Techniques in Coloproctology (2018) 22:697–701
https://doi.org/10.1007/s10151-018-1846-6

TECHNICAL ADVANCES

# The Ostom-i™ Alert Sensor: a new device to measure stoma output

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Received: 11 August 2018 / Accepted: 3 September 2018 / Published online: 15 September 2018


## Introduction

Colorectal surgery for benign and malignant conditions commonly results in the formation of a stoma, with rates reported as 2–4 per thousand of the population living with a stoma [1]. Stomas, most commonly fashioned as ileostomy or colostomy, may be temporary or permanent and may follow elective or emergency surgery. Approximately 102,000 individuals live in the UK with an excretory stoma and in the 2015 UK National Bowel Cancer Audit 83% of patients had a stoma following a major operation to remove a rectal cancer [2]. Half of these patients still had a stoma 18 months after the operation. Complication rates for stoma patients vary between 6 and 59%. Perioperative high stoma output has been associated with increased length of hospital stay and readmission rates. Stoma output can reach volumes of 2000 ml/days and adaptation and subsequent reduction in output can take several weeks.

In recent years, advancements in technology have enabled medical devices to be small and mobile. At the same time commercial wearable devices, smartwatches and activity trackers are evolving in such a way that we can easily collect data from patients. Wearable technology is an emerging industry which can be adopted and easily translated into clinical use to improve standards of clinical care.

The Ostom-i™Alert Sensor (11 Health and Technologies Limited, Borehamwood Herts UK) is a CE-marked (Conformité Européenne, indicating conformity with health, safety and environmental protection standards for products sold within the European Economic Area) and FDA (Food and Drug Administration)-approved medical device. It uses a flexible sensor, clipped to the lower part of a stoma bag to sense when a bag is filling and to relay that data back to the patient in real time via a smartphone application (Fig. 1). The volume of stoma output is recorded, and alerts can be set by patients to prevent bag overflow and leakage. The data can also be shared via a ward dashboard with the nursing staff and have the potential to be integrated directly into the patient's electronic medical record. It is accurate within 10% at measuring the volume of stoma output (Figs. 2, 3).

The aim of our study was to assess the efficacy and usability of Ostom-i™ sensor, clipped to the lower part of a stoma bag to sense when a bag is filling and to relay that data back to the patient in real time via a smartphone application.

## Materials and methods

Operated patients with an ileostomy were recruited from Chelsea Westminster NHS Foundation Trust and St Mary's hospital Imperial College NHS Trust.

### Inclusion criteria

- Abdominal surgery resulting in an excretory small bowel stoma (loop ileostomy or end ileostomy);
- able to freely give written informed consent to participate in the study and have signed the Informed Consent Form;
- males or females, age 18 and older at the time of study screening;
- no plan for stoma reversal for the next 2 months to allow adequate time for study inclusion.

### Exclusion criteria

- Mentally incompetent or unable or unwilling to provide informed consent or comply with study procedures;
- children < 18;

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**Fig. 1** Example of the Ostom-I sensor in situ clipped onto a stoma bag

- patients with planned ileostomy closure in the next 2 months;
- patients unable or unwilling to come in for in-person Ostomi-i™ Alert teaching and screening visits.

Follow-up was 30 days post-discharge.

## Results

There were nine patients [six males, three females, mean age 52 years (range 26–76 years)]. There were five benign cases of inflammatory bowel disease (IBD) and four cancer cases. Median length of stay was 10.1 days (range 2–29 days). One patient was readmitted due to blockage of urinary catheter. Three postoperative complications were recorded (Table 1).

### Usability and acceptability of the device

Patients understood the instructions easily, supported by the research team, were able to pair the device to smart device and to remove and re-attach the device to the stoma bag with no problems.

There were network problems when patients had to be moved on different wards and when discharged in the community.

### Stoma Quality of Life Questionnaire (SQOLS) [3]

Six out of nine patients (66.6%) completed parts 1 and 2 of the SQOLS. SQOLS part 1 rates overall satisfaction with life on a scale of 1–100 with 0 being totally unsatisfied and 100 being totally satisfied.

Part 1 results:

- overall satisfaction with life in general following stoma formation was 35–75%;
- overall satisfaction with life in general 1 month following stoma formation was 30–75%.

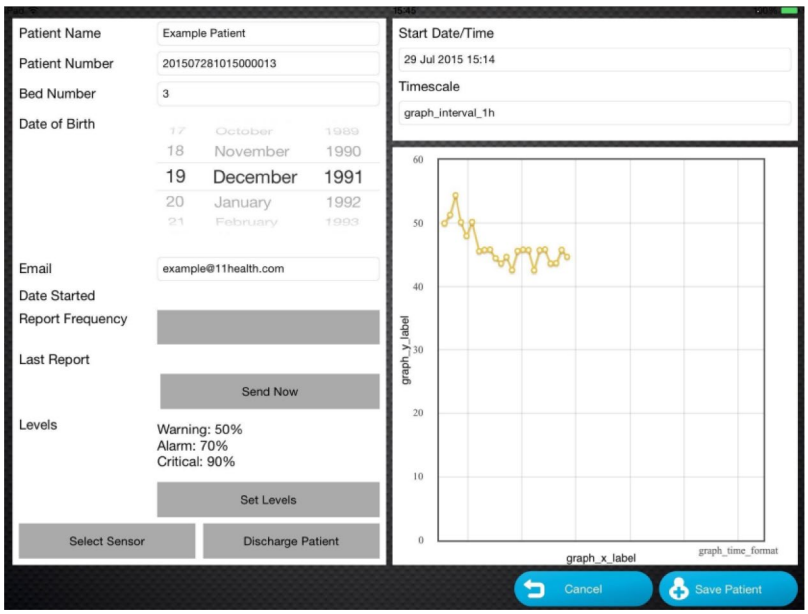


**Fig. 2** Example of the individual patient view visible to members of the care team

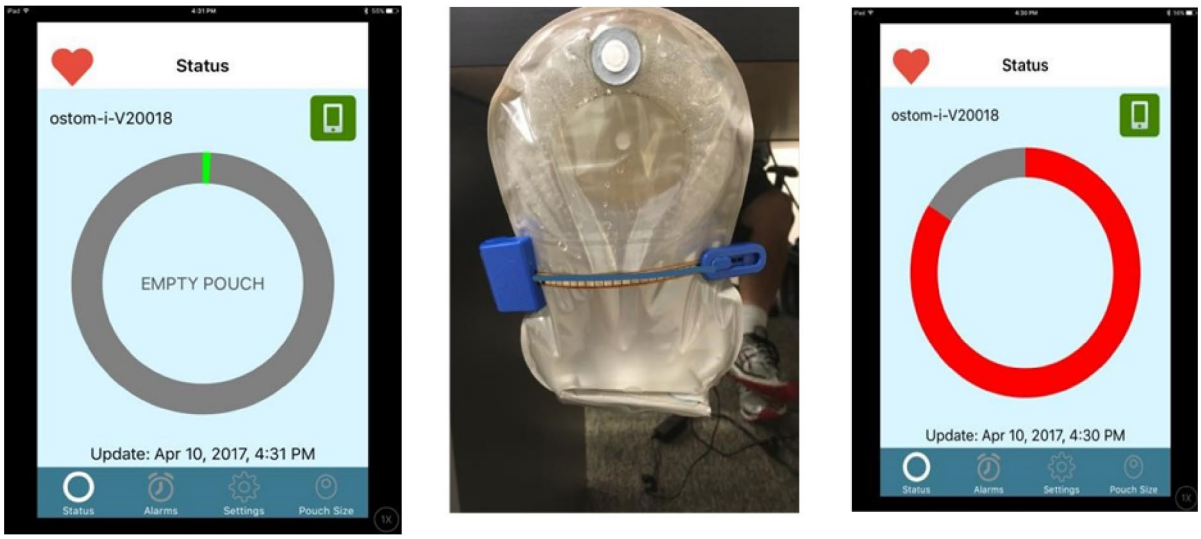


**Fig. 3** Example of the individual patient view visible to smart device screen

**Table 1** Patient characteristics

| Total number of patients | 9 |
|---|---|
| Age, mean (range) | 52 years (26–76) years |
| Sex | 6 male/3 female |
| Reason for surgery | 5 IBD/4 cancer |
| Emergency/elective | 1/8 |
| Neo adjuvant CRT | 1/4 cancer cases |
| Length of stay median (range) | 10.1 days (2–29)days |
| Postoperative complications | 3 |
| Readmission | 1 |

*IBD* inflammatory bowel disease, *CRT* chemoradiation therapy

Part 2 results are described in Table 2.

## Discussion

An ileostomy enables individuals to enjoy a full range of activities and is performed for many different diseases and conditions. However, the rate of complications following stoma creation is not insignificant.

### Dehydration, high-output stoma and acute kidney injury

In a retrospective study of 201 patients who underwent ileostomy formation at a single surgical centre, readmission for dehydration and renal failure within 30 days of discharge occurred in 17% of patients [4]. Another study revealed a 16.9% all-cause 60-day readmission with dehydration the reason for readmission in 7.3% of cases [5]. Generally, readmission for dehydration occurs in 10–15.5% of patients who undergo stoma formation. High-output stoma (HOS) is a major cause of morbidity in this patient group. This has been defined as ostomy output > 1500 ml/d for ≥ 2 consecutive days and can be considered early HOS (< 3 weeks after stoma formation) and late HOS (> 3 weeks after stoma formation). HOS occurs in up to 17% of stoma patients. Whilst infection and use of prokinetic agents predict the majority of HOS, the cause is unknown in 43% and probably involves bowel wall edema and motility changes perioperatively. Thirty to seventy-one percent of patients who develop HOS develop acute kidney injury. Trace element deficiencies (magnesium, phosphate and calcium) are also common in this group. Patients that develop postoperative HOS stay in hospital longer (18 vs. 12 days).

### Economic costs

Readmission following colorectal surgery adds a significant financial cost to healthcare. In a US study evaluating 70,484 patients who had undergone colorectal surgery, 13.7% were readmitted within 30 days, with the presence of a stoma being one of the strongest independent risk factors for readmission (OR 1.53; 95% CI 1.45–1.61). Stoma patients had higher rates of readmission for fluid and electrolyte imbalance/failure to thrive, and infection (12% readmission rates in stoma patients vs. 7% overall). The median combined direct hospital cost was over twice as high ($26,917 vs. $13,817) [6]. Other studies have also consistently found that acute healthcare resource utilisation is higher than expected in stoma patients.

**Table 2** Stoma Quality of Life Scale

| | | | | | | |
|---|---|---|---|---|---|---|
| I am able to participate in hobbies that I enjoy | 5 | 4 | 2 | 3 | 2 | 2 |
| I am able to go out with friends | 5 | 3 | 2 | 2 | 3 | 2 |
| My stoma interferes with my ability to work or go to school | 1 | 3 | 4 | 3 | 4 | 5 |
| I worry about travelling because of my stoma | 2 | 4 | 2 | 4 | 4 | 4 |
| I enjoy sexual activity | 1 | 2 | 4 | 2 | 2 | 4 |
| I feel attractive | 3 | 2 | 3 | 3 | 2 | 1 |
| My sexual partner is bothered by my stoma | 1 | 2 | 1 | 2 | 2 | 1 |
| It bothers me that others are aware that I have a stoma | 3 | 4 | 3 | 4 | 4 | 3 |
| I worry about lack of privacy when I need to change my pouch | 4 | 4 | 3 | 5 | 4 | 4 |
| I feel comfortable in my clothing | 3 | 4 | 4 | 4 | 2 | 2 |
| I am satisfied with the foods that I eat | 3 | 4 | 5 | 4 | 4 | 2 |
| I have financial concerns regarding my ostomy supplies | 1 | 1 | 1 | 1 | 1 | 1 |
| I have problems with odour | 4 | 4 | 2 | 3 | 4 | 4 |
| I am able to share my ostomy concerns with a family member or friend | 4 | 3 | 3 | 2 | 2 | 4 |
| I am embarrassed by gas (noises or rapid filling of bag) | 3 | 4 | 4 | 4 | 4 | 4 |
| I worry that my ostomy appliance may leak | 3 | 5 | 2 | 4 | 4 | 5 |
| I am bothered by skin irritation around the stoma | 4 | 1 | 1 | 2 | 2 | 2 |
| Social situations make me feel anxious | 3 | 3 | 1 | 3 | 3 | 2 |
| I perform the same household and family duties | 5 | 3 | 2 | 3 | 3 | 2 |

Never (1), Seldom (2), Occasionally (3), Frequently (4) and Always (5)

## Quality of life

The impact a stoma has on quality of life (QOL), either permanent or temporary, is considerable. A systematic review assessed the results of 14 studies on quality of life in colorectal cancer stoma patients. Despite variation in methodology, all studies demonstrated that living with a stoma influenced the overall QOL negatively. Painful or irritated peristomal skin, odour and noise from the appliance were the most commonly reported ostomy-related difficulties [7]. The Stoma Quality of Life Scale (SQOLS) is a tool that contains 21 items in 3 domains (work/social function, sexuality/body image, stoma function). It has been validated in cancer and non-cancer populations and in both ileostomy and colostomy groups.

## Self-management

Empowering patients to self-manage can reduce complications in stoma patients. In a single-centre pilot study, ward staff, community clinicians and patients were educated to be aware of the importance of stoma self-management. Emphasis was placed on the importance of hydration and fluid balance. Readmission rates were reduced from 14.9 to 2.4% as a result [8]. In another example, a patient-centred self-care checklist introduced in the postoperative period for patients with ileostomy reduced readmission rates from 28 to 20% [9]. A study at the University of East Anglia revealed that mastering stoma management was key in rebuilding social confidence after stoma surgery [1]. It is important to note that the mean time to develop early HOS postoperatively was 8 days, stressing the importance of patient education and self-management given the general drive towards enhanced recovery and earlier discharge of patients in the current healthcare economy.

## Use of medical devices to enhance patient care

The Institute of Medicine in the USA (2001) recognises patient-centred care as one of six major domains of healthcare quality and defines it as "care that is respectful of and responsive to individual patient preferences, needs, and values", ensuring that patient values guide all clinical decisions. Health information technology is expected to enhance patient safety, improve communication between patients and providers, and contribute to better patient care. This in turn is expected to lead to cost efficiencies in healthcare. It is not yet known whether a wireless sensor, tethered to a patient's smartphone and able to report data to the patient's care team, could enhance patient-centred care and lead to improved outcomes.

With Ostom- I™ data are transmitted from the patient's device to a smartphone or tablet via Low-Energy Bluetooth where it is received and processed by the companion 'Alfred' application (11 Health and Technologies Ltd. 2018). Encrypted data are then sent over secure socket layer to a Health Insurance Portability Act (HIPAA)-compliant secure cloud server and is accessible only to authorised users. The HIPAA sets standards for healthcare data security and provides assurance against the risk of unintentional or malicious

access or compromise by any third party. Each device lasts about 3–4 months based on average use, and then patients would be expected to purchase another one. The cost of the device is approximately $100 per device.

Every new technology has to have a value proposition. Ostom- I™ can deliver value from both an economic perspective and a patient satisfaction with cost saving against current methods of treatment up to 33%.

## Conclusions

Ostom-I ™Alert Sensor is a discretely connected medical device alerting patients in real time when their stoma bag is at a point where it should be emptied, helping to prevent any unpleasant surprises. It is a safe and effective tool in monitoring of stoma patients postoperatively in the hospital resulting in reduced hospital stay and allowing nursing staff to attend more patients. It can remotely monitor patients in the community with real-time data access by the clinicians. Technological and hospital environment limitations must be further addressed for wide-scale adoption into clinical practice.

**Acknowledgements** Thanks are due to NIHR Imperial Biomedical Research Centre, Innovation and Impact department of CW + Charity of Chelsea and Westminster NHS Foundation Trust.

**Funding** 11-Health company.

### Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

**Ethical approval** The research was carried out with the ethical standards of the institutional research and ethics committee (London—Fulham Research Ethics Committee) and with the 1964 Helsinki declaration and its later amendments.

**Informed consent** Informed consent was obtained from all individual participants.



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