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

Please direct questions to the Clinical Sciences and Operations Team at EndoclinicalIIS@Stryker.com

KEY POINTS

Study design: A prospective single-institution study was designed to correlate intraoperative angiography with outcomes following breast reconstruction using SPY-QP on SPY-PHI.

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

Methods: A prospective study enrolled patients who underwent breast reconstruction with implant-based or autologous techniques. Data collection included patient demographics, operative details, and outcomes at 2-week, 1-month, and 3-months post operation. The primary outcome was post-operative skin necrosis classified based on interventional-based criteria. Stage 1necrosis 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 rates. Skin necrosis was correlated with fluorescence angiography relative values (%) using logistic regressions. Statistical analyses were conducted using R-Studio.

Inclusion

- Age ≥ 18 years
- Undergoing implant-based or autologous breast reconstruction

Exclusion criteria

- Current tobacco smoking status
- Active immunosuppression
- Intolerance to indocyanine green dye or fluorescein
- Inability to provide consent

Patient Demographics:

- In total, 39 patients and 59 breasts were included in the study. Patients had an average age of 54.0 ± 10.6 years and an average body mass index of 26.8 ± 4.5 kg/m2. 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%). 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.

Results:

- Of the 59 breasts included in the study, forty-nine (83.5%) breasts underwent implant-based reconstruction with tissue expanders, whereas 10 (17.0%) were reconstructed with autologous tissue. 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 standardized protocol was implemented to minimize bias and increase reliability. Intraoperatively the device operator selected a baseline for maximum fluorescence by using a well-perfused tissue area over the patient's sternum and was set to 100% perfused. This area was selected 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

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- square within the field of vision of the handheld device. For prosthetic reconstructions, the mastectomy skin was evaluated using SPY-QP, whereas for autologous reconstructions, the flap skin was evaluated. In delayed reconstructions, a similar protocol was utilized depending on whether the reconstruction was prosthetic-based or autologous.
- Five (12.8%) patients had evidence of skin necrosis, 6 (15.4%) of fat necrosis, and 9 (23.1%) of postoperative infection. Mean SPY-QP 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%, $P<0.05$). 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-QP relative values were not significantly correlated with fat necrosis ($P>0.05$). The mean relative value for no infection was 31.1%±6.2%, and 32.7%±15.3% for infection. Cutoff evaluation demonstrated that a SPY-QP % of 10 was specific for necrosis, whereas a SPY-QP % of 36 was sensitive for necrosis. However, the authors noted that although generating cutoff values is convenient, they cannot replace clinical judgement, as gray zones are an indicator of partial ischemia.

Conclusion:

- This study prospectively explored the use of SPY-QP in predicting postoperative complications after breast reconstruction. The study found that SPY-QP readings are significantly correlated with skin necrosis ($P<0.05$). Fat necrosis and infection did not correlate with lower SPY-QP readings. It also demonstrated that the 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 complexity of postoperative recovery of ischemic tissue.

Takeaways:

- SPY-QP shows a correlation with skin necrosis, especially at low perfusion values
- Results suggest:
  - <10% → Likely necrotic
  - 10–36% → Gray zone
  - 36% → Likely viable
- Gray zone (10–36% SPY) remains ambiguous
- Cutoffs can guide resection, but gray zone decisions still rely on surgeon expertise
- Autologous reconstructions tolerate ischemic tissue better than prosthetic cases
- Conservative SPY thresholds may lead to unnecessary tissue removal
- SPY-QP should be used as an adjunct, not a replacement for clinical judgment

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