

Snapshot₂^{NIR}

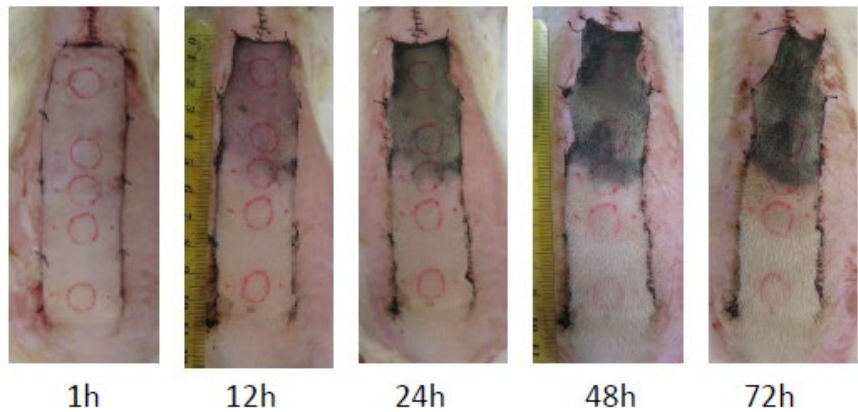
Advancing Tissue Assessment

A comparison of imaging technologies in predicting tissue viability^{1,2}

How well can outcome be predicted?

Based on the premise that informed assessment of tissue viability is critical to positive outcomes in cosmetic and reconstructive procedures, Dr. Glyn Jones, MD and colleagues compared the accuracy of two imaging methods to predict outcome:

1. Indocyanine green (ICG) laser fluorescence angiography – a widely used yet costly imaging technique requiring the injection of dye for image capture
 - Assesses local tissue perfusion
2. Snapshot_{NIR}, a novel, completely non-invasive imaging method using near infrared spectroscopy (NIRS)
 - Evaluates oxygen delivery and usage in the microvasculature through the measurement of oxyhemoglobin and deoxyhemoglobin values obtained via NIR reflectance
 - Captures local mixed venous/arterial oxygen saturation in the capillary bed within the area of measurement (S_tO_2)

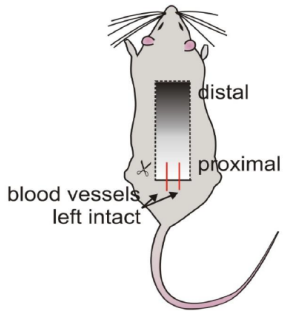


The aim of the study was to use imaging techniques immediately following surgery and 30-minutes post-op to predict 72-hour tissue viability. With confidence in prediction of skin flap survival, physicians will be better situated to make real time critical treatment decisions that impact both patient outcome and costs.

¹Jones, G. et al. *Snapshot multispectral imaging is not inferior to SPY laser fluorescence imaging when predicting murine flap necrosis*. *Plast Reconstr Surg*. 2020; 145(1): 85e-93e.

²Data on file.

Study Design



The reverse McFarlane skin flap model on nine rats was used to compare the accuracy of both imaging methods. The McFarlane flap is a pedicled flap and is widely accepted as a model for evaluating post-surgical tissue viability.

Digital color images of the flap were taken immediately before and after surgery, and again at 72 hours post surgery. This final digital color picture served as the outcome image for assessment.

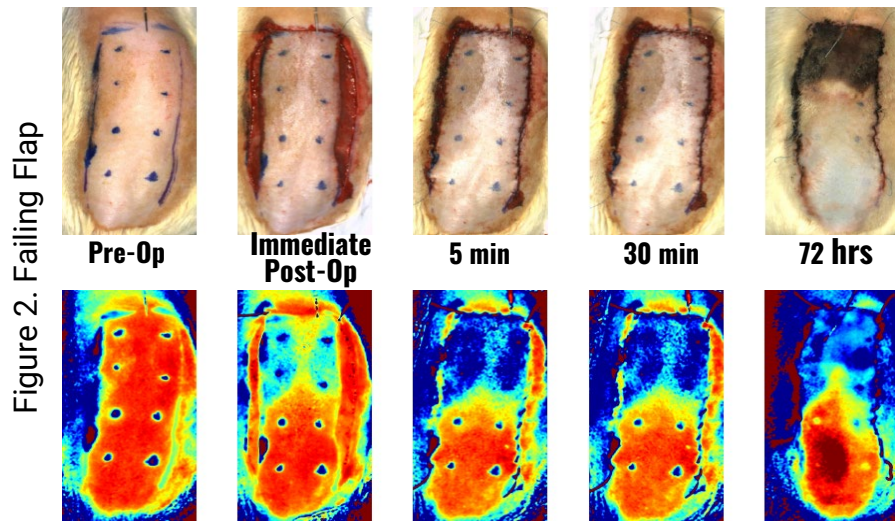
In this study, both ICG angiography and NIRS (Snapshot_{NIR}) images were captured at three time points:

1. Pre-surgery,
2. Immediately post-surgery; and
3. 30 minutes post-surgery.

Additionally, Snapshot_{NIR} images were captured at 2- and 5-minutes post-surgery as the technology, unlike ICG angiography, can perform rapid serial imaging.

The early post-surgery images were compared against clinical outcome digital color images taken at 72 hours post-op to determine which method more accurately predicted flap necrosis, as assessed by three (3) independent clinical evaluators blinded to the images.

Observations

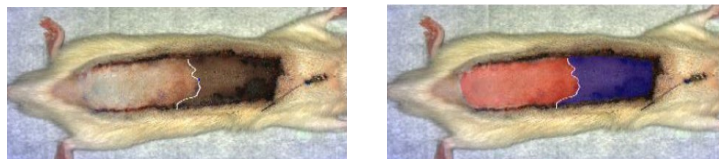


With visual inspection in the early post-operative period it can be difficult to assess the health of the flap. Figure 2 illustrates that Snapshot_{NIR} detects the rapid hemoglobin oxygen desaturation at the distal end of the flap. As observed in the series of S_tO₂ images, oxygenation at the distal end of the flap at 5 minutes post-op is critically low and remains so at 30 minutes post-op. Distal end necrosis of the flap could be inferred based on the 5 min post-op S_tO₂ image.

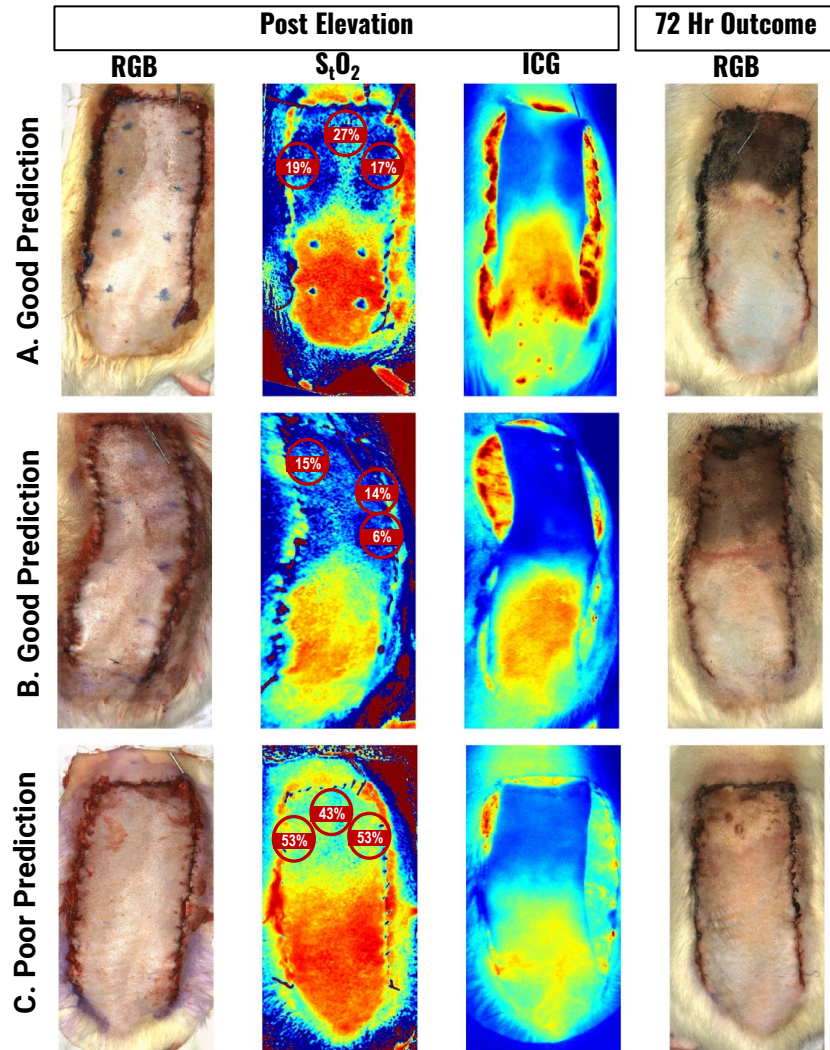
Early prediction of flap outcome allows the surgeon to make timely decisions regarding course of action.

Evaluation

Digital color pictures of the flap taken 72 hours after surgery (the outcome image) were independently reviewed by 3 experienced surgeons blinded to the ICG and S_tO₂ images. Each evaluator drew lines demarking the viable and necrotic zones of the flap. The ability of S_tO₂ & ICG post-op imaging to predict these zones was determined.



Predicting Necrosis Examples of good and poor predictions



Both ICG and S_tO₂ images captured immediately following the surgery indicate a challenged distal zone. The NIRS images display S_tO₂ percentage whereas the ICG images show a measure of fluorescence with an arbitrary value. In image sets A and B, both imaging techniques illustrate a similar pattern 30 minutes post-op, predicting likely distal failure at 72-hours. The flap outcome at 72 hours post-op clearly shows distal end necrosis in those cases. In image set C, ICG images show a lack of perfusion to the distal zone of the flap whereas the S_tO₂ image illustrates compromised S_tO₂ but not critically low oxygenation levels. The flap outcome at 72 hours post-op has little distal end necrosis. In the 9 rats studied, 2 had surviving flaps at 72 hours post-op.

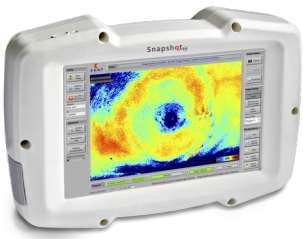
Evaluation Outcome

Sensitivity for Predicting Tissue Viability

*Specificity fixed at 90%

Predicting Tissue Viability 30 Minutes Post-Elevation Sensitivity (95% Confidence Intervals)*		
Evaluator	Snapshot _{NIR} NIRS	ICG Fluorescence Angiography
Average	86.3 – 91.0 %	79.1 – 86.9 %
1	82.1 – 86.0 %	71.1 – 75.5 %
2	81.6 – 85.4 %	70.6 – 75.2 %
3	86.7 – 90.1 %	79.3 – 85.6 %

For each evaluator, Snapshot_{NIR} S_tO₂ values had greater sensitivity than ICG in predicting 72-hour tissue necrosis.



Snapshot₂^{NIR}

Advancing Tissue Assessment

Integrating Snapshot_{NIR} Into Reconstructive Surgery

"Understanding mastectomy skin flap blood flow is critical in the reducing complications. Having used ICG-based technology for skin flap perfusion assessment for over a decade, I have switched to Snapshot_{NIR}. It provides reliable, non-invasive, immediate tissue oxygenation assessment in a compact, highly affordable, hand-held device without the need for disposables or IV access."

**Dr. Glyn Jones MD,
Cosmetic & Plastic Surgery**

"Snapshot_{NIR} has helped our team to evaluate flaps throughout the entire care continuum: pre-operative planning, perforator identification, flap design, and post-operative monitoring on the OR floor and in the office."

**Dr. C. Rammos, MD
PSG Plastic Surgery**

Dr. Jones and Dr. Elwood of Cosmetic & Plastic Surgery of Illinois and Dr. Rammos of PSG Plastic Surgery share their experience implementing Snapshot_{NIR} into their practices. Snapshot_{NIR} provides the ability to assess oxygen delivery and usage in the micro-vasculature. They have successfully integrated Snapshot_{NIR} into their regular surgical protocol for various procedures including breast reconstruction.

- **Cost-effective.** Snapshot_{NIR} is sensibly priced with no required consumables and can be used at all stages of their patients' care with no additional fees
- **Immediate information** to determine preoperative plan, make decisive intraoperative surgical decisions and monitor flaps, and document healing postoperatively. The enhanced practice workflow supports delivery of better patient outcomes
- **Speed of capture and ease of image interpretation** with Snapshot_{NIR} are favored features, especially when assessing tissue viability intraoperatively. In the PACU and on the floor, staff can capture images quickly with minimal disruption to the patient's care
- **Case times have been shortened** noticeably. Snapshot_{NIR} images are captured and displayed in ~5s, with no limitation on the number of images captured
- In clinic, surgeons and staff will confirm any suspicions of concerning tissue using Snapshot_{NIR}

"With the advantages of non-invasiveness, portability, affordability, and lack of disposables, multispectral reflectance imaging with Snapshot_{NIR} has an exciting potential for widespread use in cosmetic and reconstructive procedures."¹, p.92e