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NEW TECHNOLOGY REPORT

Stoma-Output Reinfusion Device for Ileostomy Patients: A Feasibility Study

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The use of this device in the United States is only under an approved Investigational Device Exemption (IDE) from the FDA.

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BACKGROUND

Patients with ileostomy experience considerable morbidity before reversal. Dehydration is common, accounting for up to 43% of unplanned readmissions,[1] and rates of prolonged postoperative ileus (PPOI) after reversal are up to 20%.[2] Chyme reinfusion and preoperative bowel stimulation have attracted growing interest as strategies to mitigate these risks.[3,4] Widespread use has yet to gain traction because existing methods are labor intensive, purpose-built equipment is lacking, and patient acceptance is poor.[2,5] We recently reported first-in-human feasibility-level results of a novel chyme reinfusion device, known as the Insides System[fi] (The Insides Company) for use in enteroatmospheric fistula and enterostomy patients.[6] Here we report the clinical findings and technologic advances during an extended feasibility study using this device in a larger cohort of patients with ileostomy exclusively.

IMPACT OF INNOVATION

The Insides System[fi] is described in Figure 1. To activate the pump, the driver unit is held adjacent (external) to the stoma appliance, achieving magnetic coupling. Five speed settings facilitate bolus chyme reinfusion targeted to viscosity and patient comfort.

The device overcomes several limitations associated with previous techniques. Components are small and portable so patients may readily mobilize, and manual handling of effluent is avoided. Because of its simplicity, patients can use the device at home, with no major dietary modifications required.

The previous first-in-human study population included only 10 patients, with a mixture of ostomies and fistulas, and most managed as inpatients.[6] The present study details the results of a larger cohort of ileostomy patients exclusively, with all but 2 being managed as outpatients. The final device iteration also presents a

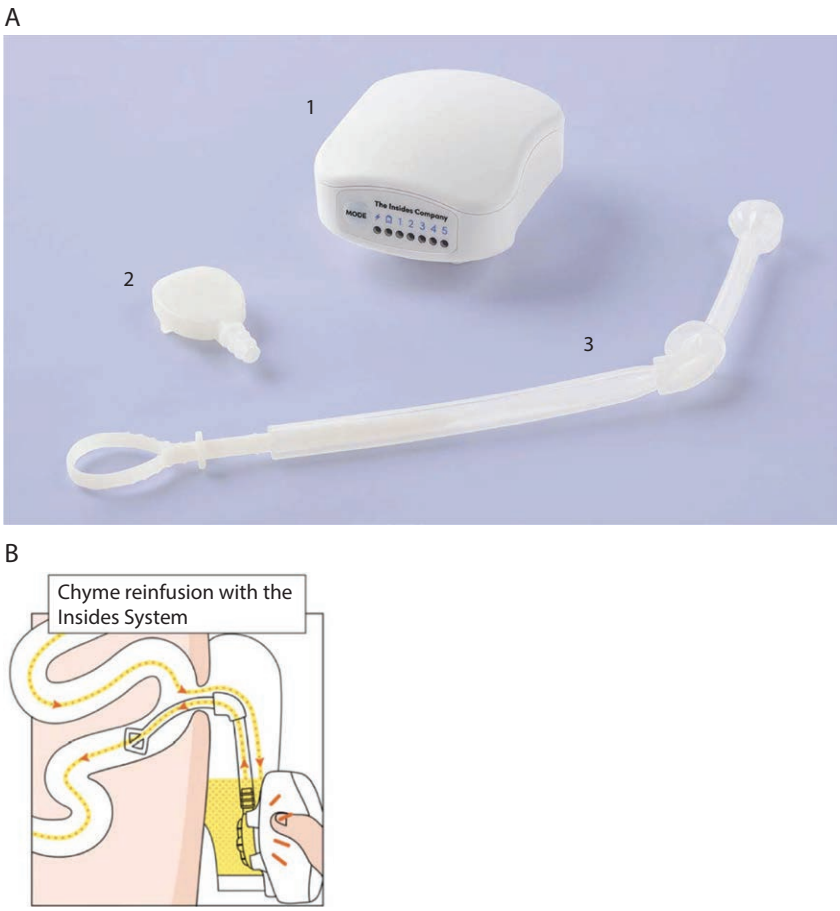

FIGURE 1. The Insides System[6]: a novel stoma output reinfusion device. A, Three device components: (1) driver unit: handheld, portable, battery-operated, rechargeable; (2) impeller: compact, contains neodymium magnetic bar, placed within stoma appliance and connected to the proximal end of the feeding tube; and (3) custom enteral feeding tube: 24F, silicone, inserted into the downstream ileostomy limb. B, Diagram schematic of the system in situ. Depiction of magnetic coupling between the driver unit and impeller pump. Enteral feeding tube is located within the downstream ileostomy limb.

significant improvement on earlier versions, which used off-the-shelf gastrostomy tubes.[6] These caused multiple issues (detailed below), instigating the sequential development of a custom tube specifically designed to overcome the shortcomings.

This feasibility study aimed to assess user experience, device performance, and relevant clinical outcomes in patients undergoing ileostomy. Ethical approval was granted (HDEC:17/NTA/241) and the trial was registered (ANZCTR12618001964202).

TECHNOLOGY MATERIALS AND METHODS

Primary Outcome

Demonstrate device feasibility as indicated by the end points of successful stoma-output reinfusion and improved patient satisfaction with device use. Successful reinfusion was demonstrated by lowering of stoma bag fluid levels after device use coupled with bowel movements. Improved patient satisfaction was demonstrated by improvements in user-experience feedback scores between the first 7 patients who used the off-the-shelf gastrostomy tubes (group 1) and the final 5 patients who used a final iteration of the new custom chyme-reinfusion tube (group 2). Ease of use, preference, and perceived health benefit were measured on 10-point Likert scales, with scores of 10 representing high ease of use, high preference for reinfusion, and high perceived health benefit.

Secondary Outcomes

Secondary outcomes included preoperative stoma-related outcomes (eg, net stoma losses) and device-related outcomes (eg, use metrics). Postoperative recovery outcomes included length of stay, recovery of bowel function (measured by "time to GI2," being tolerance of oral diet and passage of stool),[7] incidence of PPOI (defined as per Vather et al[8]), and incidence of complications to discharge. Adverse events were recorded.

Participants

Patients ≥18 years of age with a defunctioning ileostomy created at least 2 weeks before enrollment were eligible. Their ileostomy closure date must have been at least 3 days after the enrollment date. For patients with distal anastomoses, anastomotic leak was first excluded via radiologic examination. Exclusion criteria included pregnancy, inability to insert a 24F feeding tube into the distal stoma limb, distal obstruction, anastomotic leak, gut motility disorder, estimated glomerular filtration rate <30 mL/min/1.73 m^2, and inability to provide informed consent. A stoma nurse installed the device in at least 75% of the patients and reported that this was technically easy to accomplish (the other installations were performed by authors C.L. and G.O.). The device was to remain in place from enrollment until ileostomy reversal. A summary of the instructions provided to patients is detailed in Appendix 1 (see Supplemental Digital Content 1, http://links.lww.com/DCR/B720), and the method of outpatient stoma-output volume measurement is detailed in Appendix 2 (see Supplemental Digital Content 2, http://links.lww.com/DCR/B721). Patients were divided into 3 groups in chronologic order. The first group used off-the-shelf gastrostomy tubes (group 1), the second group was part of the iterative development phase when new tube designs were trialed (development group), and the third group used a late iteration of the tube design (group 2).

Data Collection

Background medical data were obtained from electronic medical charts. Where possible, baseline stoma output volumes were obtained via either inpatient fluid balance charts or self-measurement at home. Patients were provided with questionnaire logbooks to complete daily, and regular telephone contact (by study investigators C.L. or E.L.) was maintained to assess secondary outcomes. A questionnaire was administered toward the end of the intervention period to assess primary outcomes. After reversal, patients were reviewed daily to assess postoperative outcomes.

Statistical Analysis

Quantitative data analysis was performed. Clinical data were synthesized across the themes of device performance, user experience, clinical outcomes, and adverse events. Descriptive statistics were used to summarize key outcomes. The median (range) is reported for continuous and ordinal variables, and the frequency (percentage) is reported for categorical outcomes.

RESULTS

Enrollment

Nineteen patients were recruited between April 2019 and May 2020 (Fig. 2). Demographic and baseline data are shown in Table 1. Median (range) time elapsed between stoma formation and enrollment was 121 days (range, 8–697 d).

Primary Outcomes

A total of 549 patient-days of device use (median = 10 d (range, 1–142 d)) were captured. All 5 of the group 2 patients had successful reinfusion of stoma output coupled with bowel movements. In total, 15 patients (79%) experienced at least 1 bowel movement. Median (range) reported an ease-of-use score improved from 7 of 10 (3–10) in group 1 to 9 of 10 (8–9) in group 2. Median (range) preference score also improved from 3 of 10 (1–8) in group 1 to 7 of 10 (1–9) in group 2. Median (range) perceived health benefit score was 8 of 10 (1–10) in group 1 and 6 of 10 (1–8) in group 2. Comparison of demographics and other outcomes between group 1 and group 2 patients is found in Table S1 (see Supplemental Digital Content 3, http://links.lww.com/DCR/B670).

Secondary Outcomes

Device Outcomes

Frequency of device use was available for 295 patient-days; median frequency was 3 reinfusion attempts per day (range, 0–20). Duration of device use was available for 273 patient-days; the most common duration of device use per attempt was 2 to 5 minutes (30% of patient-days).

The gastrostomy feeding tubes used by patients in group 1 exhibited multiple issues. Five patients (71%) experienced tube-specific difficulties, including dislodgement (n = 4), localized abdominal pain (n = 3), inadequate fit of the tube/pump complex within their stoma appliance (n = 1), and bending of the tube leading to partial obstruction (n = 1). These problems (also noted previously)[6] provided impetus for the development of a custom enteral feeding tube specifically adapted for use in a stoma (Fig. 3 and Table S2, see Supplemental Digital Content 4, http://links.lww.com/DCR/B669). Patients from group 2 exhibited few tube-related issues with no complaints pertaining to poor device fit.

Nontube-related device issues were also identified. Eight patients (42%) reported that the device was ineffective when chyme viscosity was high. Other issues included pump blockage (n = 7), unsuccessful reinfusion of unknown cause (n = 3), inability to tolerate dietary restrictions (n = 2), and difficulty exchanging the pump (n = 1). Early device cessation occurred in 7 patients (37%), however, for only 1 group 2 patient. Reasons included abdominal discomfort (n = 4), inability to maintain suitable diet because of poor dentition (n = 1), concerns regarding recurrence of rectovaginal fistula (n = 1), and multifactorial (n = 1).

Clinical Outcomes

Data on stoma output before versus after device use were available for 14 patients. The median net change in daily

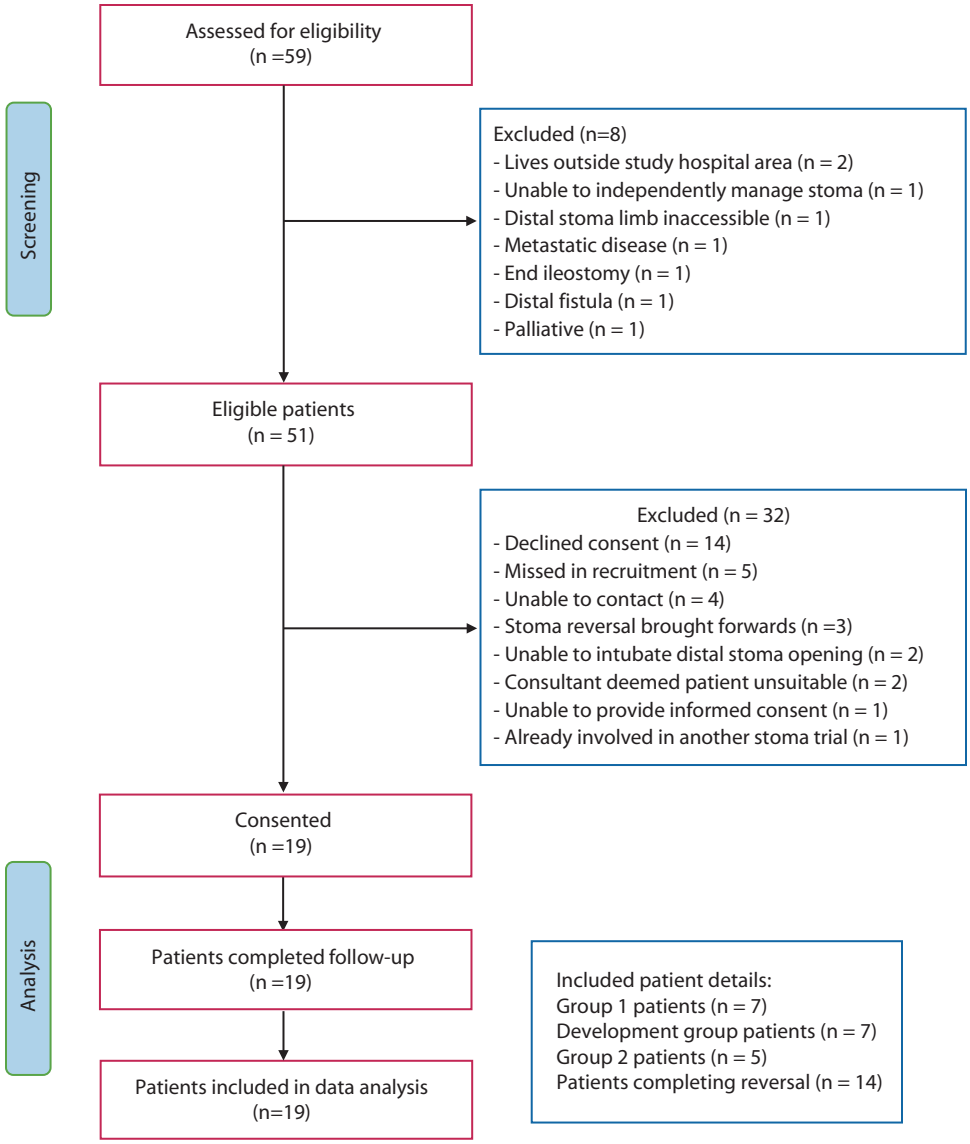

FIGURE 2. Flow diagram of feasibility study patients.

stoma output was a reduction of 452 mL (range, −1905 to +575 mL). Eleven patients (79%) demonstrated a reduction in net stoma losses per day. Five of the 9 patients using antidiarrheal medications at baseline ceased or reduced these medications.

Fourteen patients underwent stoma reversal. Median length of stay was 3.5 days (range, 1–28 d). Median time to GI2 was 72 hours (range, 24–336 h). Three patients (21%) experienced PPOI after ileostomy reversal diagnosed on or after postoperative day 4, lasting a median 2 days (range, 2–10 d).

Adverse Events and Complications

Thirteen patients (68%) experienced at least 1 device-related minor adverse event before ileostomy reversal. Two patients experienced device-related serious adverse events, and 3 patients experienced nondevice-related serious adverse events. After ileostomy reversal, 4 (29%) of the 14 patients experienced at least 1 postoperative complication (Table 2). Both instances of acute kidney injury (which occurred before ileostomy reversal) were attributed to reduced adherence to reinfusion therapy in response to social stressors. The episode of small bowel obstruction was unrelated to the device as demonstrated by CT imaging and intraoperative findings of adhesions. After completion of the trial period, 1 patient developed ingrowth around the flanges of the Malecot tube tip (resulting in the subsequent development of the biconcave half-balloon tip depicted in Figs. 1 and 3).

Table 1. Feasibility study patient characteristics

Patient No.	*Study site*	*Sex*	*Age, y*	*Ethnicity*	*Indication*	*Smoking*	*BMI*	*ASA*	*Stoma type*	*Anti-diarrheal medications*	*Stoma duration at time of enrollment, d*	*Duration of device use, d*[a]	*Tube used*	*Patient group*
1	ADHB	M	40	Asian	Colon cancer	No	27	2	Loop ileostomy	Nil	267	7	Halyard Gastrostomy	Group 1
2	ADHB	M	67	NZ European	Diverticular disease	Yes	23	3	Loop ileostomy	Loperamide 4 mg TDS	200	3	Halyard Gastrostomy	Group 1
3	ADHB	M	59	NZ European	Rectal cancer	No	27	2	Loop ileostomy	Nil	68	18	Halyard Gastrostomy	Group 1
4	ADHB	F	47	NZ European	Ulcerative colitis	No	26	2	Loop ileostomy	Nil	405	2	Halyard Gastrostomy	Group 1
5	ADHB	M	71	Other European	Rectal cancer	No	19	2	Loop ileostomy	Loperamide 6 mg TDS	35	19	Halyard Gastrostomy	Group 1
6	ADHB	M	43	Pacific Islander	Rectal cancer	No	30	2	Loop ileostomy	Nil	176	6	Cook Entuit	Group 1
7	ADHB	M	54	NZ European	Mesenteric ischemia	No	20	3	Loop ileostomy	Loperamide 10 mg TDS	697	42	Cook Entuit	Group 1
8	ADHB	F	45	Maori	Anastomotic leak	No	53	3	Loop ileostomy	Loperamide 4 mg TDS	80	3	Custom (early)	Development group
9	ADHB	F	72	NZ European	Rectal cancer	No	22	2	Loop ileostomy	Nil	121	20	Custom (early)	Development Group
10	CMDHB	F	65	NZ European	Rectal cancer	No	19	1	Loop ileostomy	Nil	222	7	Custom (early)	Development Group
11[b]	CMDHB	M	55	Pacific Islander	Rectal cancer	No	30	2	Loop ileostomy	Nil	293	1	Cook Entuit	Development group
12[b]	ADHB	F	75	Other European	Ovarian cancer	No	18	3	Loop ileostomy	Nil	118	38	Halyard Gastrostomy	Development group
13	CMDHB	M	60	Maori	Rectal cancer	Yes	29	3	Loop ileostomy	Nil	69	8	Custom (early)	Development group
14	ADHB	M	49	NZ European	Crohn's disease	No	24	2	Double-barrel ileostomy	Loperamide 2 mg TDS	8	142	Custom (late)	Group 2
15	CMDHB	M	52	Maori	Incarcerated hernia	Yes	43	4	Abcarian stoma	Loperamide 16 mg QID	27	140	Custom (late)	Group 2
16	SDHB	F	68	NZ European	Anastomotic leak	No	27	3	Loop ileostomy	Loperamide 4 mg QID	221	10	Custom (early)	Development group
17	ADHB	M	78	NZ European	Anastomotic leak	No	21	3	Abcarian stoma	Nil	15	6	Custom (late)	Group 2
18	BOPDHB	M	54	Maori	Anastomotic leak	No	24	4	Double-barrel ileostomy	Loperamide 40 mg daily, Codeine 60 mg BD	71	40	Custom (late)	Group 2
19	LDHB	M	55	NZ European	Rectal cancer	No	20	2	Loop ileostomy	Loperamide 40 mg daily, codeine 60 mg TDS	623	37	Custom (late)	Group 2

ADHB = Auckland District Health Board; BOPDHB = Bay of Plenty District Health Board; CMDHB = Counties Manukau District Health Board; F = female; LDHB = Lakes District Health Board; M = Male; NZ = New Zealand; SDHB = Southern District Health Board; TDS = 3 times a day; BD = 2 times a day QID = 4 times a day.

[a]*Duration of device use* was defined as the number of days the patient had the device fitted.

[b]These development group patients were unable to use the custom enteral feeding tube because their stomas could not be accessed. The off-the-shelf gastrostomy tubes were used instead.

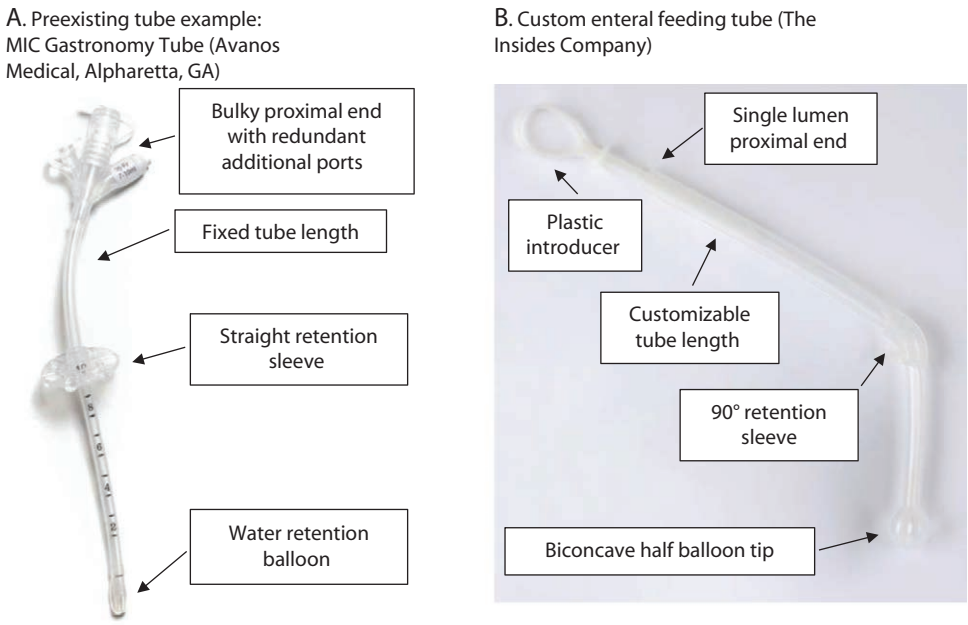

FIGURE 3. Comparison of preexisting and custom enteral feeding tubes. A, Preexisting tube example. B. Custom enteral feeding tube (The Insides Company).

Table 2. Adverse events/complications before and after ileostomy reversal

Variable	*n*	*Enteral feeding tube involved*
Minor device-related adverse event before ileostomy reversal		
Abdominal pain/discomfort[a]	10	Off-the-shelf tube: 4, early custom tube: 4, late custom tube: 2
Constipation	3	Off-the-shelf tube: 1, early custom tube: 1, late custom tube: 1
Nausea/vomiting	2	Early custom tube: 2
Subjective fevers	1	Early custom tube
Skin irritation	1	Early custom tube
Diarrhea	1	Late custom tube
Urinary tract infection with possible recurrence of rectovaginal fistula	1	Early custom tube
Serious device-related adverse event before ileostomy reversal[b]		
Possible pressure ulcer in distal ileostomy limb – requiring a small increase of the resected terminal ileum length at time of ileostomy reversal[c]	1	Early custom tube
Unable to exchange the custom feeding tube due to bowel mucosa ingrowth around the flanges of the Malecot tube tip–requiring removal under general anaesthetic[d]	1	Late custom tube
Serious nondevice related adverse event before ileostomy reversal		
Dehydration with acute kidney injury – readmission and intravenous fluid therapy	2	Late custom tube
Small bowel obstruction proximal to stoma – readmission and laparotomy with adhesiolysis	1	Off-the-shelf tube
Complication after ileostomy reversal		
CD 1: Postoperative ileus requiring observation	2	
CD 2: Postoperative ileus requiring total parenteral nutrition	1	
CD 2: Wound collection requiring local washout at bedside and negative pressure dressing	1	
CD 3: Intra-abdominal collection requiring radiological drainage	1	
CD 4: Small bowel enterotomy requiring laparotomy and ICU admission	1	

CD = Clavien–Dindo; ICU = intensive care unit.
[a]These symptoms of mild abdominal discomfort were anticipated.
[b]*Serious adverse event* is defined as an event that results in death, is life threatening, requires hospitalization or prolongation of existing hospitalization, or results in persistent or significant disability. Minor adverse events were events that did not meet this definition.
[c]This event led to a modification of the tube tip design to minimize pressure placed on the bowel lumen.
[d]This event led to the development of the biconcave half balloon tube tip, which avoided the flanges of the earlier iteration.

CONCLUSION

Chyme reinfusion and preoperative distal bowel stimulation could mitigate the morbidity associated with ileostomy formation.[3,5] Previous techniques have failed to achieve popularity because of high labor demands, poor adherence to strict dietary regimes, and low tolerability.[5] The results of the present feasibility study suggest that our novel chyme reinfusion device is easy to use, effective, and acceptable to outpatient ileostomates. Advances in device design during the trial, including a custom enteral feeding tube, led to improved patient-reported ease of use and preference scores. The minor adverse events were often transient, and the serious adverse events were either nondevice related or led to design changes.

The current device has advanced significantly compared with earlier versions.[6] The custom enteral feeding tube, in particular, resolves the issues associated with previous off-the-shelf gastrostomy tubes. The soft silicone material, customizable length, and 90° retention sleeve cuff facilitated improved comfort and accommodation within any stoma appliance. Insertion of the custom enteral feeding tube was simple and performed at the bedside without the need for radiologic guidance.

The present feasibility study has some limitations. Our cohort exhibited a relatively high rate of PPOI,[2,9] which may be explained by the highly variable duration of device use among feasibility study participants (range, 1–142 d). A previous study demonstrating improved reversal recovery outcomes had a minimum intervention period of 2 weeks.[2] Two of the 3 patients who experienced PPOI had used the device for ≤8 days. Patient adherence to daily logbook entries was only moderate, leading to some missing data.

FUTURE DIRECTIONS

This device has potential applications for prevention of dehydration, bowel rehabilitation, restoration of gut microbiome, assessment of bowel function, and preoperative bowel stimulation for loop ileostomy patients awaiting reversal. A stronger pump component able to reinfuse chyme of any viscosity is in development. A multicenter, randomized controlled trial is currently underway to assess the impact of this chyme reinfusion device on bowel recovery after ileostomy reversal.

KEY WORDS: Chyme reinfusion; Colorectal; Ileostomy; Medical device; Stoma.

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