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Guidelines Breast
Version 2025.1D

In Zusammen-
arbeit mit:



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HEILEN

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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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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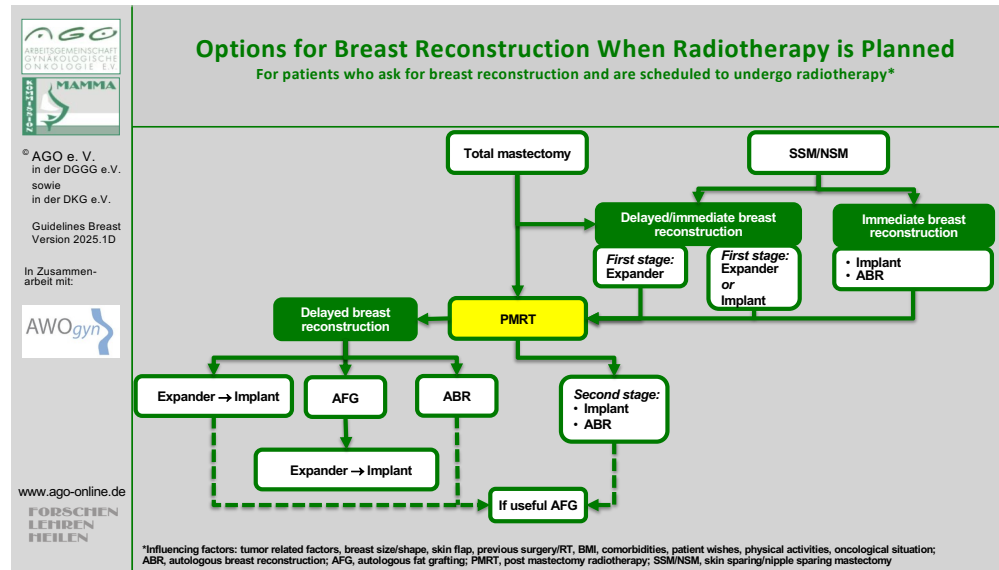
Onkoplastische brusterhaltende Operation (OPS)

	Oxford	
	LoE	GR
<ul style="list-style-type: none"> ▪ OPS kann in ausgewählten Fällen eine Mastektomie ersetzen <ul style="list-style-type: none"> ▪ auch bei multizentrischen/multifokalen Tumoren 	2b	B
<ul style="list-style-type: none"> ▪ OPS und BEO sind onkologisch gleichwertig 	2a	B
<ul style="list-style-type: none"> ▪ Komplikationsraten nach OPS und BEO sind vergleichbar 	2a	B
<ul style="list-style-type: none"> ▪ Bei Mammahypertrophie ist eine tumoradaptierte Reduktion vor RT mit weniger Komplikationen assoziiert als eine sekundäre Reduktion nach bereits erfolgter RT; letztere ist in Bezug auf Komplikationsrate (major complications) allerdings noch möglich 	3a	B

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for Reexcision: A Database Evaluation. *Ann Plast Surg.* 2022 Dec 1;89(6):e11-e17.

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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**

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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	+/-
▪ AFG vor Expander / Implantat nach Mastektomie und Radiatio	2b	B	+/-

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

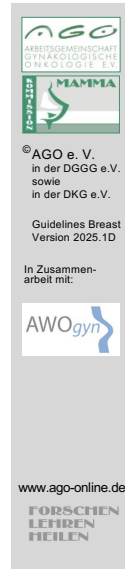
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Prior reconstruction after mastectomy and radiotherapy

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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	+

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Rekonstruktion mit Implantaten und Strahlentherapie

	Oxford		
	LoE	GR	AGO
▪ Implantat-Rekonstruktion			
▪ ohne Radiotherapie (RT)	2a	B	+
▪ vor RT	2a	B	++
▪ nach RT	2b	B	+/-
▪ nach sekundärer Mastektomie nach BET	2a	B	+/-
▪ Moderat hypofraktionierte RT nach Mastektomie (Gesamtdosis ca. 40 Gy in ca. 15-16 Fraktionen in ca. 3 bis 5 Wochen)	1a	A	++
▪ nach Brustrekonstruktion	1b	B	++

Cave: Risiko einer Kapselbildung nach Radiatio insbesondere bei prolongierter Wundheilung, prolongiertem Schmerz, Serom und Schwellung

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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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Infektionsprophylaxe und Brustrekonstruktion

	Oxford		
	LoE	GR	AGO
Heterologe Rekonstruktion:			
▪ Perioperative antibiotische Prophylaxe (max. 24 h)	1a	A	+
▪ Verlängerte antibiotische Prophylaxe (> 24 h)	2a	B	+
▪ Prophylaktische antibiotische Spülung intraoperativ	2a	B	+
▪ Antibiotische Therapie nach Kultur aus Drainage (Woche 2)	3a	C	+/-
▪ Handschuhwechsel vor Implantateinlage	4	C	+
▪ Antiseptische Spülung	2a	B	+
Autologe Rekonstruktion:			
▪ Perioperative antibiotische Prophylaxe (max. 24 h)	2b	B	+
▪ Verlängerte antibiotische Prophylaxe > 24 h	2a	B	+/-
▪ Verlängerte antibiotische Prophylaxe > 24 h im Rahmen eines AFG	3b	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.
4. Jin L, Ba T. Effect of prolonged antibiotic prophylaxis on the occurrence of surgical site wound infection after instant breast reconstruction: A meta-analysis. *Int Wound J*. 2024 Apr;21(4):e14631. doi: 10.1111/iwj.14631. Epub 2023 Dec 30.

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.

Early Cultures and targeted antibiotics:

1. Moyer HR, Sisson KM. The Effect of Early Cultures and Dual-port Expanders on Two-stage, Prepectoral Breast Reconstruction: The 25/25 Study. Plast Reconstr Surg Glob Open. 2024 Jan 8;12(1):e5507. doi: 10.1097/GOX.0000000000005507. eCollection 2024 Jan.

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.
8. Olsen MA, Nickel KB, Fraser VJ et al. Prevalence and Predictors of Postdischarge Antibiotic Use Following Mastectomy. *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.
11. Yamin F, Nouri A, McAuliffe P et al. Routine Postoperative Antibiotics After Tissue Expander Placement Postmastectomy Does Not Improve Outcome. *Ann Plast Surg* 2021 Jul 1;87(1s Suppl 1):S28-S30.

Exchanging sterile gloves:

1. Perez A, Baumann DP, Viola GM. Reconstructive breast implant-related infections: Prevention, diagnosis, treatment, and pearls of wisdom. *J Infect*. 2024 Aug;89(2):106197. doi: 10.1016/j.jinf.2024.106197. Epub 2024 Jun 13.

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,
2. Liu DZ, Dubbins JA, Louie O et al. Duration of Antibiotics after Microsurgical Breast Reconstruction Does Not Change Surgical Infection Rate. *Plast Reconstr Surg* 2012 Feb;129(2):362-367.
3. Drury KE, Lanier ST, Khavanin N et al. Impact of Postoperative Antibiotic Prophylaxis Duration on Surgical Site Infections in Autologous Breast Reconstruction. *Ann Plast Surg*. 2016 Feb;76(2):174-9.
4. Rijkx MEP, Schiebroek EJM, Hommes JE et al. The efficacy of prolonged antibiotic prophylaxis in total breast reconstruction with Autologous Fat Transfer (AFT): A retrospective cohort study. *J Plast Reconstr Aesthet Surg*. 2024 Oct;97:221-229. doi: 10.1016/j.bjps.2024.07.041. Epub 2024 Jul 25.

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.



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.0000000000010952.

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
2. Bae J, Lee DDU, Lee KT, et al. The early postoperative effects of rinsing the breast pocket with tranexamic acid in prepectoral prosthetic breast reconstruction. J Plast Reconstr Aesthet Surg. 2024 Feb;89:125-133. doi: 10.1016/j.bjps.2023.12.004. Epub 2023 Dec 11. PMID: 38181633

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.
2. Guggenheim L, Magni S, Catic A et al. The Effects of Systemic Tranexamic Acid Administration on Drainage Volume, Duration of Drain Placement, and Length of Hospital Stay in Skin- and Nipple-Sparing Mastectomies with Immediate Expander-Based Breast Reconstruction. J Clin Med. 2024 Oct 30;13(21):6507. doi: 10.3390/jcm13216507. PMID: 39518646

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.
2. Weissler JM, Banuelos J, Alsayed A et al. Topical Tranexamic Acid Safely Reduces Seroma and Time to Drain Removal Following Implant-Based Breast Reconstruction. Plast Reconstr Surg Glob Open. 2020 Oct 9;8(9 Suppl):9-10.

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3. Weissler JM, Banuelos J, Jacobson SR et al. Intravenous Tranexamic Acid in Implant-Based Breast Reconstruction Safely Reduces Hematoma without Thromboembolic Events. *Plast Reconstr Surg.* 2020 Aug;146(2):238-245.



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,
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.
3. St Cyr TL, Pockaj BA, Northfelt DW et al. Breast Implant-Associated Anaplastic Large-Cell Lymphoma: Current Understanding and Recommendations for Management. *Plast Surg (Oakv)*. 2020 May;28(2):117-126.
4. Clemens MW, DeCoster RC, Fairchild B et al. Finding Consensus After Two Decades of Breast Implant-Associated Anaplastic Large Cell Lymphoma. *Semin Plast Surg*. 2019 Nov;33(4):270-278.
5. Ward JA, Calderbank T, Tang CC, et al. Estimating the prevalence of Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) - a systematic review. *Plast Reconstr Surg*. 2024 Sep 23.

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.
4. Rosenberg K, McGillen P, Zanfagnin et al. Invasive squamous cell carcinoma of the breast associated with breast augmentation implant capsule. *J Surg Oncol*. 2023 Sep;128(4):495-501.
5. Yadav S, Yadav D, Zakalik D. Squamous cell carcinoma of the breast in the United States: incidence, demographics, tumor characteristics, and survival. *Breast Cancer Res Treat*. 2017 Jul;164(1):201-208.
6. Santanelli di Pompeo F, Firmani G, et al. Breast Implants and the Risk of Squamous Cell Carcinoma of the Breast: A Systematic Literature Review and Epidemiologic Study. *Aesthet Surg J*. 2024 Jun 14;44(7):757-768.

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
3. Atiyeh B, Emsieh S. Breast Implant Illness (BII): Real Syndrome or a Social Media Phenomenon? A Narrative Review of the Literature. *Aesthetic Plast Surg*. 2022 Feb;46(1):43-57.
4. Magnusson MR, Cooter RD, Rakhorst H et al. Breast Implant Illness: A Way Forward. *Plast Reconstr Surg*. 2019 Mar;143(3S A Review of Breast Implant-Associated Anaplastic Large Cell Lymphoma):74S-81S
5. Kabir R, Stanton E, Sorenson TJ, et al. Breast Implant Illness as a Clinical Entity: A Systematic Review of the Literature. *Aesthet Surg J*. 2024 Aug 20;44(9):NP629-NP636
6. Taritsa IC, Jagasia PM, Boctor M, Breast Implant Silicones and B Cell-Mediated Immune Responses: A Systematic Review of Literature. *JPRAS Open*. 2024 Jul 8;41:353-367. doi: 10.1016/j.jpra.2024.06.013. eCollection 2024 Sep. PMID: 39188658



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In Zusammen-
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FORSCHEN
LEHREN
HEILEN

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: 1,264 with 63 deaths
- Number of global cases reported by the American Society of Plastic Surgeons (ASPS) by 25.11.2024: 1,593
- 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
 - 30.54/10,000 for textured implants (1 case per 3,274 implanted patients) and 6.70/100,000 for implants any type (1 case per 14,925 implanted patients)
- 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 28.12.2024)
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7. Correction to: Epidemiology of Breast Implant-Associated Anaplastic Large Cell Lymphoma in the United States: A Systematic Review. Aesthet Surg J. 2023 Oct 9:sjad324.

8. McCarthy CM, Roberts J, Mullen E, et al. Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology (PROFILE): Updated Report 2012-2020. *Plast Reconstr Surg.* 2023 Oct 1;152(4S):16S-24S.
9. Wang Y, Zhang Q, Tan Y et al. Current Progress in Breast Implant-Associated Anaplastic Large Cell Lymphoma. *Front Oncol.* 2022 Jan 6;11:785887.
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14. Collett DJ, Rakhorst H, Lennox P et al. Current Risk Estimate of Breast Implant-Associated Anaplastic Large Cell Lymphoma in Textured Breast Implants. *Plast Reconstr Surg.* 2019 Mar;143(3S A Review of Breast Implant-Associated Anaplastic Large Cell Lymphoma):30S-40S.
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16. Quesada AE, Medeiros LJ, Clemens MW et al. Breast implant-associated anaplastic large cell lymphoma: a review. *Mod Pathol.* 2019 Feb;32(2):166-188.
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Systematic review (prevalence)

1. Ward JA, Calderbank T, Tang CC, et al. Estimating the prevalence of Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) - a systematic review. *Plast Reconstr Surg.* 2024 Sep 23.

Meta-analysis

1. Elameen AM, AlMarakby MA, Atta TI, Dahy AA. The Risk of Breast Implant-Associated Anaplastic Large Cell


Lymphoma; A Systematic Review and Meta-Analysis. *Aesthetic Plast Surg.* 2024 May 9. doi: 10.1007/s00266-024-03956-9. Online ahead of print. PMID: 38724638



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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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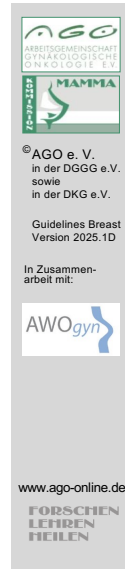
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Meta-analysis

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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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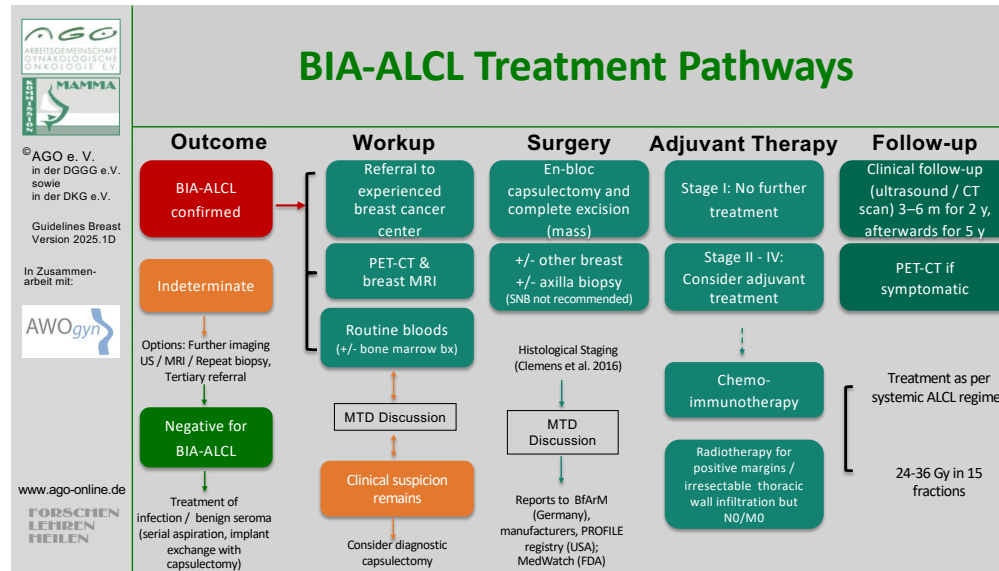
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TNM Staging of BIA-ALCL

	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		


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Breast Implant Capsule-Associated Squamous Cell Carcinoma

- By March 22, 2023, the FDA had reported 19 cases of BIA-SCC; 30 cases were described up to 11/2023 (Aesthet Surg J. 2024;44(7):757-768)
- 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
- Prevalence 0,61/100,000, lifetime risk 1:164,884
- 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
- More patients with "cosmetic" vs. "reconstructive" reasons (cosmetic, 3864/4109 [94.0%] vs. reconstruction, 245/4109 [5.96%]; $p < 0.001$) experience BII symptoms
- Breast implant explantation can show significant improvement of systemic complaints as well as improvement of overall quality of life

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Kabir R et al. Breast Implant Illness as a Clinical Entity: A Systematic Review of the Literature. *Aesthet Surg J.* 2024 Aug 20;44(9):NP629-NP636

Fifteen studies of 2572 patients reported implant explantation status, with 72.4% of the patients (1861/2572; 72.4%) choosing to remove their implants:

Implant removal status and patient outcome	
Explantation status	
Implant removed	1861 (1861/2572; 72.4%)
Implant removal with total capsulectomy	(1000/1861; 53.7%)
Symptom improvement	658 (658/788; 83.5%)
Implant to explant time (years)	13.1 (6.58)

1. <https://www.fda.gov/medical-devices/breast-implants/things-consider-getting-breast-implants#:~:text=Although%20treatable%2C%20there%20is%20a,be%20categorized%20as%20a%20disease> (assessed 25.12.2024)
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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.“

1. Cardoso MJ, Wyld L, Rubio IT et al. EUSOMA position regarding breast implant associated anaplastic large cell lymphoma (BIA-ALCL) and the use of textured implants. Breast. 2019 Apr;44:90-93.



Implantatloge, Netze und ADMs mit Implantat-rekonstruktion- Endpunkt QoL / Komplikationen

	Oxford		
	LoE	GR	AGO
▪ Kein signifikanter Unterschied zwischen prä- und subpektoraler Implantatloge (Komplikationsrate)	2b	B	
▪ Azelluläre Dermis (ADM)			
▪ subpektoral	1b	A	+/-
▪ präpektoral	2b	B	+/-
▪ Synthetische Netze			
▪ subpektoral	2a	B	+/-
▪ präpektoral	2b	B	+/-

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AFG (autologous fat grafting)

	Oxford		
	LoE	GR	AGO
<ul style="list-style-type: none"> ▪ AFG ▪ nach Mastektomie und Radiatio und vor Rekonstruktion ▪ nach Mastektomie und nach Rekonstruktion ▪ nach brusterhaltender Therapie ▪ nach autologer Brustrekonstruktion ▪ als alleinige Technik zur Brustrekonstruktion ▪ Mit Stammzellen angereicherte, autologe Fettgewebstransplantation vs. ohne Stammzellen 	<p>2b</p> <p>2a</p> <p>2a</p> <p>2a</p> <p>1b</p> <p>2a</p>	<p>B</p> <p>B</p> <p>B</p> <p>B</p> <p>B</p> <p>B</p>	<p>+/-</p> <p>+</p> <p>+</p> <p>+</p> <p>+</p> <p>+/-</p>

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Piatkowski AA et al. Effect of total breast reconstruction with AFG using an expansion device vs. implants on quality of life among patients with breast cancer - a randomized controlled trial, JAMA Surg 2023

- BREAST trial - multicenter, randomized clinical trial with an active control including a 1:1 allocation ratio.
- n = 193, 11/2015 - 11/2021
- Patients receiving postmastectomy radiotherapy were excluded.
- The predefined primary outcome was QoL at 12 months after final surgery. This was measured by the BREAST-Q questionnaire.
- 193 patients (mean [SD] age, 49.2 [10.6] years) 18 years or older who desired breast reconstruction were included, 91 patients in the AFG group and 80 in the immediate breast reconstruction (IBR) group received the allocated intervention. In total, 64 women in the AFG group and 68 women in the IBR group completed follow-up. The BREAST-Q scores were higher in the AFG group in all 5 domains and significantly higher in 3: satisfaction with breasts, physical well-being: chest, and satisfaction with outcome. QoL change over time was dependent on the treatment group in favor of AFG. No differences in oncological serious adverse events were found.
- Higher QoL and an increase in QoL scores over time in the AFT group compared with the IBR group. No evidence was found that AFT was unsafe.

Piatkowski AA et al., Effect of Total Breast Reconstruction With Autologous Fat Transfer Using an Expansion Device vs Implants on Quality of Life Among Patients With Breast Cancer - a randomized controlled trial, JAMA Surg 2023,158(5):456-464

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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 (unilateral)	3a	B	+/-
▪ Radiotherapie:			
▪ Brustrekonstruktion nach RT	2a	B	+
▪ Brustrekonstruktion vor RT	2a	B	+/-

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

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Omentum flap

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Freie Lappen zur Rekonstruktion

	Oxford		
	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)	2a	B	+/-
▪ Omentum Lappen	3a	B	+/-
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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DIEP

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SIEA

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PAP

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Omentum flap

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ICG

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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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Guidelines Breast
Version 2025.1D

In Zusammen-
arbeit mit:



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

	Oxford		
	LoE	GR	AGO
▪ Hautsparende Mastektomie (SSM / NSM)			
▪ Sicher (gleiche Rezidivrate wie bei Mastektomie bei geeigneter Pat.auswahl)	2a	B	++
▪ Höhere Lebensqualität für Patientin	2b	B	++
▪ Erhalt des Mamillen-Areola-Komplex unter bestimmten Bedingungen	2b	B	++
▪ Möglich nach Mastopexie / Reduktionsplastik	4	C	++
▪ Nutzung von ICG* zur Vorhersage von Nekrosen	1b	B	+
▪ Hautschnitte → verschiedene Möglichkeiten:			
▪ Periareolär			
▪ Hemi-periareolär mit / ohne medialer / lateraler Erweiterung			
▪ Reduktionsschnittbild: „inverses T“ oder vertikal			
▪ Inferior-lateraler Zugang / Inframammärfalte			
▪ Niedrigste Inzidenz von Komplikationen	2b	B	+

* ICG = Indocyaningrün


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NSM and oncological safety

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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 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 ▪ Präferenz einer präpektoralen Implantatloge (bei Postmastektomie-Radiatio) ▪ Lokale Antibiotika / Antiseptika ▪ PVP (Povidone-Iodine) ▪ Leukotrien-Antagonisten ▪ Brustmassage ▪ Operative 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>2a</p> <p>3a</p> <p>2a</p> <p>2a</p>	<p>A</p> <p>B</p> <p>C</p> <p>B</p> <p>B</p> <p>B</p> <p>C</p> <p>B</p> <p>B</p>	<p>+</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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- Prevent Capsular Contracture: A Systematic Review. *Plast Surg (Oakv)*. 2018 May;26(2):110-119
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Textured implants:

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Leukotriene antagonists:

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Pre- vs. subpectoral implant position and post-mastectomy radiation:

1. Kim YH, Yang YJ, Lee DW et al. Prevention of Postoperative Complications by Prepectoral versus Subpectoral Breast Reconstruction: A Systematic Review and Meta-Analysis. *Plast Reconstr Surg*. 2024 Jan 1;153(1):10e-24e


ADM:

1. Zhu L, Liu C. Postoperative Complications Following Prepectoral Versus Partial Subpectoral Implant-Based Breast Reconstruction Using ADM: A Systematic Review and Meta-analysis. *Aesthetic Plast Surg*. 2023 Aug;47(4):1260-1273
2. Nolan IT, Farajzadeh MM, Boyd CJ et al. Do we need acellular dermal matrix in prepectoral breast reconstruction? A systematic review and meta-analysis. *J Plast Reconstr Aesthet Surg*. 2023 Nov;86:251-260


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Seroma after Implant Reconstruction I

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

* Participation in the SERMA study is recommended.

1. Köpke MB, Wild CM, Schneider M, Pochert N, Schneider F, Sagasser J, Kühn T, Untch M, Hinske C, Reiger M, Traidl-Hoffmann C, Dannecker C, Jeschke U, Ditsch N. Elderly and Patients with Large Breast Volume Have an Increased Risk of Seroma Formation after Mastectomy-Results of the SerMa Pilot Study. *Cancers (Basel)*. 2023 Jul 13;15(14):3606
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7. Varghese J, Gohari SS, Rizki H et al. A systematic review and meta-analysis on the effect of neoadjuvant chemotherapy on complications following immediate breast reconstruction. *Breast*. 2021 Feb;55:55-62
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Serome nach Implantatrekonstruktion II

	Oxford		
	LoE	GR	AGO
Prävention			
▪ Drainage	3b	C	+
▪ Entfernung der Drainage bei Fördermenge < 30 ml	2b	B	+
▪ Tranexamsäure			
▪ i. v. / per os (wenn keine Kontraindikationen)	2a	B	+
▪ Topisch	1b	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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2. Liechti R, van de Wall BJM, Hug U, Fritsche E, Franchi A. Tranexamic Acid Use in Breast Surgery: A Systematic Review and Meta-Analysis. Plast Reconstr Surg. 2023;151(5):949-957
3. Weissler JM, Banuelos J, Alsayed A, Tran NV, Martinez-Jorge J, Manrique OJ, Nguyen MDT, Harless CA. Topical Tranexamic Acid Safely Reduces Seroma and Time to Drain Removal Following Implant-Based Breast Reconstruction. Plast Reconstr Surg Glob Open. 2020;8(9 Suppl):9-10
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Systemic TXA:


1. Guggenheim L, Magni S, Catic A et al. The Effects of Systemic Tranexamic Acid Administration on Drainage Volume, Duration of Drain Placement, and Length of Hospital Stay in Skin- and Nipple-Sparing Mastectomies with Immediate Expander-Based Breast Reconstruction. *J Clin Med*. 2024 Oct 30;13(21):6507.
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3. 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.

Topic TXA / Nipple-sparing mastectomy:

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.
2. 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.
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Tranexamic Acid (TXA) in Implant Surgery - Schedules, Dosage and Timing -

Topic tranexamic acid (Safran T et al., PRS 2023), prospective randomized, double-blind, n = 53, 106 breasts

- 3 g TXA in 100 ml sodium chloride solution for rinsing the implant cavity after NSM and prior implant insertion

Systemic TXA (Guggenheim L et al, J Clin Med 2024), retrospective, n = 132, 155 mastectomies

- First 24 hours:
 - 1 g at the beginning of the operation
 - Then 1 g every 8 hours i.v.
- Second 24 hours:
 - 1 g oral every 8 hours for the next 24 hours

Systemic:

1. Guggenheim L, Magni S, Catic A et al. The Effects of Systemic Tranexamic Acid Administration on Drainage Volume, Duration of Drain Placement, and Length of Hospital Stay in Skin- and Nipple-Sparing Mastectomies with Immediate Expander-Based Breast Reconstruction. J Clin Med. 2024 Oct 30;13(21):6507.

Topic:

1. Safran T, Vorstenbosch J, Viesel-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

Meta-analysis

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



Nekrosen des Hautmantels nach Mastektomie

Prävention

- Nitroglycerin lokal *
- Unterdrucktherapie (ciNPT)
- Dimethylsulfoxid lokal
- Cilostazol oral
- Präoperative lokale Wärmetherapie
- Prostaglandin E1

Oxford		
LoE	GR	AGO
1a	A	+
2a	B	+/-
2b	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
3. Kutun S, Agac Ay A, Ulucanlar H et al. Is transdermal nitroglycerin application effective in preventing and healing flap ischaemia after modified radical mastectomy? *S Afr J Surg.* 2010 Nov;48(4):119-21

Nitroglycerin / glycerol nitrate: prospective cohort studies:

1. Yao A, Greige N, Ricci JA et al. Topical Nitroglycerin Ointment Reduces Mastectomy Flap Necrosis in Immediate Autologous Breast Reconstruction. *Plast Reconstr Surg.* 2023 Oct 1;152(4):728-735

Nitroglycerin / glycerol nitrate: retrospective cohort studies:

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2. Liew AN, Lim KY, Khoo JF. Closed Incision Negative Pressure Therapy vs Standard of Care Dressing in Breast Surgery: A Systematic Review. *Cureus.* 2022 Apr 26;14(4):e24499.
3. Akhter HM, Macdonald C, McCarthy P et al. Outcomes of Negative Pressure Wound Therapy on Immediate Breast Reconstruction after Mastectomy. *Plast Reconstr Surg Glob Open* 2023 Aug; 11(8): e5130
4. Gabriel A, Sigalove S, Sigalove N et al. The Impact of Closed Incision Negative Pressure Therapy on Postoperative Breast Reconstruction Outcomes. *Plast Reconstr Surg Glob Open.* 2018 Aug 7;6(8):e1880
5. Ferrando P, Ala A, Bussone R et al. Closed Incision Negative Pressure Therapy in Oncological Breast Surgery:

Comparison with Standard Care Dressings. Plastic and Reconstructive Surgery - Global Open 6(6):p e1732, June 2018

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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

Prostaglandin E1

1. Hwang JW, Lim WS, Kim HG, Effects of Prostaglandin E1 on Mastectomy Flap Necrosis in Immediate Implant-Based Breast Reconstruction. Plast Reconstr Surg. 2024 Aug 1;154(2):278-286.



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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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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
2a	B	+
2a	B	+


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

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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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
14. Pelegrina Perez TC, Desai A, Tadisina KK et al. Prevalence, clinical characteristics, and management of silicone lymphadenopathy: A systematic review of the literature. *J Plast Reconstr Aesthet Surg*. 2024 Mar;90:76-87.



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Prevalence, clinical characteristics, and management of silicone lymphadenopathy: A systematic review of the literature

Pelegrina Perez TC et al., J Plast Reconstr Aesthet Surg 2024

- **279 cases of silicone lymphadenopathy and 107 with information on initial diagnosis, 35 (33%) were incidental.**
- **The most common symptom was painless lymphadenopathy, followed by painful lymphadenopathy.**
- **251 (95%) and 13 (5%) patients had silicone and saline implants, respectively, 149 (68%) patients had implant rupture.**
- **Axillary lymphadenopathy was the most affected region (136 cases, 72%), followed by internal mammary (40 cases, 21%), cervical/supraclavicular (36 cases, 19%), and mediastinal (24 cases, 13%) regions.**
- **25% of patients underwent fine-needle aspiration, 12% core needle biopsy, and 59% excisional biopsy. 32% of cases underwent explantation and/or implant exchange.**
- **The most common indication for surgery was implant rupture.**

1. Pelegrina Perez TC, Desai A, Tadisina KK et al. Prevalence, clinical characteristics, and management of silicone lymphadenopathy: A systematic review of the literature. J Plast Reconstr Aesthet Surg. 2024 Mar;90:76-87.

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"> ▪ Axilladisektion oder Sentinel-Lymphknoten Exzision bei RRME 	2a	B	--

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.

Chirurgische Prävention bei gesunden *BRCA1/2* Mutationsträgerinnen

	Oxford		
	LoE	GR	AGO
■ Risiko-reduzierende bilaterale Salpingo-Oophorektomie (RR-BSO)**	2a	B	
<ul style="list-style-type: none"> ■ reduziert die Eierstockkrebsinzidenz und -mortalität ■ reduziert die Gesamtmortalität 			++*
■ Risiko-reduzierende bilaterale Mastektomie (RRBM)			
<ul style="list-style-type: none"> ■ reduziert die Brustkrebsinzidenz ■ reduziert die Mortalität bei <i>BRCA1</i> 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.
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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 Gesamtmortalität (gegensätzliche Ergebnisse bzgl. kontralateraler Brustkrebsinzidenz) ▪ Risikoreduzierende kontralaterale Mastektomie (RRCM)* reduziert kontralaterale Brustkrebsinzidenz und die Mortalität ▪ Tamoxifen (reduziert kontralaterale Brustkrebsinzidenz) ▪ Indikationsstellung für RRCM sollte Alter, Ersterkrankungsalter und betroffenes Gen berücksichtigen. ▪ Risikoreduzierende bilaterale Mastektomie nach Ovarialkarzinom 	2b	B	+*
	2b	B	+*
	2b	B	+/-*
	2a	B	++*
	4	C	+/-**

* Gesamtprognose muss berücksichtigt werden, Studienteilnahme empfohlen.

** In Abhängigkeit vom Tumorstadium (FIGO I/II), rezidivfreier Zeit (≥ 5 Jahre), Alter.

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