# RETROSPECTIVE CHART REVIEW OF NIPPLE SPARING MASTECTOMIES WITH AND WITHOUT AN ENABLING INTRACAVITY ILLUMINATION AND VISUALIZATION SYSTEM

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ABSTRACT: Nipple Sparing Mastectomy (NSM) has become a desirable option for oncologic treatment of breast cancer with excellent clinical and aesthetic outcomes in appropriate patients. Still, this procedure can be technically challenging for surgeons, and patient selection is a critical factor. Technological advances have enabled surgeons to improve their surgical efficiency and proficiency, decrease complications, reduce surgical times, and improve aesthetic outcomes. Shorter anesthesia times are beneficial for patients. The addition of advanced technologies has enabled us to further decrease surgical times, increase flap viability, nipple areolar viability, contractility and sensation and improve aesthetic outcomes – including Hidden Scar<sup>TM</sup>.

#### INTRODUCTION

Nipple Sparing Mastectomy (NSM) is an advanced surgical option for the treatment of breast cancer. NSM has become a popular treatment choice due to an increased desire by both surgeons and patients to achieve an improved aesthetic outcome after breast cancer surgery. It offers both patient and surgeon an opportunity for an effective oncologic surgical outcome while preserving the skin and the nipple-areola complex (NAC) for the optimal aesthetic result. As breast surgeons continue to base their interventions on patient safety and oncologic efficacy, this advanced technique has enabled cosmesis to become a significant endpoint in surgical outcomes.<sup>6</sup>

NSM allows a patient to have an optimal cosmetic outcome without sacrificing local regional recurrence rates.<sup>1</sup> The psychological and emotional gains for patients are innumerable. Being able to look in the mirror after breast cancer surgery and see the reflection of themselves as close to normal as possible and, in most cases, with a hidden scar is immeasurable. The inframammary fold (IMF) incision approach has been described as a superior approach for this procedure but comes with its own technical challenges.<sup>2 3 4</sup> The major technical challenge has been access to, and visualization of the superior pole of the breast and the axilla for identification of the section lymph node. Visualization to identify the second intercostal

<sup>&</sup>lt;sup>1</sup> Sacchini V. Nipple-Sparing Mastectomy for Breast Cancer and Risk Reduction: Oncologic or Technical Problem? Journal of the American College of Surgeons. 2006; 203(5) 5: 704-714

<sup>&</sup>lt;sup>2</sup> Plastic & Reconstructive Surgery: March 2014 - Volume 133 - Issue 3 - p 496–506 doi: 10.1097/01.prs.0000438056.67375.75.

<sup>&</sup>lt;sup>3</sup> Plastic and Reconstructive Surgery 2013, November 132(5):1043-53.

<sup>&</sup>lt;sup>4</sup> Spear SL, Hannan CM, Willey SC, Cocilovo C. Plast Reconstr Surg. 123(6):1665-73. 2009

perforator, axillary vein, long thoracic nerve and thoracodorsal nerve artery and vein is essential to perform safe meticulous surgery.

However, adding technology to an established procedure, such as nipple sparing mastectomy, can face obstacles in the medical economic climate. There are four key factors that are taken into account in assessing new technology in the operating room:

- 1. Does it improve patient safety?
- 2. Does it improve outcomes (e.g., flap viability) and decrease complications?
- 3. Does it save operative time which has been estimated to cost the OR \$30 per minute on average? <sup>5,6,7</sup>
- 4. Does it improve upon the aesthetic outcome and thus patient experience and satisfaction?

Justification for new technology is always a challenge for surgeons in our modern age evolving technology, as cost containment is a recurring conversation.

A recent survey of breast surgeon thought leaders (Simmons et al.)<sup>8</sup> indicated that recent improvements in intracavity illumination and visualization technology reduced surgical challenges and potential complications of NSM. Specifically, 100% of surveyed surgeons believed that the Eikon<sup>TM</sup> Illuminated Retractor System with integrated Intelligent Photonics<sup>TM</sup> (Invuity Inc., San Francisco, CA) overcomes the primary challenge of visualization when performing NSM, 100% of surgeons reported it improved their surgical efficiency, and 92% believed that it decreased surgical time. In addition, 92% reported that it increased their success in maintaining flap and nipple integrity and improved patient safety, and therefore improved patient experience.



Image #1: Eikon™ Illuminated Retractor System in Nipple Sparing Mastectomy

In order to further validate and quantify the value perceptions that differences in procedural efficiency and quality outcomes exist between cases performed with and without the Eikon<sup>™</sup> Illuminated Retractor System, a retrospective chart review was undertaken at one of the participating breast centers from the prior survey. In this study, we investigated the qualitative and quantitative findings of the breast surgeon

<sup>&</sup>lt;sup>5</sup> Shippert et al. American Journal of Cosmetic Surgery – Vol. 22, no 1, pp 25-34 (2005)

<sup>&</sup>lt;sup>6</sup> The American Journal of Cosmetic Surgery, A Cost-Savings Analysis of Skin Closure Devices: Incorporating Opportunity Cost Into Operating Time Efficiency

<sup>&</sup>lt;sup>7</sup> LIT 11922 Healthcare Consulting Firm: NSM Economic Findings, July 2015

<sup>&</sup>lt;sup>8</sup> LIT 11195 --- NIPPLE SPARING MASTECTOMY AND THE ADVENT OF AN ENABLING SURGICAL ILLUMINATION AND VISUALIZATION SYSTEM Clinical Experience Survey of Thought Leaders in Breast Surgery, Rache Simmons, MD, et al

survey by performing a retrospective medical record review of one pair of participating surgeons' cases. Nipple Sparing Mastectomies performed by surgical oncologist Dr. Beth DuPree at Holy Redeemer Hospital and reconstruction by plastic surgeon Dr. William Scarlett prior to and after adopting the Eikon<sup>TM</sup> System were assessed in terms of the anesthesia time and complications.

## METHODS

## *STUDY PROTOCOL*

A retrospective chart review was designed to capture patient characteristics, surgical parameters, and clinical outcomes. Data fields recorded are shown in Table 1 and 2. Select data field definitions are as follows:

- Anesthesia time: the time from the start of induction until anesthesia is discontinued (selected as the preferred time metric due to the consistency of reporting in medical records)
- Breast dimensions: the distance measured in centimeters standing pre-operatively
  - Inframammary fold (IMF) to nipple
  - Sternal notch to nipple
  - o Breast base width
- Ptosis as per Regnault classification: Grade I III, psuedoptosis, and parenchymal malposition
- Flap necrosis: any full thickness necrosis noted in the medical chart, or pending exposure of the tissue expander
- Epidermolyis: any presence of epidermolyis (blistering or pealing of the skin or nipple-partial thickness) unilateral or bilateral as noted in the medical chart
- Surgical approach
  - Posterior: sentinel lymph node identification and biopsy after breast was reflected off pectoral muscle, allowing for the frozen section to be performed as the anterior flap dissection was undertaken through a single inframammary fold incision.
  - Anterior: sentinel lymph node dissected after anterior flap creation
    - Axillary counter incision was not required using this approach: Traditionally a separate incision for the lymph node identification is used by many surgeons to allow for the frozen section to be performed at the beginning of the procedure to save time intra-operatively. This approach leaves a visible scar in the axilla and can lead to a deformity of the axillary tail and migration of the nipple areolar complex laterally. Poor tissue elasticity may be a reason that a counter incision would be required.
  - All patients had immediate breast reconstruction utilizing a tissue expander and an acellular dermal matrix (ADM). The expander had a maximal fill of 50% done at the time of the mastectomy in order to avoid excess pressure on the skin flap and NAC.

While, nipple sensation and contractility were also captured as part of the review, data was not available on all cases as sensation and contractility can return up to three years post-surgery. Therefore, patients will continue to be followed and final analyzed data will be reported at a later date when all patients are at least 12-36 months post-surgery.

The initial approach to NSM prior to 2010 was via a standard anterior flap dissection often through a lateral keyhole or lazy-S incision followed by a posterior removal of the breast from the pectoral muscle. In 2010, the technique was altered to facilitate the surgical dissection and attempt access to the axillary sentinel lymph node via a posterior approach to decrease operative time as the frozen section could be performed while the anterior dissection was being completed. The headlight and traditional fiber optic lighted retractors available combined with the traditional electrosurgical cautery devices made the procedure manageable. However, using these traditional tools contributed to a much longer operative time and made for a difficult and cumbersome procedure to perform with the additional risk of patient burns and visible scars.

#### DATA COLLECTION

Dr. Beth DuPree and Dr. William Scarlett at Holy Redeemer Hospital (Meadowbrook, PA) began using Invuity's Eikon<sup>TM</sup> Illuminated Retractor System in August of 2012. A time interval from June 2011 to July 2012 was selected to represent posterior approach with traditional lighted retractors and cautery as (Cohort A) procedures and cases from August 2012 to December 2014 were selected to represent procedures performed with the posterior approach and the Eikon<sup>TM</sup> Illuminated Retractor System as (Cohort B) procedures. Procedures performed by Dr. Beth DuPree and Dr. William Scarlett were selected for evaluation. A total of 19 consecutive medical records of patients that underwent a nipple sparing mastectomy prior to the transition to Eikon<sup>TM</sup> were collected in Cohort A. A total of 26 consecutive medical records of patients that underwent a nipple-sparing mastectomy after the transition to Eikon<sup>TM</sup> were collected in Cohort A was excluded due to insufficient data and one from Cohort B. Of these records, one from Cohort A was excluded due to insufficient data and one from Cohort B was excluded as the case was filmed for training purposes and times were increased. Holy Redeemer operative records were matched to the corresponding records at Bucks County Aesthetic Center (Bensalem, PA) de-identified data was entered into a Microsoft Excel<sup>®</sup> database.

### DATA ANALYSIS

Navigant Consulting was given access to the de-identified Microsoft  $\text{Excel}^{\&}$  database for data analysis. Statistical significance of differences between cohorts was evaluated using a two-sample t-test assuming unequal variances and z test. Statistical significance was defined as p<0.05.

#### **RESULTS AND DISCUSSION**

### PATIENT CHARACTERISTICS

Patient characteristics were evaluated, such as age, BMI, smoking history and breast dimensions were compared, as these factors influence the complexity of cases and complication rates. Patients in Cohort B tended to be younger than Cohort A, but differences were not statistically significant. Patient BMI and smoking history were comparable in all cases, as the reduction in patients that never smoked in Cohort B was not statistically significant. In general, breast dimensions (IMF to nipple, clavicle to nipple) were comparable, but breast width was slightly reduced in Cohort B. In addition, the data showed a trend towards more patients in Cohort B with greater than 'Grade 1' ptosis (13% more in all cases and 9% more in the bilateral cases) and a slight increase in the number patients with a C or D cup size, both of which increase the complexity of cases.

Patients in each cohort were segmented based on whether a bilateral or unilateral mastectomy was performed. There were two and six patients in Cohorts A and B that underwent a unilateral mastectomy, respectively. Given the low number of unilateral cases, bilateral cases were the primary focus of the analysis.

						d Post-Eikon <sup>1</sup> Tasas			
	All Cases Pre- Delta			Bilateral Cases Pre- Delta			Unilateral Cases Pre- Delta		
Characteristics	Eikon	Eikon	(post-pre)	Eikon	Eikon	(post-pre)	Eikon	Eikon	Delta (post-pre)
Ν	18	25	7	16	19	3	2	6	4
Age	50.0	47.4	-2.6	49.7	45.0	-4.7	52.5	54.8	2.3
Average BMI	23.6	22.8	-0.8	24.1	22.6	-1.5	20.2	23.6	3.4
Smoking									
Current	11%	12%	1%	13%	5%	-7%	0%	33%	33%
Former	39%	32%	-7%	38%	26%	-11%	50%	50%	0%
Never	50%	56%	6%	50%	68%	18%	50%	17%	-33%
Cup Size									
Α	22%	28%	6%	19%	26%	8%	50%	33%	-16.7%
В	61%	52%	-9%	63%	53%	-10%	50%	50%	0.0%
С	11%	20%	9%	13%	21%	9%	0%	17%	16.7%
D	6%	0%	-6%	6%	0%	-6%	0%	0%	0.0%
<b>Prior Breast Procedure</b>									
None	44%	52%	8%	44%	47%	4%	50%	67%	17%
Biopsy	33%	16%	-17%	38%	16%	-22%	0%	17%	17%
Lumpectomy	17%	16%	-1%	19%	16%	-3%	0%	17%	17%
Mastectomy (unilateral)	6%	0%	-6%	0%	0%	0%	50%	0%	-50%
Augmentation	0%	12%	12%	0%	16%	16%	0%	0%	0%
Delay Nipple	0%	4%	4%	0%	5%	5%	0%	0%	0%
Breast Dimensions									
Clavicle to Nipple	21.8	21.4	-0.4	22.0	21.3	-0.7	19.5	22.2	2.7
IMF to Nipple	4.6	4.6	0.0	4.6	4.7	0.1	4.0	4.2	0.2
Width	10.4	9.2	-1.2*	10.6	9.3	-1.4*	8.5	9.0	0.5
Percent Bilateral Cases	89%	76%	-13%	NA	NA	NA	0%	0%	0%
Percent Bilateral Risk Reduction	22%	16%	-6%	25%	21%	-4%	NA	NA	NA
Ptosis									
Grade 1	61%	48%	-13%	56%	47%	-9%	100%	50%	-50%
Grade 1-2	0%	4%	4%	0%	5%	5%	0%	0%	0%
Grade 2	22%	36%	14%	25%	37%	12%	0%	33%	33%
Grade 2-3	11%	12%	5%	13%	11%	-2%	0%	17%	17%
Grade 3	6%	0%	-6%	6%	0%	-6%	0%	0%	0%

Table 1: Patient Characteristics Pre-Eikon<sup>™</sup> and Post-Eikon<sup>™</sup>

\*p<0.05

## SURGICAL APPROACH AND DEVICES USED

With Cohort B the Eikon<sup>™</sup> Illuminated Retractor System with integrated Intelligent Photonics<sup>™</sup> was used for both surgical retraction and intracavity illumination and visualization. The Eikon<sup>™</sup> System is comprised of eight illuminated retractors of different lengths and widths that are used systematically during flap creation and performing the mastectomy and sentinel lymph node biopsy and dissection as

well as for implant pocket preparation, formation and placement during breast reconstruction. The Intelligent Photonics<sup>™</sup> is delivered via a proprietary optical waveguide which is moved from retractor to retractor during the case to maximally assist with dissection and decrease pressure put on the skin flap and nipple areolar complex. The waveguide uses critical angles and the properties of total internal reflection to retain and transmit maximum light as it travels through the device. In addition, the waveguide utilizes novel optical methods to mix light during the total internal reflection transmission process to enable more uniform light extraction across its output surface. The output surface consists of a complex geometry of micron-sized refractive microstructures that extract, direct and shape volumetric illumination into the surgical cavity while eliminating shadows and glare. This complex geometric structure provides redundancy of light at different angles to enable illumination of the surgical target, even if blood or debris accumulates on the surface of the waveguide. The enhanced coupling of light and thermally cool illumination together virtually eliminate the known thermal hazards associated with traditional fiber optic lighted retractors. The Eikon<sup>™</sup> Retractors include an atraumatic blade and tip design that decreases breast flap trauma during retraction.

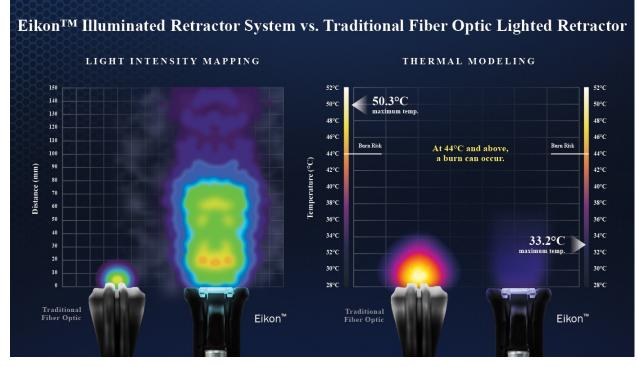


Image #2: Eikon<sup>™</sup> Illuminated Retractor System vs. Traditional Fiber Optic Lighted Retractor – Light Intensity Mapping and Thermal Modeling –

Electro cautery on settings of 70 cut and 35 coag (Blend 1) were used for dissection of anatomic planes prior to May 2013. After that time an advanced electrosurgery device was used for both dissection and coagulation to reduce thermal damage to adjacenttissue.

The advanced electrosurgery device uses radiofrequency current delivered via an electrode that has a thermal protective shield. Plasma is discharged along the exposed active electrode edge that device tip is 99.5% insulated. The plasma acts as a conductive medium allowing for transfer of energy to the target

tissue at much lower power levels reducing thermal damage to the surgical field.<sup>9</sup> This technology plays a role in improved flap viability, decreased postoperative drainage duration and volume.<sup>10</sup>

## ANESTHESIA TIME REDUCTION

In both bilateral and unilateral cases, a reduction in anesthesia time was observed in Cohort B relative to Cohort A. Bilateral mastectomy procedures had a 31-minute reduction in anesthesia time on average (median reduction of 33 minutes) (Table 2, p<0.05). Unilateral cases also showed a trend towards a reduction in anesthesia time in Cohort B (average reduction of 33 minutes), but there were too few cases to show statistical significance. One would have anticipated a smaller reduction in anesthesia time in unilateral cases compared to bilateral cases; however, given that there were only two unilateral cases in Cohort A, it is difficult to draw comparisons or conclusions. Surgical times may vary for a multitude of reasons. Patient tissue type, ease of surgical plane identification and ease of identification of the sentinel node are factors that can create a difference in time case per case. Surgical times increase when breast surgical oncology fellows participate in the cases as they are still being educated and trained on the NSM techniques.

	All Cases			Bilateral Cases			Unilateral Cases		
Characteristics	Pre- Eikon	Eikon	Delta (post-pre)	Pre- Eikon	Eikon	Delta (post-pre)	Pre- Eikon	Eikon	Delta (post-pre)
Average Anesthesia time (median)	295 (305)	251 (258)	$NA^{\text{F}}$	306 (305)	275 (272)	-31* (-33)	207	174	-33
Average number of nodes removed (median)	3.5 (2)	2.2 (2)	-1.3 (0)	3.7 (2)	2.4 (2)	-1.3 (0)	2.0 (2)	1.8 (2)	-0.2 (0)
SLN Surgical Approach									
Anterior	62%	25%	-37%	55%	27%	-28%	100%	20%	-80%
Posterior	23%	75%	52%	27%	73%	46%	0%	80%	80%
Axillary	15%	0%	-15%	18%	0%	-18%	0%	0%	0%
Cutting and Coagulation									
Cautery	100%	24%	-76%	100%	21%	-79%	100%	33%	-67%
Advanced Electrosurgical Device	0%	76%	76%	0%	79%	79%	0%	67%	67%
Complications									
Returned to OR	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Cases with Post- operative bleeding	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Percent Flap Necrosis	11%	0%	-11%	13%	0%	-13%	0%	0%	0%
Epidermolysis	67%	20%	-47%*	69%	21%	-48%*	50%	17%	-33.3%
Infection	0%	0%	0%	0%	0%	0%	0%	0%	0%
Seroma	0%	0%	0%	0%	0%	0%	0%	0%	0%
Hematoma	6%	0%	-6%	6%	0%	-6%	0%	0%	0%

Table 2: Surgical Parameters and Patient Outcomes Pre-Eikon<sup>™</sup> and Post-Eikon<sup>™</sup>

<sup>\*</sup>Given the sensitivity of procedure type to time and the non-uniformity in the number of unilateral versus bilateral cases, the combined time savings is not calculated

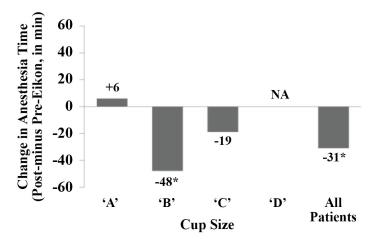
\*p<0.05

<sup>&</sup>lt;sup>9</sup> Vose JG, McAdara-Berkowitz J. Reducing scalpel injuries in the operating room. *AORN J.* 2009;90(6):867-872.

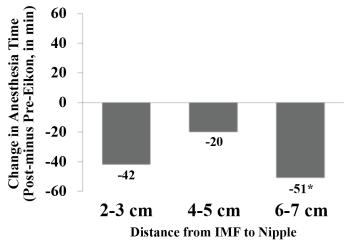
<sup>&</sup>lt;sup>10</sup> Ruidiaz ME, Messmer D, Atmodjo DY, et al. Comparative healing of human cutaneous surgical incisions created by the PEAK PlasmaBlade, conventional electrosurgery, and a standard scalpel. *Plast Reconstr Surg*. 2011;128(1):104-111.

The reduction in anesthesia time of bilateral mastectomy cases was greatest in patients with a B cup size (48 minute reduction, p<0.05), as seen in Graph 1. Comparing the anesthesia time of bilateral mastectomy patients by the distance from the IMF to the nipple shows the largest reduction in time of 51 minutes when the distance is greater than or equal to 6 cm (p<0.05), Graph 2. A comparison of patients within each group represented in Graph 2 is shown in Table 2. The patients in Cohort B tended to have smaller breast width and clavicle to nipple measurements, but these patients had a higher proportion of patients with greater than grade 1 ptosis. In addition, the patients in Cohort B had slightly longer IMF to nipple measurements.

It was hypothesized that using the Eikon<sup>TM</sup> System would show a greater benefit in traditionally more challenging patients (e.g., higher BMI, higher degree of ptosis) given the enhanced visualization. Indeed, there is an overall improvement in anesthesia time in Cohort B, but a trend for greater time-savings was not observed as the procedural complexity increased (Graph 3 and 4). As one would anticipate, the anesthesia time did trend longer as the complexity of the case increased in Cohort B, but this did not translate into time savings from Cohort A to B. The greatest difference between Cohort A and B within the four BMI categories was seen at normal BMIs (13% reduction, p<0.05). However, Cohort B included one obese patient, whereas no obese patients underwent a nipple-sparing mastectomy in Cohort A.



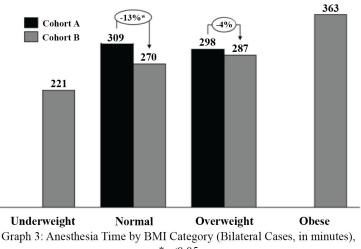
Graph 1: Change in Anesthesia Time by Cup Size from Cohort A to Cohort B (Bilateral Cases) \*p<0.05



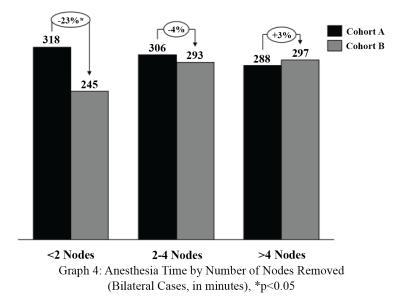
Graph 2: Change in Anesthesia Time by Distance from IMF to Nipple Between Cohort A to Cohort B (Bilateral Cases) \*p<0.05

Table 2: Comparison of Breast Dimensions by IMF to Nipple Range

	2-3	cm	4-5	cm	6-7 cm	
Breast Characteristics	Pre- Eikon <sup>TM</sup>	Post- Eikon <sup>TM</sup>	Pre- Eikon <sup>TM</sup>	Post- Eikon <sup>TM</sup>	Pre- Eikon <sup>TM</sup>	Post- Eikon <sup>TM</sup>
IMF to Nipple	2.7	3.0	4.4	4.4	6.3	6.4
Clavicle to Nipple	22.0	19.8	21.7	20.9	22.8	23.0
Breast Width	10.0	8.7	10.6	9.4	11.3	9.4
% with Greater than Grade 1 Ptosis	0%	0%	44%	55%	75%	80%

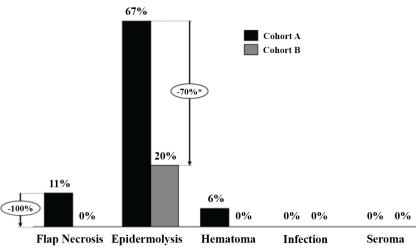


\*p<0.05

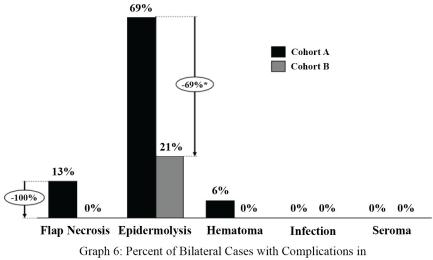


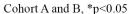
#### COMPLICATION REDUCTION

The overall complication rate decreased with the introduction of the Eikon<sup>TM</sup> Illuminated Retractor System and potentially the advanced electrosurgical device. Specifically, there was a statistically significant reduction in epidermolyis of 70% (p<0.05), Graph 5. Data suggest that there was also a reduction in flap necrosis; however, there were too few cases to show statistical significance. A similar relative reduction in complications was observed in the bilateral cases, 69% reduction in epidermolyis (p<0.05) and 100% for flap necrosis (not statistically significant), Graph 6. The two cases of necrosis in Cohort A consisted of "triangle of doom" necrosis and necrosis at the right inferior lateral. It is important to note that there was one case of a superficial partial skin burn in Cohort B; this was due to human error in using the electrosurgical device with a thin skin flap. This area healed completely without need for intervention. In addition, there was one case in Cohort A in which a small hematoma was found, while no hematomas were noted in Cohort B.



Graph 5: Percent of All Cases Cases with Complications in Cohort A and B, \*p<0.05





## CONCLUSION

The case volume of nipple sparing mastectomies is increasing due to oncologic and risk reduction patient demand for improved aesthetics. However, these procedures are challenging and require specialized surgical instrumentation to facilitate these cases. Greater illumination and visualization of the surgical site may improve patient outcomes and overall operative safety. The combination of superior illumination and visualization and diminished flap trauma of the Eikon<sup>™</sup> System combined with the precision dissection and decreased thermal spread of an advanced electrosurgical device allow for technically challenging cases such as a single IMF incision Hidden Scar<sup>™</sup> NSM to be offered to more patients. This chart review at a single center was designed to determine if an improvement in surgical time or outcomes could be achieved upon transitioning to the Eikon<sup>™</sup> Illuminated Retractor System which improves intracavity illumination and visualization of the surgical field. Being able to visualize and identify the sentinel lymph node early in the case via the posterior approach after lifting the breast off of the pectoral muscle initially, allowed us to have the frozen section performed as we dissected the anterior flap and nipple complex. It also allowed for axillary node dissection to follow immediately without a waiting delay in those cases where the sentinel nodes are positive. The axillary tail remains tethered until the frozen section is completed to facilitate axillary lymph node dissection if required.

There was a statistically significant reduction in bilateral NSM anesthesia time of 31 minutes. This decrease in time was likely more significant than the records reflect as there was a 5-6 case "adoption learning curve" resulting in increased surgical time when we transitioned to the advanced electrosurgical device for electro cautery, and as the breast surgeon became more adept at this procedure, she allowed the breast surgical oncology fellows to have a more active role in the procedures.

Secondary literature suggests the cost of operating room and anesthesia time to the hospital is approximately \$30 per minute. Applying the cost per minute time-savings achieved with the Eikon<sup>TM</sup> Illuminated Retractor System results in a positive economic impact of \$580 per procedure. In addition, the time saved can increase the contribution margin of a procedure and/or allow the hospital to add an

additional one-hour procedure such as a lumpectomy. This leads to a total potential economic impact of over \$2,000.<sup>11</sup>

Improved intracavity illumination and visualization from the Eikon<sup>TM</sup> System is critical in performing safe, time efficient surgical dissection. This also means that the breast flap is exposed to the stress and trauma of retraction for less time. In addition, complication rates declined. The atraumatic blade and tip design of the Eikon<sup>TM</sup> Retractors allows for decreased stress and trauma to the flap during retraction, therefore, decreasing the chance for iatrogenic physical trauma. With respect to epidermolysis and flap necrosis, 70% and 100% reduction respectively pre and post Eikon<sup>TM</sup>, we believe that the Eikon<sup>TM</sup> Illuminated Retractor System, along with the use of an advanced electrosurgical device, play a synergistic role in this improvement.

There are several limitations to the chart review. The study was retrospective and not prospective; the number of cases was limited. These results were from a single breast surgeon who works exclusively with one breast reconstruction surgeon, so the results may not apply to other physicians. Meticulous surgical technique can be enhanced by novel technologies that are designed to alleviate the degree of difficulty of a procedure. Nipple sparing mastectomies are becoming mainstream as an option for breast cancer treatment and prevention. As surgeons begin these more technically challenging procedures, having the appropriate tools at their disposal from the beginning of their learning curve will not only assist them in becoming proficient in their technique, but they can potentially decrease post-operative complications, reduce surgical times and improve patient outcomes and satisfaction. Today, patient satisfaction is a key component of healthcare delivery and is being evaluated via HCAPS on a daily basis. These scores will directly impact hospital reimbursement.

A conscious decision to perform a single inframammary fold (IMF) incision with nipple sparing mastectomy was chosen by the surgical team when they began to offer this approach to breast cancer treatment. The desire to "hide the scar" in NSM is to provide optimal aesthetic results post reconstruction. The intent was to have a positive impact on the patient's psychological and emotional recovery when they have no visual reminder that they had a mastectomy or breast cancer. The plastic surgery literature supports the IMF approach due to decreased complications and superior aesthetic results. Advanced technologies such as the Eikon<sup>TM</sup> Illuminated Retractor System enabled improved illumination, visualization and retraction access to the axilla, which allowed for identification of the sentinel lymph node early in the procedure, without a counter incision, and played a key role in anesthesia and operative time-savings.

The psychosexual implications of NSM are currently being compared to traditional non-nipple sparing mastectomy and lumpectomy and radiation therapy in a multi-institutional study. The authors feel that these survivorship assessments are lacking in our literature, and that surgeons need to be aware of the implications of the procedures that we perform and the surgical approach that we take to adequately treat breast cancer.

<sup>&</sup>lt;sup>11</sup> LIT 11922 Healthcare Consulting Firm: NSM Economic Findings, July 2015