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# Diagnosis and Treatment of Patients with early and advanced Breast Cancer

## Oncoplastic and Reconstructive Breast Surgery



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## Oncoplastic and Reconstructive Breast Surgery


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## Definition of oncoplastic surgery


**Use of plastic surgical techniques at the time of tumor removal to improve aesthetic and quality of life outcomes without compromising oncological safety.**

**Focus on favorable scar placement, adequate soft tissue formation, choice of a suitable reconstructive technique (taking radiation therapy into consideration) and contralateral symmetrization.**

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## Classifications


**1. Hoffmann / Wallwiener (2009):**  
**Classification by reconstructive surgery complexity with respect to breast conservation and mastectomy**

**2. Clough et al. (2010):**  
**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**

**3. American Society of Society of Breast Surgeons (2019):**  
**Level 1: < 20% breast tissue removed; Level 2: 20–50% of breast tissue removed; Volume replacement: > 50% of breast tissue removed**

Hoffmann D et al., BMC 2009; Clough KB et al., Ann Surg Oncol 2010; Chatterjee A et al. Ann Surg Oncol 2019


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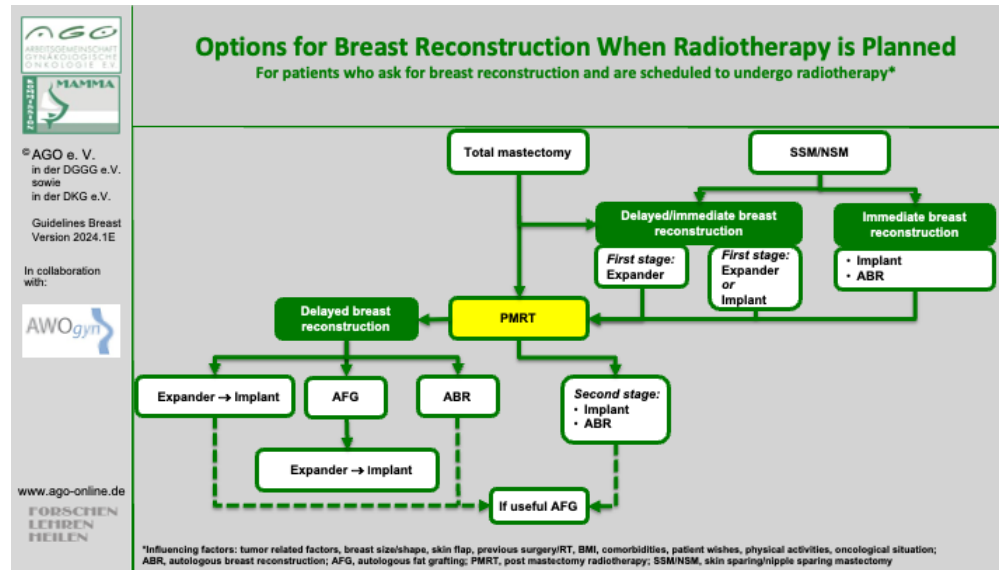
## Oncoplastic Breast-Conserving Surgery (OPS)

	Oxford		
	LoE	GR	AGO
<ul style="list-style-type: none"> <li>▪ OPS may replace mastectomy in selected patients               <ul style="list-style-type: none"> <li>▪ also in case of multicentric / multifocal tumors</li> </ul> </li> </ul>	2b 2b	B B	+ +
<ul style="list-style-type: none"> <li>▪ OPS and BCS have equivalent oncological safety</li> </ul>	2a	B	++
<ul style="list-style-type: none"> <li>▪ Complication rates of OPS and BCS are similar</li> </ul>	2a	B	+/-

1. Boughey JC, Rosenkranz KM, Ballman KV et al. Local Recurrence After Breast-Conserving Therapy in Patients With Multiple Ipsilateral Breast Cancer: Results From ACOSOG Z11102 (Alliance). J Clin Oncol. 2023 Jun 10;41(17):3184-3193.
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	<h2 style="color: green;">Breast Reconstruction Principles Good Clinical Practice</h2>
<p>© AGO e. V. in der DGGG e.V. sowie in der DKG e.V.</p> <p>Guidelines Breast Version 2024.1E</p> <p>In collaboration with:</p>  <p>www.ago-online.de FORSCHEN LEBEN HEILEN</p>	<p style="text-align: center; color: green; font-weight: bold;">AGO: ++</p> <ul style="list-style-type: none"> <li>▪ <b>Planning of breast reconstruction by interdisciplinary tumor board before mastectomy</b></li> <li>▪ <b>Counseling regarding all surgical techniques, including advantages and disadvantages</b></li> <li>▪ <b>Preference for autologous reconstruction after radiotherapy or if radiotherapy is planned</b></li> <li>▪ <b>Offer second opinion</b></li> <li>▪ <b>Discussion of neoadjuvant treatment (if indicated based on tumor biology) in case of unfavorable breast-tumor relation</b></li> <li>▪ <b>Consideration of contralateral breast:</b> <ul style="list-style-type: none"> <li>▪ <b>Discuss symmetrization procedures</b></li> </ul> </li> <li>▪ <b>Preference for less radical surgical technique with stable long-term aesthetic result (prefer BCS / OPS over mastectomy)</b></li> <li>▪ <b>Avoid delay of adjuvant therapy due to reconstruction</b></li> <li>▪ <b>Assessment of outcome, e.g. Patient Reported Outcome (PRO)</b></li> <li>▪ <b>Oncologic safety is not impaired</b></li> </ul>


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## Mastectomy and Reconstruction Options

	Oxford		
	LoE	GR	AGO
■ <b>Heterologous reconstruction *</b>	2a	B	+
■ <b>Autologous reconstruction</b>	2a	B	+
■ <b>Pedicled flap reconstruction</b>	2a	B	+
■ <b>Free flap reconstruction (including vascular anastomoses)</b>	2a	B	+
■ <b>Autologous reconstruction combined with implant placement</b>	3a	C	+/-


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

\* Documentation in implant registry  
Germany: <https://www.bundesgesundheitsministerium.de/implantateregister-deutschland>  
Mandatory documentation of breast implants in the Medical Implants Registry begins on 1st July 2024

1. Marquez JL, Sudduth JD, Kuo K et al. A Comparison of Postoperative Outcomes Between Immediate, Delayed Immediate, and Delayed Autologous Free Flap Breast Reconstruction: Analysis of 2010-2020 NSQIP Data. J Reconstr Microsurg. 2023 Oct;39(8):664-670.
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## Timing of Reconstruction

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


1. Cook P, Yin G, Ayeni FE et al. Does Immediate Breast Reconstruction Lead to a Delay in Adjuvant Chemotherapy for Breast Cancer? A Meta-Analysis and Systematic Review. Clin Breast Cancer. 2023 Jul;23(5):e285-e295.
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## Timing of Implant-Based Reconstruction and Radiotherapy

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

- **Implant reconstruction**
  - **without radiotherapy**
  - **prior to radiotherapy**
  - **following radiotherapy**
  - **following secondary mastectomy after breast-conserving therapy**

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<b>Antibiotics and Breast Reconstruction</b>			
	<b>Oxford</b>		
	<b>LoE</b>	<b>GR</b>	<b>AGO</b>
<b>Heterologous reconstruction:</b>			
▪ Perioperative antibiotic prophylaxis (max. 24 h)	<b>1a</b>	<b>A</b>	<b>+</b>
▪ Extended antibiotic prophylaxis > 24 h	<b>2a</b>	<b>B</b>	<b>+/-</b>
<b>Autologous reconstruction:</b>			
▪ Perioperative antibiotic prophylaxis (max. 24 h)	<b>2b</b>	<b>B</b>	<b>+</b>
▪ Extended antibiotic prophylaxis > 24 h	<b>2a</b>	<b>B</b>	<b>+/-</b>

### **Implant-based reconstruction:**

#### **Meta-analyses:**

1. Hai Y, Chong W, Lazar MA. Extended Prophylactic Antibiotics for Mastectomy with Immediate Breast Reconstruction: A Meta-analysis. *Plast Reconstr Surg Glob Open*. 2020 Jan 27;8(1):e2613.
2. Hu Y, Zhou X, Tong X et al. Postoperative antibiotics and infection rates after implant-based breast reconstruction: A systematic review and meta-analysis. *Front Surg*. 2022 Aug 17;9:926936.
3. Klifto KM, Rydz AC, Hultmann CS et al. Evidence-Based Medicine: Systemic Perioperative Antibiotic Prophylaxis for Prevention of Surgical-Site Infections in Plastic and Reconstructive Surgery. *Plast Reconstr Surg* 2023 Dec 1;152(6):1154e-1182e.

#### **Randomized trials: Single-dose vs. 24 h (4 doses):**

1. Gahm J, Konstantinidou AL, Lagergren J et al. Effectiveness of Single vs Multiple Doses of Prophylactic Intravenous Antibiotics in Implant-Based Breast Reconstruction. A Randomized Clinical Trial. *JAMA Network Open*. 2022;5(9):e2231583.



Randomized trials: 24 h vs. until drain removal (implant + ADM):

1. Phillips BT, Fourman MS, Bishawi M et al. Are Prophylactic Postoperative Antibiotics Necessary for Immediate Breast Reconstruction? Results of a Prospective Randomized Clinical Trial. J Am Coll Surg 2016 Jun;222(6):1116-24.

Randomized trials: preoperative vs. no antibiotics:

1. Amland PF, Andenaes K, Samdal F et al. A prospective, double-blind, placebo-controlled trial of a single dose of azithromycin on postoperative wound infections in plastic surgery. Plast Reconstr Surg 1995 Nov;96(6):1378-83

Retrospective cohort studies:

1. Rothe K, Münster N, Hapfelmeier A et al. Does the Duration of Perioperative Antibiotic Prophylaxis Influence the Incidence of Postoperative Surgical-Site Infections in Implant-Based Breast Reconstruction in Women with Breast Cancer? A Retrospective Study. Plast Reconstr Surg 2022 Apr 1;149(4):617e-628e.
2. Ranganathan K, Sears ED, Zhong L et al. Antibiotic Prophylaxis after Immediate Breast Reconstruction: The Reality of Its Efficacy. Plast Reconstr Surg 2018 Apr;141(4):865-877.
3. Avashia YJ, Mohan R, Berhane C et al. Postoperative antibiotic prophylaxis for implant-based breast reconstruction with acellular dermal matrix. Plast Reconstr Surg 2013 Mar;131(3):453-461,
4. Hunsicker LM, Chavez-Abraham V, Berry C et al. Efficacy of Vancomycin-based Continuous Triple Antibiotic Irrigation in Immediate, Implant-based Breast Reconstruction. Plast Reconstr Surg Glob Open 2017 Dec 28;5(12):e1624.
5. Clayton JL, Bazakas A, Lee CN et al. Once is not enough: withholding postoperative prophylactic antibiotics in prosthetic breast reconstruction is associated with an increased risk of infection. Plast Reconstr Surg 2012 Sep;130(3):495-502.
6. Goh SCJ, Thorne AL, Williams G et al. Breast reconstruction using permanent Becker expander implants: an 18 year experience. Breast 2012 Dec;21(6):764-8.
7. McCullough MC, Chu CK, Duggal CS et al. Antibiotic Prophylaxis and Resistance in Surgical Site Infection After Immediate Tissue Expander Reconstruction of the Breast. Ann Plast Surg 2016 Nov;77(5):501-505.
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Infect Control Hosp Epidemiol 2017 Sep;38(9):1048-1054. doi: 10.1017/ice.2017.128

9. Townley WA, Baluch N, Bagher S et al. A single pre-operative antibiotic dose is as effective as continued antibiotic prophylaxis in implant-based breast reconstruction: A matched cohort study. J Plast Reconstr Aesthet Surg 2015 May;68(5):673-8.
10. Holland M, Lentz R, Sbitany H. Utility of Postoperative Prophylactic Antibiotics in Prepectoral Breast Reconstruction: A Single-Surgeon Experience. Ann Plast Surg 2021 Jan;86(1):24-28.
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### **Autologous reconstruction:**

#### Meta-analyses:

1. Aldarragi A, Farah N, Warner CM et al. The Duration of Postoperative Antibiotics in Autologous Breast Reconstruction: A Systematic Review and Meta-Analysis. Cureus 2023 Jun 19;15(6):e40631
2. Klifto KM, Rydz AC, Hultmann CS et al. Evidence-Based Medicine: Systemic Perioperative Antibiotic Prophylaxis for Prevention of Surgical-Site Infections in Plastic and Reconstructive Surgery. Plast Reconstr Surg 2023 Dec 1;152(6):1154e-1182e.

#### Randomized trials:

1. Franchelli S, Leone MS, Rainero ML et al. Antibiotic prophylaxis with teicoplanin in patients undergoing breast reconstruction with the transverse rectus abdominis myocutaneous flap. Eur J Plast Surg. 1993;16:204–207
2. Amland PF, Andenaes K, Samdal F et al. A prospective, double-blind, placebo-controlled trial of a single dose of azithromycin on postoperative wound infections in plastic surgery. Plast Reconstr Surg 1995 Nov;96(6):1378-83

#### Retrospective cohort studies:

1. Changchien CH, Fang CL, Tsai CB et al. Prophylactic Antibiotics for Deep Inferior Epigastric Perforator Flap Breast Reconstruction: A Comparison between Three Different Duration Approaches. Plastic and Reconstructive Surgery - Global Open 2023, 11(2):p e4833,

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**Aesthetic surgery (reduction mammoplasty, augmentation), meta-analyses:**

1. Hardwicke JT, Bechar J, Skillman JM. Are systemic antibiotics indicated in aesthetic breast surgery? A systematic review of the literature. *Plast Reconstr Surg* 2013 Jun;131(6):1395-1403.
2. Klifto KM, Rydz AC, Hultmann CS et al. Evidence-Based Medicine: Systemic Perioperative Antibiotic Prophylaxis for Prevention of Surgical-Site Infections in Plastic and Reconstructive Surgery. *Plast Reconstr Surg* 2023 Dec 1;152(6):1154e-1182e.

<b>Tranexamic Acid in Complex Breast Surgery</b>				
		<b>Oxford</b>		
		<b>LoE</b>	<b>GR</b>	<b>AGO</b>
<b>Prevention of:</b>				
■	<b>Hematoma</b>	<b>2a</b>	<b>B</b>	<b>+/-</b>
■	<b>Seroma</b>	<b>2a</b>	<b>B</b>	<b>+/-</b>
<b>No increased risk for thromboembolic complications in patients without history of thromboembolic events</b>		<b>2a</b>	<b>B</b>	<b>+</b>
<b>CAVE: Dosage and application routes (local, i.v., oral) differ between studies, consider history of thromboembolic events</b>				

### Metaanalyses:

#### **TXA topically and intravenously or both in breast surgery:**

1. Huynh MNQ, Wong CR, McRae MC et al. The Effects of Tranexamic Acid in Breast Surgery: A Systematic Review and Meta-Analysis. *Plast Reconstr Surg.* 2023 Dec 1;152(6):993e-1004e.

#### **TXA intravenously (breast-conserving surgery, mastectomy +/- reconstruction)**

1. Liechti R, van de Wall BJM, Hug U et al. Tranexamic Acid Use in Breast Surgery: A Systematic Review and Meta-Analysis. *Plast Reconstr Surg.* 2023 May;151(5):949-957.

### Prospective randomized studies:

#### **Topical TXA / Nipple-sparing mastectomy:**

1. Safran T, Vorstenbosch J, Viezel-Mathieu A et al. Topical Tranexamic Acid in Breast Reconstruction: A Double-Blind Randomized Controlled Trial. *Plast Reconstr Surg.* 2023 Oct 1;152(4):699-706.

**Topical TXA / Reduction mammoplasty:**

1. Plast Reconstr Surg. 2023, Yao A, Wang F, Benacquista T et al. Topical Tranexamic Acid Does Not Reduce The Incidence Of Hematoma In Reduction Mammoplasty: A Double-Blinded, Randomized Placebo-Controlled Trial. Plast Reconstr Surg. 2023 Jul 25. doi: 10.1097/PRS.00000000000010952.

**Topical TXA / Mastectomy without reconstruction:**


1. Ausen K, Hagen AI, Østbyhaug HS et al. Topical moistening of mastectomy wounds with diluted tranexamic acid to reduce bleeding: randomized clinical trial. BJS Open. 2020 Apr;4(2):216-224

**Systemic TXA / breast-conserving surgery and mastectomy:**

1. Oertli D, Laffer U, Haberthuer F et al. Perioperative and postoperative tranexamic acid reduces the local wound complication rate after surgery for breast cancer. Br J Surg. 1994 Jun;81(6):856-9.

**Retrospective Cohort Studies:**


1. Sipos K, Kämäräinen S, Kauhanen S. Topical tranexamic acid reduces postoperative hematomas in reduction mammoplasties. J Plast Reconstr Aesthet Surg. 2023 Aug;83:172-179.
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## Breast Implant-associated Diseases

**BIA-ALCL = Breast implant-associated anaplastic large cell lymphoma**

**BIA-SCC = Breast implant-associated squamous cell carcinoma**

**SSBI = Systemic Symptoms Associated with Breast Implants**  
Synonyms:  
Breast Implant Illness (BII); Autoimmune syndrome induced by adjuvants (ASIA);  
Shoenfeld's syndrome; Silicone implant incompatibility syndrome (SIIS)

1. von Fritschen U, Kremer T, Prantl L et al Breast Implant-Associated Tumors. Geburtshilfe Frauenheilkd. 2023 Jun 6;83(6):686-693

### BIA-ALCL

1. Santanelli di Pompeo F, Clemens MW, Paolini G et al. Epidemiology of Breast Implant–Associated Anaplastic Large Cell Lymphoma in the United States: A Systematic Review, *Aesthetic Surgery Journal* 2024 Jan, 44,1 January 2024, NP32–NP40,
2. Santanelli di Pompeo F, Clemens MW, Atlan M et al. 2022 Practice Recommendation Updates From the World Consensus Conference on BIA-ALCL. *Aesthet Surg J.* 2022 Oct 13;42(11):1262-1278.
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### BIA-SCC



1. Niraula S, Katel A, Barua A et al. A Systematic Review of Breast Implant-Associated Squamous Cell Carcinoma. *Cancers*

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2. Möllhoff N, Ehrl D, Fuchs B et al. Brustimplantat assoziiertes Plattenepithelkarzinom (BIA-SCC) – eine systematische Literaturübersicht [Breast implant-associated squamous cell carcinoma: a systematic literature review]. *Handchir Mikrochir Plast Chir.* 2023 Aug;55(4):268-277.
3. Glasberg SB, Sommers CA, McClure GT. Breast Implant-associated Squamous Cell Carcinoma: Initial Review and Early Recommendations. *Plast Reconstr Surg Glob Open.* 2023 Jun 14;11(6):e5072.
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	<h2 style="color: green;">Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)</h2>
<p>© AGO e. V. in der DGGG e.V. sowie in der DKG e.V.</p> <p>Guidelines Breast Version 2024.1E</p> <p>In collaboration with:</p>  <p>www.ago-online.de FORSCHEN LEBEN HEILEN</p>	<ul style="list-style-type: none"> <li>▪ Peripheral non-Hodgkin's T-cell lymphoma arising around a textured breast implant or in a patient with a history of a textured surface device</li> <li>▪ Number of global cases reported as MDR (medical device regulation) to the FDA by 30.06.2023: 1264 with 63 deaths</li> <li>▪ Approximately 35,000,000 implant carriers worldwide (According to a survey by the International Society of Aesthetic Plastic Surgeons (ISAPS) 2023: 2,174,616 augmentations worldwide were performed)</li> <li>▪ Prevalence and incidence vary greatly, as the number of women with implants can only be estimated</li> <li>▪ The current lifetime risk ranges between 1:355 and 1:86,029 patients with textured implants</li> <li>▪ Time interval between last implantation and lymphoma diagnosis: 8 years (median)</li> <li>▪ 5-year-OS 89-92 %</li> <li>▪ Clinical presentation             <ul style="list-style-type: none"> <li>*Frequently periprosthetic seroma, breast asymmetry</li> <li>*in rarer cases tumor, regional lymphadenopathy, skin rash and/or capsular contracture</li> </ul> </li> <li>▪ Tumor cells are CD30-positive / ALK-negative</li> <li>▪ Obligation to notify the BfArM as SAE according to §3 MPSV*</li> </ul> <p>* Germany: BfArM <a href="https://www.bfarm.de/SharedDocs/Formulare/DE/Medizinprodukte/BIA-ALCL-Meldung.html">https://www.bfarm.de/SharedDocs/Formulare/DE/Medizinprodukte/BIA-ALCL-Meldung.html</a></p>

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		<b>BIA-ALCL – Diagnosis</b>		
		<b>Oxford</b>		
		<b>LoE</b>	<b>GR</b>	<b>AGO</b>
 <p>© AGO e. V. in der DGGG e.V. sowie in der DKG e.V.</p> <p>Guidelines Breast Version 2024.1E</p> <p>In collaboration with:</p>  <p>www.ago-online.de FORSCHEN LEBEN HEILEN</p>	▪ <b>Breast ultrasound (assessment of new seromas &gt; 1 year after implant placement, solid lesions, axillary lymph nodes)</b>	3a	D	++
	▪ <b>Cytology of late seromas</b>			
	▪ Assessment of min. 50 ml	3a	D	++
	▪ Complete assessment incl. BIA-ALCL specific cytologic diagnostic (CD 30+)			
	▪ Flow cytometry (T-cell clone)			
	▪ <b>Core needle biopsy of solid lesions</b>	3a	D	++
	▪ <b>Breast-MRI in confirmed cases</b>	3a	D	++
	▪ <b>Staging (PET-CT, alternatively: CT [neck, chest, abdomen, pelvis])</b>	3a	D	++
▪ <b>Lymphoma assessment in resected tissue and histologic staging</b>	3a	D	++	
▪ <b>Documentation of the implant in the Implant Registry *</b>	5	D	++	

\* Germany: <https://www.bfarm.de/SharedDocs/Formulare/DE/Medizinprodukte/BIA-ALCL-Meldung.html>

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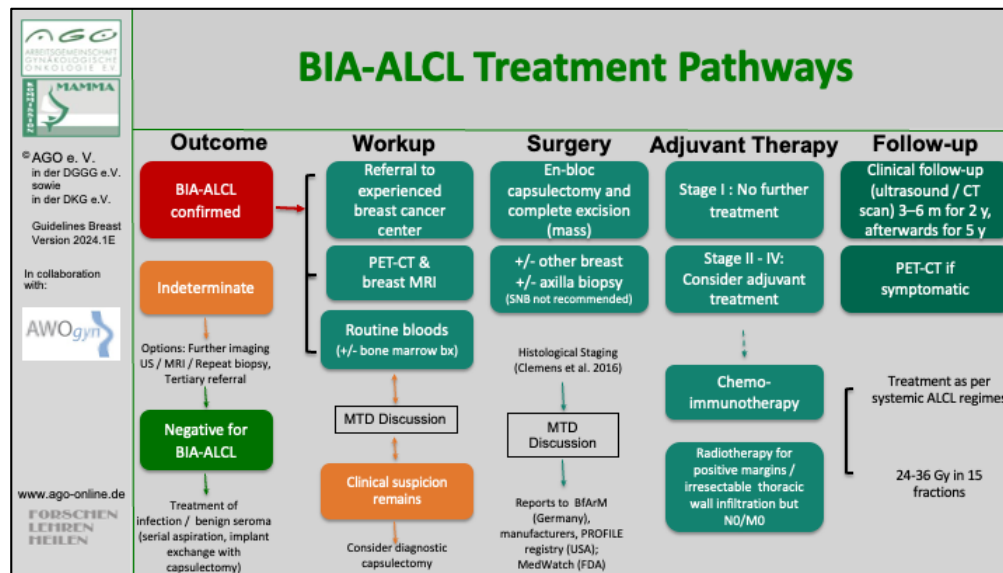
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<b>BIA-ALCL – Therapy</b>			
	<b>Oxford</b>		
	<b>LoE</b>	<b>GR</b>	<b>AGO</b>
▪ <b>Case discussion in a multidisciplinary tumor board in the presence of a lymphoma specialist</b>	5	D	++
▪ <b>Implant resection and complete capsulectomy including tumorectomy</b>	3a	C	++
▪ <b>Contralateral implant removal and capsulectomy in case of bilateral implants (4-6% bilateral BIA-ALCL)</b>	4	D	+/-
▪ <b>Resection of suspicious lymph nodes, no routine use of sentinel node biopsy or axillary lymph node dissection</b>	4	D	++
▪ <b>Systemic therapy depending on disease stage</b>	4	D	+
▪ <b>Radiotherapy in unresectable tumors</b>	5	D	+/-

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TNM Staging of BIA-ALCL				
Tumor extent (cT/pT)	T1	Confined to seroma or a layer on luminal side of capsule	IA	T1 N0 M0
	T2	Early capsule infiltration	IB	T2 N0 M0
	T3	Cell aggregates or sheets infiltrating the capsule	IC	T3 N0 M0
	T4	Lymphoma infiltrates beyond the capsule	IIA	T4 N0 M0
Regional lymph nodes (cN/pN)	N0	No lymph node involvement	IIB	T1-3 N1 M0
	N1	One regional lymph node positive	III	T4 N1-2 M0
	N2	Multiple regional lymph nodes positive	IV	T any N any M1
Metastasis (cM/pM)	M0	No distant spread		
	M1	Spread to other organs or distant sites		

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## Breast Implant Capsule-Associated Squamous Cell Carcinoma


- By March 22, 2023, the FDA had reported 19 cases of BIA-SCC; 21 cases were described up to 5/2023 (J Surg Oncol. 2023;128(4):495-501)
- BIA-SCC occurred approximately 7 to 42 years after initial implant placement (median time 18 years) in aesthetic and reconstructive cases
- BIA-SCC was located in the capsule around the breast implant, often in the posterior aspect
- There is not a consistent type of implant (textured vs. smooth), content (silicone vs. saline), or location (subglandular vs. retropectoral) that is associated with BIA-SCC
- Periprosthetic fluid should be sent for CK5/6 and p63, should be rich in keratin and cytology should display abnormal squamous cells
- Initial presentation with breast pain, erythema and swelling
- Overall poorer prognosis
  - 7/21 cases had recurrent cancer within 12 months after definitive resection
  - in a review of 18 cases the estimated 12-month mortality rate was 23.8% (calculated from 10 cases with survival data reported)
- In this limited cohort it is difficult to ascribe prognostic factors, but extracapsular extension does appear to be a concerning finding.

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## Systemic Symptoms Associated with Breast Implants = SSBI


Breast Implant Illness (BII); Autoimmune syndrome induced by adjuvants (ASIA); Shoenfeld's syndrome; Silicone implant incompatibility syndrome (SIIS);

- Summarize a variety of systemic symptoms that have been reported by some women following reconstruction or augmentation with breast implants, independent of the type of implant, filling, shape or surface characteristics, with an onset anywhere from immediately after implantation to years later
- The most frequent systemic symptoms reported in the FDA MDR database (sorted by frequency more to less common):
 


>40%	Fatigue
>30%	Joint pain
>20%	Brain fog, Autoimmune diseases, Hair loss
10-20%	Depression, Rash, Headache, Weight changes
- Currently SSBI are not recognized as a formal medical diagnosis
- SSBI remain a diagnosis of exclusion, there are no specific tests or defined criteria to characterize it
- Any persistent symptoms reported by patients with breast implants should be evaluated for other medical diseases prior to consider implant removal surgery
- Breast implant explantation can show significant improvement of systemic complaints as well as improvement of overall quality of life

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## BIA-ALCL – EUSOMA-Recommendation

- **Despite an increase of BIA-ALCL in association with textured 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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	Oxford		
	LoE	GR	AGO
<ul style="list-style-type: none"> <li>Insufficient evidence to conclude superiority of the prepectoral or subpectoral approach</li> </ul>	3a	C	+/-
<ul style="list-style-type: none"> <li>Acellular dermal matrix (ADM)               <ul style="list-style-type: none"> <li>subpectoral</li> </ul> </li> </ul>	1b	A	+/-
<ul style="list-style-type: none"> <li>prepectoral</li> </ul>	2b	B	+/-
<ul style="list-style-type: none"> <li>Synthetic meshes               <ul style="list-style-type: none"> <li>subpectoral</li> </ul> </li> </ul>	2b	B	+/-
<ul style="list-style-type: none"> <li>prepectoral</li> </ul>	2b	B	+/-

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## Lipotransfer

Oxford		
LoE	GR	AGO
<b>2a</b>	<b>B</b>	<b>+</b>
<b>2a</b>	<b>B</b>	<b>+</b>
<b>2a</b>	<b>B</b>	<b>+/-</b>

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


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<b>Pedicated Flap Reconstruction</b>			
	<b>Oxford</b>		
	<b>LoE</b>	<b>GR</b>	<b>AGO</b>
▪ <b>TRAM, latissimus dorsi flap (both can be performed as muscle-sparing techniques)</b>	<b>2a</b>	<b>C</b>	<b>+</b>
▪ <b>Delayed TRAM in high-risk patients</b>	<b>3a</b>	<b>B</b>	<b>+</b>
▪ <b>Ipsilateral pedicled TRAM</b>	<b>2a</b>	<b>B</b>	<b>+</b>
▪ <b>Omentum Flap</b>	<b>4</b>	<b>C</b>	<b>+/-</b>
▪ <b>Radiotherapy:</b>			
▪ <b>Breast reconstruction following radiotherapy</b>	<b>2a</b>	<b>B</b>	<b>+</b>
▪ <b>Breast reconstruction prior to radiotherapy</b>	<b>2a</b>	<b>B</b>	<b>+/-</b>
<b>(higher rates of fibrosis, wound healing disorders, liponecrosis and reduced aesthetic outcome)</b>			

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## Free Flaps for Reconstruction

	Oxford		
	LoE	GR	AGO
▪ <b>DIEP</b> (deep inferior epigastric artery perforator)	2a	B	+
▪ <b>Free TRAM</b> (transverse rectus abdominis myocutaneus)	2a	B	+
▪ <b>SIEA</b> (superficial inferior epigastric artery)	3a	C	+/-
▪ <b>Glutealis flaps (SGAP</b> [superior gluteal artery perforator] / <b>IGAP</b> [inferior gluteal artery perforator], <b>FCI</b> [fasciocutaneous infragluteal])	4	C	+/-
▪ <b>Free gracilis flap (TMG, transverse myocutaneous gracilis)</b>	4	C	+/-
▪ <b>PAP</b> (profunda artery perforator)	2b	B	+/-
▪ <b>Omentum Flap</b>	4	C	+/-
<b>Use of ICG* to assess flap perfusion</b>	2a	B	+

**Advantages**

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

**Disadvantages**


- Time- and personnel consuming microsurgical procedures, intensified postoperative monitoring

\* ICG: indocyanin green


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## Pedicled versus Free Tissue Transfer

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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 with all flap techniques**

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<b>Skin-/ Nipple-Sparing Mastectomy (SSM / NSM) and Reconstruction</b>			
	Oxford		
	LoE	GR	AGO
<ul style="list-style-type: none"> <li>▪ <b>Skin-/nipple-sparing Mastectomy (SSM / NSM)</b> <ul style="list-style-type: none"> <li>▪ <b>Oncologically safe (equivalent recurrence rate as in total mastectomy in suitable patients)</b></li> <li>▪ <b>Higher QoL</b></li> <li>▪ <b>NAC can be preserved under special conditions</b> <ul style="list-style-type: none"> <li>▪ <b>Feasible after mastopexy / reduction mammoplasty</b></li> <li>▪ <b>Use of ICG* to predict skin necrosis</b></li> </ul> </li> </ul> </li> <li>▪ <b>Skin incisions → different possibilities:</b> <ul style="list-style-type: none"> <li>▪ <b>Periareolar</b></li> <li>▪ <b>Hemi-periareolar with / without medial / lateral extension</b></li> <li>▪ <b>Reduction pattern: „inverted-T“ or vertical</b></li> <li>▪ <b>Inferior lateral approach, inframammary fold</b> <ul style="list-style-type: none"> <li>▪ <b>Lowest incidence of complications</b></li> </ul> </li> </ul> </li> </ul>			
	2b	B	++
	2b	B	++
	2b	B	++
	4	C	++
	1b	B	+
	2b	B	+



\* ICG = Indocyanine Green

  
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## Mastectomy + Reconstruction

### Risk of complications with the addition of radiotherapy

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

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<b>Prevention and Therapy of Capsular Contracture</b>			
	<b>Oxford</b>		
	<b>LoE</b>	<b>GR</b>	<b>AGO</b>
<b>Prevention</b>			
▪ Textured implantats (Caveat: BIA-ALCL)	<b>1a</b>	<b>A</b>	<b>+</b>
▪ Acellular Dermal Matrix (ADM) vs. nil	<b>2a</b>	<b>B</b>	<b>+</b>
▪ Synthetic mesh vs. nil	<b>3a</b>	<b>C</b>	<b>+</b>
▪ Topical antibiotics / antiseptics	<b>2a</b>	<b>B</b>	<b>+</b>
▪ PVP (Povidone-Iodine)	<b>2a</b>	<b>B</b>	<b>+/-</b>
▪ Leukotriene-antagonists	<b>2a</b>	<b>B</b>	<b>+/-</b>
▪ Breast massage	<b>3a</b>	<b>C</b>	<b>-</b>
<b>Surgical interventions</b>			
▪ Capsulectomy	<b>3b</b>	<b>C</b>	<b>+</b>
▪ Capsulotomy (Caveat: exclusion of BIA-ALCL)	<b>3b</b>	<b>C</b>	<b>+</b>

Povidone-Iodine:

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Topical antibiotic irrigation:

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Mesh:

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		Oxford	
		LoE	GR
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<p> <b>Incidence: approx. 5-10 % (2-50 %)</b> </p>		2a	B
<p><b>Influencing factors:</b></p>			
<p> <b>History of radiation increases risk (RR approx. 3)</b> </p>		2a	B
<p> <b>Obesity increases risk (e.g. BMI &gt; 30 vs. &lt; 30; RR approx. 3)</b> </p>		2a	B
<p> <b>Use of ADM increases risk (RR approx. 3)</b> </p>		2a	B
<p> <b>Use of expander with smooth surface increases risk (RR approx. 5)</b> </p>		3b	C
<p> <b>History of neoadj. chemotherapy does not appear to increase risk</b> </p>		2a	B
<p> <b>Prepectoral approach does not appear to increase risk</b> </p>		2b	B

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		Oxford		
		LoE	GR	AGO
<b>Prevention</b>				
▪	<b>Drain</b>	<b>3b</b>	<b>C</b>	<b>+</b>
▪	<b>Drain removal at &lt; 30ml per 24 hours</b>	<b>2b</b>	<b>B</b>	<b>+</b>
<b>Therapy</b>				
▪	<b>Evacuation of serma by FNA or re-insertion of drain</b>	<b>4</b>	<b>C</b>	<b>+</b>
▪	<b>Pressure dressing</b>	<b>5</b>	<b>D</b>	<b>+/-</b>
▪	<b>Revision surgery with capsulectomy (ultima ratio)</b>	<b>5</b>	<b>D</b>	<b>+</b>
▪	<b>Revision surgery with implant removal (ultima ratio)</b>	<b>5</b>	<b>D</b>	<b>+</b>

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<b>Skin necrosis after mastectomy</b>			
	<b>Oxford</b>		
	<b>LoE</b>	<b>GR</b>	<b>AGO</b>
<b>Prevention</b>			
▪ Local nitroglycerin *	1a	A	+
▪ Closed-incision negative pressure therapy (ciNPT)	2a	B	+/-
▪ Local dimethylsulfoxid	2b	B	+/-
▪ Oral cilostazol	2b	B	+/-
▪ Preoperative local heat preconditioning	2b	B	+/-

\* Dose and regimen vary between studies, off-label



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## Efficacy and safety of topical nitroglycerin in the prevention of mastectomy flap necrosis – a systematic review and meta-analysis


Wang P et al. Sci Rep 2020

- **7074 patients (3 randomized clinical trials, 2 retrospective cohort studies)**
- **Intervention: transdermal nitroglycerin treatment (ointment; 4.5-45 mg nitroglycerin, applied immediately after end of surgery and in some studies in the first postoperative period until day 6)**
- **Nitroglycerin significantly reduced the mastectomy flap necrosis rate (immediate breast reconstruction [IBR]: OR, 0.48, 95% CI, 0.33–0.70, P < 0.01)**
- **Full-thickness flap necrosis rate in patients receiving IBR was significantly lower in the nitroglycerin group than in the control group (OR, 0.42; 95% CI, 0.25–0.70; P < 0.01)**

1. Wang P, Gu L, Qin Z et al. Efficacy and safety of topical nitroglycerin in the prevention of mastectomy flap necrosis: a systematic review and meta-analysis. Sci Rep. 2020 Apr 21;10(1):6753



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## Siliconomas

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- In breast parenchyma or regional lymph nodes, rarely in distant organs (pleura, ribs, muscles)
- Incidence unclear
- May occur with or without implant rupture (“silicone bleeding”)
- Migration of silicone to the lymph nodes takes 6-10 years
- Risk of malignancy is not increased

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

- Asymptomatic siliconomas do not require removal
- Complete removal of implant and silicone gel (in capsule, if possible) in case of implant rupture

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## Surgical Prevention

	Oxford		
	LoE	GR	AGO
▪ Risk-reducing unilateral or bilateral mastectomy (RRME) without the presence of clearly defined genetic risk factors	2a	B	-*
▪ Axillary dissection or Sentinel lymph node excision during RRME	2a	B	--

\* study participation recommended

### RRME ohne gentisches Risiko

1. Kurian AW, Lichtensztajn DY, Keegan TH, et al. Use of and mortality after bilateral mastectomy compared with other surgical treatments for breast cancer in California, 1998-2011. JAMA. 2014;312(9):902-14.
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### Sentinel-Lymphknoten Exzision bei RRME

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

	Oxford		
	LoE	GR	AGO
<ul style="list-style-type: none"> <li>▪ <b>Risk-reducing bilateral salpingo-oophorectomy (RR-BSO)**</b> <ul style="list-style-type: none"> <li>▪ Reduces OvCa incidence and mortality</li> <li>▪ Reduces overall mortality</li> </ul> </li> </ul>	2a	B	
<ul style="list-style-type: none"> <li>▪ <b>Risk-reducing bilateral mastectomy (RR-BM)</b> <ul style="list-style-type: none"> <li>▪ Reduces BC incidence</li> <li>▪ Reduces BC mortality in <i>BRCA1</i> mutation carriers***</li> </ul> </li> </ul>	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.

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Breast Cancer Risk in BRCA1 and BRCA2 Mutation Carriers. *J Natl Cancer Inst.* 2016 Sep 6;109(1). doi: 10.1093/jnci/djw177. Print 2017 Jan.

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

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

\* Study participation recommended  
 \*\* Depends on tumor stage (FIGO I/II), recurrence free interval (≥ 5 yrs.), age

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