



Diagnosis and Treatment of Patients with early and advanced Breast Cancer

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Oncoplastic and Reconstructive Surgery

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Plastic-reconstructive aspects after mastectomy



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Definition of oncoplastic surgical procedures

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Use of plastic surgical techniques at the time of tumor removal to enable safe resection margins and to preserve aesthetic breast contour.

Focus on favorable scar placement, adequate soft tissue formation, choice of proper reconstruction procedure (including in the context of radiation) and reconstruction of the contralateral side to achieve symmetric results.

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Classifications

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1. By Hoffmann/Wallwiener:

Classification by reconstructive surgery complexity with respect to breast conservation and mastectomy: PubMed Central, Figure 1: BMC Cancer. 2009; 9: 108. Published online 2009 Apr 8. doi: 10.1186/1471-2407-9-108 (nih.gov)

2. By Clough:

Oncoplastic classification for breast conservation according to relative resection volume: Level 1: < 20% of breast volume resection („simple oncoplastic surgery“) and Level 2 > 20% of breast volume resection with quadrant per quadrant techniques of mastopexy.

Oncoplastic breast conserving surgery (OPS)

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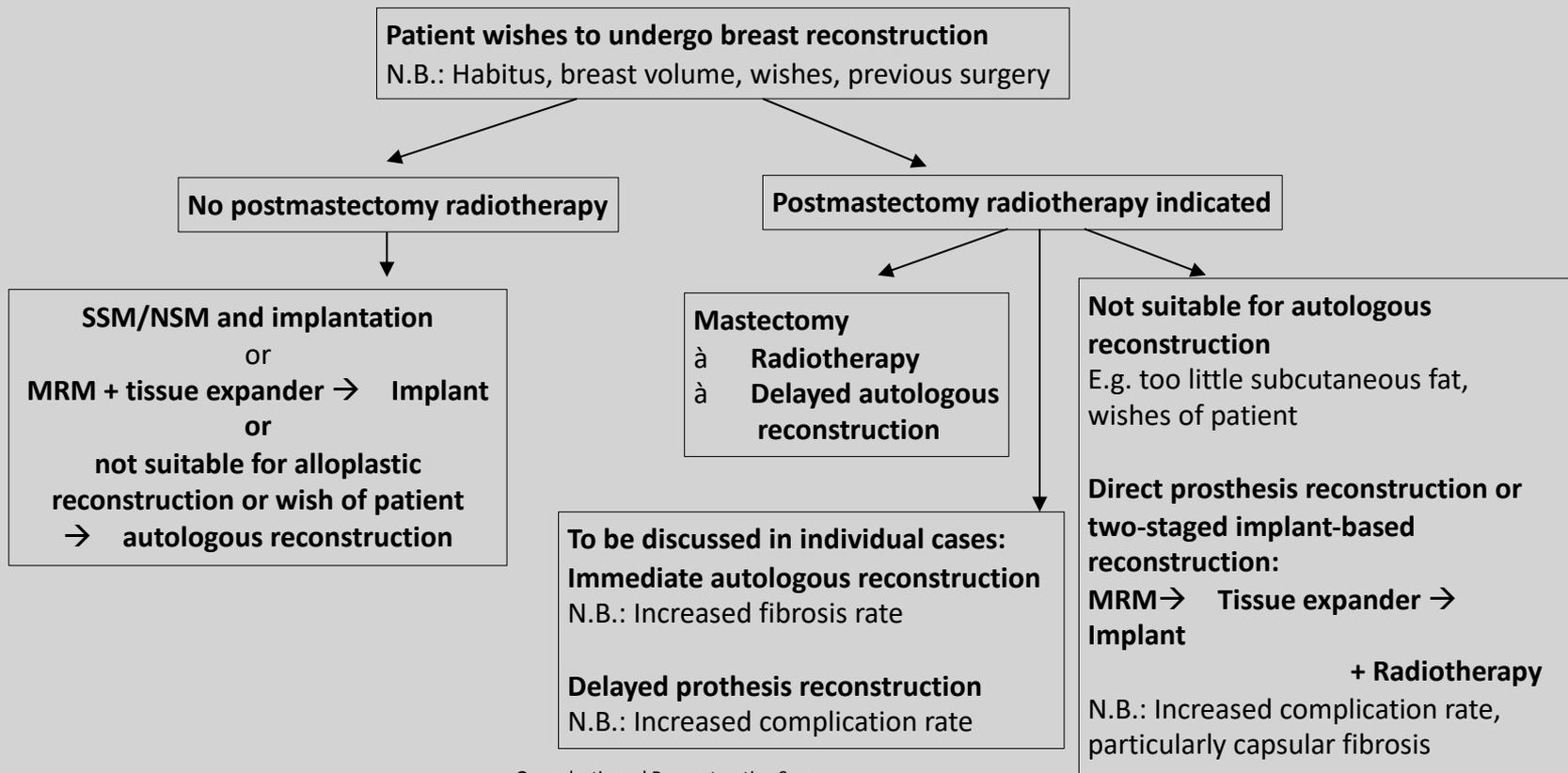
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	Oxford		
	LoE	GR	AGO
▪ OPS may replace mastectomy in selected patients	2b	B	+
▪ OPS and BCS are oncologically equivalent	2b	B	+
▪ Aesthetic outcome of OPS might be better in selected cases	2b	B	+
▪ Complication rates of OPS and BCS are similar	3b	C	+

Algorithm of Breast Reconstruction

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Breast Reconstruction Principles

Good Clinical Practise

AGO: ++

- **Planning of reconstructive procedure by interdisciplinary tumor board before mastectomy**
- **Counseling regarding all surgical techniques, including advantages and disadvantages**
- **Preference for autologous reconstruction after radiotherapy or if radiotherapy is planned**
- **Offer second opinion**
- **Discussion of neoadjuvant treatment if unfavorable tumor-breast-relation**
- **Consideration of contralateral breast;**
 - **discuss possible alignment / sequencing surgical procedures to produce symmetry; usually after at least 3-6 months (Caveat: need for post-resections, consider effects of radiotherapy for affected side)**
- **Preference for less stressful surgical technique with stable long-term aesthetic result (prefer BCS / OPS over mastectomy)**
- **Avoid delay of adjuvant therapy due to reconstruction**
- **Assessment of outcome (e.g. PROM)**
- **Ensure that oncologic safety is not impaired**

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Postmastectomy Reconstruction

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- **Use of silicone gel filled breast implants one step or two steps after expander**
 - Safety comparable to saline implants
- **Autologous tissue reconstruction**
- **Pedicled tissue reconstruction**
- **Free tissue reconstruction (including vascular anastomoses)**
- **Autologous tissue procedure plus implants**

	Oxford		
	LoE	GR	AGO
	2a	B	+
	2b	B	
	2a	B	+
	2a	B	+
	2a	B	+
	3a	C	+/-

Caveat: BMI >30, smoking status, diabetes, radiotherapy, age, bilateral mastectomy

Timing of Reconstruction

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	Oxford		
	LoE	GR	AGO
<ul style="list-style-type: none"> ▪ Immediate breast reconstruction <ul style="list-style-type: none"> ▪ Mandatory: SSM/NSM ▪ Avoidance of a postmastectomy syndrome 	3b	B	++
<ul style="list-style-type: none"> ▪ Delayed breast reconstruction (2-step) <ul style="list-style-type: none"> ▪ No interference with adjuvant procedures (CHT, RT) ▪ Disadvantage: loss of skin envelope 	3b	B	++
<ul style="list-style-type: none"> ▪ „Delayed-immediate“ breast reconstruction (placeholder before definitive reconstruction) 	3b	B	+

Timing of implant Based Reconstruction and Radiotherapy



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■ Implant reconstruction (IR)

- IR without radiotherapy
- IR prior to radiotherapy
- IR following radiotherapy
- IR following secondary mastectomy (after BCS* with radiotherapy)
- Perioperative antibiotic prophylaxis (max. 24 hours)

Oxford

LoE	GR	AGO
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2a	B	+
----	---	---

2a	B	++
----	---	----

2a	B	+
----	---	---

2b	B	+/-
----	---	-----

2a	B	+/-
----	---	-----

2a	B	+
----	---	---

* BCS: Breast Conserving Surgery

Metaanalysis of Prophylactic Antibiotics >24h in Implant-based Immediate Breast Reconstruction (IBR)

- **11 studies (15,966 mastectomy procedures)**
- **Three studies comparing topical antibiotics with no topical antibiotics demonstrated statistical significance (RR= 0.26, 95% CI: 0.12–0.60, $P = 0.001$)**
- **8 studies comparing extended systemic antibiotics with standard of care found no statistical significance (RR = 0.80, 95% CI: 0.60–1.08, $P = 0.13$).**

LoE 2a B

In the setting of immediate breast reconstruction (IBR) following mastectomy, there is insufficient evidence for the use of extended prophylactic antibiotics to reduce surgical site infection (SSI) rates. Well-designed randomized controlled trials in patients undergoing IBR should be conducted to determine the appropriate regimen and/or duration of prophylactic antibiotics on SSI outcomes.



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Radiotherapy and Implant-based Reconstruction

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Cave: High complication rate in combination with radiotherapy (capsular contracture, revision surgery, reconstruction failure, reduced cosmetic outcome and patient satisfaction)

Cave: Lower patient satisfaction with implant-based reconstruction plus radiotherapy compared to autologous reconstruction plus radiotherapy

LoE 2b B

Possible Associations between Implants and rare Diseases

- **US FDA Breast Implant Postapproval Studies (LPAS)**
Long-term Outcomes in 99,993 Patients
(Primary Augmentation: N= 71.937 / Primary Reconstruction: N= 9942)
 - **56% of implants were silicone implants**
- **Possible Associations:**
 - Sjogren syndrome: (SIR*8.14)
 - scleroderma: (SIR 7.00)
 - rheumatoid arthritis: (SIR5.96)
 - stillbirth: (SIR4.50)
 - melanoma: (SIR3.71)
- **At 7 years, reoperation rate is 11.7% for primary augmentation, and 25% for primary/revision reconstruction.**
- **One case of BIA-ALCL**

**Associations need to be further analyzed with
patient-level data to provide conclusive evidence !**

*Standardized incidence ratio

Possible Associations between Implants and rare Diseases

Rare Systemic Harms Compared With the General Population:

	Manufacturer, y	Study Events	Study Event Rate (Per 10,000 Person Yr)	General Population Event Rate (Per 10,000 Person Yr)	SIR	SIR 95% CI	P Value
Fibromyalgia	Allergan	9	1.8	112.8	0.02	0.01–0.03	<0.001
	Mentor	307	28.4	112.8	0.25	0.22–0.28	<0.001
Rheumatoid arthritis	Allergan	4	0.8	5.4	0.15	0.04–0.38	<0.001
	Mentor	349	32.2	5.4	5.96	5.35–6.62	<0.001
Scleroderma	Mentor	46	4.2	0.6	7.00	5.12–9.34	<0.001
Sjogren syndrome	Mentor	62	5.7	0.7	8.14	6.24–10.44	<0.001
Systemic lupus erythematosus	Allergan	3	0.6	5.4	0.11	0.02–0.32	<0.001
	Mentor	66	6.0	5.4	1.11	0.86–1.41	0.398
Cancer	Allergan	80	16.0	41.3	0.39	0.31–0.48	<0.001
	Mentor	532	63.8	41.3	1.54	1.42–1.68	<0.001
Breast cancer	Mentor	116	13.9	12.5	1.11	0.92–1.33	0.26
Lung cancer	Mentor	5	0.6	5.2	0.12	0.04–0.27	<0.001
Brain cancer	Mentor	3	0.4	0.6	0.67	0.14–1.95	0.639
Melanoma	Mentor	65	7.8	2.1	3.71	2.87–4.73	<0.001
Neurological disorder	Allergan	18	3.6	22.5	0.16	0.09–0.25	<0.001
	Mentor	394	35.8	22.5	1.59	1.44–1.76	<0.001
Multiple sclerosis	Mentor	47	4.3	2.5	1.72	1.26–2.29	0.001
Myositis	Mentor	17	1.5	0.8	1.88	1.09–3.00	0.018

Allergan follow-up 2 years
Mentor follow-up 7 years

Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)



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- **Approximately 10.000.000 implant carriers**
- **Rare disease, 3 % of Non-Hodgkin Lymphomas, 0.04-0.5 % of all malignant breast diseases**
- **1:3.000 – 30.000 in women with textured implants (caveat: underreporting!)**
- **Estimated incidence 0.6-1.2 / 100.000 women with implants (median age: 54 y)**
- **Mainly associated with textured implants**
- **Interval to diagnosis: 8 years (median)**
- **Clinical symptoms**
 - **Swelling and seroma. (60 %)**
 - **Solid tumor (17 %)**
 - **Seroma and solid tumor (20 %)**
- **Histology: CD30+ / ALK-T-Cell Lymphoma**
- **Mandatory registration as SAE (§3 MPSV to BfArM)**

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BIA-ALCL - Surfaces of Breast Implants

- The cause of BIA-ALCL is not established; however, it has been proposed that lymphomagenesis may be driven by a chronic inflammatory reaction induced by capsule contents or surface. **The risk for BIA-ALCL has been shown to be significantly higher for implants with grade 3 and 4 surfaces.**

Process	Polyurethane foam	Salt Loss (Biocell/ Eurosilicone)	Gas Diffusion	Salt Loss (Nagotex)	Imprinting	Smooth/ Nano
Surface Area	high	intermediate	intermediate	low	low	minimal
Roughness	high	intermediate	low	low	low	minimal
SURFACE TYPE	4	3	3	2	2	1

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BIA-ALCL– Diagnosis

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LoE	GR	AGO
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<ul style="list-style-type: none"> ▪ Breast US (assessment of new seromas > 1 year after implant insert, solid lesion (sensitivity: 84%, specificity: 75%)) 	3a	D	++
<ul style="list-style-type: none"> ▪ Breast-MRI in confirmed cases 	3a	D	++
<ul style="list-style-type: none"> ▪ Staging (Imaging, e.g. CT, PET-CT) 	3a	D	++
<ul style="list-style-type: none"> ▪ Cytology of late seromas <ul style="list-style-type: none"> ▪ - > 50 ml ▪ - Complete assessment ▪ - flow-cytology (T-cell clone) ▪ - BIA-ALCL specific cytologic diagnostic (CD 30+) 	3a	D	++
<ul style="list-style-type: none"> ▪ Core needle biopsy in solid lesions 	3a	D	++
<ul style="list-style-type: none"> ▪ Lymphoma assessment of resected tissue and histologic staging 			
<ul style="list-style-type: none"> ▪ Documentation of the implant (manufacturer, size, volume, surface, Batch-number) and entry in registry 	5	D	++

BIA-ALCL – Therapy

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- **Implant resection and complete capsulectomy including tumorectomy**
- **Resection of suspicious lymph nodes, no routine use of sentinel-node-biopsy, no axillary dissection**
- **Polychemotherapy (e.g. CHOP) in cases of extra capsular extension**
- **Radiotherapy in unresectable tumors**
- **Case discussion in an interdisciplinary tumor board in the presence of a lymphoma specialist**

Oxford

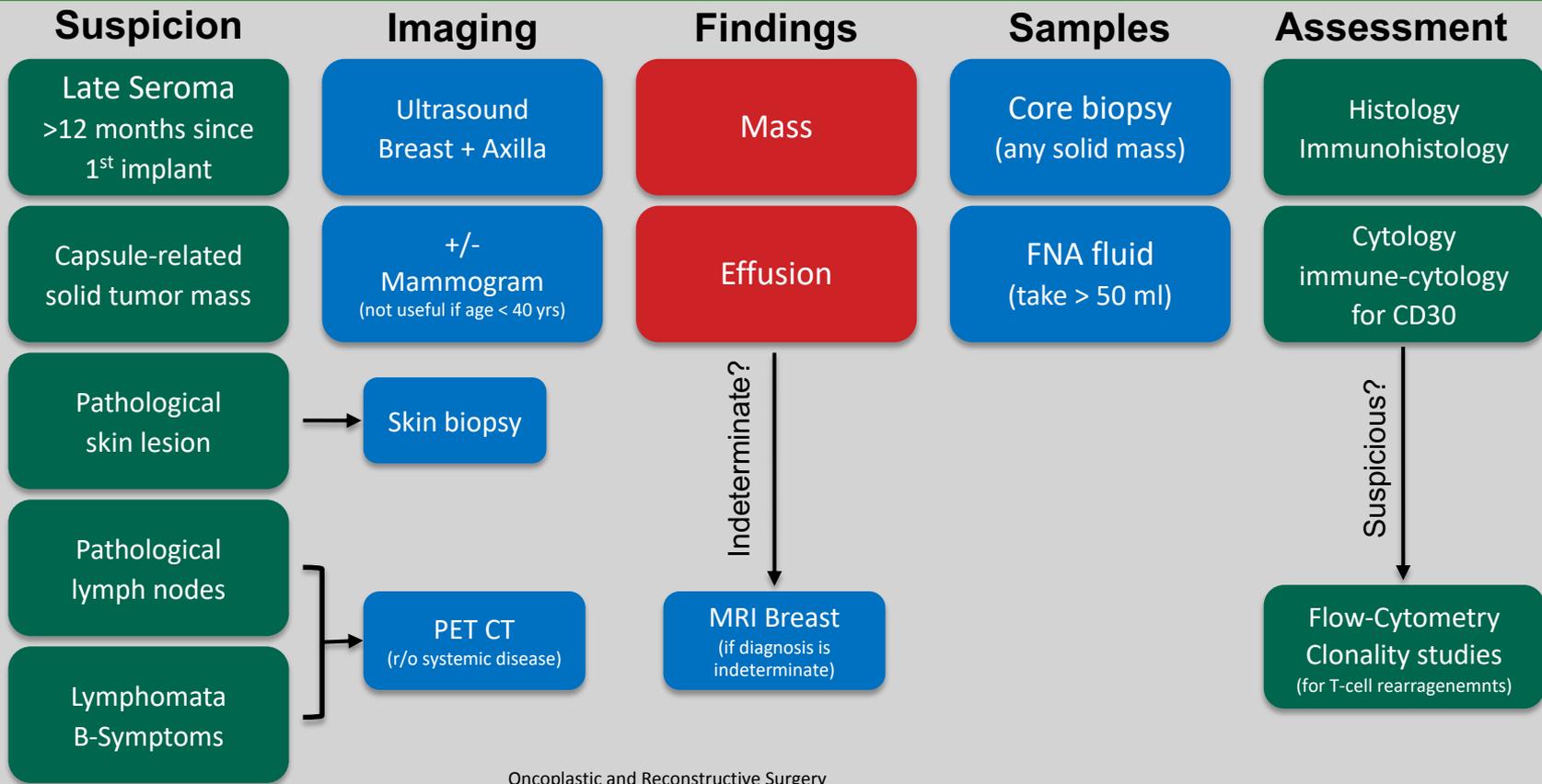
LoE	GR	AGO
3a	C	++
4	D	++
4	D	+
5	D	+/-
5	D	++

Diagnostic Pathways and Assessment

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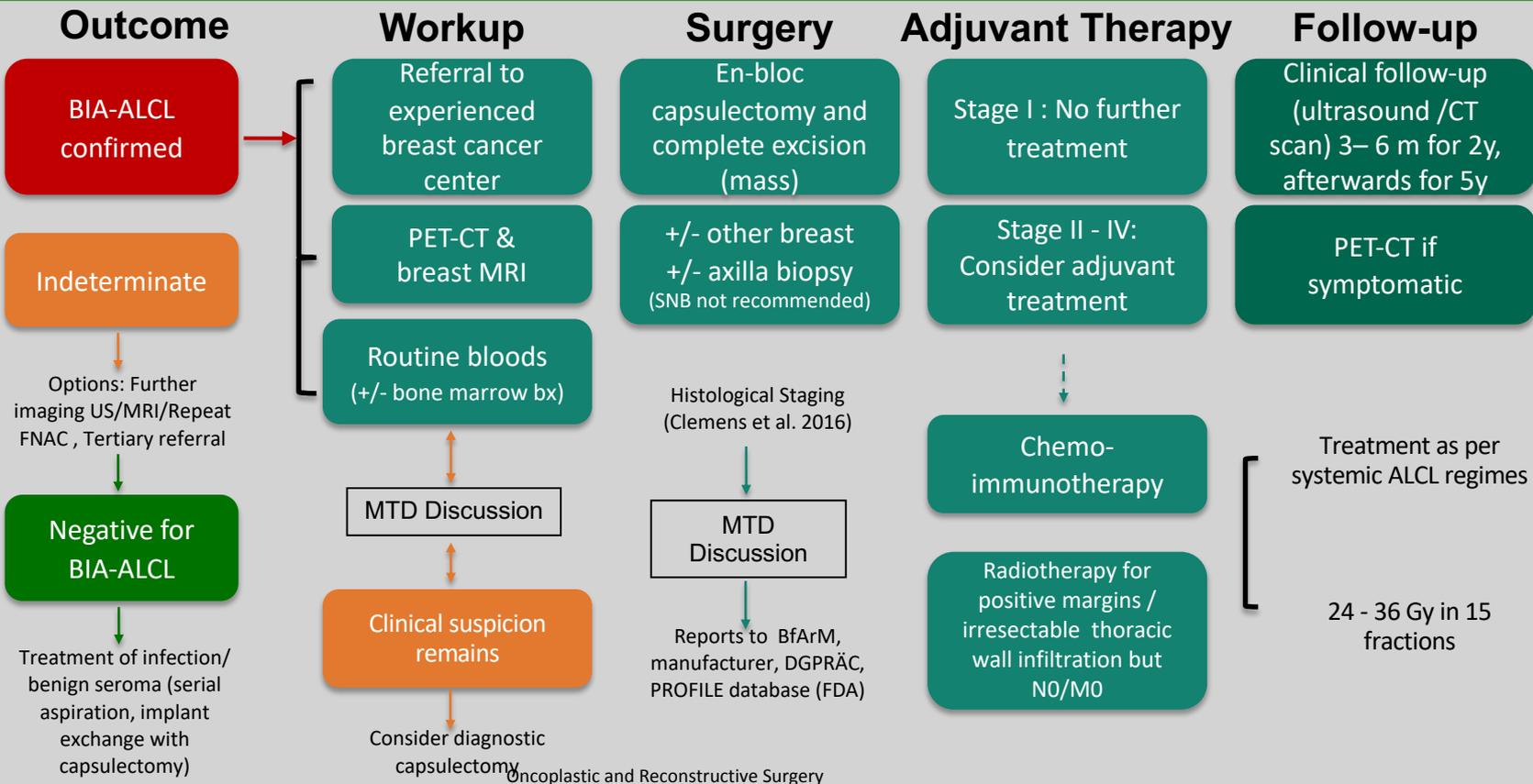
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BIA-ALCL Treatment Pathways

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TNM Staging of BIA-ALCL

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	TNM-Kategorie	Definition
Tumor extent (cT/pT)	T1	Confined to seroma or a layer on luminal side of capsule
	T2	Early capsule infiltration
	T3	Cell aggregates or sheets infiltrating the capsule
	T4	Lymphoma infiltrates beyond the capsule
Regional lymph nodes (cN/pN)	N0	No lymph node involvement
	N1	One regional lymph node positive
	N2	Multiple regional lymph nodes positive
Metastasis (cM/pM)	M0	No distant spread
	M1	Spread to other organs or distant sites

Stage	Definition
IA	T1 N0 M0
TB	T2 N0 M0
TC	T3 N0 M0
IIA	T4 N0 M0
IIB	T1-3 N1 M0
III	T4 N1-2 M0
IV	T any N any M1

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BIA-ALCL – EUSOMA-Recommendation

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- **Despite an increase of BIA-ALCL in association with texture implants the use of textured implants is still permitted!**

„For the moment, textured implants can safely continue to be used with patient's fully informed consent, and that women that have these type of implants already in place don't need to remove or substitute them, which would undoubtedly cause harm to many tens of thousands of women, to prevent an exceptionally rare, largely curable and currently poorly understood disease.“

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Tissue Replacement Techniques and Meshes (Details of Implant Reconstruction)

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- **The subcutaneous lodge is superior to the subpectoral lodge**
- **Acellular dermal matrix (ADM)**
 - **subpectoral**
 - **subcutaneous**
- **Synthetic meshes**
 - **subpectoral**
 - **subcutaneous**

Oxford		
LoE	GR	AGO
3b	C	+/-
1b	A	+/-[#]
2b	B	+/-[#]
2b	B	+[#]
2b	B	+[#]

Participation in registry studies recommended

Lipotransfer

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- **Lipotransfer following mastectomy and reconstruction**
- **Lipotransfer after BCS***
- **Autologous adipose derived stem cells (ASCs)-enriched fat grafting vs. without stem cells**

Oxford		
LoE	GR	AGO
2a	B	+
2a	B	+
2a	B	-

*BCS: Breast Conserving Surgery

Postmastectomy Pedicled Reconstruction

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	Oxford		
	LoE	GR	AGO
Breast reconstruction (BR) with autologous tissue			
▪ TRAM, latissimus-dorsi-flap (both can be performed as a muscle-sparing technique)	2a	C	+
▪ Delayed TRAM in patients at high-risk	3a	B	+
▪ Ipsilateral pedicled TRAM	2a	B	+
▪ Radiotherapy:			
▪ BR following radiotherapy	2a	B	+
▪ BR prior to radiotherapy	2a	B	+/-
▪ (higher rates of fibrosis, wound healing problems, liponecrosis and reduced aesthetic outcome)			

Free flaps for reconstruction

Oxford		
LoE	GR	AGO

Type of free flap

- DIEP
- Free TRAM
- SIEA
- Glutealis flaps (SGAP- / IGAP, FCI)
- Free gracilis flap (TMG)
- Use of ICG* to assess flap perfusion

2a	B	+
2a	B	+
3a	C	+/-
4	C	+/-
4	C	+/-
2a	B	+

Advantages

- DIEP and free TRAM are potentially muscle-sparing procedures. DIEP has a lower rate of abdominal hernias, especially in obesity

Disadvantages

- Time- and personnel consuming microsurgical procedures
- Intensified postoperative monitoring
- Pre-reconstruction radiotherapy increases rate of vascular complications

*ICG: indocyanin green

Pedicled versus free tissue transfer

Oxford

LoE	GR	AGO
3a	A	++

- **Muscle-sparing techniques and accuracy of abdominal wall closure lead to low rates of late donor site complications independent of method used**
- **Autologous abdominal-based reconstructions have highest satisfaction rates (PROM)**
- **Donor site morbidity (e.g. impaired muscle function) has to be taken into consideration for all flap techniques**

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Skin-/nipple-sparing Mastectomy (SSM/NSM) and Reconstruction

Oxford
LoE GR AGO

- | | LoE | GR | AGO |
|--|--|--|--|
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> Safe (same recurrence rate as MX) Higher QoL for patients NAC can be preserved under special conditions <ul style="list-style-type: none"> Feasible after mastopexy / reduction mammoplasty Use of ICG* to predict necrosis of the skin | <p>2b</p> <p>2b</p> <p>2b</p> <p>4</p> <p>1b</p> | <p>B</p> <p>B</p> <p>B</p> <p>C</p> <p>B</p> | <p>++</p> <p>++</p> <p>++</p> <p>++</p> <p>+</p> |
| <ul style="list-style-type: none"> <ul style="list-style-type: none"> Periareolar Hemi-periareolar with/without medial/ lateral extension Reduction pattern: „inverted-T“ or vertical Inferior lateral approach, inframammary fold <ul style="list-style-type: none"> Lowest incidence of complications | <p>2b</p> | <p>B</p> | <p>+</p> |

* ICG = Indocyanine Green



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Prevention and therapy of capsular contracture

Oxford

LoE GR AGO

Prevention

- | | | | |
|--|----|---|-----|
| ▪ Textured implantats (Caveat: BIA-ALCL) | 1a | A | + |
| ▪ Acellular Dermal Matrix (ADM) vs. nil | 2a | B | + |
| ▪ Synthetic mesh vs. nil | 3a | C | + |
| ▪ Topical antibiotics/antiseptics | 2a | B | + |
| ▪ PVP (Povidone-Iodine) | 2a | B | +/- |
| ▪ Leukotriene-antagonists | 2a | B | +/- |
| ▪ Breast massage | 3a | C | - |

Surgical interventions

- | | | | |
|---|----|---|---|
| ▪ Capsulectomy | 3b | C | + |
| ▪ Capsulotomy (Caveat: exclusion of BIA-ALCL) | 3b | C | + |

Seroma after implant-based reconstruction I

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	LoE	GR	AGO
<ul style="list-style-type: none"> Incidence: around 5-10% (2-50%) 	2a	B	
<p>Co-variates:</p> <ul style="list-style-type: none"> History of radiation increases the risk (RR ca. 3) Obesity increases risk (e.g. BMI > 30 vs. < 30; RR ca. 3) ADM increases risk (RR ca. 3) Smooth expanders increase risk (RR ca. 5) History of neoadjuvant systemic chemotherapy does not increase the risk Epipectoral pocket does not increase the risk 	2a	B	
	2a	B	
	2a	B	
	3b	C	
	2a	B	
	2b	B	

Seroma after implant-based reconstruction II

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Prevention

- Drain with no, little and much suction
- Drain removal at < 30ml per 24 hours

Therapy

- Evacuation of serma by FNA or re-insertion of drain
- Dressings
- Revision surgery with capsulectomy (ultima ratio)
- Revision surgery with implant removal (ultima ratio)

	Oxford		
	LoE	GR	AGO
Drain with no, little and much suction	3b	C	+
Drain removal at < 30ml per 24 hours	2b	B	+
Evacuation of serma by FNA or re-insertion of drain	4	C	+
Dressings	5	D	+/-
Revision surgery with capsulectomy (ultima ratio)	5	D	+
Revision surgery with implant removal (ultima ratio)	5	D	+

Risk-reducing bilateral mastectomy for healthy women (RRBM)

Oxford

LoE GR AGO

▪ RRBM reduces breast cancer incidence	2b	B	++
▪ RRBM in deleterious BRCA1/2 mutation	2a	B	++*
▪ RRBM in high-risk situation without BRCA 1/2 mutation (individual decision depending on personal- family history and mutational status – e.g. high and moderate-risk genes, Hodgkin lymphoma)	4	D	+/-*
▪ High risk and no BRCA counselling in specialized centre*	5	D	--
▪ Non-directive counselling prior to RR-BM	2b	B	++*
▪ RR-BM should be considered with other risk-reducing surgical options incl. bilateral salpingoophorectomy (BSO) and in the context of pre-existing diseases	2a	A	++*
▪ Further need for education of physicians regarding possibilities and advantages of RRBM	1b	A	++

* Counselling, risk prediction, and follow-up in specialized centers recommended

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Surgical Prevention for Healthy Female *BRCA1/2* Mutation Carriers



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Oxford		
LoE	GR	AGO
2a	B	*
		++*
		++*
2b	B	++*
2b	B	++*

- Risk-reducing bilateral salpingo-oophorectomy (RR-BSO)**

- Reduces OvCa incidence and mortality
- Reduces overall mortality

- Risk-reducing bilateral mastectomy (RR-BM)

- Reduces BC incidence
- Reduces BC mortality in *BRCA1* mutation carriers***

*study participation recommended

** The RR-BSO is recommended from about 35 years for *BRCA1* and from about 40 years for *BRCA2* mutation carriers, taking into account the age of ovarian cancer diagnosis in the family and family planning status.

*** No reduction in mortality could be shown for *BRCA2* mutation carriers. RRM counselling should be individualised.

Risk-reducing Interventions for BRCA1/2 Female Mutation Carriers Affected by Breast Cancer



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Synchronisierung
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	Oxford		
	LoE	GR	AGO
<ul style="list-style-type: none"> ■ Risk-reducing bilateral salpingo-oophorectomy (RR-BSO) <ul style="list-style-type: none"> ■ Reduces OvCa incidence and mortality ■ Reduces overall mortality (contradictory results for reduction of cl BC incidence) 	2b	B	+*
<ul style="list-style-type: none"> ■ Prophylactic contralateral mastectomy (RR-CM) reduces BC incidence and mortality 	2b	B	+*
<ul style="list-style-type: none"> ■ Tamoxifen (reduces contralateral BC incidence) 	2b	B	+/-*
<ul style="list-style-type: none"> ■ Indication for RR-CM should consider age at onset of first breast cancer in affected gene 	2a	B	++*
<ul style="list-style-type: none"> ■ RR-BM after ovarian cancer 	4	C	+/-**

* study participation recommended

** Depends on tumor stage (FIGO I/II), recurrence free interval (≥ 5y), age

Forms of risk-reducing (bilateral) mastectomy (RR-BM)



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RR-BM reduces breast cancer incidence; BC-specific mortality also likely reduced**

■ Simple mastectomy	2b	B	+
■ RR-BM by SSM*	2b	C	+
■ RR-BM by NSM* (NAC# sparing)	2b	C	+
■ Contralateral prophylactic mastectomy	4	C	+/-

* SSM / NSM: Skin-/Nipple-Sparing Mastectomy

NAC: nipple-areola complex

** depending on prior illnesses, e. g. pre-existing ovarian cancer 1-2% (stage III-IV)

Oncoplastic and Reconstructive Surgery