

MASTECTOMY AND IMMEDIATE BREAST RECONSTRUCTION IN INVASIVE CARCINOMA

Node-positive breast cancer
Delayed-immediate reconstruction
versus
delayed reconstruction
"DBCG RT Recon-Protocol"

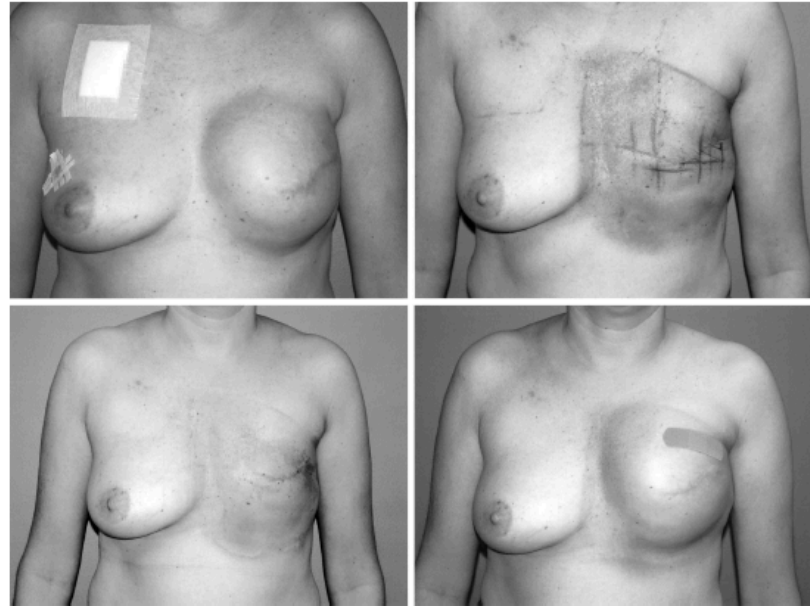
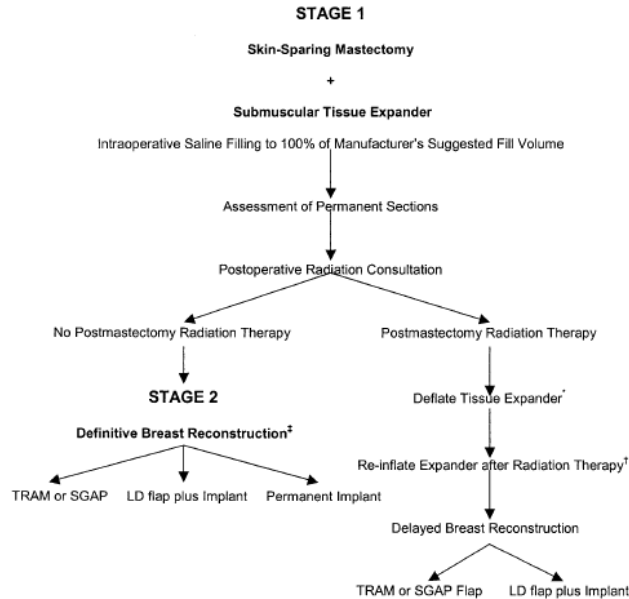
INTRODUCTION

- ✓ Multidisciplinary team
- ✓ Multidisciplinary research group
- ✓ Provide high level evidence for treatment and reconstruction to optimize the breast cancer patient's pathway
- ✓ Delayed breast reconstruction in PMRT-setting requires autologous tissue
 - ✓ Flaps
 - ✓ Fat transfer
 - ✓ Not implant-based reconstruction as stand alone



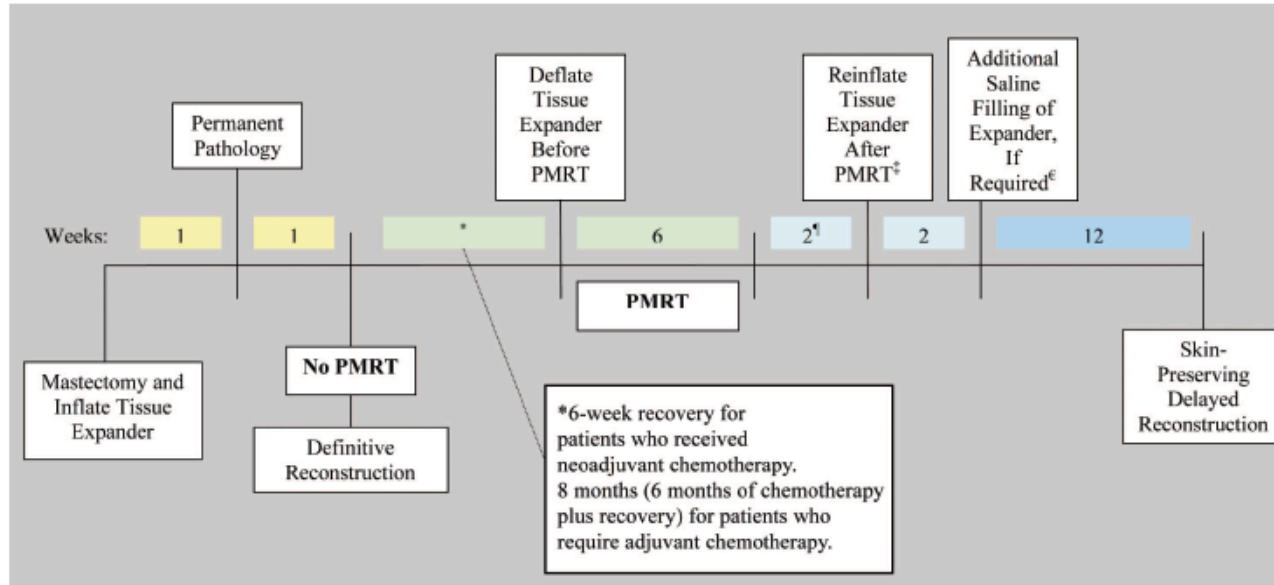
INTRODUCTION

Delayed-Immediate Breast Reconstruction



INTRODUCTION

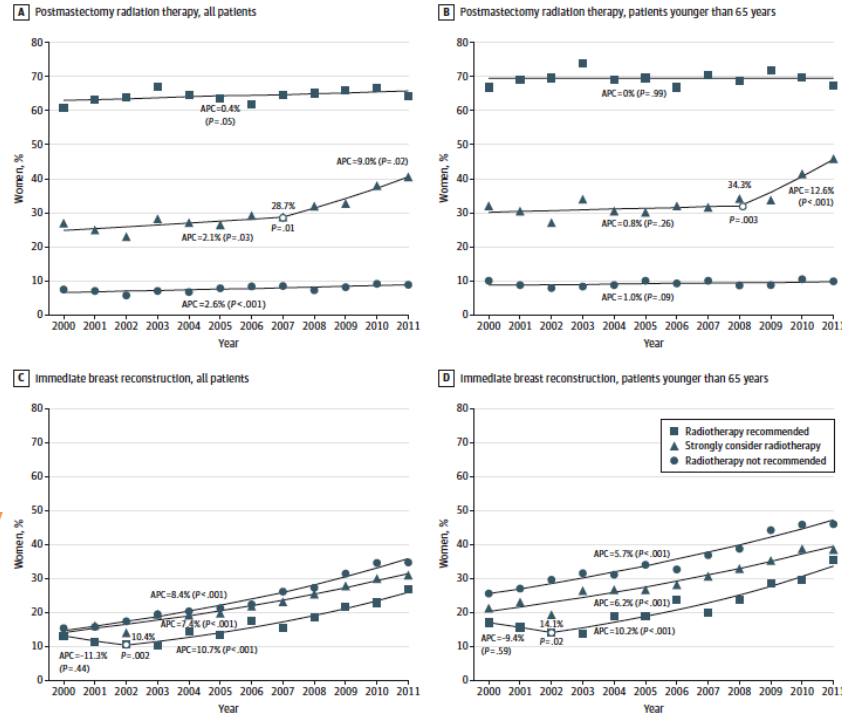
Delayed-Immediate Breast Reconstruction



No RT- skin-sparing mastectomy
RT – skin-sparing mastectomy
Similar aesthetic outcome as IBR

RT and IBR

Figure. Joinpoint Regression Analysis of Postmastectomy Radiation Therapy and Immediate Breast Reconstruction



A. Postmastectomy radiation therapy, all patients (N = 62 442).
 B. Postmastectomy radiation therapy, patients younger than 65 years (N = 30 605). C. Immediate breast reconstruction, all patients (N = 62 442).
 D. Immediate breast reconstruction, patients younger than 65 years (N = 30 605). Annual percentage change (APC) represents the change in rate on

a yearly basis. An APC of 0 would mean no change in the rate, represented by a horizontal line. Open circle indicates that a change in slope has occurred; associated P value indicates the statistical significance associated with that change in slope.

Extended use of PMRT is not followed by declining use of breast reconstruction.

May offer the patient increased cosmesis and QoL

Calls for further studies

Fraiser LL
 Temporal trends in postmastectomy radiation therapy and breast reconstruction
 JAMA Oncology 2:95. 2016

Delayed versus delayed-immediate autologous breast reconstruction

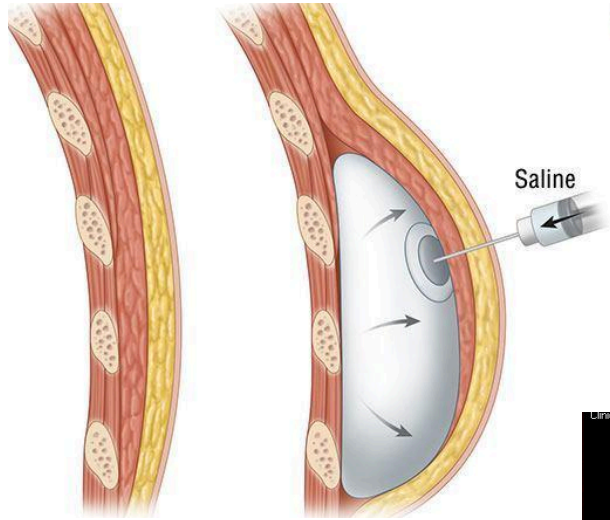
- ✓ Retrospective study n=20/20
- ✓ D-I > D
- ✓ Preservation of the skin envelope – better aesthetics
- ✓ CONCLUSION
 - ✓ “Preservation of native mastectomy-skin may allow for improved overall aesthetics”

Table 5. Associations between overall aesthetic outcomes and patient or operative factors by treatment algorithm

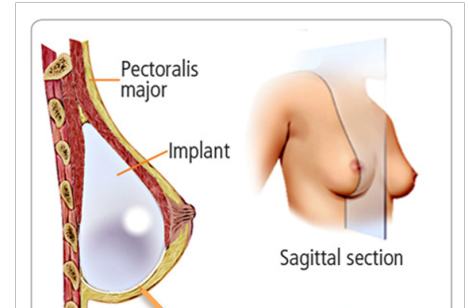
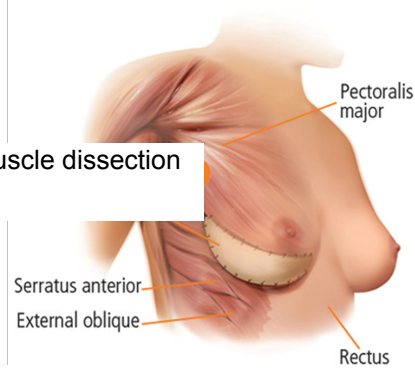
Variable	Good result (scored 4-5)	Adequate result (scored 2-3.9)	P-value
Delayed reconstruction (DR)			
Left breast reconstruction	2/8	6/8	0.63
Right breast reconstruction	4/12	8/12	0.7
DIEP	4/10	6/10	0.99
MS2	2/10	8/10	0.37
Smoking	0/6	6/6	0.52
Body mass index >30 kg/m ²	6/16	10/16	0.99
30-Day postoperative complications	0/2	2/2	0.99
Reconstruction within 90 days from radiation	0	0	NA
Delayed immediate reconstruction			
Left breast reconstruction	8/8	0/8	0.12
Right breast reconstruction	8/12	4/12	0.68
DIEP	12/14	2/14	0.13
MS2	4/6	2/6	0.99
Smoking	2/6	4/6	0.20
Body mass index >30 kg/m ²	2/6	4/6	0.20
30-Day postoperative complications	2/2	0/2	0.99
Reconstruction within 90 days from radiation	0/6	6/6	0.04

NA, not applicable; DIEP, deep inferior epigastric perforator flap; TRAM, transverse rectus abdominis myocutaneous; MS, muscle sparing.

Expander versus **temporary** silicone-gel implant

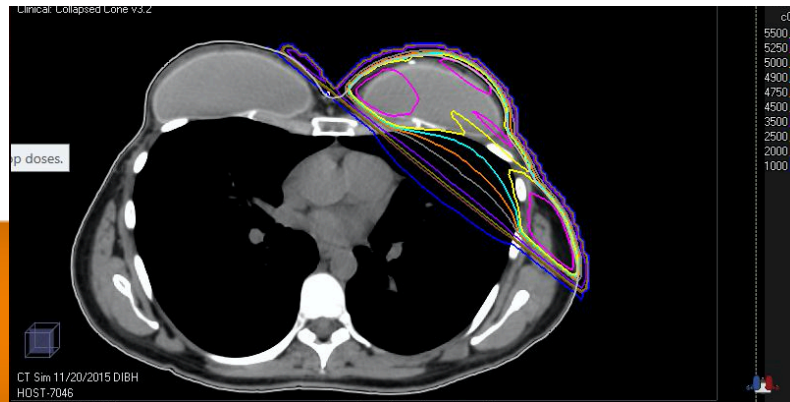


Limited muscle dissection



Sagittal section

Low-cost mesh



DBCG RT Recon-Protocol

Delayed-immediate versus delayed breast reconstruction
in
breast cancer patients under going loco-regional radiotherapy

A multicentre randomized clinical trial

DBCG RT Recon-Protocol

AIM

Compare delayed-immediate breast reconstruction with delayed reconstruction in patients with breast cancer treated with radiation therapy



STUDY POPULATION

Inclusion criteria

- ✓ Invasive breast cancer
- ✓ Indication for unilateral mastectomy and deemed fit to undergo unilateral breast reconstruction
- ✓ Post-mastectomy radiotherapy indicated according to guidelines (DBCG-guidelines must be followed in Denmark)

Exclusion criteria

- ✓ Pregnant or lactating
- ✓ Conditions indicating that the patient cannot go through breast reconstruction, the radiation therapy or follow up, or a condition where the treating specialist thinks the patient should not participate in the trial
- ✓ Not being able to participate due to language problems



TREATMENT PROTOCOL

Treatment arm A

Delayed-immediate reconstruction

- ✓ Initial surgery
 - ✓ Skin sparing/nipple sparing mastectomy and axillary surgery
 - ✓ silicone gel implant and mesh
- ✓ Final reconstruction
 - ✓ Autologous
 - ✓ Flaps
 - ✓ Fat transfer
 - ✓ Implant-based
 - ✓ +/- ADM
 - ✓ Flap + implant
 - ✓ Fat transfer

Treatment arm B

Delayed reconstruction

- ✓ Initial surgery
 - ✓ total mastectomy and axillary surgery
- ✓ Final reconstruction
 - ✓ Autologous
 - ✓ Flaps
 - ✓ Fat transfer
 - ✓ Implant-based
 - ✓ +/- ADM (?)
 - ✓ Flap + implant
 - ✓ Fat transfer

OUTCOME

✓ Primary endpoint

- ✓ Any complication deeming invasive intervention necessary
 - ✓ Infection
 - ✓ Haematoma
 - ✓ Seroma
 - ✓ Explantation of implant

OUTCOME

✓ Secondary endpoints

- ✓ Patient's satisfaction and QoL
 - ✓ BREAST-Q (reconstructive module) incl aesthetic evaluation
 - ✓ Psycho-oncological endpoints
- ✓ Timely initiation of adjuvant therapy (DBCG-database)
- ✓ Lymphoedema (DBCG-database+Skagen Trial)
- ✓ ROM shoulder
- ✓ Recurrence (DBCG-database)
- ✓ Anatomical localization of recurrence
- ✓ Death including cause of death

STATISTICAL CONSIDERATIONS

- ✓ Overall 20 % complications deeming invasive intervention
- ✓ Acceptable level - 27%
- ✓ Sample-size estimation - 350 randomized patients
- ✓ Inclusion through 5 years – until patient No. 350 has been followed for 12 months

ADDITIONAL BONUS

- ✓ European and International network
 - ✓ Oncology
 - ✓ Breast surgery
 - ✓ Plastic and reconstructive surgery
- ✓ Investigate other autologous options
- ✓ Perfusion studies
- ✓ Platform for innovative research

