Proof-of-principle validation of a novel intra-luminal optical sensor for dynamic monitoring of intestinal anastomosis: An in vivo animal model case study

K Budidha[1], MA Thaha[2,3], M Eschbach[4], E Mejía-Mejía[1], and PA Kyriacou[1]

[1] Research Centre for Biomedical Engineering, City, University of London, UK

[2] Blizard Institute, Queen Mary University of London, London, UK

[3] Department of Colorectal Surgery, Royal London Hospital, London, UK

[4] Medtronic PLC, North Haven, CT, USA

***Abstract*— Intestinal resections are commonly performed to treat different colorectal conditions, including colorectal cancer. A successful primary anastomosis is the desired optimal outcome after intestinal resection. Maintaining adequate blood flow across the anastomosis is paramount for reducing anastomotic failure. Currently, there are no clinical devices capable of continuously assessing blood flow and blood perfusion at an anastomosis during and after surgery. The aim of this study was to develop an indwelling optical sensor for the monitoring of perfusion biomarkers using photoplethysmography and near-infrared spectroscopy principles. In an animal in-vivo proof-of-principle study, it was found that the developed sensor performed appropriately for the assessment of blood flow and perfusion in an anastomosis, showing changes in the assessed parameters after gradual devascularization of the transected bowel.**

***Keywords*— Photoplethysmography, near-infrared spectroscopy, bowel resection, anastomosis**

I. INTRODUCTION

Intestinal resection is a common surgical procedure in both elective and emergency settings. It is often the primary treatment and the only curative option for colorectal cancer patients. The optimal outcome after bowel resection is a primary anastomosis to restore continuity of gastrointestinal (GI) tract. Despite improvements in surgical techniques, anastomotic devices and perioperative care, an intestinal anastomosis still has up to 20% risk of failure, which results in high morbidity and prolonged hospital stays, increased mortality, and early cancer recurrence [1,2].

One of the major factors that contribute to the failure of an anastomosis is suboptimal blood flow to the bowel ends at the site of the anastomosis [2,3]. Currently, there is no simple-to-use monitoring tool in routine clinical practice for early identification of intestinal ischemia. Various imaging and biochemical techniques such as X-rays, computerized tomography, magnetic resonance imaging and gastrointestinal luminal pCO2 have been evaluated, but all have proved inadequate [4-10]. Other techniques, including Doppler and fluorescence imaging, have been previously tested to assist surgical decision but have also failed to reach routine clinical use due to a combination of the complexity of the technology or due to cost factors [5]. Increasingly, indo-cyanine green (ICG) based intra-operative bowel perfusion assessment is carried out when constructing anastomoses. The commercially available systems allow the surgeon to assess perfusion during surgery with real-time endoscopic high definition visible (VIS) and near-infrared (NIR) fluorescence imaging [8]. However, the technique is highly qualitative and does not measure tissue perfusion postoperatively [11] and has limited possible measurements.

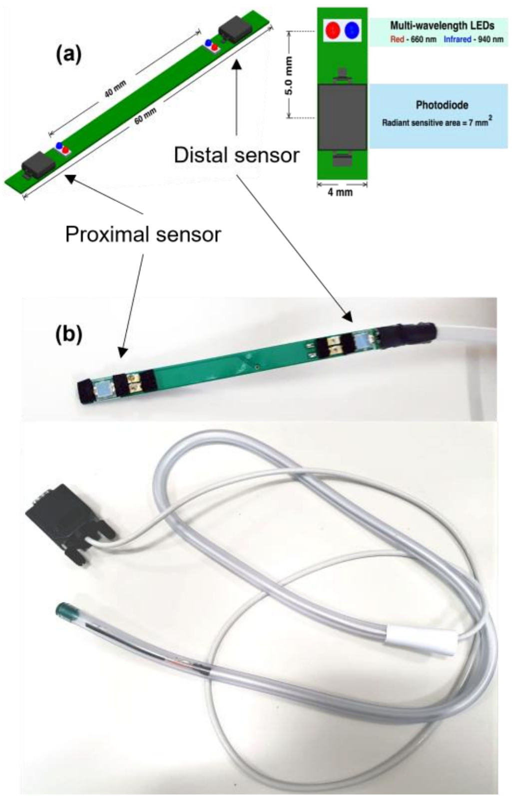

Figure 1: Intraluminal probe for the assessment of optical signals from the bowel. (a) Designed probe with 2 optical sensors and light sources. (b) probe housed in a Fr 22 rectal catheter.

Hence, the aim of this study was to develop a novel intraluminal optical sensor for monitoring tissue perfusion directly from the intestine and at the site of the anastomosis. Furthermore, and for the first time, this will provide clinicians with a tool that can dynamically monitor intestinal perfusion across both limbs of the anastomosis postoperatively.

II. MATERIALS AND METHODS

An optical sensor based on the principles of multiwavelength, reflection photoplethysmography (PPG) and near infrared spectroscopy (NIRS) was developed. The probe consists of two identical multi-wavelength reflectance sensors, which are intended to shine near-infrared (940 nm) and visible light (660 nm) into the intestinal mucosa and detect the changes in reflected and attenuated light. The light photons detected from the intestinal tissue can be converted into relative changes in concentrations of oxygenated (ΔHbO_2), reduced (ΔHHb) and total haemoglobin (ΔtHb), along with arterial oxygen saturation (SpO_2) [12]. The sensor is housed inside a Fr 22 rectal catheter and provides continuous assessment of perfusion, oxygen delivery, oxygen consumption, and total blood volumes at both ends of the anastomosis, and hence a more comprehensive assessment of intestinal perfusion.

The sensor was connected to a custom-made, research-grade PPG acquisition system, BioBlocks™ (Pleth AILytics Ltd, United Kingdom), for the acquisition and processing of the optical signals. Then, signals were digitized, visualized and stored in a computer using a virtual instrument (VI) developed in LabVIEW™ (National Instruments, United States). Algorithms were

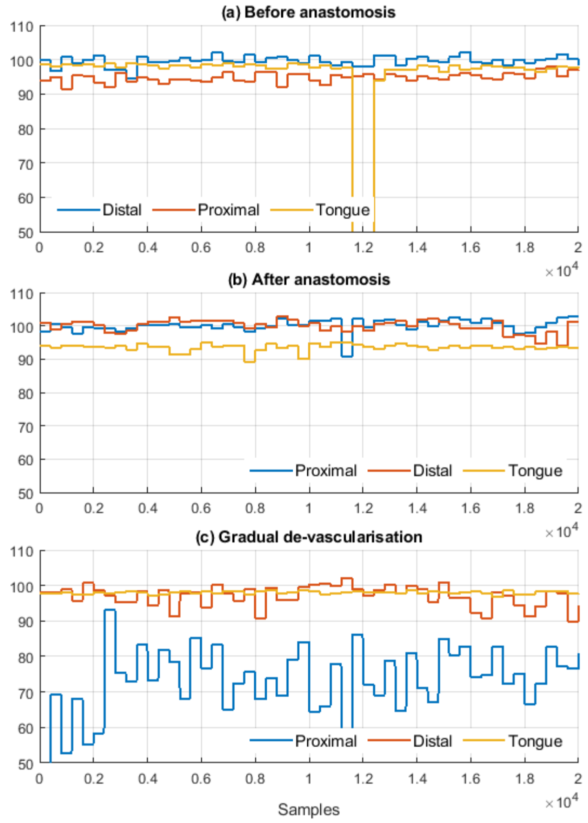

Figure 2:Behavior of arterial oxygen saturation (SpO2) measured from the proximal and distal sensors on the bowel, and from the tongue, (a) before bowel transection, (b) after anastomosis, and (c) after de-vascularization. column), and after gradual de-vascularization (right column).

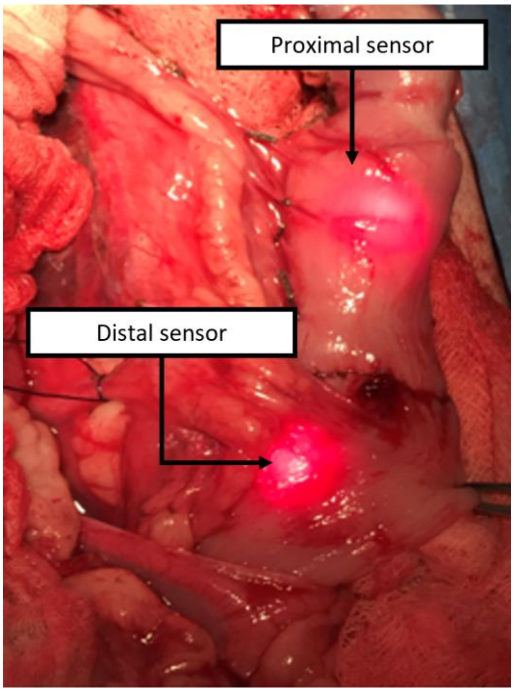

Figure 3: Location of the sensor in the canine model during the experiment. Following the anastomosis, the dual intraluminal optical sensor was placed inside the bowel. The distal and proximal sensors were at 10 cm and 6 cm from the anal verge.

also developed for real-time assessment of SpO2, ΔHbO2, ΔHHb and ΔtHb.

A proof-of-principle in-vivo study involving a canine model undergoing transection surgery was performed to evaluate the performance of the developed sensor and system. The canines in this study were housed in an accredited facility and handled in a manner consistent with the Guide for Care and Use of Laboratory Animals and the Animal Welfare Act. The procedure was conducted pursuant to an Institutional Animal Care and Use Committee approved protocol. To test the performance of the intraluminal sensor, a second PPG sensor was also connected to the BioblocksTM as a reference of optical signals acquired from canine tongue. The canine model was anesthetized and sedated, and a bowel transection was performed by an expert colorectal surgeon. Before transection, the bowel was prepped and optical signals were acquired from it using both proximal (4 cm from the rectum) and distal (at the rectum) sensors. Simultaneously, signals were acquired from the tongue of the canine model as a reference. SpO2, ΔHbO2, ΔHHb and ΔtHb were measured from the bowel and the tongue. Then, the transection and anastomosis were performed. The dual intraluminal optical sensor was placed inside the bowel at nearly 8 cm from the anal verge, hence the proximal and distal sensors were at 10 cm and 6 cm from the anal verge. Optical signals were acquired from this sensor and the peripheral sensor simultaneously, and SpO2 and haemoglobin concentrations were measured using all three sensors for 10 minutes after the anastomosis. Finally, selective ischemia on one side of the anastomosis was caused by incrementally de-vascularizing the branches of the mesenteric arteries. The probe was placed inside the bowel such that the proximal probe monitored the ischemic area and the distal sensor monitored the perfused area. SpO2, ΔHbO2, ΔHHb and ΔtHb were also measured and compared to the values obtained simultaneously from the tongue probe.

III. Results

Fig. 1 illustrates the developed probe for the measurement of optical signals from the bowel. This probe was connected to the Bioblocks^{TM} system for the acquisition of optical signals, while Fig. 2 shows the location of the probe after the anastomosis was performed in the canine model. Fig. 3 and 4 show the behaviour of SpO2 and haemoglobin concentrations measured from the bowel and the tongue before and after anastomosis, and after devascularization.

SpO_2 measured from the bowel is comparable to the SpO_2 from the tongue before anastomosis. In comparison, after anastomosis, SpO2 measured from the peripheral site dropped while both the distal and proximal sides of the anastomosis remained stable. This demonstrates the ability of the intraluminal sensor in measuring perfusion and oxygenation accurately in the bowel even when the peripheral sensor fails. Finally, it can be observed that with gradual de-vascularization, SpO2 measured from tissues proximal to the anastomosis was reduced, while SpO2 estimated from the distal tissue and the tongue remained stable and constant. A similar behaviour can be observed from the changes in haemoglobin concentration. While before anastomosis the behaviour of the measured indices was similar among locations, it can be observed that the concentration of haemoglobin species did not change much in the tongue after anastomosis, but the changes at the site of the anastomosis were vivid. These changes, if measured over long duration, can provide useful information about the perfusion of the bowel and the progression of ischemia at the site of the anastomosis. Also, during gradual de-vascularization the changes in total, oxy and deoxy haemoglobin were more vivid in the proximal bowel compared to the bowel tissue distal to the anastomosis and to the tongue. This demonstrates the ability of the intraluminal dual sensor to distinguish the changes in perfusion of the bowel proximal and distal to an anastomosis.

IV. Discussion

A novel intraluminal optical sensor for monitoring tissue perfusion directly from the intestine and at the site of the anastomosis was developed and tested in a canine model. The results obtained from this study demonstrated that the current prototype device is effective at monitoring perfusion changes in bowel tissue, that would commonly occur following an anastomosis in colorectal surgery. The sensing system has also verified that a combined approach of using NIRS derived parameters along with traditional pulse oximetry can provide a superior assessment of intestinal perfusion. Based on the success of this first proof-of-principle study in a canine model, larger in-vivo studies both with animal models and with patients that require a bowel resection need to be conducted to validate the feasibility of using the sensor in long term, dynamic monitoring. This would also give the opportunity for the first time to understand the hemodynamic changes that occur in the bowel following an anastomosis.

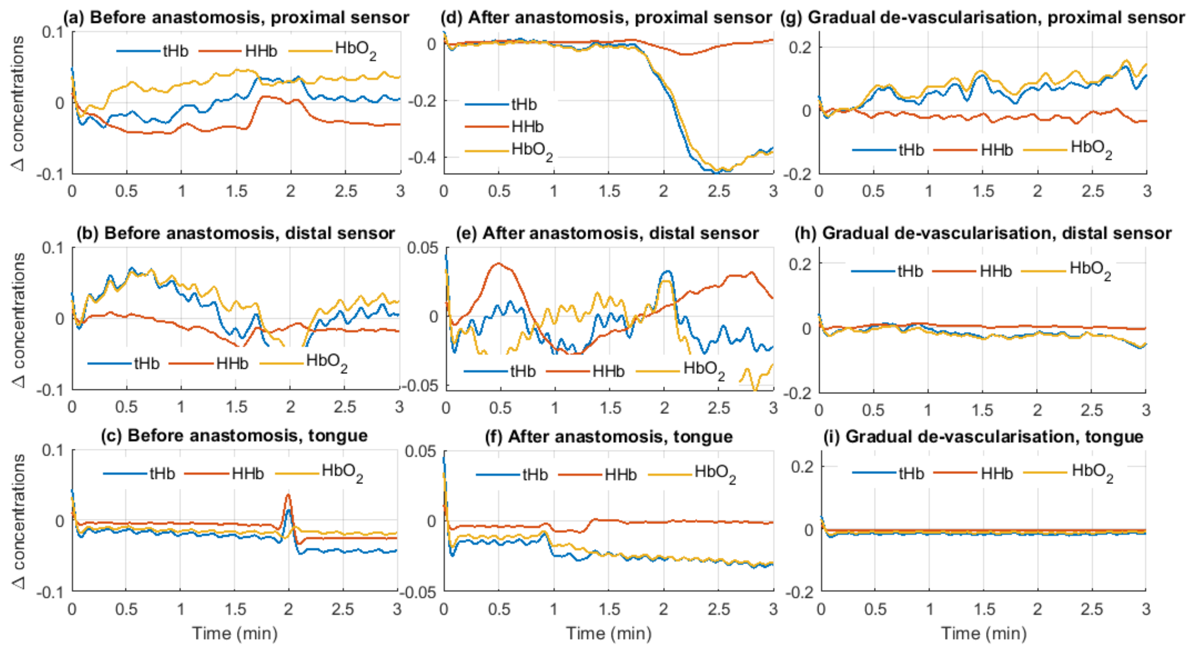

Figure 4:Behaviour of relative changes in concentrations of oxygenated (ΔHbO2), reduced (ΔHHb) and total hemoglobin (ΔtHb) measured from the distal (first row) and proximal (second row) sensors on the bowel, and from the tongue (third row), before bowel transection (left column), after anastomosis (middle column), and after gradual de-vascularization (right column).

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