



Omental Free-Shaped Flap Reinforcement on Anastomosis and Dissected Area (OFFROAD) Following Reconstruction after Gastrectomy: A Retrospective Case-Control Study

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Purpose: We devised omental free-shaped flap reinforcement on anastomosis and dissected area (OFFROAD) following reconstruction after gastrectomy. This study aimed to evaluate its safety and early clinical outcomes.

Methods: One hundred fifty-six patients who underwent totally laparoscopic distal gastrectomy with delta anastomosis from July 2016 to April 2018 were divided into the OFFROAD group (80 patients) and non-OFFROAD group (76 patients). Differences in short-term operative outcomes and surgical complications were compared between the groups. All patients' inflammatory marker levels were measured to monitor flap necrotic change and inflammatory reactions. The clinical features of both groups in terms of anastomotic leakage were transcribed.

Results: Pain score in postoperative day1 was significantly lower in OFFROAD group. The serum WBC count on POD 1 was significantly lower in OG than in NOG. The mean duration of OFFROAD was shorter than five minutes. There were no statistical differences in short-term outcomes and surgical complications between two groups. Anastomotic leakage occurred in three patients in each group and there was no statistical difference in incidence. However, clinical features were notable when anastomotic leakage occurs. Unlike all three patients of non-OFFROAD group manifested every features of peritonitis, each patient of OFFROAD group just manifested only one of the three.

Conclusion: This study showed the safety and feasibility of OFFROAD procedure. It might mitigate septic complications when there is an anastomotic leakage. Additional large-scale study is needed to assess the versatile usefulness of OFFROAD aside from its role as a physical barrier.

Keywords: Gastric cancer, Surgery, Anastomosis, Omental flap, Omentopexy, Omental reinforcement

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INTRODUCTION

The surgical field of early gastric cancer treatment has made remarkable progress in terms of its survival rate and minimally invasive accessibility. At the same time, as the detection and early surgical approach of gastric cancer increases, the

extent of surgery is gradually decreasing and the paradigm continuously shifts toward individualized treatment. Therefore, technical advances in surgery are required to achieve more completeness and lower complication rates than before in these current trends.

The complication after gastrectomy with the highest di-

minishing rate is anastomotic leakage (AL). The incidence of AL after gastrectomy has been reported to be 0.9% to 8%. Although the incidence has been reduced because of advances in surgical techniques, its mortality has been reported to be as high as 20%.¹⁻³

On the basis of previous studies, we noted the possibility of utilizing the omentum as an autologous graft, particularly in two ways: to add a physical barrier and to enhance blood flow to the anastomotic site. The omentum has been used as an anatomical supplementary material, especially in the field of reconstructive surgery,^{4,5} and in 1968, Goldsmith first reported a case in which the omentum was to reinforce an anastomosis.⁶ Theoretically, there is further versatility of utilizing the omentum based on previous studies. Difficulties in future secondary intra-abdominal surgery could be avoided by preventing the anastomosis from forming adhesions to nearby organs.^{7,8} Furthermore, from an oncological viewpoint, enhancing blood perfusion at the anastomotic site not only promotes anastomotic healing but also magnifies the effect of adjuvant chemotherapy and reduces cancer recurrence.^{9,10} Additionally, gradually inclining trends of preserving the omentum encourages attempts to utilize residual omentum.^{11,12}

We devised omental free-shaped flap reinforcement on the anastomosis and dissected area (OFFROAD) to assess the versatile usefulness of omental reinforcement, and this study aimed to evaluate its safety and early clinical outcomes.

MATERIALS AND METHODS

Study population

The study population comprised 156 patients diagnosed

with early gastric cancer who underwent totally laparoscopic distal gastrectomy (TLDG) between July 2016 and April 2018. We compared historical non-OFFROAD control group of 76 patients who met criteria until May 2017. All 80 OFFROAD group patients are after July 2017. Both groups of patients underwent TLDG with Billroth type I delta anastomosis by same surgeon. We selected historical control group to minimize selection bias. The selection criteria of this retrospective case-control study are presented in a flow chart (Fig. 1). Inclusion criteria were as follows: 1) a tumor confirmed to be malignant in pathology, 2) gross endoscopic finding of early gastric cancer, 3) a tumor located in the antrum, angle, or lower body of the stomach, and 4) patients who underwent TLDG and Billroth I anastomosis. Patients with any suspicion of advanced cancer in the preoperative diagnostic work-up, high risk of preoperative morbidity (grade IV or higher according to the American Society of Anesthesiologists [ASA] score),¹³ and history of previous upper abdominal operation were excluded. One hundred fifty-six patients were divided into the OFFROAD group (OG: case group, 80 patients), and non-OFFROAD group (NOG: control group, 76). All patients' data were collected retrospectively. This study was approved by institutional review board in National Cancer Center, Korea (NCC2019-0271).

Variables indicating initial success of surgery and overall course of recovery

Short-term operative outcomes were collected to evaluate initial success of surgery and overall course of recovery. These variables included the operating time, estimated blood loss, length of stay, body weight change (comparison of values pre-

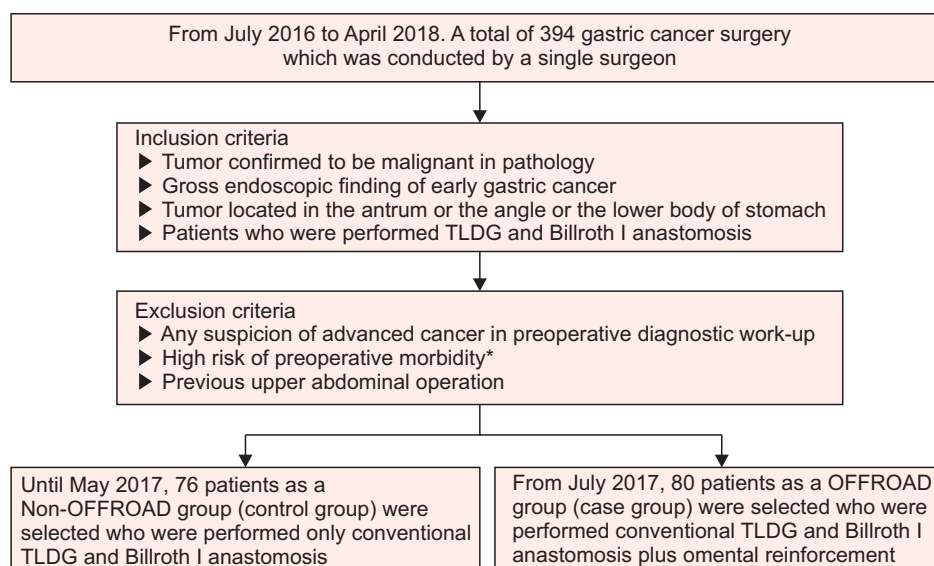


Fig. 1. Selection criteria of this retrospective case-control study are shown in a flow chart. *American Society of Anesthesiologists grade IV or higher.¹³ TLDG = totally laparoscopic distal gastrectomy; OFFROAD = omental free-shaped flap reinforcement on the anastomosis and dissected area.

operatively and at discharge), first flatus day, and pain score on the third day after surgery, as measured by the numerical rating scale (NRS).

Monitoring of surgical complications and inflammatory reactions

Data of compromising events during the OFFROAD procedure and surgical complications including postoperative ileus, pneumonia, surgical site infection, delayed gastric emptying, and AL or stricture were collected for both groups.

In order to monitor flap necrotic change and inflammatory reactions, which could be due to manipulation of the omentum during OFFROAD, we measured patients' inflammatory markers: serum white blood cell (WBC) and C-reactive protein (CRP) concentrations on postoperative days (PODs) 1, 3 and 5.

Definition of anastomotic leakage and the surveillance protocols

AL was defined as follows: When AL was found based on the results of diagnostic EGD performed when patients showed suspicious clinical manifestations of peritonitis (high fever

>38.3 degrees,¹⁴ abrupt abdominal pain that was not previously shown, and sudden increase in the serum WBC concentration >100 cells/ml). When AL occurred, immediate abdominal computed tomography (CT) and EGD were conducted, and we compared the clinical features between both groups.

Anastomotic stenosis was defined as anastomotic narrowing that could not accommodate the insertion of a 10-mm endoscope with the presence of symptoms suggestive of stricture (dysphagia, inability to progress from the liquid to solid diet, nausea, vomiting, and/or epigastric pain).

Surgical procedure of OFFROAD

The process of OFFROAD was consistently conducted as follows. After finishing TLDG and Billroth I anastomosis with partial omentectomy, the residual omentum was mobilized upward to widely cover the stomach. Then it was divided vertically using an energy device and made into two wings. For the OFFROAD procedure, preserving the omental feeding branch of left gastroepiploic artery was important not to make an omental infarction. After placing the left side wing beneath the anastomosis and the right side wing on the surface of the anastomosis (both wings were designed to wrap the entire anastomotic site), we fixed them with endo-clips (Fig. 2).

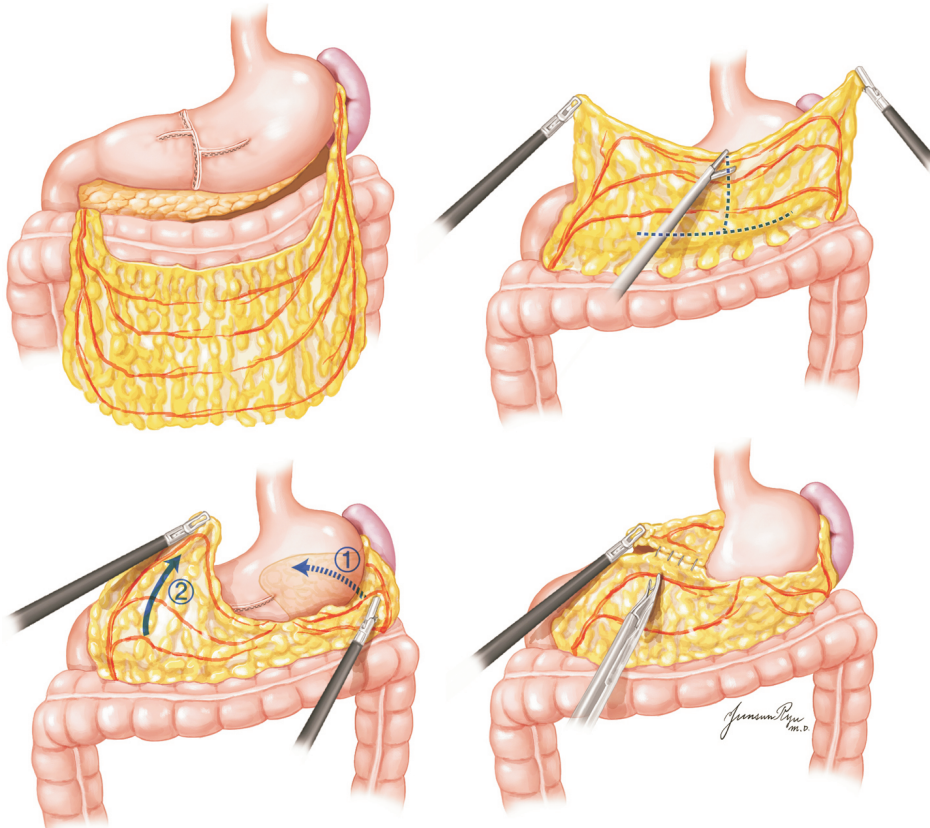


Fig. 2. Illustration of OFFROAD procedure. The residual omentum was mobilized upward to widely cover the stomach. Then it was divided vertically using an energy device and made into two wings. After placing the left side wing beneath the anastomosis and the right side wing on the surface of the anastomosis (both wings were designed to wrap the entire anastomotic site), we fixed them with endo-clips.

Statistical analyses

Nominal, qualitative data were analyzed with the Chi-square test and Fisher exact test. Comparisons between the two groups were performed using the t-test for independent samples in the case of normal data distribution or the Mann-Whitney U test in the case of abnormal data distribution. A *p*-value <0.05 was regarded as significant. The SPSS statistical software package 20.0 (IBM Corp., Armonk, NY) was used for all statistical analyses.

Table 1. Patients' clinicopathologic factors

	Non OFFROAD group (n=76)	OFFROAD group (n=80)	<i>p</i> value
Age (years)	59.66 ± 11.61	60.60 ± 9.69	0.513
Sex			0.189
Male	55 (72.4%)	50 (62.5%)	
Female	21 (27.6%)	30 (37.5%)	
Histology			0.197
Differentiated	59 (77.6%)	61 (76.3%)	
Undifferentiated	17 (22.4%)	19 (23.7%)	
Location			0.622
Antrum	40 (52.6%)	42 (52.5%)	
Lower body	36 (47.4%)	38 (47.5%)	
Tumor size (cm)	3.2 ± 2.02	3.2 ± 1.69	0.421
ASA score*			0.642
1	24	31	
2	41	39	
3	11	10	
pT category			0.428
T1	61 (80.3%)	67 (83.8%)	
T2	8 (10.5%)	6 (7.5%)	
≥T3	7 (9.2%)	7 (8.7%)	
pN category			0.499
N0	62 (81.6%)	62 (77.5%)	
N1	9 (11.8%)	10 (12.5%)	
≥N2	6 (6.6%)	8 (10.0%)	
pStage			0.280
I	68 (89.4%)	69 (86.3%)	
II	4 (5.3%)	9 (11.3%)	
≥III	4 (5.3%)	2 (2.4%)	

*American Society of Anesthesiologists Physical Status Classification System.

RESULTS

Clinicopathologic features

The clinical and pathologic characteristics of the two groups are shown in Table 1. There were no significant differences in age, sex, pathological histology, tumor location and size, ASA score, and postoperative pathologic findings between the groups.

Short-term operative outcomes

The short-term operative outcomes are presented in Table 2. The operating time was comparable between the two groups. The mean duration of the OFFROAD procedure was shorter than 5 minutes. There was no significant difference in estimated blood loss, length of stay, body weight change, and first flatus day between the groups. However, the postoperative pain score was significantly lower in OG than in NOG (NRS: 3.43 ± 1.19 versus [vs.] 2.94 ± 0.90, *p*=0.004).

Comparison of surgical complications

The surgical complications are listed in Table 3. There was one case of immediate bleeding during the OFFROAD procedure. Mild to moderate postoperative complications occurred in 3 patients (3.95%) in NOG (postoperative ileus in 1, surgical site infection in 1, delayed gastric emptying in 1) and 6 patients (7.50%) in OG (postoperative ileus in 1, pneumonia in 1, surgical site infection in 1, and delayed gastric emptying in 3). The incident rate of all postoperative complications was not significantly different between both groups.

AL occurred in 3 patients in each group; thus, there was no

Table 2. Short term operative outcome

	Non OFFROAD group (n=76)	OFFROAD group (n=80)	<i>p</i> value
Operating time (minutes)	217 ± 35.08	197 ± 32.70	0.101
Estimated blood loss (mL)	45 ± 62.02	42 ± 51.21	0.734
Length of hospital stay (days)	9.82 ± 6.06	10.60 ± 7.20	0.464
Body weight change (%)	-3.26 ± 1.38	-5.10 ± 0.69	0.109
First flatus time (days)	3.67 ± 1.02	3.53 ± 0.99	0.367
Postoperative pain score (NRS of POD#3)	3.43 ± 1.19	2.94 ± 0.90	0.004

significant difference in the incidence of AL (NOG: 3.95%, OG: 3.75%). Anastomotic strictures occurred in only OG. According to the Clavien–Dindo classification of surgical complications, the distribution of severity was similar between the groups ($p=0.608$). There was no mortality in both groups.

Comparison of inflammatory marker levels

The serum WBC and CRP concentrations measured on PODs 1, 3, and 5. The serum WBC count on POD 1 was significantly lower in OG than in NOG (11.8 ± 1.7 vs. 10.8 ± 2.4 ; $p=0.02$). However, the general inflammatory marker levels of

WBC and CRP were comparable between the groups.

Comparison of clinical features of anastomotic leakage between the groups

When AL occurs, different clinical manifestations were shown in both groups (Table 4). All patients in NOG had all 3 symptoms of peritonitis (>38.3 degree fever, abrupt abdominal tenderness, and sudden increase in the serum WBC concentration >100 cells/ml), whereas all patients in OG showed only 1 symptom of peritonitis.

When patients showed the feature of peritonitis, immediate CT and diagnostic EGD were performed (Fig. 3, 4). Unlike NOG, OG showed omental flap sealed leakage hole and only localized inflammatory changes.

Table 3. Surgical complications

	Non OFFROAD group (n=76)	OFFROAD group (n=80)	p value
Omental bleeding during OFFROAD procedure	N/A	1 (1.25%)	
Mild to moderate postoperative complications			
Postoperative ileus	1 (1.32%)	1 (1.25%)	0.971
Pneumonia	0	1 (1.25%)	0.330
Wound problem	1 (1.32%)	1 (1.25%)	0.971
Delayed gastric emptying	1 (1.32%)	3 (3.75%)	0.338
Severe postoperative complications*			
Anastomotic leakage	3 (3.95%)	3 (3.75%)	0.949
Anastomotic stricture	0	1 (1.25%)	0.330
Mortality	0	0	

*Clavien-Dindo classification grade III or higher; requiring surgical, endoscopic or radiological intervention.²⁵

DISCUSSION

Based on our study's results, OFFROAD could not prevent AL itself. However, OFFROAD was able to prevent peritonitis aggravated by AL. When AL occur, we perform EGD and tried endoscopic interventions like clipping and stent. In OF-

Table 4. Clinical manifestations in anastomotic leakage cases between the two groups

	Non-OFFROAD patients (n=3)	OFFROAD patients (n=3)
Features of peritonitis		
1. Fever (>38.3)	3/3 (100%)	1/3 (33.3%)
2. Onset of abrupt abdominal pain	3/3 (100%)	1/3 (33.3%)
3. WBC and CRP Increases	3/3 (100%)	1/3 (33.3%)
The number of symptoms each patient had	3	1

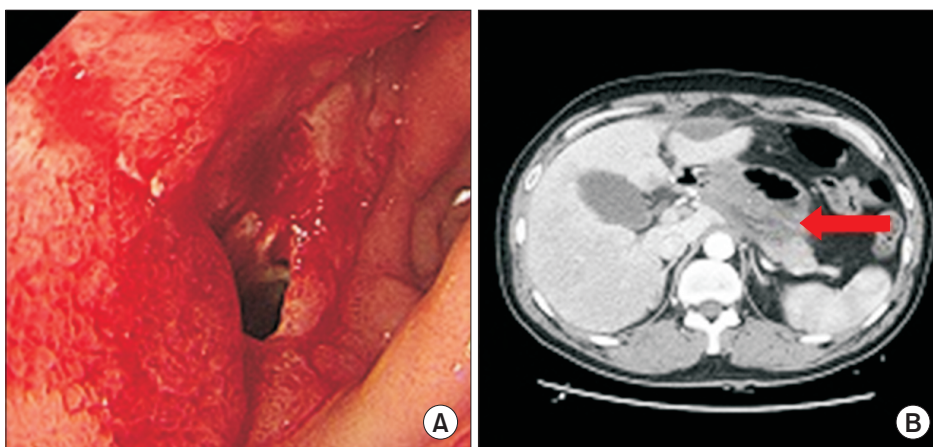


Fig. 3. (A) Image from esophagogastroduodenoscopy shows the leakage hole that communicated with the peritoneal cavity, and (B) computed tomography scan shows aggravated peritonitis around the anastomosis (arrow) in a patient of the non-omental free-shaped flap reinforcement on the anastomosis and dissected area group.

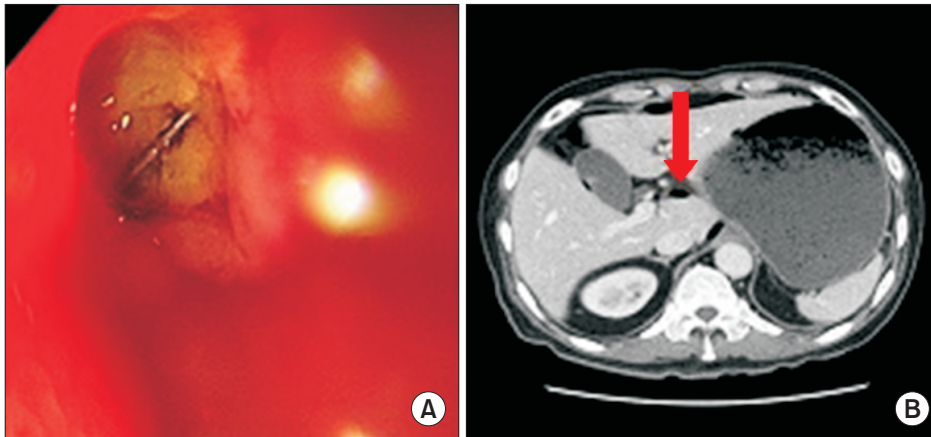


Fig. 4. (A) The surface of the omental flap is observed through the leakage hole. (B) There is no complicated fluid collection found on the computed tomography scan, and only peritoneal free air around the anastomosis is confirmed (arrow) in a patient of the omental free-shaped flap reinforcement on the anastomosis and dissected area group.

FROAD group, obviously fewer needs were observed to specific intervention but conservative treatment like intravenous hyperalimentation and controlling septic state with percutaneous drainage and antibiotics. However, because of lack of number of the cases, we could not show statistical differences.

Although there was an additional procedure, OG had a shorter operating time than NOG. This finding could be caused by the fact that in OG the omentum is distributed temporally later and the surgical technique improves over time. The results of the pain score and inflammatory marker levels were different from our hypothesis that manipulation of the omentum would promote an inflammatory reaction. Rather, OG showed less inflammatory change in the pain score and serum WBC concentration than NOG. However, because statistical significance is only proven in part, it is limited in evaluating the anti-inflammatory effect of OFFROAD.

Delayed gastric emptying and anastomosis stricture were more in the OFFROAD group. Although it was not statistically different, it is important not to wrap the anastomosis site with omentum too tight. For this, we have tried just cover the anastomosis and not give a force to tighten. From the early 2000s, it has been reported that partial omental resection, which preserves the physiological function of the omentum, shows no oncological inferiority compared to the former standard complete omentectomy.^{15,16} Considering these current paradigm shifts, attempting anastomotic reinforcement by utilizing the residual omentum has a timely relevance, especially in the field of gastric cancer surgery.

This is the first study to investigate reinforcement of anastomosis using the omentum in the field of gastric cancer surgery. Until recently, studies have been led by physicians in the field of esophageal and colorectal cancer surgery. In esophageal surgery, Dai et al. in 2011, Bhat et al. in 2006, and Sepesi in 2012 reported that the occurrence of AL could be controlled significantly by omental reinforcement.¹⁷⁻¹⁹ In colorectal surgery, Tocchi et al. in 2000 and Nasiri et al. in 2017 reported

significant positive effects of omental reinforcement on anastomotic leakage. However, Merad et al. in 1998 and Ozben et al. in 2016 reported no preventive effect of omental reinforcement.²⁰⁻²² Of the studies in which anastomosis was reinforced with the omentum, our study is the first to conduct routine EGD and measure inflammatory marker levels. In addition, immediate CT scan and EGD were performed together if AL occurred.

The omentum has been utilized clinically as a mere physical barrier so far,^{4,23,24} but clearly it has further versatility based on previous studies. Some histopathological studies demonstrated neo-vascularizing effects of the omentum.⁵ More long-term large-scale study is needed to assess the versatile usefulness of OFFROAD aside from its role as a simple physical barrier.

Since OFFROAD requires additional manipulation after completion of regular surgery, the following complications had to be considered. 1) Necrotic change of the omental flap was a possible complication of OFFROAD, and it could occur when excessive tension was imposed on the flap or omental feeding vessels were damaged. Intraoperatively, care was taken to avoid excessive tension on the omental flap and to preserve omental feeding vessels, and we monitored all patients' serum WBC and CRP concentrations. As a result, no suspicious findings were observed. 2) A risk of postoperative omental bleeding due to OFFROAD existed. Of 80 cases in OG, 1 patient, who was our second case, showed postoperative omental bleeding. Since this case, in which the bleeding stopped spontaneously without trace of a bleeding source, we have made efforts to preserve omental feeding vessels more carefully, and this complication has not occurred again.

This study has some limitations. 1) This study was designed as a case-control study without a prospective cohort, so the level of evidence is insufficient. 2) All patients in this study were in the laparoscopic setting without laparotomy because of the high proportion of laparoscopic approaches required for managing early gastric cancer. However, there is no reason to

limit this procedure to a particular surgical approach considering its fundamental principles.

CONCLUSIONS

This study showed the safety and feasibility of OFFROAD procedure. It might mitigate septic complications when there is an anastomotic leakage. Additional large-scale study is needed to assess the versatile usefulness of OFFROAD aside from its role as a physical barrier.

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CONFLICT OF INTEREST

None.

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