

MAP Breast 2015

Breast cancer overview and problems I

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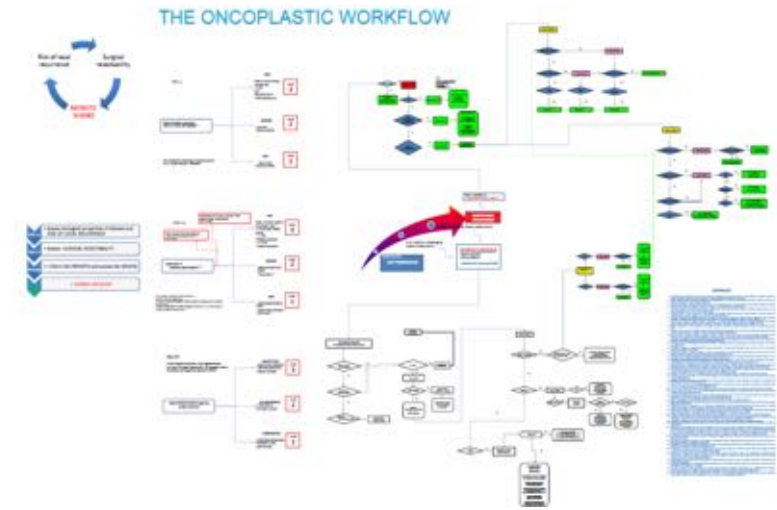
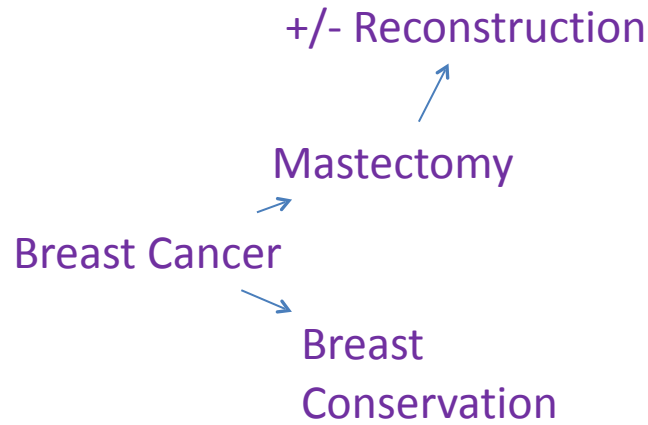
THE INCREASED COMPLEXITY OF DECISION MAKING IN BREAST CANCER SURGERY



NO CHOICE !

EASY CHOICE

COMPLEX CHOICE



Breast Cancer= Mastectomy

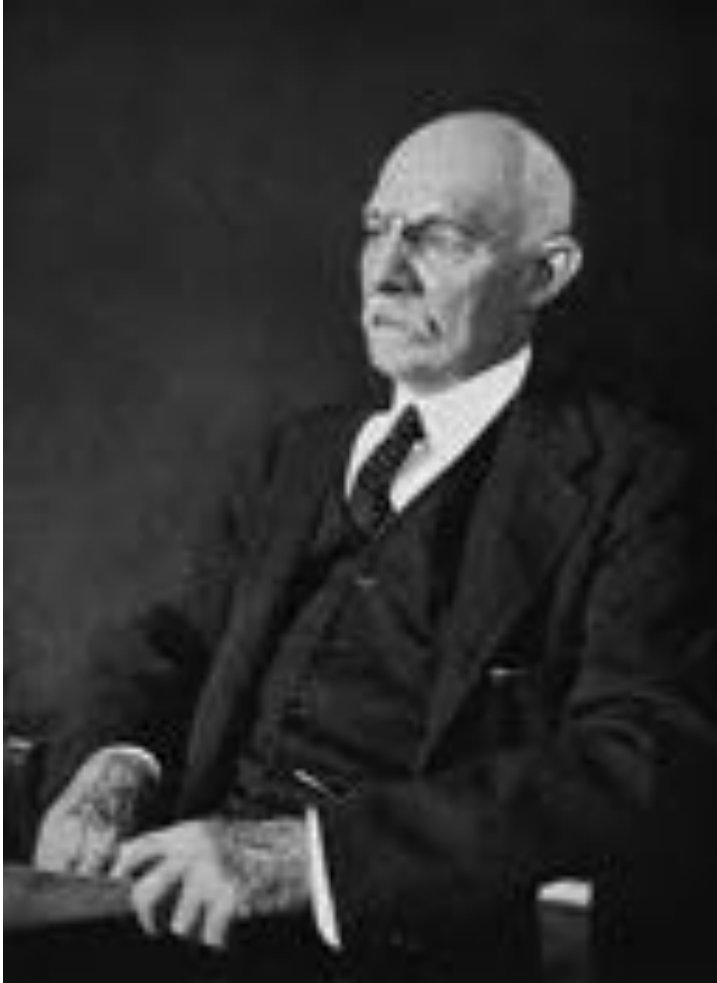


1970

1980-2000

2000-10

The historical background of the modern surgical treatment of breast cancer

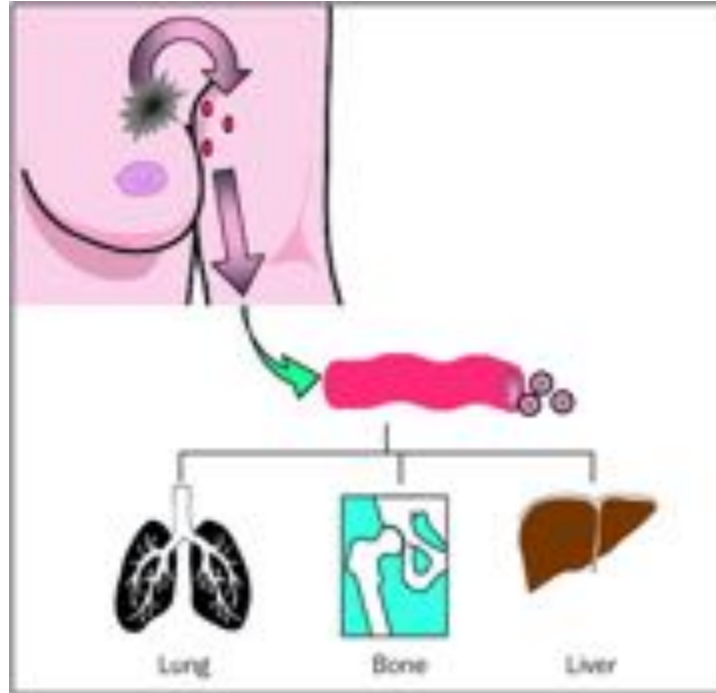


The Halstedian paradigm

Cancers usually do not spread through the bloodstream:

Adequate **local removal** of the cancer **would cure** it – if the cancer later appeared elsewhere, it was a new process.

Metastatic spread to distant organs by haematogenous dissemination is preceded by infiltration of the lymph nodes, which provide a circumferential line of defence.



The Halsted radical mastectomy resulted in a dramatic reduction in the rates of local recurrence (from 60% to 6%). However, long-term survival was unaffected the procedure caused considerable disfigurement.



From about 1895 to the mid-1970s about 90% of the women being treated for breast cancer in the U.S. underwent the Halsted radical [mastectomy](#).

The alternative paradigm



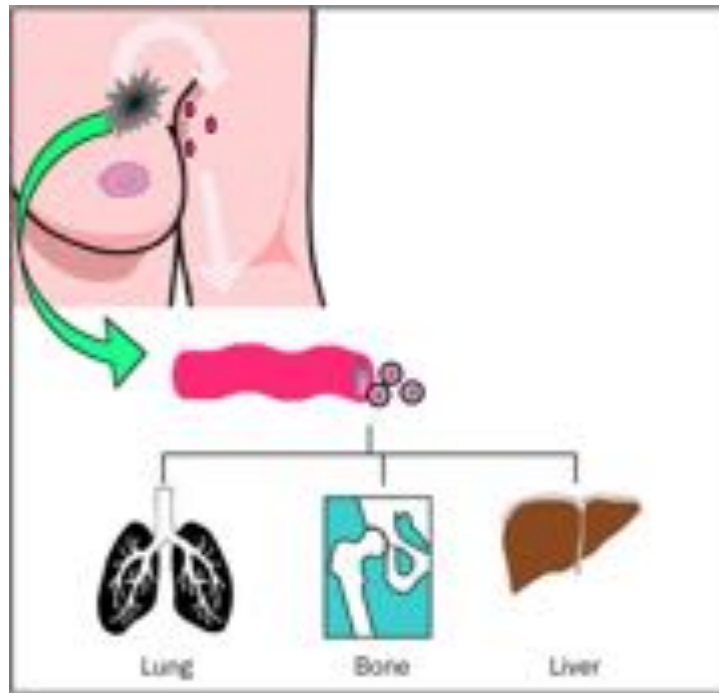
George Crile proposed that breast cancer was a systemic disease at an early stage in its natural history.

This alternative hypothesis led to early attempts at local tumour excision and clinical trials of conservative breast-cancer surgery.



Bernard Fisher undertook extensive clinical and laboratory studies over 30 years and **formulated a hypothesis of biological predeterminism** that challenged the existing Halstedian paradigm

Fisher “demonstrated that the **regional lymph nodes were not a barrier to the dissemination of tumor cells**, as postulated earlier, but were routes traversed by tumor cells to gain access to the circulating bloodstream and lymphatic system. Out of this basic work on cancer metastasis came **a new model for the management of breast cancer based on the premise that the disease is systemic from its inception.**



Thus breast cancer metastasis is not solely determined by anatomic considerations, but is also influenced by biologic activity of both the tumor and the host.

TWENTY-YEAR FOLLOW-UP OF A RANDOMIZED TRIAL COMPARING TOTAL MASTECTOMY, LUMPECTOMY, AND LUMPECTOMY PLUS IRRADIATION FOR THE TREATMENT OF INVASIVE BREAST CANCER

BERNARD FISHER, M.D., STEWART ANDERSON, PH.D., JOHN BRYANT, PH.D., RICHARD G. MARGOLESE, M.D., MELVIN DEUTSCH, M.D., EDWIN R. FISHER, M.D., JONG-HYEON JEONG, PH.D., AND NORMAN WOLMARK, M.D.

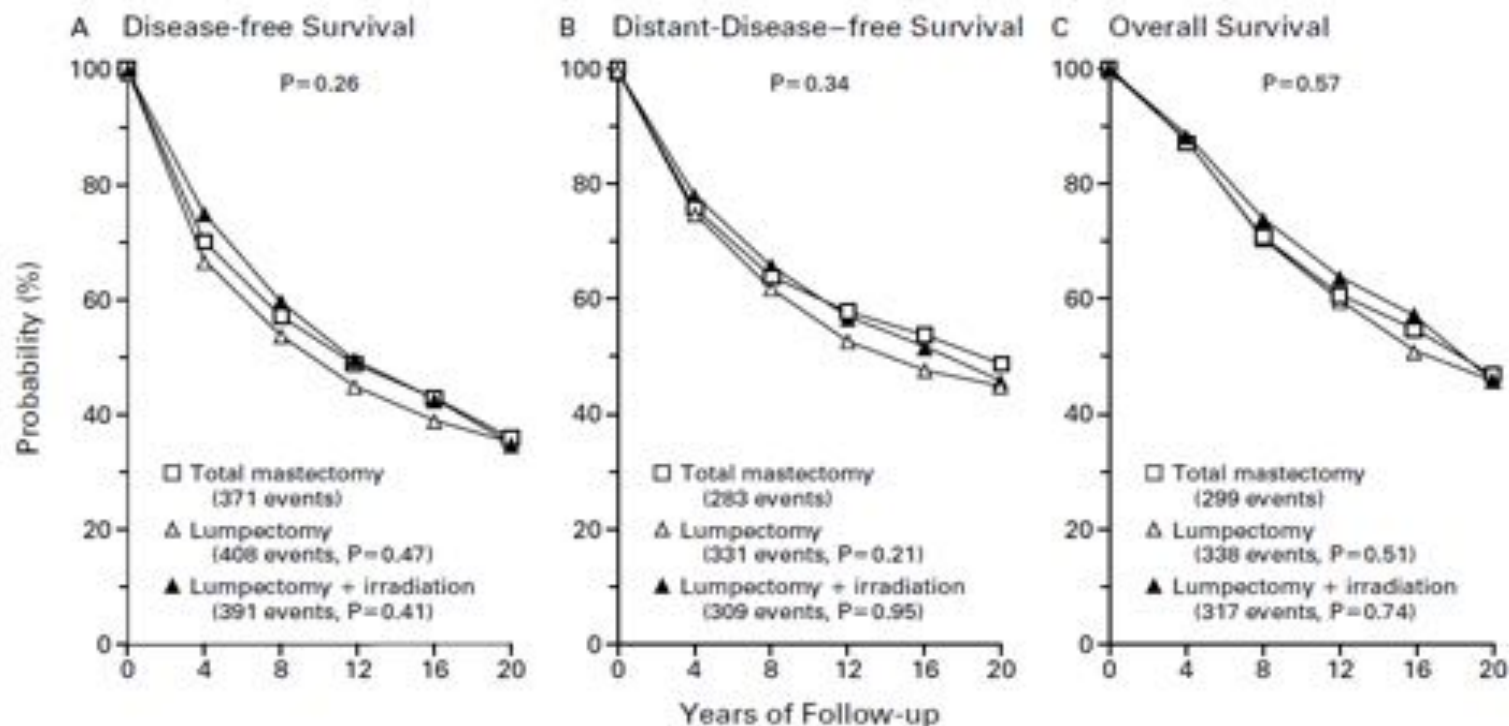
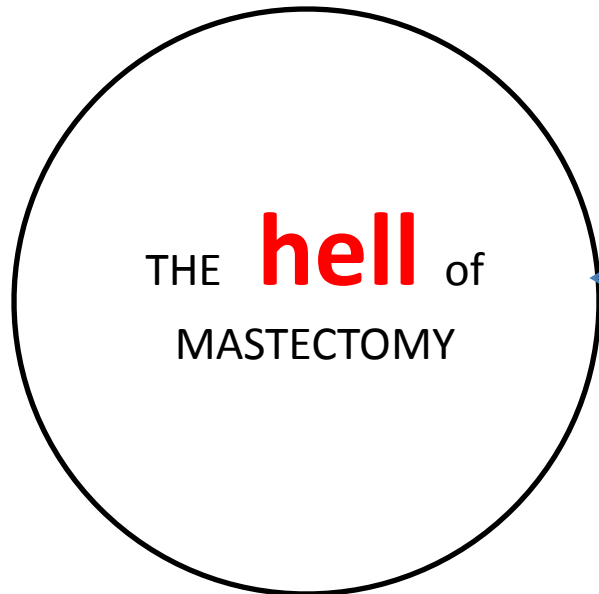


Figure 2. Disease-free Survival (Panel A), Distant-Disease-free Survival (Panel B), and Overall Survival (Panel C) among 589 Women Treated with Total Mastectomy, 634 Treated with Lumpectomy Alone, and 628 Treated with Lumpectomy plus Irradiation.

In each panel, the P value above the curves is for the three-way comparison among the treatment groups; the P values below the curves are for the two-way comparisons between lumpectomy alone or with irradiation and total mastectomy.

However Fisher still recommended free margins of excision and therefore about 20% of patients were condemned to receive a mastectomy

80's & early90's
TWO SEPARATE WORLDS



**IS BREAST CONSERVING SURGERY
AN UNFAILING PROMISE OF INTEGRITY ?**

APPARENTLY NOT ! Breast conserving surgery can be failing !

Rates of **failed breast conservation** are reported up to **30%**

These have been associated with tumor size and location by Cochrane and have been classified by Fitoussi:

New	Description
Type I	Ipsilateral minor deformity
Type II	Contralateral symmetrisation
Type III	Ipsilateral moderate deformity
Type IV	Ipsilateral major deformity
Type V	Unsalvageable

Chronicle effects of radiotherapy must be added in this classification !

Cochrane RA, Valasiadou P, Wilson AR, Al-Ghazal SK, Macmillan RD. Cosmesis and satisfaction after breast-conserving surgery correlates with the percentage of breast volume excised. *Br J Surg.* 2003;90:1505–1509.

Management of the post-breast-conserving therapy defect: extended follow-up and reclassification. Fitoussi AD, Berry MG, Couturaud B, Falcou MC, Salmon RJ. *Plast Reconstr Surg.* 2010 Mar;125(3):783-91



Fig. 1. An example of grade I deformity showing good form and volume of the treated breast but a depressed scar (*above*) managed with a Z-plasty (*below*).



Fig. 2. A grade II deformity where the treated breast is perfectly acceptable but symmetrization is required (*above*), in this case using an inverted-T mammoplasty (*below*).



Fig. 3. A grade III deformity where the breast has not retained an acceptable form (*above*); addressed by lateral mammoplasty to the treated breast and contralateral symmetrization (*below*).



Fig. 5. An example of grade IV deformity in which there is both loss of volume and anatomical distortion (above). The volume loss is revealed on excision of the scar tissue (center) and a latissimus dorsi musculocutaneous flap has been used to restore both volume and form (below).

But also devastating results that may require a mastectomy and reconstruction



The effects of failed breast conservation have been investigated

Women who reported pronounced asymmetry were significantly **less likely to be satisfied with the decision for surgery.**

(odds ratio [OR], 0.43; 95% confidence interval [95% CI], 0.21– 0.89).

Women with pronounced asymmetry were **less likely to be certain about their surgical decision** (OR, 0.36; 95% CI, 0.21–0.60)

Less likely to believe that they were prepared to make the decision for surgery (OR, 0.25; 95% CI, 0.14–0.43).

Increasing **breast asymmetry** was associated with **higher surgeon distrust scores** (2.14 vs. 2.30 vs 2.35; P 5.04)

Conservative mastectomies: closing the gaps between the two techniques



The extra-projection model: implant based reconstructive surgery bearing in mind cosmetic surgery

**Can reconstructive surgery eliminate the differences between BCS and Mastectomy?
Were are we now?**

EORTC-B23 (mean +/- SD)	IBR	BCS	p
Functional score	78.1 +/-13.4	81.2 +/- 12.6	0.083
Symptom score	13.8 +/- 12.0	14.1 +/- 11.4	0.852
Global health score	76.3 +/- 18.5	77.1 +/- 19.9	0.797
Overall FACT-B	112.7 +/- 20.1	113.3 +/- 19.4	0.801
General heath (FACT-G score)	87.6 +/- 15.3	97.8 +/- 99.2	0.346
Breast specific score	71.2 +/- 13.2	70.8 +/- 13.5	0.814

Most of the **scores do not vary significantly** in a study comparing Mastectomy and reconstruction with pedicled LD flaps+ implants or other autologous flaps

Quality of life after immediate **breast** reconstruction and **skin-sparing mastectomy** - a comparison with patients undergoing **breast conserving surgery**.

Heneghan HM, Prichard RS, Lyons R, Regan PJ, Kelly JL, Malone C, McLaughlin R, Sweeney KJ, Kerin MJ.
Eur J Surg Oncol. 2011 Nov;37(11):937-43. Epub 2011 Sep 6.

Can reconstructive surgery eliminate the differences between BCS and Mastectomy? Were are we now?

TABLE 3. Linear Regression Model of Satisfaction With Breast Cosmetic Outcomes* (N = 1245†)

Characteristic	Estimated Coefficient	SE	95% CI	P
Intercept	3.41	0.13	3.15 to 3.67	<0.001
Surgical treatment				0.0002
Mastectomy without reconstruction	-0.38	0.093	-0.56 to -0.20	
Mastectomy with autologous reconstruction	0.21	0.16	-0.093 to 0.52	
Mastectomy with implant reconstruction	-0.12	0.13	-0.38 to 0.14	
Breast conservation	0	0	0 to 0	
Chemotherapy	-0.16	0.071	-0.30 to -0.017	0.028
BMI‡	-0.027	0.006	-0.038 to -0.016	<0.0001
Smoking	-0.26	0.11	-0.46 to -0.048	0.016
Age§	0.003	0.003	-0.004 to 0.010	0.42
Education				0.23
High school or less	-0.14	0.093	-0.33 to 0.038	
Some college	-0.11	0.082	-0.28 to 0.049	
College or more	0	0	0 to 0	
Race				0.093
White (non-Latina)	0	0	0 to 0	
Black	0.20	0.084	0.039 to 0.37	
Latina (English-speaking)	0.015	0.097	-0.18 to 0.21	
Latina (Spanish-speaking)	0.010	0.12	-0.22 to 0.24	
Family income at diagnosis				0.011
<\$20,000	0	0	0 to 0	
\$20,000-\$70,000	0.20	0.11	-0.023 to 0.43	
>\$70,000	0.054	0.13	-0.19 to 0.30	
Unknown	0.34	0.13	0.092 to 0.60	

Table 3 presents a multivariable linear regression model of the scaled measure of Satisfaction With Breast Cosmetic Outcomes in the 1245 patients with complete variable information. **Satisfaction was not significantly different between the group receiving breast conservation and the group receiving mastectomy with reconstruction with either implant technique or autologous technique.**

The advent of oncoplastic surgery and its impact on cosmetic outcome



Mastectomy and reconstruction nowadays



Nipple sparing mastectomy in large and ptotic breast
With Skin Reducing mastectomy

The advent of oncoplastic surgery and its impact on cosmetic outcome early 90'



Oncoplastic surgery: It represents the **integration of plastic surgery techniques into breast cancer surgery** .

In order to preserve aesthetical outcomes and quality of life of the patients without compromising local control of disease



Oncoplastic Techniques Allow Extensive Resections for Breast-Conserving Therapy of Breast Carcinomas

Krishna B. Clough, MD,* Jacqueline S. Lewis, FRCS,* Benoît Couturaud, MD,* Alfred Floussi, MD,* Claude Nos, MD,* and Marie-Christine Falouf

From the Departments of *General and Breast Surgery and †Biostatistics, Institut Curie, Paris, France

The advent of oncoplastic surgery and its impact on cosmetic outcome



The central quadrantectomy



Therapeutic Wide local excision and breast reshape



Breast conserving surgery post-neoadjuvant chemo

The use of systemic treatment to allow breast conserving surgery

A woman whose tumor can be removed by mastectomy may instead receive neoadjuvant therapy to shrink the tumor enough to allow breast-conserving surgery

Fisher B, Bryant J, Wolmark N, et al. Effect of preoperative chemotherapy on the outcome of women with operable breast cancer. *Journal of Clinical Oncology* 1998; 16(8):2672–2685.

van der Hage JA, van de Velde CJ, Julien JP, et al. Preoperative chemotherapy in primary operable breast cancer: results from the European Organization for Research and Treatment of Cancer Trial 10902. *Journal of Clinical Oncology* 2001; 19(22):4224–4237.

Mauri D, Pavlidis N, Ioannidis JP. Neoadjuvant versus adjuvant systemic treatment in breast cancer: a meta-analysis. *Journal of the National Cancer Institute* 2005; 97(3):188–194.

The use of post-mastectomy radiotherapy and its integration with reconstructions

Postmastectomy

Postoperative chest wall and regional lymph node adjuvant radiation therapy has traditionally been given to **selected patients considered at high risk for local-regional failure after mastectomy.** [[49-51](#)]

Four or more positive axillary nodes.

- Grossly evident extracapsular nodal extension.
- Large primary tumors.
- Very close or positive deep margins of resection of the primary tumor.

Ragaz J, Jackson SM, Le N, et al.: Adjuvant radiotherapy and chemotherapy in node-positive premenopausal women with breast cancer. N Engl J Med 337 (14): 956-62, 1997. [[PUBMED Abstract](#)]

Overgaard M, Hansen PS, Overgaard J, et al.: Postoperative radiotherapy in high-risk premenopausal women with breast cancer who receive adjuvant chemotherapy. Danish Breast Cancer Cooperative Group 82b Trial. N Engl J Med 337 (14): 949-55, 1997. [[PUBMED Abstract](#)]

Sharing decisions improves patients' satisfaction

Patients were subdivided in three groups: **paternalistic; informed consumeristic; shared.**

There were **differences in overall general satisfaction** ($P = 0.034$), in the comparison between the informed group to the paternalistic group (66.7% versus 38.9%, $P = 0.020$) and the shared to the paternalistic group (69.3% versus 38.9%, $P = 0.016$). There were no differences in aesthetic satisfaction. There **were differences found in the SF-12 physical component summary score** across all groups ($P = 0.033$), and a difference was found between the informed and paternalistic groups ($P < 0.05$).

The authors concluded that **who adopted a more active role had better results in terms of general satisfaction and physical summary scores.**

THE MODERN SCENARIO

- **Breast Conserving surgery can be failing**
- **Modern Therapeutic mammoplasties may optimize the outcome of breast conserving surgery**
- **Breast reconstruction provides comparable outcome to breast conserving surgery**
- **Integration of other systemic treatment/ local regional treatments may affect the surgical decision**

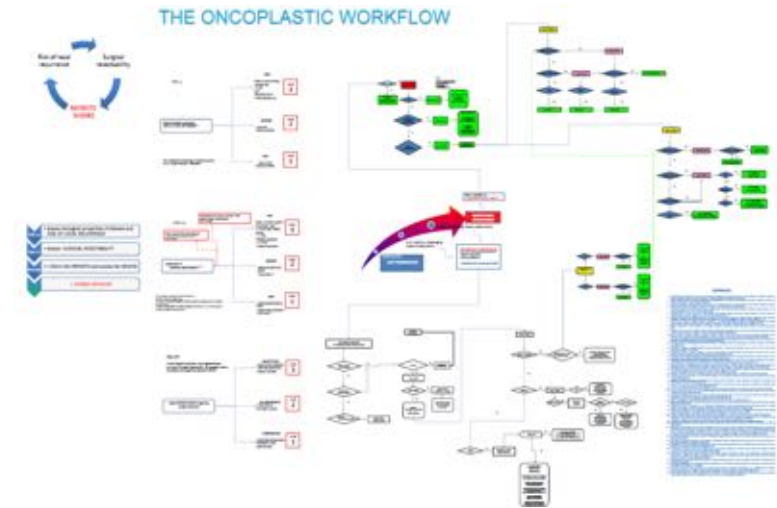
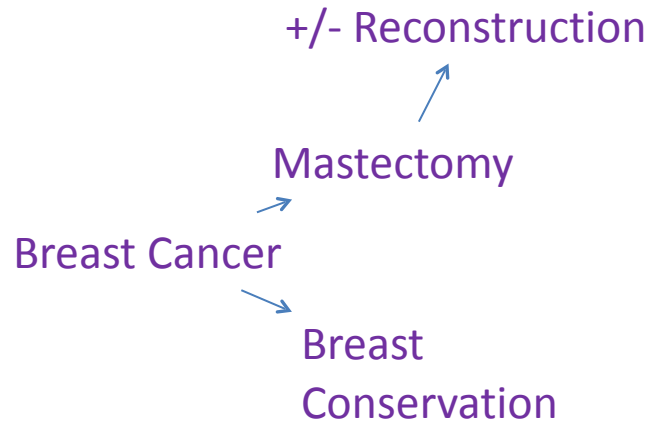
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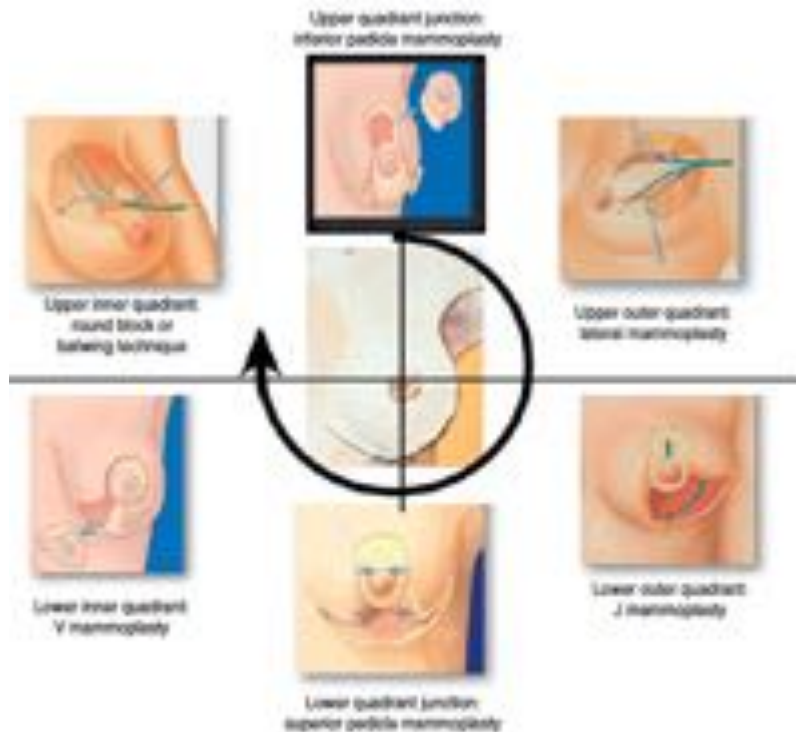
2000-10

FLOW CHARTS –ALGHORITHMS- NOMOGRAMS

Oncoplastic surgery for breast cancer based on tumour location and a quadrant-per-quadrant atlas

K. B. Clough¹, T. Ihrai¹⁻², S. Oden¹, G. Kaufman¹, E. Massey¹ and C. Nos¹

¹The Paris Breast Centre – L'Institut du Sein, Paris, and ²Breast Cancer Unit, Centre Antoine Lacassagne, Nice, France
Correspondence to: Dr K. B. Clough, The Paris Breast Centre – L'Institut du Sein, 7 Avenue Bugeaud, 75116 Paris, France
(e-mail: krishna.clough@orange.fr)



LOCATION

SURGICAL TECHNIQUE

**No consideration of tumor size, shape
ptosis, integration of pre-post op
Adjuvant treatment**

Assessment of Immediate Conservative Breast Surgery Reconstruction: A Classification System of Defects Revisited and an Algorithm for Selecting the Appropriate Technique

Alexandre Mendonça
Munhoz, M.D.
Eduardo Montag, M.D.
Eduardo Arruda, M.D.
Leandro Pellarin, M.D.
José Roberto Filassi, M.D.
José Roberto Piato, M.D.
Alfredo Carlos de Barros,
M.D., Ph.D.
Luis Carlos Prado, M.D.
Alexandre Fonseca, M.D.
Edmund Baracat, M.D., Ph.D.
Marcus Castro Ferreira, M.D.,
Ph.D.

São Paulo, Brazil

Background: Although various techniques have been used for breast conservation surgery reconstruction, there are few studies describing a logical approach to reconstruction of these defects. The objectives of this study were to establish a classification system for partial breast defects and to develop a reconstructive algorithm.

Methods: The authors reviewed a 7-year experience with 209 immediate breast conservation surgery reconstructions. Mean follow-up was 31 months. Type I defects include tissue resection in smaller breasts (bra size A/B), including type IA, which involves minimal defects that do not cause distortion; type IB, which involves moderate defects that cause moderate distortion; and type IC, which involves large defects that cause significant deformities. Type II includes tissue resection in medium-sized breasts with or without ptosis (bra size C), and type III includes tissue resection in large breasts with ptosis (bra size D).

Results: Eighteen percent of patients presented type I, where a lateral thoracodorsal flap and a latissimus dorsi flap were performed in 68 percent. Forty-five percent presented type II defects, where bilateral mastopexy was performed in

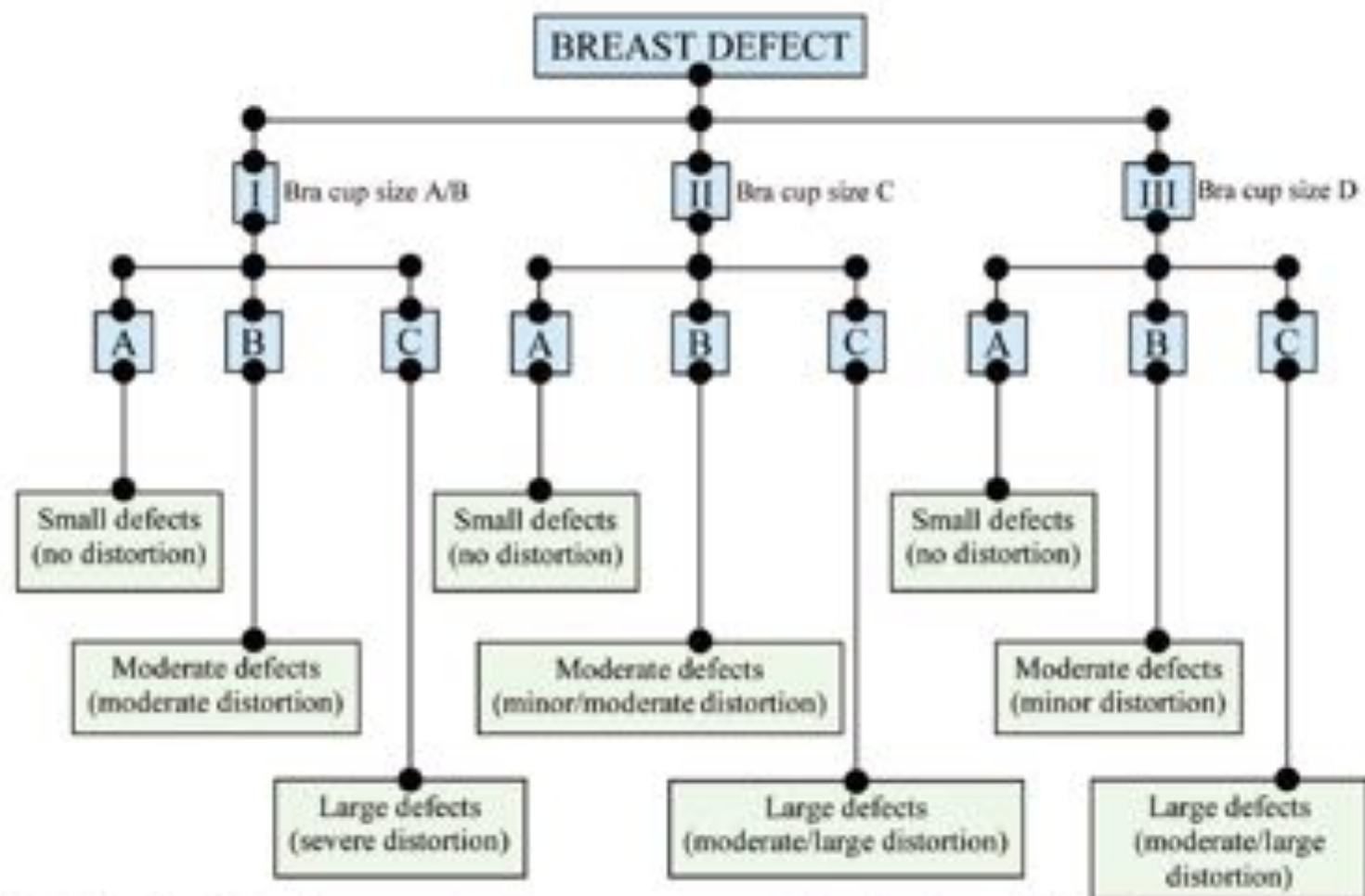


Fig. 1. Algorithm for immediate conservative breast surgery reconstruction based on the type of breast and extent of defect.

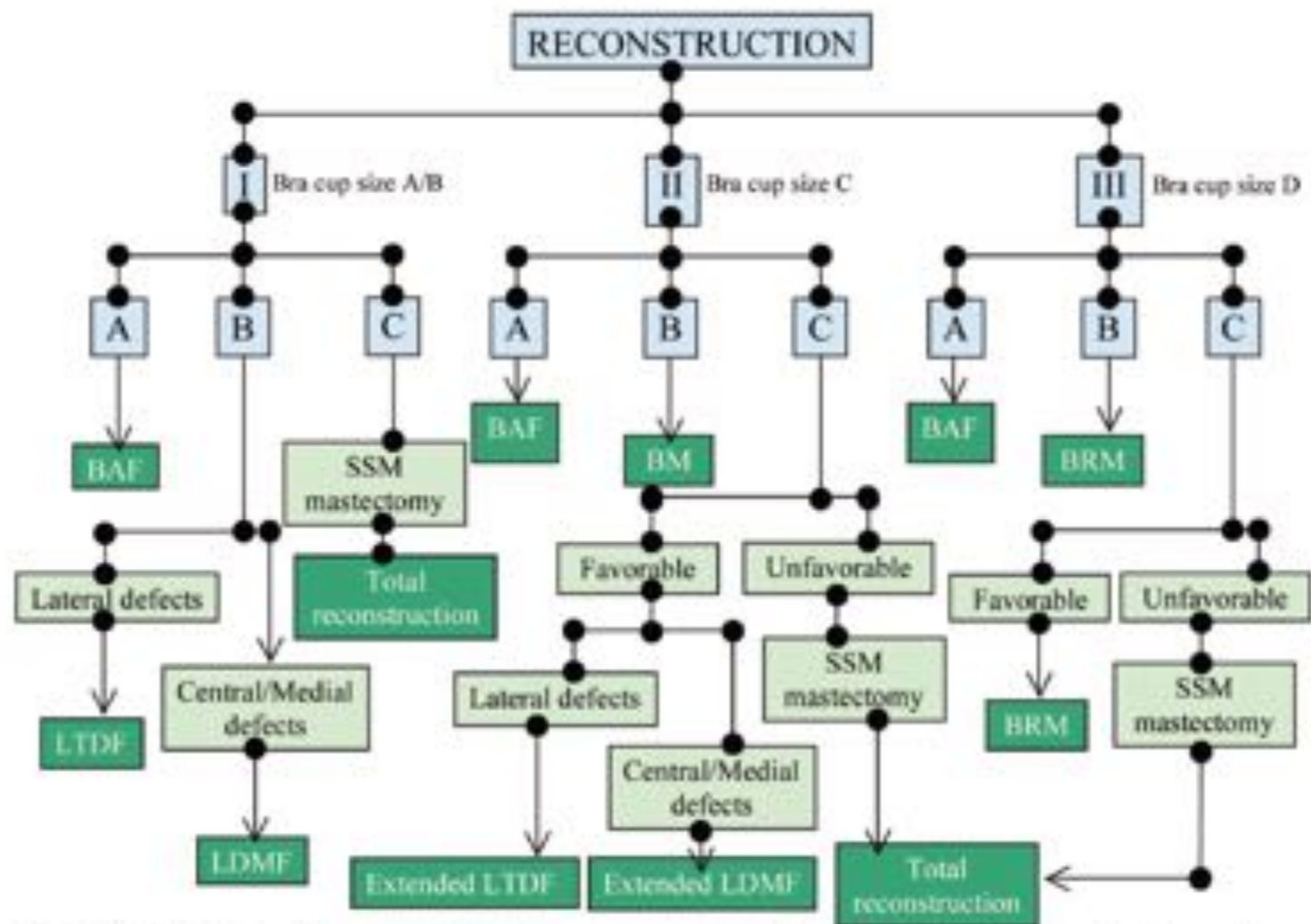


Fig. 2. Algorithm for immediate conservative breast surgery reconstruction based on the breast type, tumor location, and reconstructive options. BAF, breast tissue advancement flap; SSM, skin-sparing mastectomy; BM, bilateral mastectomy; BRM, bilateral reduction mammoplasty; LTDF, lateral thoracodorsal flap; LDMF, latissimus dorsi myocutaneous flap.

Practical Guidelines for Repair of Partial Mastectomy Defects Using the Breast Reduction Technique in Patients Undergoing Breast Conservation Therapy

Steven J. Kronowitz, M.D.

Kelly K. Hunt, M.D.

Henry M. Kaerer, M.D.

Eric A. Strom, M.D.

Thomas A. Buchholz, M.D.

Joe E. Ensor, Ph.D.

Cindy A. Koutz, M.S.,

P.A.-C.

Geoffrey L. Robb, M.D.

Houston, Texas

Background: The authors previously compared the local tissue rearrangement, breast reduction, and latissimus dorsi flap reconstruction techniques for repairing partial mastectomy defects and showed the benefits of breast reduction.

Methods: In this study, the authors focused solely on factors influencing outcome in 41 patients who underwent repair of a partial mastectomy defect using breast reduction.

Results: Tumor location had a significant effect on the design of the parenchymal pedicle ($p = 0.05$). Most repairs were performed with an inferior pedicle. Fifty percent of the lower outer and central quadrant tumors required an amputative design with a free nipple graft. The complication rates for immediate and delayed repair were 24 and 50 percent, respectively. The superior pedicle was associated with the highest complication rates. Tumors in the upper outer

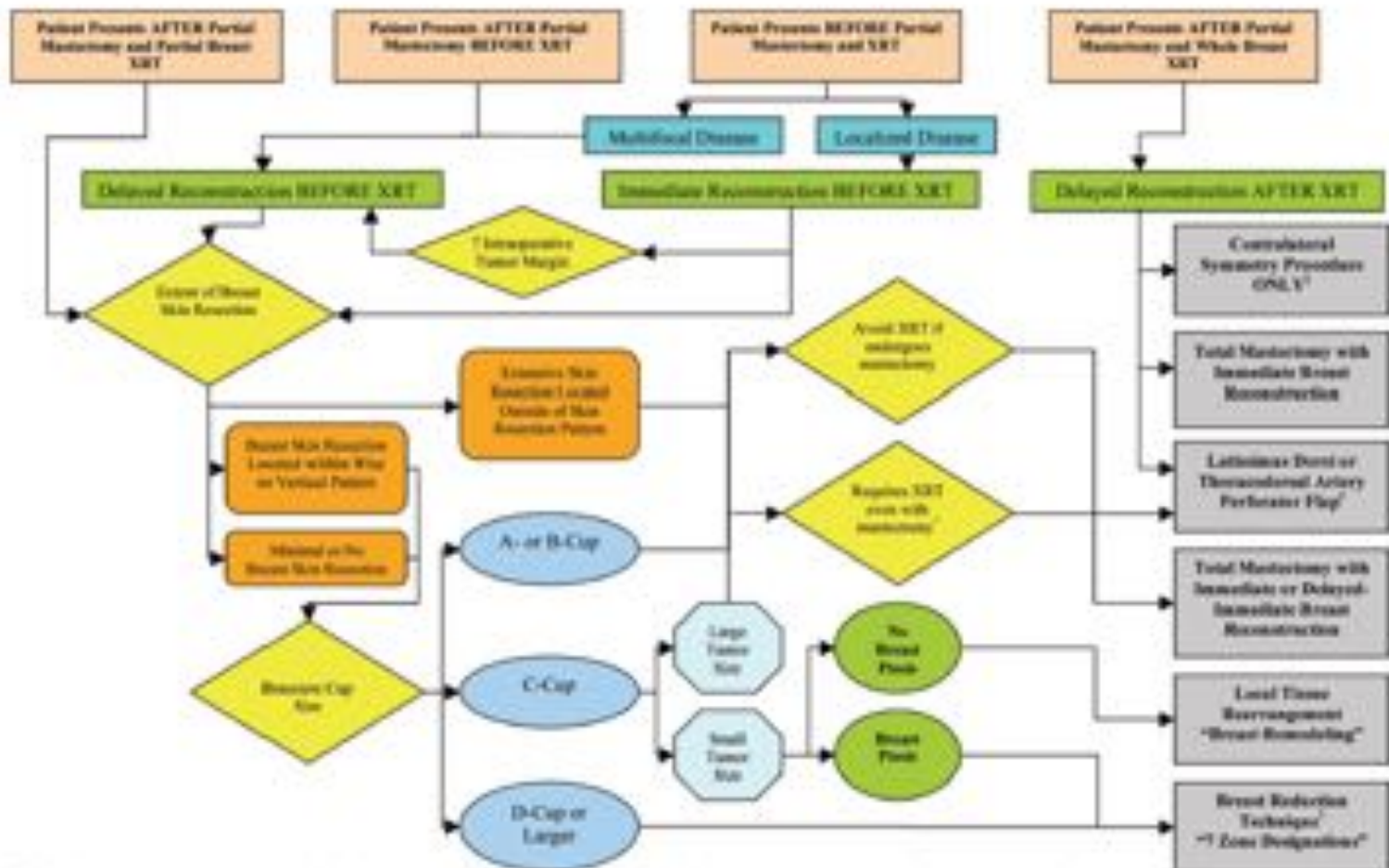


Fig. 1. Management algorithm for repair of partial mastectomy defects. *Scenario of patient who undergoes neoadjuvant chemotherapy with reduction of tumor size and becomes amenable to breast-conserving therapy instead of mastectomy. †Prior to radiation therapy, only perform the breast reduction on the ipsilateral involved breast, and then 6 months or more later, use the same pedicle design as used to repair the ipsilateral breast to perform the breast reduction for symmetry on the contralateral breast. ‡Most applicable to patients with partial defects located in zone 6 or 7 of the breast. §When performing a contralateral breast reduction for symmetry procedure only, allow for adequate time for the involved breast to achieve a steady state with regard to volume before performing the procedure. XRT, radiation therapy.

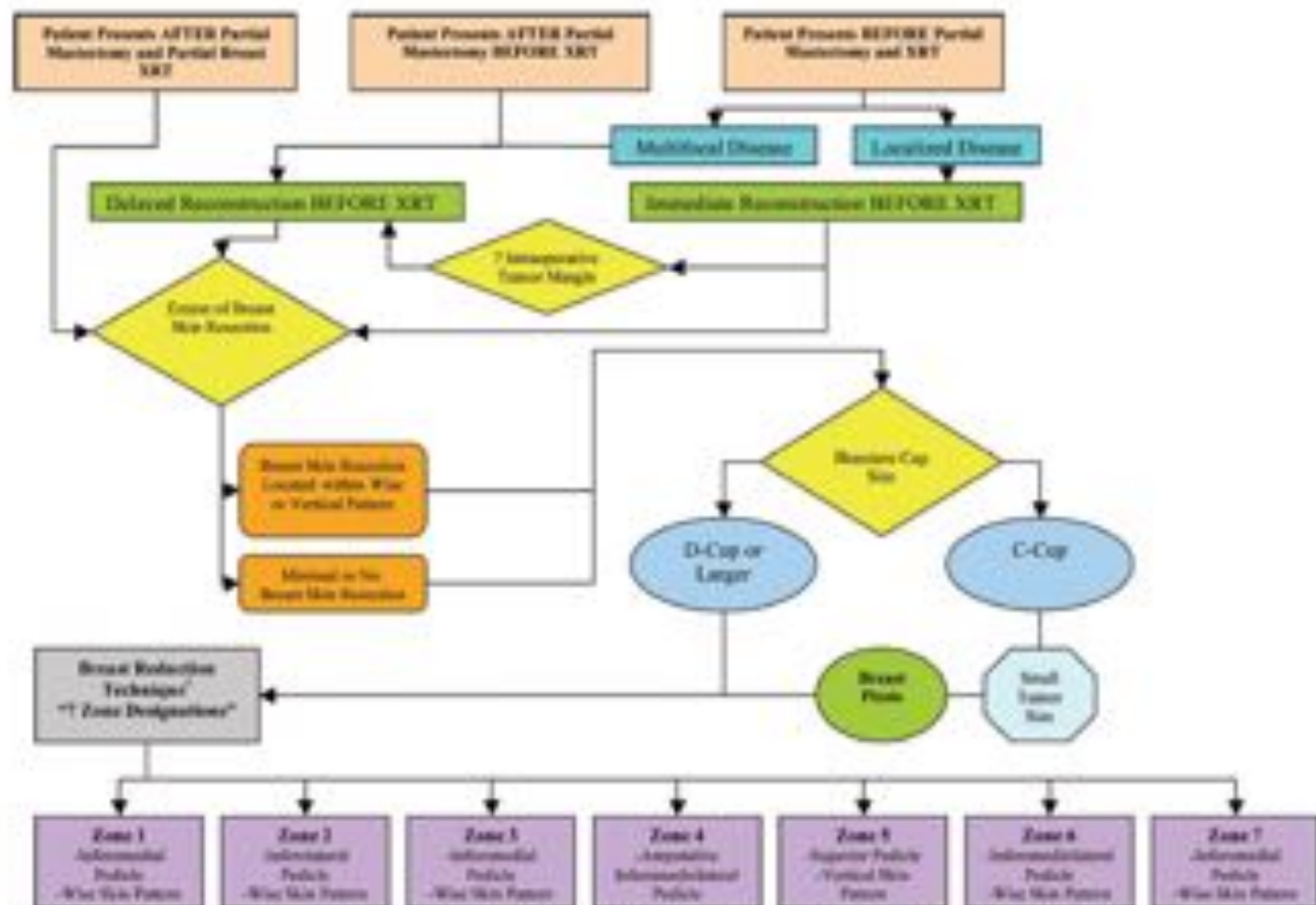
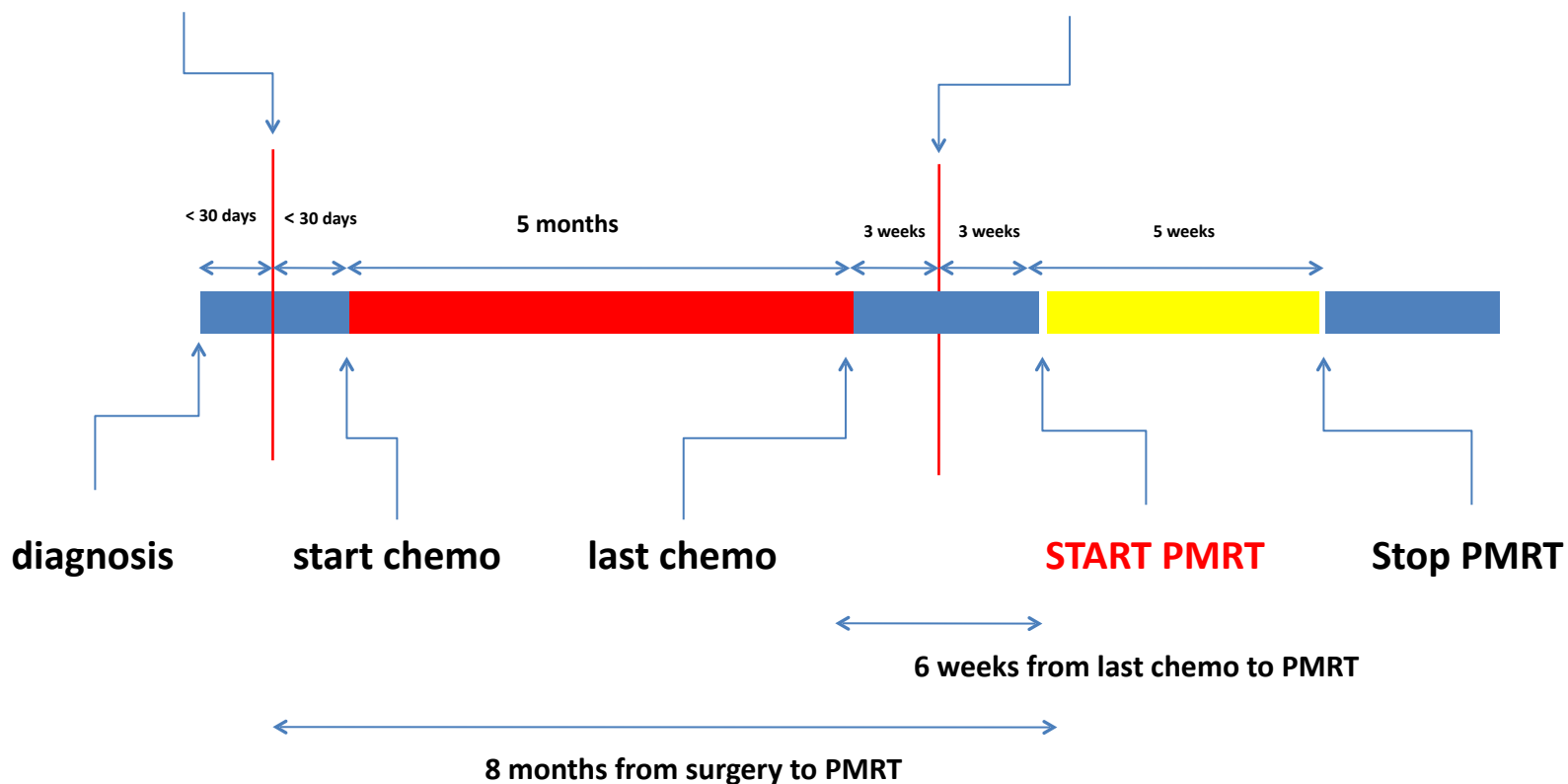


Fig. 2. Management algorithm for patients undergoing breast conservation therapy who may be candidates for oncoplastic breast reduction techniques. Many of the same considerations that are addressed in Figure 1 are also included within this algorithm, which was specifically designated for patients who are being considered for repair of a partial mastectomy defect with the breast reduction technique. However, absent are patients who present after partial mastectomy and whole breast radiation therapy because of the high rate of associated wound healing complications. Another distinguishing feature of this algorithm is that it provides specific recommendations for design of the dermoglandular pedicle, based on tumor location. If prior to radiation therapy, only perform the breast reduction on the ipsilateral involved breast, and then 6 months later, use the same pedicle design as used to repair the ipsilateral breast to perform the breast reduction for symmetry on the contralateral breast. XRT, radiation therapy.

The use of post-mastectomy radiotherapy and its integration with reconstructions

MASTECTOMY+EXPANDER

PERMANENT IMPLANT



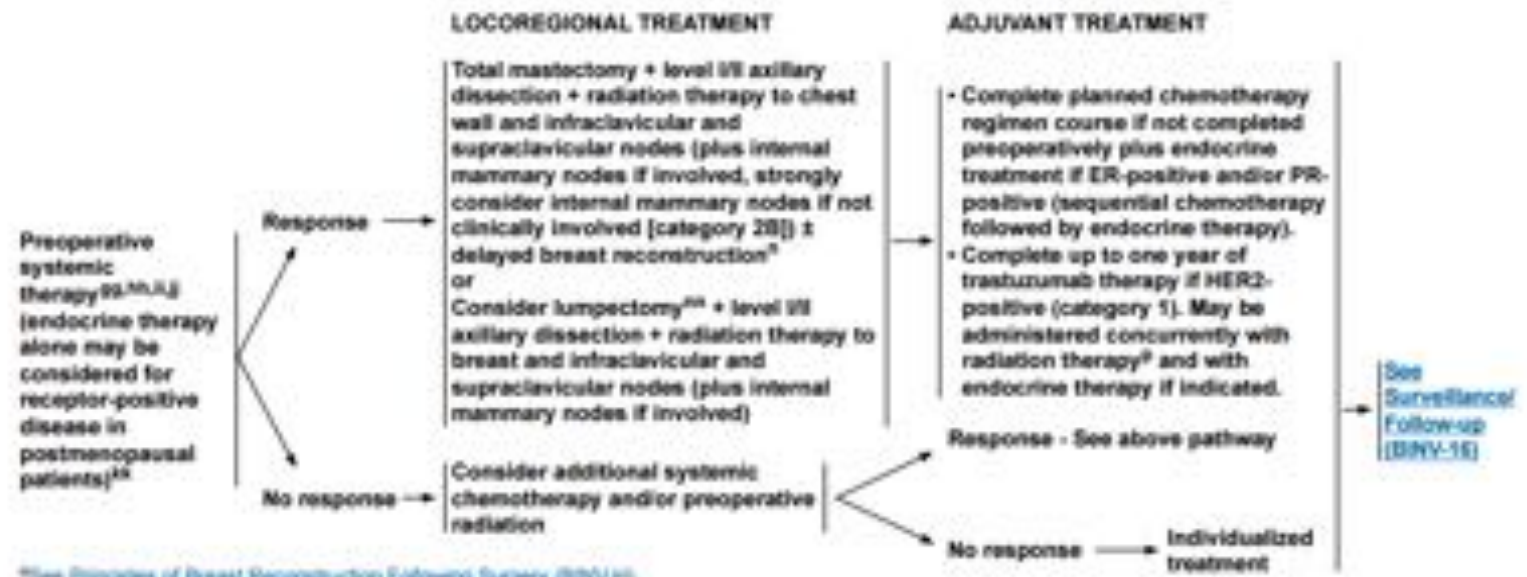


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NCCN Guidelines Version 2.2015 Invasive Breast Cancer

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PREOPERATIVE SYSTEMIC THERAPY FOR LOCALLY ADVANCED INVASIVE BREAST CANCER (NON-INFLAMMATORY)



^{1A}See Principles of Breast Reconstruction Following Surgery (B1V-1C).

²See Principles of Radiation Therapy (B1V-1D).

^{3A}A number of chemotherapy regimens have activity in the preoperative setting. In general, those chemotherapy regimens recommended in the adjuvant setting may be considered in the preoperative setting. See Neoadjuvant/Adjuvant Chemotherapy (B1V-1G). If treated with endocrine therapy, an aromatase inhibitor is preferred for postmenopausal women.

⁴Patients with HER2-positive tumors should be treated with preoperative systemic incorporating trastuzumab for at least 9 weeks of preoperative therapy.

See Neoadjuvant/Adjuvant Chemotherapy (B1V-1G).

⁵A pertuzumab-containing regimen may be administered preoperatively to patients with greater than or equal to T2 or greater than or equal to N1, HER2-positive breast cancer.

Administration of all chemotherapy prior to surgery is preferred.

⁶See Definition of Monoclonal (B1V-1L).



Breast Cancer Nomogram: Breast Additional Non SLN Metastases

This nomogram can be used to help newly diagnosed breast cancer patients assess the likelihood that their breast cancer has spread to the [sentinel lymph nodes](#).



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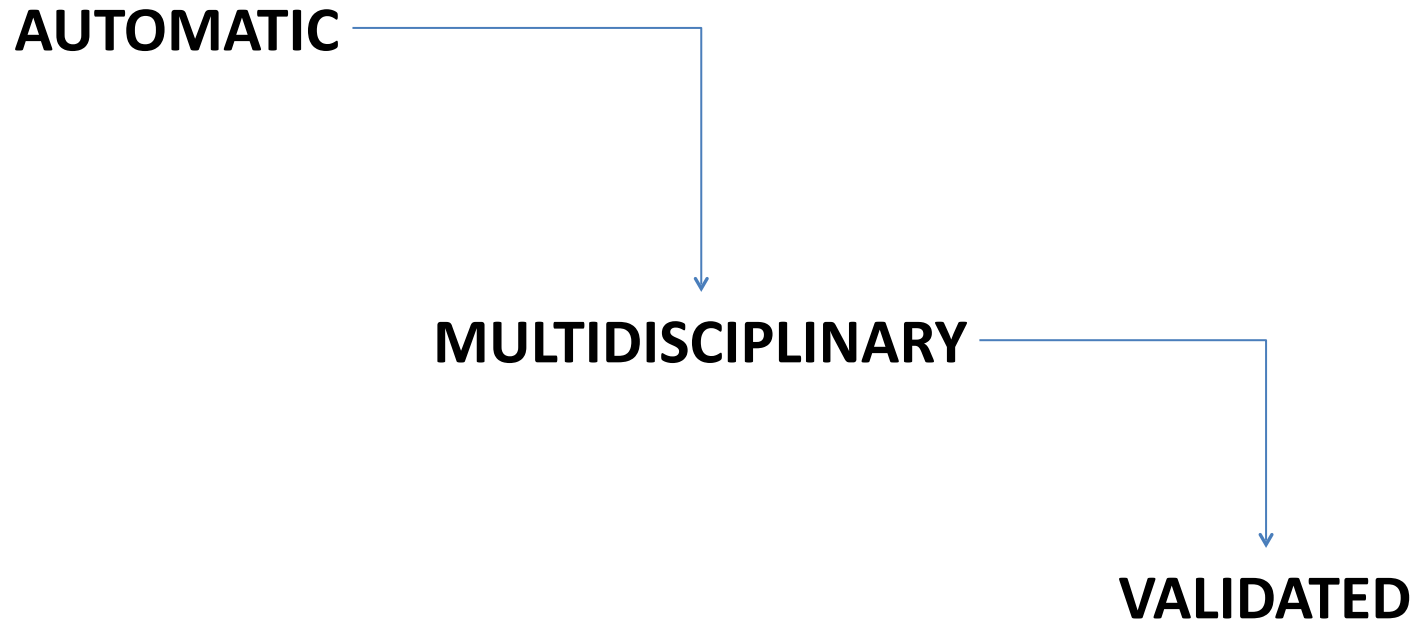
[Professional Educational Resources](#)

Breast Cancer Nomogram to Predict Additional Positive Non-SLN, without Neoadjuvant Chemotherapy

This software calculates the probability of finding additional positive non-sentinel lymph nodes in breast cancer patients found to have disease on sentinel lymph node biopsy without completion of neoadjuvant chemotherapy. This nomogram was developed at the University of Texas M. D. Anderson Cancer Center and has been externally validated.

THE ARCHITECTURE OF OUR PROJECT : The Oncoplastic Framework

How to deal with complexity in breast cancer surgery



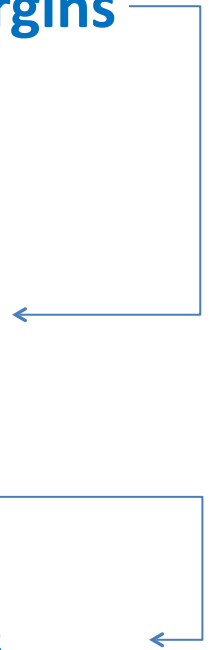
THE ARCHITECTURE OF OUR PROJECT : The Oncoplastic Framework

STEP 1: the selection of ENDPOINTS

Endpoint 1: Safe removal of breast cancer on negative margins

**Endpoint 2: design surgery to preserve cosmetic outcome
and Q.o.L**

Endpoint 3: Let the patient be at the center of the process



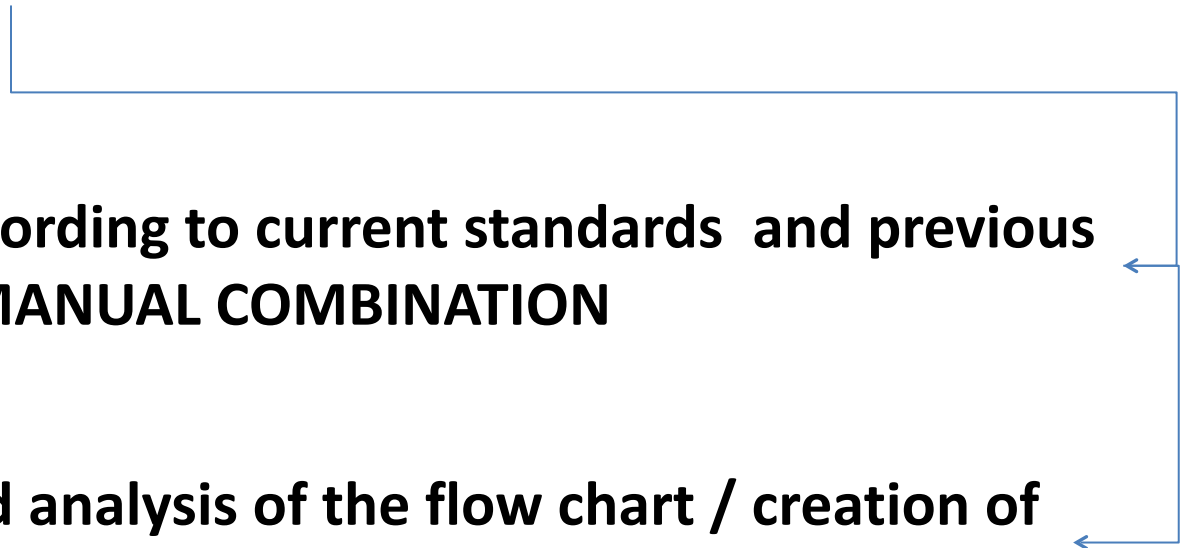
THE ARCHITECTURE OF OUR PROJECT : The Oncoplastic Framework

Step 2: How can we address these endpoints

1: Creation of a set of decisional drives

2: Combination according to current standards and previous personal studies: MANUAL COMBINATION

3. Visualization and analysis of the flow chart / creation of the DSS tool



THE ARCHITECTURE OF OUR PROJECT : The Oncoplastic Framework

The cluster of decisional drivers

T- Stage or Multi-centric disease	Location*	Volume	Ptosis	Risk of margin+°	Pt wishes
T>2cm	Central	Minimal	Nil	High	Mastectomy
T<2cm	Upper	Medium	Moderate	Intermediate	Max. reshape
Extensive DCIS	Lower	Large	Severe	Low	Min. Aggressiveness
LABC	Upper outer	Very Large			
DCIS<4cm	Upper Inner				
MULTICENTRIC	Lower outer				
	Lower inner				

THE ARCHITECTURE OF OUR PROJECT : The Oncoplastic Framework

Identification of FOUR subgroups

- **ESBC:** full set of drivers including risk of positive margins (2268 combinations)
- **Localized DCIS<4cm:** full set except risk of +margins (252 combinations)
- **Multicentric ESBC and ext. DCIS:** Exclusion of «Location» (36 combinations)
- **LABC:** Exclusion of «Location»- «Volume» - «Ptosis» (36 combinations)

THE ARCHITECTURE OF OUR PROJECT : The Oncoplastic Framework

Information gain on the four subgroups

Unifocal invasive ESBC

T	GAIN= 0.858487793387
Sede	GAIN= 0.75121949299
Volume	GAIN= 0.99903913739
Ptosis	GAIN= 0.363660816584
Risk of margin+	GAIN= 0.0331718273945
Pt wishes	GAIN= 1.18641558197

localized DCIS

T	GAIN= 0.6248549757
Sede	GAIN= 0.5593845630
Volume	GAIN= 0.7905348966
Ptosis	GAIN= 0.219430856
Pt wishes	GAIN=1.09847556

Caso LABC

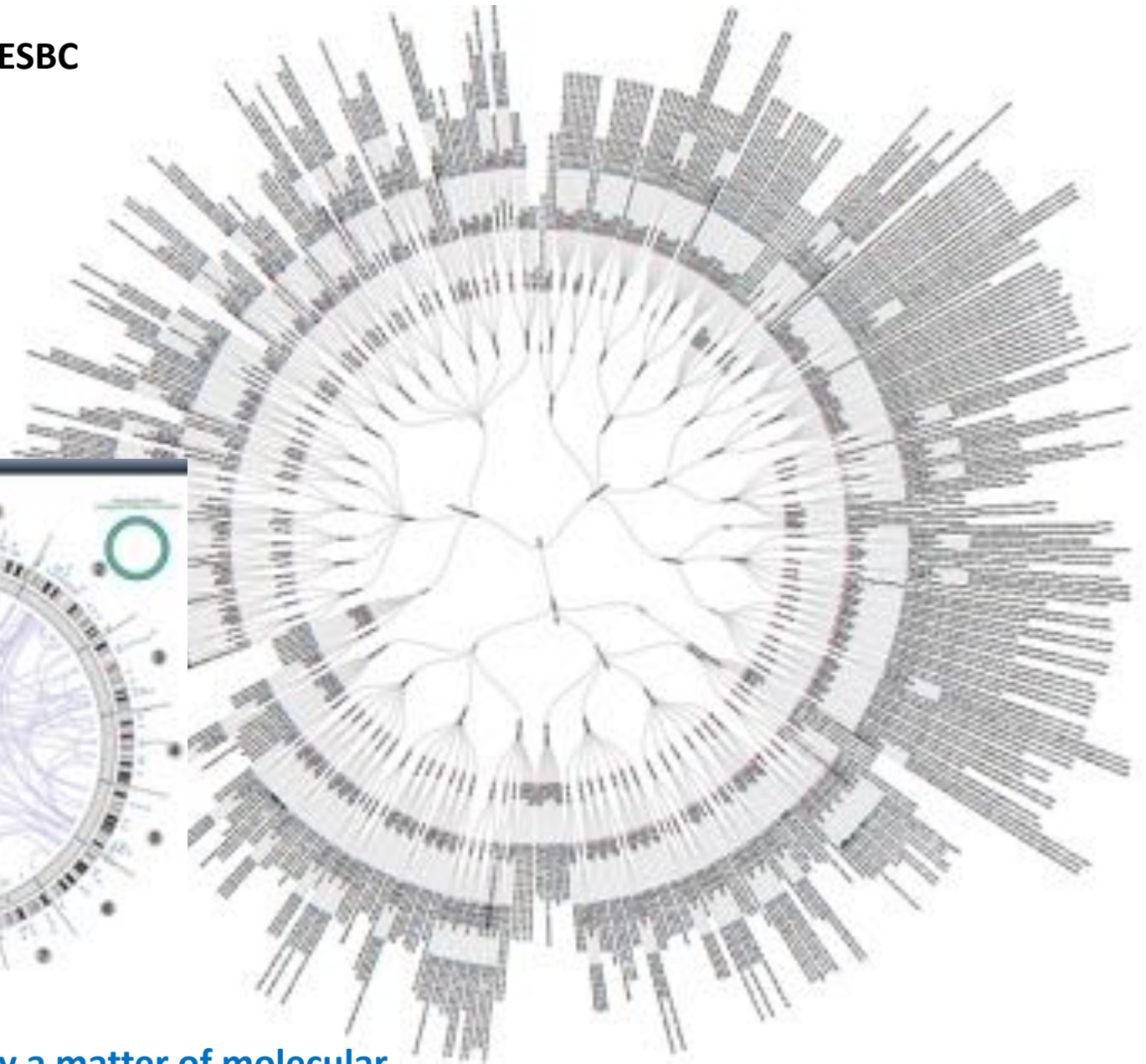
T	GAIN= 0.912948676
Volume	GAIN= 1.003948575755
Ptosis	GAIN= 0.459385976897
Pt wishes	GAIN= 1.293848556676

Caso Ext_DCIS

T	GAIN= 0.919838958
Volume	GAIN= 0.8927374758
Ptosis	GAIN= 0.23938598966
Pt wishes	GAIN= 1.00011938596

**The formal analysis revealed that patients' wishes are the root of
The decision process**

The decision tree for ESBC



Complexity is not only a matter of molecular biology

THE ARCHITECTURE OF OUR PROJECT : The Oncoplastic Framework

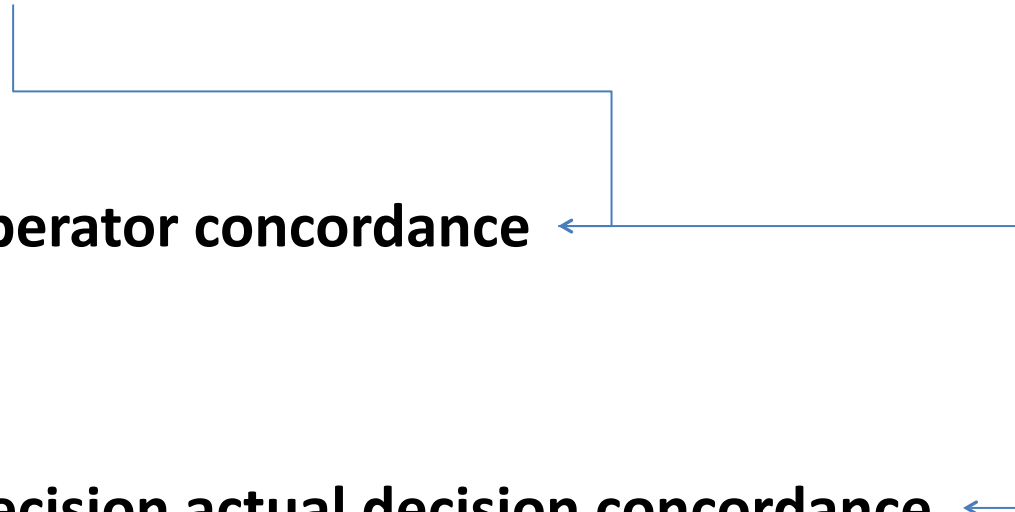
Step 3: Can we really use this tool in clinical practice

1: Pilot study on a short cohort

2: inter/intraoperator concordance

3: Suggested decision actual decision concordance

4: Assessment of post breast conservation defects



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Clinical evaluation of drivers

T- Stage or Multi-centric disease

→ Standard triple assessment: C.E./imaging/Core B

Location*

→ Imaging/ C.E.

Volume Ptosis

→ Cup size/ Regnault Classification

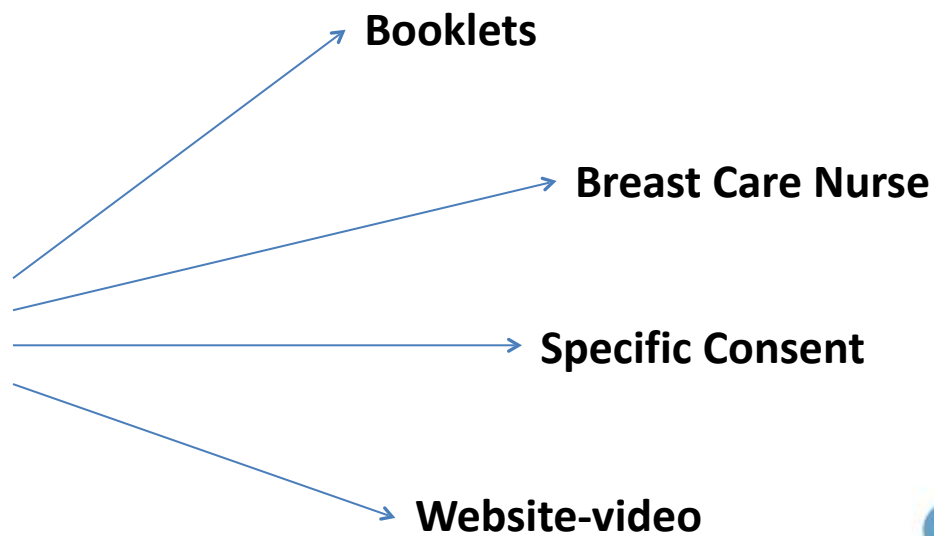
Risk of margin+°



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Clinical evaluation

Pt. Wishes
Mastectomy
Max. reshape
Min. Aggressiveness



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Clinical Testing: subgroups

SUBGROUPS Mean (%)	
ESBC	39 (77)
DCIS < 4 cm	2 (3.8)
MULTICENTRIC ESBC/ Extensive DCIS	8 (15.4)
LABC	2 (3.8)

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Clinical Testing: concordance

Comparison	Observed concordance (95% C.I.)
EXPERT TP1 vs. EXPERT TP2	0.98 (0.90 to 1.00)
EXPERT VS NON EXPERT	0.88 (0.77 to 0.96)
DSS SUGGESTION vs ACTUAL DECISION	0.69 (0.55 to 0.81)

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Clinical testing: Comparison of Baseline Characteristics of patients presenting concordance between Expert User “OF” assessment and Actual Decision and those without concordance (ESBC patients only).

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	Concordance (N=28)	No concordance (N=14)	P-value
Age years, mean (SD)	50.1 (12.8)	62.1 (16.0)	0,012
EXTENT OF DISEASE			0,256
Breast Location			0,176
Breast Volume			0,928
Ptosis			0,088
Risk of positive margins			0,014
LOW	12 (42.9)	13 (92.9)	
INTERMEDIATE	5 (17.9)	1 (7.1)	
HIGH	7 (25.0)	0 (0)	
N/A	4 (14.3)	0 (0)	
Patient's wishes			0,052
FITOUSSI SCORE			0,002
1	18 (64.3)	7 (50.0)	
2	2 (7.1)	3 (21.4)	
3	0 (0)	4 (28.6)	
N/A	8 (28.6)	0 (0)	

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N. of sessions to reach a decision: 3.4

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Strenghts of our system

Automatic tool - no more complex flowcharts

Patient's wishes at the center of the decision process

Integration with adjuvant and neo-adjuvant treatment

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Limitations of our system

More drivers to be introduced: Age-Comorbidities etc.

Lengthy process

Clinical validation still required with comparative trials including evaluation of cosmetic outcome, q.o.l. , safety and oncological outcome