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Intraoperative Near-infrared Spectroscopy Can Predict Skin Flap Necrosis

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Background: The study aimed to validate the previously identified capacity of near-infrared spectroscopy (NIRS) to detect clinically relevant differences in tissue perfusion intraoperatively.

Methods: Consecutive patients undergoing oncologic resection requiring flap reconstruction were analyzed. Clinicians were blinded to tissue oxygen saturation (StO_2) measurements taken intraoperatively. Measurements were taken at (1) control areas not affected by the procedure, (2) areas at risk of necrosis based on distal location, and (3) areas of skin flap necrosis (SFN) identified during the follow-up period. Mean StO_2 values were compared using a single-sample *t* test and analysis of variance (ANOVA) to determine differences in oxygenation.

Results: There were 102 patients included from April 2018 to May 2019. Reconstruction was undertaken following resection for breast cancer (46), melanoma (35), sarcoma (9), and other cutaneous malignancies (12). Breast reconstruction involved 38 alloplastic reconstructions and eight autologous free flaps. Other skin flap reconstruction involved 42 local/regional skin flaps, 13 pedicled flaps, and one free flap. Eighteen patients (17.6%) developed SFN. Mean intraoperative StO_2 measurements for control areas, areas at risk, and areas of SFN were 74.8%, 70.9%, and 54.3%, respectively. StO_2 values equal to or less than 60% were highly specific (96%) for SFN, whereas StO_2 values above 85% were highly sensitive (96%) to rule out SFN.

Conclusion: These results further support the use of NIRS to objectively assess variations in skin flap oxygenation and tissue perfusion that are correlated with the development of postoperative SFN. *(Plast Reconstr Surg Glob Open 2024; 12:e5669; doi: 10.1097/GOX.0000000000005669; Published online 26 March 2024.)*

INTRODUCTION

In reconstructive surgery, understanding and assessing tissue perfusion and viability is central to the discipline. Unfortunately, even with meticulous planning, careful tissue handling, and clinical experience, skin-flap necrosis (SFN) occurs in 19%–30% of patients undergoing breast reconstruction.[1,2] Historically, intraoperative clinical evaluation has been relied upon to predict SFN, and areas are debrided if SFN is expected. Clinical assessment uses subjective parameters, including tissue color, temperature, the extent of dermal bleeding, and capillary refill to predict tissue viability and inform intraoperative decision-making. Although various technologies exist to enhance the clinical assessment of tissue viability, such as SPY (SPY-Elite Fluorescence Imaging System, Life- Cell Corp., Branchburg, N.J.) and others, concerns with their efficacy, cost, and feasibility persist.[3,4]

Near-infrared spectroscopy (NIRS) is an efficacious, convenient, and cost-effective technology to assist in the intraoperative assessment of tissue perfusion. The Kent KD203 SnapshotNIR (Kent Imaging Inc, Calgary, AB, Canada) device has harnessed NIRS in a hand-held device that noninvasively measures tissue oxygen saturation (StO_2). Due to its portability, this device can be easily incorporated into the surgical workflow. This is in contrast to other modalities using indocyanine green-angiography that utilize large and expensive equipment and rely on recurring disposables and injectables that increase costs and invasiveness.[5]

Intraoperative NIRS has shown promise, and in our earlier proof of concept pilot study of 42 patients, intraoperative measures correlated with SFN in the postoperative period.[6] This larger study, including the original cohort

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Table 1. Patient Demographics, Comorbidities and Outcomes (N = 102)

Demographics	
Age (range)	56.2 (25–87)
Female (%)	67 (66%)
Weight (kg)	79.7 kg
Oncologic diagnoses	
Breast cancer	46
Melanoma	35
SCC/BCC	8
Sarcoma	9
Other	4
Comorbidities	
Actively smoking	7
Smoking history	27
Diabetes	12
Radiation	19
Chemotherapy	27
Hypertension	23
Outcomes and complications	
Infection	14
Dehiscence	7
Seroma	18
Hematoma	1
Implant failure	1
Total flap failure	1
Skin necrosis	18
Mortality	0

and expanding the numbers of patients and types of flaps, is designed to validate the previously identified capacity of NIRS to detect clinically relevant differences in tissue perfusion intraoperatively, and help narrow down cutoff points of perfusion that are reassuring and those that require intervention.

METHODS

Patients

Institutional ethics board approval was obtained (HREBA.CC-18-0154) to recruit consecutive patients undergoing oncologic resection and flap reconstruction (local, regional, or free) from April 2018 to May 2019. Creation of a mastectomy flap was included in this analysis for alloplastic breast reconstruction. Consent was obtained from all patients including consent for photography. All flaps were imaged intraoperatively after wound closure using NIRS by a research coordinator. The surgical team was blinded to the device measurements taken, and intraoperative decisions regarding tissue viability were based solely on traditional clinical criteria. NIRS StO_2 measurements were also taken postoperatively at follow-up appointments, with final measurements at 4 weeks.

Patient demographics, oncologic diagnosis, comorbidities, wound healing risk factors, and operative procedures were recorded (Table 1). Patients were followed up for a minimum of 30 days postoperatively to ensure all cases of skin necrosis were included, and the areas of necrosis were well demarcated. In the cases of skin necrosis, wounds were treated by standard wound care principles, including local wound care or surgical debridement if required.

Takeaways

Question: What is the capacity of near-infrared spectroscopy to detect clinically relevant differences in tissue perfusion? What measurements are reassuring, and which suggest ischemia?

Findings: There were 102 patients undergoing oncologic resection with flap reconstruction. Clinicians were blinded to device tissue oxygen saturation (StO_2) measurements taken intraoperatively. These were correlated to postoperative skin flap necrosis (SFN). SFN occurred in 18 patients. Intraoperative StO_2 values less than 61% were specific (96%) for SFN, and values above 85% were sensitive (96%) to rule out SFN.

Meaning: These results support the use of near-infrared spectroscopy to objectively assess variations in skin flap oxygenation and tissue perfusion.

EVALUATION AND PROCESSING OF IMAGING

The protocol for imaging, processing and evaluation of postoperative imaging and intraoperative NIRS has been previously described.[6] The Kent system was used to measure StO_2 intraoperatively of skin flaps (Fig. 1).

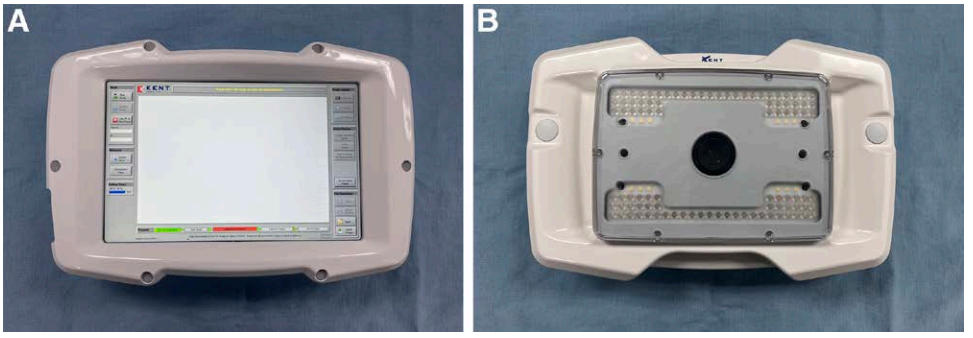

Fig. 1. The Kent system (KD203 SnapshotNIR, Kent Imaging Inc, Calgary, AB, Canada) used to measure StO_2 intraoperatively and in the postoperative period. A, Frontal view of system. B, Rear view.

Anonymized color pictures of the surgical sites taken during follow-up appointments were presented to two blinded evaluators (C.T.O., W.F.H.) who stratified anatomic zones of skin as (1) control areas, (2) areas at risk of necrosis, and (3) areas of skin necrosis. These anatomic zones identified on the follow-up color images were transposed onto intraoperative NIRS imaging taken after wound closure by the same assessors.

STATISTICAL ANALYSIS

Twenty random pixels representing distinct StO_2 measurements from each zone identified on the intraoperative StO_2 measurements after wound closure were extracted and separated. The mean StO_2 values and corresponding 95% confidence intervals were determined for each of the anatomic zones. Intraoperative StO_2 measurements were analyzed by calculating the difference between both areas at risk and areas of necrosis relative to control areas. Areas of necrosis were subsequently compared with areas at risk as well. A subgroup analysis of patients who developed SFN was performed to determine the sensitivity and specificity of intraoperative NIRS. A P value less than 0.05 was considered statistically significant.

RESULTS

Patient Data

In total, 102 patients were enrolled in the study, of whom 67 were women (66%). Patients' average age was 56 years (25–87 years) and with a mean weight of 79.7 kg (49.9–150.0 kg). Patient comorbidities included seven active smokers, 27 previous smokers, 12 with diabetes, 19 with previous radiotherapy, 27 having undergone chemotherapy, and 23 with hypertension. Oncologic reconstruction involved defects resulting from breast cancer (46), melanoma (35), sarcoma (9), and other cutaneous malignancies (12).

Flap Data

Breast reconstruction involved 38 alloplastic reconstructions and eight free flaps. Other skin flap reconstruction involved 42 local/regional skin flaps, 13 pedicled flaps, and one free flap.

Flap Necrosis

There were 18 patients (17.6%) with areas of skin flap necrosis (SFN). In patients with SFN, the average age was 56 years (25–87 years), patients' mean weight was 84.1 kg (52.2–150kg), and there were 13 women (72%). Patients actively smoking had a rate of SFN of 28.6% ($P = 0.51$).

StO_2 Data

Mean intraoperative StO_2 measurements for control areas, areas at risk, and areas of SFN were 74.8%, 70.9%, and 54.3%, respectively. Relative to control areas, mean intraoperative StO_2 measurements were lower by 20.6% ($P < 0.001$) in ultimate areas of SFN, whereas areas at risk were lower by 4.0% ($P = 0.14$). Relative to areas at risk, mean StO_2 measurements from areas of ultimate SFN were lower by 16.6% ($P < 0.001$).

A subgroup analysis of patients with SFN was performed comparing StO_2 measurements for areas of necrosis to control areas. Using the intersection point of 72.5% StO_2 to predict SFN, there was a sensitivity of 86% and specificity of 86%. An StO_2 measurement of 60% or less strongly predicted SFN with 95% positive predictive value and 96% specificity. An StO_2 measurement of 85% or greater had an 89% negative predictive value and was 96% sensitive to predict viability (Fig. 2).

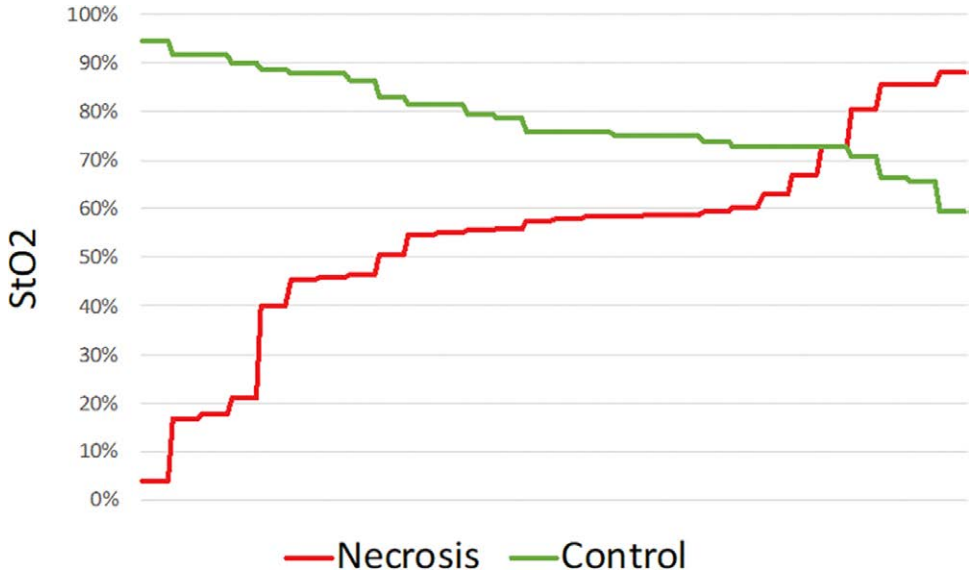

Fig. 2. Subgroup analysis of patients who developed SFN (n = 18) comparing intraoperative StO_2 measurements of regions that ultimately necrose to control regions. StO_2 values less than 60% (red zone) is predictive of necrosis, whereas measurements above 85% (green zone) can rule out skin flap necrosis.

DISCUSSION

The intraoperative clinical assessment of skin flap viability is not always accurate, and thus, technological adjuncts can help guide clinicians.[7] Intraoperative NIRS has shown promise in our earlier pilot study in correlating with SFN,[6] a finding repeated in a variety of clinical scenarios.[1,2,7–10]

Since the first description of NIRS by Jobsis in 1977 for monitoring cerebral and myocardial perfusion, NIRS has been shown to be a safe and reliable modality for flap monitoring in preclinical and clinical studies.[11] In mouse models, it has been showed that NIRS detected early ischemic changes and may predict the extent of flap necrosis.[8] Subsequently, NIRS measurements were shown to correlate with pedicle occlusion in a rat model.[12] NIRS has been reported to have a positive and negative predictive value of 100% for detecting early flap failure.[13] Moubayed et al found that compared with clinical examination, NIRS had a salvage rate in compromised flaps of 85% versus 61.5%. NIRS has been shown to be applicable in various clinical situations for detecting flap ischemia.[14]

The results of this prospective cohort study further validates the use of NIRS intraoperatively to predict postoperative SFN or viability. There were stark differences in StO_2 measurements for areas of necrosis compared with control and at-risk areas. The impact of this study is to further characterize parameters to guide surgeons and clinicians using NIRS. It was found that StO_2 measurements less than or equal to 60% were predictive of SFN, and consideration to perform debridement or other intervention should be taken. For instance, if the skin edges in a skin-sparing mastectomy/direct to implant reconstruction had StO_2 values under 60%, the clinician could consider replacement with a tissue expander to decrease volume, and could trim the skin edges back to better StO_2 levels. On the other hand, with StO_2 measurements above 85%, SFN can reliably be ruled out, giving the clinician an additional indicator beyond clinical examination, that the tissue was adequately perfused.

In the intermediate perfusion zone (between 60% and 85%) further thought is required. The midway point of this zone at StO_2values of 72.5% has a sensitivity of 86% and specificity of 86% for predicting SFN. This would suggest that for skin flaps with StO_2 measurements below 72.5% and above 60%, perfusion has been compromised but may still be salvageable with adjuncts such as hyperbaric oxygen,[15] topical vasodilators,[16,17] negative pressure dressings,[18] and avoidance of additional insults such as compressive dressings, smoking, pressure, hypoxia, and hypotension.[19,20]

This study has limitations. The generalizability of this oncologic reconstructive patient population of a single surgeon may not be applicable to other clinical scenarios, although the oncologic resections and mastectomies were done by a number of different oncologic surgeons. The total of 102 patients in this study may not be sufficient to draw definitive conclusions regarding the StO_2 parameters to rely on, particularly as only 18 patients developed SFN. Additionally, the relatively limited number of patients who developed SFN precluded any subgroup analysis. The patients were also mainly White based on the population presenting, with patients with darker skin tones representing only 3% of the cohort. This limits the generalizability of this technology to other races where melanin pigment may alter the readings on this device. Differences in experience, reconstructive approach, flap selection and surgical technique may result in variable rates of SFN between different surgeons that would not be captured in this study. The use of NIRS intraoperatively may be limited in its ability to predict SFN, as the development of this can be multifactorial and contributed to by postoperative insults such as the tension of closure, edema formation, smoking, pressure necrosis, and systemic derangements such as hypotension.

In summary, this study further supports the usefulness of NIRS intraoperatively to predict SFN. Based on these results, StO_2 values below 60% are predictive of SFN, whereas values above 85% are likely to survive. The use of NIRS intraoperatively to augment the clinical examination of tissue perfusion can help guide management. Future directions of this application would be to identify areas of hypoperfusion intraoperatively that could be debrided before flap inset, to decrease the incidence of this complication.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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