Clinical development of a patient calibrated intraoperative ICGFA computational bowel transection recommender.

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Background

Near Infrared (NIR) surgical camera systems enable intraoperative indocyanine green fluorescence angiography (ICGFA) in colorectal surgery to potentially diminish ischaemic anastomotic leakage (AL). The interpretation of the ICGFA signal is subjective and is also operator dependent. Patient variables (e.g. blood volume, serum protein concentration, body habitus and age), perioperative factors (including ventilation and anaesthetic gas composition) and camera system optics (including distance:intensity as well as centre versus periphery field of view relationships) are other considerations impacting consistent signal interpretation. An objective computerized recommender system could be a valuable addition to the field of ICGFA in colorectal surgery if it could account for these variables. Here we demonstrate an algorithmic method for this that standardises factors on a per patient basis by inclusion of an early intraoperative control as a patient-specific reference perfusion profile. Thereafter the system automatically indicates the site of optimum ICGFA signal along the bowel at the time of proximal transection during colonic surgery on recordings from human patients undergoing colonic surgery.

Methodology

Within a clinical trial (IRB 1/378/2092) patients undergoing elective right and left sided colonic resections were studied. A commercially available NIR laparoscopic stack (Pinpoint, Novadaq/Stryker) was used for ICGFA as this system includes simultaneous white light and NIR imagery enabling a novel tracker-quantifier to generate a fluorescence intensity-time series from the display. For this work, two ICGFA recordings are made in each patient and mathematically compared post-hoc to indicate the area of optimum ICGFA signal at the time of proximal transection. The first ICGFA recording ("*control*") is made immediately after general anaesthesia, patient positioning and preparation and induction of pneumoperitoneum with port placement. A segment of untouched colon is observed using the NIR camera after systemic ICG (0.1mg/kg) administration. Later, after colonic mobilization and vascular ligation, a second ICGFA recording ("*acquisition*") is made with the NIR camera now observing the colonic segment being planned for proximal transection (same dose ICG). Post-hoc analysis enables the synthesis of a *Reference Profile* from the *Control* ICGFA recording which is scaled and time shifted to indicate the most distal optimally (relative to the control ICGFA) perfused region of the *Acquisition* ICGFA thereby recommending an 'ideal' ICGFA colonic transection point.

Experimental Operative and Computational Workflow

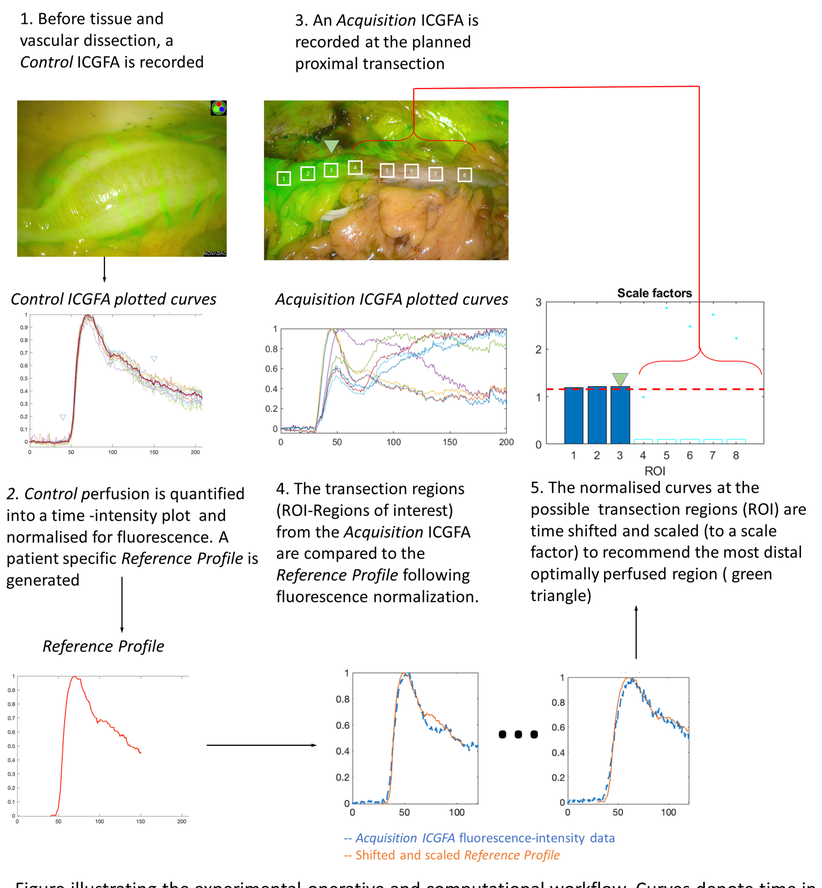


Figure illustrating the experimental operative and computational workflow. Curves denote time in seconds vs normalised fluorescence ratio.

Results

A region of bowel was consistently selected on ICGFA recordings of right and left sided resections using this method across a variety of cases (n=16, mean age 66.47 years male:female=13:3 , cancer:benign=11:5). In all cases the region was close to the intended transection site demonstrating proof of potential usefulness to compare ICGFA recommendation with measures of tissue perfusion (such as local capillary lactate levels and/or tissue oxygen saturation levels).

Table: Patient (n=16) and analysis data	
Mean Age	66.47 years
Male:Female	13:3
Cancer:Benign	11:5
T Stage n=11	T4(3) T3(4) T2(2) T1(1)
Left: Right	10:6
Bowel Continuity Restored	15/16
Large:Small Bowel Analysis	16:4

Conclusion

Mathematical representation of ICGFA enables algorithmic comparisons between baseline and subsequent operative time points enabling a standardized method for automatic ICGFA signal discrimination. Future work will benchmark this against local metabolic indicators and clinical outcomes and move also from post-hoc to intra-op algorithmic applications.