



Colon Myoelectric Activity Measured After Open Abdominal Surgery with a Noninvasive Wireless Patch System Predicts Time to First Flatus

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Abstract

Background Passage of flatus after abdominal surgery signals resolution of physiological postoperative ileus (POI) and often, particularly after complex open surgeries, serves as the trigger to initiate oral feeding. To date, there is no objective tool that can predict time to flatus allowing for timely feeding and optimizing recovery. In an open, prospective study, we examine the use of a noninvasive wireless patch system that measures electrical activity from gastrointestinal smooth muscles in predicting time to first flatus.

Methods Eighteen patients who underwent open abdominal surgery at El Camino Hospital, Mountain View, CA, were consented and studied. Immediately following surgery, wireless patches were placed on the patients' anterior abdomen. Colonic frequency peaks in the spectra were identified in select time intervals and the area under the curve of each peak times its duration was summed to calculate cumulative myoelectrical activity.

Results Patients with early flatus had stronger early colonic activity than patients with late flatus. At 36 h post-surgery, a linear fit of time to flatus vs cumulative colonic myoelectrical activity predicted first flatus as much as 5 days (± 22 h) before occurrence.

Conclusions In this open, prospective pilot study, noninvasive measurement of colon activity after open abdominal surgery was feasible and predictive of time to first flatus. Interventions such as feeding can potentially be optimized based on this prediction, potentially improving outcomes, decreasing length of stay, and lowering costs.

Keywords Noninvasive wireless patch · Postoperative recovery · Colon myoelectrical activity · First flatus · Ileus · Open abdominal surgery

Introduction

Gastrointestinal recovery after any visceral surgery is a complex dynamic process with multiple factors ranging from

complexity of the surgery, degree of bowel handling, and pre-operative comorbidities affecting whether the recovery happens over few days, or is a slow prolonged affair lasting weeks.¹ Delays in the gastrointestinal recovery process or ileus are accompanied by distention of the abdomen, pain, nausea, vomiting, and the inability to tolerate oral feeding.^{2,3} Interventions to alleviate the ileus/distention include insertion or reinsertion of a nasogastric tube, instating nil per os and, if necessitated, parenteral nutrition.⁴ All of these factors contribute not only to patient discomfort, but extend length of stay (LOS), increase hospital resource utilization, and thereby add to overall costs.^{5–7}

Clinically, the markers of gastrointestinal recovery are noted by passage of flatus, defecation, and the ability to tolerate solid food without significant nausea and vomiting.⁸ Passage of stool or flatus—considered a surrogate for intestinal and anastomotic continuity—is often used as the trigger to start stepwise dietary orders with the patient's ability to tolerate each step marking their readiness for the subsequent meal. Fast-track programs

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that promote early feeding in advance of these clinical markers have shown some success in reducing the incidence of ileus, but not entirely. In a recent study of 513 consecutive colorectal patients who were on an enhanced recovery after surgery (ERAS) protocol, 128 patients (24.7%) needed postoperative reinsertion of nasogastric tube at the 3.9 ± 2.9 postoperative day.⁹ This suggests that, while early postoperative feeding is beneficial to patients in whom recovery is on track, it does not work in cases where they are not ready for it.

At present, there is no reliable measurement that can predict gastrointestinal recovery/diet readiness for patients in advance of these clinical markers that may allow for interventions or fast-track programs to facilitate timely recovery. Auscultation for return of bowel sounds, long part of the standard of care, is controversial in its usefulness to indicate recovery. Bowel sounds have shown to have poor correlation with flatus/defecation and have proved unsuccessful in guiding diet interventions.^{10,11} Some authors have recently argued for discontinuation of the practice.¹²

Smooth muscle electrical activity on the other hand is directly related to gastrointestinal function and motility. Researchers have previously shown a 1:1 correlation between electrical and mechanical (contractile) events in the colon with internally placed electrode-strain gauge force transducers.^{13–15} Electrical activity in the colon has been reported across a wide range of frequencies, ranging from 0 to 40 cycles per min (cpm).^{16,17} Researchers have documented the progressive return of colonic electrical activity within these frequencies related to resolution of postoperative ileus and clinical recovery following surgery.^{16–18} These measurements have been performed using electrodes placed internally during surgery, a major impediment towards broader use of such technology.

To overcome this limitation, we have developed a noninvasive wireless patch system that measures electrical activity from the gastrointestinal smooth muscles on the abdominal surface. We have previously reported on the co-occurrence of colon frequency peaks in the 12–28 cpm range in the electrical activity with that of pressure recordings measured internally in the colon via the SmartPill across a multitude of subjects.¹⁹ Herein, we examine the feasibility and usefulness of this measurement from the noninvasive wireless patch system in determining gastrointestinal recovery following open abdominal surgery.

Methods

Patients and Clinical Parameters

Nineteen patients who underwent open abdominal surgeries at a community hospital were consented and enrolled in this trial between March 2016 and May 2017. The study was approved by the Institutional Review Board of El Camino Hospital,

Mountain View, CA. Patients were asked to self-report passage of flatus, bowel movement, and intake of diet through a smartphone app. In cases where the patients were not smartphone savvy, information was logged for them through daily rounds by the study coordinator.

Wireless Patch

Immediately following surgery, three disposable wearable wireless patches (G-Tech Medical, Fogarty Institute for Innovation, Mountain View, CA) that acquire myoelectrical signals from the gastrointestinal tract were placed on the anterior abdomen. Prior to patch application, the skin was prepared using isopropyl alcohol and NuPrep gel (Weaver and Company, Aurora, CO, USA) to optimize the conductivity from skin to electrode and minimize variability between patients. The variation in body size and tissue thickness between patients was addressed by a compensation factor which uses their body mass index and a patent-pending compensation algorithm that uses certain aspects of the acquired data itself to arrive at the correction.

The G-Tech 6-day wearable patch (Fig. 1a) consists of a flexible substrate material approximately 2.7" diameter which is made up of Ag/AgCl electrodes, a medical grade adhesive, and electronics, to acquire, digitize, and transmit myoelectrical data via Bluetooth Low Energy (BLE) to a paired iPod Touch App. The patch includes a 3-V CR2354 battery to power its electronics. These patches have a runtime of 6 days and were replaced as needed until the patients' discharge. The custom app has a patient interface to enter clinical information, such as overall mobility, diet status, pain control, nausea or emesis, and the return of bowel function. The application periodically uploads the raw data to a cloud server to be downloaded and analyzed (Fig. 1b). The G-Tech system is currently investigational.

Processing of Myoelectrical Activity Data and Cohort Analysis

Figure 2a shows an example of the raw data containing a burst of rhythmic colonic myoelectrical activity with the corresponding frequency spectrum in Fig. 2b showing the peak for the rhythmic activity at ~20 cpm. Data processing was performed in a custom LabVIEW version 14.0.1 program and included removal of large amplitude artifacts and band-pass filtering, followed by Fourier transformation to frequency space over 10-min time intervals. Peaks in the frequency spectrum were identified in the 12–28 cpm range within each 10-min interval and the area under the curve (AUC) was calculated. Cumulative colonic myoelectrical activity was then calculated by summing over each 10-min interval the respective AUC multiplied by its duration. One unit of colonic myoelectrical activity represented in this paper in ADC (analog to

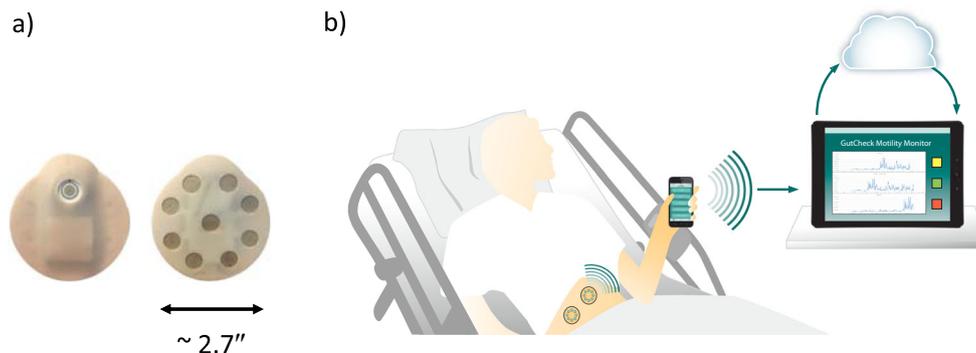


Fig. 1 The G-Tech system consists of **a** wireless patches with onboard electronics that acquire electrical activity from gastrointestinal smooth muscles and transmit it via Bluetooth LE; and **b** a custom G-Tech app

on an iPod with a user interface to enter clinical events and acquire data from the patches. The app periodically uploads the data to a cloud server for data processing and analysis

digital conversion) counts is equivalent to $3.6e-7 \text{ mV}^2$. Cohort analysis was performed in a custom program developed in Python version 3.5.2 and R version 3.3.1.

were passing flatus and tolerating regular diet without nausea and vomiting and were discharged.

Results

Study Cohort and Clinical Outcomes

Eighteen patients were considered for the final analysis; one patient withdrew from the study. Patches were well tolerated by all patients, with no adverse events noted. The clinical characteristics of the cohort are shown in Table 1. Flatus occurred in all cases with an average time to first flatus of 4.34 days (± 1.5 days). Bowel movement was closely linked with the first flatus occurring—together or within hours of it—in 9/18 (50%) of the cases. The average time to first bowel movement was 5.57 days (± 2.9 days). In two cases, a bowel movement never occurred during their stay but the patients

Postoperative Orders and Clinical Measurements

All 18 patients had postoperative dietary orders of nil per os (NPO) until return of bowel function. Six of the 18 cases were nutritionally supported with total parenteral nutrition (TPN) in addition to jejunal feeding in one case following a Whipple procedure. A nasogastric tube was used in 15 of the 18 cases through postoperative day 2 at the minimum. Clear liquids were started after affirmation of passage of flatus or bowel movement, followed by full liquids and regular diet. Figure 3a shows the close relation of time to bowel movements vs time to regular diet. Similarly, regular diet was tied closely to the length of stay as shown in Fig. 3b. Operating time and blood loss during the surgery did not have an impact on time to flatus or length of stay.

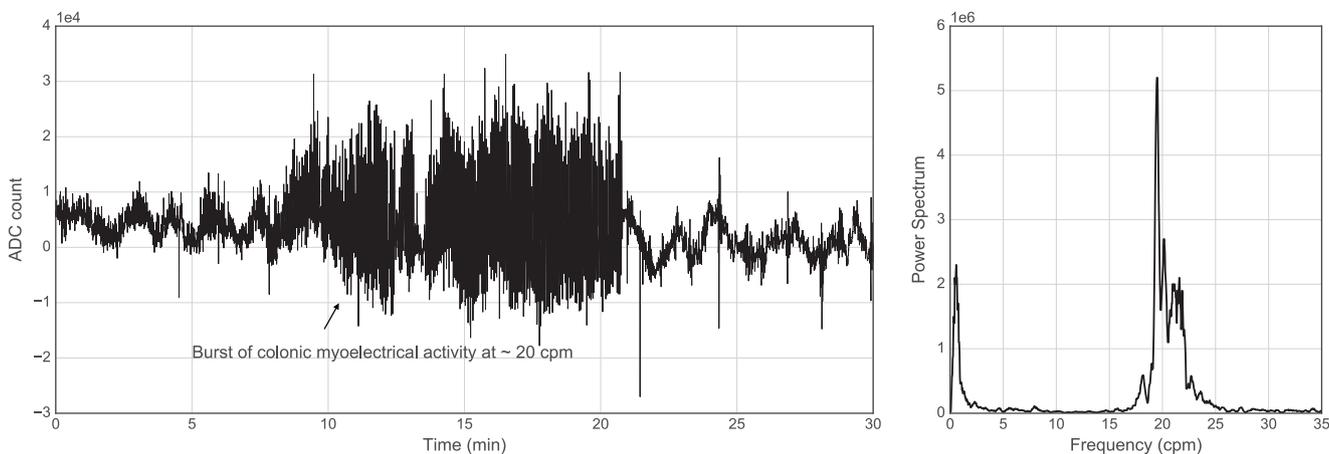


Fig. 2 **a** Raw data showing burst of rhythmic ~ 20 cpm colonic myoelectrical activity. **b** Frequency spectrum computed over the raw data demonstrating the ~ 20 cpm peak

Table 1 Patient characteristics

Subject (age, sex)	Procedure	Diagnosis	Days to first flatus	Days to first bowel movement	Days to regular diet	Days to discharge
64 M	Distal pancreatectomy	Cystic neoplasm of the pancreatic body	4.5	5.5	5.7	6
70 M	Distal pancreatectomy and splenectomy	Pancreatic cancer—tail of pancreas, renal metastases	4.4	4.4	6.1	7
33 M	Distal pancreatectomy, splenectomy and mobilization of splenic flexure	Pancreatic cancer—mid body of pancreas	5.5	9.2	12.3	13
73 F	Whipple procedure	Pancreatic cancer—head of pancreas adenocarcinoma	3.8	12.4	15.4	16
69 M	Whipple procedure (pylorus preserving)	Cancer of the ampulla of Vater	4.5	—	9.3	10
74 M	Whipple procedure and feeding jejunostomy tube	Pancreatic cancer—head of pancreas adenocarcinoma and cholestasis secondary to obstructive jaundice	4.7	5.9	—	32
83 F	Greater than 3-segment partial hepatectomy, left lobe of the liver, hepatocellular carcinoma	Hepatocellular carcinoma	4.3	4.3	5.4	7
60 F	Exploratory laparotomy with lysis of adhesions, reconstruction of anterior abdominal wall, ventral hernia repair of Strattice biologic mesh, component separation repair and excision of hypertrophic scar	Incisional hernia, acquired deformity of anterior abdominal wall	2.7	—	3.1	5
70 F	Reversal of colectomy, partial colectomy, lysis of adhesions, and takedown of splenic flexure	Obstructive perforated colon cancer, partial colectomy, end colectomy	8.7	9.9	10	10
82 F	Hartman’s end colectomy procedure reversal, partial colectomy with colorectal anastomosis (handsewn 2 layers)	Perforated sigmoid colon diverticulitis, Hartmann’s procedure	4.8	6.1	6.1	6.2
48 M	Low anterior resection, Hartman’s end colectomy procedure reversal with EEA (end to end) colorectal anastomosis and lysis of adhesions	Perforated sigmoid colon diverticulitis, Hartmann’s procedure	3.5	3.6	4.8	5
72 M	Low anterior resection with EEA anastomosis (32-French EEA)	Rectal cancer	2.8	2.9	4.5	6
91 M	Right colectomy	Colon cancer	4.5	4.5	6.4	23
33 M	Ileocectomy, and debridement and drainage of abdominal wall abscess	Crohn’s disease	3.2	3.2	4.9	6
52 F	Right hemicolectomy	Cecal cancer	4.2	4.2	8.7	9
84 M	Sigmoid colectomy	Sigmoid volvulus	2.2	2.2	5.1	7
61 M	Sigmoid colectomy	Recurrent sigmoid colon diverticulitis	3.5	3.5	4.9	5
68 M	Left colectomy with primary anastomosis and mobilization of splenic flexure, resection of the left lateral segment of liver tumor and resection of dome of liver tumor	Colon cancer with liver metastasis	6.3	7.2	10.9	11

Myoelectrical Measurements

Peaks in the 12 to 28 cpm range were consistently observed in all 18 patients compared to the other frequency regions of colon activity and were chosen for analysis. Colonic frequency activity plots, for a patient with later than average flatus and for a patient with earlier than average flatus, are shown in Fig. 4, with the earlier flatus patient demonstrating strong

peaks early in the recovery process, compared to the patient with later flatus.

Time to First Flatus vs Cumulative Colon Activity

Cumulative colonic activity over the initial 36-h period following surgery had a high correlation with time to flatus. The 36-h time period was found to be optimal for such correlation

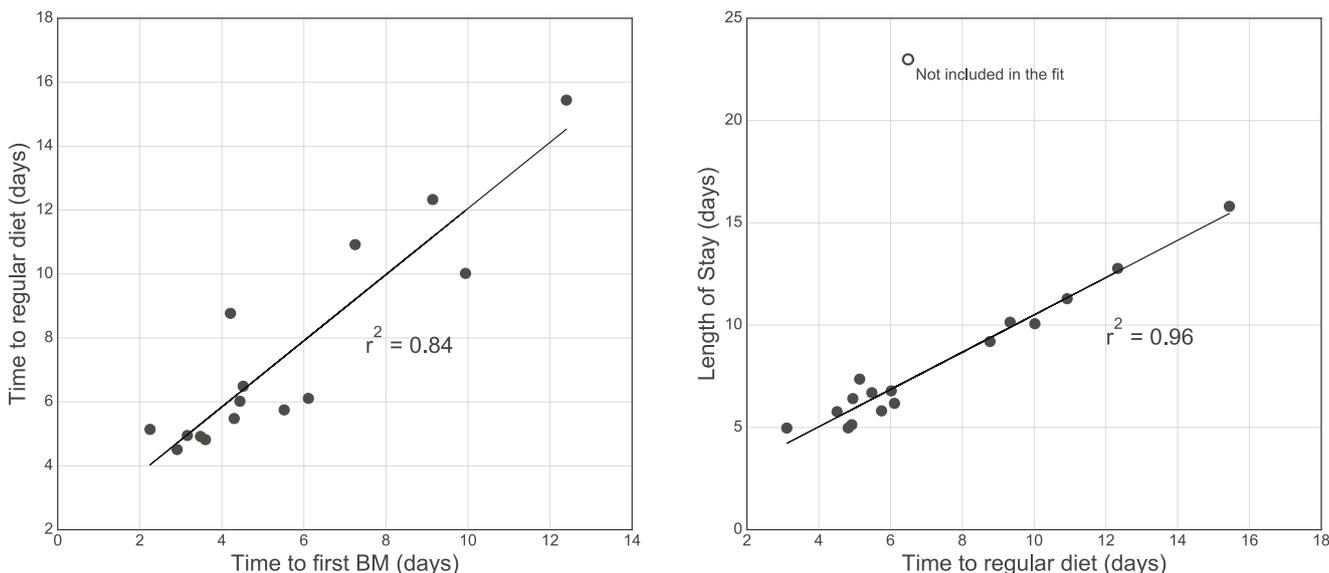


Fig. 3 **a** Scatter plot of time to regular diet and time to first bowel movement shows a linear relationship. **b** Scatter plot of time to regular diet and length of stay was also closely linked

as shown in Fig. 5. A linear least square fit between time to first flatus and cumulative colonic myoelectrical activity at 36 h (CA_{36}) was calculated. Patients’ predicted time to first flatus is equal to $-1.32E-12 \times CA_{36} + 7.35$. The standard deviation in the prediction errors as calculated by the root mean square error (RMSE) for the residuals was 21.7 h.

Time to First Bowel Movement vs Cumulative Colon Activity

Similar to time to flatus, an inverse linear relationship was observed between cumulative colonic myoelectrical activity at 36 h and time to first bowel movement as shown in

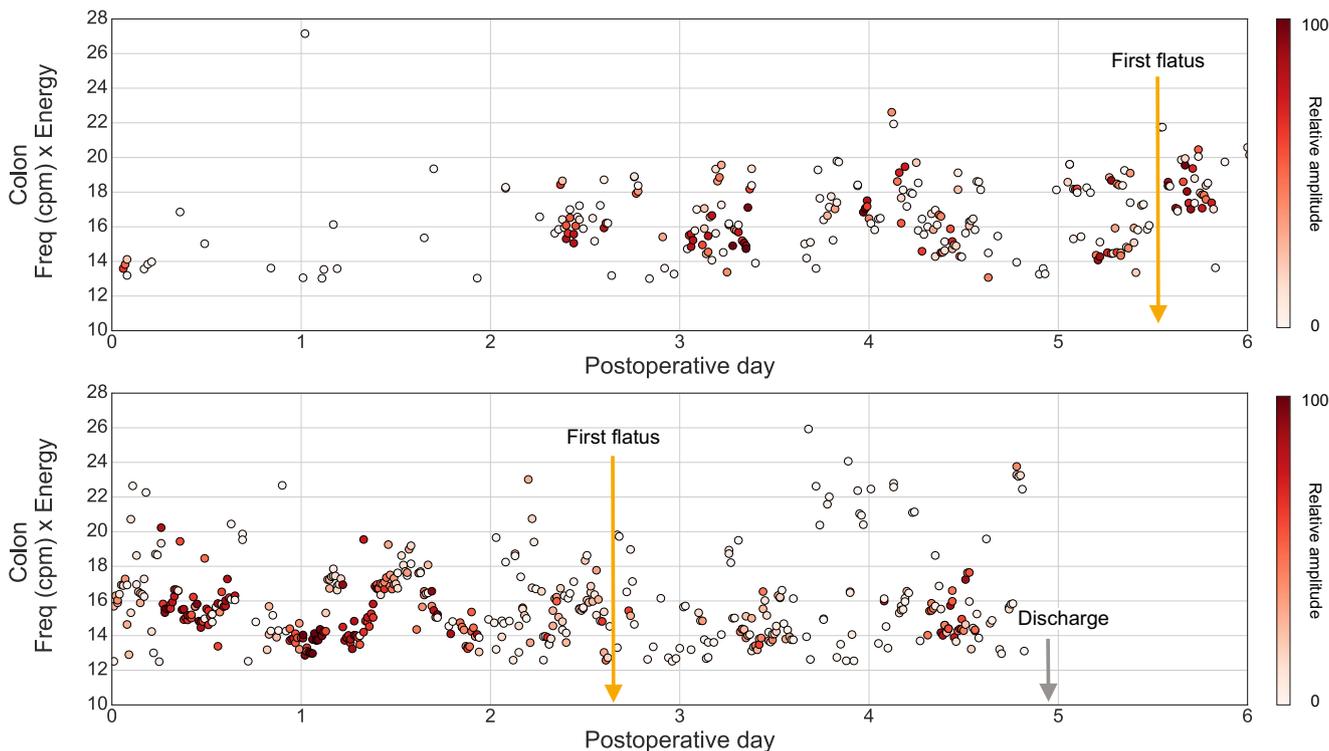


Fig. 4 Colon frequency peak plots for the first 6 days of a representative patient with later than average first flatus and a representative patient with earlier than average first flatus. The patient with the earlier first flatus demonstrates strong peaks early in the recovery process, within the first

2 days post-surgery, compared to the patient with the later first flatus for whom onset of activity occurs largely beyond postoperative day 2. The color gradient represents amplitude of the observed peaks, with the darker color reflecting a stronger peak and the lighter color a weaker peak

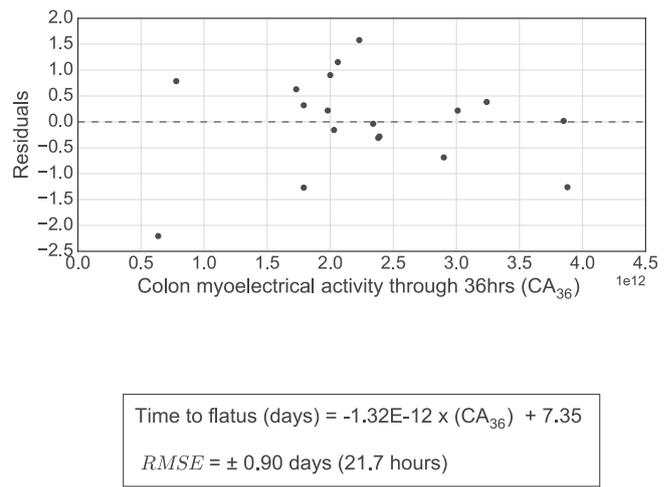
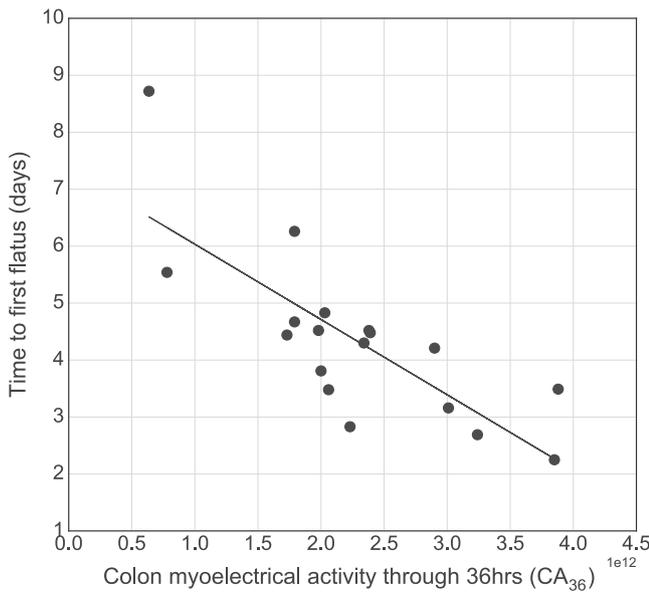


Fig. 5 **a** Scatter plot of time to first flatus vs cumulative colon myoelectrical activity at 36 h shows an inverse linear relationship; a least squares fit was calculated and the residuals for the fit between the predicted and actual values are shown in **b**

Fig. 6. A linear least squares fit was calculated. Patients’ time to first bowel movement is equal to $-1.98E-12 \times CA_{36} + 9.53$. The standard deviation in the prediction errors with the RMSE of the residuals was 29.8 h. For the fit, one individual who had their first flatus on postoperative day 3.8 but did not have their first bowel movement until day 12.4 (shown as a hollow circle) was not included. Their predicted time to first bowel movement would have been 5.7 days. The patient during this period developed an intra-abdominal infection which may explain their slow progress.

Discussion

This pilot prospective, open clinical trial suggests that colonic myoelectrical activity, measured on the abdominal surface with a noninvasive wireless patch system, carries predictive value in determining time to flatus and time to bowel movement following open abdominal surgery. Having such information in advance of clinical measures could facilitate timely interventions, be it early feeding or delaying feeding as dictated by the patient’s unique recovery profile.

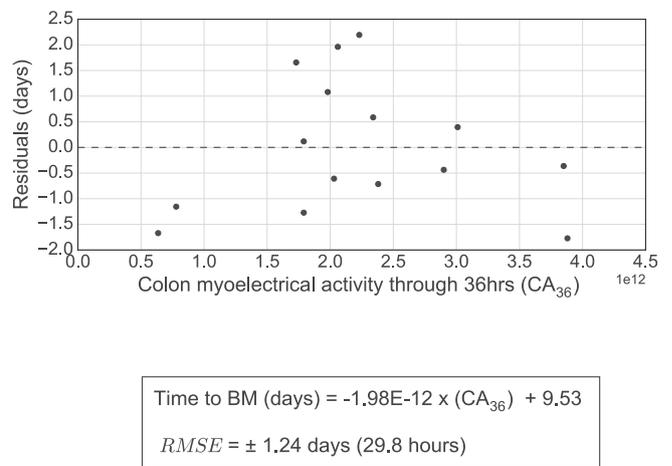
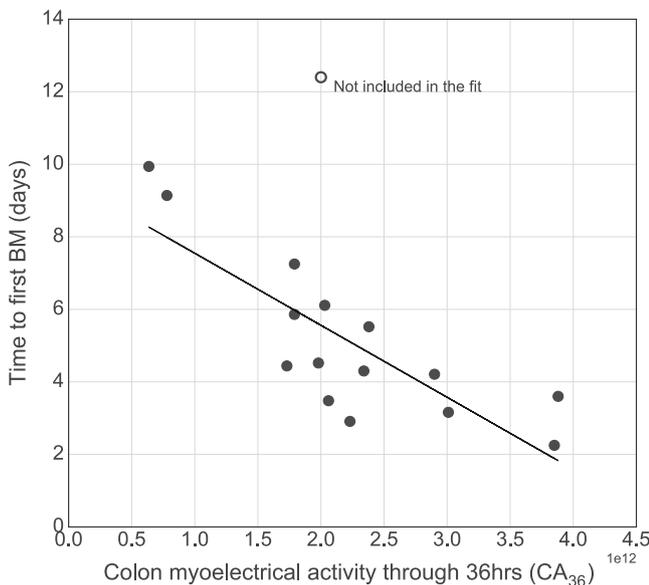


Fig. 6 **a** Scatter plot of time to first bowel movement vs cumulative colon myoelectrical activity at 36 h shows an inverse linear relationship; a least squares fit was calculated and the residuals for the fit between the

predicted and actual values are shown in **b**. For the fit, one individual who had their first bowel movement on postoperative day 12.4 was not included

ERAS protocols which promote early feeding, along with opioid sparing techniques and use of minimally invasive procedures, have been shown to be safe and beneficial for many patients by demonstrating earlier recovery and shorter length of stay.^{9,20,21} However, it has also been shown that, for as many as 25% of cases, the strategy does not work as noted earlier, with the need of reinsertion of the nasogastric tube and reinstating nil per os status. These findings are similar to our own findings where a third of the patients under the ERAS protocol following a Whipple procedure did not tolerate the early feeding (Am J Physiol. In press). The patch system would provide a unique insight into the process allowing for a tailored protocol that could improve patient satisfaction and optimize recovery. The system could also enable feedback on the impact to the colonic myoelectrical activity of medications, particularly opioids, used for pain management that are known to inhibit gastrointestinal function by disrupting the normal recovery patterns of colonic motility.^{22–24}

While it remains to be seen, in addition to predicting time to flatus/bowel movement early on, the ability to continue monitoring the patient may allow one to predict onset of secondary complications, such as wound infections or anastomotic leaks, that are associated with ileus. Similarly, given the wireless noninvasive nature of the system, the patients could be discharged home with the patches, whereby they would serve as a remote monitoring tool. This could be particularly useful in cases where the patients may have been discharged early and may be at a high risk for readmission. The system would then send updates/alerts to the care team for management and potentially avoid preventable readmissions.

Colon myoelectrical activity, as compared to the stomach and the small intestine, is complex, occurring over a wide range of frequencies while an individual segment can oscillate at multiple frequencies.^{25–28} In terms of range of frequencies, Sarna et al., having placed internal electrodes in 15 patients undergoing cholecystectomy, have observed frequencies in the 2–40 cpm range, grouping them in low (2–9 cpm), mid (9–13 cpm), and high (25–40 cpm) ranges.¹⁶ In contrast, Stoddard et al. with serosal electrodes in the ascending and transverse colon of 20 patients only observed frequencies in the 2–4 cpm and 6–12 cpm ranges.²⁹ One of the major limitations of both of these studies and others during that time was that these recordings were done 1 to 2 h per day, thus missing activities that may occur through the day intermittently. A good example of such activity is the contractile electrical complex (CEC) seen in the higher frequency ranges.¹⁶ The CEC, also known as the colonic migrating motor complex (CMMC) in the animal model, is the physiological equivalent of the high amplitude propagating contraction (HAPC) seen in manometry studies and is responsible for mass movement of fecal matter,²⁷ that occur only few times a day.³⁰

Testing over 200 individuals using the patch system over multiple days (unpublished data), we have noted that most individuals exhibit well-defined frequencies in the 12–28 cpm range and that Sarna's low and mid-range frequencies are observed less

frequently. The 12–28 peaks also tend to follow the pattern of intermittent behavior, typical of the colon. Performing colon muscle strip recordings, Huzinga et al. noted that, at frequencies above 12 cpm, contractions were likely to be prolonged and of higher amplitude, with increased superimposed spiking activity.³¹ The 12–28 cpm range is also distinctive from that of the small intestine which is known to have frequencies in the mid-range (6–12 cpm), although some researchers have argued for the range to be 8–12 cpm with the 8 cpm representing the lower limit for the ileum.^{11,32,33} Using serosal electrodes, Chen et al. observed frequencies centered around 12 cpm for the duodenum and between 9 and 11 cpm for the jejunum.³⁴ At the low range of frequencies, most often the well-characterized ~3 cpm signal from the stomach is observed.³⁵ In a recent study where we monitored gastric activity using the patch system following pancreaticoduodenectomy (Am J Physiol. In press), cumulative gastric activity—calculated from peaks in the ~3 cpm range—could distinguish patients with shorter and longer times to oral diet. On the whole, it is possible that some peaks in the frequency ranges below 12 cpm belong to the colon and were subsequently missed with the current assignment; however, as we have shown here, the activity in the 12–28 cpm range was sufficiently predictive of recovery and time to flatus following surgery.

Our study has several strengths and limitations. Prospective in nature, it was performed in an everyday community practice setting in a moderate number of patients undergoing open abdominal surgery, and in this respect, its findings could be reflective of general surgical practice. The safety and easy applicability of the patch system were attractive to patients and clinicians alike, while its analyses were robust and reproducible. Obvious limitations include the lack of prospective evidence on feeding and other clinical decision-making based on the patch data as well as the validation that this approach can reduce perioperative length of stay and hospital costs. Nevertheless, our preliminary data is quite promising and could be used to guide clinical decision-making in a larger, prospective multicenter clinical trial, where the use and degree of postoperative analgesia and rate and range of complications and other parameters contributing to ileus could be better assessed and correlated.

In conclusion, in an open, prospective pilot study, noninvasive measurement of colonic myoelectrical activity after abdominal surgery can predict time to first flatus and first bowel movement. We believe that this technology objectively identifies patients that may be at risk for developing postoperative ileus and can guide timing of oral intake by “readiness,” thereby potentially shortening the LOS and decreasing costs.

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Author Contributions Study design: AN, SA, SS, GT
 Acquisition of data: AN, SA, LA, SS, KT, PL
 Analysis and interpretation: AN, SA, LA, SS, KT, PL, GT
 Manuscript draft: AN, SA, KT, GT
 Critical review and revision: AN, SA, SS, KT, GT

Compliance with Ethical Standards

Conflict of interest Authors SA, LA, and AN are employees of G-Tech Medical. Author GT is an advisor to G-Tech Medical. Patches for this study were supplied by G-Tech Medical.

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