Incorporating Nipple-Sparing Mastectomy Into Your Practice

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plastic surgery
THE MEETING
AMERICAN SOCIETY OF PLASTIC SURGEONS
THE PLASTIC SURGERY FOUNDATION
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Disclosures

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Learning Objectives

- Understand oncologic & prophylactic basis of NSM
- Familiar with oncologic & quality of life outcomes data
- Understand patient selection criteria for NSM
- Gain familiarity with methods for performing NSM & subsequent reconstruction
- Understand how to anticipate, prevent, and treat complications
- Gain insight into encouraging breast surgeon buy-in

Rationale for NSM

- Latest stage of a continuum from total mastectomy to skin-sparing mastectomy
- The nipple is the focal point of the breast
- Nipple reconstruction has variable results
  - Lack of sensation
  - Projection
  - Temporary grafting ill-advised

Rationale for NSM

- NAC sparing has a positive impact on patient satisfaction, body image and psychological adjustment
- May increase patient willingness to consider mastectomy for risk reduction and thus save lives

NSM for Prophylactic Mastectomy

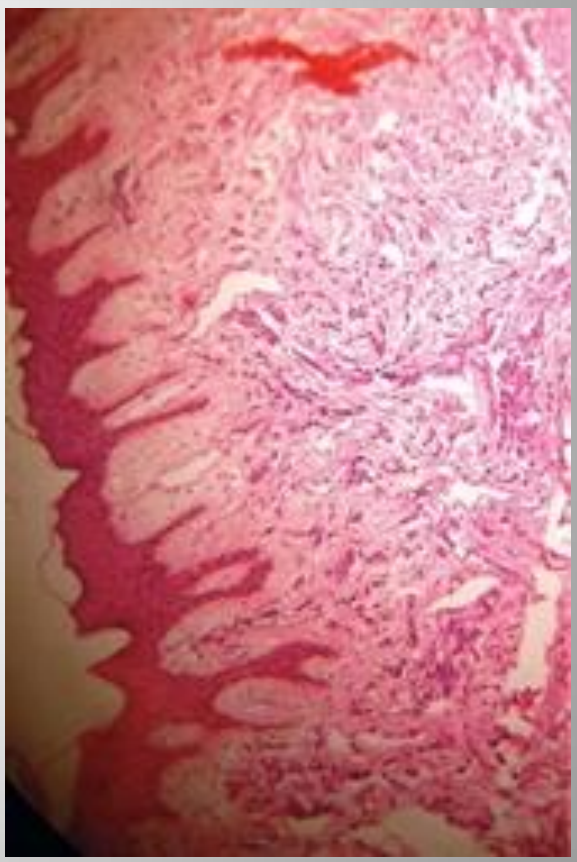
- Has been in use for over 50 years
- Primary tumors rarely arise in the nipple
- It is estimated that adoption of NSM for BRCA carriers could reduce the incidence of breast cancer in this group by one third

NSM for Prophylactic Mastectomy

- Hartmann
  - Subcutaneous mastectomy performed on 575 high-risk women
  - 14 year follow up: 7 cancers arose, one in the nipple
- Sacchini
  - 124 NSM for risk-reduction 25 month follow up
  - 2 subsequent cancers, neither in the nipple

NSM for Breast Cancer and DCIS: Occult involvement of the NAC

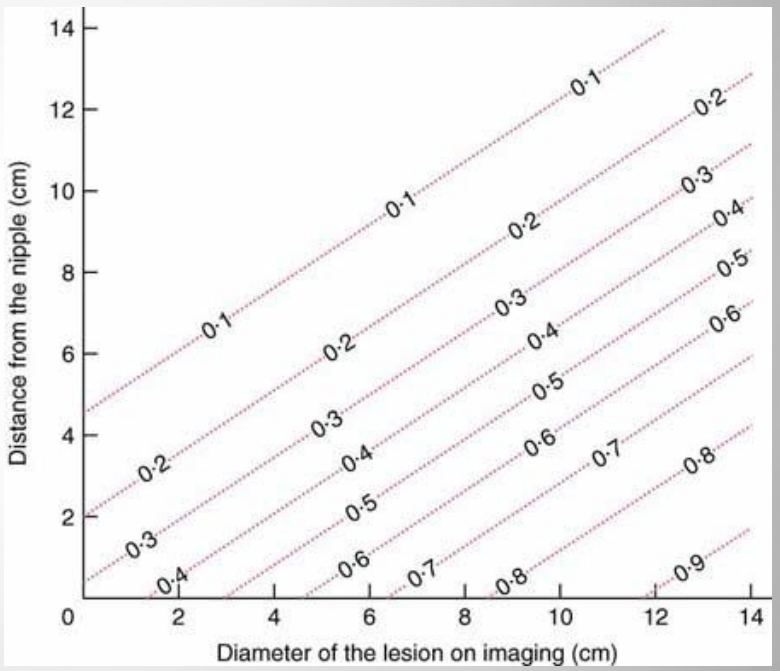
- Wide range quoted (0-58%)
- Larger studies report involvement of 6-31% among patients with breast cancer
  - Variable study design and execution
  - Some include patients with clinically involved nipple or consider LCIS



NSM for Breast Carcinoma and DCIS: Involvement of the NAC

Two models predict nipple involvement

- Size of tumor
- Distance from NAC



NSM for Breast Carcinoma and DCIS: Involvement of the NAC

- Other risk factors
  - Stage III (30%) vs. stage I or II (10%)
  - Central (68%) vs. peripheral (2.5%) tumor
  - Axillary lymph node involvement
  - Lymphovascular invasion
- With careful patient selection, rates are 3-10%
- Frozen sections
  - Sensitivity of 91-99%

NSM for Breast Carcinoma and DCIS: Recurrence

- Benediktsson 2008
  - 216 patients, T1-T3, 40% N1
  - 20.8% local recurrence rate at 10 years; none at NAC
  - Overall survival unchanged
- Gerber 2009
  - 60 NSM, 48 SSM, 130 MRM
  - LRR: NSM 11.7%; SSM 10.4%; MRM 11.5%

NSM for Breast Carcinoma and DCIS: Recurrence

- Kim 2010
  - 115 NSM, 368 SSM prospectively followed
  - 5 year survival same (Stage IIB-III)
  - LRR NSM 2% (2/4 at NAC); SSM 0.8% (p=0.27)
- Petit 2009
  - Used ELIOT; 579 NSM, T1-T3
  - 5mm of glandular tissue retained
  - LRR 0.9% (none at NAC) at 19 months

NSM for Breast Carcinoma and DCIS: Recurrence

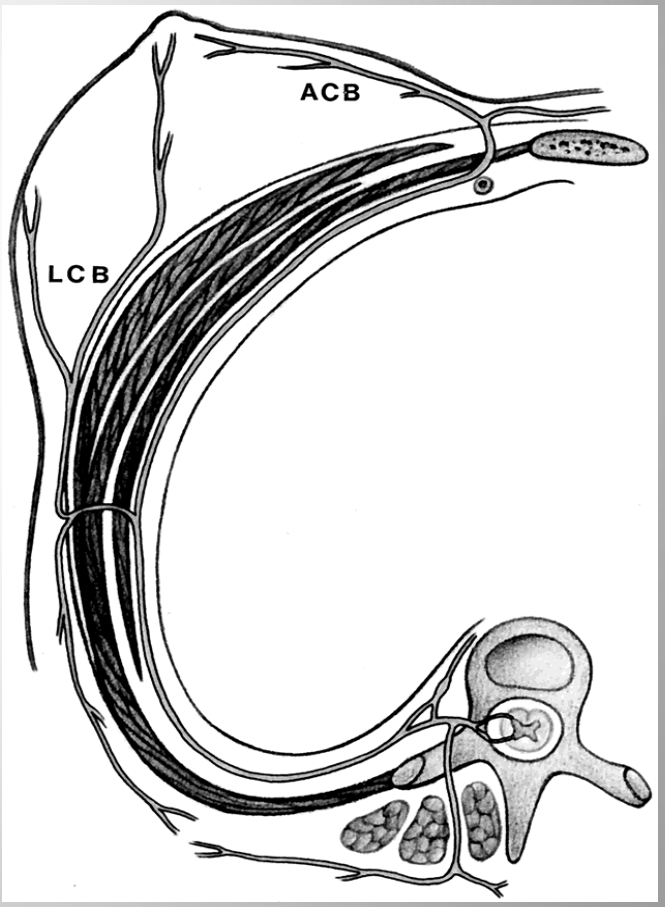
- Regolo 2008
  - 84 NSM for DCIS and T1-T2 carcinoma
  - No LRR at 16 months
- Crowe 2008
  - 109 NSM (cored) in 83 patients with carcinoma or DCIS
  - 2 LRR at 41 months, neither at NAC

Outcomes: Sensation

"Normal" sensation: 0-31%

Sensation absent: 14-57%

"You *may* retain some sensation"



Outcomes: Patient Satisfaction

- Djohan 2010
  - 78/141 (53%) women who underwent NSM completed questionnaire
  - 73% would definitely have NSM again
  - Lower satisfaction with larger breasts and BMIs
  - Most dissatisfaction resulted from nipple sensation and position

Outcomes: Quality of Life

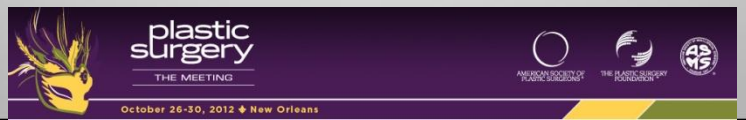
- Didier 2008
  - 310 NSM; 143 nipple reconstruction pts
  - 56 item questionnaire (51.2% response)
  - *Significant differences in favor of NSM for body image, satisfaction with nipple appearance, and feelings of mutilation*

Patient Selection

- Prophylactic/Risk Reducing mastectomy
- Ipsilateral cancer cases
  - Smaller tumors
  - Located distant from the NAC

Patient Selection

- Small to medium breast size
  - A--->C cup – ideal
  - D or greater – use CAUTION!
    - Increased difficulty with mastectomy
    - Skin flap risk
    - Skin flap excess
- Patient must be psychologically comfortable with concept and theoretical slight risk increase
- Realistic expectations
  - Cosmesis/sensation/absent function

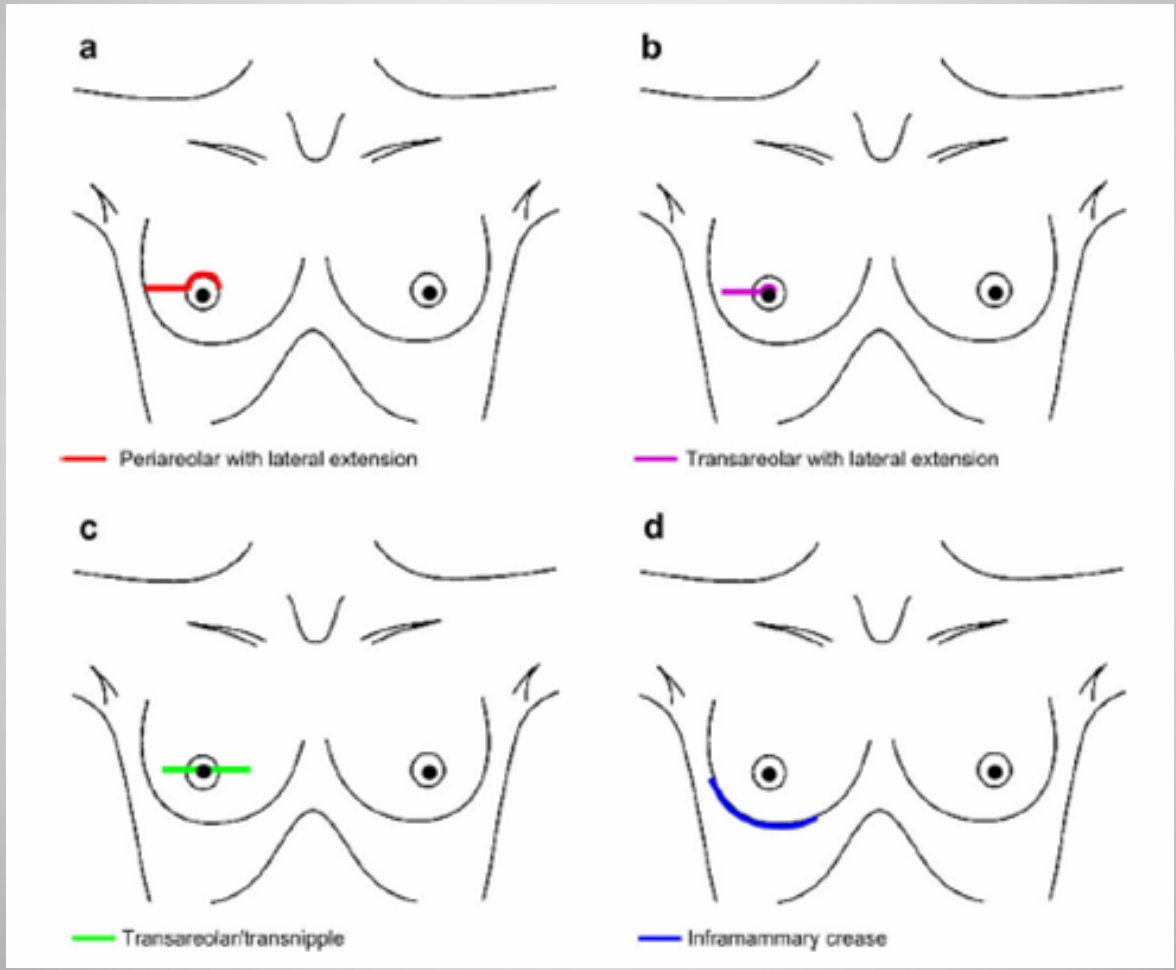


NSM & Patient Exclusion

- Smokers or Tobacco use
- “Large” breasts
- Unwilling to accept possibility of NAC loss
- Unrealistic expectations

Surgical Technique: Incision

- 76% utilized IMF or Inferolateral
- IMF and omega incision with slightly higher complication rates
- Make decision with breast surgeon
  - Breast size/access
  - Future shape or size change


a
b
Periareolar with lateral extension
Transareolar with lateral extension
c
d
Transareolar/transnipple
Inframammary crease

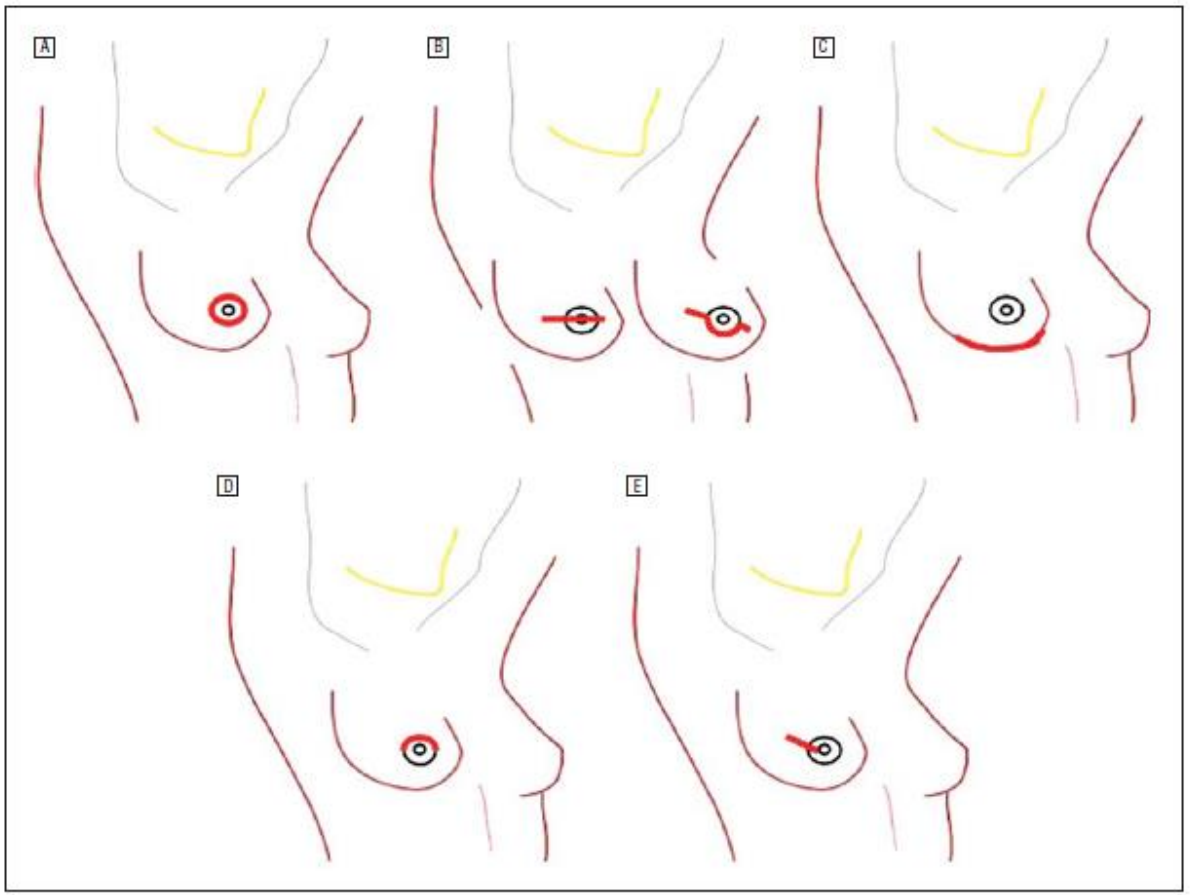
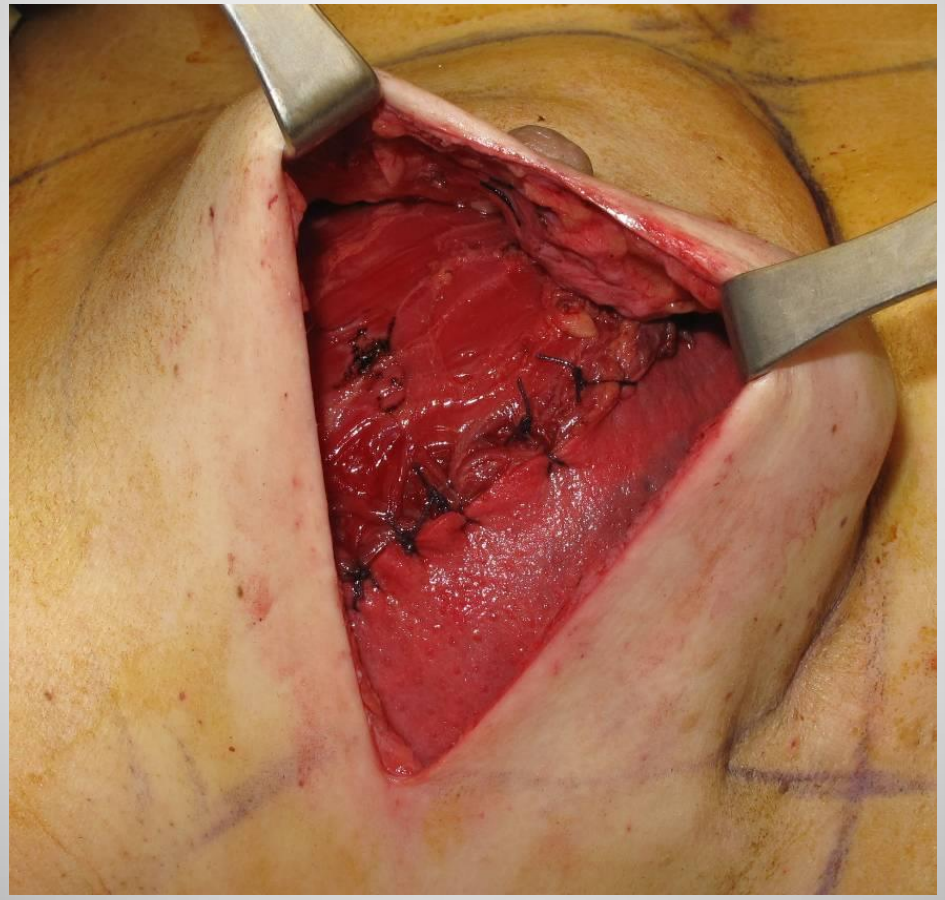


Figure 2. Surgical incisions used for total skin-sparing mastectomy. A, Skin-sparing dissection of nipple skin as a free graft with dissection and removal of nipple duct tissue. B, Incisions crossing the nipple-areola complex. C, Inframammary incision. D, Mastopexy incision. E, Radial incision.

Positioning of Nipple Over Muscle



Reconstruction Method

- Majority are 2-stage, expander/Gel implant
- Majority utilize allograft
  - Have tried: Alloderm, Strattice, Surgimend, Neoform
  - Currently using Allomax (Bard) – institutional decision
  - No major preference

Size Change

- As with all reconstructions, change is possible, just is more difficult
  - Augmentation:
    - often requires 2-step reconstruction
    - I prefer allograft
  - Reduction:
    - From 6’ at NAC can reduce skin flap with a “J” or “T”
    - This does not address skin excess above NAC
      - Contracts
      - May reduce later with staged excision
    - Consider staged reduction/NSM

Shape Change

- Mastopexy
  - I prefer to stage
    - Allows for skin envelope contraction which often does most of the work for you
    - Guide NAC placement in OR and early postop
  - May address initially with inferiorly based omega

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Part II

Nipple Assessment

Nipple Surgical Technique

NSM & Radiation Therapy

NSM Complications

Building the NSM Team

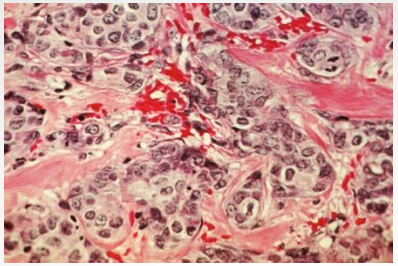
Nipple Involvement

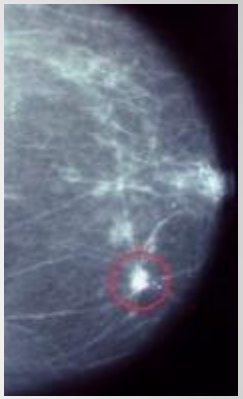
NSM contraindications

- Neoadjuvant chemotherapy
- Inflammatory breast cancer
- Paget disease of the nipple
- Tumor size
- Tumor distance
- Tumor location

Nipple Assessment for NSM

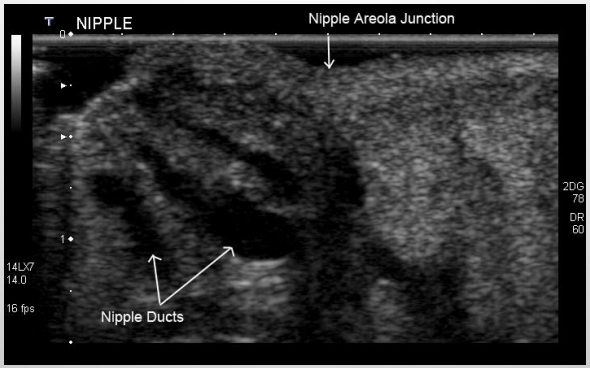
- Tumor
  - Size
  - Location
  - Type
- Physical Exam
- Imaging
  - US
  - MRI





US for NSM Assessment

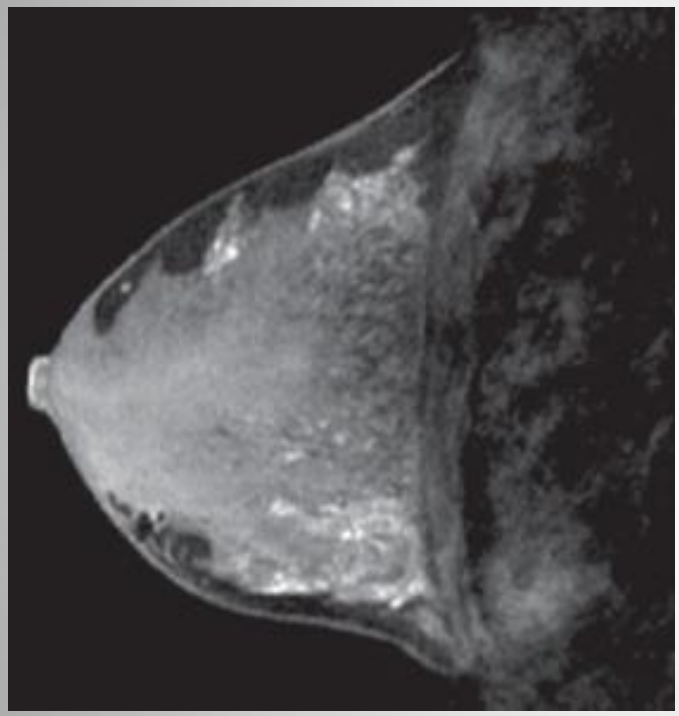
- Preoperative ultrasound-guided vacuum-assisted biopsy of ducts beneath NAC
- 36 nipples without clinical involvement
- 7 of 36 had involvement on biopsy
- 100% correlation with findings in mastectomy



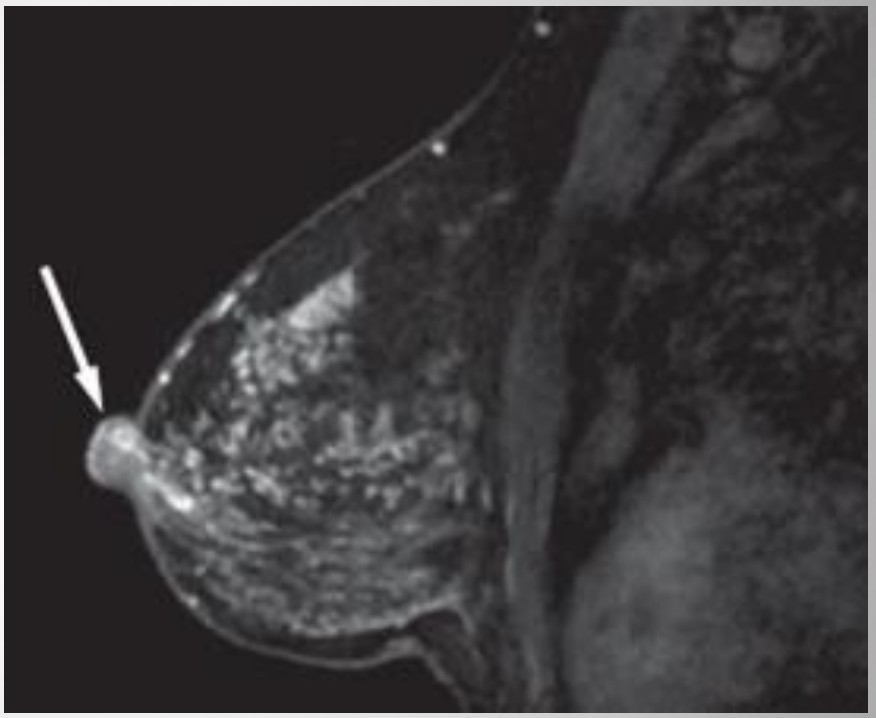
MRI Nipple Evaluation

- Preoperative MRI to exclude patients with disease near the nipple
- Excluded from NSM
  - Large centrally located tumors
  - Skin involvement
  - Carcinoma within 2 cm of the nipple
  - Disease in ductal tissue near nipple
- Use in place of intraoperative frozen sections
- If malignancy on final pathology, remove NAC later - 97% accurate

MRI Nipple Evaluation



No nipple contrast enhancement
Suitable for NSM



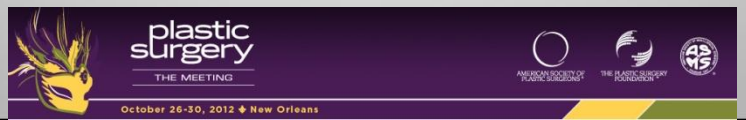
Nipple with contrast enhancement
Extension of DCIS
Not suitable for NSM

1.5-T magnet, high-resolution MRI with fat suppression using 3 time point technique

Surgical Technique: Nipple

Technique affects oncologic safety & nipple viability

- Nipple core excision
  - Sharp dissection vs point diathermy
  - Minimize chance of residual disease
  - Risks compromising nipple viability
- Preserve pad of breast retroareolar tissue
  - Maintains blood supply to nipple
  - May have higher recurrence or new disease risk
- Intraoperative electron-beam radiotherapy
  - Allows preservation of glandular layer 5mm thick
  - No compromise of oncologic safety
- Summary data
  - Too heterogeneous to detect difference in nipple necrosis rates

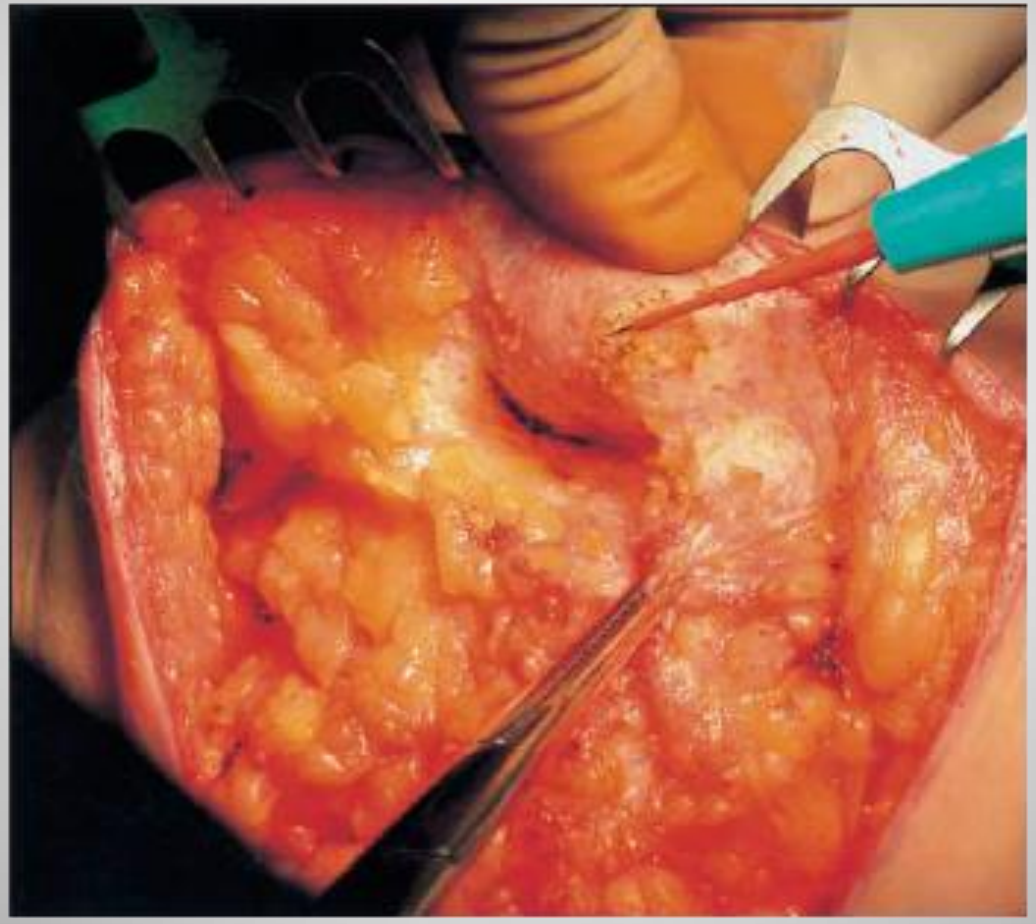


Surgical Technique: Details

- Leave nipple dermis & epidermis intact
  - Remove major ducts from nipple lumen
  - Dissection ducts with scissors (not electrocautery)
- Nipple eversion facilitates dissection & core removal
- Send core/ducts to pathology as separate specimen
- Avoid traction of the mastectomy flaps

Nipple Eversion

Complete Nipple Core Removal



Intra-Operative Nipple Oncologic Assessment

- Frozen-section analysis no malignancy
  - Proceed with NSM
  - Up to 5% false negative
- Frozen-section analysis suggests malignancy
  - Nipple removed
- Await final paraffin section analysis

NAC Delay to Decrease Nipple Loss

- Minor outpatient procedure
- 3 weeks before NSM
- Tissue beneath nipple divided with diathermy
  - Nipple dependent on blood supply from surrounding skin
- 1 case of nipple loss in 18 women
  - Attributed to thermal injury

Palmieri 2005

NAC Free Graft

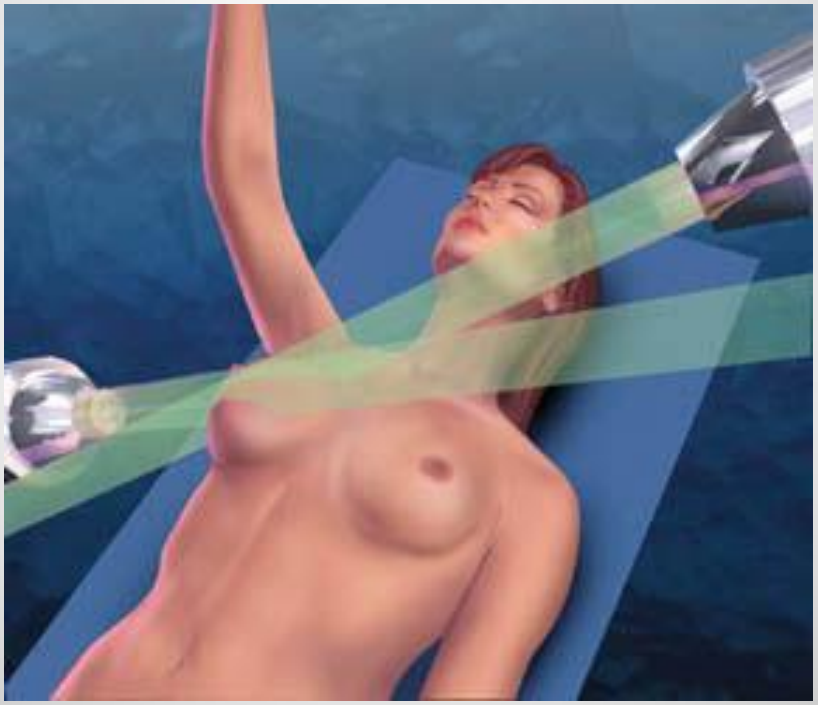
- Initially popular in Europe
- High failure rate
- Long time to reepithelialize when successful
- Avoid if possible

ASM: Areola Sparing Mastectomy

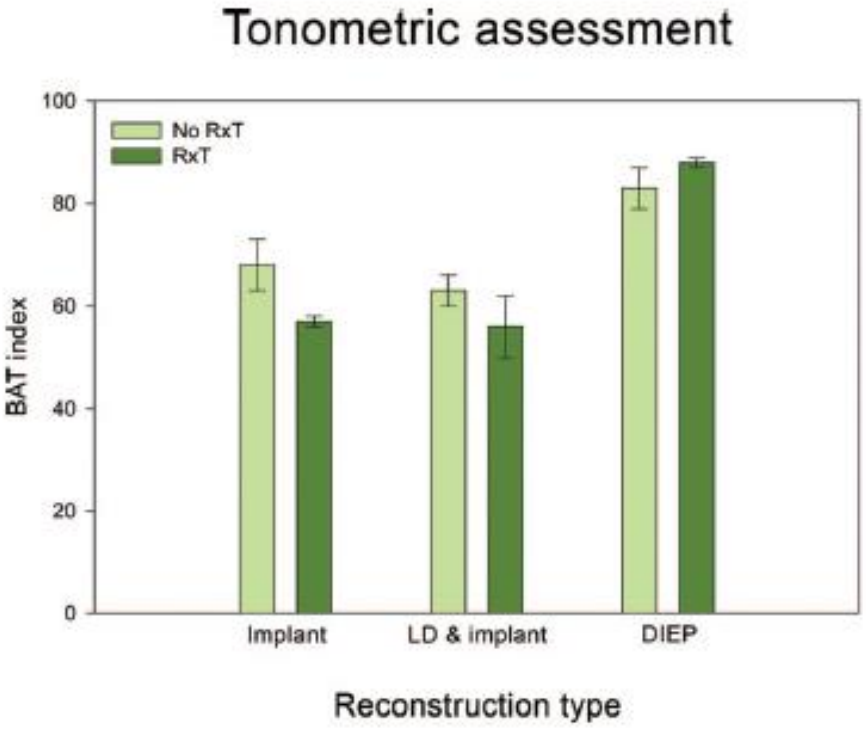
- Alternative to NSM
- Nipple removed but areola preserve
- Areola involved in 2 of 23 cases of positive NACs
  - 0.9% of all mastectomy specimens
- Superior cosmetic outcome compared to SSM
  - Requires only nipple reconstruction
- However, nipple reconstruction is difficult

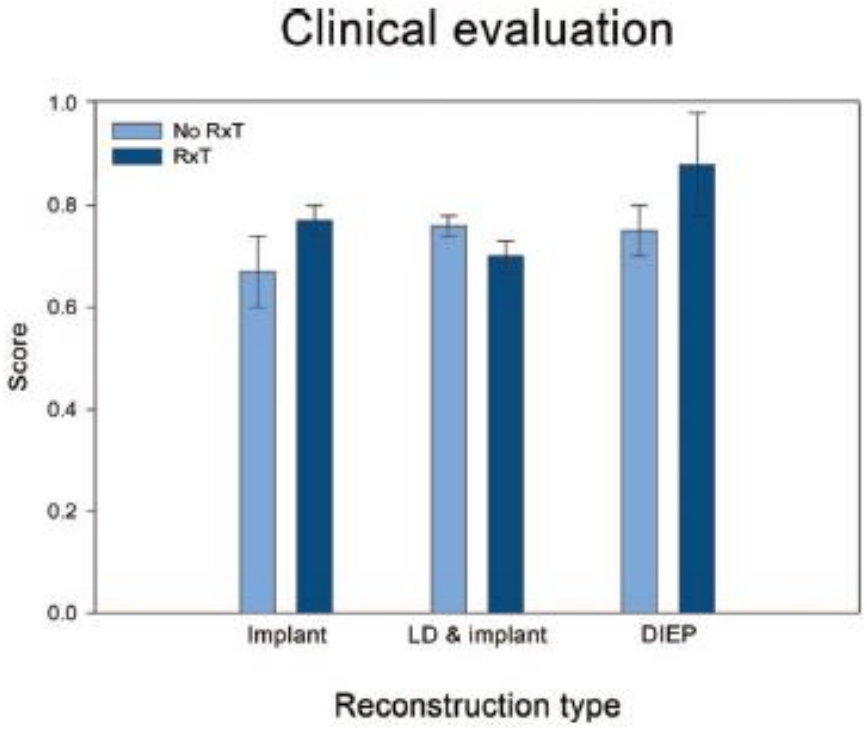
Simmons 2002

NSM & Radiation Therapy



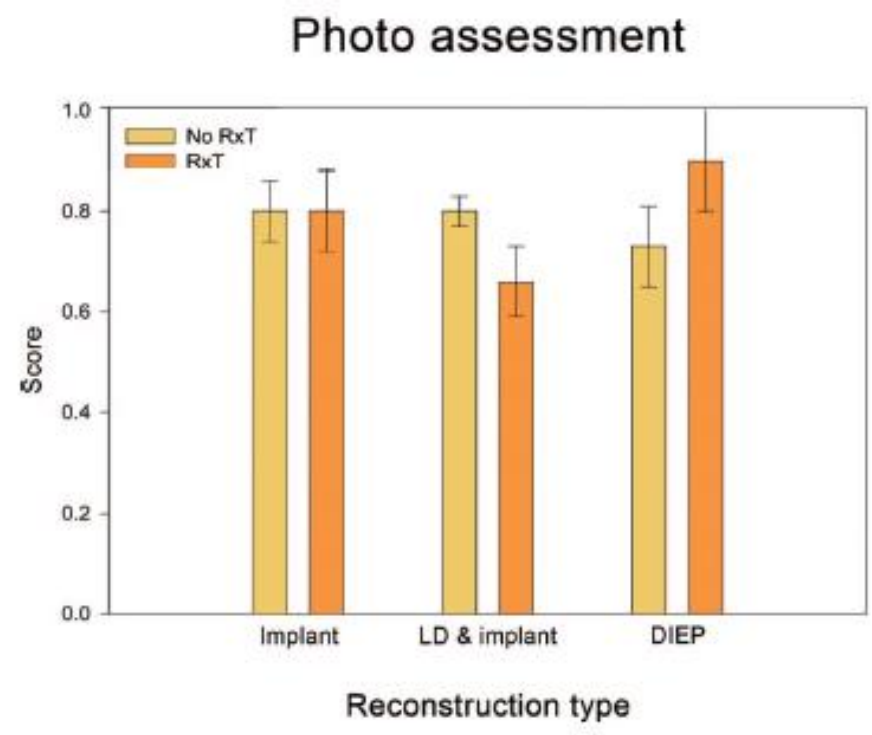
NSM & XRT Aesthetic Results

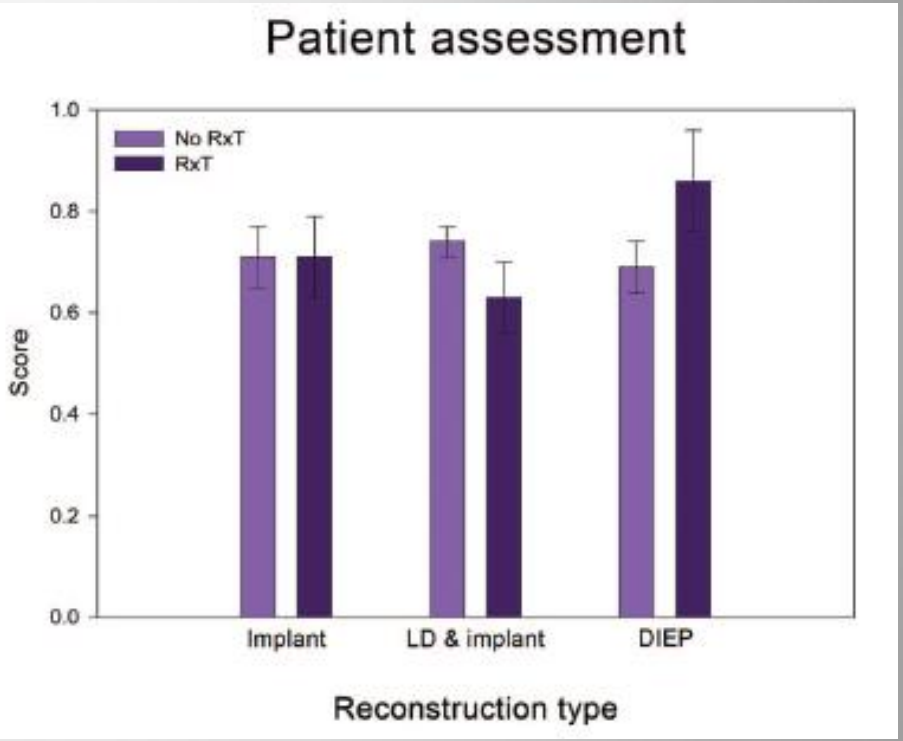




Mosahebi 2007

NSM & XRT Aesthetic Results

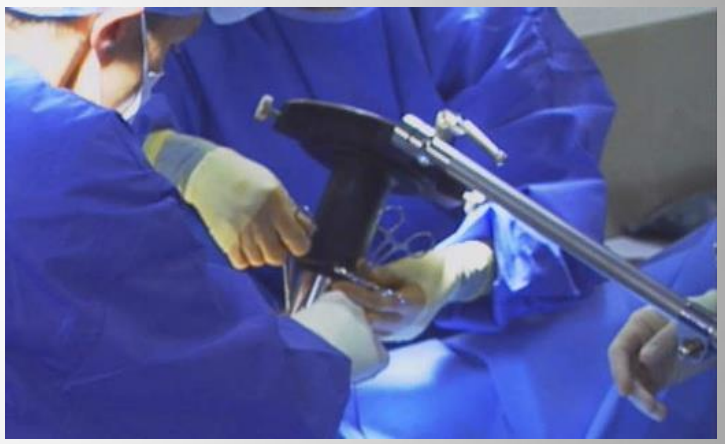




Mosahebi 2007

NSM & Intra-Operative XRT

- 1001 NSM
  - 82% invasive carcinoma
  - 20 month median follow-up
- 800 intra-operative XRT
- 201 post-op “one-shot” XRT
- 1.4% local tumor recurrence
  - None in NAC
  - All far from NAC XRT field
  - 10 close to original tumor site



NSM & Intra-Operative XRT Outcomes

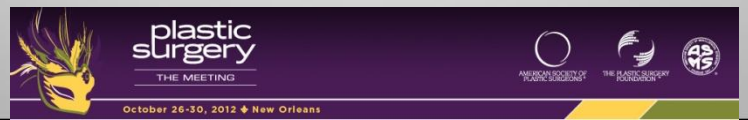
- NAC necrosis 9.0%
  - Partial 5.5%
  - Total 3.5%
- NAC removed 5.0%
- Infection 2.0%
- Prosthesis removal 4.3%
- Patient & surgeon cosmetic score 8 (0-10)
  - Most skin necrosis & poor aesthetic results in patients with large breasts + implant reconstruction

Petit 2009

NSM & Intra-Operative XRT Pathology

8.6% false (-) frozen sections

- 71% were DCIS
- 92% NAC preserved
  - 53 DCIS
  - 23 invasive
  - No recurrences after average 20 month follow-up
- Intra-operative XRT may improve oncologic safety of NSM



Petit 2009

Nipple & Areola Complications

- Partial necrosis
- Full necrosis
- Infection
- Malposition

Nipple Necrosis

Nipple Loss Management

- Local wound care – resulting NAC may be surprisingly good
- Excise if threatened exposure – allograft contamination
- Local flap/tattoo as needed

Nipple Necrosis

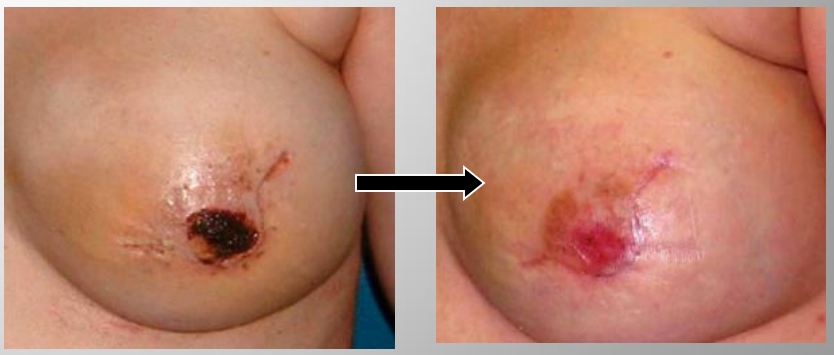
Nipple Necrosis

- Variable incidence
  - 0 to 48% (higher with XRT)
  - Typically < 10%
- Depends on
  - Patient age > 45, breast size, smoking
  - Surgical incision & technique
  - Surgeon's experience
- May lead to
  - Unfavorable aesthetic result
  - NAC excision (< 10%)
  - Implant or expander removal (< 5%)

Study	No. of cases	Partial necrosis (%)	Total necrosis (%)
Crowe et al. [33]	48	6.3	0
Caruso et al. [26]	50	2	0
Sacchini et al. [27]	192	6.8	4.5
Psaila et al. [34]	139	1	1
Komorowski et al. [35]	38	5.7	7.9
Petit et al. [28]	300 (IORT)	9.7	3.3
Bistoni et al. [36]	10 (RT)	20	0

What to do when NAC Compromised?

- Assess perfusion with fluorescein + Wood's lamp
  - Need experience with normal tissue
- Indocyanine green perfusion (SPY) imaging if available
- Consider placing tissue expander instead of implant or flap
  - Combined implant/expander if available
- Total expander/implant muscle coverage if possible
- Nitropaste if venous congestion
- Hyperbaric oxygen treatment
  - Indication: Failing flap
- Conservative treatment
  - Hand holding
  - Frequent follow-up



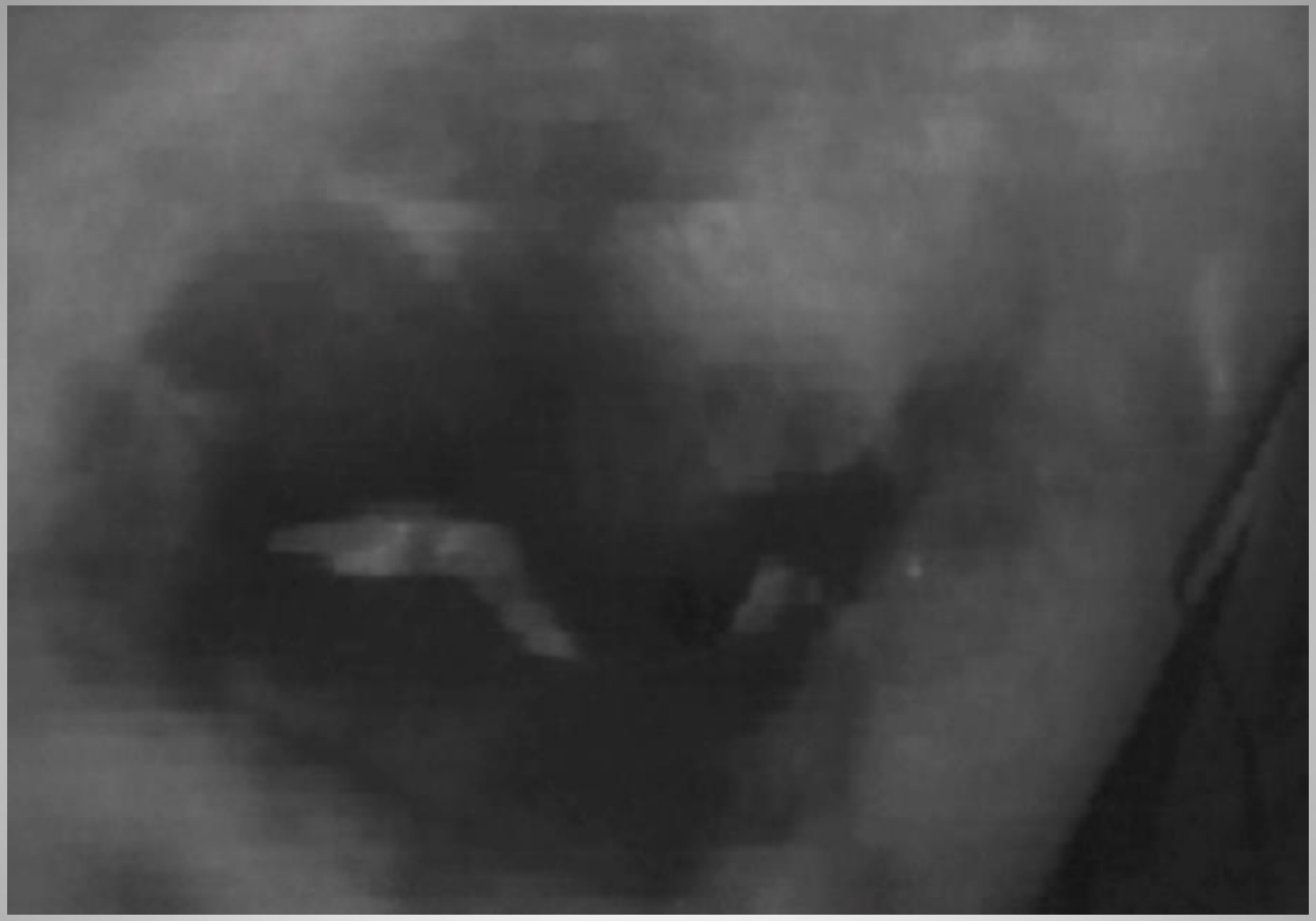
Treated with Hyperbaric Oxygen

After 2 Weeks of Hyperbaric Oxygen

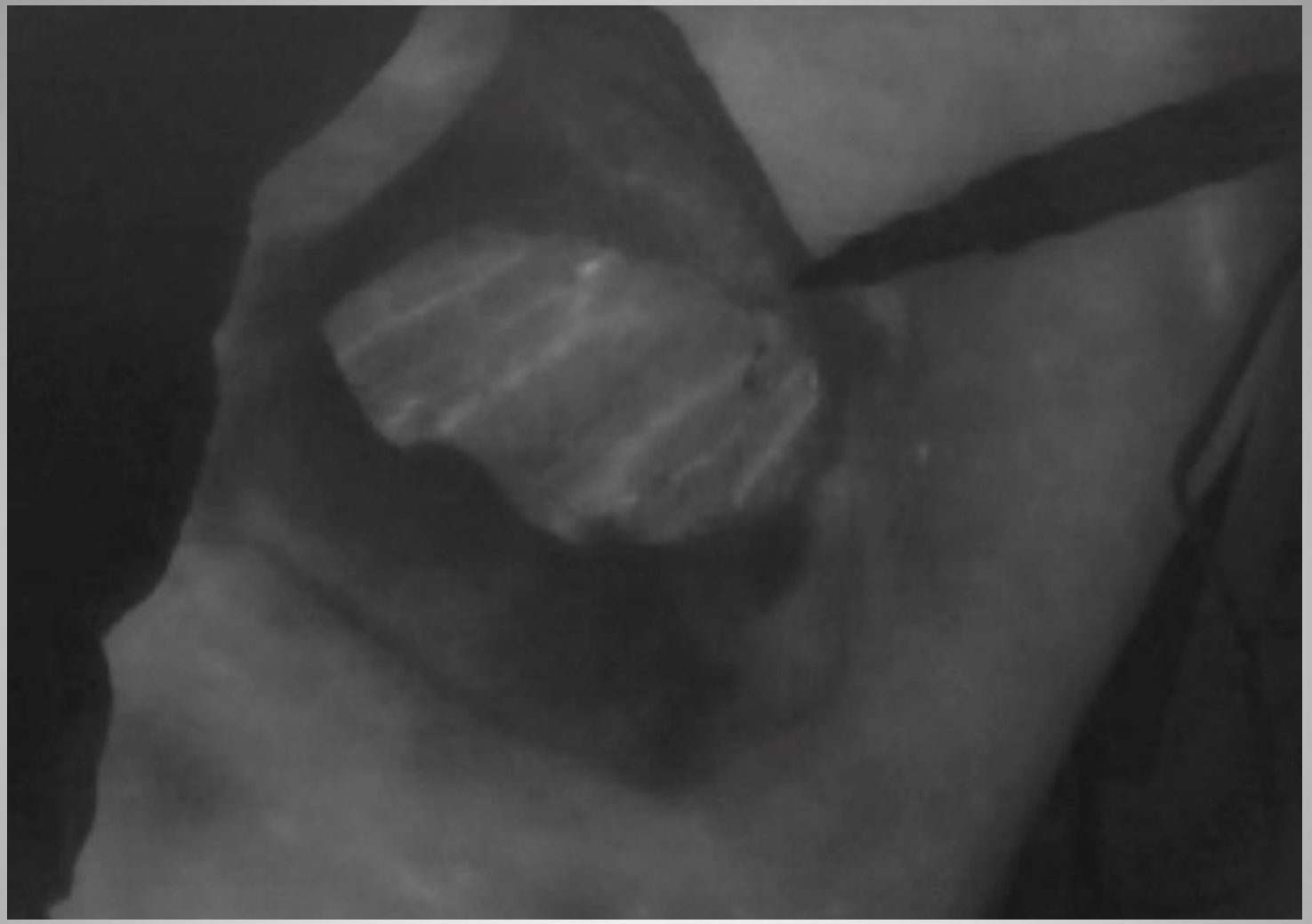
SPY (Indocyanine Green Fluorescence Imaging) for intraoperative evaluation of mastectomy skin flaps

Michael Zenn, MD

Duke University Medical Center



Decreased perfusion at 1 minute of nipple and surrounding skin
Recommend re-evaluation at 3 minutes



Use SPY to valuate both sides (only penetrates a few mm)
Viable fat is significant for good perfusion

Mastectomy flaps

Mastectomy flaps

Mastectomy flaps

Mastectomy flaps

Full thickness necrosis as predicted by SPY

NAC Malposition

- May be worse than no NAC
- Set NAC on chest in sitting position with multiple internal sutures
- Place NAC over muscle, not ADM
- Fibrin glue for skin adhesion to underlying tissue
- External superior pole dressings
- Inferior pole compression & bra
- See frequently until NAC in proper position

Late Implant Extrusion

Nipple Sensation

- Predominantly anterior 4th lateral intercostal nerve
  - Travels through breast parenchyma
  - Contributions from intercostal nerves
- Expect preserved nipples would be insensate
- After 2 years, up to 75% may have sensation
- Quality of sensation very limited
  - < 1/3 regain normal sensation
- Further study required to delineate the effect of incision placement

NSM & Risk-Reducing Mastectomy

- Few primary breast cancers arise in nipple
- Most series have not demonstrated any abnormality (except LCIS) in nipple after risk-reducing mastectomy
- Need careful preoperative imaging
- Perform histopathological examination of specimen
- Majority of NSM series for risk reduction report no primary breast cancers during follow-up

NSM: Who Needs to be Involved?

- Surgical oncologist
- Medical oncologist
- Breast radiologist
- Breast pathologist
- Radiation oncologist
- Nursing staff
- Research support?

Getting Breast Surgeons Involved

- Recall the RM - MRM - SSM debate
- Use published data to demonstrate
  - Safety
  - Patient satisfaction
  - Surgical technique
- Assist in OR with initial NSMs
  - May be more physically challenging
  - Consider tumescent technique in subcutaneous space
- Offer NSM as research protocol
- You will follow the complications
- Don’t start with the casual mastectomy surgeon
  - Start with the one who has breast good SSM technique
- Bill for NSM with -22 modifier (+ appropriate documentation)

NSM & Sentinel Lymph Node Mapping

Can SLN biopsy be done without axillary counterincision?

- 87 NSM through IMF incision
- Starts 6–8 cm from midline & extends 7–12 cm laterally
- SLN biopsy successfully in 97% of cases
- Mean 2.8 SLN removed
- No complications regarding SLN procedure

SLN biopsy can be performed through an IM incision

Limitations: Generally patients with small breast (A or B cup)

Kilik 2008

Breast Pathologist

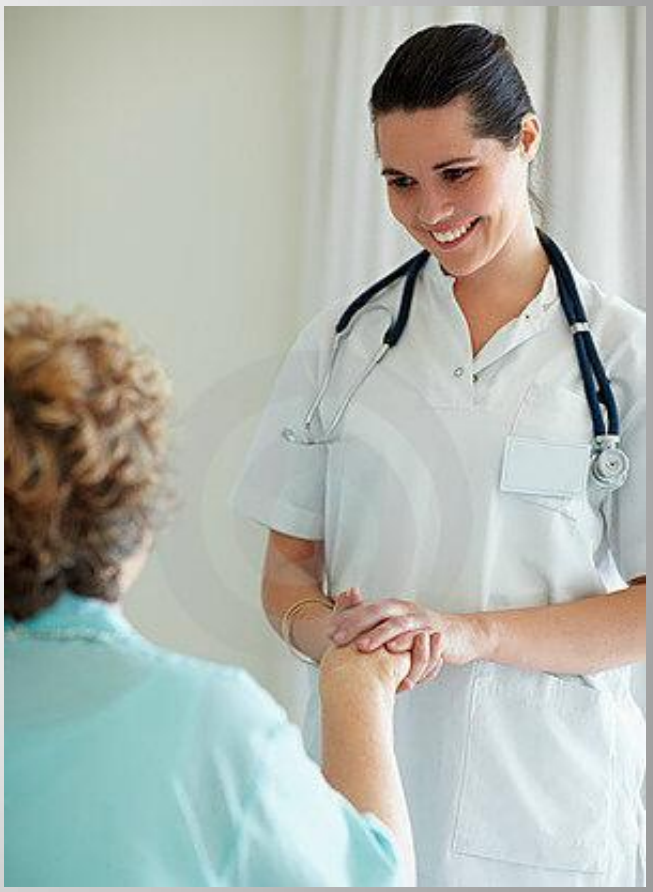
- Send 2cm x 2cm x 0.5cm subareolar tissue for frozen tissue intraoperative analysis
  - Should have results in $\leq$ 20 min
  - Takes longer to process if tissue too large
- Mark subareolar area on mastectomy tissue
- Obtain feedback from surgical pathologist
- Understand possibility of false (-) results
  - Await final pathology report

Patient Discussion

- Possibility of NAC malposition or asymmetry
- Nipple will have less projection
- Don’t expect nipple sensation
- Risk of NAC color variation
- Potential for NAC removal
  - Intraop or post op
  - Malignancy
  - Viability
  - Poor aesthetic outcome

Post NSM Course

- Expect more office visits
- Monitor position of NAC
- More hand-holding if NAC compromised
- Discussion on when to remove nipple/NAC if appears nonviable

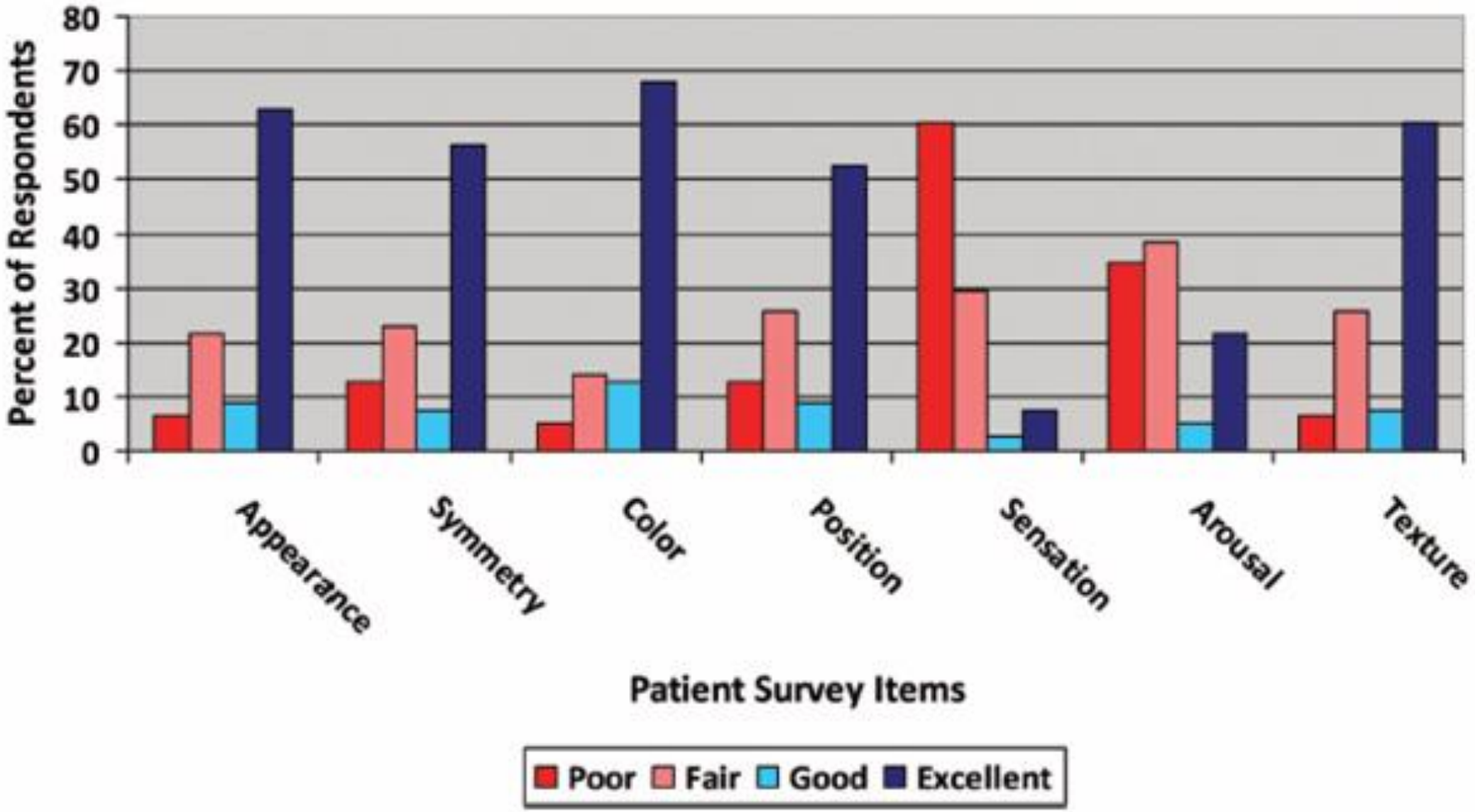


Patient Expectations & Dissatisfaction

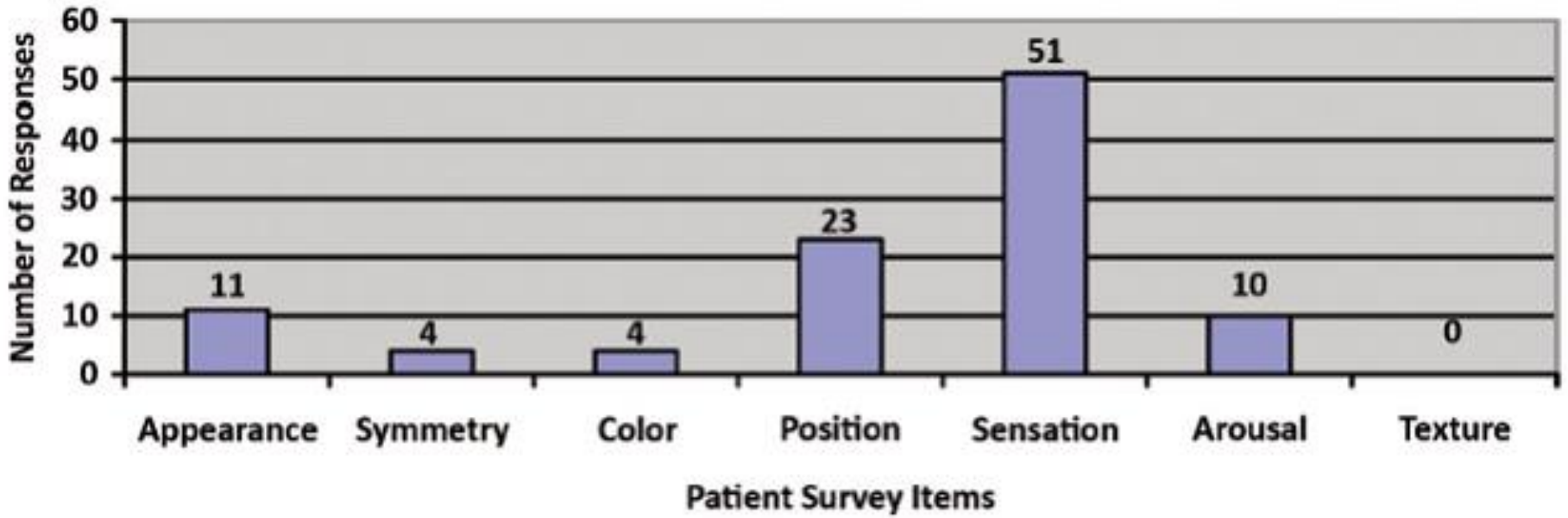
- Decreased patient satisfaction with
  - Occurrence of complications
  - Potential for complications
  - Large breast size
  - High body mass

- Patients must be counseled that loss of nipple arousal & sensation is the norm

NSM Patient Satisfaction



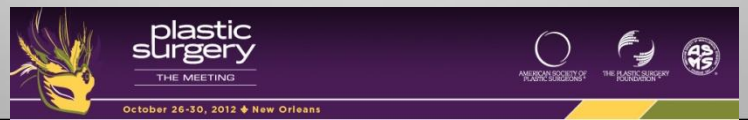
What NSM Patients would Change



NSM as part of IRB Protocol

"Currently, NSM should be performed under protocol or with special surveillance, and explicit consent should be obtained from patients. It should still be presented to patients as an investigational modality in those who meet certain selection criteria and not as a replacement for the standard total mastectomy." – Chung, 2008

- Additional work to get IRB approval
- Staff for research consent
  - Additional 30 to 60 minutes per patient
- Our experience
  - 95% willing to participate
  - Breast cancer patients more overwhelmed
  - RRM patients more excited about participating
  - Incorporate Breast-Q
- American Society of Breast Surgeons: **NSM Registry**



NSM Conclusions

- Data supports oncologic safety of NSM
- Patient selection not fully defined
- Results depend on technique and experience
- High patient satisfaction
- Incorporate minor technique modifications
- Prepare for a new level of complications
- Expect to see better aesthetic results
- Consider NSM with investigational protocol

Getting Started

- Meet with key medical & surgical oncologist
- Review latest literature
- Set inclusion criteria
  - Be conservative and selective to start
- Expect longer OR time to start
- Work together in OR initially
- Monitor your results

For copies of this presentation or questions, please email:

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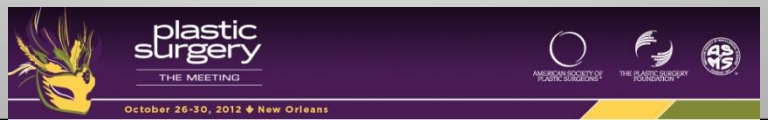

Incorporating Nipple-Sparing Mastectomy Into Your Practice

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Karol A Gutowski, MD, FACS

plastic surgery
THE MEETING
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