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ORIGINAL ARTICLE

Ileostomy versus fecal diversion device to protect anastomosis after rectal surgery: a randomized clinical trial

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Abstract

Purpose Patients with rectal anastomosis commonly experience various ileostomy-related complications. This study aimed to elucidate the usefulness of a fecal diversion device (FDD) as an alternative to ileostomy for protecting rectal anastomosis.

Methods Patients with rectal anastomosis were randomly assigned to the ileostomy and FDD groups except in cases of emergency surgery. The primary endpoint was the clinical safety and effectiveness of FDD. The mean operation time, delay of diet advancement, length of hospital stay, FDD and stoma durations, and anastomotic leakage (AL) management methods were compared.

Results A total of 54 patients were enrolled in this study. No cases of mortality occurred. Overall morbidity was similar between groups ($P = 0.551$). Six patients (22.2%) in the FDD group and nine (29.0%) in the stoma group ($P = 0.555$) had AL. The mean total hospital stay was 16.4 ± 6.7 and 23.4 ± 8.7 days in the FDD and stoma groups, respectively ($P = 0.002$). The mean total hospital cost was 12,726.8 ± 3422.8 USD and 17,954.9 ± 9040.3 USD in the FDD and stoma groups, respectively ($P = 0.008$). The mean FDD and stoma durations were 21.6 ± 6.1 days and 114.9 ± 41.3 days, respectively ($P < 0.0001$).

Conclusions This study demonstrated FDD safety and effectiveness. We identified the possibility of FDD as an alternative technique to conventional stoma procedures.

Keywords Anastomotic leakage · Stoma · Ileostomy · Low anterior resection · Fecal diverting device

Introduction

Patients undergoing rectal surgery showed a high incidence (≥ 10%) of anastomotic leakage (AL), which causes fatal abdominopelvic sepsis and leads to severe morbidity and mortality [1, 2]. Although defunctioning ileostomy protects the anastomosis, various complications can arise, including peristomal skin breakdown, stoma necrosis, stoma hernia, stoma retraction, and dehydration [3]. Another study demonstrated that patients with ileostomy immediately felt anxiety and depression [4].

Studies have aimed to reduce stoma-associated complications and rapidly achieve intestinal continuity. Some studies introduced a ghost ileostomy, which allowed for easy ileostomy creation regardless of the primary operation in patients requiring ileostomy [5]. The use of ghost ileostomy was intended to secure the terminal ileum loop to the abdominal wall using a rubber band [5]. The Coloshield, introduced in 1988, is a soft, pliable tube that is secured to the proximal colon to protect the anastomosis as an intracolonic bypass procedure [6, 7].

Here, we tested a device to protect anastomosis and replace ileostomy. Based on previous animal experiments, we developed a fecal diversion device (FDD) with an absorbable mesh band for fixation [8]. Thus, this study aimed to identify the clinical safety and efficacy of the FDD.

Methods

This single-center randomized clinical trial of stoma versus FDD was conducted at a tertiary referral hospital in accordance with the declaration of Helsinki and approved by the Institutional Review Board of Yeungnam University Hospital

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(2015-04-008). When an eligible patient was identified, study inclusion was proposed. After providing informed consent, patients were randomly assigned in a 1:1 ratio to the stoma or FDD group.

Inclusion and exclusion criteria

The inclusion criteria were as follows: 1) benign or malignant disease of the left colon and rectum, 2) extraperitoneal colorectal anastomosis, 3) age > 18 years, and 4) an American Society of Anesthesiologists (ASA) score of 1–3.

The exclusion criteria were as follows: 1) need for emergent surgery for obstruction or perforation, 2) abdominoperineal resection or total proctocolectomy, 3) no curative resection of the primary lesion, 4) anastomosis above the peritoneal reflex, and 5) refusal to participate.

FDD and band

The FDD, which consists of a head and tail portion, is a newly designed tube that is inserted into the colon to protect the anastomosis (Fig. 1). The head of the FDD consisted of an inner balloon, two external balloons, and a hole for colon cleansing (Fig. 2). The tail portion of the FDD consisted of a thin silicone tube, catheter complex for the balloons, and wash hole. The thin silicon tube passes through the inside of the anastomosis to prevent feces from coming into contact with the anastomosis.

We used a band and tension-measuring device to better affix the FDD to the colon. To prevent band erosion, an automatic tension-measuring instrument (ATMI; JSR Medical Inc., Daegu, Korea, Patent pending) was used (Fig. 3a). The ATMI measures the pressure acting on the colon wall and helps ensure that the absorbable poly lactic-co-glycolic acid mesh bands (NEOSORB MESH®; Samyang Biopham. Co., Daejeon, Korea; Fig. 3b) are of adequate length. The band has a half-life of 6 weeks and helps affix the FDD.

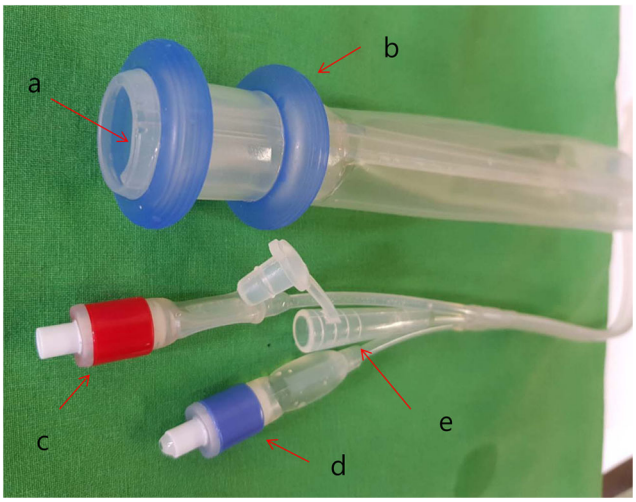

Fig. 2 Details of fecal diversion device: a inner balloon: open and close the inner lumen; b external balloon: affix the FDD to the colon; c a catheter for inner balloon; d catheter for external balloon; e catheter for irrigation: water to enter the colon from the outside

Surgical procedure

All procedures were performed by experienced colorectal surgeons with an open or laparoscopic technique. Bowel preparation using a polyethylene glycol solution was performed the day before the surgery. After colon mobilization was confirmed, the diseased segment was resected. The colorectal anastomosis was performed using the double stapling technique or handsewn method, followed by a loop ileostomy or FDD procedure.

All stoma group patients underwent ileostomy using standard conventional methods [9]. All patients received enterostomal care education.

The FDD installation process was performed as follows. After the colorectal anastomosis, we marked an installation area in the colon 10–15 cm above the anastomosis site and used the ATMI to determine the appropriate band length. The band was placed through the mesocolon on the outer wall of

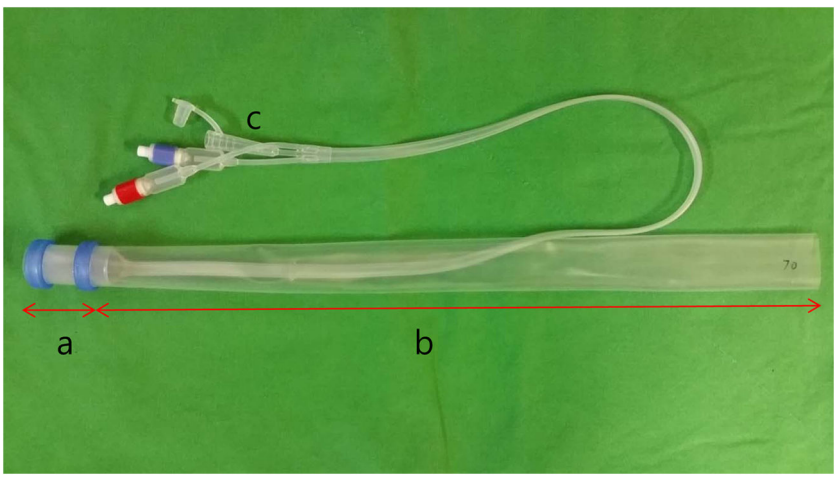

Fig. 1 Fecal diversion device (FDD): a head portion of FDD; b a tail portion of FDD; c a catheter of FDD

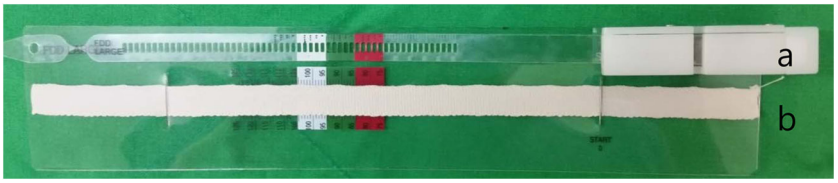

Fig. 3 Band and automatic tension measuring instrument: a automatic tension measuring instrument; b band

the colon. The inner balloon of the FDD was inflated and inserted into the colon through the anus. The FDD was inserted where the band was located. The band was placed between the external balloons of the FDD and fixed. The external balloon of the FDD was then expanded and its tail portion was cut outside the body to an appropriate length (Fig. 4).

All patients were allowed to drink water immediately after the surgery. Once gas was released into the stoma or the anus, a soft diet was started. Patients were discharged if they were able to consume soft diets for 2 consecutive days without problems.

Colonic irrigation through the FDD began the day after the diet was started. Irrigation of the FDD was performed as follows. After the inner FDD balloon was inflated, tepid water (600–1000 mL) was placed through the irrigation catheter into the colon above the FDD. To evacuate the irrigated colonic contents, the patients deflated the inner balloon of the FDD and opened its inner lumen. The evacuation took 15–30 min. Twice-daily irrigation was recommended (Fig. 5).

All patients routinely underwent abdominopelvic computed tomography (CT) scans at 1 week and a contrast study at 3 weeks postoperative, while an additional contrast study was performed in the stoma group at 10–12 weeks to confirm anastomosis integrity prior to stoma reversal. AL was defined as a defect in the intestinal wall integrity at the anastomosis site regardless of clinical symptoms [10]. The defect was proven by a contrast study or CT scan. Clinical peritonitis without evidence of defects as well as perianastomotic fluid collection with or without gas were considered as AL. The FDD was removed when no evidence of AL was found in the contrast study at 3 weeks postoperative. If AL was found, the FDD was maintained for up to 3 additional weeks and the contrast study was repeated. If the anastomosis was normal on the last contrast study, the FDD was removed. The stoma takedown was performed when no evidence of AL was found in the contrast study at 10–12 weeks; otherwise, it was delayed by 1–2 months. If a persistent sinus was observed, stoma takedown was performed once it had stabilized. The clinical trial was ended after 6 months postoperative.

Randomization

Patients were randomly assigned 1:1 to the two groups the day before surgery using a computer-generated simple randomization.

Endpoints

The primary endpoints of the study were FDD safety and effectiveness. FDD safety was defined as FDD-related morbidity and mortality. Complications were observed for 6 months. FDD effectiveness was defined as the capability of fecal diversion to prevent sepsis in cases of AL. The total hospital stay was defined as the postoperative hospital stay after the primary surgery. In the stoma group, the total hospital stay included hospitalization for ileostomy reversal. The total hospital costs included: 1) primary surgery and admission, 2) radiologic examination and sigmoidoscopy until FDD removal in the FDD group, 3) second admission including ileostomy takedown surgery in the stoma group, 4) stoma care products, and 5) treatment of complications. The total hospital costs did not include: 1) those not related to trials such as hepatectomy due to hepatic metastases or chemotherapy, and 2) examinations in regular follow-up appointments. The secondary endpoints included FDD and stoma use duration, operation time, and delay of starting the soft diet. The clinical AL results were reviewed. Data were collected during the preoperative study

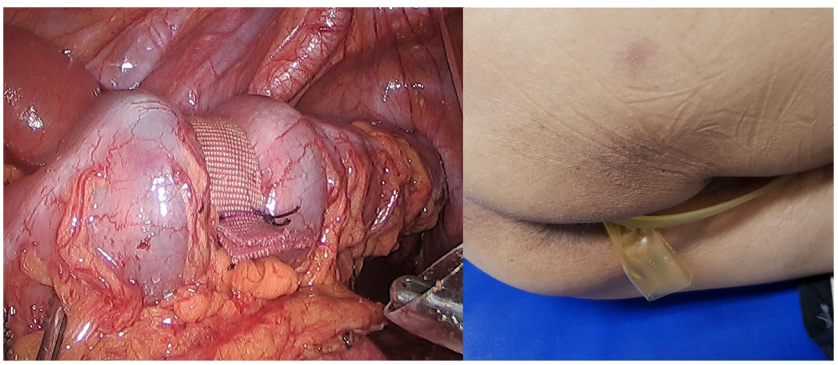

Fig. 4 Insertion of the fecal diversion device

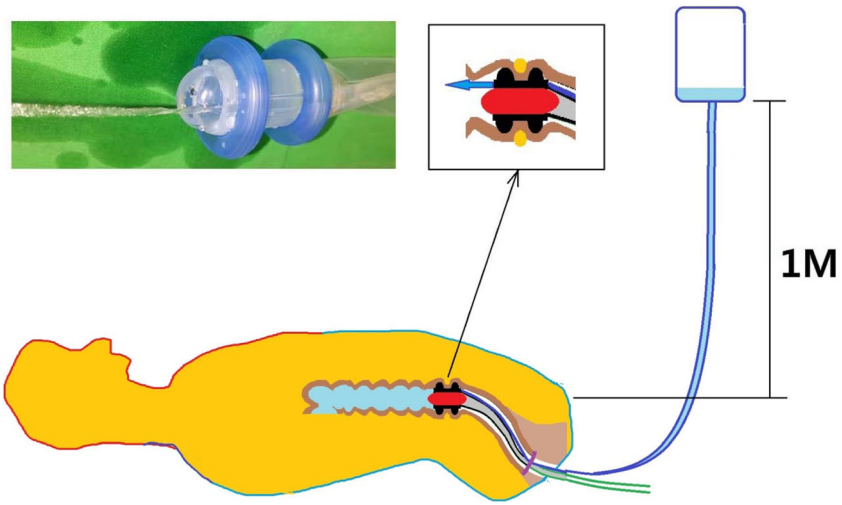

Fig. 5 Irrigation of fecal diversion device after primary surgery

until FDD removal or stoma reversal, and at 6 months of postoperative follow-up.

Sample size estimation

A preliminary study was conducted to estimate the sample size for this study because the FDD had never been used before. The authors analyzed the clinical data of 10 patients who underwent the FDD or stoma procedure. In the preliminary study, no cases of FDD-related morbidity or mortality occurred. Several complications occurred, including wound site discharge and urinary tract infections. However, these complications were not considered directly related to the FDD or the stoma since they were common and might occur in other surgeries. The authors calculated the sample size as the total medical expense from the first operation to the FDD or stoma removal. For sample size estimation, G Power (version 3.1.9.2) was used; accordingly, 19 patients must be recruited in each arm to demonstrate a statistically significant difference between groups with 80% power at the 0.05 level of significance. Allowing for a dropout rate of 10% after the randomization, the sample size was estimated as 21 patients in each group.

Statistical analysis

All analyses were conducted using IBM SPSS version 23 (IBM, Armonk, NY, USA) and R version 3.5 with the rms and Hmisc package (web-r.org). All analyses were performed using an intention-to-treat approach. Morbidity and mortality

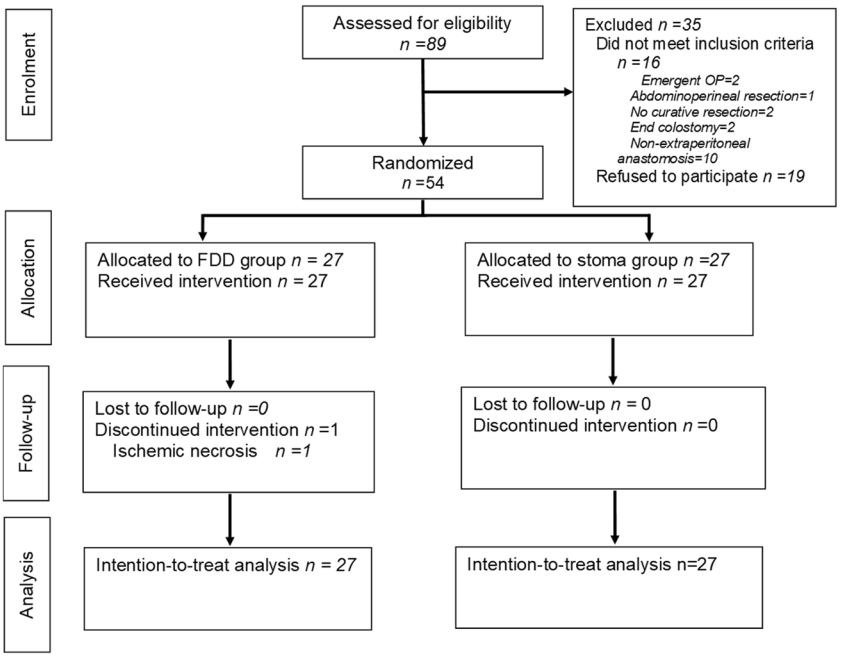

Fig. 6 CONSORT diagram for the trial. FDD, fecal diversion device

Table 1 Patients characteristics

	FDD group ($n = 27$)	Stoma group ($n = 27$)	P
Sex			0.398
Female	8 (29.6%)	12 (44.4%)	
Male	19 (70.4%)	15 (55.6%)	
Age (year), mean	65.4 (range 39–83)	65.4 (range 39–82)	0.991
Preoperative chemoradiotherapy*			0.477
No	20 (83.3%)	18 (75.0%)	
Yes	4 (16.7%)	6 (25.0%)	
Body mass index, mean ± SD	23.3 ± 4.0	23.7 ± 3.3	0.685
ASA score			1.000
1	13 (48.1%)	13 (48.1%)	
2	10 (38.5%)	10 (37.0%)	
3	4 (15.4%)	4 (14.8%)	
Disease			1.000
Benign	1 (3.7%)	2 (7.4)	
Malignancy	26 (96.3%)	25 (92.6)	
Operation			0.514
Laparoscopic	19 (70.4%)	22 (81.5%)	
Open	5 (18.5%)	4 (14.8%)	
Robotic	3 (11.1%)	1 (3.7%)	
Location of lesion			1.000
Sigmoid	2 (7.4)	1 (3.7%)	
Rectum	25 (92.6)	26 (96.3%)	
Ligation of IMA			1.000
High	18 (66.7%)	18 (66.7%)	
Low	9 (33.3%)	9 (33.3%)	
Method of anastomosis			0.142
Stapler	25 (96.2)	20 (74.1)	
Handsewn	2 (7.4)	7 (25.9)	
Anastomosis location from the anus (cm)	4.9 ± 1.2	5.0 ± 1.5	0.844

IMA, inferior mesenteric artery; ASA, American Society of Anesthesiologists; SD, tandard deviation

*Malignant rectal disease only

related to surgery, failure to protect the anastomosis, and other AL-related complications were compared using the Pearson χ^2 test or Fisher's exact test. Total hospital days, total cost, duration of FDD or stoma, operation time, and delay in establishing soft diets were analyzed using Student's t test. Values of $P < 0.05$ were considered statistically significant.

Results

Of the 89 patients assessed for eligibility, 54 were enrolled in the study. After the intervention, one patient in the FDD group required an unexpected additional surgery upon developing segmental colonic necrosis induced by ischemia after the primary surgery. The patient had undergone abdominal surgery before participating in this study, and ischemia was found in the upper 10 cm above the FDD. The patient underwent an additional colectomy and end colostomy on the 15th postoperative day. Finally, 27 patients in the FDD group and 27 patients in the stoma group were analyzed according to the intention-to-treat analysis. The CONSORT flow diagram demonstrated the flow of the participants through the study (Fig. 6).

Patient characteristics are shown in Table 1. Twenty men (37.0%) and 34 women (63.0%) were included. Preoperative radiotherapy was performed in 10 of 51 malignancy patients (19.6%). Forty-five patients (83.3%) underwent minimally invasive surgery. There were no significant intergroup differences in age, sex, body mass index, or ASA score. Operation types and anastomosis locations were similar between the groups. A hand-sewn anastomosis was created in 7 patients (25.9%) in the stoma group versus 2 patients (7.4%) in the FDD group ($P = 0.142$).

Table 2 Overall complications

	FDD group ($n = 27$)	Stoma group ($n = 27$)	P
Overall morbidity			0.551
No	7 (25.9)	9 (33.3)	
Yes	20 (74.1)	18 (66.7)	
Dindo complication grades			0.584
0/1	16 (59.3)	14 (51.9)	
2/3	11 (40.7)	13 (48.1)	
Anastomosis leakage			0.555
No	21 (77.8)	22 (71.0)	
Yes	6 (22.2)	9 (29.0)	
Intestinal obstruction			1.000
No	22 (84.5)	22 (84.5)	
Yes	5 (18.5)	5 (18.5)	
Ileus			0.484
No	21 (77.8%)	23 (85.2%)	
Yes	6 (22.2%)	4 (14.8%)	
Wound infection			1.000
No	23 (85.2%)	23 (85.2%)	
Yes	4 (14.8%)	4 (14.8%)	
Urinary tract infection			0.111
No	23 (85.2%)	27 (100.0%)	
Yes	4 (14.8%)	0	

Clinical safety of FDD

There were no cases of mortality in this study. Morbidity affected 20 (74.1%) patients and 18 (66.7%) patients in the FDD and stoma groups, respectively ($P = 0.551$) (Table 2). There were no statistically significant differences in Clavien-Dindo classification grade 2 or 3 complications between the groups ($P = 0.584$). In the stoma group, 10 patients (37.0%) underwent morbidity related to the stoma. One patient underwent partial necrosis of stoma, and two patients underwent prolapsed stoma. The other patients underwent skin erosion and peristomal pain. All patients did not need intervention, and their symptoms improved with conventional treatment. The overall AL rate was 27.8% (15 patients), but it did not differ significantly between groups (6 patients [22.2%] in the FDD group vs 9 patients [29.0%] in the stoma group, $P = 0.555$). The severity of AL is listed in Table 3 according to the grading proposed by International Study Group of Rectal Cancer [10]. The rates of postoperative obstruction, ileus, and wound infection were similar in the two groups. Two patients had FDD-related erosions, but neither had AL in the 3-week contrast test. Part of the band was noted at the mucosal defect on a sigmoidoscopy examination after FDD removal. Neither patient had generalized or localized peritonitis symptoms. Both were followed-up and did not require additional admission or further treatment.

Table 3 Classification of anastomotic leakage

	FDD group ($n = 6$)	Stoma group ($n = 9$)	P
Grade A*	2	4	0.870
Grade B*	2	3	
Grade C*	2	2	

*International classification of the anastomotic leakage

Clinical effectiveness of FDD

The FDD was in place for the required duration, and the fecal diversion capacity was comparable to that of the stoma. There was no early drop out of FDD, and no conversion to stoma until the scheduled removal. The total hospital stays and medical costs are shown in Table 4. The mean postoperative hospital stay after the primary surgery was 13.9 ± 8.8 days in the FDD group versus 10.5 ± 4.2 days in the stoma group ($P = 0.072$). However, the stoma group needed further surgery and hospitalization for the ileostomy take-down procedure. The total hospital stays contained the postoperative hospital stay after the primary surgery and reoperation for ileostomy take-down. The mean total hospital stay of the FDD group was 16.4 ± 6.7 days, statistically shorter than that of the stoma group (23.4 ± 8.7 days) ($P = 0.002$). The mean total hospital cost was $12{,}726.8 \pm 3422.8$ USD in the FDD group and $17{,}954.9 \pm 9040.3$ USD in the stoma group ($P = 0.008$).

Immediate intraoperative and postoperative outcomes

The mean operation time and intraoperative bleeding did not differ between groups (Table 5). The first bowel movement occurred at a mean of 3.1 ± 1.7 days in the FDD group versus 2.3 ± 1.1 days in the stoma group ($P = 0.034$). However, the delay in dietary progression was similar between groups ($P = 0.204$).

Fecal diversion procedure duration

The clinical AL results are shown in Table 6. The mean fecal diversion procedure duration was 21.6 ± 6.1 days in the FDD group versus 114.9 ± 41.3 days in the stoma group ($P < 0.0001$). Of the 54 patients, 15 (27.8%) had AL; all cases were effectively managed by FDD and loop ileostomy. Three patients had FDD longer than 3 weeks. Of the 3 patients, 1 patient removed the FDD at 6 weeks, and the other two patients were converted to the stoma procedure due to contrast leakage at 6 weeks postoperative. AL was clinically detected in 14 of the 15 patients at the 1-week CT examination without a significant intergroup difference. Two patients in the stoma group had persistent AL on the 10-week contrast study. After 6 months postoperative, 3 patients of each group had a stoma.

Table 4 Total hospital stay and cost

	FDD group ($n = 27$)	Stoma group ($n = 27$)	P
Length of hospital stay (day)			
Initial surgery	13.9 ± 8.8	10.5 ± 4.2	0.072
Total (including stoma reversal)	16.4 ± 6.7	23.4 ± 8.7	0.002
Total cost (USD)	12,726.8 ± 3422.8	17,954.9 ± 9040.3	0.008

Mean±standard deviation

In the FDD group, 1 patient underwent transverse colostomy due to colonic necrosis. The other patients underwent stoma due to continuous anastomotic leakage. In the stoma group, two patients kept the stoma due to continuous anastomotic leakage. The other patient underwent delayed leakage after ileostomy take-down. Of the 6 patients, 5 patients still have a stoma after finishing the follow-up.

Discussion and conclusion

The overall complication rates were similar between the FDD and stoma groups. The AL rate was also similar in both groups, and FDD did not prevent AL. FDD placement provided rapid intestinal continuity without anesthesia compared to stoma creation. There was no additional cost for maintaining the FDD. However, the FDD did not completely replace the stoma because some patients required a stoma due to AL despite FDD use.

In rectal cancer, a stoma has commonly been used to prevent resultant clinical complications of AL, but the stoma itself can cause many complications [3, 11]. The most common complication of the stoma is skin excoriation [3, 12]. Some patients experienced stomal retraction or obstruction [12]. Rarely, such patients require surgical treatment. In particular, many patients with ileostomy showed dehydration and an electrolyte imbalance such as hypokalemia due to discharge of the contents of the small intestine [3, 12]. Complications related to ileostomy also occurred during ileostomy takedown at a reported 20% incidence [13, 14]. In addition, 25% of patients with rectal cancer did not undergo ileostomy takedown [3]. To reduce those complications, several studies performed early ileostomy takedown [15, 16]. In these studies, there were no significant differences in complications between early and late ileostomy takedown [15, 16]. However, these studies demonstrated that it was possible to reduce ileostomy duration but not reduce the complications caused by the ileostomy itself.

Although the risk of AL is reportedly high in rectal surgery, not all patients who undergo this procedure require an ileostomy. AL was observed in approximately 10–12% of patients who underwent low anterior resection surgery [2, 17, 18]. Several studies demonstrated that ileostomy did not prevent AL [17, 19]. In fact, approximately 90% of patients without AL after rectal surgery did not require an ileostomy. The FDD could protect the anastomosis and provide rapid intestinal continuity in these patients. Thus, the FDD could safely replace the ileostomy in patients without AL.

In this study, the overall leakage rate was 27.8% higher than that reported by other studies [1, 2, 20]. In many studies, AL was defined differently [21]. In some studies, clinical signs of AL were considered important for defining leakage [22, 23]. In this study, all patients underwent abdominopelvic CT at 1 week and contrast enema as a contrast study at 3 weeks regardless of symptom status. If patients showed findings of leakage on the tests at week 1 or 3, whether there were symptoms or not, they were identified as having leakage. In the present study, the contrast enema performed at 3 weeks occasionally showed leakage even if there was no leakage on the CT scan at 1 week. We believe that the leakage rate was high due to our active effort to identify AL.

In this study, colonic erosion was the most common FDD-related complication. We created a band of the same material as Vicryl® (Ethicon) for safety. However, erosion was confirmed in two patients without symptoms of peritonitis. Although few studies have examined colonic erosion, an animal study of FDD had similar results [8]. In the animal study, a non-absorbable band was used. However, there were no

Table 5 Clinical results of intraoperative and postoperative outcomes

	FDD group ($n = 27$)	Stoma group ($n = 27$)	P
Operation time (min)	233.9 ± 58.4	208.1 ± 60.6	0.187
Intraoperative bleeding amount (ml)	62.6 (range 10–500)	40.0 (range 10–200)	0.321
First bowel movement (day)	3.1 ± 1.7	2.3 ± 1.1	0.034
Establishment of soft diet (day)	6.3 ± 2.1	5.6 ± 2.2	0.204

Table 6 Clinical results of anastomosis leakage patients

		FDD group ($n = 6$)	Stoma group ($n = 9$)	P
Leakage examination				
CT at 1st week	No	0 (0.0)	1 (11.1)	1.000
	Yes	6 (100.0)	8 (88.9)	
Gastrografin enema at 3rd week	No	1 (16.7)	4 (44.4)	0.580
	Yes	5 (83.3)	5 (55.6)	
Gastrografin enema at 6th week*	No	1(33.3)		
	Yes	2 (66.7)		
Successful fecal diversion	Yes	4 (66.7)	6 (66.7)	1.000
	No	2 (33.3)	3 (33.3)	
Total duration of stoma or FDD (day)		21 ± 6.1	114.9 ± 41.3	< 0.001

*Three patients underwent the test at 6th week

serious symptoms requiring reintervention. Thus far, gastric band erosion has been reported [24, 25]. In the gastric band erosion, complete erosion and obstruction were also reported [25]. We believe that the lack of serious complications due to the erosions noted in this study was due to the process occurring very slowly and the fibrosis around the mesh creating a firm seal that prevented local sepsis. We noted this phenomenon in our previous animal experiments [8]. Furthermore, we used an absorbable mesh band instead of the non-absorbable mesh in the animal study. We are currently upgrading the instrument used to measure the pressure applied to the bowel wall to prevent erosion and believe that safer operations will be possible in the next round of trials.

In this study, one patient in the FDD group underwent reoperation due to ischemic necrosis. At the time of surgery, postoperative intestinal adhesion due to previous surgery was severe in the upper abdomen. In the ultra-low anterior resection, we performed high ligation of inferior mesenteric artery and mobilization of spleen flexure for tension-free anastomosis. During the patient's reoperation, the position of the FDD was found to be satisfactory. The ischemic colitis was located 10 cm above the FDD insertion site. The authors concluded that the cause of ischemic necrosis was caused by an injury to the marginal artery of colon during mobilization of splenic flexure. We reported this situation to the IRB and independent reviewers who were appointed at the time of the study approval. Finally, we concluded that this complication could have occurred during the colon surgery regardless of FDD. We performed end colostomy for the patient's safety during re-operation.

Furthermore, we recommend using FDD within 6 weeks for safety, because the half-life of the band is 6 weeks. The FDD band is absorbable and weakens over time. If patients use FDD for more than 6 weeks, loose bands can lead to dislocation. Secondly, patients using FDD need irrigation twice a day. Hard stool can block the FDD tube. We conducted irrigation to change the hard stool to a loose stool. Patients are placed in the colon with FDD catheters for 1 l of water for colonic irrigation. Most patients feel bowel movement when they add 1 L of water, and usually one irrigation takes about 30 min.

This study had several limitations. First, it may have been underpowered. No FDD clinical study has been conducted at any other institution. Thus, FDD-related complications were undefined regardless of the preliminary study. The aim of this study was to assess the safety and effectiveness of FDD. However, we used total medical costs to indirectly calculate sample size. It may have been better to calculate the complication rate to evaluate the safety and effectiveness, but since the estimated sample size required too many cases for the study, we used medical expenses as an indirect factor. Higher expenses indicate more complications or lower safety, thus resulting in the sample size of this study. Second, this study was conducted in a single institution. We could not adopt a double-blind technique because of the need for FDD preparation. Finally, the quality of life was not evaluated in this study. However, we identified the possibility of FDD as an alternative technique to conventional stoma procedures.

This study showed the possibility of replacing ileostomy with a new device, FDD. The use of FDD provided faster bowel continuity for patients. This study has several limitations and further research is needed to ensure the safety and efficacy of FDD. However, this study confirms the possible outcomes and complications of FDD use.

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Compliance with ethical standards

Conflicts of interest Correspondence is inventor of FDD.

Research involving human participants and/or animals This study was conducted in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of Yeungnam University Hospital (2015-04-008).

Informed consent Informed consent was obtained from all study participants.

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