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

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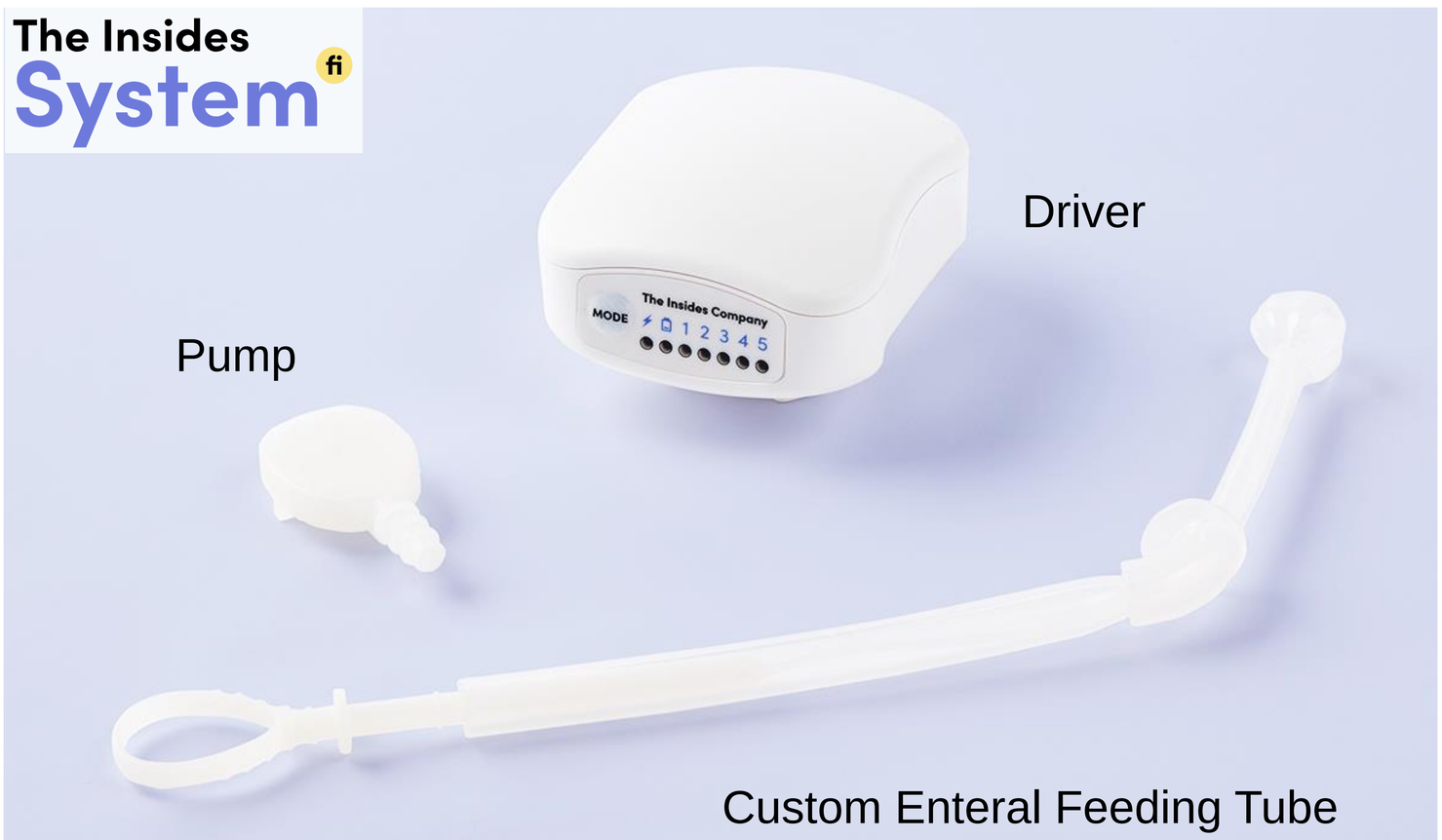
Introduction

Ileostomy patients suffer considerable morbidity prior to reversal. Dehydration is common and prolonged post-operative ileus after reversal occurs in up to 20%. Chyme reinfusion and pre-operative bowel stimulation are potential solutions. Widespread clinical use has yet to gain traction because existing methods are labour intensive, purpose-built equipment is lacking, and patient acceptance is poor. We report the clinical findings and technological advances from a feasibility study using a novel chyme reinfusion device in a cohort of ileostomy patients.

The Device: The Insides System



How It Works

The pump is connected to the enteral feeding tube which is inserted into the distal ileal limb.
To activate the pump, the driver is held adjacent but external to the stoma appliance to achieve magnetic coupling.
Five speed settings facilitates bolus chyme reinfusion targeted to viscosity and comfort.

Advantages Over Previous Systems

- Components small and portable
- No manual handling of stoma effluent
- Can be used at home
- No drastic dietary changes required
- Customisable length of enteral feeding tube allowing comfortable accommodation within any stoma appliance

Method

Adult patients with a defunctioning ileostomy created at least 2 weeks prior, and with a reversal date at least 3 days after enrolment were eligible. Anastomotic leak was first excluded via radiological examination. Primary outcomes: The differences in patient 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 enteral feeding tube (Group 2)**. Secondary outcomes: Pre-op stoma-related and device-related outcomes, post-op recovery outcomes and adverse events.

Results

Study Patients

April 2019 – May 2020 | 19 Patients | 14 Reversals | 549 patient days of device-use | Median time between stoma formation to enrolment:121 days

Primary Outcomes

	Median Score *(1-10)* Group 1	Group 2
Ease of Use *(1 = Easy)*	4	2
Preference *(10 = Prefer using device over discarding output)*	3	7
Perceived Health Benefit *(10 = high benefit)*	8	6

Secondary Outcomes

Stoma-Related Outcomes

79% of patients with fluid data: Reduced daily net stoma losses

5/9 patients using loperamide: Ceased or reduced dose

Post-Reversal Outcomes

Median LOS: 3.5 Days

Post-op Ileus: 21%

Device-Related Outcomes

71% of Group 1: Complaints about off-the-shelf gastrostomy tubes
Group 2: Few tube-related issues. Zero complaints about poor device fit.

Adverse Events (AE)

Minor AE: 13 Patients
Most common: Abdo discomfort (10 Patients)

Serious AE: 5 Patients
- Dehydration and AKI: 2
- SBO: 1
- Tube stuck: 1*
- Possible pressure ulcer in distal ileal limb: 1*

*: Device-related serious AE

Conclusion

The present feasibility study suggests our novel chyme reinfusion device is easy to use, effective, and acceptable to ileostomates in the community. The minor adverse events were often transient and the serious adverse events were either non-device related or led to design changes to prevent future events. A multi-centre randomised controlled trial is currently underway to assess the device's impact on bowel recovery following ileostomy reversal.