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RESEARCH COMMUNICATION

Real-time First-In-Human Comparison of Laser Speckle Contrast Imaging and ICG in Minimally Invasive Colorectal & Bariatric Surgery

Chibueze A. Nwaiwu[1,2] · Christopher J. McCulloh[2] · Garrett Skinner[2,3,4,5] · Shinil K. Shah[6,7] · Peter C. W. Kim[1,2] · Steven D. Schwaitzberg[3,4,5] · Erik B. Wilson[6]

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Introduction

Anastomotic leak (AL) occurs up to 5.2% in bariatric and 15% in colorectal surgery.[1, 2] The current standard for perfusion assessment is naked eye inspection. Indocyanine green fluorescence angiography (ICG-FA) can indicate tissue perfusion and may reduce AL.[1] However variabilities in dosage, timing, interpretation, and workflow pose challenges.[3] Laser speckle contrast imaging (LSCI), dye-less, on-demand, real-time imaging, detects perfusion through dynamic interference produced from coherent light scattered by erythrocyte movement.[4] We report a novel multi-modal LSCI and ICG-FA perfusion assessment in single device in a first-in-human (FIH) trial, after porcine studies.[5]

Methods

ActivSight™, an FDA-cleared laparoscopic form-factor device, was used for this study. (Houston IRB#20–0967; Buffalo IRB#20–003; NCT#04633512) LSCI and ICG-FA signals are displayed in several modes: overlay, where the signal is overlaid on standard RGB video, and contrast, where the signal is displayed without RGB video (Figs. 1 and 2).

Forty patients age ≥ 18 years undergoing elective colectomy with anastomosis ($n = 17$), Roux-en-Y gastric bypass (RNYGB, $n = 13$), and sleeve gastrectomy ($n = 10$) were enrolled. Patients were 30% male, aged 53.8 ± 15.79 years, BMI 38.09 ± 10.03 kg/m^2.

Perfusion was assessed: colectomy – 1) after devascularization, before proximal division, 2) pre- and

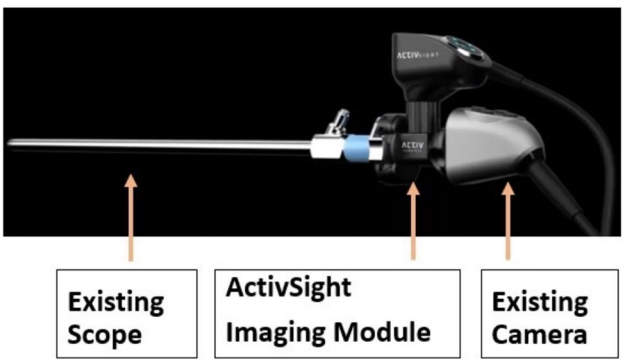

Fig. 1 ActivSight™ between a standard camera and laparoscope

Clinical Trial Registration: ClinicalTrials.gov, NCT#04633512 (18/11/2020).

✉ Peter C. W. Kim
peter.kim@brownphysicians.org

1 Department of Surgery, Rhode Island Hospital, Warren Alpert Medical School of Brown University, Providence, RI, USA

2 Activ Surgical Inc., 30 Thomson Place, 2nd Floor, Boston, MA 02127, USA

3 Jacobs School of Medicine and Biomedical Sciences, The State University of New York, Buffalo, NY, USA

4 Department of Surgery, The State University of New York, Buffalo, NY, USA

5 Buffalo General Hospital, Buffalo, NY, USA

6 Division of Minimally Invasive and Elective General Surgery, Department of Surgery, McGovern Medical School, University of Texas Health Science Center at Houston, Houston, TX, USA

7 Michael E. DeBakey Institute for Comparative Cardiovascular Science and Biomedical Devices, Texas A&M University, College Station, TX, USA

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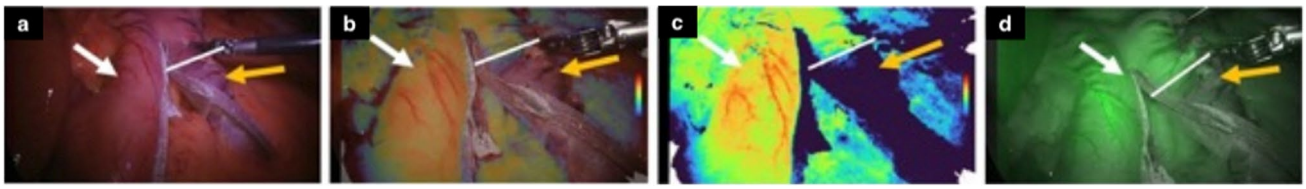

Fig. 2 Representative perfusion assessment: sleeve gastrectomy. Well-perfused remnant (white arrow), devascularized stomach (yellow arrow), perfusion margin (white line) **a.** WLI. **b.** ActivPerfusion™ overlay and **c.** contrast modes; **d.** ActivICG™

post-anastomosis; RNYGB—pouch after 1) creation, 2) gastrojejunal and jejunojejunal anastomoses; sleeve gastrectomy – after partial and complete gastric transection. Surgeons identified the line of demarcation (LOD) using white light imaging (WLI), ICG-FA, and LSCI. Surgeon ICG ingress indication was the benchmark. LSCI concordance with ICG ≤ 2 min after injection was measured.

The primary outcome was safety—the absence of device-related adverse events. Secondary outcomes included feasibility, usability, and accuracy reported by surgeons. This study was performed in accordance with the Declaration of Helsinki. This human study was approved by University of Texas Health Science Center at Houston, Houston, Texas, USA—approval: #20–0967; and University at Buffalo, The State University of New York, Buffalo, New York, USA – approval: #20–003. The study's clinical trial registration number is NCT04633512 registered with ClinicalTrials.gov. Participant registration took place from 11/17/2020 – 11/17/2022. All adult participants provided written informed consent to participate in this study.

Results

LSCI was concordant with ICG-FA on initial injection but more accurate on repeat assessments. LSCI latency averaged ≤ 150 ms and ICG-FA 31.95 s ($p < 0.0001$). Human factor 5-point scale evaluation ($n = 22$ surgeons) demonstrated good display quality (4.07 ± 0.86), form factor (3.82 ± 1.57), and ease of setup (4.26 ± 0.85).

In colorectal and bariatric cases, LSCI identified the same perfusion boundaries as ICG-FA. Anastomoses and gastric remnants appeared well perfused in LSCI and ICG-FA. There were no adverse events.

Discussion

The use of LSCI for real-time tissue perfusion assessment in MIS procedures demonstrated safety with no complications or adverse events. LSCI showed more spatio-temporal accuracy than ICG-FA and more precision on repeat assessments. Surgeons noted false-positive ICG fluorescence in non-perfused tissue distal to perfused tissue, likely due to capillary leakage.[3] Because LSCI uses erythrocyte movement, not a fluorophore, accuracy is unaffected by multiple assessments.

Limitations of this safety and feasibility study include no control group for comparison of outcomes, and case heterogeneity.

Conclusions

The dual-mode LSCI and ICG-FA imaging device is safe and usable in MIS with the added benefit of dye-less, accurate, real-time, continuous assessment of tissue perfusion.

Author Contributions C Nwaiwu: project development, data collection, data analysis, manuscript writing/editing.

C McCulloh: project development, data analysis, manuscript writing/editing.

G Skinner: project development, data collection, data analysis, manuscript writing/editing.

S Shah: project development, data collection, manuscript writing/editing.

P Kim: protocol/project development, data collection, data analysis, manuscript writing/editing.

S Schwaitzberg: protocol/project development, data collection, manuscript writing/editing.

E Wilson: protocol/project development, data collection, manuscript writing/editing.

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Data Availability The data that support the findings of this study are available from the corresponding author, PCWK, upon reasonable request.

Declarations

Competing Interests CAN: former research resident at Activ Surgical. CJM, PCWK: current employee of Activ Surgical. GCS: current contractor for Activ Surgical. SKS, EBW, and SDS: consultants of Activ Surgical.

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