

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

## *A Randomized Prospective Trial*

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**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 nine patients undergoing open appendectomy.

**Intervention:** Randomly assigned conventional retraction or retraction with the wound-protection system. Patients were blinded to the study arm in which they were enrolled. All patients were given standardized preoperative antibiotics. Demographics including age, sex, body mass index, history of diabetes, and tobacco use were recorded. The severity of appendicitis as determined by the attending surgeon at the time of operation was also noted.

**Main Outcome Measures:** Incidence of wound infection at 21 days postoperatively


**Results:** Of the 48 patients enrolled in the traditional retraction arm, there were 7 (14.6%) documented wound infections. Of the 61 patients enrolled in the wound-protection device arm, there was 1 (1.6%) wound infection. The severity of appendicitis between the 2 groups was matched. The decrease in incidence of wound infection observed with the wound-protection system was significant ( $P = .02$ ).

**Conclusion:** Use of a wound-protection system reduces the incidence of surgical wound infection in open appendectomy.

**Trial Registration:** clinicaltrials.gov Identifier: NCT00323453

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IT IS ESTIMATED THAT 2% TO 5% OF all patients who have surgery will develop a surgical site infection (SSI).<sup>1</sup> These infections lead to increased hospital length of stay, increased financial burden, as well as emotional distress for the patient. It has been shown that patients with an SSI are twice as likely to die, 60% more likely to spend

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time in an intensive care setting, and more than 5 times as likely to require a readmission to the hospital. Additionally, it has been estimated that patients who develop an SSI incur an average of more than \$3000 in added costs per hospitalization.<sup>2</sup> This translates into reported costs of \$130 million to \$845 million per year in the United States.<sup>1</sup>

Because SSI is preventable, several guidelines have been published in an attempt to reduce its incidence. These are currently outlined in the Centers for Disease Control and Prevention and the Medicare Quality Improvement Project and include such standardized hospital practices as skin preparation, hand antisepsis, antibiotic prophylaxis, maintenance of a sterile surgical environment, and postoperative wound care.<sup>3</sup> The driving purpose behind all of these measures is to prevent the contamination of the wound by bacteria at the time of surgery and to thus prevent the formation of a soft-tissue infection.

During open appendectomy, the wound is susceptible to contamination, especially in cases of perforation. Estimates of wound infection after open appendectomy have been reported to be 13% overall and even as high as 23% in cases of perforation.<sup>4,5</sup> The wound-protection system was originally designed to provide an al-

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ternative to traditional wound retraction in open cases. However, an added advantage to the device may be that it provides a physical barrier to protect the wound from bacterial contamination. Prior to this study, one other report exists in the literature that demonstrated a statistically significant decrease in SSI in a subgroup analysis of 221 patients undergoing various nontraumatic gastrointestinal surgery.<sup>6</sup>

The purpose of our study was to investigate whether or not the use of a wound-protection system leads to a decrease in SSI after open appendectomy. To this end, we undertook a randomized prospective trial of wound protection to determine if this would be of benefit in reducing infection after open appendectomy.

## METHODS

This prospective randomized trial was initiated at a single-institution community teaching hospital. The institutional review board approved the study protocol and consent. All patients undergoing an open appendectomy between May 2006 and May 2008 were evaluated for participation. Inclusion criteria were a clinical diagnosis of appendicitis, planned open appendectomy, and informed consent. Exclusion criteria were a history of insulin-dependent diabetes and an inability to follow up owing to geographic location. Patients with insulin-dependent diabetes were excluded from the study secondary to their overall increased risk of infection. All patients received a standard dose (3.375 g) of piperacillin-tazobactam intravenously within 1 hour before skin incision. If the patient had an allergy to penicillin, 400 mg of intravenous moxifloxacin was given instead.

A vernacular description of the study aim was presented to the patients in their native language (English or Spanish). All questions were entertained to the satisfaction of the subject prior to obtaining consent. The patient was blinded to his or her treatment arm.

Patients were then randomized using a computer-generated randomization allocation program to receive intraoperative retraction with either standard retractors or the small (2.5-6 cm) Alexis wound-protection system (Applied Medical, Rancho Santa Margarita, California) (**Figure**). The Alexis wound retractor is a disposable plastic surgical retractor that provides 360° retraction and wound protection for open procedures. The Alexis retractor was placed in the wound upon entry into the peritoneal cavity and remained in place for the duration of the procedure. Wound closure consisted of a 2- or 3-layered closure. Skin was reapproximated using staples. All wounds were closed primarily regardless of the severity of the appendicitis. Antibiotic treatment was given for 24 hours for simple appendicitis. For complicated appendicitis, treatment with intravenous antibiotics was continued until the patient remained afebrile for 24 hours with a normal white blood cell count. If a patient's appendix was ruptured, he or she was treated with 400 mg of oral moxifloxacin daily for an additional 5 to 7 days.

Owing to the nature of the study, it was not possible to mask the surgeon to the assigned study group. However, the treatment arm was not disclosed to the patient. In addition, the follow-up of each patient was performed by a research nurse who was blinded to the randomized study group.

Upon presentation, a surgical resident performed a history and physical examination. Once a clinical diagnosis of acute appendicitis was made, patient variables were collected, including age, sex, body mass index (calculated as weight in kilograms divided by height in meters squared), history of cur-



**Figure.** Alexis wound retractor.

rent tobacco use, history of diabetes, current immunosuppression, and presence of renal failure. The degree of appendicitis as determined by the attending surgeon at the time of operation was recorded (acute, suppurative, gangrenous, perforated, or abscess). If more than 1 modifier was used in the operative note, the more severe of the modifiers was used to categorize the patient. Other intraoperative factors, including operative time and time of preoperative antibiotic administration, were obtained. If the patient was sent home using oral antibiotics, this was also noted.

Patients were followed up for any adverse events occurring up to 3 weeks after the operation. At that time, a registered nurse, blinded to the study arm, evaluated the patient for any evidence of wound infection. This was defined as any significant subcutaneous SSI necessitating wound opening or treatment with antibiotics. This also included any subject who was prescribed a separate course of antibiotics after discharge from the hospital. All such events were coded as SSI. Deviations from the study protocol and subject withdrawals were also recorded.

Wound-infection rates in open appendectomy range from 2% to 23% in the current surgical literature, with perforated appendicitis accounting for most of these.<sup>5</sup> To achieve 80% power in demonstrating a 50% reduction of SSI with  $P < .05$ , each study arm needed 330 subjects. However, interim analysis was conducted by an independent investigator at 2 years and it demonstrated a significant difference between the 2 study arms. At this point the study was discontinued.

A 2-tailed significance level of  $P < .05$  was used for all comparisons to assess significance. The Fisher exact test was used to calculate the significance of the study variables. Means and standard deviations (SDs) were calculated to assess matched controls between the 2 study arms.

## RESULTS

From May 2006 to May 2008, 113 patients undergoing open appendectomy were enrolled in the study. Of these, 3 patients eventually chose to withdraw from the study (they did not want to commit to follow-up) and 1 patient was lost to follow-up. Of the 109 patients remaining, 48 were enrolled in the traditional retraction arm and 61 were enrolled in the wound-protection device arm of the study. There were 7 wound infections documented at the time of follow-up in the traditional arm (14.6%) and 1 wound infection in the study arm (1.6%). All infections were superficial subcutaneous wound infections. This difference was statistically significant ( $P = .02$ ).

**Table 1. Patient Characteristics**

Characteristic	Patients, No. (%)	
	Traditional Retraction (n=48)	Wound-Protection Device (n=61)
Age, mean (SD), y	33.1 (16.1)	35.4 (18.9)
Male sex	32 (64)	38 (62)
Body mass index, <sup>a</sup> mean (SD)	25.8 (5.4)	25.6 (4.6)
Tobacco use	4 (8)	6 (10)
Diabetic history	0	1 (1.6)

<sup>a</sup>Calculated as weight in kilograms divided by height in meters squared.

**Table 2. Degree of Appendicitis at the Time of Operation**

Degree of Appendicitis	No. (%)	
	Traditional Retraction (n=48)	Wound-Protection Device (n=61)
Acute	23 (48)	28 (46)
Suppurative	7 (15)	11 (18)
Gangrenous	4 (8)	7 (11)
Perforated	14 (29)	15 (25)

Patient demographics and preoperative characteristics are presented in **Table 1**. There were no statistically significant differences between our 2 study populations in terms of age, sex, body mass index, or medical history. Most patients were men (64%). The mean age in the traditional retraction group was 33.1 years (SD, 16.1 years) and the mean age in the wound-protection group was 35.4 years (SD, 18.9 years). This was not found to be statistically significant ( $P=.5$ ). Body mass indices were also comparable between the 2 study arms (traditional retraction group, 25.8 [SD, 5.4]; wound-protection group, 25.6 [SD, 4.6];  $P=.08$ ). Tobacco use was recorded in 4 of the 48 patients undergoing traditional retraction (8%) vs 6 of the 61 patients undergoing retraction with the wound-protection device (10%). Only 1 patient (in the wound-protection group) reported a history of type 2 diabetes. No patients enrolled in the study were treated with immunosuppression.

The 2 groups were also comparable in terms of the severity of appendicitis. The primary surgeon described the appendix as acute, suppurative, gangrenous, or perforated based on its gross appearance at the time of operation. If more than 1 modifier was used, the more severe of the 2 was included in the study. Most operations were performed on acute, uncomplicated appendicitis. However, between the 2 groups, numbers of more severe appendicitis were comparable (**Table 2**). Individual characteristics of subjects with postoperative wound infection are presented in **Table 3**.

### COMMENT

The purpose of this study was to determine whether or not the use of a wound-protection device during open

**Table 3. Individual Characteristics of Patients With Wound Infection**

Patient No.	Treatment Arm	Degree of Appendicitis	Body Mass Index <sup>a</sup>
1	Control	Perforated	27
2	Control	Suppurative	33.7
3	Control	Perforated	29
4	Control	Perforated	33
5	Control	Acute	30.6
6	Control	Acute	26
7	Control	Perforated	19
8	Wound-protection device	Perforated	17

<sup>a</sup>Calculated as weight in kilograms divided by height in meters squared.

appendectomy affected the rate of SSI. 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.

The mean additional cost a patient incurs with a postoperative wound infection has been estimated at \$3000.<sup>2</sup> The incidence of wound infection in open appendectomy is as high as 13%.<sup>4</sup> On average, this equates to approximately \$450 of added costs per patient undergoing open appendectomy. The mean cost of the wound-protection device is \$20, a potential savings of \$430 per patient. An estimated 250 000 appendectomies are performed in the United States every year.<sup>7</sup> Roughly 60% of these, 150 000 cases per year, are from an open approach.<sup>8</sup> If the wound-protection system were used on a routine basis in open appendectomy, it could potentially translate into a savings of more than \$65 million annually. Such a reduction in preventable costs would also further the financial advantage of open appendectomy over the laparoscopic approach.<sup>4</sup>

The specialized wound retractor device was originally designed as a disposable, circumferential surgical retractor to be used in open procedures. The advantages of this type of retractor include clear plastic walls that allow visualization of the wound during surgery, more effective maintenance of wound moisture for the duration of the case, and even distribution of force throughout the wound in a more atraumatic fashion than traditional retractors. By doing so, the wound retractor may also serve as a barrier to microbes that would otherwise contaminate the wound and potentially cause an SSI.

Current guidelines issued by the Centers for Disease Control and Prevention for the prevention of SSIs include hair clipping immediately before the operation, use of antiseptic skin preparation prior to incision, perioperative hand antisepsis, antimicrobial prophylaxis, maintenance of a sterile surgical field, and intraoperative normothermia.<sup>3</sup> Despite this, up to 13% of patients undergoing an open appendectomy will eventually develop a wound infection. In reality, this number may be much higher, as many of these patients are treated in an outpatient setting with minimal reporting. The inci-

dence of wound infection in the postoperative setting is related to the amount and overall virulence of the bacteria present. The presence of a wound infection is manifested by the imbalance between the host immune function and bacterial growth. The wound-protection device used in this study may contribute to a reduction in SSI by providing an actual physical barrier of protection against bacterial contamination.

This retractor system has been studied in only one other instance: a randomized prospective study consisting of 221 patients undergoing nontraumatic gastrointestinal surgery.<sup>6</sup> This study population included gastric, hepato-biliary-pancreatic, as well as colorectal cases, whereas our study was limited to open appendectomy. The researchers also studied the incidence of anastomotic leakage and abscess in addition to simple wound infection. They found no statistically significant difference in the rate of leakage or abscess between those with and those without the retractor. However, they too found a significant decrease in wound infection through use of the same wound-protection device in their subgroup analysis ( $P=.002$ ). Our data further support their conclusions.

Surgical site infection is the most frequent complication of gastrointestinal surgery and leads to many postoperative complications, including sepsis, increased length of hospital stay, increased burden of cost, and overall patient dissatisfaction. The ability to reduce the overall number of SSIs could translate into a major reduction in health care costs. Our data support the use of a wound-protection device in open surgery as a method of decreasing postoperative wound-infection rates. This technique could be applied to a broader spectrum of open surgical procedures and ultimately reduce the economic and emotional burden of a preventable SSI.

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sis. *Study concept and design:* Lee, Waxman, and Taylor. *Acquisition of data:* Waxman and Yim. *Analysis and interpretation of data:* Lee and Waxman. *Drafting of the manuscript:* Lee. *Critical revision of the manuscript for important intellectual content:* Waxman, Taylor, and Yim. *Statistical analysis:* Lee and Waxman. *Obtained funding:* Taylor. *Administrative, technical, and material support:* Waxman and Yim. *Study supervision:* Waxman.

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