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Guidelines Breast
Version 2024.1D

In Zusammen-
arbeit mit:



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Diagnostik und Therapie früher und fortgeschrittener Mammakarzinome

Onkoplastische und rekonstruktive Mammachirurgie



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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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STRAHALTHERAPEUTISCHE
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MAMMA

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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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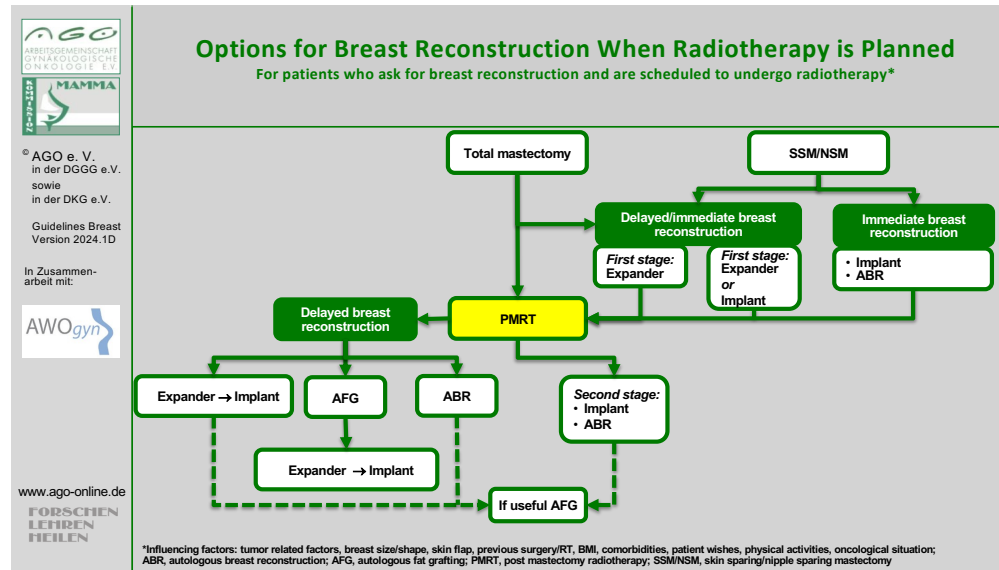
Onkoplastische brusterhaltende Operation (OPS)

	Oxford		
	LoE	G R	AGO
▪ OPS kann in ausgewählten Fällen eine Mastektomie ersetzen	2b	B	+
▪ auch bei multizentrischen/multifokalen Tumoren	2b	B	+
▪ OPS und BEO sind onkologisch gleichwertig	2a	B	++
▪ Komplikationsraten nach OPS und BEO sind vergleichbar	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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for Reexcision: A Database Evaluation. *Ann Plast Surg.* 2022 Dec 1;89(6):e11-e17.

8. Oberhauser I, Zeindler J, Ritter M et al. Impact of Oncoplastic Breast Surgery on Rate of Complications, Time to Adjuvant Treatment, and Risk of Recurrence. *Breast Care (Basel).* 2021 Oct;16(5):452-460.
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- Systematic Review and Meta-analysis. *Plast Reconstr Surg Glob Open*. 2020 Oct 29;8(10):e3120.
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Breast Reconstruction Principles Good Clinical Practice

AGO: ++

- **Planning of breast reconstruction 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 indicated based on tumor biology) in case of unfavorable breast-tumor relation**
- **Consideration of contralateral breast:**
 - **Discuss symmetrization procedures**
- **Preference for less radical 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. Patient Reported Outcome (PRO)**
- **Oncologic safety is not impaired**

1. Khajuria A, Prokopenko M, Greenfield M et al. A Meta-analysis of Clinical, Patient-Reported Outcomes and Cost of DIEP versus Implant-based Breast Reconstruction. *Plast Reconstr Surg Glob Open*. 2019 Oct 28;7(10):e2486.
2. Phan R, Hunter-Smith DJ, Rozen WM. The use of Patient Reported Outcome Measures in assessing patient outcomes when comparing autologous to alloplastic breast reconstruction: a systematic review. *Gland Surg*. 2019 Aug;8(4):452-460.
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Mastektomie und Möglichkeiten der Rekonstruktion

	Oxford		
	LoE	GR	AGO
▪ Heterologe Rekonstruktion*	2a	B	+
▪ Autologer Gewebetransfer	2a	B	+
▪ Gestielter Gewebetransfer	2a	B	+
▪ Freier Gewebetransfer (mit Gefäßanastomosen)	2a	B	+
▪ Autologer Gewebetransfer kombiniert mit Implantaten	3a	C	+/-

Cave: BMI > 30, Raucher, Diabetes, Strahlentherapie, Alter, bilaterale Mastektomie

* Dokumentation in Implantateregister

<https://www.bundesgesundheitsministerium.de/implantateregister-deutschland>

Der Regelbetrieb mit verpflichtender Meldung von Brustimplantaten durch die Gesundheitseinrichtungen startet am 1. Juli 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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5. Saldanha IJ, Broyles JM, Adam GP et al. Implant-based Breast Reconstruction after Mastectomy for Breast Cancer: A Systematic Review and Meta-analysis. Plast Reconstr Surg Glob Open. 2022 Mar 18;10(3):e4179.
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Jun;84(6S Suppl 5):S396-S400.

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10. Singh N, Picha GJ, Hardas B et al. Five-Year Safety Data for More than 55,000 Subjects following Breast Implantation: Comparison of Rare Adverse Event Rates with Silicone Implants versus National Norms and Saline Implants. *Plast Reconstr Surg.* 2017 Oct;140(4):666-679.
11. Zhu L, Mohan AT, Abdelsattar JM et al. Comparison of subcutaneous versus submuscular expander placement in the first stage of immediate breast reconstruction. *J Plast Reconstr Aesthet Surg.* 2016 Apr;69(4):e77-86.



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Zeitpunkt der Rekonstruktion

	Oxford		
	LoE	GR	AGO
<ul style="list-style-type: none"> ▪ Sofortrekonstruktion <ul style="list-style-type: none"> ▪ Vermeiden des Postmastektomie-Syndroms 	3b	B	++
<ul style="list-style-type: none"> ▪ Spätrekonstruktion (zweizeitig) <ul style="list-style-type: none"> ▪ Keine Verzögerung von adjuvanten Therapien (CTx, RT) ▪ Nachteil: Verlust des Hautmantels 	3b	B	++
<ul style="list-style-type: none"> ▪ Verzögerte Rekonstruktion (Platzhalter vor definitiver Rekonstruktion) („Delayed-immediate reconstruction“) 	3b	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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10. Jagsi R, Jiang J, Momoh AO et al. Complications After Mastectomy and Immediate Breast Reconstruction for Breast Cancer: A Claims-Based Analysis. *Ann Surg*. 2016 Feb;263(2):219-27
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12. Sharpe SM, Liederbach E, Czechura T et al. Impact of bilateral versus unilateral mastectomy on short term outcomes and adjuvant therapy, 2003-2010: a report from the National Cancer Data Base. *Ann Surg Oncol*. 2014 Sep;21(9):2920-7.

Zeitpunkt der Rekonstruktion mit Implantaten und Bezug zur Strahlentherapie

	Oxford		
	LoE	GR	AGO
▪ Implantat-Rekonstruktion			
▪ ohne Radiotherapie (RT)	2a	B	+
▪ vor RT	2a	B	++
▪ nach RT	2a	B	+
▪ nach sekundärer Mastektomie nach BET	2b	B	+/-
	2a	B	+/-

1. Awadeen A, Fareed M, Elameen AM. The Impact of Postmastectomy Radiation Therapy on the Outcomes of Prepectoral Implant-Based Breast Reconstruction: A Systematic Review and Meta-Analysis. *Aesthetic Plast Surg.* 2023 Feb;47(1):81-91.
2. Nelson JA, Cordeiro PG, Polanco T et al. Association of Radiation Timing with Long-Term Satisfaction and Health-Related Quality of Life in Prosthetic Breast Reconstruction. *Plast Reconstr Surg.* 2022 Jul 1;150(1):32e-41e.
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definitive implant in patients undergoing one- and two-stage implant-based breast reconstruction: A systematic review and meta-analysis. *J Plast Reconstr Aesthet Surg.* 2017 Oct;70(10):1329-1335.

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14. Valdatta L, Cattaneo AG, Pellegatta I et al. Acellular dermal matrices and radiotherapy in breast reconstruction: a systematic review and meta-analysis of the literature. *Plast Surg Int.* 2014;2014:472604.

Antibiose und Brustrekonstruktion

	Oxford		
	LoE	GR	AGO
Heterologe Rekonstruktion:			
▪ Perioperative antibiotische Prophylaxe (max. 24 h)	1a	A	+
▪ Verlängerte antibiotische Prophylaxe > 24 h	2a	B	+/-
Autologe Rekonstruktion:			
▪ Perioperative antibiotische Prophylaxe (max. 24 h)	2b	B	+
▪ Verlängerte antibiotische Prophylaxe > 24 h	2a	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.
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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
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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.
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Tranexamsäure in der komplexen Brustchirurgie

	Oxford		
	LoE	GR	AGO
Prävention von:			
▪ Hämatom	2a	B	+/-
▪ Serom	2a	B	+/-
Kein erhöhtes Risiko für thromboembolische Komplikationen im Kollektiv ohne thromboembolische Anamnese	2a	B	+

CAVE: Unterschiedliche Dosierungen und Applikationsformen (lokal, i.v., oral) in bisherigen Studien, Anamnese hinsichtlich thromboembolischer Ereignisse beachten

Metaanalysen:

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:

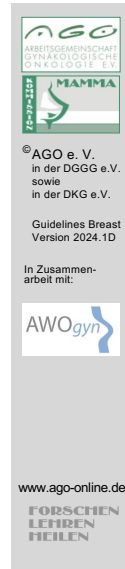
1. Ausen K, Hagen AI, Østbyhaug HS et al. Topical moistening of mastectomy wounds with diluted tranexamic acid to reduce bleeding: randomized clinical trial. BJS Open. 2020 Apr;4(2):216-224

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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Brustimplantat-assoziierte Erkrankungen

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

Brustimplantat-assoziiertes großzellig-anaplastisches Lymphom

BIA-SCC = Breast implant-associated squamous cell carcinoma

Brustimplantat-assoziiertes Plattenepithelkarzinom

SSBI = Systemic Symptoms Associated with Breast Implants

Brustimplantat-assoziierte systemische Symptome

Synonyme:

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,
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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*

(Basel). 2023 Sep 12;15(18):4516.

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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SSBI/BII


1. Cohen Tervaert JW, Martinez-Lavin M et al. Autoimmune/inflammatory syndrome induced by adjuvants (ASIA) in 2023. *Autoimmun Rev*. 2023 May;22(5):103287.
2. McGuire P, Clauw DJ, Hammer J et al. A Practical Guide to Managing Patients With Systemic Symptoms and Breast Implants. *Aesthet Surg J*. 2022 Mar 15;42(4):397-407
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Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)


- 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
- Number of global cases reported as MDR (medical device regulation) to the FDA by 30.06.2023: 1264 with 63 deaths
- 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)
- Prevalence and incidence vary greatly, as the number of women with implants can only be estimated
- The current lifetime risk ranges between 1:355 and 1:86,029 patients with textured implants
- Time interval between last implantation and lymphoma diagnosis: 8 years (median)
- 5-year-OS 89-92 %
- Clinical presentation
 - Frequently periprosthetic seroma, breast asymmetry
 - in rarer cases tumor, regional lymphadenopathy, skin rash and/or capsular contracture
- Tumor cells are CD30-positive / ALK-negative
- Obligation to notify the BfArM as SAE according to §3 MPSV*

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

1. https://www.bfarm.de/SharedDocs/Risikoinformationen/Medizinprodukte/DE/Brustimplantate_ALCL_FDA.html (access 20.01.2024)
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3. <https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma>, letzter Zugriff 01.01.2024
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BIA-ALCL– Diagnostik

	Oxford		
	LoE	GR	AGO
▪ Sonographie (Abklärung neu aufgetretener Serome 1 Jahr nach Implantateinlage, Herdbefunden, Axilla-LK)	3a	D	++
▪ Erguss-Zytologie bei Späterom	3a	D	++
▪ Untersuchung von mind. 50 ml			
▪ komplette Aufarbeitung inkl. BIA-ALCL spezifische Diagnostik (CD 30+)			
▪ Flowzytometrie (T-Zell-Klon)			
▪ Stanzbiopsie bei soliden Herdbefunden	3a	D	++
▪ Mamma-MRT bei Bestätigung der Diagnose	3a	D	++
▪ Staging (PET-CT, alternativ CT [Hals bis Becken])	3a	D	++
▪ Lymphomdiagnostik am Resektat und histologisches Staging	3a	D	++
▪ Dokumentation des Implantates in Register *	5	D	++

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

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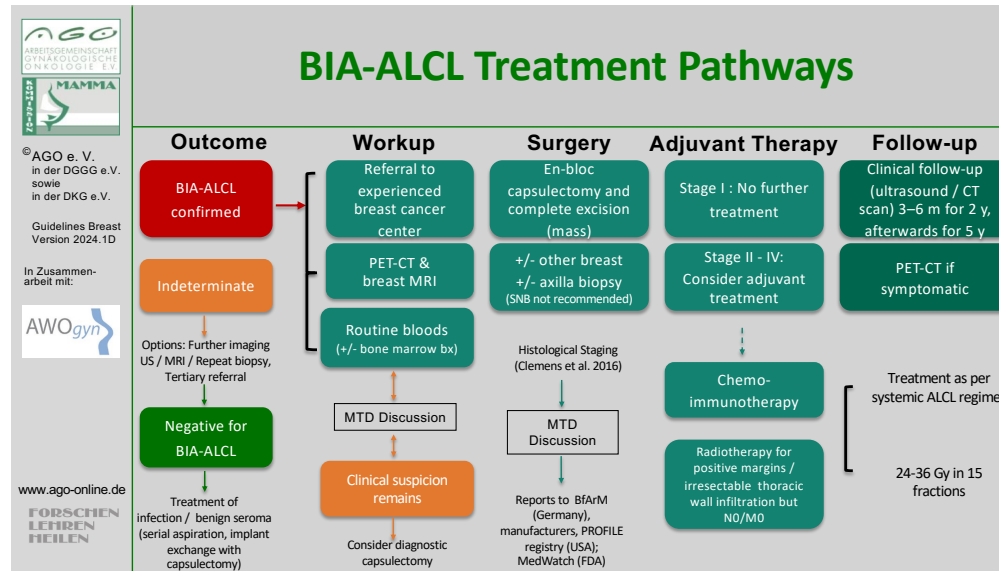
BIA-ALCL – Therapie

	Oxford		
	LoE	GR	AGO
▪ Vorstellung im interdisziplinären Tumorboard (inkl. Lymphomspezialist)	5	D	++
▪ Implantatentfernung und vollständige Kapsulektomie einschließlich Tumorentfernung	3a	C	++
▪ Kontralaterale Implantatentfernung und Kapsulektomie bei Implantateinlage bds. (4-6% bilaterale BIA-ALCL)	4	D	+/-
▪ Entfernung suspekter Lymphknoten, keine routinemäßige Sentinel-Lymphknoten-Exzision oder Axilladissektion	4	D	++
▪ Stadienabhängige lymphomspezifische Systemtherapie	4	D	+
▪ Radiotherapie bei nicht resektablen Tumoren oder R1	5	D	+/-


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TNM Staging of BIA-ALCL

	TNM-Kategorie	Definition	Stage	Definition
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		

1. NCCN-Guidelines, T-Cell Lymphomas, Version 1.2024, https://www.nccn.org/professionals/physician_gls/pdf/t-cell.pdf
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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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Implantatloge, Netze und ADMs mit Implantat- rekonstruktion- Endpunkt QoL / Komplikationen

	Oxford		
	LoE	GR	AGO
▪ Unzureichende Evidenz bzgl. der Prothesenloge	3a	C	+/-
▪ Azelluläre Dermis (ADM)			
▪ subpektoral	1b	A	+/-
▪ präpektoral	2b	B	+/-
▪ Synthetische Netze			
▪ subpektoral	2b	B	+/-
▪ präpektoral	2b	B	+/-

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Lipotransfer

- **Lipotransfer nach Mastektomie und
Rekonstruktion**
- **Lipotransfer nach brusterhaltender Therapie**
- **Mit Stammzellen angereicherte,
autologe Fettgewebstransplantation vs. ohne
Stammzellen**

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

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Gestielte Lappen zur Rekonstruktion

	Oxford		
	LoE	GR	AGO
▪ TRAM, Latissimus-dorsi-Lappen (können muskel-sparend präpariert werden)	2a	C	+
▪ Delayed-TRAM bei Risikopatientinnen	3a	B	+
▪ Ipsilateral gestielter TRAM	2a	B	+
▪ Omentum Flap	4	C	+/-
▪ Radiotherapie:			
▪ Brustrekonstruktion nach RT	2a	B	+
▪ Brustrekonstruktion vor RT	2a	B	+/-

(erhöhte Rate an Fibrosen, Wundheilungsstörungen, Lipoidnekrosen, reduziertes ästhetisches Outcome)

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Freie Lappen zur Rekonstruktion

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	LoE	GR	AGO
▪ DIEP (deep inferior epigastric artery perforator)	2a	B	+
▪ Freier TRAM (transverse rectus abdominis myocutaneus)	2a	B	+
▪ SIEA (superficial inferior epigastric artery)	3a	C	+/-
▪ Gluteallappen (SGAP [superior gluteal artery perforator] / IGAP [inferior gluteal artery perforator], FCI [fasciocutaneous infragluteal])	4	C	+/-
▪ Free gracilis flap (TMG, transverse myocutaneous gracilis)	4	C	+/-
▪ PAP (profunda artery perforator)	2b	B	+/-
▪ Omentum Lappen	4	C	+/-
Nutzung von ICG*-Angiographie zur Perfusionsbeurteilung	2a	B	+
Vorteile			
▪ Freier TRAM und DIEP sind potenziell muskelsparend; DIEP hat niedrige Rate an Hernien, vor allem bei Adipositas			
Nachteile			
▪ Zeit- und personalintensive mikrochirurgische Techniken, aufwendige postoperative Überwachung			

*ICG - Indocyaningrün

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Gestielter vs. freier Gewebettransfer

Oxford		
LoE	GR	AGO
3a	A	++

- **Muskelsparende Techniken und sorgfältiger Verschluss der Bauchdecke führen zu niedrigen Komplikationsraten unabhängig von der verwendeten Methode**
- **Autologer Gewebettransfer von der Bauchdecke hat die höchste Zufriedenheitsrate (PROM)**
- **Morbidität der Spenderregion (z. B. reduzierte Muskelfunktion) kann bei allen Lappentechniken auftreten**

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Haut / Nippel-sparende Mastektomie (SSM / NSM) und Rekonstruktion

	Oxford		
	LoE	GR	AGO
<ul style="list-style-type: none"> ▪ Hautsparende Mastektomie (SSM / NSM) <ul style="list-style-type: none"> ▪ Sicher (gleiche Rezidivrate wie bei Mastektomie bei geeigneter Pat.auswahl) ▪ Höhere Lebensqualität für Patientin ▪ Erhalt des Mamillen-Areola-Komplex unter bestimmten Bedingungen <ul style="list-style-type: none"> ▪ Möglich nach Mastopexie / Reduktionsplastik ▪ Nutzung von ICG* zur Vorhersage von Nekrosen ▪ Hautschnitte → verschiedene Möglichkeiten: <ul style="list-style-type: none"> ▪ Periareolär ▪ Hemi-periareolär mit / ohne medialer / lateraler Erweiterung ▪ Reduktionsschnittbild: „inverses T“ oder vertikal ▪ Inferior-lateraler Zugang / Inframammärfalte <ul style="list-style-type: none"> ▪ Niedrigste Inzidenz von Komplikationen 	<p>2b</p> <p>2b</p> <p>2b</p> <p>4</p> <p>1b</p> <p></p> <p></p> <p></p> <p></p> <p>2b</p>	<p>B</p> <p>B</p> <p>B</p> <p>C</p> <p>B</p> <p></p> <p></p> <p></p> <p>B</p>	<p>++</p> <p>++</p> <p>++</p> <p>++</p> <p>+</p> <p></p> <p></p> <p></p> <p>+</p>

* ICG = Indocyaningrün

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<h2 style="text-align: center;">Mastectomy + Reconstruction</h2> <h3 style="text-align: center;">Risk of complications with the addition of radiotherapy</h3>			
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 assessment of the aesthetic outcome.
NA: not available



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5;9(11):e3910



Prävention und Therapie der Kapselfibrose

	Oxford		
	LoE	GR	AGO
<ul style="list-style-type: none"> ▪ Prävention ▪ Texturierte Implantate (Cave: Aufklärung BIA-ALCL) ▪ Azelluläre dermale Matrix (ADM) vs. nil ▪ Synthetisches Netz vs. nil ▪ Lokale Antibiotika / Antiseptika ▪ PVP (Povidone-Iodine) ▪ Leukotrien-Antagonisten ▪ Brustmassage ▪ Chirurgische Interventionen ▪ Kapsulektomie ▪ Kapsulotomie (Cave: Ausschluss BIA-ALCL) 	<p>1a</p> <p>2a</p> <p>3a</p> <p>2a</p> <p>2a</p> <p>2a</p> <p>3a</p> <p>3b</p> <p>3b</p>	<p>A</p> <p>B</p> <p>C</p> <p>B</p> <p>B</p> <p>B</p> <p>C</p> <p>C</p> <p>C</p>	<p>+</p> <p>+</p> <p>+</p> <p>+</p> <p>+/-</p> <p>+/-</p> <p>-</p> <p>+</p> <p>+</p>

Povidone-Iodine:

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Topical antibiotic irrigation:

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1. Han SE, Lee KT, Bang S. Comprehensive Comparison Between Shaped Versus Round Implants for Breast Reconstruction: A Systematic Review and Meta-Analysis. *Aesthet Surg J*. 2021 Jan 1;41(1):34-44
2. Liu X, Zhou L, Pan F et al. Comparison of the postoperative incidence rate of capsular contracture among different breast implants: a cumulative meta-analysis. *PLoS One*. 2015 Feb 13;10(2):e0116071
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ADM:

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Serome nach Implantatrekonstruktion I

	Oxford	
	LoE	GR
▪ Inzidenz: ca. 5-10 % (2-50 %)	2a	B
Einflussfaktoren:		
▪ Z. n. Radiatio erhöht Risiko (RR ca. 3)	2a	B
▪ Adipositas erhöht Risiko (z. B. BMI > 30 vs. < 30; RR ca. 3)	2a	B
▪ Einsatz von ADM erhöht Risiko (RR ca. 3)	2a	B
▪ Glatte Expander erhöhen Risiko (RR ca. 5)	3b	C
▪ Z. n. neoadjuvanter Chemotherapie erhöht Risiko eher nicht	2a	B
▪ Subcutane Loge erhöht Risiko eher nicht	2b	B

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Serome nach Implantatrekonstruktion II

	Oxford		
	LoE	GR	AGO
Prävention			
▪ Drainage	3b	C	+
▪ Entfernung der Drainage bei Fördermenge < 30ml	2b	B	+
Therapie			
▪ Repetitive Serompunktionen oder Drainagen-Einlage	4	C	+
▪ Druckverband	5	D	+/-
▪ Revision mit Kapsulektomie (ultima ratio)	5	D	+
▪ Revision mit Implantatentfernung (ultima ratio)	5	D	+

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Nekrosen des Hautmantels nach Mastektomie

Prävention

- Nitroglycerin lokal *
- Unterdrucktherapie (ciNPT)
- Dimethylsulfoxid lokal
- Cilostazol oral
- Präoperative lokale Wärmetherapie

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

* Unterschiedliche Dosierungsschemata in Studien, off-label
ciNPT – closed incision negative pressure therapy

Meta-analysis of all techniques:

1. Tang N, Li H, Chow Y et al. Non-operative adjuncts for the prevention of mastectomy skin flap necrosis: a systematic review and meta-analysis. ANZ J Surg. 2023 Jan;93(1-2):65-75

Nitroglycerin / glycerol nitrate: meta-analyses:

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
2. Vania R, Pranata R, Irwansyah D et al. Topical nitroglycerin is associated with a reduced mastectomy skin flap necrosis-systematic review and meta-analysis. J Plast Reconstr Aesthet Surg. 2020 Jun;73(6):1050-1059

Nitroglycerin / glycerol nitrate: randomized studies:

1. Gdalevitch P, Van Laeken N, Bahng S et al. Effects of nitroglycerin ointment on mastectomy flap necrosis in immediate breast reconstruction: a randomized controlled trial. Plast Reconstr Surg. 2015 Jun;135(6):1530-1539

2. Fan Z, He J. Preventing necrosis of the skin flaps with nitroglycerin after radical resection for breast cancer. *J Surg Oncol.* 1993 Jul;53(3):210
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Nitroglycerin / glycerol nitrate: prospective cohort studies:

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Nitroglycerin / glycerol nitrate: retrospective cohort studies:

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Closed incision negative pressure therapy:

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Dimethylsulfoxid:


1. Celen O, Yildirim E, Berberoglu U. Prevention of wound edge necrosis by local application of dimethylsulfoxide. Acta Chir Belg. 2005 May-Jun;105(3):287-90

Cilostazol:


1. Ghosh M, Sen D, Sengupta SG et al. Mastectomy Flap Necrosis: The Role of Cilostazol in Prevention. International Journal of Research and Review Vol.7; Issue: 8; August 2020, E-ISSN: 2349-9788; P-ISSN: 2454-2237

Local heat preconditioning:

1. Mehta S, Rolph R, Cornelius V et al. Local heat preconditioning in skin sparing mastectomy: a pilot study. J Plast Reconstr Aesthet Surg. 2013 Dec;66(12):1676-82



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MAMMA

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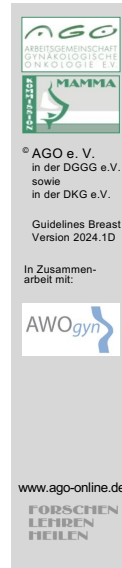
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Efficacy and safety of topical nitroglycerin in the prevention of mastectomy flap necrosis – a systematic review and meta-analysis

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



Silikonome

- Im Mammaparenchym oder regionalen Lymphknoten, seltener in distanten Organen (Pleura, Rippen, Muskulatur)
- Inzidenz unklar
- Auftreten mit oder ohne Implantatruptur ("Silikon-Bleeding") möglich
- Migration des Silikons in die Lymphknoten dauert ca. 6-10 Jahre
- Kein Anhalt für erhöhtes Malignitätsrisiko

Oxford		
LoE	GR	AGO

- Entfernung asymptomatischer Silikonome nicht notwendig
- Vollständige Entfernung von Implantat (nach Möglichkeit in der Kapsel) und Silikon bei Implantatruptur

2b	B	+
2b	B	+

1. U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health. Breast Implants - Certain Labeling Recommendations to Improve Patient Communication, Guidance for Industry and Food and Drug Administration, issued on September 29, 2020, accessed: 31 Dec 2023
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3. Elahi L, Meuwly MG, Meuwly JY et al. Management of Contralateral Breast and Axillary Nodes Silicone Migration after Implant Rupture. Plast Reconstr Surg Glob Open 2022 May 25;10(5):e4290
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5. Oh YH, Song SY, Lew DH et al. Distant Migration of Multiple Siliconomas in Lower Extremities following Breast Implant Rupture: Case Report. Plast Reconstr Surg Glob Open 2016 Oct 27;4(10):e1011
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11. Chetlen A, Niell BL, Brown A et al. ACR Appropriateness Criteria® Breast Implant Evaluation: 2023 Update. J Am Coll Radiol 2023 Nov;20(11S):S329-S350
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13. Kim HB, Han HH, Eom JS. Magnetic Resonance Imaging Surveillance Study of Silicone Implant-based Breast Reconstruction: A Retrospective Observational Study. Plast Reconstr Surg Glob Open 2023 Jun 9;11(6):e5031



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Chirurgische Prävention

	Oxford		
	LoE	GR	AGO
<ul style="list-style-type: none"> ▪ Risiko-reduzierende, unilaterale oder bilaterale Mastektomie (RRME) ohne Vorliegen von genetischen Risikofaktoren (führt nicht zu einer Mortalitätsreduktion) 	2a	B	-*
<ul style="list-style-type: none"> ▪ Axilladissektion oder Sentinel-Lymphknoten Exzision bei RRME 	2a	B	--


* Studienteilnahme empfohlen

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.
2. Copson ER, Maishman TC, Tapper WJ, et al: Germline BRCA mutation and outcome in young-onset breast cancer (POSH): a prospective cohort study. Lancet Oncol 2018, DOI: [http://dx.doi.org/10.1016/S1470-2045\(17\)30891-4](http://dx.doi.org/10.1016/S1470-2045(17)30891-4).

Sentinel-Lymphknoten Exzision bei RRME


1. Wong SM, Ferroum A, Apostolova C et al. Incidence of Occult Breast Cancer in Carriers of BRCA1/2 or Other High-Penetrance Pathogenic Variants Undergoing Prophylactic Mastectomy: When is Sentinel Lymph Node Biopsy Indicated? Ann Surg Oncol. 2022 Oct;29(11):6660-6668.



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Chirurgische Prävention bei gesunden BRCA1/2 Mutationsträgerinnen

	Oxford		
	LoE	GR	AGO
<ul style="list-style-type: none"> ▪ Risiko-reduzierende bilaterale Salpingo-Oophorektomie (RR-BSO)** <ul style="list-style-type: none"> ▪ reduziert die Eierstockkrebsinzidenz und -mortalität ▪ reduziert die Gesamtmortalität 	2a	B	
<ul style="list-style-type: none"> ▪ Risiko-reduzierende bilaterale Mastektomie (RRBM) <ul style="list-style-type: none"> ▪ reduziert die Brustkrebsinzidenz ▪ reduziert die Mortalität bei BRCA1 Mutationsträgerinnen*** 	2b	B	++*

* Studienteilnahme empfohlen
 ** Die RR-BSO wird ab ca. 35 Jahren für BRCA1 und ab ca. 40 Jahren für BRCA2 Mutationsträgerinnen unter Berücksichtigung des Erkrankungsalters in der Familie und des Familienplanungs-Status empfohlen.
 *** Für BRCA2 Mutationsträgerinnen konnte keine Mortalitätsreduktion gezeigt werden. RRBM Beratung sollte individualisiert durchgeführt werden.

1. Domchek SM, Friebel TM, Neuhausen SL, et al. Mortality after bilateral salpingo-oophorectomy in BRCA1 and BRCA2 mutation carriers: a prospective cohort study. *Lancet Oncol.* 2006;7(3):223-9.
2. Domchek SM, Friebel TM, Singer CF, et al. Association of risk-reducing surgery in BRCA1 or BRCA2 mutation carriers with cancer risk and mortality. *JAMA.* 2010;304(9):967-75.
3. Heemskerk-Gerritsen BAM, Seynaeve C, van Asperen CJ, et al.: Breast Cancer Risk After Salpingo-Oophorectomy in Healthy BRCA1/2 Mutation Carriers: Revisiting the Evidence for Risk Reduction. *JNCI J Natl Cancer Inst* (2015) 107(5): djv033
4. Heemskerk-Gerritsen BAM, Jager A, Koppert LB et al: Survival after bilateral risk-reducing mastectomy in healthy BRCA1 and BRCA2 mutation carriers. *Breast Cancer Res Treat* 2019, 177(3):723-733.
5. Hoogerbrugge N, Bult P, Bonenkamp JJ, et al. Numerous high-risk epithelial lesions in familial breast cancer. *Eur J Cancer.* 2006;42(15):2492-8.
6. Kauff ND, Satagopan JM, Robson ME, et al. Risk-reducing salpingo-oophorectomy in women with a BRCA1 or BRCA2 mutation. *N Engl J Med.* 2002;346(21):1609-15.
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10.1093/jnci/djw177. Print 2017 Jan.

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9. Mavaddat N, Antoniou AC, Mooij TM et al: Risk-reducing salpingo-oophorectomy, natural menopause, and breast cancer risk: an international prospective cohort of BRCA1 and BRCA2 mutation carriers. *Breast Cancer Res* 2020, 22(1):8.
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12. Rebbeck TR, Lynch HT, Neuhausen SL, et al. Prophylactic oophorectomy in carriers of BRCA1 or BRCA2 mutations. *N Engl J Med.* 2002;346(21):1616-22.
13. Xiao YL, Wang K, Liu Q, Li J, Zhang X, Li HY. Risk Reduction and Survival Benefit of Risk-Reducing Salpingo-oophorectomy in Hereditary Breast Cancer: Meta-analysis and Systematic Review. *Clin Breast Cancer.* 2019 Feb;19(1):e48-e65. doi: 10.1016/j.clbc.2018.09.011. Epub 2018 Oct 4. PMID: 30470623.

Risiko-reduzierende Interventionen bei erkrankten *BRCA1/2* Mutationsträgerinnen

	Oxford		
	LoE	GR	AGO
<ul style="list-style-type: none"> ▪ Risikoreduzierende Salpingo-Oophorektomie (RRSO, RR-BSO) <ul style="list-style-type: none"> ▪ reduziert Eierstockkrebsinzidenz und -mortalität ▪ reduziert die Gesamt mortalität (gegensätzliche Ergebnisse bzgl. kontralateraler Brustkrebsinzidenz) 	2b	B	+*
<ul style="list-style-type: none"> ▪ Risikoreduzierende kontralaterale Mastektomie (RRCM)* reduziert kontralaterale Brustkrebsinzidenz und die Mortalität 	2b	B	+*
<ul style="list-style-type: none"> ▪ Tamoxifen (reduziert kontralaterale Brustkrebsinzidenz) 	2b	B	+/-*
<ul style="list-style-type: none"> ▪ Indikationsstellung für RRCM sollte Alter, Ersterkrankungsalter und betroffenes Gen berücksichtigen. 	2a	B	++*
<ul style="list-style-type: none"> ▪ Risikoreduzierende bilaterale Mastektomie nach Ovarialkarzinom 	4	C	+/-**

* Gesamtprognose muss berücksichtigt werden, Studienteilnahme empfohlen, ** in Abhängigkeit vom Tumorstadium (FIGO I/II), rezidivfreier Zeit (≥ 5 Jahre), Alter

1. Domchek SM, Jhaveri K, Patil S et al. Risk of metachronous breast cancer after BRCA mutation associated ovarian cancer. *Cancer* 2013;119:1344-8.
2. Evans DG, Ingham SL, Baildam A, et al. Contralateral mastectomy improves survival in women with BRCA1/2-associated breast cancer. *Breast Cancer Res Treat.* 2013;140(1):135-42.
3. Fong A, Cass I, John C, Gillen J, Moore KM, Gangi A, Walsh C, Li AJ, Rimel BJ, Karlan BY, Amersi F. Breast Cancer Surveillance Following Ovarian Cancer in BRCA Mutation Carriers. *Am Surg.* 2020 Oct;86(10):1243-1247. doi: 10.1177/0003134820964208. Epub 2020 Oct 26. PMID: 33106023.
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