Colonic Tissue Perfusion Assessment Using Local Electrophysiological Sensing

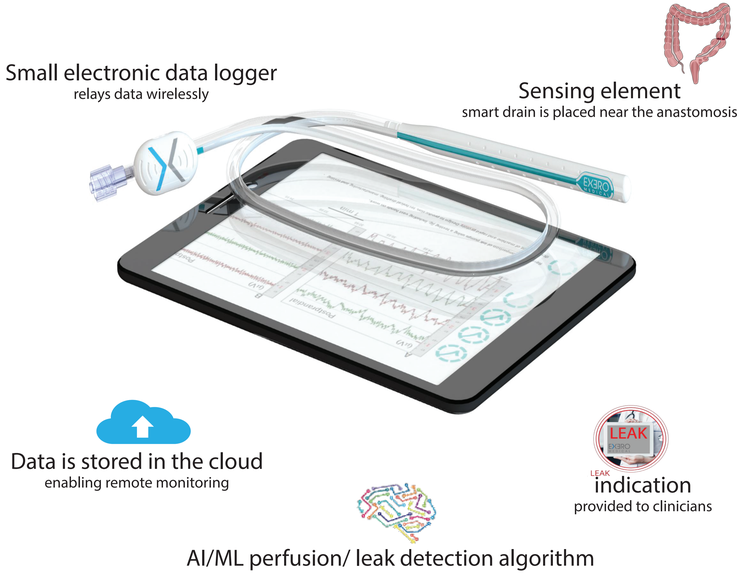
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Motivation

Verification of adequate perfusion is essential to ensure anastomosis integrity following colonic resections. Perfusion monitoring intra and postoperatively is challenging, and existing methods are unable to provide reliable perfusion metrics over time. Here we present a perfusion assessment device embedded in a standard drain which is based on measuring colonic myoelectric activity. The system (The "Smart DrainTM" by Exero Medical LTD) is designed for intraoperative and post-operative use similar to a regular drain, creating a potential solution for anastomotic leak detection with minimal changes to surgical and follow-up workflows.

Technology

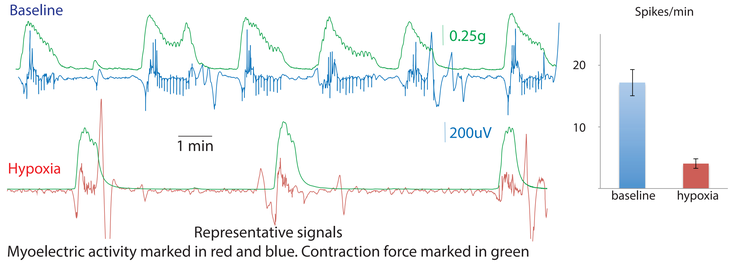


Methods

In vitro calibration and assessment: Human colon maintained in a horizontal tissue bath (oxygenated physiological solution; 37°C) was used. Spontaneous contractions were recorded from a muscle strip approximately 0.5x1.5 cm, with mucosa removed. Smart drain electrodes were placed on the tissue recording myoelectic activity. Tissue contractions and myoelectric activity was recorded under normal and hypoxic environments.

Clinical feasibility assessment: during five low anterior resection surgeries, baseline myoelectric signal was recorded for 4 minutes. After the creation of ischemia by devascularization of the bowel region prior to removal, the smart drain was placed at the devascularized region and myoelectric signals were similarly recorded. The device was used in laparoscopic, robotic and open surgeries.

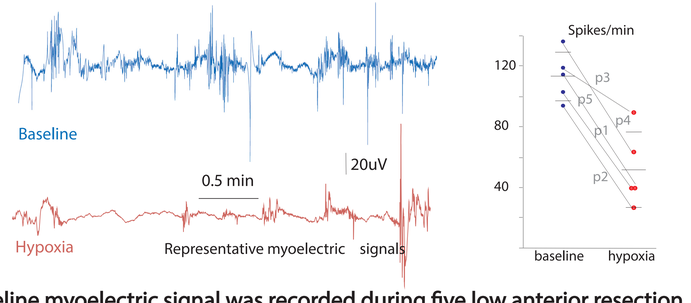
Results - In vitro data analysis



Representative signals
Myoelectric activity marked in red and blue. Contraction force marked in green

Attaching our device to the muscle enabled recording of myoelectric activity (reflecting slow wave pacemaker activity from interstitial cells of Cajal) and spike potentials from the muscle. Under hypoxic conditions the frequency and duration of contractions declined together with the spiking rate (17.12±2.1 spikes/min in baseline; 4.02±0.8 under hypoxia, 4 tissue strips).

Results - Clinical Study



Baseline myoelectric signal was recorded during five low anterior resection surgeries. After the creation of ischemia by devascularization of the bowel region prior to removal, the smart drain was placed at the devascularized region and myoelectric signals were similarly recorded. Spiking exhibited a decline in rate from 112.64±16.13 spikes/min to 51.13±24.88 spikes/min (more than 50% reduction) under these ischemic conditions (N=5 patients).- No adverse events were observed during the study and the device did not substantially alter the surgical procedure.

Conclusions

Electrophysiological parameters are sensitive to the effects of hypoxia (ex-vivo) and ischemia in clinical settings and maybe a potential biomarker for early detection of postoperative anastomotic leak. The progress reported here suggests that harnessing myoelectric data analysis to improve colonic surgical outcome is now closer to the clinic.

Disclosures

ES, TY are employees of Exero Medical. MBD is a co- founder and director at Exero Medical.