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Breast

A Prospective Study to Evaluate the SPY-QP Software for Intraoperative Perfusion Assessment in Breast Reconstruction

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Background: Laser-assisted indocyanine green angiography image quantification programs have been developed to guide the resection of ischemic tissue, but prior iterations have proved difficult to interpret. This study assesses outcomes using SPY-QP, a novel quantification algorithm of the SPY Portable Handheld Imaging system (Stryker Corporation).

Methods: A prospective study was designed to enroll patients who underwent breast reconstruction with implant-based or autologous techniques. A prospective database of patient demographics, operative details, and outcomes at 2-week, 1-month, and 3-month follow-ups were maintained. Postoperative skin necrosis, fat necrosis, and infection, among other metrics, were correlated with indocyanine green angiography relative values (%). Logistic regressions were conducted using R-Studio.

Results: Overall, 39 patients and 59 breasts were included in this study. Forty-nine (83.5%) breasts underwent implant-based reconstruction, whereas 10 (17.0%) were reconstructed with autologous tissue. Five (12.8%) patients had evidence of skin necrosis, 6 (15.4%) of fat necrosis, and 9 (23.1%) of postoperative infection. Of the patients with skin necrosis, 2 (40%) patients underwent local wound care, 2 (40%) patients required bedside debridement, and 1 (20%) patient required an operative debridement. Mean relative values were significantly lower in patients with skin necrosis in comparison to patients without skin necrosis (14.6%±12.4% versus 24.4%±13.4%, $P < 0.05$). For cutoff analysis, a 10% cutoff maximizes specificity, whereas a 36% cutoff maximizes sensitivity in this cohort.

Conclusions: The SPY-QP technology is highly specific at low values and can effectively guide surgeons in the resection of ischemic tissue. Conversely, it remains challenging to predict necrosis in gray zones. *(Plast Reconstr Surg Glob Open 2025;13:e6758; doi: 10.1097/GOX.0000000000006758; Published online 5 May 2025.)*

INTRODUCTION

Laser-assisted indocyanine green angiography (ICGa) is a technology that characterizes tissue perfusion in real time, affording surgeons critical insights that minimize complications for a variety of surgical procedures.[1] Indocyanine green is a fluorescent, nontoxic agent with a short half-life that can be injected intravenously and detected with near-infrared spectroscopy.[1] Using a variety of receivers, surgeons have utilized this technology to visualize perfusion in tissues prone to ischemia, including in the assessment of bowel perfusion, mastectomy flap perfusion, and free tissue transfer ischemia, among other applications.[2–5]

In breast reconstruction, ICGa has been adopted broadly and has been shown to decrease complications in both implant-based and autologous breast reconstruction in comparison to fluorescein angiography or clinical assessment alone.[4,6] Most surgeons use the technology without quantitative analysis, relying on their qualitative appraisal of tissue perfusion to help them resect areas

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of ischemia. Attempts at developing quantitative metrics have proved valuable but difficult to reliably implement due to issues with reliability and interpretability.[4,7,8] A more recent innovation in quantitative analysis called SPY-QP (Stryker Corporation) has been developed. This program provides relative fluorescence units on a 100-point percentage scale using a user-friendly, portable receiver called the SPY Portable Handheld Imaging (SPY-PHI) system. Few studies have utilized the SPY-PHI and SPY-QP in the assessment of tissue viability, and notably, cutoff values for resection of ischemic tissue are arbitrary.[9,10] This prospective study was designed to evaluate the use of SPY-QP in breast reconstruction and develop an outcomes-driven cutoff for this program.

Takeaways

Question: How does the SPY-QP software perform at the assessment of intraoperative perfusion during implant-based and autologous breast reconstruction?

Findings: This is a single-institution, single-surgeon prospective 39-patient series that examines SPY-QP use during breast reconstruction. At low values, the SPY-QP is highly specific in predicting skin necrosis. It is less effective at predicting fat necrosis or infectious complications.

Meaning: The SPY-QP software is valuable and specific at identifying ischemic skin that can lead to necrosis at very low values, but there exists a gray zone that requires operator intraoperative decision-making. A decision-making framework is provided herein.

METHODS

Study Design

A prospective single-institution study was designed to correlate intraoperative angiography with outcomes following breast reconstruction using SPY-QP, which is a built-in software that is programmed into the SPY-PHI system. The trial received institutional review board approval before recruitment. Inclusion criteria included patients older than 18 years of age undergoing implant-based or autologous reconstruction. Exclusion criteria included current tobacco smoking status, active immunosuppression, intolerance to indocyanine green dye or fluorescein, or an inability to provide informed consent. Nicotine testing was not performed during enrollment.

SPY-PHI consists of an open-field handheld imaging head (with an integrated light guide cable) and a video processor/illuminator. The SPY-QP software provides surgeons with real-time indicators of perfusion, utilizing a metric called a "relative value" (RV). The SPY-QP fluorescence assessment software detects and quantifies fluorescence as a percentage relative to a reference fluorescence point (SPY%).

SPY-QP Protocol

In this study, images were collected intraoperatively using the quantification software. (**See Video [online]**, which demonstrates the utilization of this technology.) The operator adjusted the imaging to near-infrared and then selected a baseline for maximal fluorescence in real time. Well-perfused tissue over the patient's sternum was set as the 100% perfused reference marker for the purposes of setting a reference range in prosthetic reconstruction and outside the zone of dissection for autologous reconstruction. The operator then compared surrounding tissue to that baseline using a designated square within the field of vision of the handheld camera. The RV metric was thereby calculated in real time as a percentage. A standardized protocol was designed by the research team to minimize bias and increase reliability. For prosthetic reconstructions, the mastectomy skin was evaluated using the SPY-QP protocol, whereas for autologous reconstructions, the flap skin was evaluated using the aforementioned protocol. For autologous reconstructions, the mastectomy skin was not evaluated. In delayed reconstructions, a similar protocol was adopted depending on whether the reconstruction was prosthetic-based or autologous. Necrosis was only evaluated for tissue that had been evaluated using the SPY technology.

Operative Technique

Patients underwent mastectomy by 1 of 6 breast surgeons, followed by reconstruction by the senior author. No tumescence, local anesthetic, or epinephrine-containing injections were used before or during surgery. In prosthetic cases, an integrated port tissue expander with or without the use of acellular dermal matrix was used for reconstruction. After hemostasis, laparotomy sponges were placed in the mastectomy pocket to simulate skin stretch related to placement of a filled tissue expander. All tissue expanders were placed in a prepectoral position with anterior coverage with acellular dermal matrix. The skin was temporarily closed with staples, and the aforementioned SPY-QP protocol was initiated. After placement of tissue expanders, they are filled with 100–200 mL of air depending on the degree of skin redundancy. In autologous cases, the deep inferior epigastric perforator flap was isolated on its pedicle, and the SPY-QP protocol was initiated before rendering the flap ischemic. The SPY-QP protocol was completed once for every case. Timing of the protocol in such a manner facilitated resection of ischemic tissue before a microsurgical anastomosis was initiated. The lowest SPY value noted after contouring the flap and resecting ischemic tissue was included for analysis. Before final closure, the wound edges were trimmed sharply to decrease the risk of traction-related necrosis. Operative dressings consisted of mupirocin ointment application to the incisions followed by a thin layer of nitroglycerin ointment application to mastectomy flaps in all cases. This was covered with clear dressings and left in place for 72 hours without reapplication.

Outcomes and Statistical Analysis

The primary outcome of this study was skin necrosis, which was classified based on previously published intervention-based criteria by Oleck et al.[11] Stage 1

Table 1. Patient Demographics

Variables	n (%)
Age, y, mean ± SD	54.0 ± 10.6
Race	
Black or African American	12 (30.0)
White	28 (70.0)
Ethnicity	
Non-Hispanic	40 (100.0)
BMI, kg/m^2, mean ± SD	26.8 ± 4.5
Neoadjuvant chemotherapy	5 (12.5)
Adjuvant chemotherapy	7 (17.5)
Radiation history	7 (17.5)
Smoking status	
Former smoker	11 (27.5)
Never smoker	29 (72.5)
Hypertension	8 (20.0)
Diabetes mellitus	3 (7.5)

BMI, body mass index.

necrosis was defined as necrosis requiring local wound care; stage 2 necrosis as necrosis requiring debridement at the bedside or in a procedure room; and stage 3 necrosis as necrosis requiring operative debridement. Secondary outcomes included fat necrosis, infection, seroma, hematoma, implant loss, reoperation, and readmission. Fat necrosis was defined as palpable nodules postoperatively based on physical examination. Infection was defined as any breast erythema or incisional purulence/abscess that required treatment with antibiotics or operative intervention. Logistic regressions were carried out to correlate RV percentages with skin necrosis, fat necrosis, and infectious complications. Metrics were correlated with SPY% on a 100-point scale. All statistical analysis was performed using R-studio (Boston, MA).

RESULTS

Demographics

In total, 39 patients and 59 breasts were included in this study. Patients had an average age of 54.0 ± 10.6 years and an average body mass index of 26.8 ± 4.5 kg/m^2. Skin-sparing (34, 57.6%), nipple-sparing (20, 33.9%), and simple (5, 8.5%) mastectomies were the most frequent oncological procedures performed. Most patients underwent immediate breast reconstruction (34, 87.1%). Tissue expanders were utilized for 49 breasts (83.0%), whereas autologous reconstruction was performed for 10 (17.0%) breasts. The tissue expander's initial fill was 220.3±79.4 mL of air, whereas the average harvested deep inferior epigastric perforator weight was 827.7 ± 195.7 g. A minority of patients received either neoadjuvant (5, 12.8%) or adjuvant (7, 17.9%) chemotherapy. Former smokers comprised 11 (28.2%) patients, and 7 (17.9%) patients underwent previous radiation therapy. Detailed demographic data can be found in Tables 1 and 2.

Outcomes

Five (12.8%) patients were noted to have developed skin necrosis. Of this cohort, skin necrosis was managed with local wound care for 3 (60%) patients, whereas 1 (20%) patient required bedside debridement and 1 (20%) underwent operative debridement. Fat necrosis was recognized in 6 (10%) patients. It was managed with observation in 3 (50%) patients and excisional debridement during revision surgery in 3 (50%) patients. Nine (15%) patients developed postoperative infections, treated with oral antibiotics in 2 (22%) patients, intravenous antibiotics in 7 (78%) patients, and tissue expander removal or exchange in 3 (33%) patients. Of the patients with implants removed, 2 (22%) patients subsequently had tissue expanders replaced after debridement and treatment with temporary placement of an instillation wound vac device. Seromas formed in 6 (10%) patients, all of whom were treated with clinic aspirations. Hematomas were reported in 3 (5%) patients with 2 (67%) patients requiring operative hematoma evacuation and 1 (33%) patient requiring serial aspirations. There were no patients with reported flap failures. Outcome data are reported in Table 3.

Table 2. Operative Details and Reconstructive Modalities

Variable	n (%)
Total patients	39
Indication for mastectomy	
Prophylactic	6 (15.4)
Oncological	33 (84.6)
Timing of breast reconstruction	
Delayed	6 (15.4)
Immediate	33 (84.6)
Total breasts	59
Mastectomy type	
Simple mastectomy	5 (8.5)
Nipple-sparing mastectomy	20 (33.9)
Skin-sparing mastectomy	34 (57.6)
Reconstructive modality	
Tissue expander	49 (83.0)
DIEP flap	10 (17.0)
Tissue expander initial fill, mL, air	220.3 ± 79.4
Average DIEP weight, g	827.7 ± 195.7

DIEP, deep inferior epigastric perforator.

Table 3. Outcomes and Complications

Variable	n (%)
Skin necrosis	5 (8.3)
Local wound care	3 (60)
In-office debridement	1 (20)
Operative debridement	1 (20)
Fat necrosis	6 (10)
Observation	3 (50)
Excision during revision	3 (50)
Postoperative infection	9 (15)
Requiring PO antibiotics only	2 (22)
Requiring IV antibiotics	7 (78)
Requiring removal/exchange of implant	3 (33)
Reconstructive salvage	2 (22)
Implant loss	1 (11)
Seroma	6 (10)
Hematoma	3 (5)
Flap failure	0 (0)
Total readmission	7 (12)
Total reoperation	5 (8)

IV, intravenous; PO, per os.

Table 4. Regression Analysis of Lowest SPY% Correlations With Selected Postoperative Complications

Outcomes	Total	Lowest SPY% (Mean ± SD)	*P*
All	59	32.7 ± 14.3	
Skin necrosis			
Necrosis	5	14.6 ± 12.4	0.0126*
No necrosis	54	34.4 ± 13.4	
Fat necrosis			
Necrosis	7	26.9 ± 11.8	0.252
No necrosis	52	33.5 ± 14.5	
Postoperative infection			
Infection	9	31.1 ± 6.2	0.97
No infection	50	32.7 ± 15.3	

*Statistical significance.

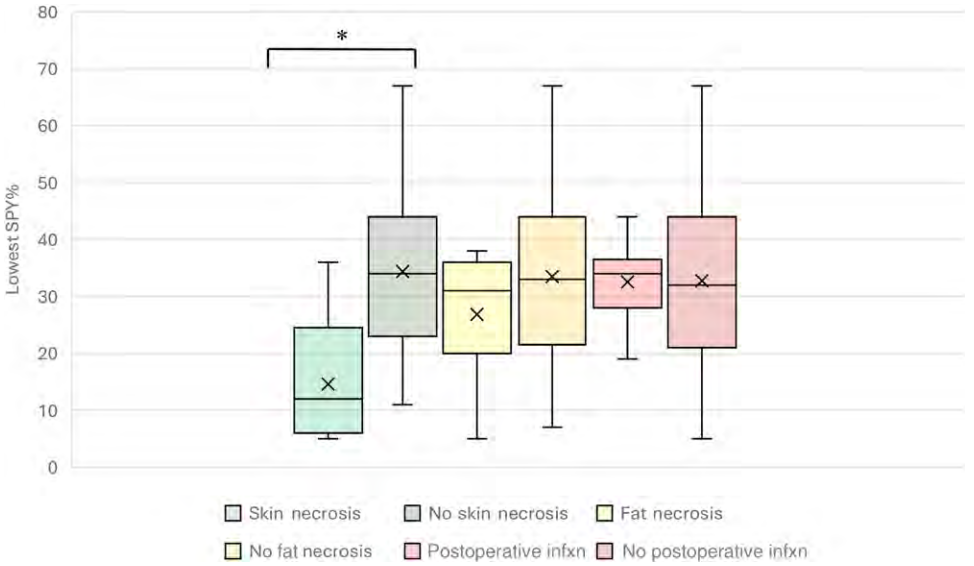


Fig. 1. this plot correlates lowest SPY% with different categories of skin necrosis, fat necrosis, and wound infections. * denotes statistical significance. "x" indicates the median; the straight line represents the mean. infxn, infection.

SPY Regression Analysis and Cutoff Analysis

A lower average SPY% was recorded in patients who experienced skin necrosis (14.6%±12.4%) in comparison to patients without skin necrosis (24.4%±13.4%). On regression analysis, the lowest SPY% was found to be a significant predictor of skin necrosis ($P < 0.05$). In patients with fat necrosis, the mean SPY% was 26.9%±11.8%, whereas patients without fat necrosis had similar readings of 33.5%±14.5%. SPY% was not significantly correlated with fat necrosis ($P > 0.05$). The mean SPY% for no infection was 31.1%±6.2%, whereas SPY% for infection was 32.7%±15.3%. These findings are delineated in Table 4. The maximum SPY% for skin necrosis was recorded at 36%, whereas the minimum SPY% was 5%. The maximum SPY% for fat necrosis was recorded at 38%, whereas the minimum SPY% was 5%. The maximum SPY% for postoperative infection was 44%, whereas the minimum SPY% was 19%. Figure 1 visually represents these findings, whereas Supplemental Digital Content 1 and 2 provide logistic regression graphs for fat necrosis and postoperative infection. (**See table, Supplemental Digital Content 1**, which displays the logistic regression curve of SPY versus fat necrosis, **http://links.lww.com/PRSGO/E18**.) (**See table, Supplemental Digital Content 2**, which displays the logistic regression curve of SPY versus infectious complications, **http://links.lww.com/PRSGO/E19**.)

To identify a threshold SPY value indicative of increased risk of skin necrosis, 5 percentages were considered: 10%, 15%, 20%, 30%, and 36%. This revealed that a cutoff value of 10% yielded a specificity of 100% and sensitivity of 40%, with 2 cases falling below 10% perfusion that both subsequently developed necrosis. Other percentages were assessed with findings reported in Table 5. A logistical regression was performed and is represented visually in Figure 2.

DISCUSSION

In this prospective analysis of the SPY-QP assessment software on outcomes after breast reconstruction, the lowest SPY% was significantly predictive of skin necrosis, which demonstrates the utility of this technology in identifying ischemic tissue. Meanwhile, fat necrosis and infection did not correlate with the lowest SPY%, suggesting that skin perfusion does not correlate with these outcomes. Cutoff evaluation revealed that a SPY% of 10 was specific for

Table 5. Sensitivity and Specific Ratios for Perfusion Readings Against the Incidence of Skin Necrosis

Lowest SPY, %	No Skin Necrosis, n	Skin Necrosis, n	Specificity	Sensitivity
≤10	0	2	100% (2/2)	40% (2/5)
≤15	3	4	57% (4/7)	80% (4/5)
≤20	8	4	33% (4/12)	80% (4/5)
≤30	22	4	15% (4/26)	80% (4/5)
≤36	32	5	13% (5/37)	100% (5/5)

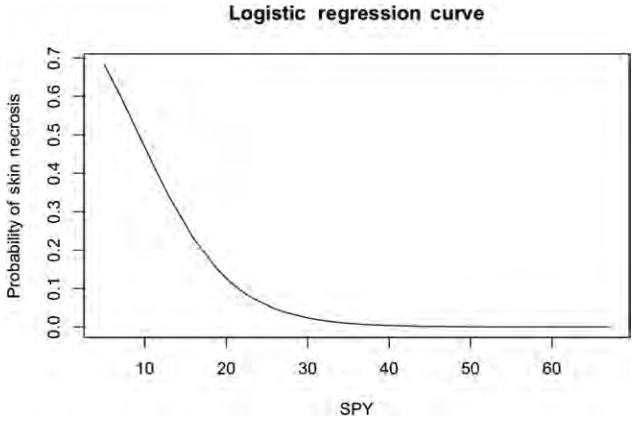


Fig. 2. t his graph represents a simulated logistic regression curve measuring the probability of skin necrosis against SPY% based on the data included in this study.

necrosis, whereas a SPY% of 36 was sensitive for necrosis. Overall, necrosis counts were low, but notably, the 2 cases of stage 2–3 necrosis that required debridement were in patients who underwent autologous reconstruction. We attribute this finding to the more liberal incorporation of ischemic tissue in autologous reconstruction, as skin necrosis can be managed more safely and effectively than in implant-based reconstruction. In addition, an evidence-based postoperative protocol has been implemented with implant-based reconstruction to decrease complication rates, including the liberal use of nitroglycerin ointment, initial tissue expander fill with air, and early postoperative follow-up.[12–15]

ICGa is a well-established adjunct to clinical judgment in the assessment of ischemic tissue, and a recent systematic review has shown that its use in breast reconstruction is significantly correlated with lower complications than when surgeons use clinical judgment alone (odds ratios of 0.54 for skin necrosis and 0.36 for reoperation).[5] Studies like the aforementioned review have established this technology as a mainstay of a reconstructive surgeon's toolkit, but there remain issues with interpretability and applicability that give many surgeons pause when using this technology. A recent study by Mattison et al[8] suggested that the SPY-Q system may be overly conservative in predicting necrosis using a variety of cutoffs in comparison to surgeon judgment alone. Although this may be the case in some surgeons' hands, Losken[16] asserts that an in-depth understanding of the strengths and limitations of a technology is necessary for its proper use. The images obtained with laser-assisted ICGa generate large gray zones where tissue appears partially perfused, but viability cannot be easily determined. Although generating cutoffs is convenient, they cannot replace clinical judgment, as gray zones are a static indicator of partial ischemia.

Gray zones are not easily correlated with the dynamic process of tissue survival.[17] These findings are reiterated in this study, where we find certain necrosis in percentages below 10% and occasional necrosis in percentages below 36%. This large gray zone remains a challenge for the reconstructive surgeon, as their clinical experience and decision-making is required to minimize the chances of reconstructive failure. In our experience, clinical decision-making in the gray zone is dependent upon reconstructive modality. With autologous reconstruction, ischemic tissue on the mastectomy skin and flap may be incorporated without significant risk to final reconstruction, whereas with implant-based reconstruction, the calculus differs. A decision aid has been generated with general considerations for care in different gray zone clinical scenarios in Figure 3. Ultimately, quantification technologies such as the SPY-QP can provide surgeons with an objective metric of tissue perfusion in real time, which surgeons can utilize to aid in their decision-making.

There are significant limitations to this study. First, due to the low overall patient numbers, our analysis is limited and susceptible to confounding bias. For implant-based reconstructions, we routinely use a 2-stage expander-based reconstructive protocol, which may decrease necrosis complications at the consequence of multiple operations. For autologous reconstruction, SPY angiography is performed before the flap is rendered ischemic. Ischemic tissue is then resected, but final modifications to the flap are performed after anastomosis to ensure proper inset. This may modify the location of the lowest perfusion of the flap, skewing our findings. Still, the majority of the flap is then de-epithelialized and buried under the mastectomy skin at this juncture, so this should have a minimal effect on skin necrosis. SPY protocol design was based on the senior author's historical preferences. In addition, the study design included both alloplastic and autologous reconstruction. This introduces bias and heterogeneity to the dataset at the expense of the more generalizable findings of the broad breast reconstruction patient population. The analysis of perfusion of fat with SPY in autologous reconstruction requires further investigation. In this study, we correlate skin readings with the development of fat necrosis, but the reliability of this technique needs to be studied further. In addition, SPY is a static indicator of intraoperative perfusion, which can be affected by volume status and temperature. Perfusion is a multifactorial process that can be affected by many parameters in the

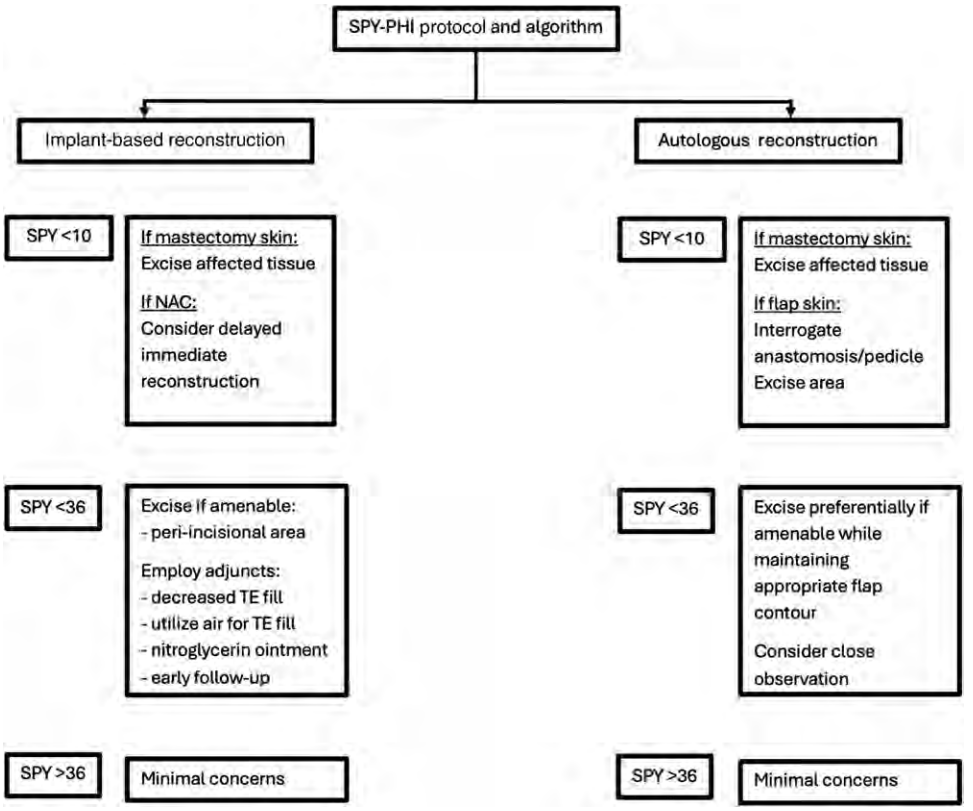


Fig. 3. a treatment decision tree is proposed that takes SPY findings and method of reconstruction into account. na c , nipple–areolar complex; te , tissue expander.

intraoperative and postoperative periods. This is likely reflected in the wide gray zone, which was found in this study. Finally, the follow-up analysis period of this study is 3 months. To fully capture results, longer term follow-up with patient-reported outcomes is necessary.

CONCLUSIONS

This study prospectively explores the use of SPY-QP in predicting postoperative complications after breast reconstruction. We find that SPY-QP readings are significantly correlated with skin necrosis. We also demonstrate that this technology is highly specific at low values and can effectively guide surgeons in the resection of ischemic tissue. Conversely, it remains challenging to accurately predict necrosis intraoperatively at higher values (gray zone) due to the complexity of postoperative recovery of ischemic tissue.

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DISCLOSURES

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