

# **NIPPLE SPARING MASTECTOMY AND THE ADVENT OF AN ENABLING SURGICAL ILLUMINATION AND VISUALIZATION SYSTEM**

## **Clinical Experience Survey of Thought Leaders in Breast Surgery**

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### **Abstract**

#### **BACKGROUND**

Recent advances in surgical techniques for breast cancer, including nipple sparing mastectomy (NSM), reflect growing interest in optimal aesthetic outcomes and associated psychological recovery without sacrificing oncologic safety and efficacy. A new surgical illumination and visualization technology addresses this need while enabling broader application and adoption of the nipple sparing technique.

#### **METHODS**

A clinical experience survey related to the use of a new illumination and visualization technology in the surgical management of breast cancer was conducted with twelve breast surgeon thought leaders in May 2013.<sup>1</sup> The survey results and published NSM data are reviewed for their impact on breast cancer surgery today.

#### **DISCUSSION**

The NSM approach has been steadily increasing at institutions globally. Based on the published data reviewed and the clinical experience survey data reported here, NSM is a safe and effective surgical option for selected patients who have or are at high risk for breast cancer. Surgical efficiency and clinical and aesthetic outcomes of NSM are enhanced with the use of an advanced illumination and visualization technology.

#### **CONCLUSIONS**

Skin and nipple preservation during breast cancer surgery is essential to attain ideal aesthetic results. NSM is technically challenging due to minimal access and limited visualization; however, the advent of an advanced illuminated retractor system makes performing a NSM less challenging, more efficient, and safer while achieving optimal breast aesthetics.

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### **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.

A survey of thought leaders in breast surgery was conducted in Chicago, in May 2013. The surgeon participants took an in-depth look at NSM from an oncologic and aesthetic perspective, and

discussed factors that could improve surgical outcomes, including new illumination and visualization technology.

### **NSM PROCEDURE DEVELOPMENT**

Surgical management of breast cancer has evolved dramatically since the 1980's, from the once touted radical mastectomy (Halsted mastectomy) to breast conserving lumpectomy. Over time surgeons have looked for ways to improve oncologic outcomes while combining the techniques of plastic surgery (Oncoplastic) to maximize both the treatment of cancer and an aesthetic outcome with the optimal goal of preserving the nipple areola complex.

With the advent of skin sparing mastectomy (SSM) in the 1980's, cosmesis became a goal in addition to oncological safety and efficacy. In performing a SSM, all breast tissue and the nipple are removed while preserving much more of the native breast skin than a traditional modified radical mastectomy. The result was a more enhanced cosmetic result in patients undergoing immediate reconstruction. Although some may consider SSM with immediate breast reconstruction the current standard of practice, NSM is rapidly becoming the preferred surgical option in selected patients.<sup>2</sup>

Patient's interest and demand for NSM has significantly increased. Low local cancer recurrence rates following NSM without irradiation have further supported the adoption of this approach.<sup>3</sup> NSM allows patients to take more control and partner with their surgeons in choosing the best treatment option or risk-reduction strategy. Furthermore, with the advent of genetic testing for breast cancer risk assessment, and information disseminated through social media and advocacy groups, there has been increasing public awareness and a corresponding increase in the number of NSMs being performed.

Historically, the technique of preserving the nipple areolar complex during mastectomy for breast cancer has been controversial as many felt that this would lead to an unacceptably high rate of breast cancer recurrence. Subsequently preservation of the NAC during risk-reduction prophylactic mastectomy has been described in a large series of high risk women with excellent results in terms of preventing breast cancer.<sup>4,5</sup>

NSM was first presented as a case report at the Southwestern Surgical Congress in 1999, followed by an editorial in 2000 describing the technique by Laronga, et al.<sup>6</sup> The first reported series from Petit described a subcutaneous mastectomy with a cuff of breast tissue on the mastectomy flaps and intraoperative radiation therapy to the NAC and remaining breast tissue. At six months follow-up, there were no local recurrences in the NAC.<sup>7</sup> Gerber studied 61 NSM patients compared with SSM or non-SSM and documented a 5% local recurrence rate in all three cohorts at five years.<sup>3</sup>

Until very recently, there has been limited published data on NSM. Now as surgeons are adopting the NSM technique and defining eligibility criteria for both oncologic safety and breast aesthetics, more outcome data has been generated and made publicly available. Gerber and Petit have both presented long-term follow-up on their original NSM patients and on expanded cohorts that demonstrate NSM outcomes are not statistically different in terms in safety and efficacy from SSM and non-SSM cohorts. Petit now has performed over 2,000 NSMs with over 50 months of follow-up with local recurrence rate of 3.9%.<sup>7</sup>

At Massachusetts General Hospital in Boston, a review of 370 patients (645 breasts) undergoing NSM from 2007 to 2012 was performed to assess trends in eligibility and outcomes over time. In this study, Coopey concluded that eligibility for NSM has expanded to include women with higher BMI and larger breasts, with no increase in nipple loss due to ischemia. She states, "Rates of positive subareolar margins have decreased over time, even though NSM is being performed more frequently for cancer, suggesting improved patient selection." At 22 months' mean follow-up, local recurrence occurred in 2.6% of breasts operated on for cancer through 2011. No recurrences involved the nipple. To-date no recurrences have occurred in patients operated on in 2012.<sup>8</sup>

In recent years, the optimization of the NSM procedure has been ongoing. The type and location of incision used in NSM is important to ensure complete removal of breast tissue, as well as access to the axilla for staging in patients with breast cancer. During the NSM, the surgeon has the ability to gain access to tissue from the base of the nipple for assessment of occult cancer.

Inframammary incisions and lateral radial incisions are increasingly being utilized during NSM. Both incisions allow complete removal of the breast tissue, access to the axilla for staging, and ease of obtaining specimens from the base of the nipple. In appropriate patients, the inframammary incision, which is similar to the incision used for breast augmentation, is increasingly becoming the preferred incision location by patients, breast surgeons, and plastic surgeons for optimal aesthetic outcomes.

## **RECENT ADVENT OF SURGICAL ILLUMINATION AND VISUALIZATION TECHNOLOGY**

The growing adoption of NSM as a preferred surgical option for selected patients has also demonstrated the current surgical limitations of the NSM procedure. Some of these limitations include limited incision location options, limited visualization and access through smaller incisions, inability or concern in the ability to maintain consistent flap thickness and viability, and access to the superior and superior medial aspect of the breast. Surgeon participants recognized optimal visualization as one of the key areas where improvements in illumination and access technology would assist in overcoming these limitations while enabling improved techniques, thus increasing the adoption of NSM, and expanding patient qualifying criteria such as larger breast size.

Traditional operating room (OR) lighting options are limited and provide ineffective illumination visualization, and compromise thermal safety (e.g., preventing thermal tissue damage, patient/staff burns, melting drapes and OR fires associated with fiber optics).

According to the American Society of Anesthesiologists Task Force on Operating Room Fires, thermal risks such as surgical fires do not occur often, but when they do, a major adverse event can occur. The Taskforce estimates there are 550 to 650 surgical fires per year in the United States.<sup>9</sup> According to Demir, et al., surgical headlights with fiber optics have the potential for patient damage if used incorrectly.<sup>10</sup> The ECRI Institute's Medical Device Safety Reports (MDSR) publishes a report investigating device-related skin burns in the OR. Thermal injury due to fiber optics is included in the 2010 top 10 list of technology healthcare hazards.<sup>11</sup> Additionally, organizations such as the AORN and the US FDA have recommended practices for safe environment of care in the OR that include burn prevention.

A San Francisco-based medical device company (Invuity, Inc.) has been leading the technological and clinical development of safer, more efficient on-field in-situ surgical illumination utilizing its Eigr™ Illumination Technology (Eigr™ Waveguide) in combination with various access systems including the Eikon™ Retractor. The Eikon Illuminated Retractor System (Eikon) includes several components; Eikon anodized aluminum retractors, Eigr Waveguide, and the optimized Fiber Optic Cable. All Invuity devices including Eikon can be used with standard 300-watt xenon OR surgical light sources with an IR (infrared radiation) blocking filter. Eikon is a Class 1 product registered with the U.S. Food and Drug Administration (FDA) in 2012, and it was based on the Invuity Britefield™ McCulloch Retractor System originally cleared in 2009. Eikon is indicated for tissue retraction and surgical illumination from a high intensity light source. In addition to thermal safety and optimal illumination, Eikon incorporates a lightweight, ergonomic retractor design, atraumatic elevated tip, low profile fiber optic cable and simple switch method that allows the user to quickly move the Eigr Waveguide between various size Eikon retractor blades during the surgical procedure.

The Eikon Retractor with integrated Eigr Waveguide (Image 1) provides optimal illumination and visualization deep inside the surgical cavity. Light output from a fiber optic cable is efficiently coupled into the solid core optical polymer thus retaining maximum light and minimizing heat buildup at the cable and waveguide connection. The light travels through the waveguide by means of total internal reflection to maximize optical efficiency. A complex geometry of microstructures then extracts light out of the waveguide off-axis eliminating shadows and glare while projecting broad, uniform, redundant illumination. Eikon broadly projects thermally safe (refer to Image 4), brilliant light to uniformly illuminate deep surgical cavities.



Image 1: Eikon™ Illuminated Retractor System – Family of Retractors

## RESULTS OF NSM AND EIKON CLINICAL EXPERIENCE SURVEY<sup>1</sup>

A survey was conducted with twelve breast surgeon thought leaders by an independent consultant at the American Society of Breast Surgery (ASBS) Meeting in Chicago on May 2013 (Table 1). The average breast surgeon in the survey had approximately twelve months of experience using Eikon and performed well over 150 breast cancer procedures annually. 100% of surgeons in the survey perform NSMs and breast conserving procedures. This clinical survey examined both the opportunities and challenges of the NSM procedure.

Table 1: Surgeon participants

Breast Surgeon	Location
<b>Rache Simmons, MD</b>	<i>Department of Surgery, New York Presbyterian/Weill Cornell Medical Center</i>
<b>Shawna C. Willey, MD, FACS</b>	<i>Department of Surgery, Medstar Georgetown University Hospital</i>
<b>Richard Fine, MD</b>	<i>The West Clinic Comprehensive Breast Center, Memphis, TN</i>
<b>Sheldon Feldman, MD, FACS</b>	<i>Department of Surgery, New York Presbyterian/ Columbia University Medical Center</i>
<b>Beth DuPree, MD, FACS, ABIHM</b>	<i>Holy Redeemer Hospital, Southampton, PA</i>
<b>Sunny Mitchell, MD</b>	<i>Department of Surgery, White Plains Hospital, White Plains, NY</i>
<b>Alison Laidley, MD, FACS, FRCS(C)</b>	<i>Texas Oncology, Dallas, TX</i>
<b>Molly Sebastian, MD, FACS</b>	<i>Reinsch Pierce Family Center for Breast Health Virginia Hospital Center, Arlington, VA</i>
<b>William Burak, MD, FACS</b>	<i>Advanced Breast Care, Marietta, GA</i>
<b>Barbara Schwartzberg, MD</b>	<i>Western Surgical Care, Denver, CO</i>
<b>Kathryn Wagner, MD, FACS</b>	<i>Cancer Care Centers of South Texas, San Antonio, TX</i>
<b>Angela Keleher, MD</b>	<i>Dyson Center for Cancer Care, Vassar Brothers Medical Center, Poughkeepsie, NY</i>

### *NSM Opportunities and Challenges*

Results from this survey clearly show that the volume of NSMs is growing significantly, with 92% of surgeon respondents indicating an average annual increase of 30% in NSM in their practices. Over 90% of respondents indicated breast aesthetics as the most important reason for performing

NSM. Other reasons include 50% for nipple preservation and 17% for the psychological benefit of the patient (sense of self-worth and feeling whole).

Of note, 100% of surgeon respondents indicated that poor or inadequate visualization is the leading challenge in performing NSMs. The next most frequent challenges are NAC preservation (67%) and limited access through small incisions (67%). 100% of respondents report Eikon overcomes all of these challenges when performing NSM (Image 2).

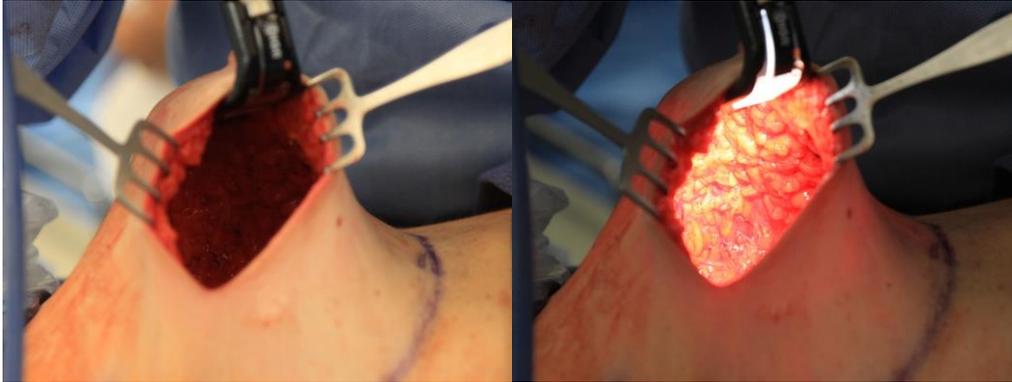


Image 2: NSM clinical image without Eigr Illumination Technology (left) and with Eigr Illumination Technology (right)

### ***Clinical Outcomes***

Using a descending scale of most important to not important, 100% of respondents rated the level of difficulty in maintaining breast flap and nipple perfusion/integrity in NSM as important to most important. 92% reported that Eikon increased their success in maintaining flap and nipple integrity. 100% of respondents rated the importance of visualizing tissue planes and anatomical landmarks as very or most important, and 100% said that Eikon provided improved visualization of tissue planes and anatomical landmarks.

### ***Surgical Efficiency***

When asked to rate the importance of improving surgical efficiency, 100% of surgeons responded important to most important. 100% indicated Eikon improves surgical efficiency. When asked to rate the importance of reducing procedure time in the OR, 100% of surgeons responded important to most important. 92% indicated Eikon reduced procedure time for NSM. The surgeon participants' average procedure time for NSM without the use of Eikon was 76.8 minutes. Their average procedure time for NSM with the use of Eikon was 58.2 minutes, resulting in a reduction of 18 minutes or 24% per breast (or 36 minutes for bilateral NSM).

### ***Safety and Visualization***

When queried on the safety of traditional lighted retractors, 100% of surgeons surveyed rated the importance of reducing associated thermal hazards with lighted retractors as very or most important. 92% of surgeons indicated Eikon reduced heat and associated thermal hazards in the OR. In addition, 92% of surgeons reported Eikon improved patient safety, 83% reported Eikon improved staff safety, and 83% reported Eikon improved OR safety.

92% said they prefer not to use a headlight in the OR. Headlights typically provide insufficient illumination of the deep surgical cavity when performing minimally invasive or minimal access surgery. They also create shadows and glare, cause headaches and neck strain, require continuous adjustment, and are a potential source of contamination. 100% of those respondents who use headlights indicated Eikon replaced or minimized their dependence on a headlight.

92% of respondents said they have used traditional fiber optic lighted retractors in the OR. Approximately 46% said that poor lighting was a significant limitation of fiber optic lighted retractors, and 55% of these surgeon respondents said heat was the primary concern. 100% of

respondents reported Eikon provided improved visualization of tissue planes and anatomical landmarks without generating heat and associated thermal hazards (Image 3,4).<sup>12</sup>

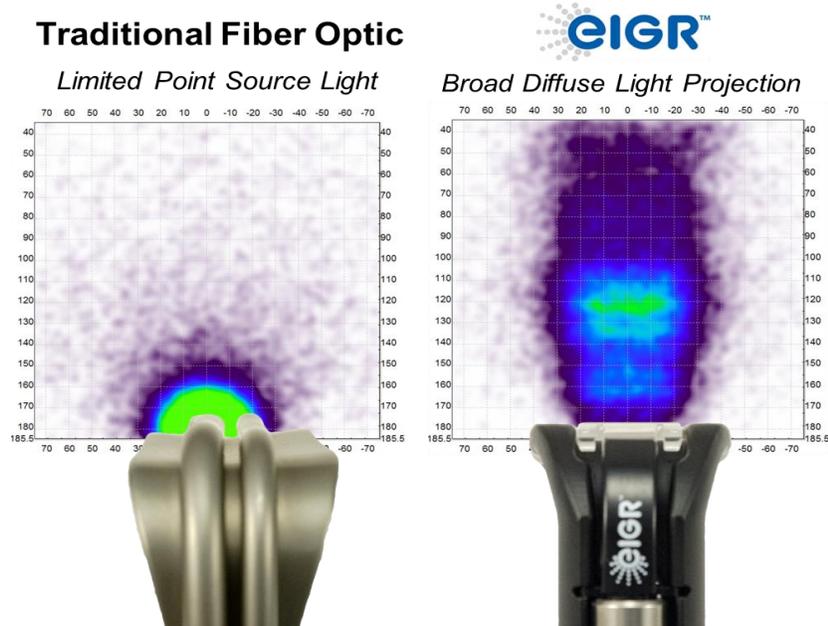


Image 3: Illumination Mapping: Traditional fiber optic (left) vs. Eigr Illumination Technology (right)<sup>12</sup>

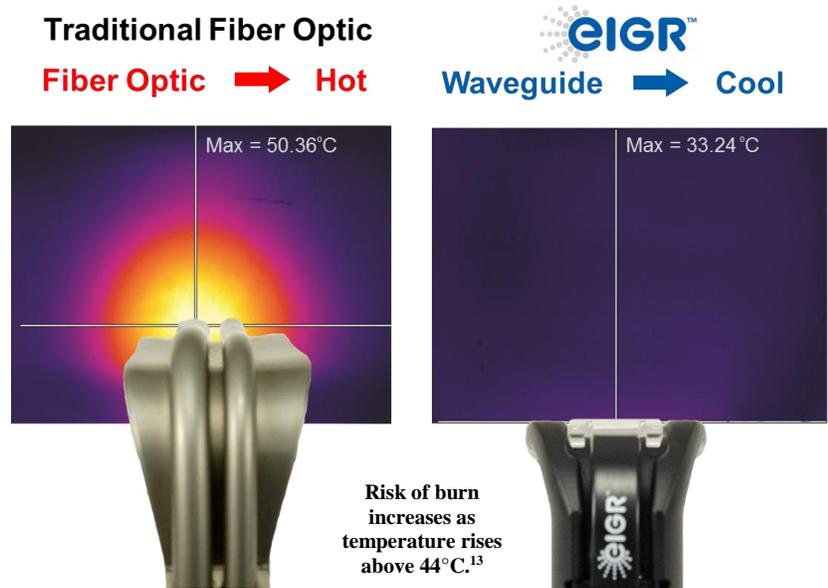


Image 4: Thermal Mapping: Traditional fiber optic (left) vs. Eigr Illumination Technology (right)<sup>12</sup>

Overall, the surgeon participants indicated that Eikon provided improved benefits to their patients, their staff and to surgeons. In Table 2, Eikon benefits are delineated along with the corresponding percent of surgeon participants indicating their agreement with the benefit being demonstrated.

Table 2: Eikon Benefits<sup>1</sup>

<b>Eikon Benefits</b>	<b>Patients</b>
<b>Improved visualization</b>	100%
<b>Improved flap integrity</b>	92%
<b>Improved clinical outcomes</b>	67%
<b>Improved aesthetic outcomes</b>	75%
<b>Improved efficiency</b>	92%
<b>Decreased surgical time</b>	92%
<b>Improved safety</b>	92%
<b>Improved quality of patient care</b>	100%

Surgeons were asked in what procedures, other than NSM, would Eikon provide the most value. They responded as follows: 75% said SSM, 67% said axillary node dissection, and 58% said both lumpectomy and sentinel node procedures.

Overall, surgeon participants indicated that offering NSM provides a competitive practice advantage over those surgeons not offering NSM. NSM will continue to grow in popularity with both patients and surgeons. All surgeon participants believe the use of the Eikon Illuminated Retractor System improves overall quality of patient care.

**DISCUSSION:**

NSM is growing rapidly among institutions globally. There are ongoing studies worldwide that will continue to assess the value of NSM to patients and to surgeons performing the procedure. From the perspective of breast surgeons and plastic surgeons, preservation of the skin and nipple is essential to provide the desired aesthetic outcome for a patient that is facing breast cancer surgery. NSM is technically challenging due to several factors including poor or inadequate visualization. Traditional headlights and on-field fiber optic illumination options have significant limitations in NSM, including thermal hazards. According to the twelve thought-leading breast surgeons who participated in this survey, Eikon clinically demonstrated an opportunity to safely and efficiently improve NSM surgical outcomes and reduce OR time.<sup>1</sup>

**CONCLUSION:**

Skin and nipple preservation during breast cancer surgery is essential to attain ideal aesthetic results. NSM is technically challenging due to minimal access and limited visualization; however, the advent of an advanced illuminated retractor system makes performing a NSM less challenging, more efficient, and safer while achieving optimal breast aesthetics.<sup>1</sup>

Ongoing efforts demonstrating the importance of superior visualization with Eikon will support the increased adoption of NSM. This will play a role in the acquisition of evidence based data documenting the key parameters of NSM clinical success: local tumor recurrence, aesthetic outcomes, patient satisfaction, quality of life, body and self image, and procedural complications and risks.

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