Aiming for zero anastomotic leaks: a hyperspectral laparoscope enables quantitative intraoperative visualisation of bowel oxygenation during surgery

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UNMET CLINICAL NEED

There is a need for new technologies to provide real-time label-free quantitative tissue oxygenation assessments intraoperatively.

Background

- **Anastomotic leak (AL)** is a common and devastating complication of bowel anastomoses.
- While the causes are multifactorial, **adequate blood supply is a key component to avoid AL.**
- Intraoperative quantitative visualisation of oxygenation can influence surgical assessment and decision-making, but current methods rely on fluorescent dyes, generally without continuous or quantitative oxygenation assessment.
- A precise tool that does not rely on dyes for perfusion assessment is needed.

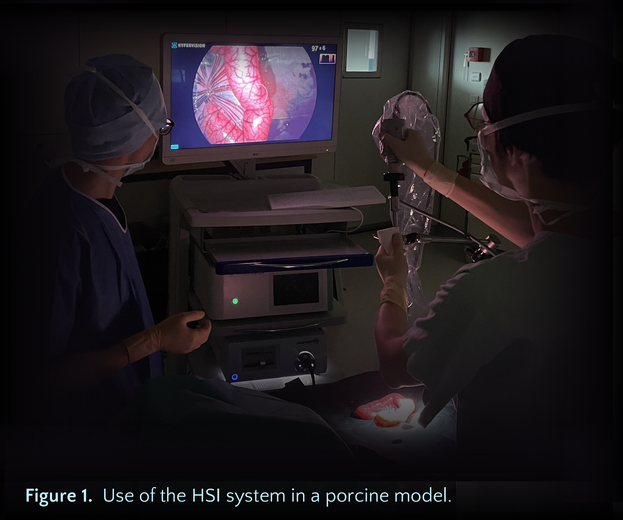


Figure 1. Use of the HSI system in a porcine model.

Methods

- A compact hand-held **hyperspectral imaging (HSI)** system (HYPERSNAP® Surgical System, Hypervision Surgical Ltd.) was evaluated in an *in vivo* porcine model (n=3).
- The minimally invasive HSI system simultaneously provides conventional **high resolution colour images and continuous quantitative widefield superficial tissue oxygenation (StO_2) maps** in real time.
- To demonstrate accuracy, **paired measurements of StO_2 were acquired using an FDA-cleared oxygenation probe and the HSI system.** Agreement was assessed using Bland-Altman analysis. Ischaemic and borderline ischemic regions were created by temporarily occluding vessels supplying pre-identified bowel region **(Figures 1 and 2).**
- To demonstrate repeatability, multiple measurements were made for the same tissue location (test-retest) and a predefined range of working distances.

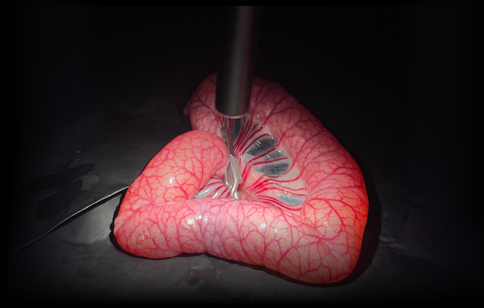


Figure 2. An externalised small bowel loop with a clamped section of the mesentery inducing a hypoperfused area.

Results

- **Quantitative measurements of StO_2** made with the HSI system agree with those made with the oxygenation probe **(Figure 3).**

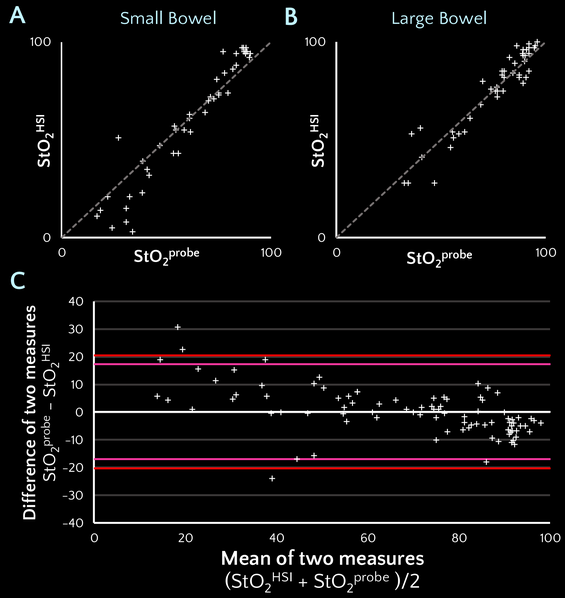


Figure 3. Measurements of StO_2 made using the HSI system and the FDA-cleared oxygenation probe agreed in **(A)** small and **(B)** large bowel tissue (results pooled across n=3 test subjects). **(C)** Bland-Altman plot of differences shows agreement. Pink lines are upper and lower 95% LOAs. Red lines are uppermost and lowermost 95% CIs of 95% LOAs.

- **Measurements were repeatable** on test re-test (SD≤1.5, X^2 test of variance $p<0.001$) and at working distances 2–9 cm (SD≤2.8, X^2 $p<0.03$, **Figure 4**).

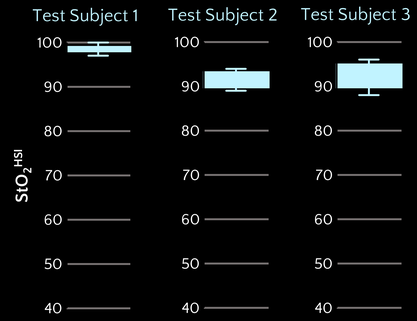


Figure 4. Boxplot showing the assessment of consistency of StO_2 values over repeat measurements with the HSI system at different working distances for the same region of tissue for each of three test subjects (n=10 repeats per subject), demonstrating the precision of StO_2 quantification of the HSI system, in terms of repeatability for the same region of tissue at different working distances.

Conclusions

HSI has the potential to reduce anastomotic complications by providing **label-free quantitative tissue oxygenation assessment in real time, highlighting changes during surgery.** The study demonstrates successful preclinical *in vivo* validation of the accuracy, precision, and efficacy, laying the foundation for first-in-human trials.