

O-Ring Protector in Prevention of SSIs in Laparoscopic Colorectal Surgery

Gabriella Teresa Capolupo, MD, PhD, FACS, Sara Lauricella, MD, Gianluca Mascianà, MD, Chiara Caricato, MD, Silvia Angeletti, MD, Massimo Ciccozzi, Roberto Coppola, MD, FACS, Marco Caricato, MD, FACS

ABSTRACT

Background: Surgical-site infections (SSIs) remain a serious complication of colorectal surgery, causing a significant financial burden to the health care system. The aim of this study is to investigate whether the use of an O-ring retractor can be effective in preventing the incidence of wound infections after elective laparoscopic colorectal surgery.

Methods: A retrospective case-control study from January 2014 to June 2018 was performed. Data were analyzed from a retrospective colorectal database. SSI was defined according to criteria published by the European Centre for Disease Prevention and Control and analyzed as a primary outcome.

Results: Three hundred twelve consecutive patients (n = 312) were enrolled in our study. Among them, 158 patients (Group A) in which an O-ring retractor device was used during surgery was compared with a control group of 154 patients (Group B) in which an O-ring retractor device was not used. Primary outcome was to determine SSIs rates among the 2 groups. No statistically differences

were observed with regard to baseline characteristics between both groups. A total of 9 patients (5.69%) and 24 (15.58%) with SSIs were identified in Group A and B, respectively, and the difference was statistically significant (OR, 0.32; 95% CI, 0.14–0.72; $P = .0045$). The median postoperative hospital stay length was 6.7 days in group A and 7.6 days in group B ($P \leq .05$).

Conclusions: SSIs infections rates were significantly higher in patients in which an O-ring retractor device was not used. This study suggests that the use of a wound protector device can be considered for routine use in elective colorectal surgery.

Key Words: Alexis®; Wound protector/retractor; Prevention; Surgical site infection; Colorectal.

Department of Geriatric Surgery Unit, Campus Bio-Medico of Rome University, Rome, Italy (Drs Capolupo, Lauricella, Mascianà, and Caricato).

MD Program, School of Medicine, Catholic University of Sacred Heart, City, State, Country (Dr. Caricato).

Unit of Clinical Laboratory Science, Department of Medicine, Campus Bio-Medico of Rome University, Rome, Italy (Dr. Angeletti).

Unit of Medical Statistic and Epidemiology, Department of Medicine, Campus Bio-Medico of Rome University, Rome, Italy (Dr. Ciccozzi).

General Surgery Unit, Campus Bio-Medico of Rome University, Italy (Dr. Coppola).

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Address correspondence to: S. Lauricella, MD, Department of Geriatric Surgery, Campus Bio-Medico of Rome University 00100, Rome, Italy. Phone: +393337094089; Fax: 06225411908; E-mail: s.lauricella@unicampus.it

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INTRODUCTION

Surgical-site infection (SSI) alone accounts for more than 20% of all hospital-acquired infections, causing a significant increase in morbidity, mortality, and health care-associated costs. SSI remains a serious complication of abdominal surgery and is considered to be the second most common type of nosocomial infection after infection of urinary tract.^{1,2}

SSIs can have a devastating impact on the patient due to increased antibiotic usage, postsurgical pain, prolonged hospitalization, wound complications, stoma persistence, and higher rate of oncologic disease recurrence.^{3,4}

Compared to other operations, colon and rectal surgery is associated with higher SSI rates with a range of 2%–45%,^{5–8} and large bowel surgery is more susceptible than other operations due to a major risk of bacterial contamination.

Therefore, many kinds of preventive measures, especially in colorectal procedures, are usually employed. Among them, several wound-protection methods have been described in the literature to reduce the incidence of SSIs. Wound protectors are designed to protect the abdominal wall from bacterial contamination and mechanical trauma during abdominal procedures. Despite the application of

these preventive measures, SSIs rates are still surprisingly high. Compared to preceding protectors, the O-Ring device provides atraumatic abdominal wall retraction and the hermetic isolation of the tissues prevents the contamination of gastrointestinal bacteria into the abdominal cavity.⁹

Only a few studies failed to find the efficacy of wound protectors in preventing postoperative infections.^{10,11} The Alexis[®] O-Ring device (Applied Medical, Rancho Santa Margarita, California, USA) represents a technical improvement compared to conventional protectors, providing wound protection and atraumatic abdominal wall retraction, and it is easily removable.

The aim of this study is to evaluate the efficacy of the O-ring retractor wound protector/retractor in preventing SSIs among patients undergoing elective laparoscopic colorectal resections.

METHODS

A retrospective case-control study from January 2014 to June 2018 was performed. A total of 312 patients who underwent elective laparoscopic colorectal surgery were evaluated in this study. Exclusion criteria were age under 18 years, surgical laparotomic approach, conversion to laparotomic approach, emergency surgery, and transanal extraction of the specimen.

The sample size calculation has been performed to estimate the number of patients to enroll in the study. In order to detect a reduction of the $\frac{2}{3}$, the expected incidence of SSI has been set to 15% according to our clinical data, the alpha cut-off value has been set to 0.05 while the beta cut-off value has been set to 20% (Power of 80%), the estimated sample size was 141 patients each.

We performed a retrospective analysis of 158 consecutive enrolled patients who underwent elective laparoscopic colorectal resections in which an O-ring retractor (Alexis[®]) retractor was intraoperatively used (Group A). A population of 154 patients in which the device was not used were randomly chosen by our Hospital database, and compared as a control group (Group B). All epidemiological data were collected by the hospital information system and a unique database has been created.

Further prevention of SSI measures were equally adopted in both groups. Preoperative antibiotic prophylaxis was given to all patients. Intravenous cefazolin, 2 g; and met-

ronidazole, 500 mg were administered during anesthetic induction and repeated in case of intervention lasting more than 3 hours. Mechanical bowel preparation and intraluminal antibiotics have been used only from January to June, 2018 in both groups.

Characteristics of SSIs were described according to the criteria published by the European Centre for Disease Prevention and Control and analyzed as a primary outcome.¹²

All patients underwent Pfannenstiel incision to remove the surgical specimen. In the Group A study population, the Alexis[®] wound protector/retractor was inserted immediately after opening the peritoneum and maintained during the extraction of the surgical specimen (**Figure 1, A and B**). After the extraction of the specimen, the cap of Alexis[®] device was placed to maintain the pneumoperitoneum in order to perform intracorporeal anastomosis before the final closure of laparotomy (**Figure 2**).

All the variables examined in both groups A and B as potential risk factors were sex, age, cardiovascular disease, chronic obstructive pulmonary disease, alcohol, smoking, hypertension, diabetes mellitus, obesity, renal failure, and preoperative radiation treatment.

American Society of Anesthesiologists grade (ASA), tumor location (colon or rectum), diagnosis, and histological type were analyzed. Tumor staging for all patients was based on tumor-lymph node-metastasis (TNM) classification.

Furthermore, surgical technique (right colectomy, left colectomy, anterior resection of rectum, total proctocolectomy, other), intraoperative complications, operative time (minutes), diverting stoma, type of diverting stoma (ileostomy or colostomy) and length of postoperative stay in hospital were analyzed.

Postoperative complications were defined as those occurring within 30 days postsurgery. Fever, urinary tract infection, SSI, anastomotic leakage, anastomotic bleeding, intestinal perforation or occlusion, intestinal ischemia, and anastomosis stenosis were analyzed as major complications occurred in this time span.

The logistic regression analysis including as dependent variables (obesity, cardiovascular comorbidity, breathing disorders, smoking, hypertension, renal failure, diabetes mellitus, previous neoplasia, and preoperative radiation treatment) and as independent variables the presence of an O-ring retractor was performed. Data have been analyzed using Med-Calc 11.6.1.0 statistical

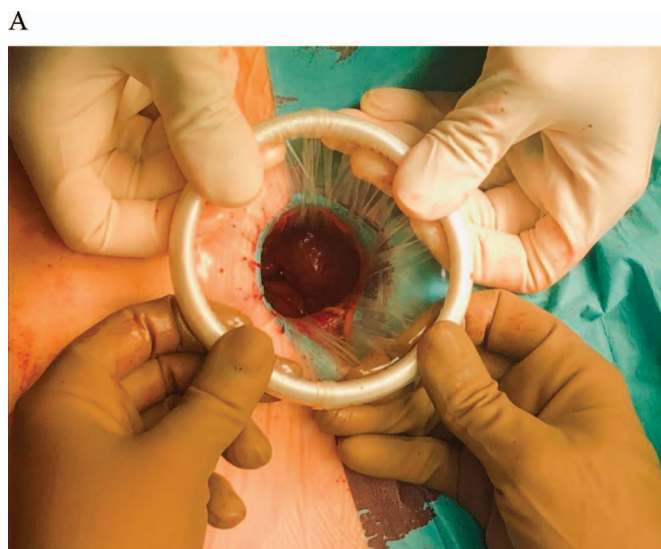


Figure 1. Insertion of the Alexis[®] wound protector retractor after opening the peritoneum and extraction of the specimen. (A) The Alexis[®] device is made up of two rings with a cylinder of polyurethane between the two rings. The outer ring is rolled over until it becomes taut circumferentially around the wound. (B) The Alexis[®] device provides a 360° wound protection preventing bacterial abdominal invasion.

package (MedCalc Software, Mariakerke, Belgium). The Student and χ^2 statistical test have been used to compare different variables. $P < .05$ was considered statistically significant. Receiver operating characteristic analysis was performed among independent variables.



Figure 2. After the extraction of the specimen the cap of Alexis[®] device is closed to re-establish pneumoperitoneum.

RESULTS

Baseline epidemiological characteristics of the patients in the two groups were shown in **Table 1**. Two hundred eight patients were within the age range, 60–80 years. Comorbidity rates, including breathing disorders, smoking, hypertension, renal failure, previous neoplasia, or preoperative radiation treatment, were computed in both groups and the comparison was not statistically significant ($P \geq .05$). The obesity rate also has been found higher in Group A, with respect to Group B, in which an O-ring retractor was intraoperatively used. This difference was not statistically significant ($\chi^2 = 0.744$; $P = .38$). The incidence of diverticular disease was higher in Group B than in Group A. Four patients operated for diverticular disease developed a SSI, all in the Group B, in which the device was not used.

One hundred five patients were classified as grade ASA II and 49 as grade ASA III in group A, whereas 117 and 35 (Group B) were classified as grade ASA II–III, respectively, χ^2 for trend was found statistically significant ($\chi^2 = 3.59$; $P = .048$). The clinical characteristics of the study population have been summarized in **Table 2**. One hundred twenty-four patients (78.48%) in Group A and 108 (70.12%) in Group B were respectively operated for colorectal cancer. Adenocarcinoma was the most represented histological type in both groups (75.94% vs 69.48%) whereas according to TNM classification, stages II and III were prevalent in both groups.

Table 1.
Baseline Characteristics of Patients (Group A and Group B)

	Alexis Group A (158)	Alexis Group B (154)	χ^2	P Value
Sex			1.05	.30
Male	81 (51.26%)	74 (48.05%)		
Female	77 (48.73%)	80 (51.94%)		
Median age (years)	66.70	66.08		
BMI, kg/m ²				
Min	17.4	15.91		
Max	39.56	40.43		
Mean	25.66	25.8		
Obesity	26 (16.45%)	20 (12.98%)	0.74	.38
Cardiovascular comorbidity	85 (53.79%)	98 (63.63%)	3.10	.38
Breathing disorders	12 (7.59%)	12 (7.79%)	0.004	.90
Smoking	31 (19.62%)	29 (18.83%)	0.072	.78
Hypertension	83 (52.53%)	86 (55.84%)	0.34	.55
Renal failure	1 (0.63%)	3 (1.94%)		
Diabetes mellitus	16 (10.12%)	24 (15.58%)	2.07	.15
Previous neoplasia	20 (12.65%)	20 (12.98%)	0.008	.90

BMI, body mass index.

Mean duration of surgery was 192.07 minutes in Group A and 187.31 minutes in Group B. The difference was not statistically significant ($P > .05$). The median postoperative hospital stay (length of stay) was 6.7 days (Group A) and 7.6 days (Group B). The difference was found to be statistically significant ($P \leq .05$). Length of stay was evaluated by receiver operating characteristic curve analysis and in Group A a cutoff of ≤ 6 days resulted in statistical significance compared to group B patients (AUC, 0.60; $P = .002$) (**Figure 3**).

Complication rates detected were of 24.68% vs 33.11% in Group A and B, respectively, and the difference was statistically significant ($\chi^2 = 5.5$; $P = .019$).

Overall SSI rate observed was of 10.12% and 19% in Group A and Group B, respectively. Organ/space SSIs were considered separately, superficial and deep wound infections were collected together.

Superficial and deep wound infections rates were higher in patients in which an O-ring retractor was not intraoperatively used, and in fact a total of 9 patients (5.69%) and 24 (15.58%) were identified in Groups A and B, respectively (OR, 0.32; 95% CI, 0.14–0.72; $P = .0045$).

Organ/space SSIs occurred in 7 (4.54%) and 5 patients (3.16%), Groups A and B, respectively.

Rectal resections were found to be associated with a higher risk of overall SSIs, 20.51% in Group A and 23.80% in Group B. Right colon resections were found to be associated with a risk of overall SSIs of 5.6% in Group A and 17.39% in Group B. Left colon resections were found to be associated with a risk of overall SSIs of 8% in Group A and 16.47% in Group B.

DISCUSSION

SSI remains a relevant question in colorectal surgery, impairing the outcome of patients, reducing quality of life, increasing hospital length of stay and the likelihood of tumor recurrence and mortality, causing a significant financial burden to the healthcare system. The advent of antibiotic prophylaxis in the 1970s and 1980s dramatically reduced the rates of wound infection in colorectal surgery from 50% to 20%.^{13–16}

In reducing postoperative infection, several preventive measures such as the use of prophylactic antibiotics, serum glucose determination in patients with diabetes mel-

Table 2.
Main Clinical Characteristics Observed in the Study Groups

	Group A (Alexis = 158)	Group B (No Alexis = 154)
Neoplasia	124 (78.48%)	108 (70.12%)
Diverticular disease	20 (12.65%)	36 (23.37%)
UC	4 (2.53%)	3 (1.94%)
Crohn disease	2 (1.26%)	2 (1.29%)
Other's	8 (5.06%)	5 (3.24%)
Preoperative radiation treatment	18 (11.39%)	21 (13.63%)
Histological type adenocarcinoma	120 (75.94%)	107 (69.48%)
Squamous carcinoma	0 (—)	0 (—)
Other	38 (24.05%)	47 (30.51%)
Stage I	25 (15.82%)	23 (14.93%)
Stage II	39 (24.68%)	34 (22.07%)
Stage III	38 (24.05%)	30 (19.48%)
Stage IV	7 (4.43%)	0 (“-“)
Operative time (Minutes)	192.07	187.31
Left colectomy	62 (39.24%)	85 (55.19%)
Right colectomy	53 (33.54%)	23 (14.93%)
LAR	39 (24.68%)	42 (27.27%)
Total colectomy	4 (2.53%)	4 (2.59%)
Stoma	38 (24.05%)	34 (22.07%)
Ileostomy	37 (23.41%)	25 (16.23%)
Colostomy	1 (2.63%)	9 (5.84%)

LAR, Low anterior resection; UC, Ulcerative colitis.

litus, the use of sterile drapes, and the change of gloves on closing the laparotomy have been adopted so far.⁸

However, surgical-wound infection in elective colorectal surgery still remain among the most common postoperative complications.¹⁷ Three categories of SSIs are defined by the Centers for Disease and Control.¹⁸ Surveillance of SSI with collection of appropriate data is an important component of strategies to reduce SSI risk.

Murray et al,¹⁹ analyzing the National Surgical Quality Improvement Program data from 2006 to 2012 in United States, reported an overall SSI rate of 12.31%, while superficial SSI rate was 7.21%. They found that operations for rectal cancer are independently associated with an increased likelihood of superficial, deep, and organ-space infections in comparison with left- or right-sided resections.¹⁹ Our experience shows a similar global SSI rate, with a higher prevalence of SSI in rectal resections.

While organ-space infections are mostly related to anastomotic failure in colorectal procedures, deep and superficial incisional infections are likely to be related to intraoperative bacterial inoculation of the wound tissues. Thus, investigators of many countries developed infection control systems to prevent such contamination. Wound protector devices are designed to prevent contamination of the skin, subcutaneous, fascia, and muscle.^{20–23}

Many studies on wound protectors use have been performed, and a systematic review by Kang et al,²⁴ which included 14 randomized controlled trials and 2,689 patients revealed that wound protectors reduced SSIs rate in abdominal surgery patients. This study suggests that SSI rates after abdominal surgery can be reduced by the use of plastic wound protectors.²⁴ Similarly, the efficacy of wound protectors in abdominal surgery have been evaluated in a systematic review and meta-analysis published

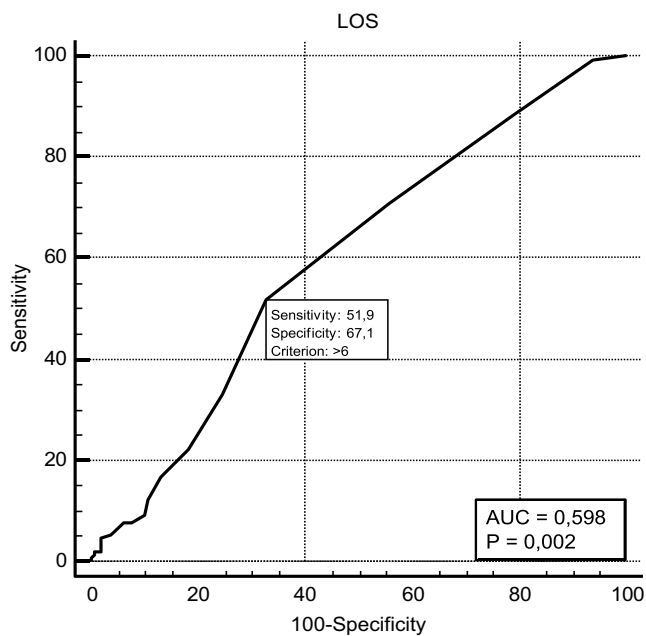


Figure 3. Roc curve analysis of length of stay (LOS) in Group A vs. Group B patients.

by Sajid et al,²⁵ including 18 randomized controlled trials. They concluded that wound protectors are effective in reducing SSIs rate in open abdominal surgery.²⁵

The O-ring retractor provides a circumferential atraumatic retraction, maximizing operative field exposure with a minimum incision size. An O-ring retractor kit consists of two stiff rings with a polyurethane cylinder in between the two rings. The inner ring is positioned within the peritoneal cavity. The cylinder can be rolled on the outer ring, making it circumferentially adherent to the wound. The hermetic isolation of the tissues reduces or avoids the contamination of gastrointestinal bacteria into abdominal cavity and in the wound tissues (**Figure 1**).

Many studies have investigated the use of such a device in different kinds of surgery, addressing mainly technical issues. In a literature search we identified only 3 papers focused on the impact of O-ring retractor on SSI in colorectal surgery. The first one, published in 2009,²⁶ studied in a population of patients operated on with the use of an O-ring retractor, the incidence of positive cultures in the peritoneal cavity and on the incision margins at the end of surgery. The study demonstrated that the incision margins cultures were negative even in the 8.8% of patients in which the peritoneal cultures were positive, supposing a protective effect of the device. Arenal et al⁹ showed a very low superficial SSI rate in a single-institution series of 95

consecutive patients operated on in a 6-year period with the use of the device. In 2012 Cheng et al²³ published a controlled randomized study on 62 patients and demonstrated the efficacy of the O-ring retractor compared to conventional methods in reducing superficial SSIs following colorectal surgery, with no effect on postoperative pain.

In recent years, many studies are focusing on multidisciplinary preventive care protocols called bundles, which has demonstrated to be the most effective tool in reducing the SSIs rate. Easy to use, plastic wound protectors are part of a comprehensive preventive SSIs bundle.²⁷

Postoperative complications are an important determinant of overall treatment-associated costs. This is due to a number of factors, including longer stay, increased use of resources such as diagnostic tools, antibiotics, interventional procedures, use of operating theatre, outpatient medications, off-work period, postoperative disability, stoma care etc. In this study, we were able to demonstrate that the use of an O-ring retractor is associated with a lower length of hospital stay. Further studies will address the economic impact of the use of device in the in-hospital costs.

CONCLUSIONS

Although surgeons have adopted several measures for the control of intraoperative wound contamination, SSIs are still a frequent postoperative adverse event related to colorectal surgery. SSIs are one of the major causes of hospital-acquired infections, accounting for more than 20%.

Due to their positive impact on the postoperative outcome, the literature demonstrates that the use of an effective wound protector should be considered for routine use in abdominal surgery.

Our study demonstrates that in elective laparoscopic colorectal surgery, the use of O-ring retractor is associated with a significantly lower SSI rate and length of stay compared with laparoscopic colorectal resections in which the wound protector is not used.

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