

Diagnosis and Treatment of Patients with early and advanced Breast Cancer

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In collaboration
with:

Oncoplastic and Reconstructive Surgery

Plastic-Reconstructive Aspects after Mastectomy

- **Versions 2002–2022:**

Audretsch / Bauerfeind / Blohmer / Brunnert / Dall / Ditsch / Fersis / Friedrich/ Gerber / Hanf/ Heil / Kühn / Kümmel / Lux / Nitz / Rezai / Rody / Scharl / Solbach / Thill / Thomssen / Wöckel

- **Version 2023:**
Dall / Ditsch

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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 presentation of the possibilities of the aligning operation of the contralateral side to achieve symmetric results.

Classifications

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.

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Oncoplastic Breast Conserving Surgery (OPS)

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- **OPS may replace mastectomy in selected patients**
 - also in case of multicentric / multifocal tumors
- **OPS and BCS are oncologically similar**
- **Complication rates of OPS and BCS are similar**

Oxford		
LoE	GR	AGO
2b	B	+
2b(a)	B	+
2a	B	++
2a	B	+/-

Algorithm of Breast Reconstruction

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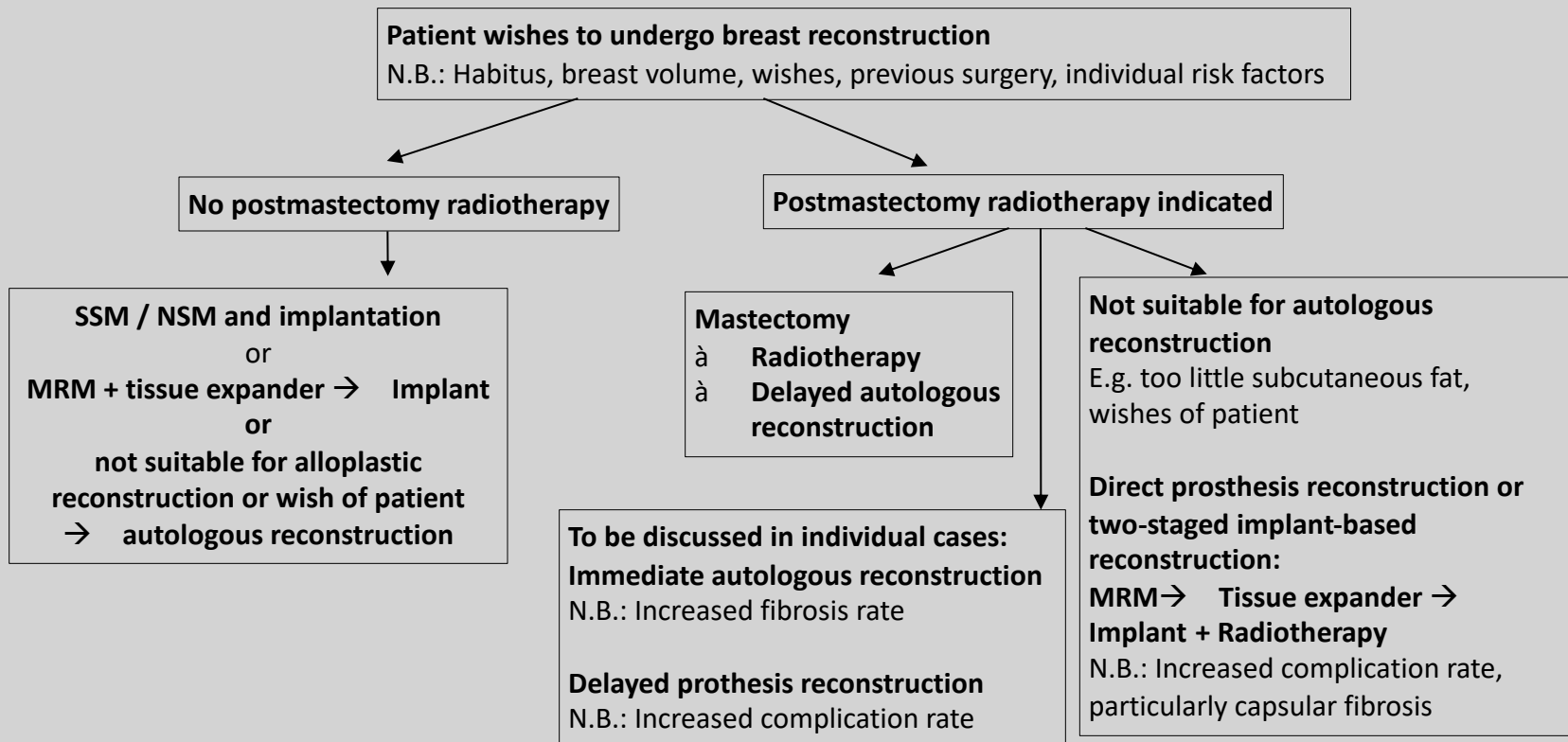
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Breast Reconstruction Principles

Good Clinical Practice

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 tumorbiologically indicated) in case of 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 esthetic result (prefer BCS / OPS over mastectomy)
- Avoid delay of adjuvant therapy due to reconstruction
- Assessment of outcome, e.g. Patient Reported Outcome (PRO)
- Oncologic safety is not impaired

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Mastectomy and Reconstruction Options

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

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

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

* Documentation in implant registry

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
-----	----	-----

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

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

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

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

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

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

* BCS: Breast Conserving Surgery

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

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- **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.

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: (SIR 5.96)
 - stillbirth: (SIR 4.50)
 - melanoma: (SIR 3.71)
- 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

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Possible Associations between Implants and Rare Diseases

Rare Systemic Harms Compared With the General Population:

	Manufacturer	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

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

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- Approximately 10.000.000 implant carrier
- 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
- Compulsory registration as SAE (§3 MPSV to BfArM)

BIA-ALCL - Surfaces of Breast Implants

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- 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

BIA-ALCL– Diagnosis

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	LoE	GR	AGO
▪ Breast US (assessment of new seromas > 1 year after implant insert, solid lesion (sensitivity: 84%, specificity: 75%))	3a	D	++
▪ Mamma-MRT in confirmed cases	3a	D	++
▪ Staging (Imaging, e.g. CT, PET-CT)	3a	D	++
▪ Cytology of late seromas	3a	D	++
▪ > 50 ml			
▪ Complete assessment			
▪ flow-cytology (T-cell clone)			
▪ BIA-ALCL specific cytologic diagnostic (CD 30+)			
▪ Core needle biopsy in solid lesions	3a	D	++
▪ Lymphoma assessment of resected tissue and histologic staging			
▪ Documentation of the implant (manufacturer, size, volume, surface, Batch-number) and enter 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 specialist for lymphomas**

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

Diagnostic Pathways and Assessment

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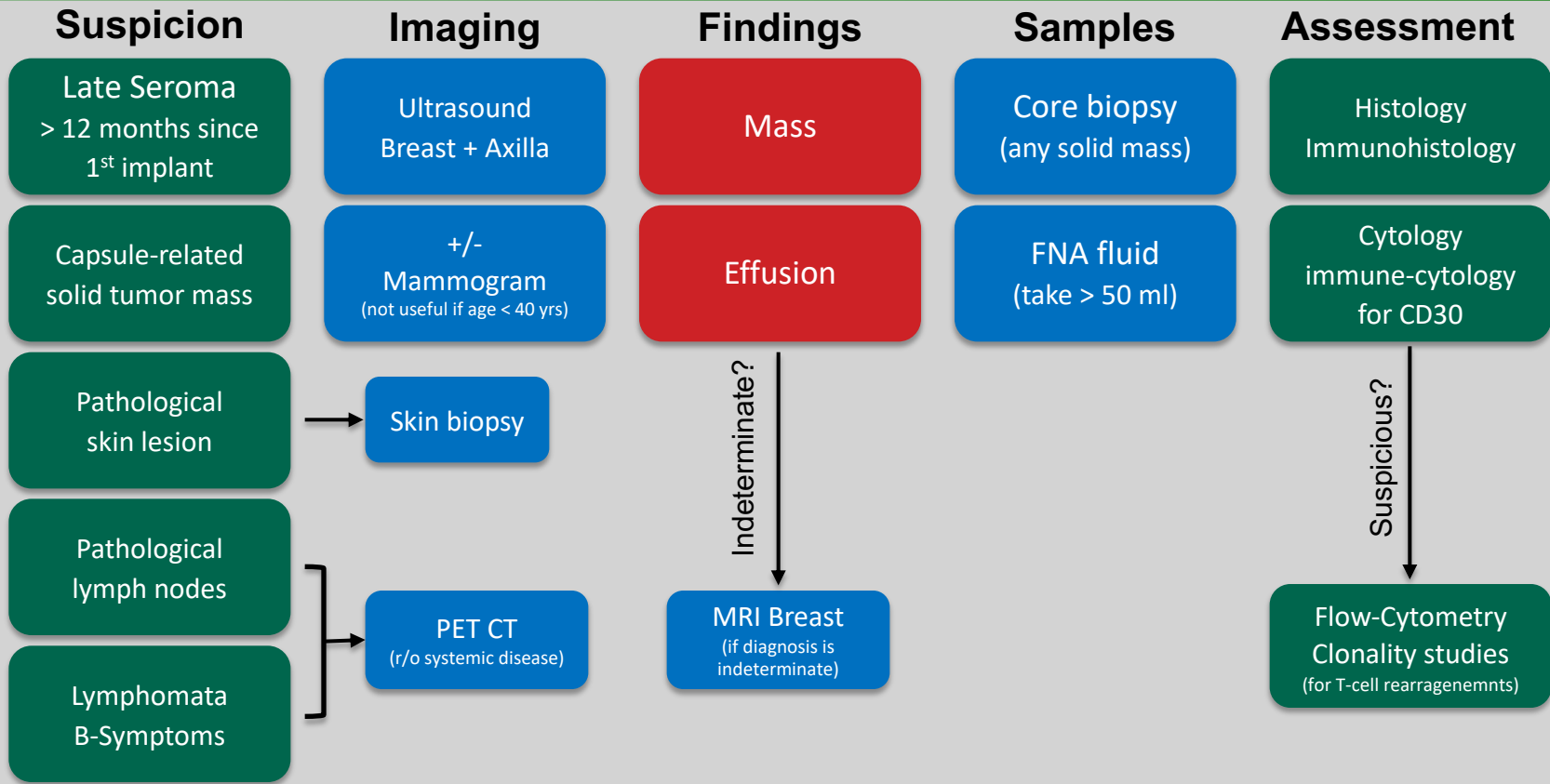
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BIA-ALCL Treatment Pathways

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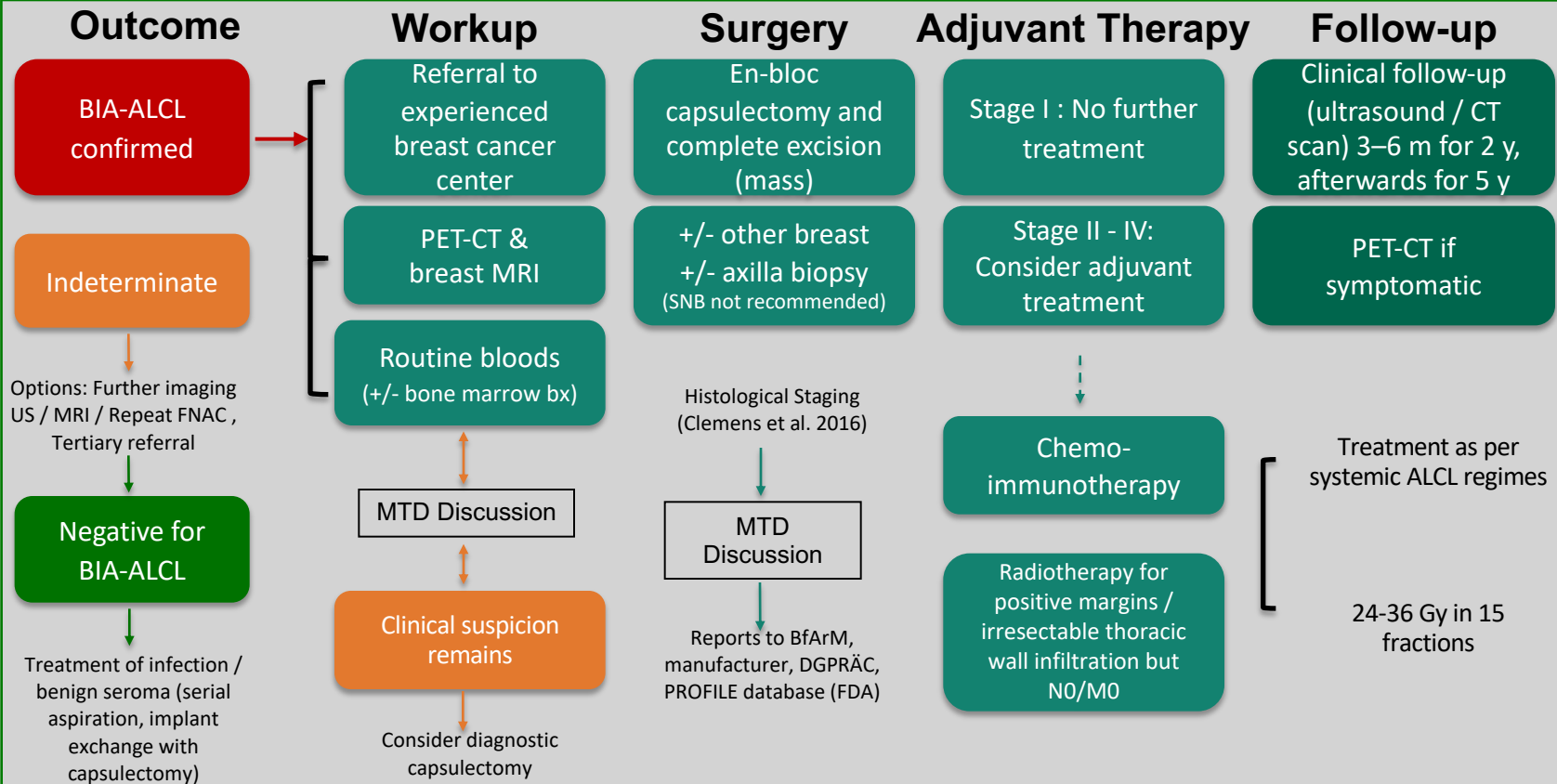
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TNM Staging of BIA-ALCL

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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

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.“

Breast Implant Capsule-Associated Squamous Cell Carcinoma

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In Zusammen-
arbeit mit:

- Squamous cell carcinomas associated with breast implant augmentation are exceedingly rare (11 cases reported).
- Breast implant capsule-associated squamous cell carcinoma occurs in patients with long standing breast implant augmentations (>11 years).
- Presentation with breast enlargement/swelling and pain, skin changes
- 3/11 pts. developed metastatic disease within 1 year.
The reported metastatic sites include axilla, soft tissue (arm and leg), liver, lung, mediastinum, retroperitoneum, and leptomeninges.
- 4/5 patients with follow-up data showed a correlation between extracapsular extension and development of metastases (1-8 months; mean 4.25 months).
- In this limited cohort it is difficult to ascribe prognostic factors, but extracapsular extension does appear to be a concerning finding.

Implant Lodge, Tissue Replacement Techniques and Meshes (Details of Implant Reconstruction)

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

Oxford		
LoE	GR	AGO
3a	C	+/-
1b	A	+/-
2b	B	+/-
2b	B	+/-
2b	B	+/-

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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Breast reconstruction (BR) with autologous tissue

- TRAM, latissimus-dorsi-flap (both can be performed as a muscle-sparing technique)
- Delayed TRAM in patients at high-risk
- Ipsilateral pedicled TRAM
- Omentum Flap
- Radiotherapy:
 - BR following radiotherapy
 - BR prior to radiotherapy
- (higher rates of fibrosis, wound healing problems, liponecrosis and reduced aesthetic outcome)

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

Free Flaps for Reconstruction

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Type of free flap

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

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

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

* ICG: indocyanin green

Pedicated versus Free Tissue Transfer

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- 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 with all flap techniques

Oxford		
LoE	GR	AGO
3a	A	++

Skin-/ Nipple-Sparing Mastectomy (SSM / NSM) and Reconstruction

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	LoE	GR	AGO
■ Skin-/nipple-sparing Mastectomy (SSM / NSM)			
■ Safe (same recurrence rate as simple mastectomy)	2b	B	++
■ Higher QoL for patients	2b	B	++
■ NAC can be preserved under special conditions	2b	B	++
■ Feasible after mastopexy / reduction mammoplasty	4	C	++
■ Use of ICG* to predict necrosis of the skin	1b	B	+
■ Skin incisions - different possibilities:			
■ Periareolar			
■ Hemi-periareolar with / without medial / lateral extension			
■ Reduction pattern: „inverted-T“ or vertical			
■ Inferior lateral approach, inframammary fold			
■ Lowest incidence of complications	2b	B	+

* ICG = Indocyanine Green

Mastectomy + Reconstruction

Risk of complications with the addition of radiotherapy

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In Zusammen-
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Autologous reconstruction		Implant-based reconstruction	
Endpoint	Risk Ratio with addition of radiotherapy (95%-CI)	Endpoint	Risk Ratio with addition of radiotherapy (95%-CI)
Wound infection	1.14 (NA)	Wound infection	2.49 (1.43,4.35)
Secondary surgery	1.62 (1.06, 2.48)	Secondary surgery	1.64 (1.17-2.31)
Reconstructive failure	0.80 (NA)	Reconstructive failure	2.89 (1.30,6.39)
Volume loss	8.16 (4.26,15.63)		
Fat necrosis	1.91 (1.45, 2.52)		
		Capsular contracture	5.17 (1.93,13.80)
		ME skin flap nekrosis	1.62 (1.27, 2.08)
		Implant extrusion	3.44 (2.18, 5.43)

Further risks of autologous reconstruction:

Distorsion of breast shape, fibrosis, vascular complications

Autologous reconstruction is favored in terms of patient satisfaction and and assessment of the aesthetic outcome.

NA: not available

Prevention and Therapy of Capsular Contracture

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	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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- Incidence: approx. 5-10 % (2-50 %)

Influencing factors:

- History of radiation increases risk (RR approx. 3)
- Obesity increases risk (e.g. BMI > 30 vs. < 30; RR approx. 3)
- Use of ADM increases risk (RR approx. 3)
- Use of expander with smooth surface increases risk (RR approx. 5)
- History of neoadj. Chemotherapy doesn't seem to increase risk
- Prepectoral lodge doesn't seem to increase risk

Oxford

LoE	GR
2a	B
2a	B
2a	B
3b	C
2a	B
2b	B

Seroma after Implant-Based Reconstruction II

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Prevention

- Drain
- 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
3b	C	+
2b	B	+
4	C	+
5	D	+/-
5	D	+
5	D	+

Surgical Prevention

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- **Risk-reducing unilateral or bilateral mastectomy (RRME) without the presence of clearly defined genetic risk factors**
- **Axillary dissection or Sentinel lymph node biopsy during RRME**

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

* study participation recommended

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

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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 	2a	B	++*
<ul style="list-style-type: none"> Risk-reducing bilateral mastectomy (RR-BM) <ul style="list-style-type: none"> Reduces BC incidence Reduces BC mortality in <i>BRCA1</i> mutation carriers*** 	2b	B	++*

* 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 the family planning status.

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

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

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Guidelines Breast
Version 2023.1E

	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)* <ul style="list-style-type: none"> ■ 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, 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 (≥ 5 yrs.), age