Intraoperative Perfusion Mapping with Laser-Assisted Indocyanine Green Imaging Can Predict and Prevent Complications in Immediate Breast Reconstruction

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Geoffrey C. Gurtner, M.D.

**Background:** Immediate breast reconstruction results in a superior cosmetic outcome. However, immediate breast reconstruction using both prosthetic and autologous techniques is associated with significantly higher complication rates than delayed procedures. These early postoperative complications are usually related to unrecognized ischemia of mastectomy skin and/or inadequate perfusion of autologous tissue used for reconstruction. Aside from clinical experience, there are no reliable tools to assist the novice surgeon with intraoperative assessment of tissue viability.

**Methods:** Laser-assisted indocyanine green imaging was applied to determine and map tissue perfusion. Indocyanine green perfusion mapping was used in 24 consecutive breast reconstructions to define the perfusion of both mastectomy skin and autologous tissue. Areas of inadequate perfusion were then removed at the time of surgery. Postoperative complications occurring within 90 days after surgery were reviewed.

**Results:** In 24 consecutive breast reconstruction (16 tissue expanders, two latissimus dorsi flaps, and six deep inferior epigastric perforator/superficial inferior epigastric arteries), there was a 4 percent complication rate. Intraoperatively, the use of indocyanine green imaging allowed all poorly perfused skin to be removed completely in each case, minimizing the incidence of mastectomy flap necrosis, partial necrosis of autologous tissue, and impaired healing. For autologous reconstruction, patency of anastomoses could also be confirmed. This complication rate was significantly less than the 15.1 percent complication rate observed in 206 reconstructions in the previous consecutive 148 patients ($p < 0.01$) with similar demographics and risk factors.

**Conclusions:** This early experience demonstrates an increased accuracy in predicting tissue necrosis (mastectomy flap, autologous tissue) as guided by indocyanine green imaging. Further prospective studies are warranted to quantify whether this technology can reduce health care costs by preventing complications in immediate breast reconstruction. (Plast. Reconstr. Surg. 125: 1065, 2010.)

Breast cancer is the most common malignancy among women, with over 180,000 women in the United States diagnosed each year. In 2007, over 57,000 breast reconstructive procedures were performed, the vast majority (76 percent) of which were performed with expanders and implants. Immediate reconstruction has been favored over delayed procedures for psychological and technical reasons. However, immediate breast reconstruction is associated with significantly higher complication rates (50 to 52 percent) than delayed procedures (32 to 36 percent), especially when a prosthetic (implant) is used. For prosthetic reconstructions, early complications include necrosis of the mastectomy skin flaps, infection, delayed wound healing, and exposure of the implant, with the published incidence of these complica-

Disclosures: At the time of the study, neither of the authors was affiliated with the company supplying the indocyanine green technology (Novadaq), nor was any financial support received for the study. Since completion of the study, Dr. Gurtner has become a consultant for Novadaq. Dr. Timek has no conflicts of interest to disclose.
Table 1. Reconstructive Modalities, Intraoperative Clinical and Angiographic Observations, and Early Complications

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age (yr)</th>
<th>Breast Abnormality</th>
<th>Prior Irradiation</th>
<th>Reconstructive Procedure</th>
<th>Skin Ischemia Clinically</th>
<th>Skin Ischemia Angiographically</th>
<th>Intraoperative Interventions Based on Angiography</th>
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<th>Decreased Expander Volume</th>
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<td>1</td>
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<td>No</td>
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<tr>
<td>2*</td>
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<tr>
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R, right; L, left; B, bilateral; DCIS, ductal carcinoma in situ; TE, tissue expander; DIEP, deep inferior epigastric artery perforator; SIEA, superficial inferior epigastric artery; N/A, not applicable.

*There was one complication (skin necrosis).
tions ranging between 10 and 40 percent. Similarly, autologous tissue (flap) reconstructions are associated with total complication rates ranging from 23 to 43 percent, including the catastrophic complication of vascular pedicle thrombosis, which occurs in up to 6 percent of the cases. Regardless of the mode of failure, complications in immediate breast reconstruction often require hospitalizations and repeated procedures, leading to a delay in adjuvant treatment for these patients with cancer.

The majority of the early complications of immediate reconstruction can be linked to inadequate perfusion at either the microcirculatory (e.g., mastectomy flap necrosis, nonhealing wounds) or macrocirculatory level (e.g., anastomotic thrombosis, inadequate perforators/fat necrosis). However, it is clear that even a seemingly unrelated complication, such as infection, has a vascular component, as demonstrated by the increase in infection seen with ischemia in human studies. Moreover, it is known that infections that occur in the presence of soft-tissue ischemia lead to a significantly worse outcome than infections that occur in well-perfused tissues.

Therefore, to decrease the high rate of complications in immediate breast reconstruction, a more reliable assessment of tissue perfusion would be desirable. This would allow nonviable or marginally perfused tissue to be removed at the time of surgery. At present, clinical judgment alone is used to determine adequate tissue perfusion. Previous studies have demonstrated that this is inherently unreliable, which may account for the current unacceptably high rate of complications.

Laser-assisted indocyanine green intraoperative imaging (SPY Intraoperative Imaging Systems; Novaq Technologies, Inc., Mississauga, Ontario, Canada) is a U.S. Food and Drug Administration–approved tool that is able to provide real-time intraoperative determination of soft-tissue vascularity and perfusion. Indocyanine green binds quickly to plasma proteins, which confines the dye to the intravascular compartment. Indocyanine green fluoresces when illuminated at 806 nm with a low-energy laser, and this fluorescence can be captured on a charge-coupled device video camera and visualized in real time. This system is currently used in cardiovascular surgery to evaluate patency of coronary artery bypass grafts during cardiac surgery and has been found to be safe and easy to use. We used the SPY intraoperative indocyanine green angiography system to evaluate perfusion of mastectomy skin flaps and tissues used for reconstruction in 24 consecutive immediate breast reconstruction using both prosthetic and autologous techniques. The subsequent complication rate in these patients compared very favorably with the previous 148 consecutive patients treated without this technology.

**PATIENTS AND METHODS**

This study was approved by the Institutional Review Board at Stanford University Medical Center. The choice of autologous and/or prosthetic reconstruction was determined based on the patients’ anatomy and wishes and the surgeons’ preference. Twenty-four consecutive immediate breast reconstructions in 20 patients with unilateral and bilateral breast cancer were enrolled in the study (Table 1).

After completion of skin-sparing mastectomy, each patient underwent reconstruction using one of the following surgical modalities. For patients undergoing tissue expander reconstruction, the pectoralis major muscle was elevated and released along its inferior and inferomedial insertion to the chest wall. A 6 × 16-cm sheet of acellular dermis (DermaMatrix; Synthes, Inc., West Chester, Pa.) was sutured to the chest wall inferomedially and to the pectoralis muscle superiorly to provide a supportive sling for the tissue expander, as described previously. The tissue expander was filled to a “safe” volume as described below. For patients undergoing autologous reconstruction, the latissimus dorsi myocutaneous flap, deep inferior epigastric perforator (DIEP) artery flap, or superficial inferior epigastric artery (SIEA) flap was used according to the patient’s preferences and anatomical considerations. The transposition of the latissimus dorsi myocutaneous flap and microsurgical transfer of the DIEP/SIEA flaps was performed using standard techniques as described previously.

Intraoperative indocyanine green imaging was used in slightly different ways, depending on whether the patient was undergoing an expander or an autologous reconstruction as described below. Regardless, in each patient who underwent indocyanine green intraoperative imaging, a standardized protocol was used. Before each perfusion, 25 mg of powder indocyanine green dye was dissolved in 5 ml of saline, yielding a concentration of 5 mg of indocyanine green per 1 ml. With each image run, 2 ml of this solution was administered by anesthesia personnel into a peripheral intravenous line followed by a 10-ml bolus of normal saline. Images were captured 15 seconds after injection on a charge-coupled device video camera and visualized in real time. Skin of the mastectomy flaps was imaged after completion of the
mastectomy. Areas where no perfusion was seen were marked and resected.

After this, skin perfusion was checked again after instillation of the initial volume of saline into the tissue expander. The intraprosthetic volume was adjusted subsequently based on changes in perfusion-based indocyanine green imaging. The adequacy of skin perfusion was assessed qualitatively by angiographic images and fluid removed if this was abnormal. At the conclusion of this process, perfusion in the overlying mastectomy flaps was almost the same as in the surrounding chest wall skin.

For autologous tissue reconstruction, the cutaneous skin islands of the autologous harvest site were imaged with intravascular angiography before making the skin incision. The major skin perforators were marked on each flap surface, and the flap boundaries and mastectomy incisions were adjusted depending on the location of the major perforators. After completion of breast reconstruction, the viability of the breast skin envelope was verified with intraoperative angiography and areas of no perfusion sharply excised as described above. In autologous cases, the viability of the transferred tissue and the patency of the vascular pedicle during the arterial and venous contrast flow phases were also confirmed using this technology, which was able to demonstrate flow through both the arterial and venous anastomoses. If filling defects were observed, the anastomoses were redone. The patients remained hospitalized for 1 to 5 days. During weekly outpatient follow-up visits, the reconstructed breasts were evaluated comprehensively for early complications, including necrosis, cellulitis, hematoma, capsular contracture, extrusion, and total (combined) complications within the first 90 days after the reconstruction.

These patients and their breast reconstructions were then compared with a retrospective analysis of all patients who underwent immediate breast reconstruction by the senior author (G.C.G.) between February of 2006 and August of 2009. Patient records were reviewed for demographics, comorbidities, type of breast cancer, need for adjuvant chemotherapy, history of radiation therapy and diabetes; smoking history was not statistically different between the two groups as determined by chi-square analysis. A total of 148 patients with 206 breast reconstructions were examined and found to have an overall total complication rate of 15.1 percent. A t test (two-sided) was used to compare the incidence of total complications (as described above) between the two groups assuming unequal variances, with values of $p < 0.01$ considered significant. All statistical tests were performed using SPSS version 17 software (SPSS, Inc., Chicago, Ill.).

RESULTS

Our interest in examining the operative utility of indocyanine green angiography was based on our pilot experience with an immediate prosthetic breast reconstruction (Fig. 1) in a patient undergoing a nipple-sparing mastectomy. The patient

![Fig. 1. Left nipple after completion of immediate breast reconstruction with a tissue expander (above). (Center) The corresponding angiographic image displaying the nonperfused periareolar area (n) contrasted with well-perfused pectoralis major muscle (m). Severe necrosis of the left breast skin 7 days after reconstruction (below).](image-url)
was a 48-year-old woman with ductal carcinoma in situ and no history of breast irradiation who underwent a left nipple-sparing mastectomy. The patient had a large degree of breast ptosis, and the safety of nipple-sparing mastectomy was in doubt. After immediate breast reconstruction with a tissue expander, the left nipple appeared viable (Fig. 1, above) by gross examination performed by the senior surgeon. However, because of the very long skin flaps, further confirmation was sought. Accordingly, the Novadaq SPY Imaging System was borrowed from the cardiac surgery suite, where it is used to image the patency of coronary bypass grafts. After 2 cc of dilute indocyanine was injected intravenously, the cardiac machine was used to scan the surface of the skin flaps, including the preserved nipple. In contrast to clinical assessment, intraoperative indocyanine green angiography revealed profound perfusion defects in the mastectomy skin involving the periareolar area and nipple (Fig. 1, center). Because the reliability of indocyanine green imaging for this application (skin perfusion) had not been established, the senior author made the decision to preserve the nipple and skin that appeared viable by clinical examination (by means of blanching and warmth analysis). Unfortunately, all the areas with poor perfusion by indocyanine green angiography developed full-thickness necrosis, necessitating operative débridement in the second postoperative week (Fig. 1, below). This experience suggested the potential of using this technology to prevent early complications in immediate breast reconstruction.

Accordingly, in the next 24 consecutive breast reconstructions, indocyanine green imaging was used to predict perfusion problems in the operating room at a point where they could be corrected (i.e., by resecting tissue or removing volume from the expander). The median age of the patients was 51 ± 8 years, with breast cancer stage ranging from ductal carcinoma in situ to T3N2 (Table 1). There were no smokers or diabetics in the enrolled group of patients, but six had previously undergone radiation therapy. Table 1 summarizes the reconstructive modalities, intraoperative clinical and angiographic observations, and early complications. In 14 reconstructed breasts (58 percent), including 12 breasts reconstructed with a tissue expander or an implant, poor perfusion areas in the mastectomy flaps were noted with indocyanine green intraoperative imaging, as evidenced by inadequate or absent dye penetration. Clinically, only seven of these appeared to be at risk by gross examination. The areas of inadequate dye penetration were removed and/or the volume of the tissue expander adjusted as illustrated in case 1 below (Table 1, patient 7).

The patency of arterial and venous anastomoses was satisfactory in all free flap cases as assessed by visual inspection, strip test, and indocyanine green angiography. There were no intraoperative complications. Postoperatively, only one patient with a history of breast irradiation who underwent latissimus dorsi myocutaneous flap and implant reconstruction developed an area of mastectomy skin necrosis. Interestingly, the necrosis occurred in an area that clinically appeared viable but would have otherwise been removed if guided purely by indocyanine green imaging (Table 1, patient 2). Again, the decision to rely on clinical judgment led to tissue necrosis that needed to be resected and reclosed in the clinic. Nonetheless, the use of indocyanine green imaging resulted in a very low [one of 24 (4 percent)] early complication rate in our series that compared very favorably with the previous 206 consecutive reconstructions in 148 patients, which had a 15.1 percent complication rate \( p < 0.01 \). Surprisingly, there were no infectious complications in any of the reconstructed breasts. The following two representative cases illustrate the clinical utility of indocyanine green imaging in both prosthetic and autologous reconstruction (Table 1) in our experience.

**CASE REPORTS**

**Case 1: Tissue Expander Reconstruction (Determining Maximum Expander Fill Volume Intraoperatively)**

A 51-year-old woman presented with a history of left lumpectomy and chest irradiation for ductal carcinoma in situ, and underwent a skin-sparing mastectomy with removal of 490 g of breast tissue (Table 1, patient 7). The breast was reconstructed with a 300-ml tissue expander (Fig. 2). Intraoperatively, the lateral aspect of the skin around the inverted-T incision was found to be compromised by indocyanine green imaging and excised. After instillation of 250 ml of saline into the tissue expander, the area adjacent to the incision again appeared poorly perfused by indocyanine green imaging. Accordingly, 50 ml of saline was removed from the tissue expander and, subsequently, intraoperative angiography revealed normal perfusion. The gross appearance of the tissue did not differ between the two volume states. Postoperatively, 100 percent of the mastectomy flaps survived and the patient had no complications.

**Case 2: SIEA Reconstruction (Confirming Viability of Questionable Tissue)**

A 51-year-old woman with previous bilateral subpectoral augmentation underwent right areola-sparing mastectomy for multicentric high-grade ductal carcinoma in situ. Immediate reconstruction of the right breast was carried out using the left SIEA flap (Table 1, patient 10). The ability to harvest the flap across the midline was confirmed in situ using indocyanine green imaging (not shown). The patency of the microvascular...
anastomoses and the viability of mastectomy skin and SIEA flap were also verified by indocyanine green angiographically after revascularization (not shown). The flap was buried under the mastectomy skin with the exception of a tiny monitoring patch that was used to create the nipple (Fig. 3). Concern was raised about the viability of this extensively folded tissue, but adequate perfusion was verified by means of intraoperative indocyanine green imaging (Fig. 4, above). Postoperatively, this tissue and the mastectomy flaps survived entirely (Fig. 4, below), as predicted by indocyanine green imaging. Subsequently, the patient had no postoperative complications.

**DISCUSSION**

In the present series, intraoperative indocyanine green angiography was used to evaluate the

![Fig. 2. Case 1. Intraoperative images (left) compared with indocyanine green imaging (right). Areas of poor perfusion are indicated with blue arrows. (Above) The left breast after mastectomy had nonperfused lateral skin that was excised. After removal of the ischemic lateral incision border, the tissue expander was filled with 250 ml, causing obvious ischemia along the medial incision line by indocyanine green imaging (center). After the removal of 50 ml from the tissue expander, the skin perfusion returned to normal and the flap subsequently survived postoperatively (below).](image-url)
viability of mastectomy skin and flap tissue used for immediate breast reconstruction in a variety of clinical settings. The ability to reliably assess mastectomy skin perfusion and avoid necrosis is particularly important when prosthetic devices are used. With intraoperative imaging, the surgeon is provided with an on-table assessment of breast skin perfusion that facilitates identification and removal of poorly perfused tissue. This resulted in a decrease in complication rates, including skin necrosis, infection, and implant extrusion. In this series, application of indocyanine green perfusion monitoring provided a statistically significant decrease in overall complication rates from 15.1 percent to 4 percent (p < 0.01). This compares favorably with the up to 52 percent complication rates experienced following immediate breast reconstruction in previously published series.4,5

Real-time intraoperative indocyanine green imaging also allows the surgeon to recognize when a portion of the procedure (i.e., during insetting) may have resulted in decreased perfusion that might result in postoperative complications. In many cases, immediate action can be taken intraoperatively to correct this and rescue the ischemic tissue as illustrated in case 1. In this case, the effect of expander volume on skin flap perfusion can be monitored directly in real time. The optimal volume is obtained when the indocyanine green intensity of mastectomy skin becomes comparable to the dye intensity of the surrounding skin.18,19

Intraoperative imaging using laser-assisted indocyanine green differs significantly from the more familiar application of intravenous fluorescein. Fluorescein, although widely accepted as a perfusion marker, has significant shortcomings, such as rapid leakage from the capillaries into the interstitium, resulting in an impractically long half-life of over 4 hours, and a clearance time of 12 to 18 hours.20,21 In addition, local ischemia enhances fluorescein diffusion outside of capillaries, leading to false-positive results.20 In contrast, indocyanine green binds rapidly to plasma proteins and is distributed evenly throughout the vasculature, including subdermal capillaries.21 Because of the light absorption characteristics of indocyanine green (with a maximum at 805 mm in the infrared range), indocyanine green imaging displays superior tissue penetration and can demonstrate perfusion in the dermis and superficial soft tissues to a depth of 3.6 mm.20,22 The typical indocyanine green dose of 0.15 to 0.3 mg/kg (average, 10 mg per injection) allows for repetitive dye adminis-

Fig. 3. Case 2. Intraoperative appearance of right breast reconstruction with a SIEA flap from which a small monitoring patch was used to reconstruct the nipple.

Fig. 4. Case 2. On completion of the reconstruction, there was a concern that the folded skin paddle from the SIEA flap comprising the nipple would not survive. The indocyanine green image, however, showed satisfactory dye penetration into the new nipple (above) and it was left in place. At 4 months postoperatively, the entire nipple reconstruction is demonstrated to have survived (below).
tration after 9 minutes or immediately with higher doses. This presents a clear advantage to fluorescein, where perfusion reevaluation needs to be postponed for several hours until the dye has cleared adequately. This is obviously impractical in the intraoperative setting.

One potential problem with any form of intravascular imaging is that regional vasospasm may affect perfusion images and underestimate the amount of tissues capable of survival. Although not ideal, the clinical impact of this is modest, because only viable tissue is left with the patient. Moreover, ongoing basic work is defining the correlation between tissue perfusion and necrosis, and developing more quantifiable predictive guidelines. For example, in an experimental rat model, necrosis invariably occurred when the skin flap perfusion was less than 20 percent relative to normal tissues, whereas a perfusion of 50 percent or greater guaranteed tissue survival. This finding has been confirmed by Giunta et al., who observed skin necrosis when perfusion was less than 25 percent of the reference skin. In humans, in a clinical series of 15 patients, intraoperative indocyanine green filling defects, defined as a signal intensity of less than 60 percent of normal skin, were associated with delayed wound healing. Clearly, further work is needed to define precisely where the threshold for tissue necrosis and complications exists in humans.

One of the limitations of the current study was the lack of quantitative indocyanine green perfusion. Although qualitative evaluation of indocyanine green emission intensity has been correlated successfully with histologic findings in burn depth assessment, the availability of a quantitative measure of tissue perfusion was not available in the current study. Clearly, further studies are needed to quantify perfusion thresholds above which satisfactory tissue survival can be anticipated. Such an approach may hold the promise of reliably identifying and eliminating tissue ischemia after immediate breast reconstruction, leading to superior clinical outcomes.

SUMMARY

In 24 consecutive immediate breast reconstructions using various reconstructive techniques, laser-assisted indocyanine green intraoperative imaging permitted reliable identification and elimination of ischemic tissues, resulting in a 4 percent postoperative complication rate. These results compare favorably with the clinical literature and our own retrospective analysis of 206 immediate breast reconstructions where a complication rate of 15.1 percent was observed. We believe this U.S. Food and Drug Administration–approved and widely available technology holds the promise of decreasing the unacceptably high rate of complications in immediate breast reconstruction.

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REFERENCES


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