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Diagnostik und Therapie früher und fortgeschrittener Mammakarzinome

Onkoplastische und rekonstruktive Mammachirurgie

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Plastisch-rekonstruktive Aspekte nach Mastektomie


- **Versionen 2002–2021:**
Audretsch / Bauerfeind / Blohmer / Brunnert / Dall / Ditsch / Fersis /
Friedrich/ Gerber / Hanf / Heil / Kühn / Kümmel / Lux / Nitz / Rezai /
Rody / Scharl / Solbach / Thill / Thomssen
- **Version 2022:**
Kümmel / Wöckel



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Definition der onkoplastischen Operation

Einsatz plastischer operativer Techniken zum Zeitpunkt der Tumorentfernung, um sichere Resektionsgrenzen zu erreichen und eine ästhetische Brustform zu ermöglichen.

Fokus auf günstige Narbenplatzierung, adäquate Weichteilformierung, Wahl des geeigneten Wiederaufbauverfahrens (auch unter der Bedingung einer Radiatio) und Rekonstruktion der Gegenseite, um eine Symmetrie zu erreichen.


1. Abhishek Chatterjee , Jennifer Gass , Krishnabhai Patel et al.; A Consensus Definition and Classification System of Oncoplastic Surgery Developed by the American Society of Breast Surgeons. Ann Surg Oncol. 2019 Oct;26(11):3436-3444.
2. Bertozzi N, et al. Oncoplastic breast surgery: comprehensive review. 2017; 21(11): 2572-2585.
3. Kuerer H et al. Optimizing breast cancer adjuvant radiation and integration of breast and reconstructive surgery. ASCO Educational Book 2017



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Classifications

1. By Hoffmann / Wallwiener:


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

2. By Clough:

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

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


1. Hoffmann D et al Classifying breast cancer surgery: a novel, complexity-based system for oncological, oncoplastic and reconstructive procedures, and proof of principle by analysis of 1225 operations in 1166 patients. BMC Cancer. 2009 Apr 8;9:108. doi: 10.1186/1471-2407-9-108.
2. Clough KB et al Improving breast cancer surgery: a classification and quadrant per quadrant atlas for oncoplastic surgery. Ann Surg Oncol. 2010 May;17(5):1375-91. doi: 10.1245/s10434-009-0792-y. Epub 2010 Feb 6.
3. Weber WP et al First international consensus conference on standardization of oncoplastic breast conserving surgery. Breast Cancer Res Treat. 2017 Aug;165(1):139-149.



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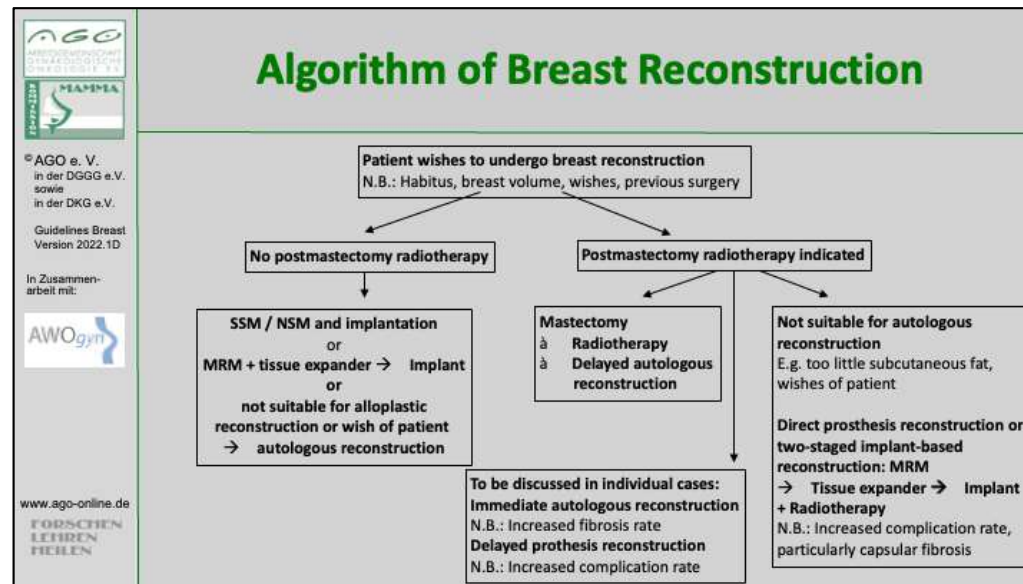
Onkoplastische brusterhaltende Operation (OPS)

	Oxford		
	LoE	GR	AGO
▪ OPS kann in ausgewählten Fällen eine Mastektomie ersetzen	2b	B	+
▪ OPS und BEO sind onkologisch gleichwertig	2b	B	+
▪ OPS und BEO Komplikationsraten sind vergleichbar	3b	C	+

1. Florian Fitzal, Michael Bolliger, Daniela Dunkler Retrospective, Multicenter Analysis Comparing Conventional with Oncoplastic Breast Conserving Surgery: Oncological and Surgical Outcomes in Women with High-Risk Breast Cancer from the OPBC-01/iTOP2 Study. Ann Surg Oncol. 2021 Oct 13. doi: 10.1245/s10434-021-10809-1.
2. Gulcelik MA et al Feasibility of level II oncoplastic techniques in the surgical management of locally advanced breast cancer after neoadjuvant treatment. Int J Clin Pract. 2021 Jan 6;e13987. doi: 10.1111/ijcp.13987.
3. Kosasih S et al Is oncoplastic breast conserving surgery oncologically safe? A meta-analysis of 18,103 patients. Am J Surg. 2020 Aug;220(2):385-392. doi: 10.1016/j.amjsurg.2019.12.019. Epub 2020 Jan 2.
4. Aristokleous I et al Quality of life after oncoplastic breast-conserving surgery: a systematic review. ANZ J Surg. 2019 Jun;89(6):639-646. doi: 10.1111/ans.15097. Epub 2019 Apr 12.
5. Mansell J et al Oncoplastic breast conservation surgery is oncologically safe when compared to wide local excision and mastectomy. Breast. 2017 Apr;32:179-185. doi: 10.1016/j.breast.2017.02.006. Epub 2017 Feb 17.
6. Piper ML et al Outcomes Following Oncoplastic Reduction Mammoplasty: A Systematic Review. Ann


Plast Surg. 2016 May;76 Suppl 3:S222-6. doi: 10.1097/SAP.0000000000000720.

7. Wiggman DJ et al Short term safety of oncoplastic breast conserving surgery for larger tumors. Eur J Surg Oncol. 2017 Apr;43(4):665-671. doi: 10.1016/j.ejso.2016.11.021. Epub 2016 Dec 18.
8. Crown A et al Oncoplastic Breast-Conserving Surgery Reduces Mastectomy and Postoperative Re-excision Rates. Ann Surg Oncol. 2015 Oct;22(10):3363-8. doi: 10.1245/s10434-015-4738-2. Epub 2015 Jul 25.



1. El-Sabawi B, et al. Radiation and breast reconstruction: Algorithmic approach and evidence-based outcomes. J Surg Oncol. 2016; 113(8):906-12
2. Gerber B, et al. Breast Reconstruction Following Cancer Treatment. Dtsch Arztebl Int. 2015; 112(35-36):593-600
3. Kuerer H , et al. Optimizing breast cancer adjuvant radiation and integration of breast and reconstructive surgery. ASCO Educational Book 2017; Memorial Sloan Kettering Cancer Center, Fig. 2 und 3
4. Cordeiro P, et al. What is the optimum timing of postmastectomy radiotherapy in two-stage prosthetic reconstruction: radiation to the tissue expander or permanent implant? Plast Reconstr Surg. 2015 Jun;135(6):1509-1517. doi: 10.1097/PRS.0000000000001278.PMID: 25742523
5. Bennett KG, Qi J, Kim HM, et al.: Comparison of 2-Year Complication Rates Among Common Techniques for Postmastectomy Breast Reconstruction. JAMA Surg. 2018 Oct 1;153(10):901-908. doi: 10.1001/jamasurg.2018.1687.
6. He WY et al. Complications and Patient-reported Outcomes after TRAM and DIEP Flaps: A Systematic


Review and Meta-analysis. Plast Reconstr Surg Glob Open. 2020 Oct 29;8(10):e3120. doi:
10.1097/GOX.00000000000003120. eCollection 2020 Oct. PMID: 33173667



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Brustrekonstruktion Grundsätze

Gute klinische Praxis

AGO: ++

- Planung der Rekonstruktion im interdisziplinären Tumorboard vor einer Mastektomie
- Beratung hinsichtlich aller OP-Techniken, sowie deren Vor- und Nachteile
- Bevorzugung einer autologen Rekonstruktion bei Z. n. oder geplanter Radiotherapie
- Möglichkeit zum Einholen einer Zweitmeinung
- Besprechung einer neoadjuvanten Systemtherapie bei ungünstiger Tumor-Brust-Relation
- Berücksichtigung der kontralateralen Brust;
 - mögliche Angleichungs- / Folge-OPs zur Symmetrierherstellung besprechen; i. d. R. sekundär im Abstand von mindestens 3–6 Monaten (Cave: Notwendigkeit von Nachresektionen, Effekte der Radiotherapie der betroffenen Seite berücksichtigen)
- Bevorzugung einer die Patientin wenig belastenden OP-Technik mit langfristig stabilem ästhetischen Ergebnis (BEO / OPS ist gegenüber einer Mastektomie zu präferieren)
- Cave: keine Verzögerung der adjuvanten Therapie durch die Rekonstruktion
- Qualitätssicherung, z. B. mit Patient Reported Outcomes (PRO)
- Gewährleistung der onkologischen Sicherheit

1. AWMF Leitlinien: S3-LL. Brustrekonstruktion mit Eigengewebe. Registernummer 015 – 075, Stand: 01.04.2015 , gültig bis 31.03.2020?
2. Bertozzi N et al. Oncoplastic breast surgery: comprehensive review. Eur Rev Med Pharmacol Sci. 2017; 21(11):2572-2585.
3. Smith BL et al. Oncologic safety of nipple-sparing mastectomy in women with breast cancer. J Am Coll Surg 2017 Sep;225(3):361-365. doi: 10.1016/j.jamcollsurg.2017.06.013. Epub 2017 Jul 17. PMID: 28728962
4. Colwell AS et al. Nipple-sparing mastectomy and direct to implant breast reconstruction. Plast Reconstr Surg. 2017; 140(5S Advances in Breast Reconstruction):44S-50S.
5. Brice Jabo, Ann C. Lin, Mayada A. Aljehani et al. Impact of Breast Reconstruction on Time to Definitive Surgical Treatment, Adjuvant Therapy, and Breast Cancer Outcomes. Ann Surg Oncol 2018 Oct;25(10):3096-3105.
6. Cordova LZ, Hunter-Smith DJ, Rozen WM. Patient reported outcome measures (PROMs) following mastectomy with breast reconstruction or without reconstruction: a systematic review. Gland Surg 2019;8(4):441-451
7. Khajuria A, Prokopenko M, Greenfield M et al. Meta-analysis of Clinical, Patient-Reported Outcomes

and Cost of DIEP versus Implant-based Breast Reconstruction. *Plast Reconstr Surg Glob Open* 2019;7:e2486

8. 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;8(4):452-460

Möglichkeiten der Rekonstruktion nach Mastektomie			
	Oxford		
	LoE	GR	AGO
▪ Einsatz von mit Silikongel gefüllten Implantaten einzeitig (primär) oder zweizeitig nach Expander	2a	B	+
▪ Sicherheit vergleichbar mit Kochsalzimplantaten	2b	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, bilaterales ME			

1. Wilkins EG, et al. Complications in Postmastectomy Breast Reconstruction: One-year Outcomes of the Mastectomy Reconstruction Outcomes Consortium (MROC) Study. Ann Surg. 2018 Jan;267(1):164-170. doi: 10.1097/SLA.0000000000002033.PMID: 27906762
2. Zhu L, et al. Comparison of subcutaneous versus submuscular expander placement in the first stage of immediate breast reconstruction. J Plast Reconstr Aesthet Surg. 2016; 69(4):e77-86.
3. Singh N, 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; 140(4):666-679.
4. Potter S et al. Short-term safety outcomes of mastectomy and immediate implant-based breast reconstruction with and without mesh (iBRA): a multicentre, prospective cohort study. Lancet Oncol 2019 Jan 9. pii: S1470-2045(18)30781-2.
5. Porter BE et al. Comparison of Saline Expanders and Air Expanders for Breast Reconstruction. Ann Plast Surg. 2020 Jun;84(6S Suppl 5):S396-S400. doi: 10.1097/SAP.0000000000002154.PMID: 31868761

Zeitpunkt der Rekonstruktion			
	Oxford		
	LoE	GR	AGO
Sofortrekonstruktion <ul style="list-style-type: none"> Obligat bei SSM / NSM Vermeiden des Postmastektomie-Syndroms 	3b	B	++
Spätrekonstruktion (zweizeitig) <ul style="list-style-type: none"> Keine Verzögerung von adjuvanten Therapien (CHT, RT) Nachteil: Verlust des Hautmantels 	3b	B	++
Verzögerte Rekonstruktion (Platzhalter vor definitiver Rekonstruktion) („Delayed-immediate BR“)	3b	B	+

1. Jagsi R et al. Complications After Mastectomy and Immediate Breast Reconstruction for Breast Cancer: A Claims-Based Analysis. Ann Surg. 2016; 263(2):219-27.
2. Maione L et al. What Is the Optimum Timing of Postmastectomy Radiotherapy in Two-Stage Prosthetic Reconstruction: Radiation to the Tissue Expander or Permanent Implant? Plast Reconstr Surg. 2016; 138(1):150e-1e.
3. Ribuffo D et al. Comparison of Delayed and Immediate Tissue Expander Breast Reconstruction in the Setting of Postmastectomy Radiation Therapy. Ann Plast Surg. 2016; 76(6):743-4.
4. Sharpe SM 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; 21:2920–7.
5. Zhong T et al. A Comparison of Surgical Complications Between Immediate Breast Reconstruction and Mastectomy: The Impact on Delivery of Chemotherapy-An Analysis of 391 Procedures. Ann Surg Oncol. 2012; 19(2):560-6.
6. D'Souza N et al. Immediate versus delayed reconstruction following surgery for breast cancer. Cochrane Database Syst Rev. 2011; (7):CD008674.
7. Srinivasa DR et al. Direct to implant versus two stage tissue expander/implant reconstruction: 2 year

risks and patient reported outcomes from a prospective, multicenter study. *Plast Reconstr Surg.* 2017; 140(5):869-877.

8. Negenborn VL, Young-Afat DA, Dikmans REG et al: Quality of life and patient satisfaction after one-stage implant-based breast reconstruction with an acellular dermal matrix versus two-stage breast reconstruction (BRIOS): primary outcome of a randomised, controlled trial. *Lancet Oncol* 2018 Sep;19(9):1205-1214.

Zeitpunkt der Rekonstruktion mit Implantaten in Bezug zur Strahlentherapie			
	Oxford		
	LoE	GR	AGO
▪ Implantat-Rekonstruktion (IR)			
▪ IR ohne Strahlentherapie (RT)	2a	B	+
▪ IR vor RT	2a	B	++
▪ IR nach RT	2b	B	+/-
▪ IR nach sekundärer Mastektomie nach BET	2a	B	+/-
▪ Perioperative antibiotische Prophylaxe (max. 24 Stunden)	2a	B	+

Radiation:

1. Santosa KB et al. Postmastectomy Radiation Therapy and Two-Stage Implant-Based Breast Reconstruction: Is There a Better Time to Irradiate? Plast Reconstr Surg. 2016; 138(4):761-9.
2. Maione L et al. What Is the Optimum Timing of Postmastectomy Radiotherapy in Two-Stage Prosthetic Reconstruction: Radiation to the Tissue Expander or Permanent Implant? Plast Reconstr Surg. 2016; 138(1):150e-1e.
3. El-Sabawi B et al. Radiation and breast reconstruction: Algorithmic approach and evidence-based outcomes. J Surg Oncol. 2016; 113(8):906-12.
4. Lee KT, Mun GH. Prosthetic breast reconstruction in previously irradiated breasts: A meta-analysis. J Surg Oncol. 2015; 112(5):468-75.
5. Albornoz CR et al. Implant breast reconstruction and radiation: a multicenter analysis of long-term health-related quality of life and satisfaction. Ann Surg Oncol. 2014; 21(7):2159-64.
6. Valdata L et al. Acellular dermal matrices and radiotherapy in breast reconstruction: a systematic review and meta-analysis of the literature. Plast Surg Int. 2014; 472604.
7. Kkelley BP et al. A systematic review of morbidity associated with autologous breast reconstruction before and after exposure to radiotherapy: are current practices ideal? Ann Surg Oncol. 2014;

21(5):1732-8.


8. Berbers J et al. Reconstruction: before or after postmastectomy radiotherapy? A systematic review of the literature. *Eur J Cancer*. 2014; 50(16):2752-62.
9. Eriksson M et al. Radiotherapy in implant-based immediate breast reconstruction: risk factors, surgical outcomes, and patient-reported outcome measures in a large Swedish multicenter cohort. *Breast Cancer Res Treat*. 2013; 142(3):591-601.
10. Momoh AO et al. Delayed autologous breast reconstruction after postmastectomy radiation therapy: is there an optimal time? *Ann Plast Surg*. 2012; 69(1):14-8.
11. Mirzabeigi MN et al. Extended trimethoprim/sulfamethoxazole prophylaxis for implant reconstruction in the previously irradiated chest wall. *Plast Reconstr Surg*. 2012; 129(1):1e-7e.
12. Barry M, Kell MR. Radiotherapy and breast reconstruction: a meta-analysis. *Breast Cancer Res Treat*. 2011; 127(1):15-22.
13. Magill LJ et al. Determining the outcomes of post-mastectomy radiation therapy delivered to the 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; 70(10):1329-1335.
14. Jagsi R et al. Impact of Radiotherapy on Complications and Patient-Reported Outcomes After Breast Reconstruction. *J Natl Cancer Inst*. 2018; 110(2).
15. Batenburg MCT et al. on behalf of the UMBRELLA study group. Patient-reported cosmetic satisfaction and the long-term association with quality of life in irradiated breast cancer patients. *Breast Cancer Research and Treatment* <https://doi.org/10.1007/s10549-019-05470-y>

Prophylactic antibiotics:

1. Phillips BT, Halvorson EG. Antibiotic Prophylaxis following Implant-Based Breast Reconstruction: What Is the Evidence? *Plast Reconstr Surg*. 2016; 138(4):751-7.
2. Hunter JG. Discussion: Antibiotic Prophylaxis following Implant-Based Breast Reconstruction: What Is the Evidence? *Plast Reconstr Surg*. 2016; 138(4):758-9.
3. Phillips BT, et al. Prophylactic Postoperative Antibiotics Necessary for Immediate Breast Reconstruction? Results of a Prospective Randomized Clinical Trial. *J Am Coll Surg*. 2016; 222(6):1116-24.
4. Townley WA, et al. 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; 68(5):673-8.


5. 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. doi: 10.1097/GOX.0000000000002613. eCollection 2020 Jan. PMID: 32095414
6. Yamin, Feras; Nouri, Andrew; McAuliffe, Phoebe BA et al.; Routine Postoperative Antibiotics After Tissue Expander Placement Postmastectomy Does Not Improve Outcome. Annals of Plastic Surgery: July 2021 - Volume 87 - Issue 1s - p S28-S30



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

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

LoE 2a B

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

Hai Y et al. Plast Reconstr Surg Glob Open 2020;8:e2613; doi: 10.1097/GOX.0000000000002613.

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. doi: 10.1097/GOX.0000000000002613. eCollection 2020 Jan. PMID: 32095414



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Radiotherapy and Implant-based Reconstruction


Cave: Hohe Komplikationsrate in Kombination mit Radiotherapie (Kapselkontraktur, Revisionsoperationen, Versagen der Rekonstruktion, reduzierte Patientenzufriedenheit, schlechtere kosmetische Ergebnisse)

Cave: Niedrigere Patientenzufriedenheit bei Implantatrekonstruktion plus Radiotherapie im Vergleich zur autologen Rekonstruktion plus Radiotherapie

LoE 2b B

1. Magill LJ et al. Determining the outcomes of post-mastectomy radiation therapy delivered to the 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; 70(10):1329-1335.
2. Jagsi R et al. Impact of Radiotherapy on Complications and Patient-Reported Outcomes After Breast Reconstruction. J Natl Cancer Inst. 2018; 110(2).
3. Sinnott CJ et al. Impact of Postmastectomy Radiation Therapy in Prepectoral Versus Subpectoral Implant-Based Breast Reconstruction. Ann Surg Oncol 2018 Oct;25(10):2899-2908
4. Naoum GE, Salama L, Niemierko A, et al. Single Stage Direct-to-Implant Breast Reconstruction Has Lower Complication Rates Than Tissue Expander and Implant and Comparable Rates to Autologous Reconstruction in Patients Receiving Postmastectomy Radiation. Int J Radiat Oncol Biol Phys. 2020 Mar 1;106(3):514-524. doi: 10.1016/j.ijrobp.2019.11.008. Epub 2019 Nov 19. PMID: 31756414
5. J et al. Determining the outcomes of post-mastectomy radiation therapy delivered to the 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; 70(10):1329-1335.
6. Jagsi R et al. Impact of Radiotherapy on Complications and Patient-Reported Outcomes After Breast Reconstruction. J Natl Cancer Inst. 2018; 110(2).


7. Sinnott CJ et al. Impact of Postmastectomy Radiation Therapy in Prepectoral Versus Subpectoral Implant-Based Breast Reconstruction. *Ann Surg Oncol* 2018 Oct;25(10):2899-2908
8. Naoum GE, Salama L, Niemierko A, et al. Single Stage Direct-to-Implant Breast Reconstruction Has Lower Complication Rates Than Tissue Expander and Implant and Comparable Rates to Autologous Reconstruction in Patients Receiving Postmastectomy Radiation. *Int J Radiat Oncol Biol Phys*. 2020 Mar 1;106(3):514-524. doi: 10.1016/j.ijrobp.2019.11.008. Epub 2019 Nov 19. PMID: 31756414
9. Dong-YunKim, EonjuPark, Chan YeongHeo et al.; Influence of Hypofractionated Versus Conventional Fractionated Postmastectomy Radiation Therapy in Breast Cancer Patients With Reconstruction. In press
<https://doi.org/10.1016/j.ijrobp.2021.09.031>



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Possible Associations between Implants and Rare Diseases

- **US FDA Breast Implant Postapproval Studies (LPAS)**
Long-term Outcomes in 99,993 Patients
(Primary Augmentation: N = 71.937 / Primary Reconstruction: N = 9942)
 - 56 % of implants were silicone implants
- **Possible Associations:**
 - Sjogren syndrome: (SIR* 8.14)
 - scleroderma: (SIR 7.00)
 - rheumatoid arthritis: (SIR 5.96)
 - stillbirth: (SIR 4.50)
 - melanoma: (SIR 3.71)
- At 7 years, reoperation rate is 11.7 % for primary augmentation, and 25 % for primary / revision reconstruction.
- One case of BIA-ALCL

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

* Standardized incidence ratio

Statistical Analysis:

LPAS data is expressed relative to normative population rates using standardized incidence ratios (SIRs)

Systemic harm rates in the study population are calculated per 10,000 person-years.


Normative population rates for systemic harms, self-harm, and reproductive outcomes are obtained from the literature; rates reflect LPAS demographics for female sex, age, and race in the United States.

1. Coroneos CJ et al. US FDA Breast Implant Postapproval Studies: Long-term Outcomes in 99,993 Patients. Ann Surg 2019 Jan;269(1):30-36.

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

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

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Brust-Implantat-assoziiertes großzellig-anaplastisches Lymphom (BIA-ALCL)


- Etwa 10.000.000 Implantatträgerinnen weltweit
- Selten, 3 % aller Non-Hodgkin-Lymphome, 0,04–0,5 % aller malignen Brusterkrankungen
- geschätzte jährliche Inzidenz 0,6–1,2 je 100.000 Frauen mit Implantaten (medianes Patientenalter 54 J.)
- 1:3.000-30.000 bei Frauen mit texturierten Implantaten (CAVE: Underreporting!)
- Auftreten überwiegend bei texturierten Implantaten
- 5-Jahres-OAS 89 %
- Intervall zur Lymphomdiagnose: 8 Jahre (Median)
- Klinische Präsentation
 - Schwellung und Serom (60 %)
 - Tumoröse Raumforderung (17 %)
 - Serom und Raumforderung (20 %)
 - Axilläre Lymphadenopathie (20 %)
- Histologisch: CD30+ / ALK- T-Zell-Lymphom
- Meldepflicht als SAE nach §3 MPSV an das BfArM

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BIA-ALCL - Implantatoberflächen

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

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

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BIA-ALCL– Diagnostik			
	Oxford		
	LoE	GR	AGO
<ul style="list-style-type: none"> ■ Sonographie (Abklärung neu aufgetretener Serome 1 Jahr nach Implantateinlage, Herdbefund (Sensitivität: 84 %, Spezifität: 75 %)) 	3a	D	++
<ul style="list-style-type: none"> ■ Mamma-MRT bei Bestätigung Verdachtsdiagnose 	3a	D	++
<ul style="list-style-type: none"> ■ Staging (Bildgebung, z. B. CT, PET-CT) 	3a	D	++
<ul style="list-style-type: none"> ■ Erguss-Zytologie bei Späterom <ul style="list-style-type: none"> ■ Untersuchung von mind. 50 ml ■ komplette Aufarbeitung ■ Flowzytometrie (T-Zell-Klon) ■ BIA-ALCL spezifische zytol. Diagnostik (CD 30+) 	3a	D	++
<ul style="list-style-type: none"> ■ Stanzbiopsie bei soliden Herdbefunden ■ Lymphomdiagnostik am Resektat und histologisches Staging 	3a	D	++
<ul style="list-style-type: none"> ■ Dokumentation des Implantates (Hersteller, Größe, Füllung, Oberfläche, Batch-Nummer) und Eingabe in Register 	5	D	++

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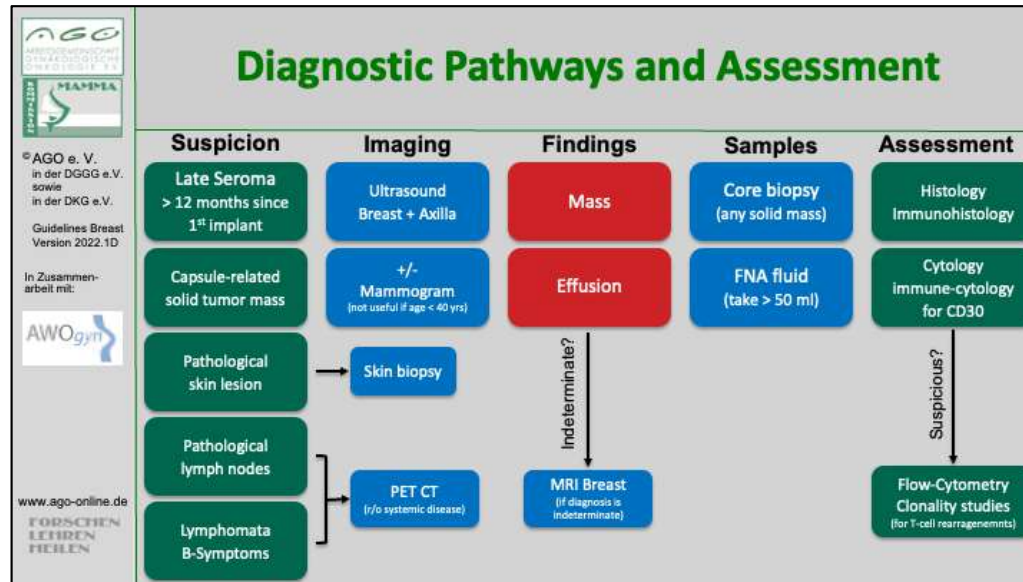
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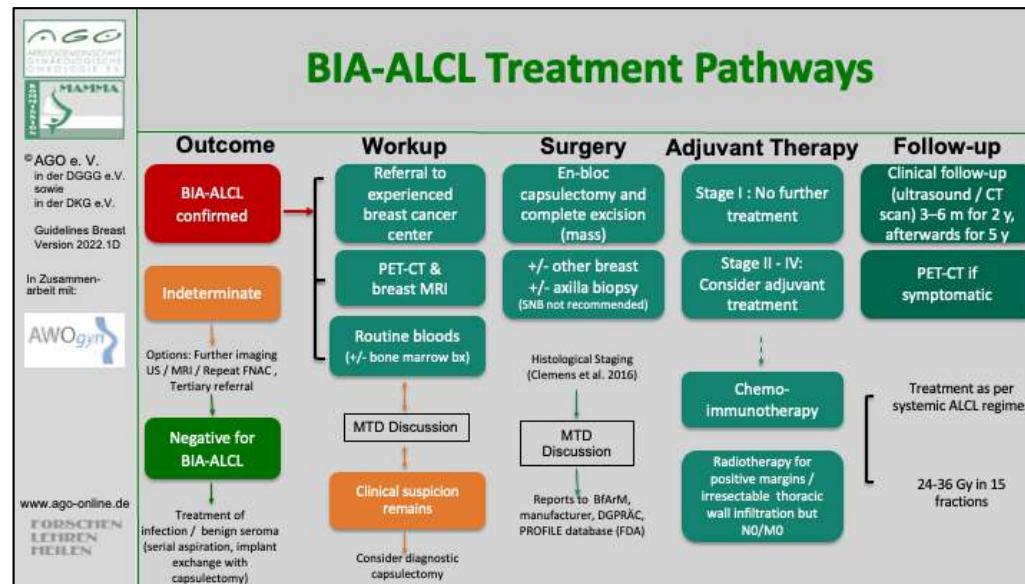
BIA-ALCL – Therapie			
	Oxford		
	LoE	GR	AGO
■ Implantatentfernung und vollständige Kapsulektomie einschließlich Tumorentfernung	3a	C	++
■ Entfernung suspekter Lymphknoten, keine routine-mäßige Sentinel-Node Biopsie, keine Axilladisektion	4	D	++
■ Polychemotherapie (z. B. CHOP) bei extrakapsulärer Tumorausbreitung	4	D	+
■ Radiatio bei unresektablen Tumoren oder R1	5	D	+/-
■ Vorstellung im interdisziplinären Tumorboard (inkl. Lymphomspezialist)	5	D	++

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<div>  <h2>TNM Staging of BIA-ALCL</h2> </div>				
<div> <p>© AGO e. V. in der DGKG e. V. sowie in der DKG e. V.</p> <p>Guidelines Breast Version 2022.1D</p> <p>In Zusammen- arbeit mit:</p>  <p>www.ago-online.de</p> <p>FORSCHEN LEBEN HEILEN</p> </div>				
	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	TB	T2 N0 M0
	T3	Cell aggregates or sheets infiltrating the capsule	TC	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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BIA-ALCL – EUSOMA-Recommendation

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

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

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Netze und ADMs mit Implantatrekonstruktion- Endpunkt QoL / Komplikationen			
	Oxford		
	LoE	GR	AGO
■ Präpektoriale Loge der subpektoralen Loge überlegen	3b	C	+/-
■ Azelluläre Dermis (ADM)			
■ subpektoral	1b	A	+/-*
■ präpektoral	2b	B	+/-*
■ Synthetische Netze			
■ subpektoral	2b	B	+/-*
■ präpektoral	2b	B	+/-*


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Lipotransfer

	Oxford		
	LoE	GR	AGO
▪ Lipotransfer nach ME und Rekonstruktion	2a	B	+
▪ Lipotransfer nach brusterhaltender Therapie	2a	B	+
▪ Mit Stammzellen (ACS) angereicherte, autologe Fettgewebstransplantation vs. ohne Stammzellen	2a	B	-

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Gestielte Lappen zur Rekonstruktion			
	Oxford		
	LoE	GR	AGO
Brustrekonstruktion (BR) mit autologem Gewebe			
▪ TRAM, Latissimus-dorsi-Lappen (können muskel-sparend präpariert werden)	2a	C	+
▪ Delayed-TRAM bei Risikopatientinnen	3a	B	+
▪ Ipsilateral gestielter TRAM	2a	B	+
▪ Radiotherapie:			
▪ BR nach RT	2a	B	+
▪ BR vor RT	2a	B	+/-
(erhöhte Rate an Fibrosen, Wundheilungsstörungen, Lipoidnekrosen, reduziertes ästhetisches Outcome)			

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Freie Lappen zur Rekonstruktion			
	Oxford		
	LoE	GR	AGO
Freier Gewebetransfer			
▪ DIEP	2a	B	+
▪ Freier TRAM	2a	B	+
▪ SIEA	3a	C	+/-
▪ Gluteallappen (SGAP- / IGAP, FCI)	4	C	+/-
▪ Free gracilis flap (TMG)	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			
▪ RT vor Rekonstruktion erhöht Rate vaskulärer Komplikationen			
* ICG: Indocyaningrün			

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AGO e. V.
in der DGGG e.V.
sowie
in der DKG e.V.

Guidelines Breast
Version 2022.1D

In Zusammen-
arbeit mit:



www.ago-online.de

FORSCHEN
LEBEN
HEILEN

Gestielter vs. freier Gewebetransfer

Oxford
LoE GR AGO
3a A ++

- **Muskelsparende Techniken und sorgfältiger Verschluss der Bauchdecke führen zu niedrigen Komplikationsraten unabhängig von der verwendeten Methode**
- **Autologer Gewebetransfer 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
Hautsparende Mastektomie (SSM / NSM)			
▪ Sicher (gleiche Rezidivrate wie bei MX bei geeigneter Pat.auswahl)	2b	B	++
▪ Höhere Lebensqualität für Patientin	2b	B	++
▪ Erhalt des Mamillen-Areola-Komplex (MAK) 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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Prävention und Therapie der Kapselfibrose			
	Oxford		
	LoE	GR	AGO
<div> <div>  <p>AGO e. V. in der DGGG e.V. sowie in der DKG e.V.</p> <p>Guidelines Breast Version 2022.1D</p> <p>In Zusammen- arbeit mit:</p>  <p>www.ago-online.de</p> <p>FORSCHEN LEBEN HEILEN</p> </div> <div> <ul style="list-style-type: none"> Prävention <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> Kapsulektomie Kapsulotomie (Cave: Ausschluss BIA-ALCL) </div> </div>			
	1a	A	+
	2a	B	+
	3a	C	+
	2a	B	+
	2a	B	+/-
	2a	B	+/-
	3a	C	-
	3b	C	+
	3b	C	+

Povidone-Iodine:

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Breast massage:

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Serome nach Implantatrekonstruktion I

- Inzidenz: ca. 5-10 % (2-50 %)

Einflussfaktoren:

- Z. n. Radiatio erhöht Risiko (RR ca. 3)
- Adipositas erhöht Risiko (z. B. BMI > 30 vs. < 30; RR ca. 3)
- Einsatz von ADM erhöht Risiko (RR ca. 3)
- Glatte Expander erhöhen Risiko (RR ca. 5)
- Z. n. neoadjuvanter Chemotherapie erhöht Risiko eher nicht
- Subcutane Loge erhöht Risiko eher nicht

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

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Serome nach Implantatrekonstruktion II			
	Oxford		
	LoE	GR	AGO
Prävention			
▪ Drainage mit wenig, mehr oder keinem Vakuum	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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Risiko-reduzierende bilaterale Mastektomie für nicht erkrankte Frauen (RRBM)			
	Oxford		
	LoE	GR	AGO
▪ RRBM verringert die Brustkrebsinzidenz	2b	B	++
▪ RRBM bei BRCA1/2 Mutationsträgerinnen	2a	B	++
▪ RRBM bei hohem Mammakarzinomrisiko (individuelle Entscheidung in Abhängigkeit von Mutationsstatus und familiärer Belastung – z. B. high-risk / moderate Gene / Hodgkin-Lymphom)	4	D	+/-*
▪ Hohes Risiko und keine Beratung in spezialisierten Zentren*	5	D	--
▪ Nicht direktive Beratung vor RRBM	2b	B	++
▪ RRBM sollte im Zusammenhang mit anderen Risiko-reduzierenden Op. wie BSO und vorbestehenden Erkrankungen gesehen werden	2a	A	++
▪ Weitere Notwendigkeit der Fortbildung von Ärztinnen und Ärzten in Bezug auf Möglichkeiten und Vorteile der RRBM	1b	A	++

* Beratung, Risikoberechnung und Nachsorge in spezialisierten Zentren empfohlen

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

* Studienteilnahme empfohlen
 ** Die RRSO 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.
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Formen der Risiko-reduzierenden (bilateralen) Mastektomie (RRBM)

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RRBM reduziert die Inzidenz von MaCa und wahrscheinlich auch MaCa-bedingte Mortalität*

- Einfache Mastektomie
- RRBM mittels SSM**
- RRBM mittels NSM** (MAK*** erhaltend)
- Kontralaterale prophylaktische Mastektomie

Oxford		
LoE	GR	AGO
2b	B	+
2b	C	+
2b	C	+
4	C	+/-

* in Abhängigkeit von Vorerkrankungen, z. B. bei vorbestehendem Ovarialkarzinom 1-2 %

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

*** MAK: Mamillen-Areola-Komplex

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