On-Organ Sensing to Improve the Lives of Individuals with Bowel Incontinence

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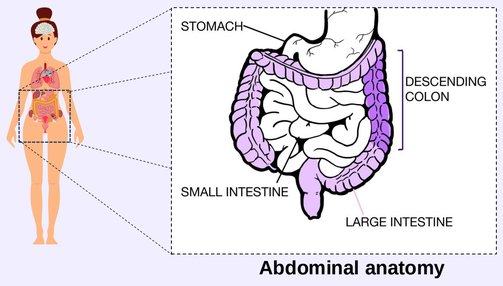
1. The UK's Bowel Problems

- Over 6.5 million people in the UK have some sort of bowel problem[1].
- Around 1.5% of the population experience bowel incontinence.
- Substantial impacts on mental health, ability to work and play, and an overall reduction in quality of life.

In the UK:
- £162 million annually spent treating constipation
- £1 billion is spent on inflammatory bowel disease
- £80 million is spent on faecal incontinence products alone.
- +7.7% in hospital admissions related to bowel issues between 2018 – 2020.

Beyond the huge cost to the NHS, the implications on resources includes over 200,000 GP appointments every week for constipation alone (equating to £9 million every week).

2. The anatomy



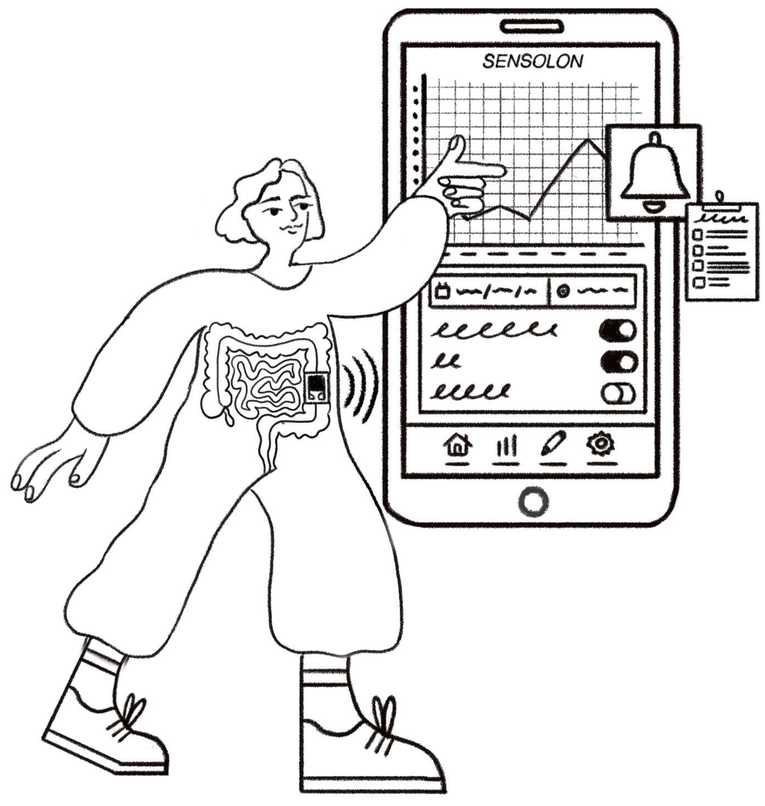
Abdominal anatomy

After food passes through our stomach for the first stage digestion, it passes through the small and large intestines where further digestion takes place over approximately 24-48 hours.

Motion through large intestine is a peristaltic "wave" or squeezing that pushes stool through towards the rectum, where we typically feel the urge to head to the bathroom. But if nerves are damaged, this urge does not appear, and this means that an individual doesn't know that they need to head to the bathroom.

3. EPSRC Project Aims

To co-create a system of implantable sensors combined with a digital interface to provide understanding and predictability to bowel behaviours so that individuals can self-manage their conditions and regain their quality of life.



Artist's concept of our full on-organ sensor system, coupled to a discrete user app

4. What are patients' perspectives?

WHAT DO PATIENTS EXPERIENCE?

- Lack of predictability
- Difficulty establishing relationship between bowel activity & daily activities/ emotions
- Lack of control and low self-worth
- Poor quality of life
- Isolation
- Embarrassment/shame/ stigma

HOW MIGHT A 'WINDOW INTO THE GUT' ASSIST BOWEL SELF-MANAGEMENT?

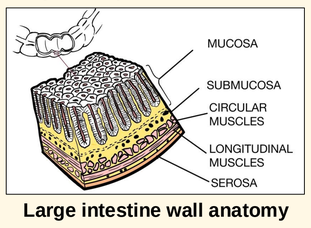
- Increased understanding/ knowledge of patterns
- Potential to adapt behaviours to suit emerging patterns
- Better quality of life and engagement with others/work
- Increased self-efficacy of bowel self-management
- Reducing reliance on memory

WHAT BARRIERS MIGHT EXIST FOR THEM FOR TECHNOLOGY UPTAKE?

- Attached to mobile device (what if I forget it?)
- Diary-recording fatigue
- Triggers remain unclear
- Lack of confidence in data

5. Clinical input

Early clinical engagement showed enthusiasm for sensing on the serosa (see anatomy below).



Large intestine wall anatomy

However, as the project progressed, concerns were raised about the risk to tissue (i.e. bowel perforation), including:

1. If we place the **sensor on the serosa**, it would need to be surgically implanted and therefore permanent.
2. If we place the **sensor on the mucosa**, it could be applied during a colonoscopy, but may interfere with bowel function.

These discussions are leading us towards devices with higher clinical acceptability

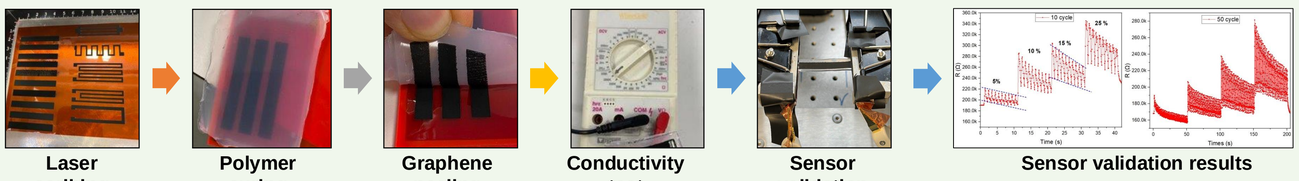
5. Sensor engineering

SENSOR DESIGN APPROACH

1. Engineering of a flexible strain gauge.
2. Development of sensing electronics and telemetry system.
3. Engineering an in vitro test rig for sensor development (reducing animal tissue requirements).
4. Development of an interface system to allow powering and transmission of sensor data to a smart phone to allow interfacing with a user app.
5. Testing the sensor attached to the bowel phantom to show that we can measure intestinal transit (movement of stool within the organ).

FLEXIBLE STRAIN GAUGE SENSOR FABRICATION USING LASER-INDUCED GRAPHENE

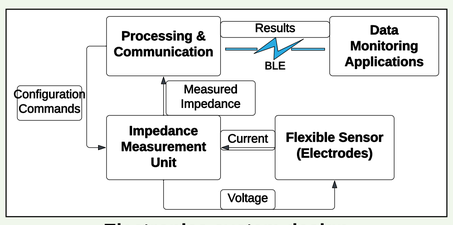
We used laser scribing of polyimide film to form graphene in geometries that would be appropriate for strain sensing. We then poured ecoflex® onto the graphene and once cured, peeled it off to remove the conductive layer. Afterwards, we added a secondary layer of ecoflex® combined with polyethyleneimine over the exposed graphene to ensure graphene would not be contacting skin, and to create an adhesive surface.



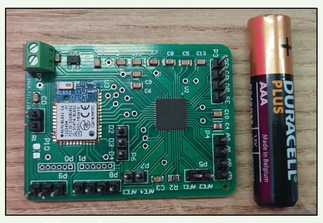
Laser scribing → Polymer curing → Graphene peeling → Conductivity test → Sensor validation → Sensor validation results

SENSOR POWER AND MEASUREMENT

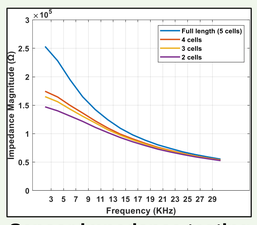
We implemented a 35x48 mm two-layer PCB prototype with the BL652, AD5941, and power management modules. The board is battery operated and equipped with Bluetooth Low Energy (BLE) protocol. The system is based on two main components: 1) an impedance measurement circuit, and 2) a processing and communication unit. Impedance measurements were wirelessly sent to a PC via BLE. The measurement rate was 5 Hz, with an excitation frequency of 100 Hz.



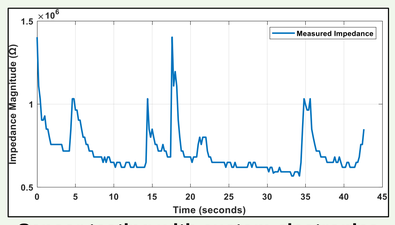
Electronics system design



Manufactured electronics



Sensor impedance testing



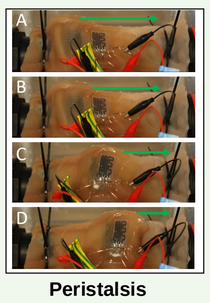
Sensor testing with custom electronics

SENSOR TESTING

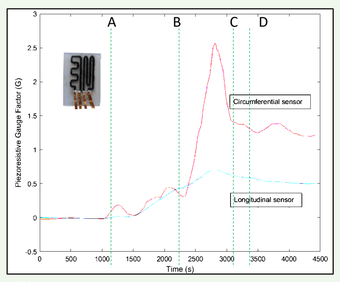
To test the sensors in a physiologically relevant environment and to reduce animal testing, we manufactured a bowel phantom. This consisted of a fluid chamber at 37°C with a phantom created using 3D mould printing with ecoflex® simulating the bowel (due to its soft, flexible nature). Motors within the bowel simulated intestinal transit.

When sensors were attached to the bowel phantom, resistance spikes were clear during bowel movement demonstrating the potential to detect intestinal transit using on-organ sensors.

Intestine phantom



Peristalsis



On-organ sensor measurements

6. User-interface design

APP DESIGN INTERFACE

PARTICIPATORY DESIGN SESSIONS

26 people with experience of bowel problems/incontinence were involved in the early design development of the app. 5 group sessions using a participatory design approach were undertaken, valuing contributors' lived experience as essential to finding problem solutions.

- Session 1: 'Day in the life' and 'User needs' statement
- Session 2: Brainstorming ideas to address each of the identified needs
- Sessions 3-5: Iteratively developing the functionality/features, using a progressively refined static (non-interactive) prototype of the app prepared in-between sessions to stimulate discussion

EVALUATION SESSIONS

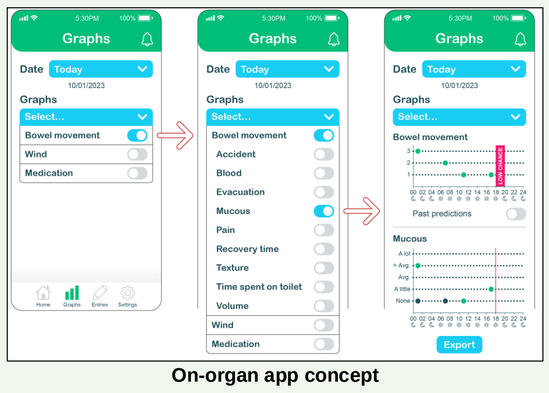
2 groups collating evaluation perspectives on the sensor-app interface proposals developed from the participatory design sessions.

- Group 1: Irritable Bowel Syndrome or Irritable Bowel Disease participants
- Group 2: Participants with non-IBS/IBD bowel issues.

FOCUS GROUPS

PRODUCTION OF A PROTOTYPE APPLICATION FOR BOWEL MONITORING

The interactive prototype was developed incrementally using Agile methodologies, with features added continuously where possible. Graphical data displays were excluded due to the early stage of development. Xamarin was used for cross-platform compatibility (Android and iOS), and the development was done in C# with Visual Studio. Firebase was implemented as the database for data storage and retrieval.



On-organ app concept

8. Outcomes and next steps

The team formed for this proposal bring complementary and interdisciplinary skillsets to the challenges in improving the health span of individuals with complex and chronic health conditions. This work, arising from a Digital Health Sandpit, has led to progress in the field of implantable sensors and digital interfaces. Feedback from potential users of the sensing approach in this work was overwhelmingly positive, with a view that if successfully translated, this would allow greater independence and freedom for the large proportion of people in the UK suffering from bowel issues.

NEXT STEPS

Since the start of this proposal the team has submitted grant applications for over £3.8 million together, to developing novel health sensors for population benefits (including reaching the final stage of a Wellcome Leap Programme). Our next steps are centred around maintaining (and growing) our team to apply our collaborative approach, technical outcomes and patient-led innovation to apply for an EPSRC Programme Grant. This structure will allow the project to continue to build towards impact for those with bowel issues, and to expand to other organs, and to bring new investigators into the research environment to address similar organ-based challenges.

Engineering and Physical Sciences Research Council

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References:

[1] Bowel Interest Group, Cost of Constipation Report 2020, Available at: https://bowelinterestgroup.co.uk/resources/cost-of-constipation-report-2020/

BOWEL RESEARCH UK.