

# A Prospective, Randomized, Controlled, Multi-Center Study Of A Real-Time, Intra-operative Probe For Positive Margin Detection In Breast Conserving Surgery For Breast Cancer

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**Re-operation rates  
due to close  
margins after BCS:**

**20-40%**



# MarginProbe: real-time margin assessment in the hands of the surgeon

An intraoperative margin assessment device (Dune Medical Devices) is designed for use by breast surgeons



- RF spectroscopy
- diameter of 7mm and depth of 1 mm measurement.
- console and a sterile disposable probe

## Objectives:

- Assess device safety and effectiveness
- Assess clinical utility of the device when used in conjunction with Standard Of Care (SOC)
- Measure re-operation rates with and without device use

# Methods: general design

- Multicenter: 10 sites, 35 surgeons
- Randomized, controlled: 2 study arms with and without device use - "DEVICE+SOC" and "SOC"
- Patient enrollment: 300 enrolled (Nov. 2006-Nov. 2007)
- Inclusion/exclusion criteria:
  - age: over 18
  - diagnosed breast carcinoma (in-situ and/or invasive)
  - scheduled for breast conserving surgery
  - no systemic neoadjuvant therapy
  - no prior surgery or implants in the breast

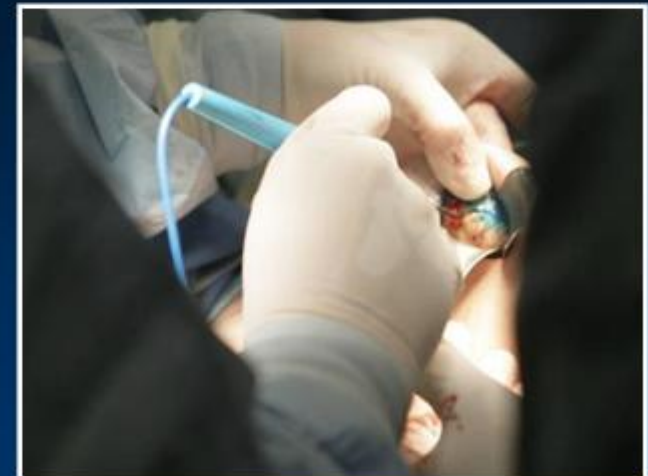
# Methods: intraoperative use

1. Excision and suture orientation

2. randomization

3. Measure all 6 margins with probe. 5-8 points per margin

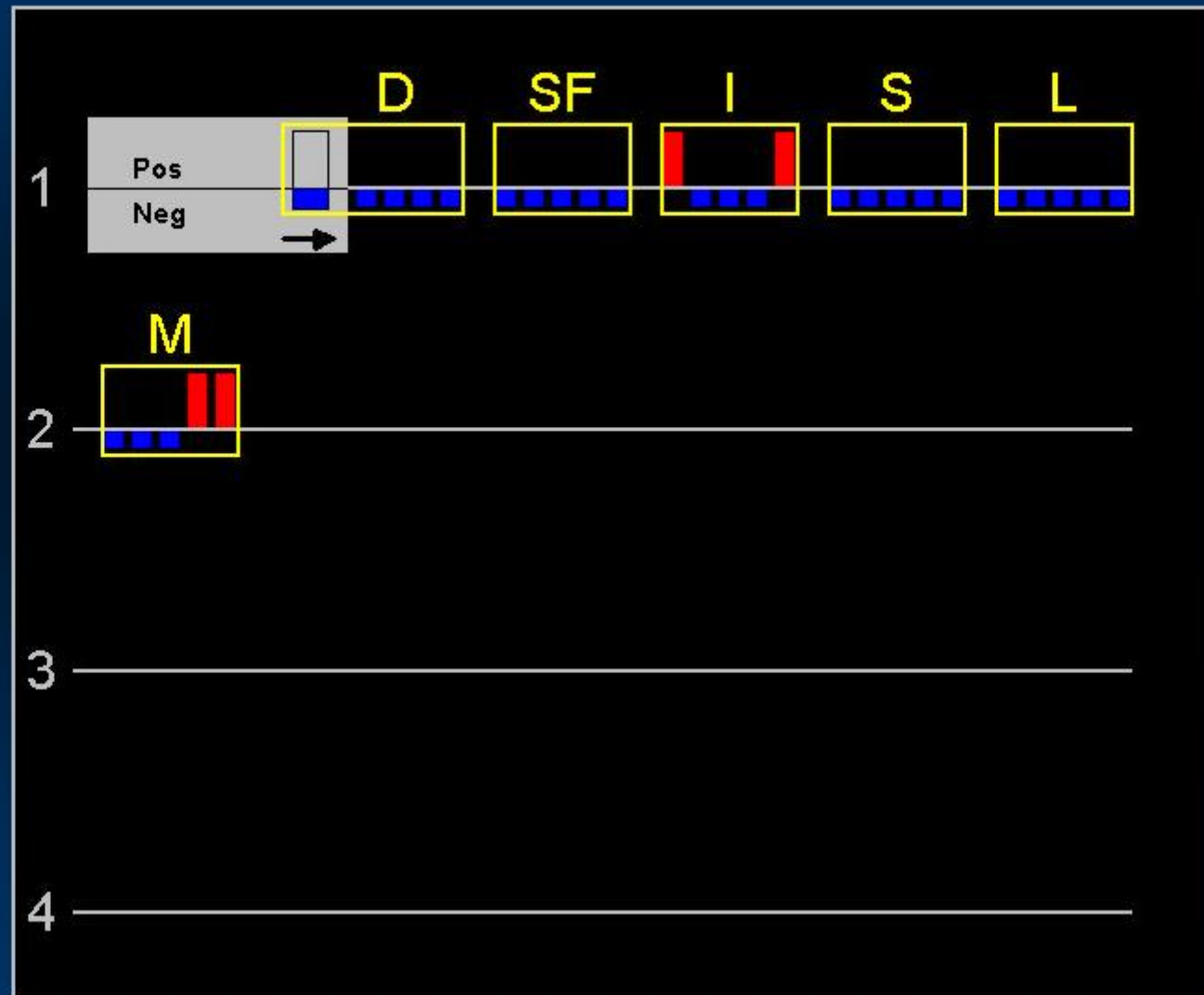
4. Re-excise all positive and suspected margins from cavity



# Methods



# Typical screen display



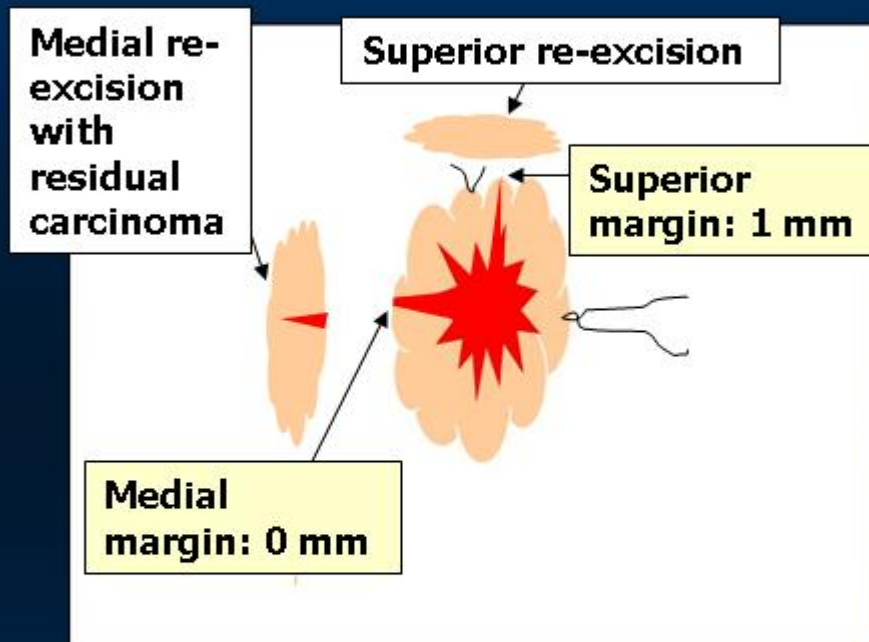
## Methods: follow up

1. Final histopathology report
2. Data on repeated surgical procedures
3. Adverse events
4. Cosmetic outcome

## Data analysis: Endpoints

- Correct Intraoperative Surgical Reaction (**ISR**):  
Intraoperative re-excision of **ALL** margins histologically detected as positive
- Re-operation rate  
(criteria were **NOT** dictated by protocol)
- Volume of tissue excised
- Adverse events
- Long term cosmetic outcome

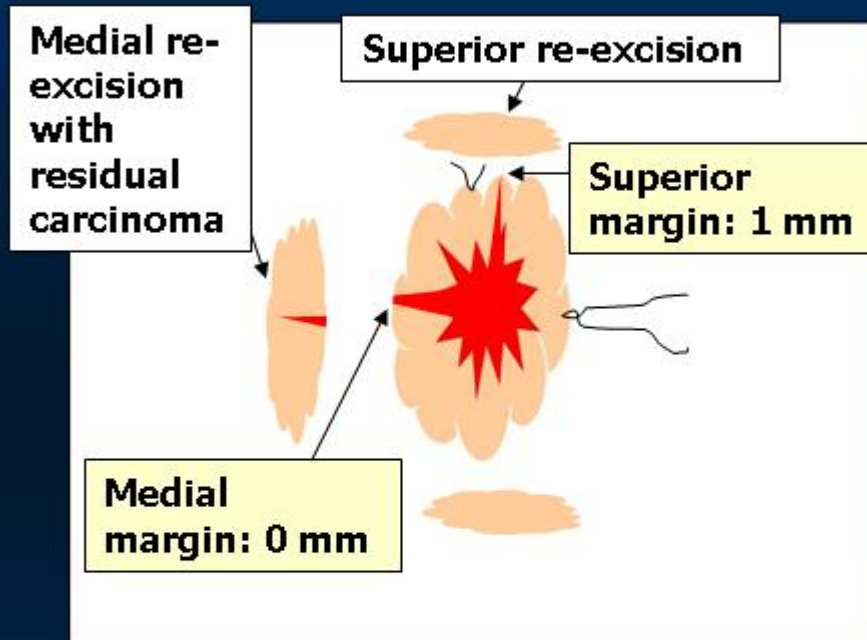
# Data analysis: ISR



**Correct**

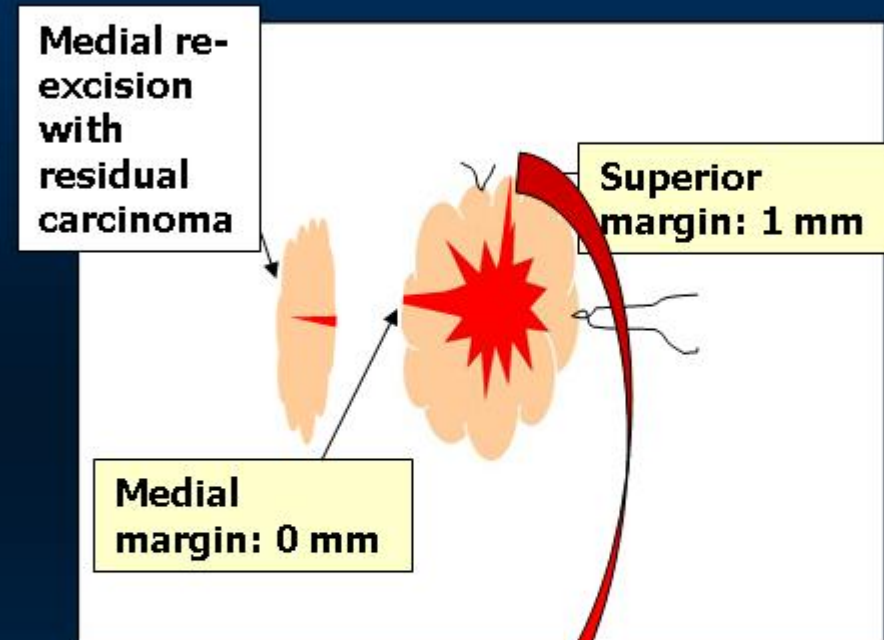
All positive margins intra-operatively re-excised

# Data analysis: ISR



Correct

All positive margins intra-operatively re-excised



Incorrect

At least one positive margin not re-excised

## Results: patient and tumor characteristics

	<b>DEVICE+SOC</b>	<b>SOC</b>
N	143	150
Age (y)	59 (32-84)	60 (28-83)
Average lesion size (mm)	18.7	17.1
Diagnosis (%)		
Invasive ductal	37	38
Ductal In-situ (DCIS)	12	8
Invasive lobular	5	6
Mixed	46	48

No statistically significant difference was observed

# Results: patient and tumor characteristics

	<b>DEVICE+SOC N=143</b>	<b>SOC N=150</b>
Tumor grade (%)		
1	18	15
2	48	44
3	34	41
ER/PR status (%)		
ER+/PR+	67	65
ER-/PR-	19	19
ER+/PR- or ER-/PR+	14	17
Her2 neu status (%)		
Positive (2+, 3+)	24	32
Negative (0, 1+)	76	68

No statistically significant difference was observed

## Results: pre-randomization specimen characteristics

	<b>DEVICE+SOC N=143</b>	<b>SOC N=150</b>
Main-specimen positivity rate (%)	41	41
Average specimen volume (cm <sup>3</sup> )	85	85

# Results: endpoints

	DEVICE+SOC N=143	SOC N=150	P
Correct ISR rate (%)	60	41	0.044
Re-operation rate (%) (excluding mastectomy)	5.6	12.7	0.0027
Total tissue volume (cm <sup>3</sup> )	107	94	0.066
Long term excellent or good cosmetic outcome (%)	71	69	1
Serious adverse events rate (%)	2.0	1.3	0.68
Mastectomy rate (%)	7.0	6.0	0.6

## Results: subgroup analysis of non-palpable lesions

	DEVICE+SOC N=82	SOC N=86	P
Correct ISR rate (%)	69	39	0.024
Re-operation rate (%) (excluding mastectomy)	6.1	12.8	0.039
Total tissue volume (cm <sup>3</sup> )	100	96	0.300
Long term excellent or good cosmetic outcome (%)	78	71	0.311
Mastectomy rate (%)	3.7	8.1	0.033

# Conclusions:

- Intra-operative use of the device for margin assessment in breast conserving surgery is safe and effective.
- When used adjunctively with Standard of Care, the device provides a significant 56% reduction in re-operation rates.
- The advantage was observed for both palpable and non-palpable lesions.

# Thank you

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