

# Randomized, Controlled Investigation of the Anti-Infective Properties of the Alexis Retractor/Protector of Incision Sites

Tetsuya Horiuchi MD, PhD, Hiroyuki Tanishima, MD, Kouji Tamagawa, MD, Ichiro Matsuura MD, PhD, Hiroaki Nakai MD, PhD, Yoshiharu Shouno MD, PhD, Hideaki Tsubakihara MD, PhD, Masaya Inoue MD, PhD, and Katsuyoshi Tabuse MD, PhD

**Background:** We prospectively investigated whether the wound-protective Alexis (Applied Medical, Rancho Santa Margarita, CA) wound retractor was effective in preventing surgical site infection (SSI).

**Methods:** We examined the actual condition of SSI in a 12-month randomized, controlled trial consisting of 221 patients who had undergone nontraumatic gastrointestinal surgery. The patients were divided into a With Alexis retractor group (n = 111) and a Without Alexis retractor group (n =

110). We also analyzed SSI separately on the basis of surgical sites such as gastric surgery or colorectal surgery.

**Results:** Overall estimation showed a significant decrease in wound infection (superficial incisional SSI) in the With Alexis retractor group. In the analysis based on surgical sites, a significant decrease in wound infection was noted in the With Alexis retractor group, the members of which had undergone colorectal surgery. There was no significant difference

between the two groups in the occurrence of organ/space SSI, including anastomotic leak or intraperitoneal abscess.

**Conclusion:** It was suggested that the use of the Alexis wound retractor would protect surgical wounds from contamination by bacteria and thus prevent infection.

**Key Words:** Wound infection, Surgical site infection, Wound retractor, Colorectal surgery.

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Surgical site infection (SSI) is the most frequent complication in gastrointestinal surgery. Occurrence of SSI leads to sepsis, prolonged hospitalization, increased hospitalization costs, and patient dissatisfaction.<sup>1</sup> The importance of perioperative care against infection was demonstrated by reports that patients with perineal infection after abdominoperineal resection have an increased incidence of local recurrence.<sup>2</sup> Because wound infection is a high percentage of SSI in colorectal surgery, preventive measures appear to be especially needed. In this article we report the results of a prospective study performed to investigate whether wound-protective Alexis wound retractor would prevent SSI, particularly wound infection at incision sites.

## METHODS

### Subjects

There were 354 cases of gastrointestinal surgery at Osaka Minami Medical Center (called Osaka Minami National Hospital until March 2004) from September 2003 to August 2004. In this study, we enrolled a total of 221 patients undergoing nontraumatic gastrointestinal surgery, excluding

the patients who had severe adhesion with a history of laparotomy (n = 42), long-term use of steroids (n = 5), laparoscopic surgery or minor surgery such as appendectomy (n = 82), and probable colon perforation (n = 4). This was a randomized, controlled study on wound protection using a wound-protective retractor. Informed consent was obtained from the enrolled patients and the study was approved by the institutional review board.

The Alexis retractor, a polyurethane wound retractor manufactured by Applied Medical, is reported to protect wounds. We placed the Alexis retractor in close contact with a wound margin immediately after making an incision in the abdomen (Figs. 1 and 2).

### Treatment During Surgery

In the With Alexis retractor group, the Alexis retractor was applied to a wound margin when an abdominal incision was made. In the Without Alexis retractor group, a wound margin was left untreated. Otherwise, the same procedure was used for each of the two groups and was performed as follows. During gastrointestinal anastomosis, an anastomotic site was covered with gauze to prevent contamination at and around the wound. After the intra-abdominal procedure was finished, 3,000 mL of physiologic saline was used to wash the intraperitoneal space for upper-gastrointestinal surgery or hepato-biliary-pancreatic surgery, and 5,000 mL for colorectal surgery. If contamination by contents from the digestive tract was suspected, 10,000 mL was used. The wound was closed after the fascia was sutured and the wound margin was washed with 500 mL of physiologic saline.

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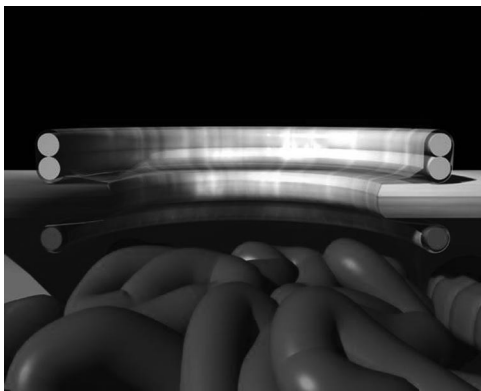
From the Department of Surgery, Osaka Minami Medical Center, Osaka, Japan.

Address for reprints: Tetsuya Horiuchi, Department of Surgery, Osaka Minami Medical Center, 2-1 Kidohigashi, Kawachinagano, Osaka 586-8521, Japan; email address: tetsuho@ommc-hp.jp.

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**Fig. 1.** Alexis, a polyurethane wound retractor manufactured by Applied Medical, is reported to protect wounds.



**Fig. 2.** Illustration of Alexis. We placed Alexis in close contact with a wound margin immediately after making an incision in the abdomen.

### Use of Antibiotics

Prophylactic use of antibiotics in upper-gastrointestinal surgery included 1 to 2 g of ampicillin and cefazolin or flomoxef twice daily for 1 to 4 days. In colorectal surgery, 1 to 2 g of cefotiam, flomoxef, or cefmetazol was administered twice daily for 3 to 4 days. If postoperative infection was suspected the administration period was extended or a different drug was used.

### Mechanical Bowel Preparations for Colorectal Surgery

Mechanical bowel preparations were performed in colorectal surgery using 2 L of polyethylene glycol.

### Assessment Method

SSI frequency and properties were analyzed according to the criteria of the United States Centers for Disease Control and Prevention (CDC). Experienced surgeons who assessed the incisions postoperatively for SSI were blinded to the treatment the patients had received (With or Without Alexis). Patient characteristics such as sex, age, preoperative albumin level, body mass index, operative time, amount of blood loss during the operation, the lowest body temperature during the operation, amount of blood transfusion, the highest postop-

erative blood sugar level, and the average hospitalization period were also analyzed.

### Statistical Analysis

The results were analyzed using Stat-View 5.0 (SAS Institute Inc., Cary, NC). Incidence rate of SSI and patient characteristics were analyzed using a  $\chi^2$  test and a Student's *t* test, respectively, and  $p < 0.05$  was considered to be statistically significant.

## RESULTS

### Patient Characteristics

The With Alexis retractor group had a total of 111 cases consisting of 37 cases of gastric surgery, 40 cases of colorectal surgery, 23 cases of hepato-biliary-pancreatic surgery, and 11 other cases. The Without Alexis retractor group had a total of 110 cases consisting of 36 cases of gastric surgery, 52 cases of colorectal surgery, 18 cases of hepato-biliary-pancreatic surgery, and 4 other cases. There was no significant difference between the two groups in sex, age, preoperative albumin level, body mass index, operative time, amount of blood loss during the operation, the lowest body temperature during the operation, amount of blood transfusion, and the highest postoperative blood sugar level (Table 1).

**Table 1** Patient Characteristics

Characteristics	With Alexis	Without Alexis	<i>p</i> Value
Number	111	110	
Sex (Male/Female)	61/50	63/47	0.7285
Age	67.0 ± 11.6	64.6 ± 11.4	0.1231
BMI	22.06 ± 3.00	21.97 ± 3.53	0.8391
Albumin (g/dl)	3.72 ± 0.61	3.69 ± 0.66	0.7457
Length of operation (min)	226.8 ± 108.4	201.7 ± 91.0	0.0635
Blood loss (ml)	416.9 ± 559.0	412.8 ± 555.9	0.9564
Temperature (°C)	35.93 ± 0.83	35.92 ± 0.75	0.9273
Transfusion (ml)	126.3 ± 440.7	85.4 ± 268.9	0.8336
Maximum BS (g/dl)	159.9 ± 75.0	144.1 ± 58.1	0.1025

Data shown as mean ± SD.

BMI, body mass index; Albumin, preoperative albumin level; Blood loss, amount of blood loss during the operation; Temperature, the lowest body temperature during the operation; Transfusion, amount of blood transfusion; Maximum BS, the highest postoperative blood sugar level.

**Table 2** Rate of SSI in All Cases

	With Alexis	Without Alexis	<i>p</i> Value
Number	111	110	
All SSI	8 (7.2)	16 (14.5)	0.0796
Wound infection	0 (0)	9 (8.1)	0.0021
Leakage	6 (5.4)	5 (4.5)	0.7688
Abscess	2 (1.8)	2 (1.8)	0.9927

Data are n (%).

Leakage, anastomotic leak; Abscess, intraperitoneal abscess.

## Overall Evaluation

SSI occurred in 8 (7.2%) cases in the With Alexis retractor group and in 16 (14.5%) cases in the Without Alexis retractor group. SSI in the With Alexis retractor group consisted of 6 (5.4%) cases of anastomotic leak and 2 (1.8%) cases of intraperitoneal abscess, but there was no wound infection in this group. SSI in the Without Alexis retractor group consisted of 5 (4.5%) cases of anastomotic leak, 2 (1.8%) cases of intraperitoneal abscess, and 9 (8.1%) cases of wound infection. Wound infection was significantly diminished in the With Alexis retractor group ( $p = 0.0021$ ) (Table 2).

## Evaluation in Gastric Surgery

SSI occurred in 2 (5.4%) cases in the With Alexis retractor group and in 4 (11.1%) cases in the Without Alexis retractor group. SSI in the With Alexis retractor group consisted of 2 (5.4%) cases of anastomotic leak, but no wound infection was found in this group. SSI in the Without Alexis retractor group consisted of 2 (5.5%) cases of anastomotic leak and 2 (5.5%) cases of wound infection. No significant difference was noted between the two groups.

## Evaluation in Colorectal Surgery

SSI occurred in 2 (5.0%) cases in the With Alexis retractor group and in 7 (13.4%) cases in the Without Alexis retractor group. SSI in the With Alexis retractor group consisted of 2 (5.0%) cases of anastomotic leak, but no wound infection was noted in this group. In the Without Alexis retractor group, there were 7 (13.4%) cases of wound infection but there was no anastomotic leak. There were significantly fewer cases of wound infection in the With Alexis retractor group ( $p = 0.0158$ ) (Table 3).

## Causative Organisms in Infected Wounds

*Enterococcus faecalis* was detected in two cases, *Pseudomonas aeruginosa* in two cases, *Bacteroides* in one case, methicillin-resistant *Staphylococcus aureus* in one case, and  $\alpha$ -streptococcus in one case.

## Clinical Course of Patients With SSI

Two patients in the With Alexis retractor group who developed anastomotic leak after total gastrectomy died of concurrent pneumonia and pyothorax on postoperative day 30 and day 120, respectively. One patient in the Without Alexis retractor group,

who developed anastomotic leak and intraperitoneal abscess after pancreaticoduodenectomy, died of subsequent sepsis on postoperative day 102. The average hospitalization period after operation in the With Alexis and Without Alexis retractor groups was 34.4 days and 33.8 days, respectively.

## DISCUSSION

SSI is the most frequent complication in gastrointestinal surgery, and occurrence of SSI leads to sepsis, prolonged hospitalization, high hospitalization costs, and patient dissatisfaction. Japanese Nosocomial Infection Surveillance (JNIS), established in 1998, has surveyed SSI to elucidate the incidences and the causes of SSI in Japan. According to JNIS, the incidence of SSI is 33 out of 149 (22.1%) cases of esophageal surgery; 185 out of 1,881 (9.8%) cases of gastric surgery; 222 out of 1,579 (14.1%) cases of colorectal surgery; and 104 out of 692 (15.0%) cases of hepato-biliary-pancreatic surgery.<sup>3</sup> JNIS reported that the percentage of wound infection was 9.4% in rectal surgery, 8.8% in colonic surgery, and 3.9% in gastric surgery.<sup>3</sup>

Judging from the percentages above, the incidence of SSI in Japan seems high. Two conceivable reasons can explain this observation. First, the hospitalization period for patients is relatively long in Japan because of generous government funding for health care. Second, unlike in other countries, after discharge, patients generally receive any necessary follow-up care or treatment at the same hospital in which they were originally treated. Thus, long-term observation of the incision site is possible, which might enhance the possibility of detecting SSI.

In the United States, the incidence of SSI at the incision site after colorectal surgery was reported to be 26% on the inpatient and outpatient basis, and 49% of the SSIs were found during a follow-up period on the outpatient basis.<sup>4</sup> The rate of SSI was substantially higher than that reported generally in the literature predicted by the National Nosocomial Infection System. They thought these discrepancies highlight the potential limitations of systematic outcomes measurement tools that were independent of the primary clinical care team.

When compared with data reported by JNIS, our data indicates a lower incidence of wound infection in the With Alexis retractor group. The incidence of wound infection in the Without Alexis retractor group was similar to that reported by JNIS. This suggests that the Alexis retractor may help reduce the incidence of wound infection and that standard preventive measures against infection are taken at our institution even when the Alexis retractor is not used. In colorectal surgery, the incidence of wound infection in the With Alexis retractor group was lower than that of a recent report.<sup>3,4</sup>

CDC guidelines show surgical techniques that are recommended and have proven to be effective in preventing SSI include hemostasis, prevention of low body temperature, careful handling of tissues, no damage to hollow organs, removal of necrotic tissue, drainage, proper use of surgical suture, and elimination of dead space.<sup>5</sup> To minimize the risk

**Table 3** Rate of SSI in Colorectal Surgery

	With Alexis	Without Alexis	<i>p</i> Value
Number	40	52	
All SSI	2 (5.0)	7 (13.4)	0.1756
Wound infection	0 (0)	7 (13.4)	0.0158
Leakage	2 (5.0)	0 (0)	0.103
Abscess	0 (0)	0 (0)	NS

Data are n (%).

Leakage, anastomotic leak; Abscess, intraperitoneal abscess; NS, not significant.



of wound infection, several strategies have been proposed. Reported among them are coverage of an incision wound in the abdomen during an operation,<sup>6</sup> use of a ring drape, and washing of wound margins.<sup>7</sup> We performed this study because we have empirically suspected that the Alexis retractor works in an anti-infective manner, though we had not obtained appropriate evidence to prove it. The results of this study demonstrate that wound infection decreased significantly in the With Alexis retractor group.

Abundance and virulence of bacteria attached to a surgical site are among the risk factors for infection.<sup>8</sup> Whether or not infection is established appears to be dependent on the balance between these factors and the resistance of a host patient. More precisely, the possibility of infection is considered to increase if there are  $10^5$  or more bacteria present in 1 gram of tissue.<sup>9</sup> It is thought that, during colorectal surgery, contamination by resident flora in the gastrointestinal tract contributes to wound infection.<sup>10</sup> We propose that the use of the Alexis retractor prevented wound infection because it inhibited wound contamination by bacteria during an operation because the Alexis retractor was in close contact with the wound. In a study using porcine model, moisture content under the skin was measured over time by capacitance in the With Alexis group and the group without treatment. Results showed that moisture content was higher in the With Alexis group when measured 1 hour after the abdominal incision. Five hours into the operation, moisture content under the skin in the With Alexis group was higher than the preoperative level by approximately 10%. However, in the group without treatment, the skin remained dry, with a moisture content of 70% of the preoperative level after 3 hours into the operation (data are not shown).

In addition, when we tried the Alexis retractor in cases that met the exclusion criteria, e.g., all cases of long-term steroid use and 20 cases of laparoscopic gastrointestinal surgery, not a single wound infection was detected. It seemed particularly important that wound infection was prevented in patients on steroids, which increase the possibility of SSI. This suggests that if the Alexis retractor is used, wound infection is likely to be prevented in patients who have conditions that predispose them to SSI (diabetes mellitus,<sup>11</sup> obesity,<sup>4</sup> use of steroids,<sup>12</sup> etc.).

The patients who developed anastomotic leak after gastric surgery were all gastric cancer patients with esophageal infiltration. Anastomotic leak among colon cancer patients was found in those who presented with ileus. Thus, anastomotic leak rates were higher than normal. The mean hospitalization period in this study was 34.4 days in the With Alexis retractor group and 33.8 days in the Without Alexis retractor group. Because cancer patients in the terminal stage were included in both groups and the frequency of organ/space SSI was similar in the two groups, there seemed to be no significant difference in the hospitalization period between the two groups. Consequently, we did not calculate hospitalization costs for either retractor group.

Patient characteristics were analyzed in the SSI group ( $n = 24$ ) and non-SSI group ( $n = 197$ ). Operative time in the SSI group was  $303.8 \pm 116.3$  minutes, whereas it was significantly shortened in the non-SSI group at  $203.2 \pm 93.6$  minutes. In addition, the amount of bleeding in the SSI group was  $775.2 \pm 901.0$  mL; it was significantly less in the non-SSI group, at  $365.2 \pm 476.5$  mL. There was no significant difference between the two groups in preoperative albumin level. This indicated that, just as the CDC had reported, large amounts of bleeding and prolonged operation time constitute risk factors of SSI.

With growing evidence that SSI contributes to the recurrence of cancer in cancer-bearing patients,<sup>2,13</sup> strategies to prevent SSI will be needed in the future. Although incidence of wound infection may decrease through the use of the Alexis retractor, the need to establish preventive measures against other forms of SSI (anastomotic leak, intraperitoneal abscess) remains.

## CONCLUSION

The Alexis wound retractor may help reduce the incidence of wound infection at incision sites. We think the Alexis retractor is especially useful when used in patients undergoing colorectal surgery.

## REFERENCES

1. Alica JM, Teresa CH, Michaele LP. Guideline for prevention of surgical site infection 1999. *Infect Control Hosp Epidemiol.* 1999; 20:247–278.
2. Kressner U, Graf W, Mahteme H, et al. Septic complications and prognosis after surgery for rectal cancer. *Dis Colon Rectum.* 2002; 45:316–321.
3. Harihara Y, Konishi T, Sanuki J, et al. Surgical site infection (SSI) surveillance and its prevention (Japanese). *Journal of Japan Society for Surgical Infection.* 2003;15:29–34.
4. Robert LS, Jamie KB, Shannon TM, et al. Wound infection after elective colorectal resection. *Ann Surg.* 2004;239:599–607.
5. Dellinger EP. Surgical infections and choice of antibiotics. In: Sabiston DC, ed. *Textbook of Surgery. The Biological Basis of Modern Surgical Practice.* 15th ed. Philadelphia: W. B. Saunders Co, 1997;264–280.
6. Hiramatsu K, Nagino M, Kamiya J, et al. A new method to prevent wound infection: a controlled clinical trial in patients with combined liver and bile resection. *Langenbecks Arch Surg.* 1998;383:437–441.
7. Enomoto T, Komori H, Hagiwara Y, et al. Surgical technique in the closure of abdominal incisions (Japanese). *Rinsho Geka.* 2001; 56:1227–1231.
8. Elek SD. Experimental staphylococcal infections in the skin of man. *Ann NY Acad Sci.* 1956;65:85–90.
9. Krizek TJ, Robson MC. Evolution of quantitative bacteriology in wound management. *Am J Surg.* 1975;13:579–584.
10. Tanaka K, Kitou F, Kanamura E, et al. Clinical study of wound infections following gastroenterological surgery (Japanese). *J Jpn Surg Assoc.* 1998;59:1195–1202.
11. Gil-Egea MJ, Pi-Sunyer MT, Verdaguer A, et al. Surgical wound infections: prospective study of 4,468 clean wounds. *Infect Control.* 1987;8:277–280.
12. Post S, Betzler M, von Ditfurth B, et al. Risk of intestinal anastomosis in Crohn's disease. *Ann Surg.* 1991;213:37–42.
13. Angelo N, Luca G, Mauro T, et al. Correlation between postoperative infections and long-term survival after colorectal resection for cancer. *Tumori.* 2004;90:485–490.