

Routine Laser-assisted Indocyanine Green Angiography in Immediate Breast Reconstruction: Is It Worth the Cost?

Shayda Mirhaidari, MD
Vitali Azouz, MD
Douglas S. Wagner, MD

Background: Laser-assisted indocyanine green angiography (LAIGA) has been proven to accurately detect mastectomy skin flap necrosis (MSFN) intraoperatively and prevent postoperative complications in breast reconstruction. The purpose of this study was to examine the cost-effectiveness of the routine use of LAIGA in immediate breast reconstruction and to perform a break-even point analysis.

Methods: This is a retrospective review of prospectively gathered data from all patients who underwent immediate breast reconstruction from January 2014 to January 2015. LAIGA was routinely used in all cases. Patients were followed for at least 90 days to capture postoperative complications. Costs were calculated by reviewing itemized bills and Medicare Reimbursement Current Procedural Terminology codes to assess surgeon fees. Outcomes and costs were compared with a historical cohort of patients who underwent breast reconstruction before the implementation of LAIGA.

Results: Two-hundred-and-six immediate breast reconstructions (126 patients) were performed using LAIGA for a total cost of \$210,700. The average cost of MSFN in our LAIGA cohort was \$30,496. The routine use of LAIGA decreased the MSFN rate from 12.4% to 6.3% and prevented MSFN on 13 breasts resulting in a gross cost savings of \$396,453, and net savings of \$185,753. Break-even point analysis demonstrated that number of cases needed to break even decreases as the average MSFN cost and MSFN reduction rate increase.

Conclusion: The routine use of LAIGA in immediate breast reconstruction is cost-effective in reducing the incidence of MSFN, implant loss, and overall unexpected reoperation rate. (*Plast Reconstr Surg Glob Open* 2019;7:e2235; doi: 10.1097/GOX.0000000000002235; Published online 25 April 2019.)

INTRODUCTION

Implant-based breast reconstruction has become the most common modality of breast reconstruction following mastectomy.¹ Postoperative complications such as mastectomy skin flap necrosis (MSFN) may lead to the need for subsequent procedures and possible reconstructive failure.^{2,3} Increased patient body mass index (BMI),

active smokers, and large breasts have been identified as predictive risk factors for complications.⁴⁻⁷ Evaluating mastectomy skin flap viability intraoperatively is crucial as it provides the opportunity to resect ischemic areas and, thereby, reduces postoperative complications. Aside from clinical judgment, angiography-based tools that measure mastectomy skin flap perfusion have been developed.

Fluorescein dye angiography, a method used to assess circulation that predates the 1940s,^{8,9} has been applied to assess skin flap viability in animal models since the 1970s.^{10,11} This method is performed by injecting a patient with fluorescein dye, that when viewed with a Wood's lamp, illuminates as different colors. Areas of adequate perfusion appear yellow, whereas those with poor perfusion appear blue. Indocyanine green angiography was used to evaluate the microcirculation of axial-pattern skin flaps in animals in 1995¹² and has since been applied to breast reconstruction through the use of laser-assisted

From the Plastic & Reconstructive Surgery, Summa Health System, Akron, Ohio.

Received for publication January 30, 2019; accepted March 1, 2019.

Presented at the Ohio Valley Society of Plastic Surgery 60th Annual Meeting, June 2, 2017, Pittsburgh, PA and American Society of Plastic Surgeons—The Meeting, October 7, 2017, Orlando, FL.

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DOI: 10.1097/GOX.0000000000002235

Disclosure: Douglas S. Wagner is a Speaker for LifeCell Corporation (Branchburg, NJ). None of the other authors has any financial disclosures.

imaging.^{13–18} To accomplish this, the patient is first injected with indocyanine green (ICG), a water-soluble tricarbocyanine dye, which binds intravascular plasma proteins. When excited with a laser, the dye becomes fluorescent and can be viewed and recorded with a vascular imaging system. ICG may safely be administered multiple times intraoperatively and has a half-life of 3–5 minutes.¹⁹ Laser-assisted indocyanine green angiography (LAIGA) grants surgeons intraoperative real-time imaging of tissue perfusion and serves as an adjunct to the surgeon's visual assessment of flap perfusion. In their prospective trial, Phillips et al. compared the utility of these 2 modalities and clinical judgment in predicting MSFN and found that LAIGA was more accurate.²⁰ In our previous study, we came to a similar conclusion. When comparing LAIGA and clinical assessment, we found that LAIGA was more accurate in predicting MSFN. The use of LAIGA decreased complications and overall unexpected reoperation rate.¹⁸

Although the utility of LAIGA has been proven, the cost-effectiveness of its use in immediate breast reconstruction remains controversial.^{16,21} The purpose of this study was to examine the cost-effectiveness of the routine use of LAIGA in immediate breast reconstruction. Additionally, we sought to perform a break-even point analysis to determine the quantity of cases needed to be performed using LAIGA routinely to break even at various complication rates and costs.

METHODS

With approval from our institutional review board, the authors performed a retrospective review of prospectively gathered data from January 2014 to January 2015. Consecutive patients undergoing therapeutic or prophylactic mastectomy with implant-based breast reconstruction during this time period were included. Patients who had delayed breast reconstruction, intolerance to ICG, or had an iodine allergy were excluded from our study. Demographic data obtained retrospectively included patient age, BMI, smoking status, radiation history, indication for mastectomy, mastectomy type, and reconstructive modality. Patients underwent mastectomies by 1 of 13 board certified general surgeons on staff at our institution. Mastectomies performed included simple mastectomy, simple mastectomy with sentinel lymph node biopsy, nipple sparing mastectomy, and modified radical mastectomy. Immediate reconstruction was performed by 1 of 3 plastics surgeons. Reconstructive modalities included direct to implant, tissue expanders (TEs), pedicled flaps, and free tissue transfer. Acellular dermal matrix (ADM-AlloDerm RTU: Perforated & Non-perforated-Branchburg N.J.) was used in all implant-based reconstructions.

After placement of a TE or sizer, the mastectomy skin flaps of all patients were temporarily closed for evaluation using LAIGA. After administering 7.5 mg of ICG and a 3-minute latency period, angiography was performed using the SPY Elite System (NOVADAQ, Bonita Springs, FL). Based on data collected and clinical judgment, the decision was made to excise additional skin, remove fluid from the TE, and change the size of the implant or not

intervene. If intervention was undertaken, a subsequent angiography was performed in a similar fashion to reexamine potentially ischemic areas. Drains were placed in all patients following reconstruction. Patients who underwent implant-based reconstruction were continued on antibiotics postoperatively until their drains were removed. Patients were followed for at least 90 days to capture postoperative complications including partial and full thickness mastectomy skin necrosis, seroma, hematoma, infection, and implant loss. Complications were defined as described in our previously published study.¹⁸

Statistical analysis was performed using SPSSV23.0 (IBM Corp. Armonk, NY). Patient demographics, complication rates, and reoperative rates were compared with a historical cohort of patients who underwent breast reconstruction before the implementation of LAIGA using the Fisher's exact test. *P* values < 0.05 were used for statistical significance.

A break-even point analysis was performed using Microsoft (Microsoft Corp., Redmond, Wash.). To calculate the break-even point the following equation was used:

$$N = FC / (S - VC).$$

The number of cases needed to break even (*N*) is calculated by dividing the fixed cost (*FC*), by the difference between the savings per case, and the variable cost (*S-VC*). The fixed cost is defined by the purchase price of the SPY Elite System (NOVADAQ, Bonita Springs, FL), which was \$150,000 at our institution. The variable cost was defined by the cost per operative kit, which was \$295 at our institution. The savings per case (*S*) was determined by multiplying the average cost of MSFN per case, by the MSFN reduction rate as represented by the following formula:

$$S = \text{Average MSFN Cost} \times \text{MSFN Reduction Rate}.$$

The average cost of readmission and reoperation due to MSFN was calculated by reviewing itemized bills and Medicare Reimbursement Current Procedural Terminology (CPT) codes to assess surgeon fees. The MSFN reduction rate was defined as the difference in rate of MSFN with and without the routine use of LAIGA.

RESULTS

Two hundred six immediate breast reconstructions (126 patients) were performed during the study time period. Eighty breast reconstructions were bilateral and 46 were unilateral. The average patient age was 51 and average BMI was 27. Patient demographics between the LAIGA cohort and the historical cohort were similar (Table 1). Nipple sacrificing mastectomy was the most commonly performed mastectomy type and malignancy was the most common indication. The majority of reconstructions were prosthetic-based reconstructions (TEs, direct to implants). Preoperative radiation was performed in 11 breasts due to failed breast conservation therapy (Table 2). The LAIGA cohort had a lower incidence of FTN, implant loss, implant loss related to necrosis, and necrosis-related reoperation than our historical cohort (*P* = 0.01, 0.01, 0.01, 0.04, respectively, Table 3). The rates of infection, implant loss, and unexpected reoperation were similar between the 2 cohorts (Table 3). The routine

Table 1. Demographics and Patient Characteristics: LAIGA Versus Historical

Variable/Statistic	LAIGA	Historical	P
Total patients	126	117	
Age	51.4	52.8	0.38
BMI, kg/m ²	27.0	26.4	0.39
Hypertension, n, %	30 (23.8)	24 (5.92)	0.54
Diabetic, n, %	10 (7.9)	9(7.7)	0.94
Smoker, n, %	12 (9.5)	9 (7.7)	0.61

Table 2. Surgical Characteristics: LAIGA Versus Historical

Variable/Statistic	LAIGA	Historical	P
Total surgeries	206	194	0.06
Bilateral breasts reconstruction	80	77	
Unilateral breast reconstruction	126	117	
Diagnosis, n, %			0.06
Cancer	82 (39.8)	80 (40.6)	
BRCAs	42 (20.4)	32 (16.5)	
Prophylaxis	82 (39.8)	82 (42.3)	
Mastectomy type			<0.001*
Nipple-sacrificing mastectomy	145	177	
Nipple-sparing mastectomy	61	17	
Reconstruction method			<0.001*
Permeant implant	165	44	
TE	15	117	
Lat and TE/implant	4	6	
Autologous	22	27	
Radiation, n, %	11 (5.4)	12 (6.2)	0.72
Matrix, n, %	191 (92.7)	167 (86.1)	0.03*

*Denotes statistical significance.

Table 3. Surgical Outcomes LAGIA Versus Historical

Total Surgeries	LAIGA (n = 206)	Historical (n = 194)	P
Total necrosis rate (PTN/FTN)	29 (14.1%)	38 (19.6%)	0.14
PTN	21 (10.2%)	18 (9.3%)	0.76
FTN	8 (3.9%)	20 (10.3%)	0.01*
Infection	18 (8.7%)	29 (14.7%)	0.05
Implant loss	4 (1.9%)	14 (7.2%)	0.01*
Implant loss related to necrosis	1 (0.5%)	8 (4.1%)	0.02*
Unexpected reoperation	18 (8.7%)	30 (15.5%)	0.05*
Necrosis-related reoperation	13 (6.3%)	24 (12.4%)	0.04*

*Denotes statistical significance.

use of LAIGA prevented MSFN in 13 breasts and led to a 6% reduction in reoperation for MSFN.

The overall cost of LAIGA utilization during the studied time period was \$210,700. The average cost of MSFN in our LAIGA cohort was \$30,496 (Table 4). The routine use of LAIGA decreased the MSFN rate from 12.4% to 6.3% (Table 5) and prevented MSFN on 13 breasts in our study resulting in a gross cost savings of \$396,453, and net savings of \$185,753.

Break-even point analysis demonstrated that number of cases needed to break even decreases as the average MSFN cost and MSFN reduction rate increase. If the average MSFN cost is \$15,000 or greater then the cost of the routine use of LAIGA could be recovered, only if the MSFN reduction rate is greater than 2%. If average MSFN costs are \$1,000 or less, then the routine use of LAIGA would incur greater costs for MSFN reduction rates between 2% and 14%. The routine use of LAIGA may be cost-effective

Table 4. Cost of MSFN

	Reoperation	Revision	Readmit	Cost (\$)
FTN				273,611
1	4	—	1	146,368
2R	2	—	1	27,184
2L	2	—	1	27,184
3	3	—	—	36,640
4	1	1	—	18,789
5R	1	—	—	10,065
5L	1	—	—	10,065
6R	2	—	—	16,105
PTN				104,053
6L	3	—	1	60,564
7	1	—	—	7,441
9R	—	3	1	32,028
9L	1	—	—	2,010
9L	1	—	—	2,010
Average				30,496

Table 5. MSFN Reoperation: LAIGA Versus Historical

Reoperation for MSFN	LAIGA (n = 204)	Historical (n=194)	P
PTN	5	4	076
FTN	8	20	0.01*
Total	13 (6.3%)	24 (12.4%)	0.01*

*Denotes statistical significance.

Table 6. Break-even Cost Analysis (Number of Cases)

Average MSFN Cost	MSFN Reduction Rate						
	2%	4%	6%	8%	10%	12%	14%
\$1,000	*	*	*	*	*	*	*
\$5,000	*	*	30,000	1,429	732	492	370
\$10,000	*	1,429	492	297	213	166	136
\$15,000	30,000	492	248	166	124	100	83
\$20,000	1,429	297	166	115	88	71	60
\$25,000	732	213	124	88	68	55	47
\$30,000	492	166	100	71	55	45	38

*Denotes loss.

for average MSFN costs between \$5,000 and \$10,000 depending on the MSFN reduction rate (Table 6). According to our analysis, 248 cases routinely using LAIGA would need to be performed to recover costs if the average MSFN cost is \$15,000 and the MSFN reduction rate is 6%. The greater the number of cases performed with routine use of LAIGA, the greater the potential savings when the break-even point is overcome (Fig. 1).

DISCUSSION

MSFN is a dreaded postoperative complication of immediate breast reconstruction that can lead to increased morbidity and cost. Identifying ischemic areas of mastectomy skin flaps at the time of reconstruction grants the opportunity for debridement to reduce postoperative complications and subsequent procedures. In our prior study, we demonstrated how the routine use of LAIGA in immediate breast reconstruction helped identify ischemic tissue and reduced the incidence of MSFN, implant loss, and the overall unexpected reoperation rate.¹⁸ In the present study, we determined the routine use of LAIGA to be cost-effective in immediate breast reconstruction.

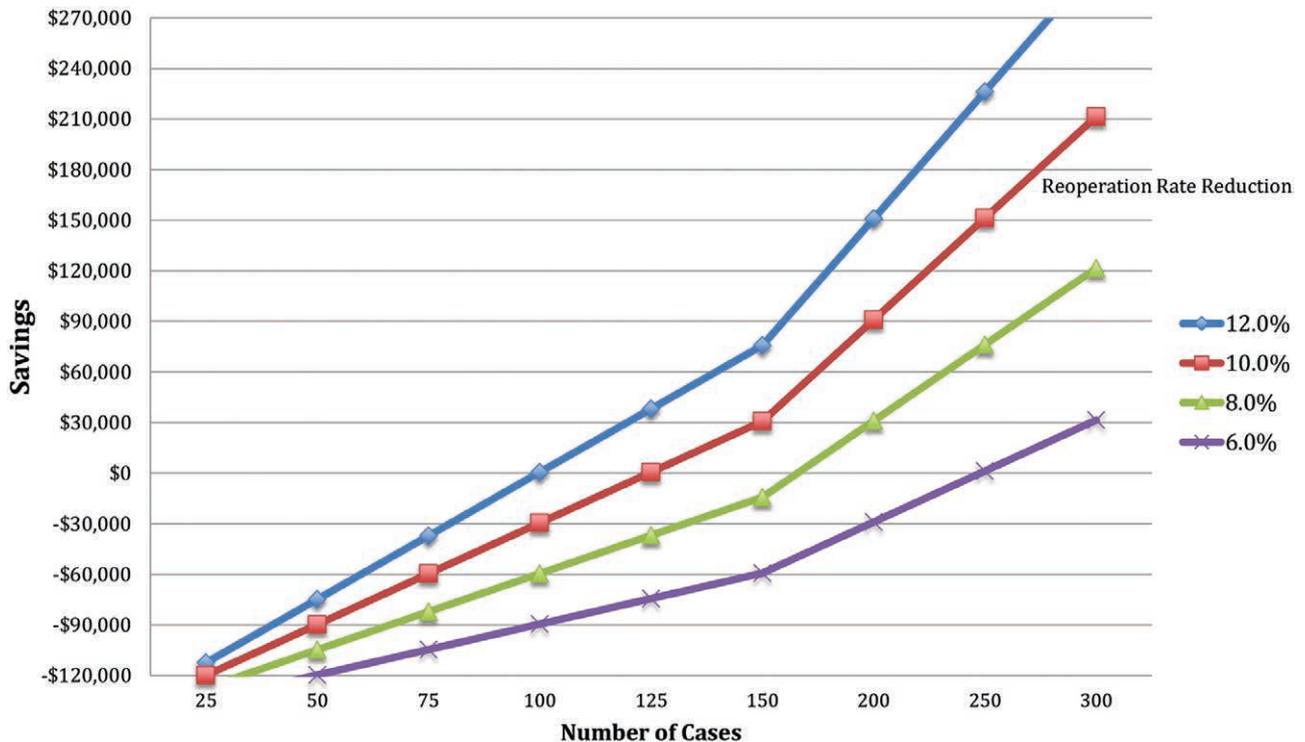


Fig. 1. \$15,000 reoperation cost analysis.

In a cost analysis by Kanuri et al., the authors calculated costs using institutional costs, costs according to treatment types, and the individual cost of using LAIGA that was provided by the company. Treatment costs varied from \$723 per case for minor necrosis to \$5,250 per case for major necrosis. Cases that involved implant loss were calculated to cost \$32,500 per case. The authors concluded that the routine use of LAIGA in immediate prosthesis-based breast reconstruction is only cost-effective in patients who are at high risk of MSFN. Interestingly, the authors noted that if the cost of LAIGA per case was equal or less than \$450 then it may be cost-effective for routine use in all patients.²¹ This contradicts the findings of Duggal et al. who performed a cost analysis on 184 patients who underwent breast reconstruction using LAIGA routinely. The authors found that the routine use of LAIGA decreased the incidence of MSFN by 10% and reduced unexpected reoperations by 8%. The routine use of LAIGA was determined to be cost-effective and saved \$614 per patient. The cost of using ICG was calculated to be \$795 per case and the cost of unexpected reoperations was calculated by adding operative costs and inpatient costs.¹⁶ In a cost-effective analysis on the use of LAIGA in free autologous breast reconstruction by Chatterjee et al., the authors also concluded that LAIGA was cost-effective, especially when the overall complication rate is 4% or greater. Of note, the authors calculated the cost of LAIGA per procedure to be \$1,295, which is substantially greater than other studies.²² In our study, the cost of using LAIGA was lower and may reflect the variance in institutional purchasing power of acquiring the imaging system and supplies.

Similar to other studies, the cost of MSFN in our study varied widely. In 1 case, the cost of MSFN was as high as \$146,368. This patient initially underwent a left-sided mastectomy with direct implant placement that was complicated by FTN, which resulted in an exposed implant despite revision. This led to delayed reconstruction with TE and implant replacement. A total of 4 operations and 1 readmission resulted in a cost that almost equaled that of the purchase price of the imaging system.

Based on our MSFN reduction rate of 6% and average MSFN cost \$30,000, the number of cases needed to be performed using LAIGA routinely to recoup the costs of LAIGA according to our analysis is 100. Our analysis only included cases of immediate breast reconstruction and did not include other applications of LAIGA. It is reasonable to conclude that the break-even point may be realized sooner if the other applications of LAIGA are also cost effective. Our analysis demonstrates that the cost-effectiveness of using LAIGA routinely ultimately depends on the costs of LAIGA, and the rate and cost of MSFN.

Our study was limited by the inclusion of a historical control and its retrospective nature. Costs in this study were calculated using itemized bills and CPT codes and, therefore, may represent charges and not true costs. Additionally, though all itemized bills were carefully examined, miscellaneous charges such as chargers for office and home care visits may not have been accounted for. Since we only accounted for monetary costs, we failed to account for the psychosocial impacts and social costs that postoperative complications have on patient wellbeing and quality of life. Postoperative complications can also

postpone adjuvant therapy and prolong patient recovery times, which may further increase lost revenue from work for patients and surgeons alike. Nonetheless, we feel our findings serve as a proxy that can guide surgeons and institutions on the cost benefits of LAIGA.

CONCLUSION

The routine use of LAIGA in immediate breast reconstruction is cost-effective in reducing the incidence of MSFN, implant loss, and overall unexpected reoperation rate.

Vitali Azouz, MD

Summa Health System
Plastic & Reconstructive Surgery Department
Akron City Hospital
55 Arch Street, Suite 2F
Akron, OH 44304
E-mail: azouzv@summahealth.org

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