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2015 SSAT PLENARY PRESENTATION

Postoperative Gastrointestinal Telemetry with an Acoustic Biosensor Predicts Ileus vs. Uneventful GI Recovery

Marc Kaneshiro[1,3,4] · William Kaiser[2] · Jonathan Pourmorady[1,3] · Phillip Fleshner[1] · Marcia Russell[3] · Karen Zaghiyan[1] · Anne Lin[4] · Bibiana Martinez[5] · Anish Patel[1,3] · Amy Nguyen[4] · Digvijay Singh[2] · Vincent Zegarski[2] · Mark Reid[5] · Francis Dailey[1,3] · Jason Xu[1,3] · Karen Robbins[1,3] · Brennan Spiegel[1,3,5,6]

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Abstract

Background Postoperative ileus (POI) can worsen outcomes, increase cost, and prolong hospitalization. We previously found that a disposable, non-invasive acoustic gastrointestinal surveillance (AGIS) biosensor distinguishes healthy controls from patients recovering from abdominal surgery. Here, we tested whether AGIS can prospectively predict which patients will develop POI in a multicenter study.

Study Design AGIS is a disposable device embedded with a microphone that adheres to the abdominal wall and connects to a computer that measures acoustic intestinal rate (IR), defined as motility events/minute. We applied AGIS for 60 min before and continuously after abdominal surgery. Clinicians blinded to AGIS recordings clinically separated patients into those with vs. without POI. We used receiver operating characteristic curve analysis to calculate sensitivity, specificity, and negative predictive value (NPV) of AGIS to predict POI.

Results There were 28 subjects; nine developed POI. Median IR was 3.01/min and 4.46/min between POI and non-POI groups, respectively (P=0.03). AGIS predicted POI onset with a sensitivity, specificity, and NPV of 63, 72, and 81 %, respectively.

Conclusion Non-invasive, abdominal, acoustic monitoring prospectively predicts POI. Surgeons may use AGIS to rule out POI with over 80 % certainty; this offers added confidence to advance feeding earlier in those for whom it is safe.

Presentations This study was presented in the SSAT Distinguished Abstract Plenary session of the 2015 Digestive Disease Week (DDW) in Washington, DC. It has not been presented or submitted for publication elsewhere.

✉ Brennan Spiegel
brennan.spiegel@cshs.org

1 Departments of Medicine and Surgery, Cedars-Sinai Medical Center, Los Angeles, CA, USA

2 Henry Samueli School of Engineering and Applied Science at UCLA, Los Angeles, CA, USA

3 Departments of Medicine and Surgery, West Los Angeles VA Medical Center, Los Angeles, CA, USA

4 Departments of Medicine and Surgery, David Geffen School of Medicine at UCLA, Los Angeles, CA, USA

5 Cedars-Sinai Center for Outcomes Research and Education (CS-CORE), Los Angeles, CA, USA

6 Department of Medicine, Divisions of Health Services Research and Gastroenterology, Cedars-Sinai Medical Center, 116 N. Robertson Blvd, 4th Floor, Los Angeles, CA 90048, USA

Keywords Postoperative ileus · Biosensor · Health technology

Introduction

Postoperative ileus remains a prevalent and expensive condition following abdominal surgery.[1–3] When prolonged or complicated, postoperative ileus (POI) can worsen patient outcomes, increase cost of care, and lengthen the hospital stay.[4,5] Delayed oral feeding can lead to poor wound healing, increased rate of infection, or need for parenteral nutrition.[1] Because of the high prevalence and impact of POI, the condition costs over $1.75 billion annually in the USA.[4,5]

Use of enhanced recovery after surgery (ERAS) protocols has led to measurable improvements in outcomes following abdominal surgery.[6–9] Although ERAS protocols are generally safe and reduce length of stay, up to 25 % of patients cannot tolerate feeding and require nasogastric tube decompression or bowel rest.[10–14] If there were an objective marker that could

predict—as early as possible—which patients are developing POI vs. those who will uneventfully recover GI function, it could help surgeons and nurses expedite feeding in patients ready to eat, yet delay feeding in those likely to experience further complications.

We previously developed and tested a disposable, non-invasive, acoustic gastrointestinal surveillance (AGIS) biosensor that provides an objective, real-time marker of postoperative intestinal motility. The AGIS sensor allows continuous and automated analysis of bowel sounds across the acoustic spectrum—including hertz ranges below the threshold detected by the human ear. Our previous work found that AGIS monitoring distinguishes healthy controls from patients recovering from abdominal surgery who are tolerating standardized feeding as well as from patients with POI.[15] In the current study, we prospectively monitored intestinal motility with AGIS biosensors in a cohort recovering from abdominal surgery and hypothesized that AGIS could predict which patients were developing POI vs. uneventful GI recovery. This is an interim report of our first 28 subjects as presented in the 2015 Digestive Disease Week (DDW) meeting; the full study of $N=100$ subjects is currently being completed per ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT02065583

Materials and Methods

Study Overview

We performed a blinded, prospective, longitudinal cohort study to measure AGIS-derived intestinal motility rates in patients recovering from colorectal surgery. We hypothesized that AGIS could use computer-analyzed bowel sounds to accurately separate patients with POI vs. uneventful GI recovery at an early postoperative stage. We developed an automated prediction rule that informs surgeons and nurses about the probability of a patient developing POI. In the sections that follow, we describe the AGIS device and its engineering, the subjects enrolled in this trial, and the analyses employed to evaluate the predictive accuracy of AGIS in colorectal surgery.

Device Description

The AGIS system is a compact, rapidly deployable unit that is designed to be unobtrusive and convenient in application. The AGIS sensor, computer, and supporting software have been described in a previous study.[15] Briefly, the AGIS sensor includes a standard microelectronic microphone that measures abdominal vibration and acoustic signals. Figure 1 shows the AGIS sensor applied to the abdomen of a subject and also demonstrates the device with its Tegaderm™ adhesive. The sensor connects to a small bedside computer that calculates an "intestinal rate" (IR) defined as the number of acoustic motility events per minute.

Subjects and Study Procedures

We consecutively recruited inpatients undergoing colorectal surgery at Cedars-Sinai Medical Center (CSMC), the West Los Angeles Veteran Administration (WLAVA) Medical Center, and Ronald Reagan UCLA Medical Center. Four different colorectal surgeons performed the operations, including two at CSMC (P.F. and K.Z.), one at WLAVA (M.R.), and one at UCLA (A.L.). Patients were 18 years of age or older, able to provide informed consent, and recovering from colorectal surgery.

We obtained a 60-min baseline preoperative acoustic recording immediately before surgery on each subject. The surgeon then re-applied AGIS upon completion of the operation. AGIS recordings continued until discharge or until the patient opted to remove the sensors. All patients, health care providers, and members of the clinical research team were blinded to the results of AGIS monitoring. The data were stored and submitted to the electrical engineering team at UCLA who analyzed the recordings using specialized software to generate IR values in events/minute for each subject. Details about the software and IR scoring are available from previously published work.[15] The engineering team was blinded to all clinical data.

Members of the research team who were blinded to sensor results monitored and recorded clinical information, including age, gender, race, and body mass index (BMI). We also recorded the indications for surgery, types of surgery performed, surgical approach (e.g., laparoscopic vs. open), and any documented operative complications. We prospectively monitored daily clinical assessments, including symptoms (nausea, vomiting, and abdominal pain), flatus, bowel movements, diet, ambulation, medication use, and length of hospitalization. If abdominal imaging was performed at the discretion of the surgical team, then that information was also recorded in our clinical records.

We classified patients into those who developed POI during the postoperative course vs. those without POI who, by definition, experienced uneventful GI recovery. Although POI has many definitions in the literature, we applied a pragmatic definition of POI including the presence of one or more of the following: (1) postoperative nausea or vomiting that precluded advancement of diet or led to regression of diet, (2) symptoms that led to the need for nasogastric tube placement for decompression.

All patients received a standardized feeding protocol as part of usual care for each participating hospital. There were differences in the standard protocol among the participating hospitals. For UCLA and WLAVA, the protocol included ice

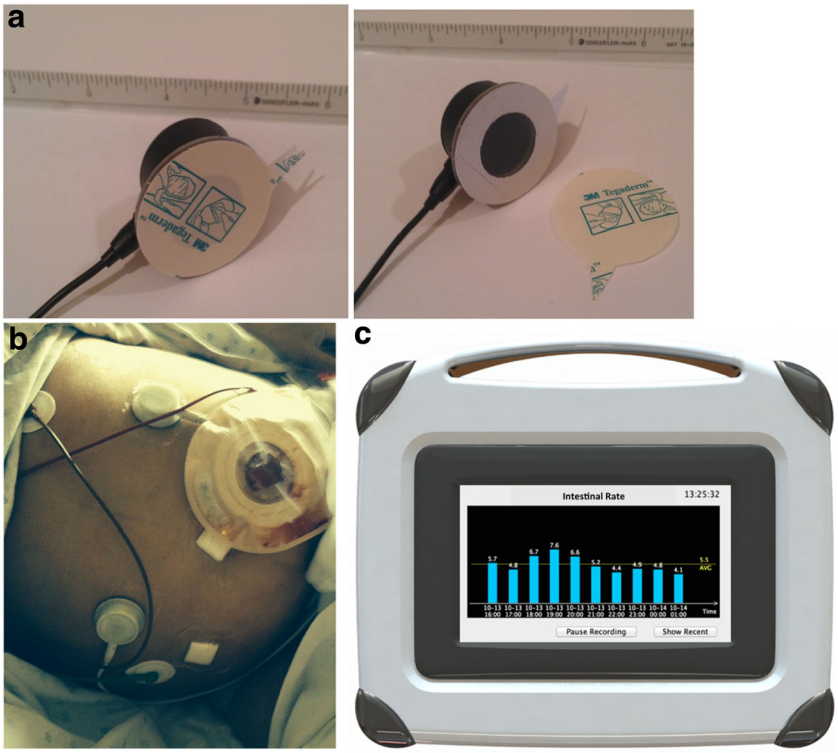

Fig. 1 Acoustic gastrointestinal surveillance (AGIS) system. **a** AGIS sensor with Tegaderm bandage. The *right image* in **a** shows the sensor ready for application, and the *left image* shows the sensor with adhesive exposed. **b** AGIS disposable sensors applied to abdominal wall of a postoperative patient. **c** Bedside computer depicting AGIS-derived intestinal rate, defined as intestinal acoustic events per minute (display not used during blinded study)

chips on postoperative day (POD) 0, sips of clear liquids on POD 1 (not to exceed 60 cc per hour), clear liquid diet on POD 2, and advancement to regular diet on POD 3. For CSMC, the standard protocol was more aggressive, with initiation of clear liquids on POD 0 and rapid progression to a regular diet by the morning POD 1 in patients without early clinical evidence of POI. Regardless of hospital, patients intolerant of the feeding protocol, including nausea or vomiting precluding advancement, or those that developed significant abdominal distension, fell off the feeding protocol. The surgical teams that made the decisions regarding diet changes were blinded to any recorded data.

Analysis

We compared the postoperative median AGIS IR values between POI and non-POI groups using the Wilcoxon rank sum test, as IR was non-normally distributed. We then examined each time segment, starting with preoperative IR, and then comparing median IR on POD 0 through POD 4. We sought the earliest point that IR diverged between POI vs. non-POI groups. Using receiver operator characteristic (ROC) curve analysis, we identified an algorithm that maximized predictive discrimination between POI vs. non-POI groups. We used the ROC-defined threshold to calculate the sensitivity, specificity, and negative predictive value (NPV) of AGIS in distinguishing between groups. We emphasized NPV because a high NPV could rule out POI; that is, achieving a high NPV could offer confidence to surgeons and nurses that POI is unlikely and diet advancement may be safe.

All analyses were conducted using Stata v10 (Stata Corp, College Station, TX). The CSMC, WLAVA, and UCLA Institutional Review Boards approved this study, which was conducted in accordance with the ethical standards of the Helsinki Declaration (Cedars IRB Pro00036771, VA IRB #PCC 2013-11143, UCLA IRB #13-000709).

Results

Participant Characteristics

We recruited 28 consecutive patients, of whom nine (32 %) developed POI during their postoperative course. Table 1 displays the patient characteristics. The types of surgeries performed were categorized into the following groups: small bowel surgery (36 %), partial colectomy (29 %), total colectomy (14 %), pelvic surgery (18 %), and other types (4 %) that did not fall into any of these categories. The indications for surgery were colorectal cancer/unresectable polyp (32 %), ileostomy (32 %), inflammatory bowel disease (IBD) (18 %), small bowel obstruction (7 %), diverticulitis (4 %), non-healing perineal wound (4 %), and chronic constipation (4 %). Table 1 provides further details regarding the study patients and their operations.

Table 1 Patient characteristics

Characteristic	Patients with POI (n=9)	Patients without POI (n=19)
Age, mean (SD)	53.4 (11.37)	44.68 (14.47)
Male gender, *N* (%)	5 (56 %)	10 (53 %)
Race, *N* (%)		
White	7 (78 %)	12 (63 %)
Black	1 (11 %)	3 (16 %)
Hispanic/other	1 (11 %)	4 (21 %)
BMI, mean (SD)	25.97 (6.34)	21.74 (4.0)
Type of surgery		
Small bowel surgery	2 (22 %)	8 (24 %)
Partial colectomy	3 (33 %)	5 (26 %)
Total colectomy	3 (33 %)	1 (5 %)
Pelvic surgery (APR, LAR, IPAA)	1 (11 %)	4 (21 %)
Other	0 (0 %)	1 (5 %)
Indication for surgery		
Colorectal cancer/unresectable polyp	3 (33 %)	6 (32 %)
Inflammatory bowel disease	2 (22 %)	3 (16 %)
Ileostomy	2 (22 %)	7 (37 %)
Diverticulitis	1 (11 %)	0 (0 %)
Small bowel obstruction	0 (0 %)	2 (11 %)
Non-healing perineal wound	0 (0 %)	1 (5 %)
Constipation	1 (10 %)	0 (0 %)
Open vs. laparoscopic		
Open	5 (56 %)	15 (79 %)
Laparoscopic	3 (33 %)	4 (21 %)
Laparoscopic hand-assisted	1 (11 %)	0 (0 %)
Ostomy created		
None	6 (67 %)	15 (79 %)
Ileostomy	2 (22 %)	2 (11 %)
Colostomy	1 (11 %)	2 (11 %)
Elective vs. urgent		
Elective	8 (89 %)	19 (100 %)
Urgent	1 (11 %)	0 (0 %)
Epidural anesthesia used		
No epidural used	3 (33 %)	10 (53 %)
Yes epidural used	1 (11 %)	2 (11 %)
TAP block used	5 (56 %)	7 (37 %)
Diet protocol		
Sips on POD 1	2 (22 %)	4 (21 %)
Regular on POD 1	7 (78 %)	15 (79 %)

APR abdominoperineal resection, *LAR* low anterior resection, *IPAA* ileal pouch anal anastomosis, *TAP* transverse abdominal plane

Comparisons of AGIS Intestinal Rates Between Groups

Figure 2 shows IR tracings for sample subjects with and without POI. Figure 3 shows the median IR by POD for the POI and non-POI groups. Over the entire postoperative course, the median IR in the POI group was significantly lower (3.0 events/min) than in the non-POI group (4.6 events/min) (P= 0.03); these results are consistent with previous work that AGIS-derived IR significantly distinguishes POI from non-POI.[15] Figure 3 reveals that the IR was not significantly different between groups on POD 0 and POD 1. However, between POD 1 and POD 2, there was a divergence in IR curves between groups. When examining the rate of IR change between POD 1 and POD 2, there was a significant difference

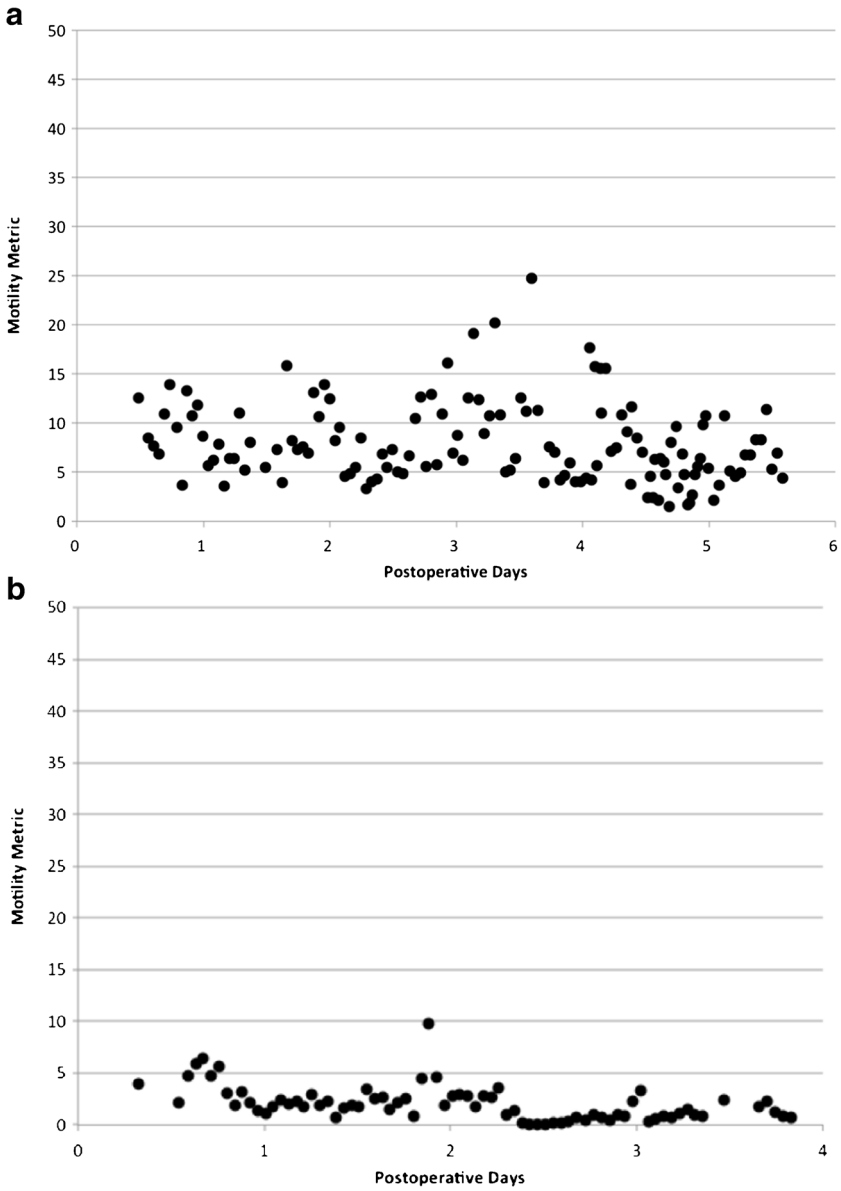

Fig. 2 Sample longitudinal AGIS motility tracings. **a** Example patient with excellent recovery of bowel function. The intestinal rate (IR) rarely falls below 1.5 for prolonged period and does not drop significantly between POD 1 and POD 2. **b** Example patient with severe postoperative ileus. This patient was fed according to protocol but was later found to have an anastomotic leak and intra-abdominal infection on POD 3

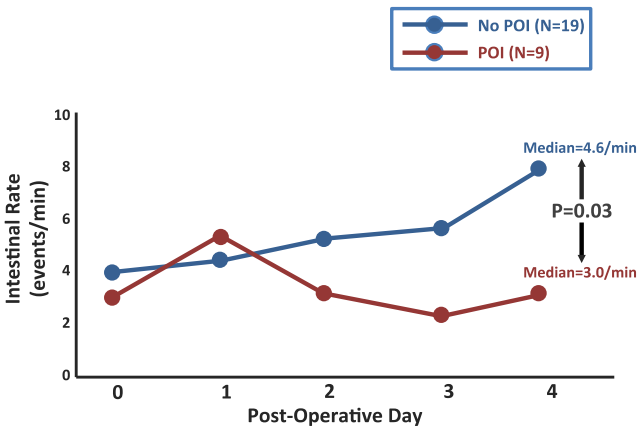

Fig. 3 Median intestinal rate (IR) by postoperative day: POI vs. non-POI groups. There was no significant difference in IR on POD 0 or POD 1, but the rates diverged between POD 1 and POD 2. The overall IR was significantly different between groups. See text for details

between POI and non-POI groups; whereas POI patients had a 32 % *drop* in IR between days, non-POI patients had a 15 % *increase* during the same time period (P=0.05), shown in Fig. 4.

As an additional metric to distinguish between POI vs. non-POI groups, we examined the percentage of time each subject had an IR below the fifth percentile—namely, below a floor of 1.5 events/min. Whereas patients with POI spent 40 % of their postoperative course below this threshold, patients without POI spent only 22 % of their time below 1.5 events/min (P= 0.007).

Receiver Operating Characteristic Curve Analysis

Because both the POD 1 vs. POD 2 IR change and the percentage of time spent below an IR of 1.5/min both

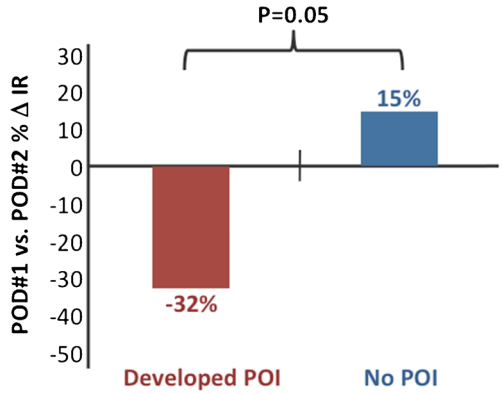

Fig. 4 IR change between POD 1 and POD 2 for the POI and non-POI groups. POI patients had a 32 % *drop* in IR between days, whereas non-POI patients had a 15 % *increase* during the same time period (P=0.05)

distinguished POI from non-POI, we entered both terms into a logit model to predict POI. The area under the resulting ROC curve was 0.83 (Fig. 5). Using an AGIS test threshold of 0.4 to define a "positive" test (that is, if AGIS predicts ≥40 % chance of POI, then consider test positive), the resulting sensitivity, specificity, and NPV were 63, 72, and 81 %. In other words, if the AGIS test is negative, then the surgeon could rule out POI with 81 % certainty using this sample of data.

Discussion

In this study, we report the initial results of prospectively monitoring bowel sounds in postoperative patients using a computer-aided, non-invasive AGIS biosensor. Similar to our previous cross-sectional analysis with AGIS,[15] here we found that longitudinally recorded IR measurements are significantly lower in patients who develop POI vs. patients tolerating a standardized feeding protocol.

Beyond distinguishing POI from non-POI groups, we found that AGIS could prospectively identify early warning signs of evolving POI. Specifically, the change in IR between POD 1 and POD 2 was a significant and early predictor of POI. This may be a useful and objective biomarker because it can be calculated and recognized early in the postoperative course, providing the opportunity for early intervention. In contrast, AGIS could not reliably distinguish between groups using data from POD 0 and POD 1; the IR appeared unreliable during these early stages of the postoperative course. This may not be important, because surgeons do not require a biosensor or other prediction model in patients already exhibiting POI in POD 0 or POD 1.

It is often difficult to know on POD 1 and POD 2 if a patient is already developing (or will soon develop) notable POI. This is a vulnerable period because hospital policies often prompt surgeons to advance the diet aggressively, even if it remains uncertain how the patient will respond over the subsequent days. The data from this series suggest that AGIS may offer assurances through POD 1 and POD 2 by tracking dynamic changes in IR during diet advancement. If the IR is falling between these days, then it may portend POI and the surgeon should consider delaying diet advancement, reducing use of narcotics if possible, or both. Similarly, if a patient exhibits very low IR values for extended periods of time—particularly less than 1.5 motility events per minute—then it further increases the risk of POI.

In contrast, AGIS may rule out POI with a high degree of certainty. In particular, if the AGIS prediction algorithm yields a POI risk of 40 % or less, then the surgical team can rule out evolving POI with a NPV of 83 %. In this scenario, AGIS may provide further confidence to advance the diet according to ERAS protocols and expedite discharge where possible. Future research will evaluate if AGIS-guided feeding protocols can reduce resource utilization (e.g., shortening length of stay without increasing readmissions).

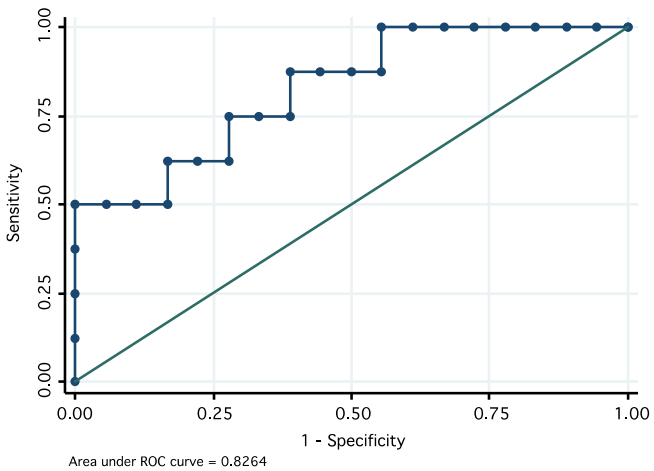

Fig. 5 Receiver operator characteristic (ROC) curve. The AGIS algorithm achieved an area under the curve of 0.83 and predicted POI with a sensitivity, specificity, and negative predictive value of 63, 72, and 81 %, respectively

The longitudinal nature of the study revealed the real-world feasibility of monitoring intestinal motility using a non-invasive sensor. The unobtrusive components allowed patients and health care providers to use AGIS without difficulty. Specifically, our surgeons and ancillary staff did not experience complications with AGIS, which only contacts the patients with time-tested Tegaderm™ adhesive.

These results suggest that the AGIS biosensor can play an incremental role in improving the recognition and management of POI. The current approach to evaluating POI is limited by non-standardized and imperfect methods. The ability of clinicians to use auscultated bowel sounds to identify POI has proven to be unreliable.[16] However, there is strong evidence to support that bowel sounds do have a proven relationship with gastrointestinal motility.[17] In a study of healthy fasting subjects, Tomomasa and colleagues performed computer-aided analysis of bowel sounds using microphones attached to the abdominal walls and compared the results to readings from an invasively positioned antroduodenal manometry catheter. Using this gold standard of motility evaluation, they found that acoustic signals accurately represented propulsive migrating motor complex (MMC) events and intestinal transit.[17]

There are several strengths to our study. First, analyses were conducted in a blinded fashion; neither patients nor providers had access to real-time AGIS data, so it could not be used to modify behaviors or management during the study period. In addition, the engineering team who compiled and presented the IR data were blinded to the clinical patient information. A separate research team collected the clinical data and determined which patients had POI based on a priori definitions; this team was also blinded to the recorded data. This eliminated risk of bias on the part of the research team when comparing the recorded and clinical data. Another strength is that this was a multicenter study conducted across three diverse institutions, including a large community-based teaching hospital (CSMC), a VA medical center (WLAVA), and a large university teaching hospital (UCLA). Four colorectal surgeons performed the operations, and a diverse group of procedures is represented. Moreover, there were different feeding protocols employed at the different sites; these factors help to increase the generalizability of the findings and speak to the pragmatic, "real-world" study design.

This study also has several limitations. First, although we found statistically significant results in this study, our sample size remains relatively small. Ongoing recruitment in our current trial (ClinicalTrials.gov study: https://clinicaltrials.gov/ct2/show/NCT02065583) will allow us to evaluate whether the results can be repeated in another larger scale test of the AGIS sensor. However, small sample size is a risk for a type II error, not a type I error, and this study was positive despite the small sample size. Second, we cannot know for sure whether the IR measurements directly correlate with physiologically significant motility, vs. non-propulsive acoustic signals. However, short of placing a concurrent antroduodenal manometry in post-operative patients, which is highly invasive, the AGIS-derived IR appears to correlate with clinically important events. We are currently testing whether AGIS correlates with manometry in non-operative subjects, and previous research has shown that acoustic intestinal measurements do track with true motility.[17]

In conclusion, we found that a novel, non-invasive, disposable, computer-aided acoustic surveillance biosensor can distinguish patients with POI vs. non-POI in a longitudinal study. The dynamic changes in IR early in the postoperative course are predictive of which patients are developing or will develop POI. The test yields a high NPV that may offer surgeons further confidence to rule out POI and feed patients safely. This study provides early and preliminary evidence that AGIS monitoring may predict POI, but future research is needed to evaluate the ability of AGIS to proactively direct postoperative feeding decisions and reduce cost of care.

Grant Support None to declare.

Conflicts of Interest This study was conducted with funding from the Principal Investigators (B.S. and W.K.). The technology described in this study is managed by the UCLA Office of Intellectual Property (OIP) and the Cedars-Sinai Technology Transfer Office. At the time of this study, UCLA submitted a patent application and was evaluating university in-licensing options. The authors did not receive outside funding to conduct this study. This is an interim report of an ongoing study per ClinicalTrials.gov: https://clinicaltrials.gov/ct2/show/NCT02065583

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Primary Discussant

John T. Mullen, M.D. (Boston, MA)

Thank you Dr. Kaneshiro for your excellent presentation. You and your co-authors are to be congratulated for building on your prior work demonstrating that gastrointestinal telemetry with an Acoustic Gastro-Intestinal Surveillance (AGIS) biosensor distinguishes healthy controls from patients recovering from abdominal surgery with or without post-operative ileus (POI). In this prospective, multicenter study, you and your colleagues show that AGIS can prospectively predict POI with approximately 80 % certainty. I have three questions for you:

1) In order to obtain reliable and actionable data from AGIS, do the recordings need to be captured continuously, thus committing the patient to being connected to this device at all times, or can brief snapshots provide data that is just as reliable? Is it difficult for patients to ambulate with this device?

2) Is there any correlation between the intestinal rate as measured by AGIS and the more traditional clinical signs we look for to determine whether a patient has an ileus or not, such as the presence of bowel sounds on auscultation or the passage of flatus or a bowel movement?

3) At my medical center, there is certainly a huge push to shorten length of stay while at the same time minimizing readmissions. I can see how this instrument might aid the clinician in determining which patients can be safely fed and discharged early after surgery, even as soon as POD#2. However, we cannot afford to be wrong 20 % of the time. Are efforts underway to devise a different algorithm with better discrimination between the POI and non-POI groups?

Closing Discussant

Dr. Kaneshiro

1. Thank you for the thoughtful questions. No, the recordings do not need to be performed continuously in an uninterrupted manner to yield useful data. However, the more data captured the better, as the predictive algorithms do require multiple data points over multiple days to establish patterns. We have not currently determined the minimum data necessary to make these decisions and that is something we are investigating.

Patients can easily ambulate with the low-profile sensors, similar to ambulating with EKG leads. They simply need to disconnect the wires from the sensors when ambulating and plug them back in when they return, where AGIS resumes recording.

2. The main focus of our current study is to predict POI, however we are also collecting data points such as presence of bowel sounds, flatus and bowel movements for all the study patients and that is something we certainly intend to look at. Given the fact that there is no universally accepted definition of POI, we are defining POI by the outcomes that seem clinically most important such as ability to advance diets, avoid severe symptoms and decreased hospitalizations and costs.

In regards to the question specifically about capturing the presence of bowel sounds by clinicians, the device has the ability to measure sounds of a spectrum wider than the human ear can perceive, so it can potentially show meaning in acoustic signals captured by the device that physicians have been unable to hear with a stethoscope.

3. Although 100 % would certainly be better, we feel that the 80 % accuracy and 80 % NPV are quite good as an additional piece of information that clinicians can use. The device is not necessarily meant to be a stand-alone test, but rather an adjunctive piece of information to help assist the gestalt of clinicians. Currently with ERAS protocols, the default appears to be leaning towards feeding and this device could help to assist with feeding with more confidence.

As far as a different algorithm, as we continue to recruit more patients and data points, we will look for other predictive patterns that could be used to update our current algorithm which already appears to show utility.