The FLARE Intraoperative Near-Infrared Fluorescence Imaging System: A First-in-Human Clinical Trial in Perforator Flap Breast Reconstruction

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Background: The ability to determine flap perfusion in reconstructive surgery is still primarily based on clinical examination. In this study, the authors demonstrate the use of an intraoperative, near-infrared fluorescence imaging system for evaluation of perforator location and flap perfusion.
Methods: Indocyanine green was injected intravenously in six breast cancer patients undergoing a deep inferior epigastric perforator flap breast reconstruction after mastectomy. Three dose levels of indocyanine green were assessed using the fluorescence-assisted resection and exploration (FLARE) imaging system. This system uses light-emitting diodes for fluorescence excitation, which is different from current commercially available systems. In this pilot study, the operating surgeons were blinded to the imaging results.
Results: Use of the FLARE system was successful in all six study subjects, with no complications or sequelae. Among the three dose levels, 4 mg per injection resulted in the highest observed contrast-to-background ratio, signal-to-background ratio, and signal-to-noise ratio. However, because of small sample size, the authors did not have sufficient power to detect statistical significance for these pairwise comparisons at the multiple-comparison adjusted type I error of 0.017. Six milligrams per injection provided a similar contrast-to-background ratio but also a higher residual background signal.
Conclusion: Based on this pilot study, the authors conclude that near-infrared assessment of perforator flap breast reconstruction is feasible with a light-emitting diode–based system, and that a dose of 4 mg of indocyanine green per injection yields the best observed contrast-to-background ratio compared with a dose of 2 or 6 mg for assessment of flap perfusion. (*Plast. Reconstr. Surg.* 126: 1472, 2010.)

The use of imaging as an adjunct is becoming increasingly popular in perforator flap reconstruction. As perforating vessels demonstrate a high degree of variability in size and location, identification of target vessels can decrease operative time and increase reliability. The currently used techniques for imaging include duplex ultrasound, computed tomography, and magnetic resonance imaging.[1–8] With improvements in technology and

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Received for publication March 11, 2010; accepted May 10, 2010.
The clinical study "Objective Flap Assessment During Reconstructive Surgery" is registered with the Clinical Trials registry at http://www.clinicaltrials.gov (no. NCT00952107).

DOI: 10.1097/PRS.0b013e3181f059c7

Disclosures: *FLARE technology is owned by Beth Israel Deaconess Medical Center, a teaching hospital of Harvard Medical School. As inventor, Dr. Frangioni may someday receive royalties if products are commercialized. Dr. Frangioni is the founder and unpaid director of The FLARE Foundation, a nonprofit organization focused on promoting the dissemination of medical imaging technology for research and clinical use. The other authors have no financial interest to declare.*