

Incorporating Nipple-Sparing Mastectomy Into Your Practice

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Disclosures

Mark Sisco has no relevant disclosures.

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Topics

- Why Nipple Sparing Mastectomy?
- Patient Selection
- Patient Counseling
- Type of Reconstruction
- Operative Technique/Postoperative Care
- Case Examples
- Pitfalls

Why Nipple Sparing Mastectomy?

- Nipple sparing mastectomy (NSM) is the latest stage of a continuum in breast care:
 - Radical mastectomy
 - Modified radical mastectomy
 - Skin-sparing mastectomy
 - Nipple-sparing mastectomy (NSM)

Why NSM?

- Up to 1/3 of patients are dissatisfied with nipple areola reconstruction.
 - lack of projection
 - color match
 - shape
 - size
 - texture

Jabor MA, et al. *Plast Reconstr Surg.* 2002;110:457–463



Why Else Is Saving the NAC Helpful?



Is NSM Really Better?

- Didier 2008
 - 310 NSM, 143 NAC recon
 - 56 item questionnaire
 - *Significant differences in favor of NSM for body image, satisfaction with nipple appearance, and feelings of mutilation*



Didier F. Breast Cancer Res Treat. 2009 Dec;118(3):623-33.

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Is NSM Really Better?

- 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 malposition

Djohan R et al. Plast Reconstr Surg. 2010 Mar;125(3):818-29.

Patient Selection

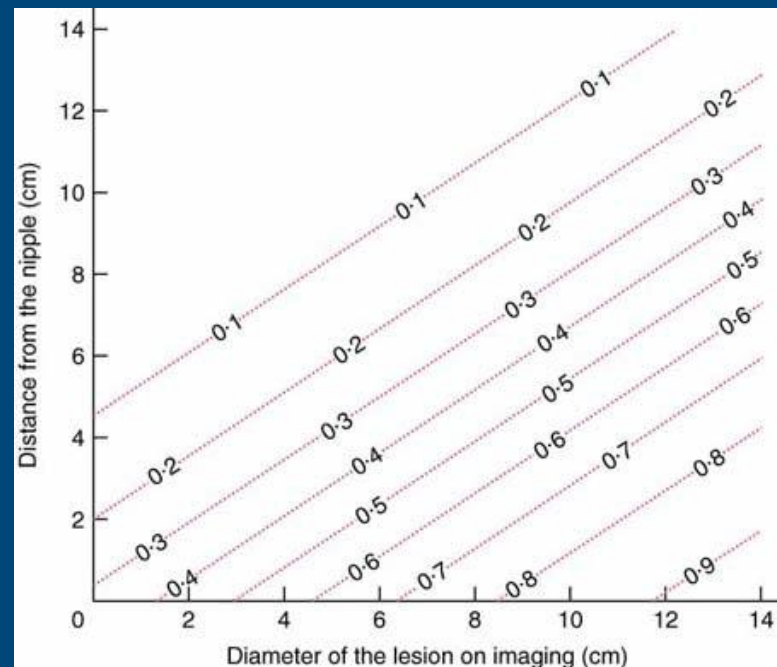
- Patient factors
 - Smoking
 - Radiation
 - Previous breast surgery
 - Expectations
- Breast surgeon

Patient Counseling

- Is it safe?
- Will the nipple have sensation?
- How will it look?
- Can I go straight to an implant?
- What about doing NSM on one side and a SSM on the other side?
- What if I don't like it or if something goes wrong?

Is It Safe?

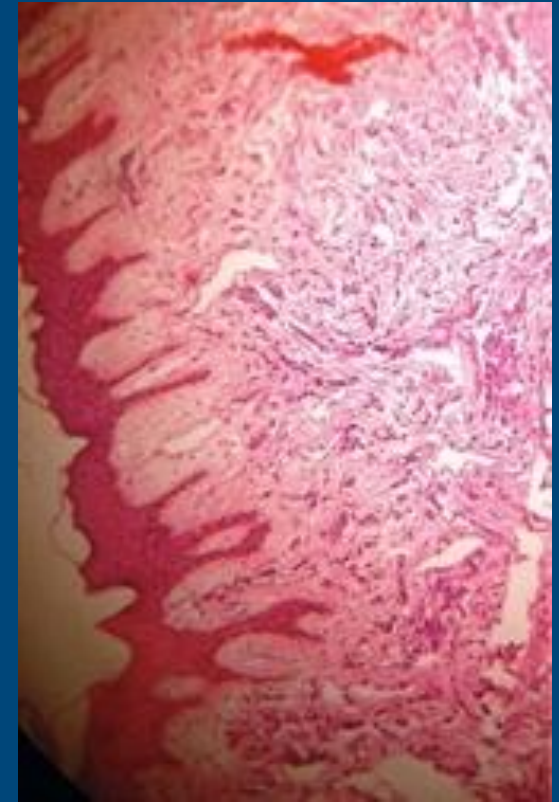
- Two models have been developed to predict nipple involvement
 - Size of tumor
 - Distance from NAC



Rusby JE et al. Br J Surg. 2008 Nov;95(11):1356-61.
Loewen MJ et al. Am J Surg. 2008 Mar;195(3):391-4.

NSM for Breast Carcinoma and DCIS: 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 LCIS



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: Involvement of the NAC

- 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: Involvement of the NAC

- 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

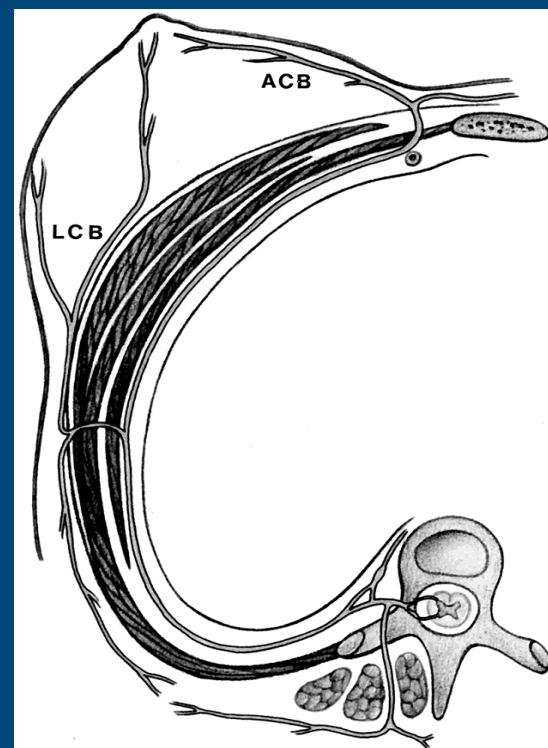
Is NSM Safe?

- No randomized trials
- Locoregional recurrence appears similar, but follow-up is limited
- NCCN 2013:

“Current data are inadequate to support the routine use of NAC-sparing procedures for breast cancer therapy.”

Will I Have Sensation?

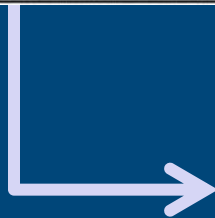
- “Normal” sensation in 0-31%
- Sensation absent in 14-57%
- “you *may* retain some sensation; do not expect erogenous sensation”



Screening Oncologic Criteria
Tumor size < 3cm
Tumor > 2cm from nipple
Clinically negative axillary nodes
No skin involvement or inflammatory CA/ Paget's disease
*Possible preoperative MRI to exclude nipple involvement



Patient Anatomic Criteria
No excessively large breasts
No excessively ptotic breasts



Operative Criteria
Intraoperative frozen section negative
Permanent pathology negative

Spear et al. Plastic and Reconstructive Surgery. 123(6):1665-1673.

Can I Go Straight to an Implant?

- Tissue Expansion
 - Lowest risk
 - Best cosmetic outcome
 - Patient has more control
 - Can be uncomfortable
 - More visits for expansion
 - Adjuvant therapies may be affected by second stage
- Direct-to-Implant
 - Potential to avoid second procedure
 - Convenient
 - Cost effective
 - Higher risk
 - Smokers
 - Previous radiation
 - Cannot go significantly larger
 - More difficult to deal with complications

Type of Reconstruction

- What about autologous reconstruction?
 - Need for monitoring of free flaps
 - Need to consider relationship of recipient vessels to incision
 - May be better for larger or more ptotic breasts

What If Something Goes Wrong?

- Positive margin
- Necrosis
- Malposition

“There is up to a 10% chance we may need to remove the nipple after your mastectomy”

- Expect changes in:
 - Sensation
 - Pigmentation
 - Position
 - Projection

...and the possibility of necrosis

Operative Technique



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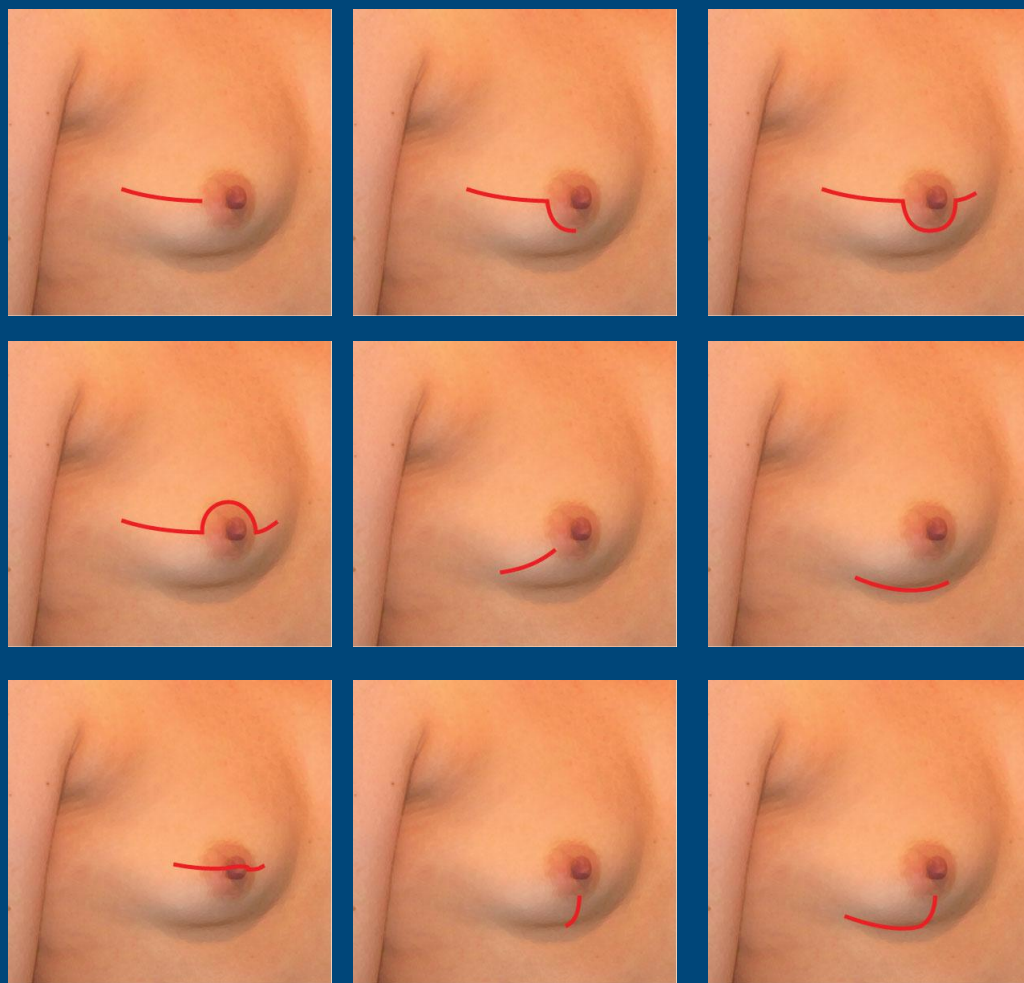


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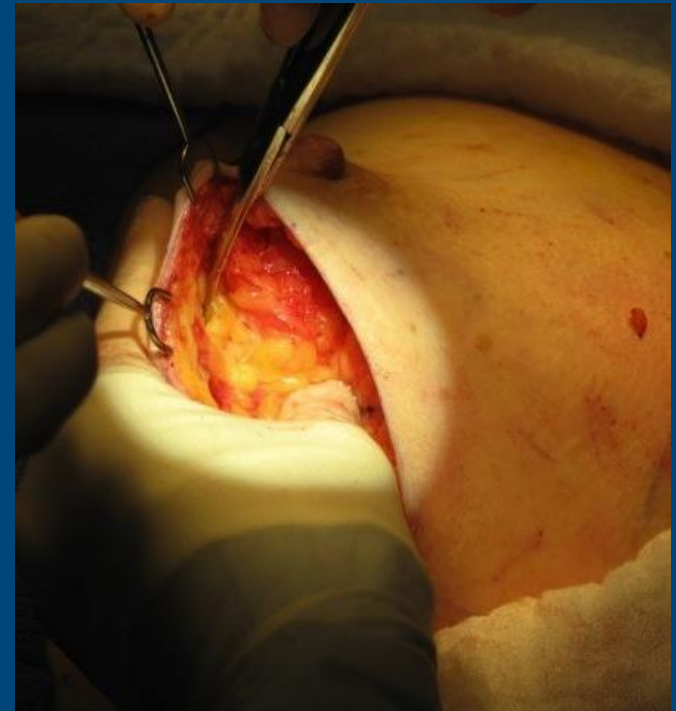
Operative Technique

- Incision planning
- Evaluating mastectomy flaps
- Biologic vs. total muscle coverage
- Post-op Care



Mastectomy Flap Evaluation

- Blanching
- Ecchymosis
- Thickness of flaps
- Surgeon
- Consider Perfusion Imaging



What About Biologics?

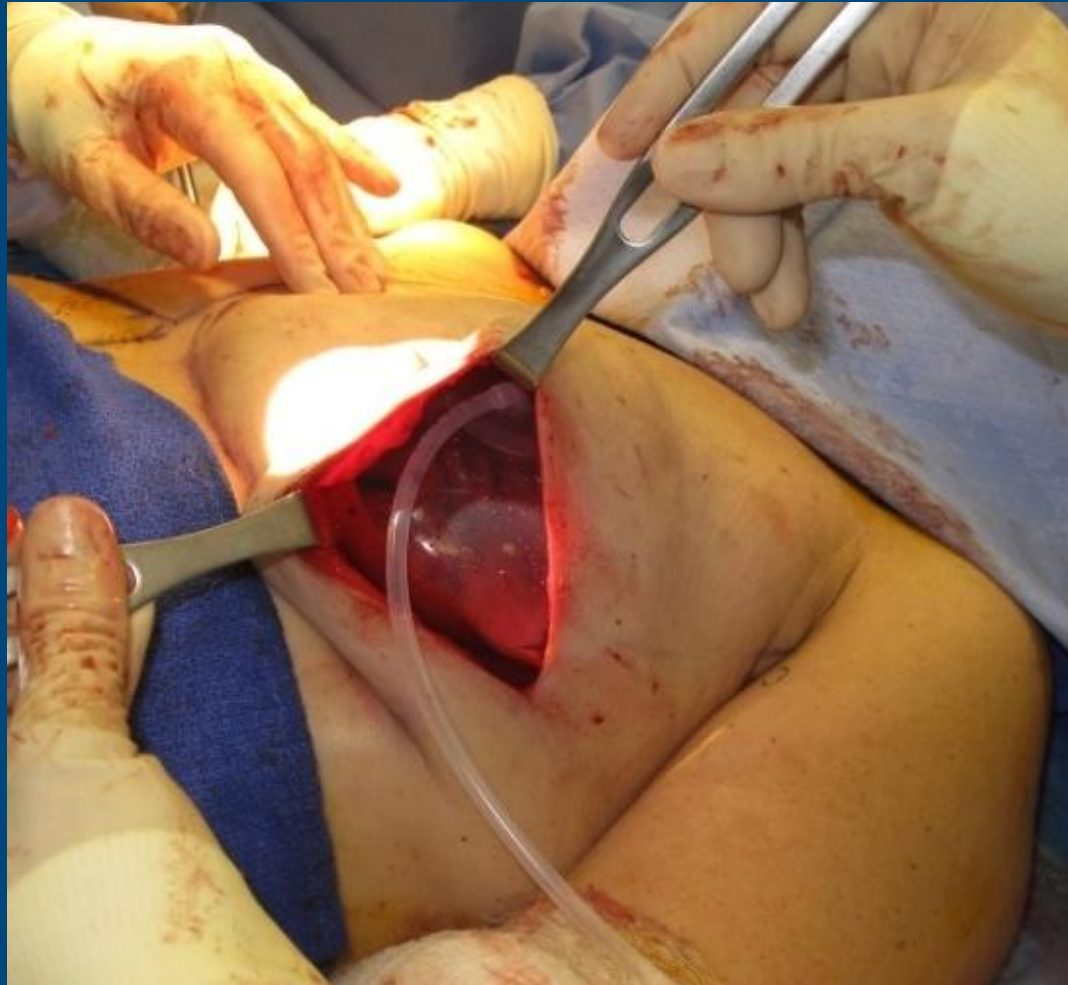
- I rarely use biologics for skin-sparing mastectomies
- I use a biologic for all NSMs
 - Facilitate one-step reconstruction
 - More rapid expansion minimizes issues with nipple positioning



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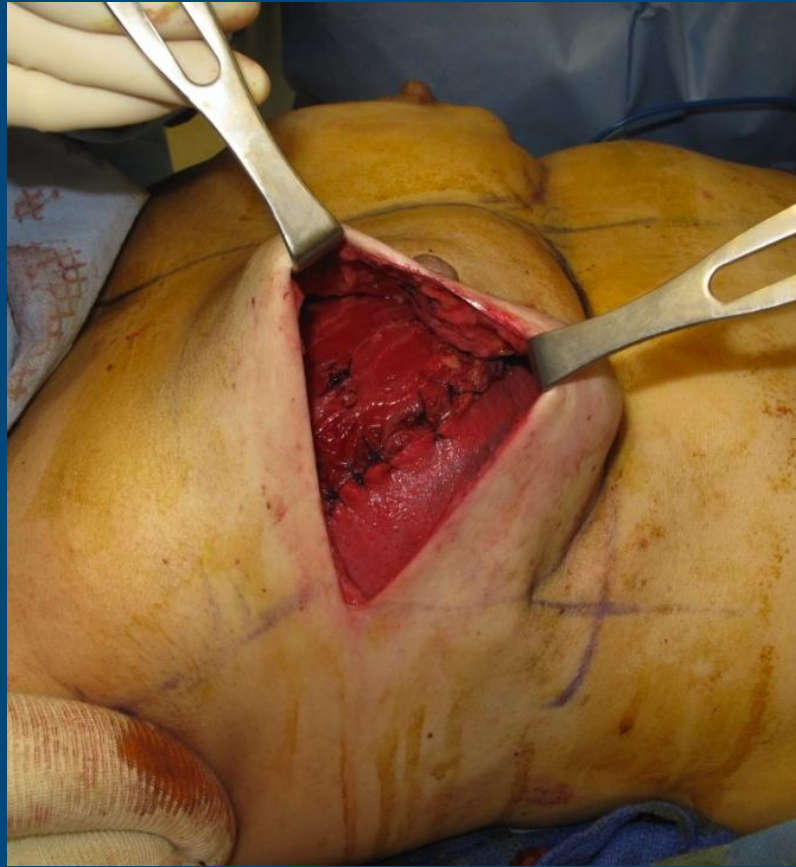
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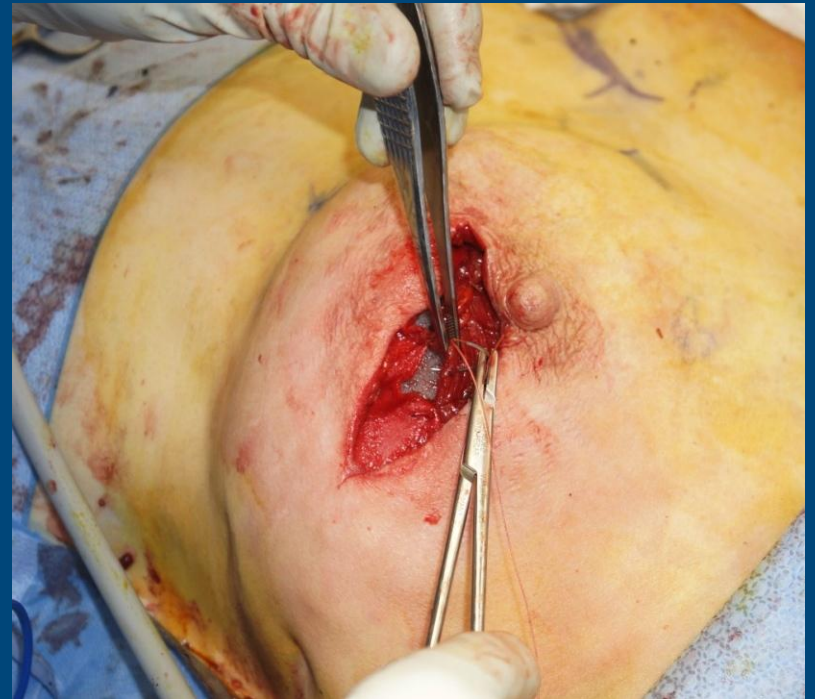
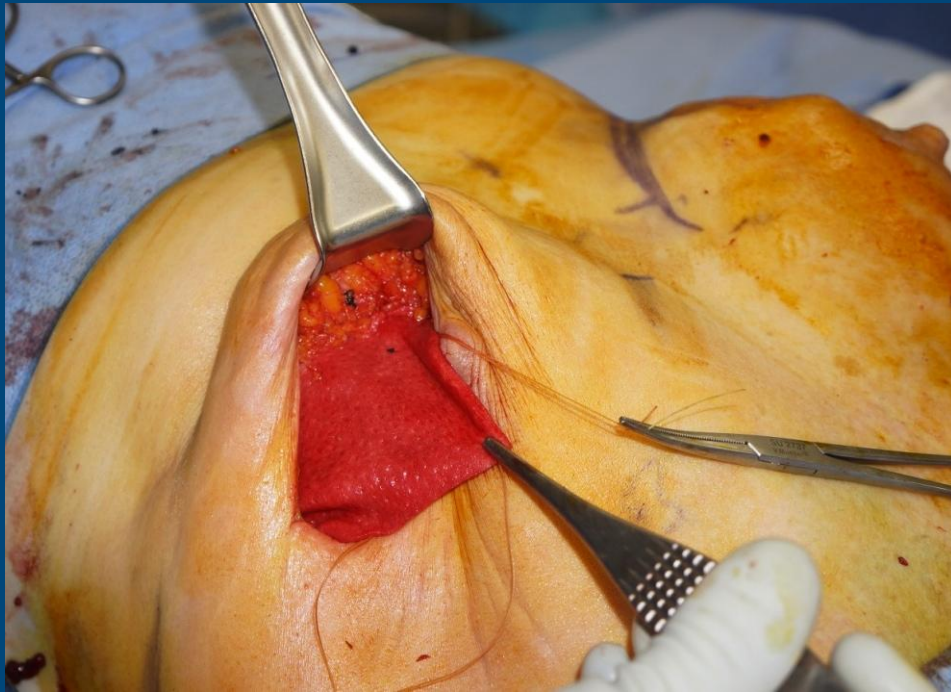


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Pitfalls



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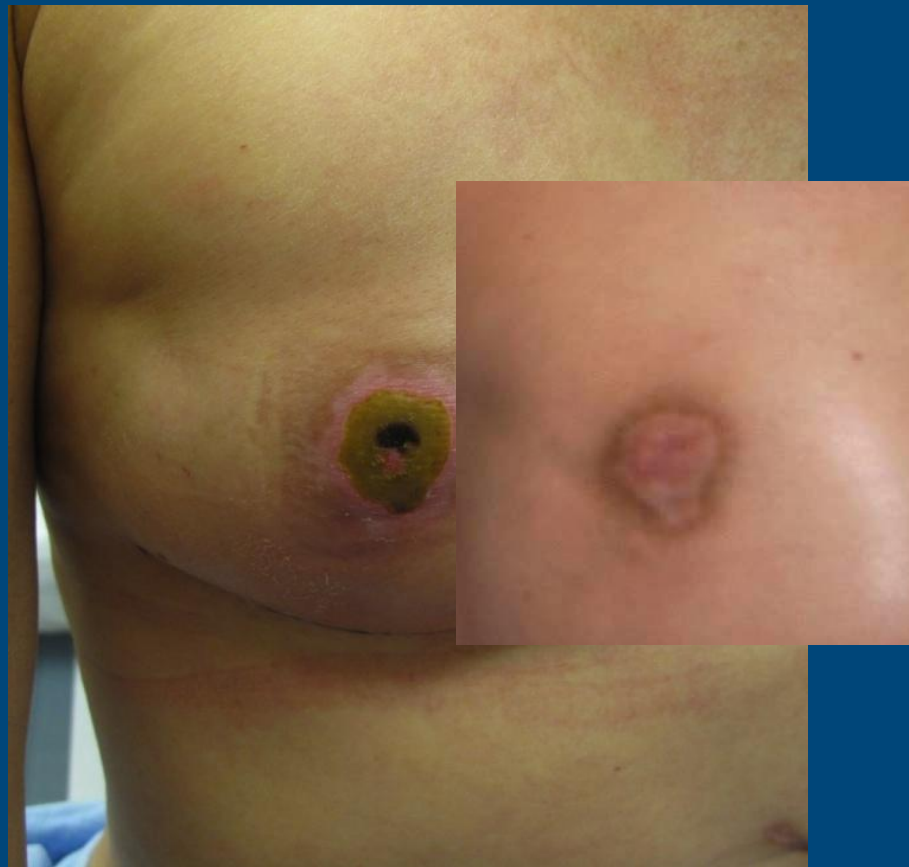
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Prior History of Radiation



Nipple excised in office

Heavy Smoker



Large Nipple



Flap Compromise

(History of Periareolar Augmentation)



One-stage Mentor gel 800 ml

2 Weeks of Hyperbaric Oxygen



Implant Extrusion



Pointers

- Expect complications
- Patient counseling is paramount
- Start with tissue expanders or adjustable implants
- Spend time with your breast surgeon

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

Part II

Nipple Assessment
Nipple Surgical Technique
NSM & Radiation Therapy
NSM Complications
Building the NSM Team

- The following photos are Mike and yours I think...

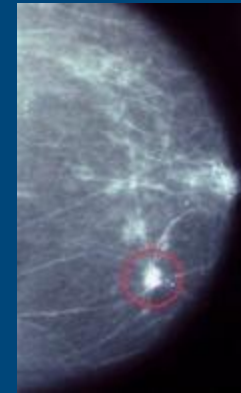
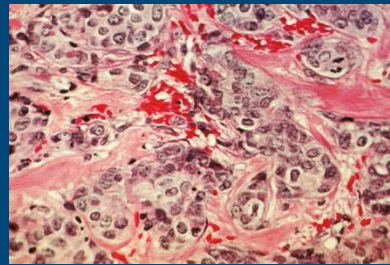
Nipple Involvement

NSM contraindications

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

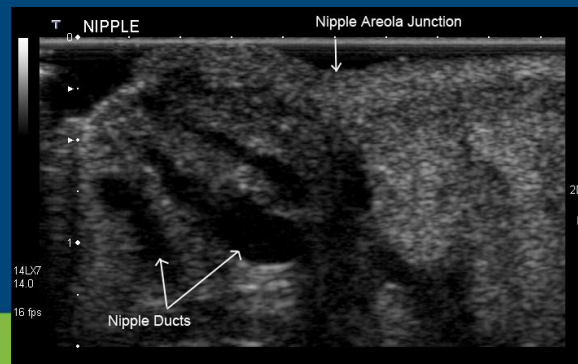
Nipple Assessment for NSM

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



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

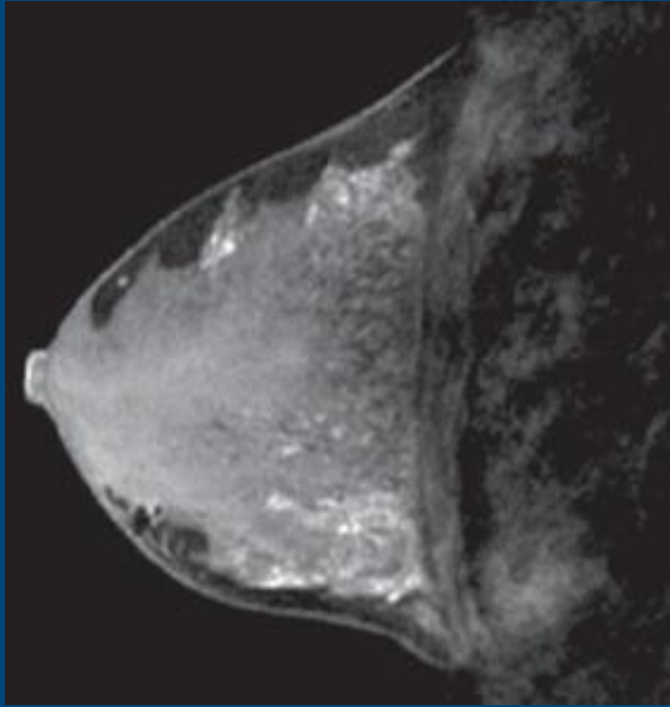


MRI Nipple Evaluation

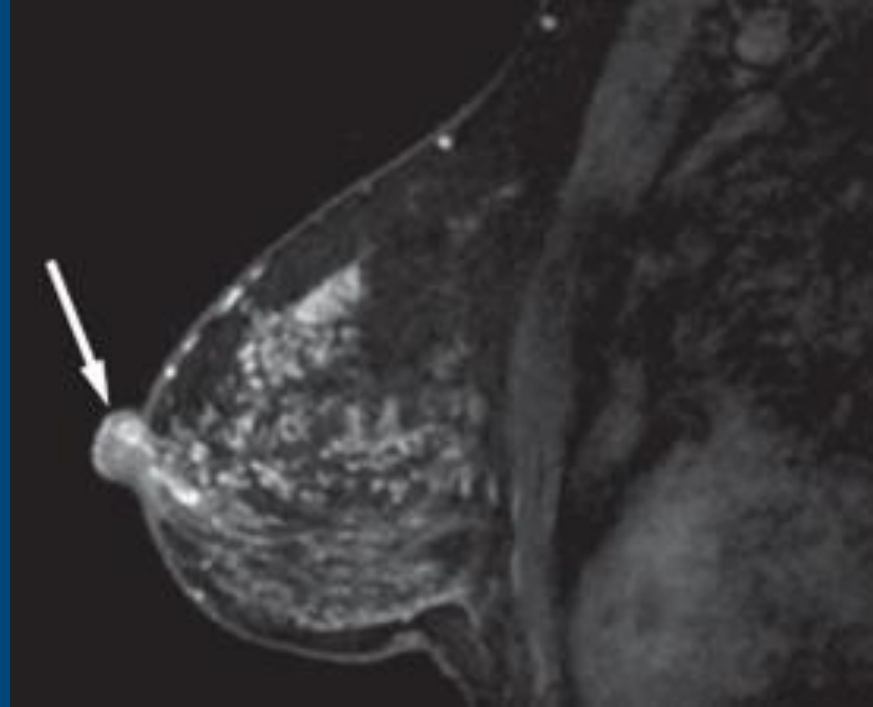
- Preoperative MRI to exclude patients with disease near the nipple
- Excluded from NSM
 - Large centrally located tumors
 - Skin involvement
 - Carcinoma within 2 cm of the nipple
 - Disease in ductal tissue near nipple
- Use in place of intraoperative frozen sections
- If malignancy on final pathology,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

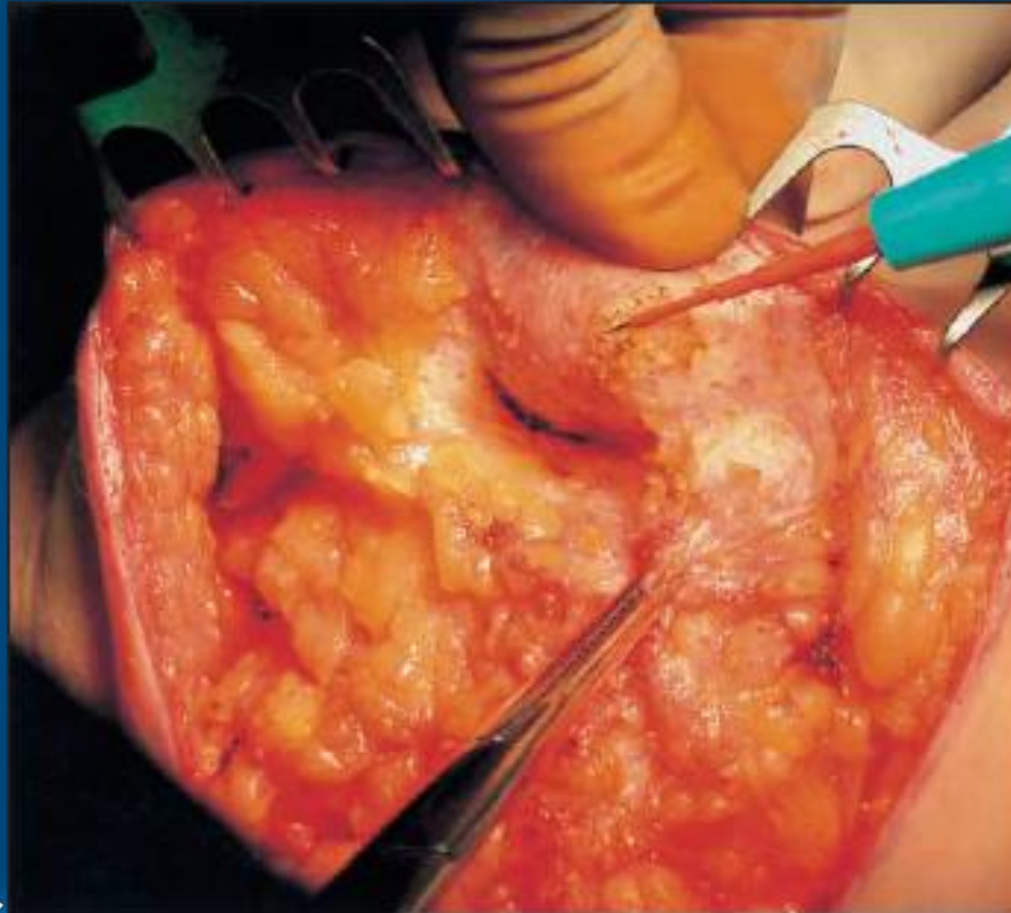
Surgical Technique: Details

- 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

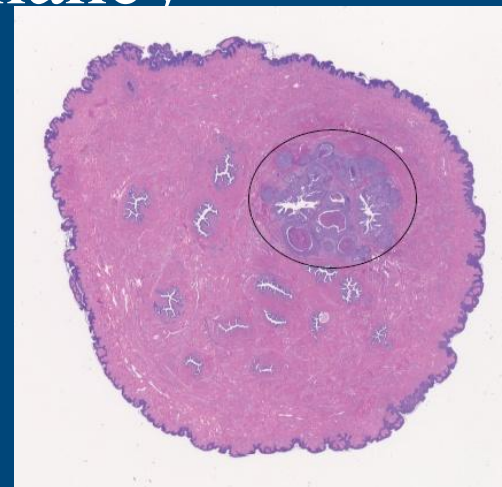


Complete Nipple Core Removal



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

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

NSM & Radiation Therapy



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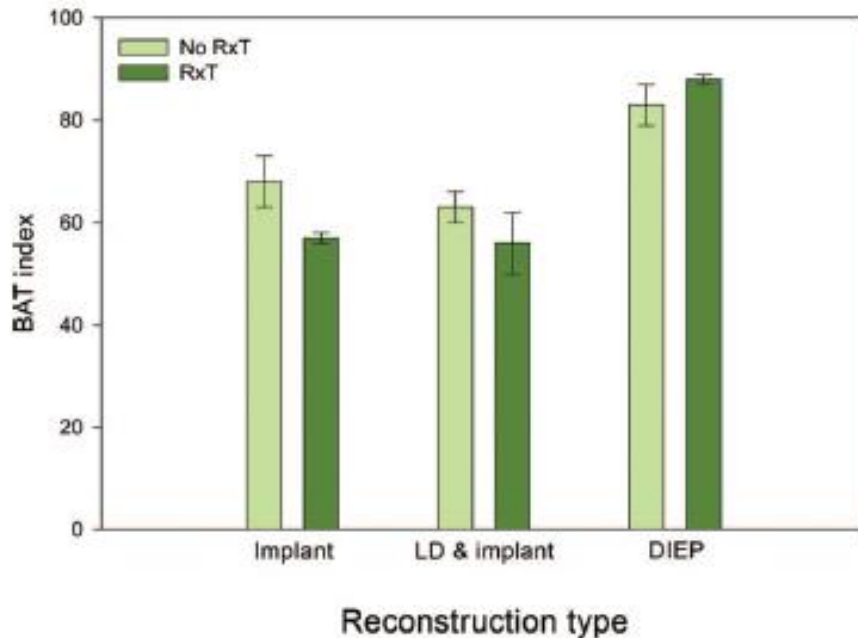


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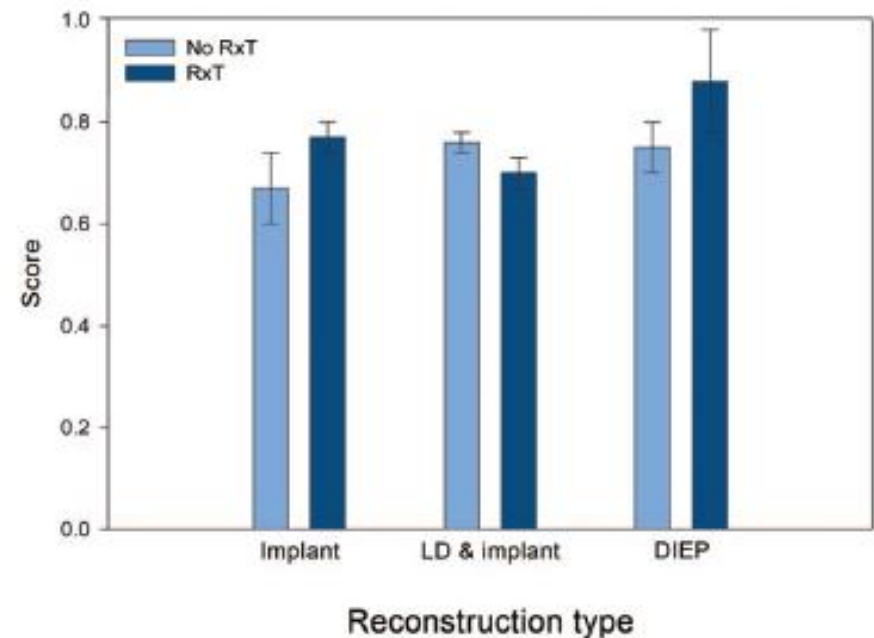
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NSM & XRT Aesthetic Results

Tonometric assessment

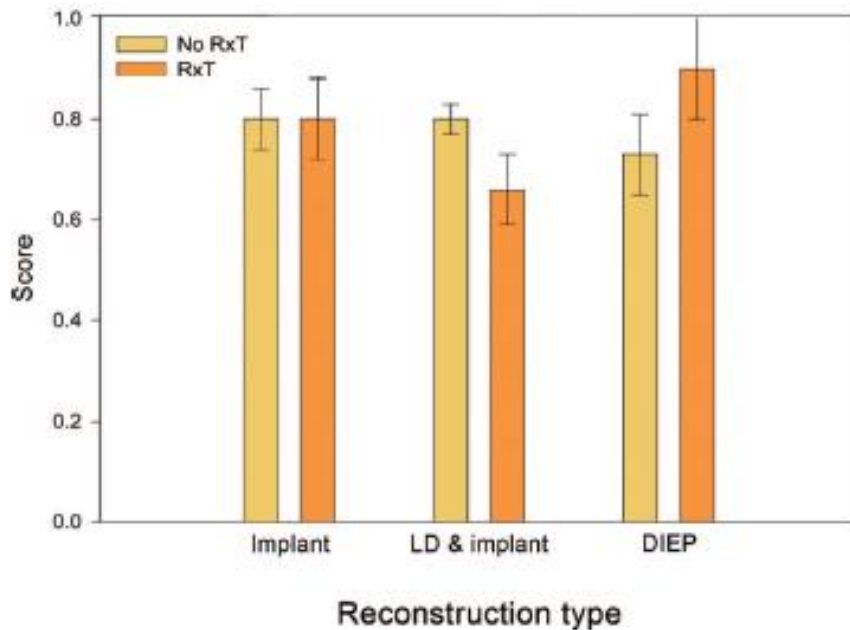


Clinical evaluation

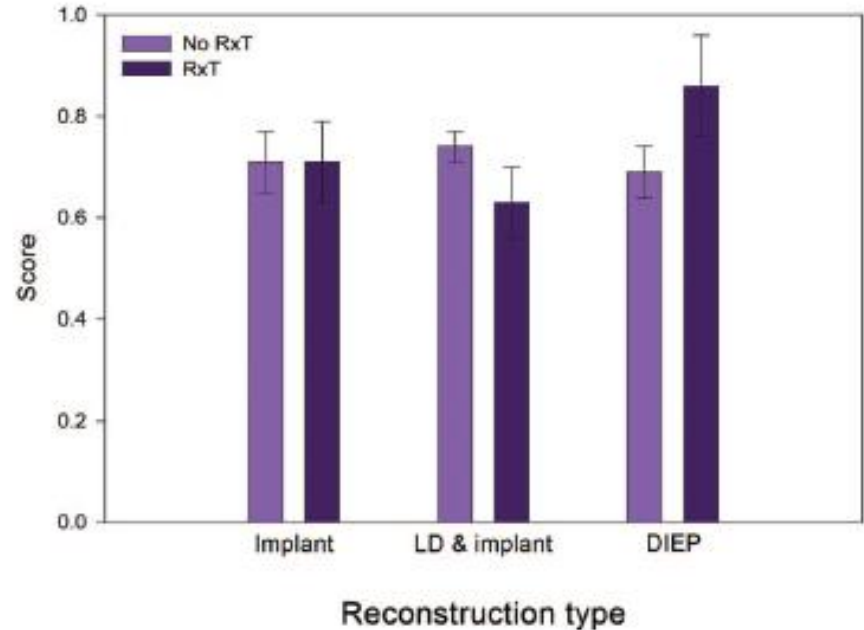


NSM & XRT Aesthetic Results

Photo assessment

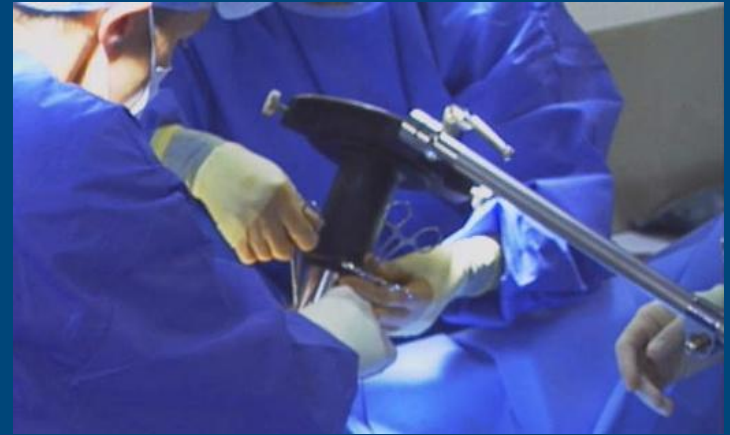


Patient assessment



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

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

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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



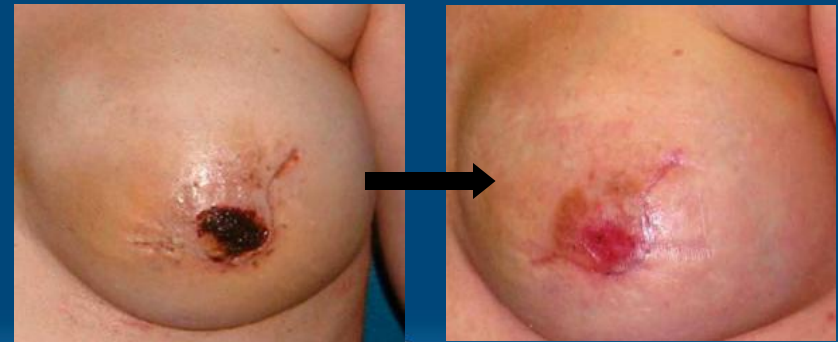
Nipple Necrosis

- 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



9/25/09
1st Day

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 evaluate 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)

Breast Pathologist

- Send 2cm x 2cm x 0.5cm subareolar tissue for frozen tissue intraoperative analysis
 - Should have results in ≤ 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

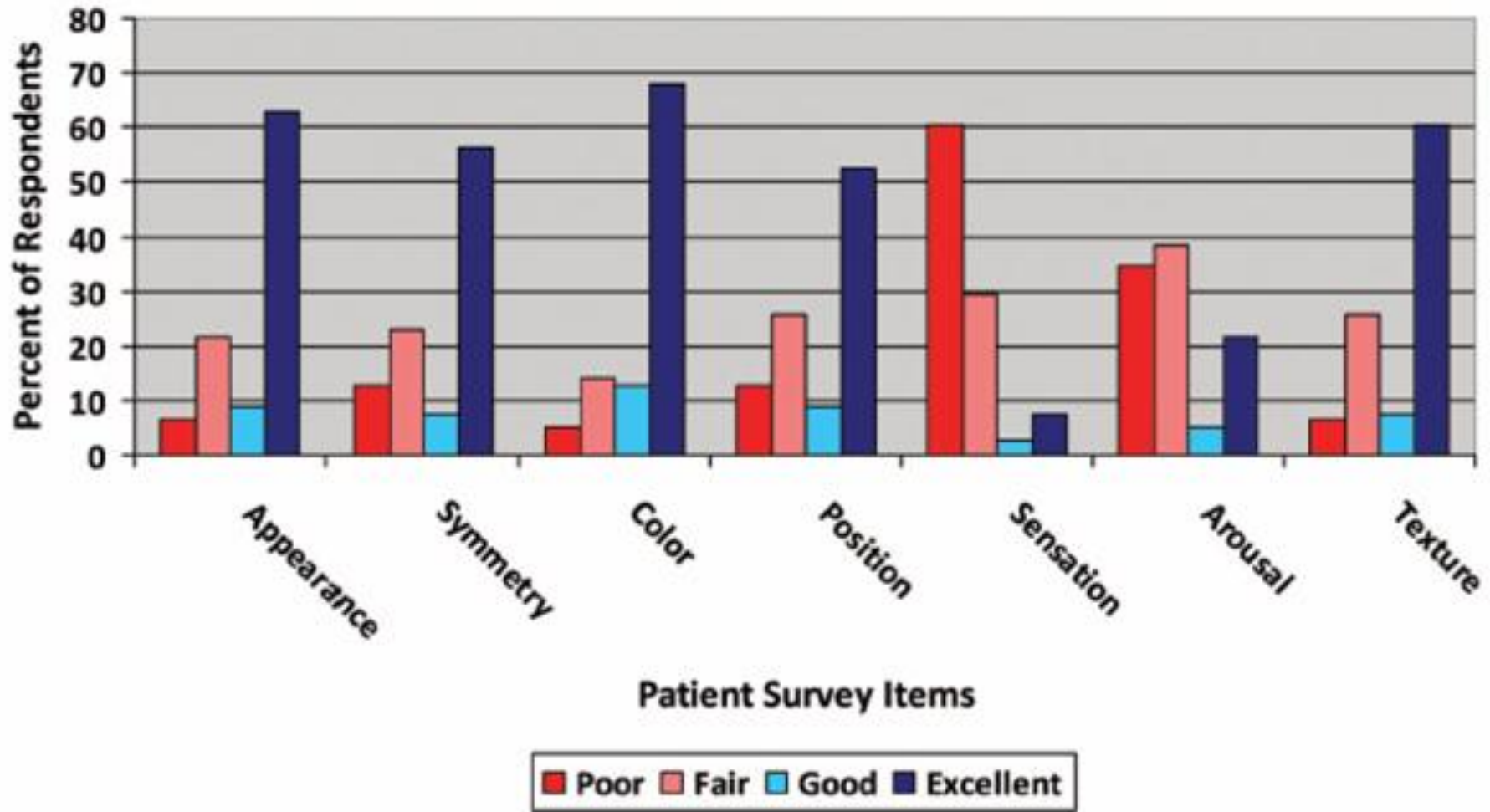


Patient Expectations & Dissatisfaction

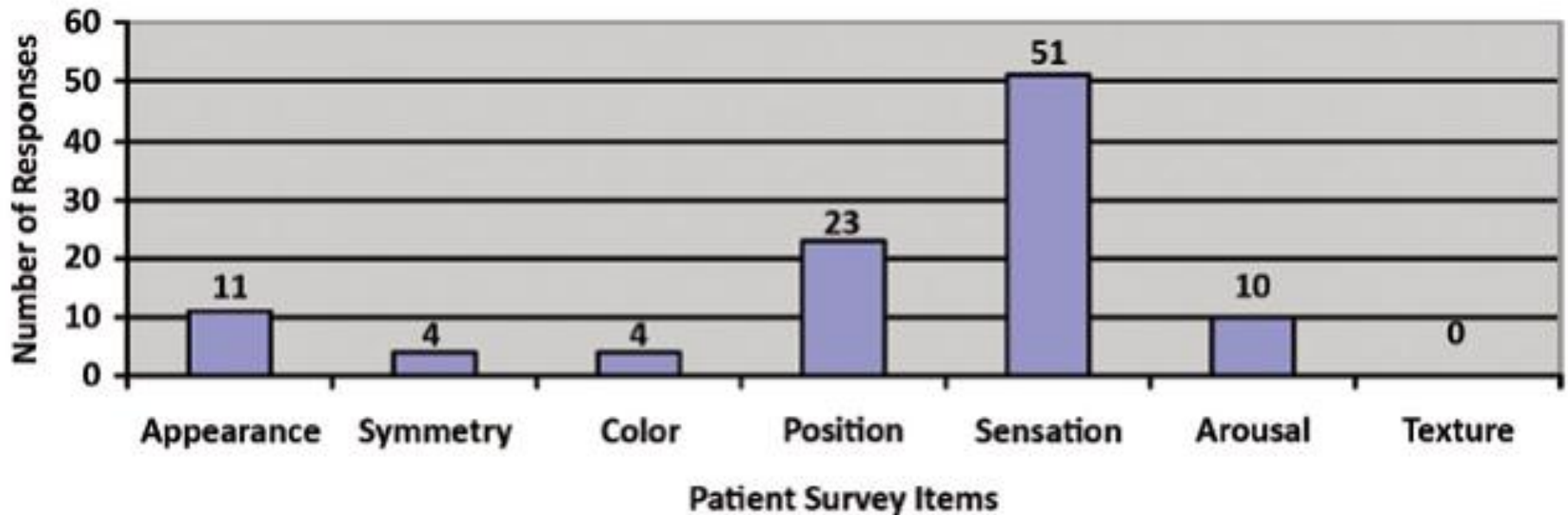
- Decreased patient satisfaction with
 - Occurrence of complications
 - Potential for complications
 - Large breast size
 - High body mass
- Patients must be counseled that loss of nipple arousal & sensation is the norm



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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