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TECHNICAL NOTE

Chyme reinfusion nutritional management for enterocutaneous fistula: first international application of a novel pump technique

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Abstract

Aim: High-output enterocutaneous fistulas (ECFs) are an established cause of intestinal failure. Parenteral nutrition (PN) remains the gold standard for nutritional management but is complex, expensive and associated with significant complications. Chyme reinfusion (CR) has been reported by multiple centres as a viable option for nutritional management that improves nutritional status, provides the capacity to cease PN and is cost-effective. The aim of this paper is to describe the first use of a novel pump device (The Insides System™) by an independent centre in Australia for the nutritional management of a patient with high-output ECF.

Method: CR was performed on a 66-year-old woman with a high-output ECF. The device consists of two main components: a centrifugal pump that sits inside the stoma appliance and a battery-powered driver that is magnetically coupled externally onto the pump. The device allows for bolus CR at a rate of infusion that is manually controlled by the patient based on comfort, volume and effluent viscosity.

Results: CR provided adequate nutritional support, with successful cessation of PN. Effective use of the device was learnt easily by the patient with minimal demands on nursing assistance. Side effects of CR (diarrhoea, abdominal cramping) were overcome by the patient's ability to manually adjust the reinfusion rate.

Conclusion: Our experience with the novel Insides System™ device showed promising results in maintaining nutritional status as well as providing a minimally invasive, easy to use and low-cost system for CR. CR should be considered as a viable alternative for the nutritional management of patients with a high-output ECF.

KEYWORDS
chyme reinfusion, eneterocutaneous fistula, general surgery, nutrition

INTRODUCTION

Enterocutaneous fistulas (ECFs) are challenging to manage and associated with high morbidity and mortality. Mortality ranges from 5% to 20%, with sepsis being the leading cause of death. Factors influencing the outcomes of patients with ECF include fistula anatomy, output volumes and patient comorbidities [1,2]. Specialist intestinal failure centres have improved outcomes significantly and have decreased mortality [1,3].

Chapman et al. described the four management principles for ECF as: source control, fluid resuscitation, effluent management and skin protection [4]. Nutrition has also been identified as a key factor influencing patient outcomes [1,4]. A high-output ECF (losses >500 ml/day) can result in fluid and electrolyte loss and malnutrition, culminating in intestinal failure [2,5,6]. The gold-standard nutritional support is parenteral nutrition (PN). However, this is associated with significant complications and is resource intensive and expensive [5,7,8].

Chyme reinfusion (CR) was promoted by Levy et al. as extracorporeal reinfusion of the proximal fistula output into the distal bowel [5,9]. Therapeutic effects include weight gain, improved liver function, normalized fluid and electrolyte balance and distal bowel rehabilitation [10], as well as potential cessation of PN and cost effectiveness [2,5,7–9,11,12].

Sharma et al. described the use and patient outcomes for a novel battery-powered, magnetically activated pump used for CR (The Insides System™; The Insides Co.) [11]. This is the first use of this device by an Australian-based independent centre whereby CR was performed for nutritional management of a patient with a high-output ECF.

METHOD

A 66-year-old woman with a mid-small bowel high-output ECF, secondary to iatrogenic injury following laparoscopic salpingo-oopherectomy, underwent CR for a total of 125 days prior to restoration of intestinal continuity and abdominal wall repair (Table 1). The history of her index procedure was that on the second postoperative day she was admitted to the ICU with intra-abdominal sepsis secondary to an unrecognized enterotomy, and despite operative reintervention an ECF had developed by postoperative day 18. CR was commenced with the novel device on day 58 (fistula output ~1–1.5 L/day). Institutional approval and informed consent for device use was obtained. Total PN was ceased 2 days after establishing CR. The patient was subsequently discharged on a full diet with ongoing CR. However, she required two readmissions for rehydration due to inadequate compliance with oral fluids and CR due to psychosocial factors. After the second readmission she remained an inpatient in a peripheral hospital and continued self-administered CR therapy off PN and intravenous (IV) fluids, with nursing staff performing CR overnight.

The device consists of two components: a centrifugal pump with a magnetic bar (Figure 1C), which sits inside the wound management appliance (WMA), and a battery-powered driver (Figure 1A) that magnetically couples externally onto the pump. This device facilitates bolus CR whilst avoiding direct contact with fistula effluent, disturbance of the WMA or significant disruption to the patient's activities. Five speed settings allow the user to manually adjust the rate of infusion (Video S1 in the Supporting Information).

The distal limb of the fistula was cannulated with a 32Fr Foley catheter (balloon inflated with 5 ml of water). A similar catheter (Figure 1B) may also be used. The pump was connected to the Foley catheter and situated within the WMA (Figure 2A). A WMA with a clear window allows visualization and access to the pump. To commence refeeding, the pump is immersed in the effluent and then coupled externally to the driver (Figure 2B). The speed of refeeding is determined by the volume of effluent and patient comfort.

During the day fistula effluent was collected directly into the WMA and CR performed when the appliance was sufficiently full (approximately 250 ml) or earlier at the discretion of the patient. Overnight, a drainage bag was connected to the WMA collecting fistula effluent over an 8–12 h period which was refed in the morning by decanting the effluent back into the WMA in boluses of 150 ml to avoid overflow and patient discomfort.

The patient, family and nursing staff were educated in the use of the device. An outpatient protocol was designed, adapted from the device's instructions for use (Appendix 1). The patient underwent fistula repair with restoration of intestinal continuity and abdominal wall reconstruction without complications 8 months after initial diagnosis.

DISCUSSION

Comparison with other methods, advantages and disadvantages, difficulties and complications

Nutritional support remains a key priority in ECF. Enteral nutrition (EN) promotes gut function, allows maintenance of gut flora and reduces infections associated with IV lines, yet increasing oral intake increases fistula output [13]. PN meets nutritional demands and reduces gastrointestinal secretions by 30%–50%, thereby minimizing the incidence of dehydration and electrolyte deficiencies [1,2,6]. However, PN carries significant risks including line sepsis and liver dysfunction, and is resource intensive [8,12,13].

Several techniques for CR have been described [2,5,7–9,11]. Experience with manual reinfusion (straining and syringing chyme), was found to be labour intensive and unpleasant for staff, leading to design of this novel device. Previously, Teubner et al. described a technique in which EN (polymeric, semi-elemental or elemental feed) was infused into the distal fistula limb ('fistuloclysis'), using an improvised connection system through the WMA [8]. Feeding rates were titrated to reach the required patient-specific rate, infused over 12–16 h [8]. Picot et al. and Layec et al. used a CR method involving extracorporeal circulation of chyme, without manipulation, in a closed system, with a pump able to operate continuously. The Enteromate 2 (Les Clayes-Sous-Bois, France) pump constantly aspirates chyme and recycles it directly at a flow-rate adjusted to aspiration volume, maintaining an empty pouch [2,9]. In all described

TABLE 1 Patient characteristics and nature of the enterocutaneous fistula

Anatomy	Aetiology	Duration of CR	Past medical history	Medication	Social history
Mid-small bowel	Iatrogenic small bowel injury	125 days	a. Hypertension, pen cholecystectomy, nxiety	Telmisartan, mirtazepine	Independent ADLs, moker

Abbreviations: ADL, activities of daily living; CR, chyme reinfusion.

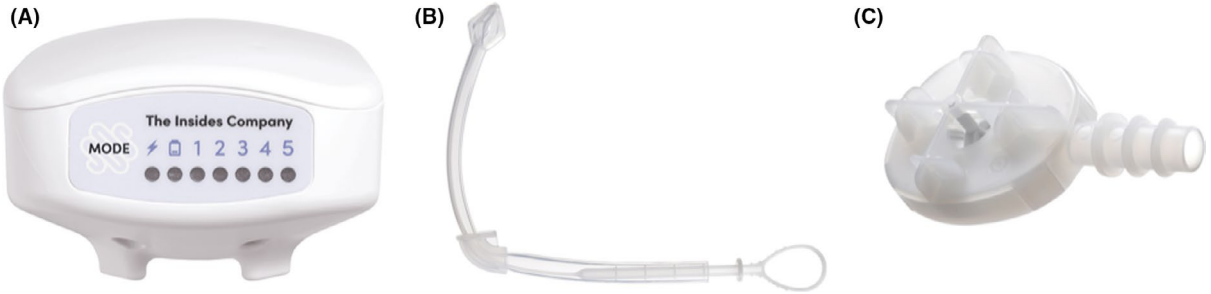

FIGURE 1 (A) Driver unit with a five-speed setting that couples externally to the pump across the wound management appliance. (B) Feeding tube which is cannulated into the distal limb of the fistula, alternatively a Foley catheter may be used. (C) Centrifugal pump with a magnetic impeller which sits inside the stoma appliance and couples to the base of the driver unit. The pump connects to a Foley catheter or feeding tube.

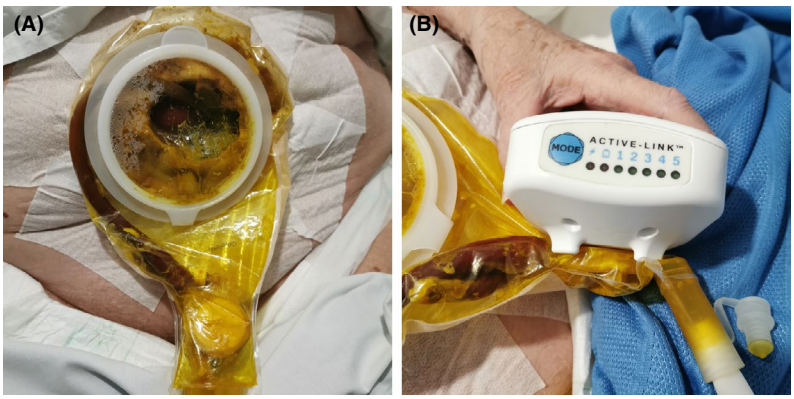

FIGURE 2 (A) A 32 Fr Foley catheter cannulated into the distal limb of the fistula with a centrifugal pump attached to the catheter end, lying within the wound management appliance (Coloplast Sensure Miop Post Op pouch). The pump remains immersed within the effluent during chyme reinfusion (CR). (B) The driver is coupled magnetically to the pump across the stoma appliance avoiding direct contact with chyme. The five speed options for CR are visible.

TABLE 2 Nutritional measurements throughout the 3 month period of chyme reinfusion (CR)

Date	Weight (kg)	Albumin (g/L)	ALT (U/L)	AST (U/L)	GGT (U/L)	ALP (U/L)	Transferrin (g/L)	Prealbumin (g/L)
14 Jan 2020	NR	20	38	15	14	159	1.7	0.14
12 Feb 2020[a]	81	24	12	15	24	135		
15 March 2020	80	33	33	32	49	135		
5 May 2020	79.3	32	20	16	55	161	2.4	0.33

Abbreviations: ALP, Alkaline phosphatase; ALT, Alaline aminotransferase; AST, Aspartate aminotransferase; GGT, Gamma-glutamyl transferase; NR, not recorded.

[a]Denotes the first day of CR.

techniques, the majority of patients were able to achieve cessation of PN.

The Insides System™ is a commercially available system allowing for bolus CR at the discretion and convenience of patients with minimal disruption to their activities. The methods described above require prolonged reinfusion times (12–16 h or continuously over 24 h). From our experience, 200–250 ml of chyme can be comfortably reinfused over a 5–10 min period with good patient tolerance once therapy is established. The external coupling of the device to the pump eliminates contact with chyme without the need for improvised connection systems prone to WMA leakage. The five-speed reinfusion system is adjusted easily so patients can control the CR rate based on their tolerance and symptoms.

Once CR was established in our patient using The Insides System™, nutrition was maintained over a period of 3 months with successful cessation of PN (Table 2). Sharma et al. assessed feedback from nursing staff, with a median usability score of 2.5 [scale of 1 (very easy to use) to 10 (very difficult to use)] [11].

The main side effects of CR were abdominal cramping, nausea and diarrhoea, which affected patient motivation and the volume

of reinfusion. Pharmacological agents such as hyoscine butylbromide (Buscopan), ondansetron and loperamide were used with variable efficacy. Symptoms improved as the patient learned to adjust CR to a personal level of comfort, and also with adaptation of the gut. These symptoms have been described with other methods and were overcome by readjusting infusion rates and volumes [2,5,7–9,11]. The psychological and physical unpleasantness of decanting over-night effluent into the WMA was a challenge for the patient, with a significant volume being discarded and poor compliance in the outpatient setting due to psychosocial factors. Clogging of the pump and dislodgement of the tube also reduced efficiency. Sharma et al. overcame this by eliminating stringy or highly fibrous dietary items [11]. Dislodgement of the tube was managed by increasing the volume in the balloon to 5 ml but higher volumes should be avoided due to the risk of pressure necrosis. No complications were encountered with CR and the use of this novel device.

CONCLUSION

CR has been shown to provide adequate nutritional support in patients with a high-output ECF minimizing the associated cost and risks of PN. Our experience with The Insides System™ device showed it to be a simple and promising solution for CR. CR could be considered as a viable alternative for nutritional management in patients with a high-output ECF. As our experience is the first international use of the system in one patient, further research with larger cohorts is now required.

CONSENT STATEMENT

Patient written and verbal consent has been obtained for this article.

ACKNOWLEDGEMENTS

We thank all the nursing staff and our stoma clinical nurse consultants who assisted in the education and care of the patient.

CONFLICT OF INTEREST

GOG holds patents on chyme reinfusion and is a member of The Insides Company. The device was supplied free by The Insides Company, New Zealand.

AUTHOR CONTRIBUTIONS

ES was involved in the acquisition of data, writing of manuscript and video editing. DW, GOG and GC participated in the conception and design, interpretation of data and reviewing of manuscript.

ETHICAL STATEMENT

Institutional permission obtained by author GC (Head of Colorectal Department) and the patient was consented fully on the risks and benefits of the novel therapy.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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APPENDIX 1

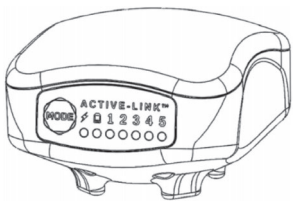
ACTIVE-LINK PROTOCOL

(NOTE: since the initial development of this protocol, Active-Link™ has been renamed the The Insides System™.)

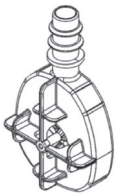
Equipment

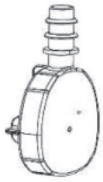
- apron
- gloves
- glasses
- measuring jug
- drainage bag

Active-Link equipment



Active-Link™ Driver





Active-Link™ Pump

KEY INFORMATION

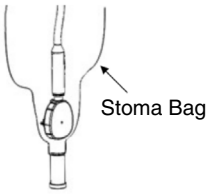
- Sterility is not essential for this procedure.
- Apron, gloves and protective eye wear may help for personal cleanliness.
- Intestinal effluent can be collected for a total of 12 hours but beyond that it should not be reused and we recommend discarding the effluent.
- During the day, refeeding is best done when stoma bag fills.
- Successful refeeding is considered when there is a lack of backflow, minimal cramping and manageable bowel movements.
- Please refer to the Active-Link Manual for more detailed instructions.

ACTIVE-LINK DRIVER

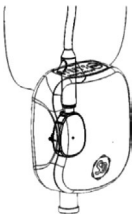
- To turn 'On' the driver press 'MODE' button.
- The driver has five different speed modes commencing from 1 to 5.
- Mode 1 is the slowest and most useful for thin bowel contents. Mode 5 is the fastest and most useful for thick bowel contents.
- Pressing the 'MODE' button will work up through the different mode speeds as indicated by the green light.
- To turn 'Off' the driver, press the 'MODE' button until you reach mode 5 then press again to see the green light go off.

DAY TIME PROCEDURE

- Intestinal effluent is collected in the stoma bag.
- However, if the patient requires an extended interval between refeeds, e.g. going to the shops, then the drainage bag may be used for collection during that period and effluent can be refed as per 'Overnight Procedure'
- Ensure that the Active-Link pump is immersed in the effluent and aligned for easy attachment to the Active-Link driver.
- Orientate Active-Link pump so that flat surface docks with the Active-Link driver.



- Place the Active-Link pump between the four feet of the Active-Link driver.
- The flat surface of the Active-Link pump should sit flush against the Active-Link driver.



- To stop re-feeding, pull the Active-Link driver away from the Active-Link pump or push the 'MODE' button until the Active-Link driver turns off.

OVERNIGHT PROCEDURE

- Intestinal effluent should be collected overnight but recycled within the 12 h period.
- To collect effluent a drainage bag needs to be connected to stoma bag.
- To commence refeeding, decant 150 ml of effluent into a measuring jug.
- Open the stoma bag window, pour the 150 ml effluent into the stoma bag and attach the Active-Link driver to the Active-Link pump to commence refeeding.
- Continue to refeed at 150 ml volumes until all effluent has been refed.
- Refeeding may be done over an extended period as determined by successful refeeding and patient comfort.

CONDITIONS FOR USE

Active-Link™ is suitable for patients who:

- Are aged 18 years or older.
- Have two stomal openings which are both serviced by a single stoma bag.
- Have been approved by a healthcare professional to have bowel contents pumped into the lower intestine.
- Have had the Active-Link™ tube inserted into the lower intestine.
- Have the physical dexterity to use Active-Link™, or have a carer that does.

- Have the mental capacity to use Active-Link™, or have a carer that does.
- Have access to mains power for charging the device.
- Have bowel contents which are of suitable thickness. Refer to the 'Active-Link™ Driver Operation' section for more information.

Contact your healthcare professional if any of the following occur:

- More than 1 litre (0.25 gal) of bowel contents is emptied from the stoma bag per day
- Irritation or bleeding around the Active-Link™ tube or stoma
- Blood in stool
- Dehydration, fainting, dizziness.
- Profuse or watery diarrhoea
- Fevers, chills
- Abdominal pain
- Inability to eat or drink sufficient food or fluids
- Severe nausea or vomiting
- The Active-Link™ stops working