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The use of indocyanine green angiography in postmastectomy reconstruction: Do outcomes improve over time?☆

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Summary *Background:* Indocyanine green angiography (ICGA) reduces ischemic complications by assessing mastectomy flap perfusion intraoperatively. However, outcomes of ICGA can be surgeon-dependent due to its relative novelty. We aimed to determine whether patient outcomes improved with the adoption of ICGA over time.
Methods: We conducted a single-institution retrospective study of mastectomy patients between March 2012 (date of ICGA introduction) and October 2016. We included patients who underwent immediate expander-based reconstruction with intraoperative ICGA, followed by second-stage permanent implant placement. Patients were chronologically sorted into 3 groups, of 45 patients each, based on the date of ICGA. Complications and reconstruction wait times (time between initial expander placement and subsequent final reconstruction) amongst the 3 groups were evaluated. Using the Cochran–Armitage test for trend, we tested the change in median adjusted expander fill volumes (expander fill volume in milliliter per gram of breast removed) over time.
Results: We identified 135 patients. Rates of ischemic complications significantly decreased (Group 1, 36%; Group 2, 22%; Group 3, 11%; $p = 0.03$), despite significantly increasing median adjusted expander fill volumes (Group 1, 0.46 mL/g; Group 2, 0.63 mL/g; Group 3, 0.76 mL/g; $p = 0.003$) over time. The rates of unexpected returns to the operating room across the 3

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groups were not significantly different. The median reconstruction wait time was significantly reduced in the later groups (Group 1, 146 days; Group 2, 122 days; Group 3, 87 days; $p = 0.01$). *Conclusions:* Outcomes for mastectomy with immediate expander-based reconstruction were found to improve with increasing case volume after implementation of ICGA.

Introduction

Breast cancer continues to be the most commonly diagnosed malignancy among women in the United States, with an estimated 252,710 cases in 2017.[1] Surgical management options for women with breast cancer include breast conservation or mastectomy; and most mastectomy patients can also opt for immediate reconstruction. In 2016, over 79,000 tissue expander- and implant-based reconstructions were performed in the United States,[2] with complication rates reportedly as high as 52%.[3-5] Complications due to inadequate perfusion of the mastectomy skin flaps, in particular, are major causes of postoperative morbidity,[6-8] resulting in cellulitis, loss of implant, delayed expansion/reconstruction, longer hospitalizations, reoperations, and increased costs.[9,10] These ischemic complications can be particularly devastating in breast cancer patients because they can lead to a delay of oncologic adjuvant treatment.

Historically, flap perfusion at the time of tissue expander placement was assessed based on a surgeon's clinical judgment alone. This proved to be an unreliable predictor of flap viability, as multiple studies have consistently reported unacceptably high rates of ischemic complications when flap assessment is based on surgeon judgment alone.[8,11-13] In recent years, laser-assisted indocyanine green angiography (ICGA) was introduced as an objective measurement of mastectomy flap perfusion.[14-16] This technique involves the intraoperative administration of intravenous indocyanine green, followed by fluorescent excitation by an 805-nm laser. The fluorescence is captured on a charge-coupled video camera, providing visualization of flap perfusion in real-time, and guiding the surgeon to nonviable tissue.[17,18] Since its introduction, multiple studies have reported the superiority of ICGA as compared to clinical judgment alone on postmastectomy ischemic complications.[8,19-21]

Despite superior outcomes, this technique can be user-dependent due to its relative novelty and the lack of clear-cut protocols or guidelines. In addition, even the visualized fluorescent perfusion is prone to some degree of subjective interpretation as it relates to tissue viability. It is unclear whether user variability and outcomes improve with increased use. Few studies to date have thoroughly evaluated the association between surgeon experience with ICGA evaluation of flap perfusion assessment in immediate postmastectomy reconstruction and patient outcomes. The objective of this study was to evaluate the case volume-outcome relationship for intraoperative ICGA in the setting of tissue expander-based reconstruction and to determine whether outcomes improve with utilizing this technique over time.

Methods

Following approval from the local Institutional Review Board, we conducted a single-institution retrospective review of consecutive mastectomy patients at the University of Minnesota (Minneapolis, MN) between March 2012 (date of ICGA introduction) and October 2016. Inclusion criteria were defined as follows: (i) receipt of mastectomy for invasive breast cancer, carcinoma in situ, or prophylaxis; and (ii) immediate expander-based reconstruction with intraoperative ICGA, followed by second-stage placement of permanent implants. Patients were excluded if they received autologous tissue flap reconstruction, delayed reconstruction, or if they never underwent second-stage reconstruction. Three surgical oncologists performed all of the mastectomies, and two plastic surgeons performed the immediate ICGA (SPY Imaging, Novadaq, Missisauga, Canada) and tissue expander placement, and subsequent implant exchange. Using the perfusion map from the ICGA, ischemic areas with values of 20% or less were marked and debrided by the surgeon before placement of the tissue expander.

Patient demographics, clinical data, and operative techniques were abstracted from the medical record, including age, body mass index, current smoking status, prior breast surgery, prior history of radiation therapy, receipt of neoadjuvant chemotherapy, use of tumescence, receipt of nipple-sparing mastectomy, breast weight, and intraoperative tissue expander fill volume. In order to create symmetric groupings and meaningfully measure patient characteristics, outcome and surgical process in sufficiently powered samples we sorted patients chronologically based on the date of ICGA into three groups of 45 patients each (Groups 1–3). We performed sensitivity analyses around these groups to confirm that our observed effects were not a product of our grouping decisions, including an adjustment from three groups of 45 patients each to two groups of 68 patients. Smaller groupings did not allow us to effectively measure post-operative complications and outcomes. Complication rates could be extensively higher for expander and implant breast reconstruction after radiation therapy. Therefore, patients with a history of radiation therapy were excluded as part of our sensitivity analysis to confirm that these patients did not introduce bias. Removing radiation therapy patients did not produce results of different magnitude or direction (see Supplementary Tables 1 and 2).

The rates of postoperative complications (recorded per patient and not per breast) amongst the three groups were compared using the Fischer exact test. Based on the definition provided by the Centers for Disease Control and Prevention,[22] postoperative complications were defined as events occurring within 90 days of the mastectomy. Ischemic

Table 1 Patient and operative characteristics of 135 consecutive patients who underwent mastectomy, followed by indocyanine green angiography and immediate expander-based reconstruction. Patients were sorted chronologically into Groups 1–3.

Characteristic	Group 1 ($n = 45$)		Group 2 ($n = 45$)		Group 3 ($n = 45$)		p value
	n	%	n	%	n	%	
Age, years							0.86
<50	25	56	26	58	23	51	
≥50	20	44	19	42	22	49	
Body mass index							0.36
<25.0	21	47	18	40	25	56	
≥25.0	24	53	27	60	20	44	
Current smoker							0.59
Yes	6	13	3	7	3	7	
No	39	87	42	93	42	93	
Prior breast surgery							0.22
Yes	15	33	13	29	8	18	
No	30	67	32	71	37	82	
History of radiation therapy							0.17
Yes	8	18	3	7	3	7	
No	37	82	42	93	42	93	
Neoadjuvant chemotherapy							**0.01**[a]
Yes	9	20	21	47	20	44	
No	36	80	24	53	25	56	
Mastectomy							0.31
Unilateral	11	24	18	40	15	33	
Bilateral	34	76	27	60	30	67	
Nipple-sparing mastectomy							**0.001**[a]
Yes	10	22	10	22	26	58	
No	35	78	35	78	19	42	
Breast weight, g							0.26
<500	21	47	17	38	25	56	
≥500	24	53	28	62	20	44	
Tumescence use							0.30
Yes	9	20	11	24	5	11	
No	36	80	34	76	40	89	

[a] Statistically significant as defined by $p < 0.05$.

complications were defined as mastectomy flap necrosis or cellulitis. Flap necrosis was further divided into three categories as previously described: mild (spontaneous healing, requiring no intervention), moderate (requiring in-office debridement), and severe (requiring debridement in the operating room).[20] Other postoperative complications recorded were unexpected returns to the operating room, hematoma, and seroma. The adjusted expander fill volume was calculated for each patient using the ratio of intraoperative expander fill volume in milliliters to gram of breast removed. The median adjusted fill volume of the tissue expander was then determined for each group. Using the Cochran-Armitage test for trend, the change in median adjusted fill volumes was tested over time. Finally, we compared the reconstruction wait time between the three groups, defined as the median number of days between (i) the index mastectomy with ICGA and tissue expander placement, and (ii) the second-stage reconstruction with implant exchange. Patients who received adjuvant chemotherapy or radiation therapy between the two stages of reconstruction were excluded from this analysis. Statistical analyses were completed by SAS software, version 9.3 (SAS Institute, Cary, NC).

Results

Patient characteristics

We identified a total of 135 consecutive patients who underwent mastectomy and immediate tissue-expander based reconstruction with intraoperative ICGA, followed by second-stage placement of permanent implants. The baseline characteristics of these patients are found in Table 1. The median age of the patients across the groups was similar (Group 1, 47; Group 2, 47; Group 3, 49; $p = 0.86$). The majority of patients underwent bilateral mastectomy (Group 1, 76%; Group 2, 60%; Group 3, 67%; $p = 0.31$). Twenty-six patients (58%) underwent nipple-sparing mastectomies in Group 3, as compared to only 10 patients (22%) in each of Groups 1 and 2 ($p = 0.001$). Twenty-one patients (47%) in Group 2 and 20 patients (44%) in Group 3 received neoadjuvant chemotherapy, as opposed to only 9 patients (20%) in Group 1 ($p = 0.01$). There were otherwise no significant differences between the three groups in terms of body mass index, current smoking status, history of breast surgeries, receipt of radiation therapy, breast weight, and tumescence use.

Table 2 Postoperative complications after implementation of indocyanine green angiography in mastectomy with immediate expander-based reconstruction over time. Patients were sorted chronologically into Groups 1, 2, and 3 ($N = 135$).

	Group 1 ($n = 45$)		Group 2 ($n = 45$)		Group 3 ($n = 45$)		p value
	n	%	n	%	n	%	
Flap necrosis							
Mild	8	18	4	9	0	0	
Moderate	2	4	1	2	1	2	
Severe	2	4	2	4	2	4	
Total	12	26	7	15	3	6	0.05
Cellulitis	9	20	3	7	2	44	0.06
Ischemic complication[a]	16	36	10	22	5	11	**0.03**[b]
Return to operating room	5	11	4	9	3	7	0.93
Hematoma or seroma	16	53	10	33	4	13	**0.01**[b]

[a] Ischemic complication is defined by flap necrosis of any severity or cellulitis.
[b] Statistically significant as defined by $p < 0.05$.

Complications

Patient outcomes as related to complications are reported in Table 2. Specifically, the rates of flap necrosis of any degree of severity significantly decreased over time (Group 1, 26%; Group 2, 15%; Group 3, 6%; $p = 0.05$). However, no difference was noted in the rates of severe flap necrosis, with 2 patients (4%) in each of the three groups. We also observed a trend of decreasing rates of cellulitis over time (Group 1, 20%; Group 2, 7%; Group 3, 4%; $p = 0.06$). In addition, the rates of overall ischemic complications (i.e., cellulitis or flap necrosis) significantly decreased over time, (Group 1, 36%; Group 2, 22%; Group 3, 11%; $p = 0.03$).

The rates of unexpected return to the operating room were not significantly different across the 3 groups ($p = 0.93$). The reasons for return to the operating room included: debridement for severe flap necrosis, removal of infected tissue expander, replacement of exposed or deflated tissue expander, and hematoma evacuation. Of note, we observed a significantly lower incidence of hematoma or seroma over time (Group 1, 53%; Group 2, 33%; Group 3, 13%; $p = 0.01$), complications that are considered unlikely to be directly related to mastectomy flap perfusion.

Expander fill volumes and time to definitive reconstruction

The median intraoperative adjusted expander fill volumes significantly increased over time (Group 1, 0.46 mL/g; Group 2, 0.63 mL/g; Group 3, 0.76 mL/g; $p = 0.003$; Figure 1(a). Additionally, we observed a significant reduction in the median reconstruction wait time over the course of the study (Group 1, 146 days; Group 2, 122 days; Group 3, 87 days; $p = 0.01$; Figure 1(b). We excluded patients who received adjuvant therapy, i.e., chemotherapy and/or radiation therapy between the 2 stages of reconstruction (9 in Group 1, 18 in Group 2, 9 in Group 3), from this reconstruction wait time analysis.

Discussion

In this retrospective review of a single institutional database of postmastectomy reconstruction, outcomes after ICGA implementation appear to improve over time. With increasing surgeon experience, ischemic flap complications have decreased over time, despite increasing initial expander fill volumes, higher rates of nipple-sparing mastectomy, and higher rates of neoadjuvant chemotherapy use. Increasing fill volumes appear to decrease the time to definitive reconstruction, as well.

Laser-assisted ICGA was introduced to assist in the evaluation of mastectomy flap perfusion in real-time. The clinical benefit of ICGA over surgeon assessment alone with regard to ischemic complications has been demonstrated in multiple studies, as ICGA has been reported to be highly sensitive and specific in predicting postoperative flap necrosis.[15,23,21] In 2010, Komorowska-Timek and Gurtner found that the rate of flap necrosis decreased from 15% to 4% with the implementation of ICGA.[8] Similarly, in 2014, Duggal et al. reported a significant reduction in rates of necrosis from 23% to 13% after ICGA introduction.[19] In 2016, Harless and Jacobson reported a significant decrease in flap necrosis from 7% to 0.9% with the introduction of ICGA.[20] Our group has also previously identified a significant reduction of severe flap necrosis rates from 18.9% to 4.9% after ICGA implementation.[21] Given the decrease in postoperative complications, ICGA has also been shown to be cost-effective in comparison to surgeon assessment alone.[19,24] These improved outcomes have likely contributed to the significantly increased use of ICGA over the past years, along with higher rates of debridement, as shown in a recent study including over 100,000 patients.[25]

Despite the benefit of ICGA in evaluating tissue perfusion to reduce postoperative complications, there can be a transition period during which the surgeon begins using ICGA on his/her first patients. Sood and Glat reported an initial period of about 3 months during which surgeons were reluctant to rely on ICGA findings when the findings were inconsistent with their clinical observations.[26] During that time, surgeons were more likely to rely on clinical judgment, and complication rates were higher.[26] As with any new technology in surgery, outcomes can vary based on the surgeon's experience and number of cases performed, as part of the so-called learning curve. The theory of learning curves is well known in the behavioral sciences and its applications have been recognized to improve productivity in the workplace. The two major phases to a learning curve are the

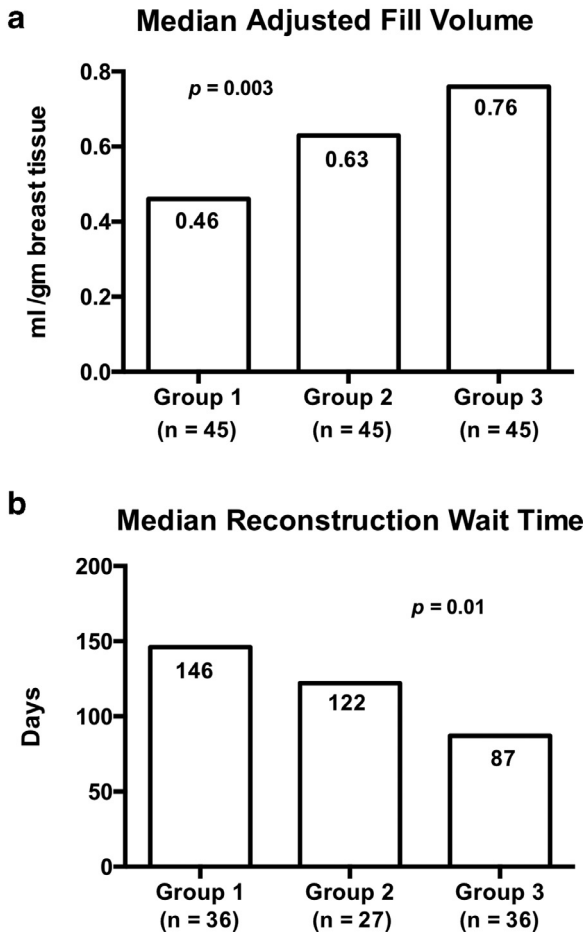

Figure 1 Outcomes of 135 consecutive patients who underwent mastectomy with indocyanine green angiography (ICGA) and immediate expander-based reconstruction, reported as (a) median intraoperative adjusted expander fill volume (expressed as milliliters per gram of breast tissue removed), and (b) reconstruction wait time (defined as the number of days between the mastectomy with ICGA and immediate expander placement, and the second-stage reconstruction with implant exchange). Patients who received adjuvant therapy (chemotherapy and/or radiation therapy) during the reconstruction wait time period were excluded in (b).

initial phase and the plateau phase. The initial phase reflects the number of times a task needs to be performed before an individual learns it, i.e., until failure to perform that task is lowered to a minimum or eliminated. The initial phase of the learning curve classically shows a sharp rise, reflecting improvement of that individual in performing that task with repetition. The plateau phase is reached when improvement slows and finally ceases. The plateau phase is a reflection of the number of times the task needs to be repeated to obtain maximal improvement.[27]

The learning curves of various surgical procedures have been carefully evaluated. The learning curve for laparoscopic cholecystectomy shows an initial phase of about 10 to 30 cases. Once that threshold is reached, the complication rates decrease. Additionally, operative time gradually decreases over time with improvement persisting for about 200 cases, until it reaches the plateau phase, where improvement ceases.[28-30] Similarly, a learning curve has been shown for laparoscopic colectomy and laparoscopic gynecological procedures, with decreased complications and improved outcomes with more operative experience.[31,32] However, few studies have evaluated the learning curve associated with ICGA. To our knowledge, only one study has mentioned the ICGA learning curve and the authors have reported a learning period of about 3 months.[26] In our study, we found that the rate of ischemic complications significantly decreased with increasing surgeon experience, as defined by the number of cases performed, rather than a defined time period.

In addition to reducing ischemic complications, ICGA may also guide the surgeon to maximize the fill volume of the tissue expander intraoperatively. Because the effect of the tissue expander on the mastectomy flap perfusion can be assessed in real-time, the surgeon may optimize the volume of the expander while ensuring flap viability, to potentially allow the patient to reach the final stage of reconstruction earlier. In this report, we found that our surgeons were able to significantly increase the adjusted expander fill volumes over time, which ultimately led to a significantly shorter wait time between the two stages of reconstruction for patients in the later groups.

On the other hand, the improved outcomes over time could also be due to the learning curve associated with the surgical technique and operation as a whole, as opposed to just the increased experience with ICGA. In other words, the improvement in mastectomy technique during this study period could theoretically have contributed to these findings, and therefore the improved outcomes may not all be attributable to the increased use of ICGA. However, of the five surgeons who operated on the patients included in this study, four are senior surgeons, while the remaining surgeon contributed few patients to this study. Consequently, it is highly unlikely that the improved outcomes noted over time are secondary to the improvement in mastectomy technique, although this possibility cannot be entirely ruled out.

We recognize several limitations to this study, including its retrospective nature and small sample size. Moreover, this study is a single institutional experience, making generalizability challenging. Although our results indicate improved outcomes with increasing case volume, our study does not provide a complete picture of the ICGA learning curve since we have not yet reached the plateau phase, with observed continued improvement through the entirety of our study. And finally, although we identified an inflection point with our cohort grouped into thirds, we were unable to confirm the cut-off point for a generalizable learning curve plateau. Future work with a larger cohort will allow us to identify a learning curve plateau.

Conclusions

Despite the above limitations, this is the first study to evaluate the outcomes of using ICGA for mastectomy with immediate expander-based reconstruction as a function of surgeon experience. We found that the outcomes of mastectomy with reconstruction using ICGA improved over time since its implementation, with lower rates of ischemic

complications, increased expander fill volumes, and shorter wait time to final reconstruction. Prospective studies should be conducted to further assess the learning curve of ICGA and determine the number of consecutive cases a surgeon needs to perform to complete the learning curve.

Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study, formal consent is not required. This article does not contain any studies with animals performed by any of the authors.

Conflict of interest

Dr. Cunningham is a consultant for Novadaq Corp and Mentor Corp. The remaining authors declare that they have no conflicts of interest.

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Supplementary material

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