Fiber Bragg grating manometry catheters for in-vivo monitoring of peristalsis

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ABSTRACT

The human gastrointestinal tract or ‘gut’ is one of the body’s largest functional systems spanning up to 8 metres in length from beginning to end. It is formed of a series of physiologically different sections that perform the various functions required for the digestion of food, absorption of nutrients and water, and the removal of waste products. To enable the gut to perform correctly it must be able to transport digesta through each section at the appropriate rate, and any breakdown or malfunction of this transport mechanism can have severe consequences to on-going good health.

Monitoring motor function deep within the gut is challenging due to the need to monitor over extended lengths with high spatial resolution. Fiber Bragg grating (FBG) manometry catheters provide a near ideal method of monitoring physiologically significant lengths of the gut in a minimally invasive fashion. Following the development by our group of the first viable FBG based manometry catheter we have undertaken a series of clinical investigations in the human esophagus, colon, stomach and small bowel. Each region presents its own technological challenge and has required a range of modifications to the basic catheter design. We present the design of these catheters and clinical results from over 100 in-vivo studies.

Keywords: fiber optic sensing, fiber Bragg gratings, in-vivo sensing, gastroenterology, manometry, functional gastrointestinal disorders, clinical trials

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1. INTRODUCTION

Gastrointestinal motility disorders are highly prevalent in the general population with reports of up to 30% of the population suffering from some form of functional disorder of the gut at some point during life.

The measurement of variations in pressure due to contractions of the gut wall is referred to as ‘intraluminal manometry’, and is the primary diagnostic technique used for diagnosing functional disorders of the gut. However its clinical use is currently restricted to the oesophagus and anorectum. This largely due to traditional technologies that limit the number and reach of discrete sensing elements that can be incorporated into catheters designed to be placed in the human gut. Recent advances in Draw Tower Gratings (DTGs) [1] and solid state spectrometers have allowed the development of a new form of fiber optic manometry catheters which are providing dramatic improvements in the quality of data available from the regions of the gastrointestinal tract below the stomach [2-5].

Since 2009 we have been using our proprietary sensor technology to make the fiber optic catheters that are now being used to record clinical data in healthy volunteers and patients with a range of functional disorders of the small and large bowel[6-12].

In this presentation, we report the design of our high resolution catheters and the outcomes of clinical studies conducted using these devices. Specifically we highlight the improvement in data available from these catheters compared to technologies traditionally used in these regions of the body.

2. CATHETER DESIGN

2.1 Transduction mechanism

The basic sensing mechanism used in our pressure transducers is a sideways deflection of a fiber Bragg grating (FBG). The fiber containing the FBG is held between two fixed points on a rigid substrate so that the fiber forms a curve away from the axis of the substrate. The fiber and substrate are contained within a flexible pressure sensitive sleeve with the curved fiber in direct contact with the inner surface of the sleeve, as shown in Figure 1. Variations in pressure or force acting on the sleeve distort the fiber sideways changing the axial strain in the fiber and hence shifting the Bragg wavelength of the FBG. The curved form of the fiber significantly increases the sensitivity of the transducer and also allows both positive and negative pressures to be differentiated. Further details of the design are given in a previous publication [13].

Figure 1: Schematic of the 3 mm diameter transducer design used in the fiber optic manometry catheters.

In addition to increasing the sensitivity of the transducer, the design of the substrate and the curvature of the fiber also permit a second fiber to be included in the transducer that can be used either to compensate for temperature changes or to provide additional sensing regions.

2.2 Clinical requirements

Accurate measurement of muscular activity in the human gut imposes three significant design criteria on manometry devices.

1. The catheter must be flexible enough to allow intubation into the region of gut to be investigated.
2. The overall diameter of the catheter should be no more than 5 mm.
3. The sensing regions need to be spaced no more than 10 mm apart along the axis of the catheter.

The first criterion is achieved as a consequence of the outward curvature of the fiber at the point of sensing. This causes the fibers to cross over each other in between the transducers creating a natural point of articulation allowing the catheter to flex freely. Figure 2 shows an array of 3 sensors fabricated in this way showing the point of articulation between the substrates. The high degree of flexibility of the catheters allows intubation into the complex and convoluted regions of the gut below the stomach.

Figure 2: Three concatenated transducer elements showing the points of articulation between each substrate.

The second criterion is also easily achieved using optical fiber as the pressure sensitive region can be created with diameters as small as 1.2 mm[14].

The third criterion can be achieved using Draw Tower Grating arrays, however, the requirement for fixing the FBG regions to rigid substrates limits the FBG length to 3 mm. This introduces some limitations to the catheter design. A 3 mm long grating operating in the 1550 nm region has a spectral bandwidth of approximately 1 nm (to the first zeros). To monitor physiologically significant gastrointestinal pressures requires a dynamic range of approximately 500 mmHg. Our transducers have a typical sensitivity of approximately 1 pm/mmHg and we typically apply a safety factor of x2 to the dynamic range. The solid state spectrometer used with these devices (FBGS FBG Scan 804D, FBGS International, Jena, Germany) has a usable spectral bandwidth of 80 nm (1510 – 1590 nm) and a 1x4 optical switch inputs.

The required dynamic range and the bandwidth of the 804D interrogator permits approximately 40 FBGs to be contained on each fiber, however to provide an additional buffer we have standardized on using 36 FBGs per fiber to make our catheters. This allows us to fabricate temperature compensated catheters with up to 72 sensing elements, or uncompensated catheters with up to 144 sensing elements.

The studies presented here were carried out in the small and large bowel, regions of the body that are essentially isothermal, hence uncompensated catheters with 72 sensing regions were used in all cases. The diameter of the catheters was 3 mm.

2.3 Transducer calibration

The catheters are calibrated in a pressure vessel prior to each use. A standard sphygmomanometer bulb is used to apply pressure in steps of 10 mmHg as these devices are very familiar to medical staff. The sphygmomanometers are periodically checked against a NIST traceable pressure sensor to ensure accurate calibration.

Figure 3 shows the change in wavelength of a single transducer as a function of applied pressure. The sensitivity of this transducer was -0.8 pm/mmHg.

Figure 3: Change in reflected wavelength of the pressure transducer fibers as a function of applied pressure.

2.4 Clinical studies

Results from two separate clinical studies are reported here. Firstly an on-going series of studies into the performance of the human colon in both healthy volunteers and patients; and secondly a preliminary study in the human small bowel.

In both studies, the primary benefit of using fiber optic catheters instead of traditional manometry catheters is the larger number of sensing regions that can be incorporated into the catheters. This allows significantly longer regions of the gut to be monitored using sensors spaced closely enough to produce a pseudo-continuous map of pressure variations along physiologically significant regions of the gut.

2.5 Colonic manometry

For the colonic studies, patients and volunteers are asked to undergo a bowel cleansing preparation and abstain from eating solids for 24 hours. On the day of the procedure the catheters are placed in the subjects trans-anally using a colonoscope. The catheters are advanced to the caecum and the tip of the catheter is then clipped superficially to the

mucosa of the gut. The colonoscope is then removed, and following a recovery period of 1-2 hours, the catheters are connected to the 804D interrogator and recording is started. Details of the full protocol used has been described elsewhere [11]. Typically data is analysed from the period 2 hours before and 2 hours after a standard meal is given. Figure 4 shows an x-ray image of a catheter placed into the colon of one of the subjects after the colonoscope has been removed. Analysis of the data is based on the differences in recorded patterns before and after the meal. Details of the analysis and interpretation of data will not be given here but are reported in manuscripts submitted to medical journals[6, 9, 11, 12, 15].

Figure 4: X-ray image of a fiber optic catheter placed in the colon of a patient.

A typical traditional colonic catheter contains sensors spaced at approximately 10 cm intervals, so Figure 5(a) shows data recorded from every 10th channel of a fiber optic catheter. In this figure, time is shown along the x-axis and sensor location along the y-axis. The data from each channel has been separated along the y-axis for clarity. The data shows variations in pressure measured at each location as a function of time, so that the sequence indicated by the arrow would suggest a descending pressure wave running along the colon in an anal direction. Figure 5(b) shows the same section of the recording, but with data from all channels included. The image is now very different. Instead of an apparent downward propagating wave it is clear that the actual activity that is occurring as a sequence of waves propagating in the opposite (upward) direction. In a sample of 31 studies in patients and healthy controls analysed using 10 cm spaced sensors it was estimated that <5% of the propagating sequences were correctly identified compared to the full data set using 1 cm spaced sensors [7].

Figure 5: Data recorded in the human colon using a fiber optic manometry catheter with (a) 10 cm spacing between displayed channels; and (b) 1 cm spacing between displayed channels.

Over 130 colonic studies have now been completed in the human colon in healthy volunteers, and patients with functional disorders. The data from these studies has led to the identification of X new manometric signatures of colonic propagation [8]. While these studies are still in the early stages it is hoped that the increased diagnostic potential of the high spatial resolution will provide greater insight into these often intractable disorders.

2.6 Small bowel manometry

For studies of the small bowel the catheters are placed trans-nasally. During placement, the measured data from the catheters are used to identify the location of the lower oesophageal sphincter. This can be done easily as the behavior of the lower oesophagus and sphincter during swallowing are well documented and provide a characteristic pressure signature that identifies the point when the sensor passes into the stomach. Once the tip of the catheter enters the stomach, x-ray images are used to position the catheter in the distal stomach from where natural peristaltic action draws it into the small bowel. The catheter is positioned so that the proximal end of the sensing array was in the stomach and the distal tip was close to or beyond the duodenojejunal flexure (the anatomical location of the start of the jejunum). Figure 6 shows an x-ray image of a fiber optic catheter placed in the small bowel of a healthy volunteer. A total of 15 studies have been conducted in the human small bowel of healthy female volunteers and the results from the study are now being prepared for publication. The advantages of the fiber optic catheter were again very evident. The placement of the catheter deep into the small bowel represents the first detailed study of high resolution manometry of the segment spanning from stomach to the jejunum. Similarly to the colonic data shown in Figure 5, Figure 7 shows the difference in 10 cm and 1 cm spaced data and again clearly shows the benefits of recording with closely spaced sensors.

Figure 6: X-ray image of a fiber optic catheter placed in the small bowel of a healthy volunteer.

Figure 7: Data recorded in the human small bowel using a fiber optic manometry catheter with (a) 10 cm spacing between displayed channels; and (b) 1 cm spacing between displayed channels

3. CONCLUSIONS

In both colonic and small bowel applications, the fiber optic catheters provide significantly more information than traditional manometry catheters. The increase in data at 1 cm spacing over physiologically significant lengths of the bowel is being hailed as a breakthrough in interpretation of colonic manometry [16]. At present, fiber optic manometry catheters are the only way of providing 1 cm spaced sensors over lengths longer than 36 cm and so are the only realistic technology for conducting manometric evaluations in regions of the gut below the stomach.

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