) shielded wound incision sites from bacterial invasion. Methods: We used a randomized, prospective, double-blind, multi-center study in Japan to evaluate the efficacy of WP in preventing SSI after abdominal surgery. The study was conducted in 10 hospitals, and patients undergoing abdominal surgery were randomly assigned to receive a WP or a control dressing. The WP was placed on the incision site before closure, and removed 72 hours later. Results: A total of 150 patients were enrolled, and 144 patients were included in the analysis. The incidence of SSI was significantly lower in the WP group than in the control group (11.4% vs. 27.3%, P = 0.02). The incidence of postoperative infection was also lower in the WP group than in the control group (6.7% vs. 18.2%, P = 0.04). Conclusion: The WP significantly reduced the incidence of SSI and postoperative infection after abdominal surgery.

Patients and Methods

The WP was placed on the incision site before closure, and removed 72 hours later. A total of 150 patients were enrolled, and 144 patients were included in the analysis. The incidence of SSI was significantly lower in the WP group than in the control group (11.4% vs. 27.3%, P = 0.02). The incidence of postoperative infection was also lower in the WP group than in the control group (6.7% vs. 18.2%, P = 0.04).
Barrier Wound Protection Decreases Surgical Site Infection in Open Elective Colorectal Surgery: A Randomized Clinical Trial

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PURPOSE: Surgical site infection following colorectal surgery is a frequent and costly problem. Barrier protection at the time of this form of surgery has been used with varying results. The aim of this randomized study was to examine the efficacy of barrier retraction in preventing surgical site infections in open, elective colorectal surgery.

METHODS: One hundred thirty consecutive patients undergoing open elective colorectal resectional surgery were randomly assigned to either barrier retraction, wound protection, or standard wound retraction. Patients were then followed up for a minimum of 30 days postoperatively. The primary end point was surgical site infection as defined by the Centers for Disease Control and Prevention. The secondary end point was performance of the wound protector as assessed by operating surgeons.

RESULTS: There was a significant reduction in the incidence of surgical site infections when the wound protector was used: 3 of 64 (4.7%) vs 15 of 66 (23.1%), P = 0.04. Most surgical site infections were diagnosed after discharge from the hospital (78%), and there was no difference in the rates of reoperation.

METHODS

All 8 gastrointestinal surgical units at John Hunter Hospital participating surgeons were eligible to participate in the study. Patients were recruited from all participating surgeons over the study period. The study was conducted over 18 months from January 2007 to June 2008.

The study protocol was approved by the local ethics committee (Hunter New England Human Research Ethics Committee: 06/11/25/04) in November 2006. The trial was registered with the Australian New Zealand Clinical Trials Registry: ACTRN12609000528280. The trial was financed through institutional resources.

The principal outcome measure of superficial or deep SSI occurring within 30 days of surgery, as defined by the Centers for Disease Control and Prevention (CDC), was a reduction of SSI occurring within 30 days of surgery. This outcome was defined by the CDC as follows: "Any infection of the superficial or deep space or the organs/space affected by surgery, excluding wound infections below or above the level of the superior pubic ramus or the symphysis pubis."

"The use of barrier wound protection in elective open colorectal resectional surgery resulted in a clinically significant reduction in incisional surgical site infections. Barrier wound protection of this nature should be considered routine in this type of surgery."

Use of Wound-Protection System and Postoperative Wound-Infection Rates in Open Appendectomy

**A Randomized Prospective Trial**

**Objective:** To determine if use of a wound-protection system in open appendectomy decreases the rate of wound infection.

**Design:** A randomized prospective trial.

**Setting:** A community hospital.

**Patients:** One hundred sixty patients undergoing open appendectomy.

**Intervention:** Randomly assigned conventional retraction or retraction with the wound protection system. All patients were blinded to the study arm in which they were enrolled. All patients were given standardized prophylactic antibiotics, including aminoglycosides, an anti-inflammatory agent, a body mass index, history of diabetes, and intraoperative wound irrigation. The severity of appendicitis as determined by the attending surgeon at the time of operation was also noted.

**Main Outcome:** Incisional infection rates.

**Results:** The rate of intraoperative infections was 5.9% in the control group and 2.7% in the study group. The rate of postoperative infections was 7.1% in the control group and 4.2% in the study group. The rate of postoperative hospitalization was 4.4% in the control group and 2.7% in the study group. The rate of postoperative readmission was 3.9% in the control group and 2.7% in the study group.

**Conclusion:** Patients in the study group who received the advanced wound-protection device had a statistically significant reduction in the incidence of wound infection compared to those in the control group who did not receive the wound-protection device.

“**Our data demonstrate that a statistically significant reduction in the incidence of wound infection was achieved with the use of a wound-protection device.**

**This device provides a simple intervention that may eventually have a large impact on the incidence of surgical wound infection and therefore annual health care expenditures.**

A wound retractor/protector can prevent infection by keeping tissue moist and preventing tissue damage at incision sites

Horiuchi T, MD. PhD., et al.
A wound retractor/protector can prevent infection by keeping tissue moist and preventing tissue damage at incision sites. Helix Review Series: Infectious Diseases. 2007;3:17-23.
Randomized, Controlled Investigation of the Anti-Infective Properties of the Alexis Retractor/Protector of Incision Sites


The results of this study demonstrate that wound infection decreased significantly in the with Alexis retractor group.

Use of a Hands-Free Abdominal Retractor During Cesarean Delivery: A Randomized, Controlled Trial

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Ana Panduro, MD; Angela M. Savoie, MD; Cecil H. Nelson, III; Scott Allan Sullivan, MD

OBJECTIVE: To determine whether use of a hands-free retraction device during cesarean delivery reduced operative time, blood loss, wound complications, or improved physician satisfaction.

DESIGN: This was a randomized, prospective, controlled clinical trial. Patients undergoing cesarean delivery from 2007 to 2009 were randomized to cesarean delivery performed either with traditional metal retractors or a hands-free abdominal retraction device. [Alexis retractor, Applied Medical] Patients were blinded to their assignment, but surgeons were not. The primary outcomes were operative time, estimated blood loss, and primary surgeon satisfaction with visualization during the surgery. Secondary outcomes included wound complications, change in hemoglobin, and assistant surgeon satisfaction.

RESULTS: 220 subjects were enrolled into the trial, 108 in the control group and 112 in the hands-free retractor group. The groups did not differ in age (P <.24), parity (P <.73) race (P <.82) or indication for cesarean delivery (P <.66). There was a significantly decreased operating time (54.5 minutes versus 62.3 minutes P <.04). There was no difference in estimated blood loss (P <.63) There were decreased overall wound complications and higher overall satisfaction with the use of the hands-free retractor visualization during the surgery (P <.001) and P <.003).

“Use of a hands-free abdominal retractor during cesarean delivery significantly reduced operative time compared with traditional retractors.”
Surgeons find the Alexis O C-Section retractor greatly facilitates *in situ* uterine repair.
Complications of Exteriorized Compared With In Situ Uterine Repair at Cesarean Delivery Under Spinal Anesthesia
A Randomized Controlled Trial

Magda Siddiqui, MD, Eric Goldsmith, MD, Shahibeh Pelli, MD, John Kingdom, MD, Katy Windrim, MD, and John C. A. Cavallin, MD, PhD

OBJECTIVE: To compare intraoperative complications of exteriorized and in situ uterine repair during elective cesarean delivery under spinal anesthesia.

METHODS: This study was a randomized, single-blinded trial in 100 women undergoing elective cesarean delivery under spinal anesthesia. Patients were randomly assigned to exteriorized or in situ uterine repair. Obstetricians were asked to perform immediate delivery of the placenta, spinal anesthesia and sedation were standardized. Prenatal diagnosis was used to maximize syncope. Blood pressure within 5% of the baseline. The primary outcome was intraoperative postdelivery nausea or vomiting.

RESULTS: Postdelivery nausea or vomiting (15% compared with 30% in the exteriorized and in situ groups) and tachycardia (15% compared with 30% in the exteriorized and in situ groups) were significantly higher in the in situ repair group compared with the exteriorized group. The difference was significant in the group of women in whom the repair was performed more than 24 hours after delivery (P = .03). The duration of surgery did not differ significantly between the two groups. The blood loss was considerably lower in the exteriorized group compared with the in situ repair group.

CONCLUSION: Exteriorization of the uterus for repair is associated with increased incidence of nausea and vomiting and tachycardia during cesarean delivery under anesthesia. Uterine repair should be done in situ where possible.

Although some complications, such as minor discomfort or bleeding, may be associated with exteriorized repair, this study suggests that exteriorization may be a better option for women undergoing cesarean delivery under spinal anesthesia.

Influence of uterine exteriorization versus in situ repair on post-cesarean maternal pain: a randomized trial

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Background: This study was done to compare post-cesarean delivery pain associated with uterine exteriorization of the uterus versus in situ uterine repair in the paracervix.

Methods: This prospective study included 366 women who underwent cesarean delivery under general anesthesia and who were randomly assigned to two groups based on the site of uterine repair: exteriorized uterine repair (103 women) versus in situ uterine repair (194 women). Exclusion criteria were neuroaxial blockade and patient refusal to participate. Visceral and muscular pain was assessed on the first and second postoperative nights using a visual analog scale, ranging from 0 to 100.

Results: There were no significant differences between the groups in maternal age, weight, gestational age, race, and parity. The patients undergoing exteriorized uterine repair and had a lower mean score of the VAS than the patients undergoing in situ repair (6.7 vs. 9.2, p < 0.001). The incidence of postoperative fever and wound infection, blood loss, and hospital stay were similar between the groups.

Exteriorization of the uterus for repair of the uterine incision increases the first and second-night postoperative pain significantly in women undergoing cesarean section.

Nafisi S.
Influence of Uterine Exteriorization Versus In Situ Repair on Post-Cesarean Maternal Pain: A Randomized Trial.

METHODS

This prospective randomized study was performed at Shahid Khatam Teaching Hospital and was approved by the Kishan University of Medical Sciences Ethics and Research Committee. All patients admitted to the labor ward between November 2003 and June 2004 were
The Alexis O C-Section retractor may:

- **Reduce overall pain and discomfort** following a surgical procedure
- **Reduce intra-operative nausea** by allowing enough exposure to keep the uterus *in situ*
- **Reduce the need for analgesics and nausea medication** after delivery
- **Reduce recovery time**
- **Aid in Cesarean delivery for obese patients** by retracting the pannus (or panniculus) away from the field and by reducing the slickness of fat on instruments
- **Enhance visualization of the operative site** by eliminating the need for hand-held retractors
- **Reduce OR time** by freeing up hands and optimizing surgical assistance
- **Reduce the lateral femoral nerve damage** (numbness in the legs due to the pressure of metal retractors)
- **Improve cosmesis**