Diagnosis and Treatment of Patients with early and advanced Breast Cancer

Guidelines Breast
Version 2023.1E

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Oncoplastic and Reconstructive Surgery

Plastic-Reconstructive Aspects after Mastectomy

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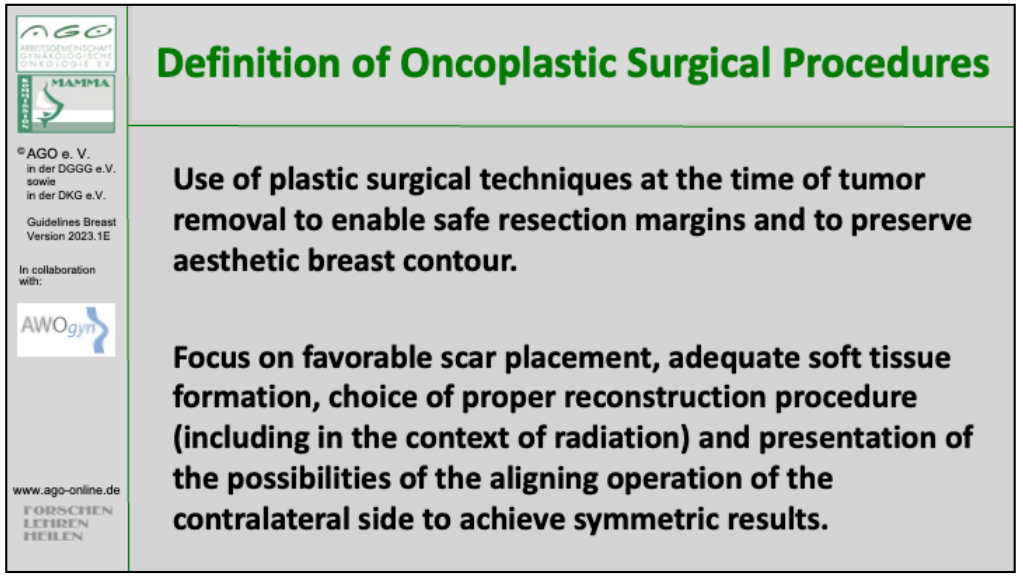

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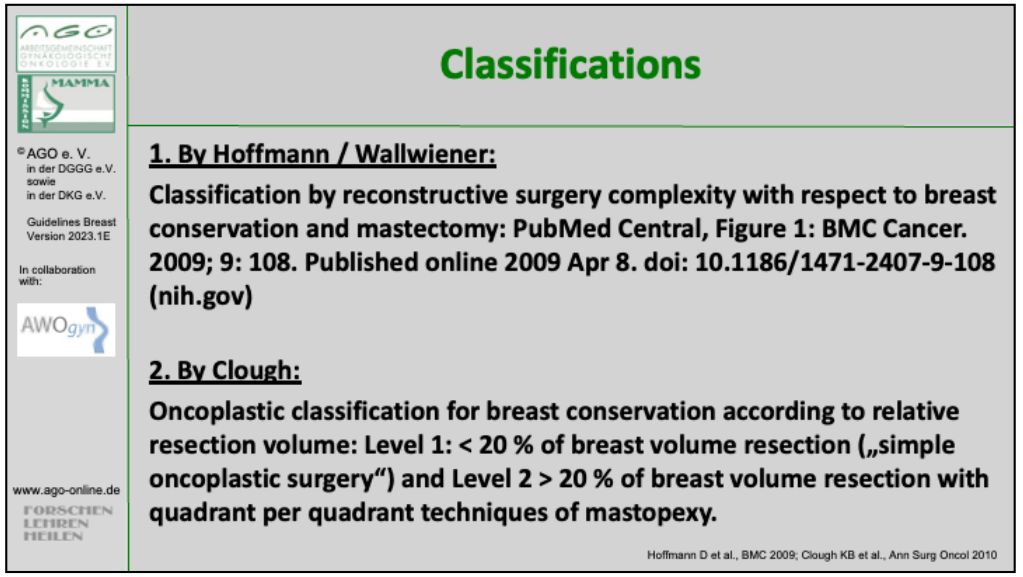

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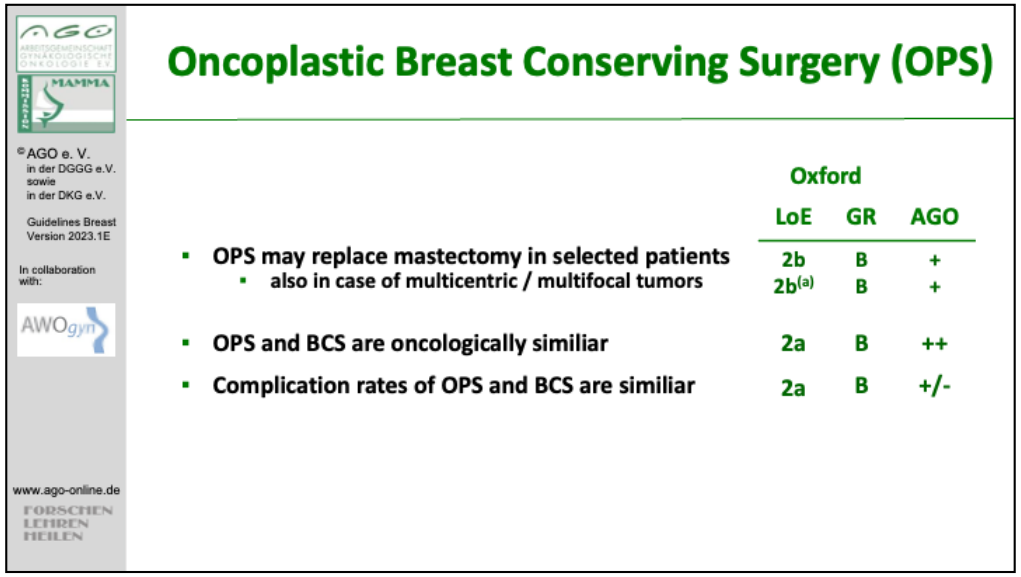

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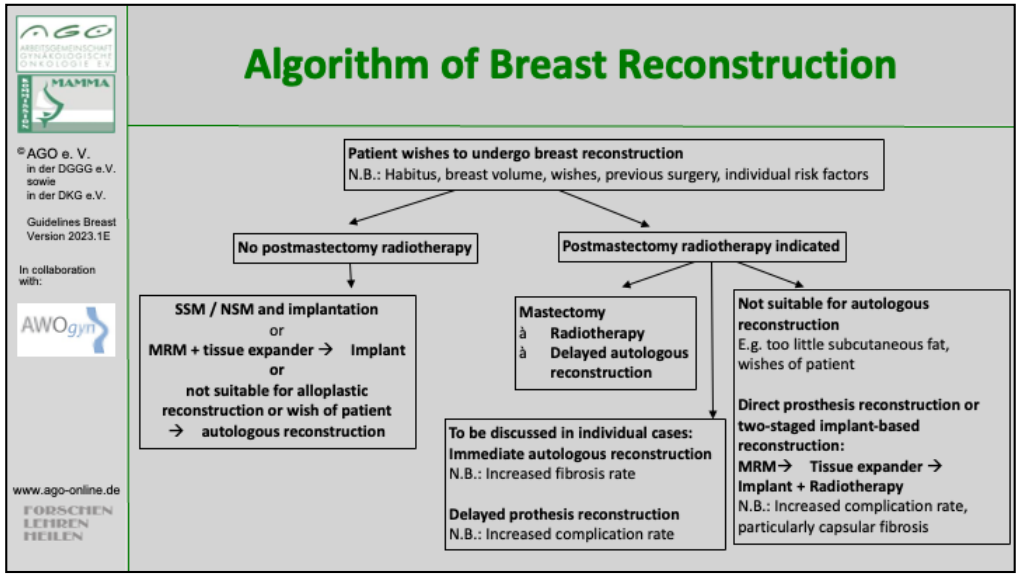

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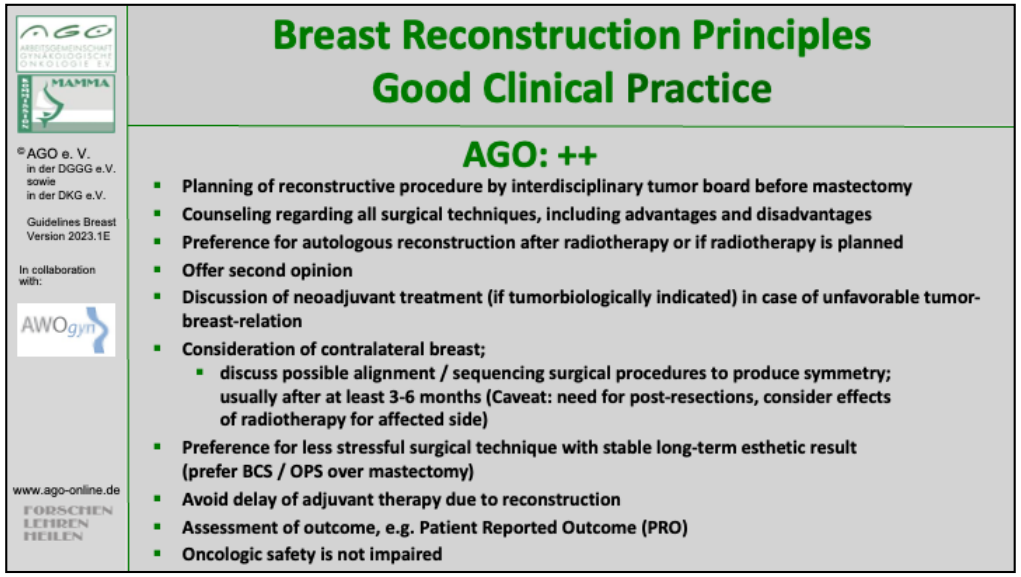

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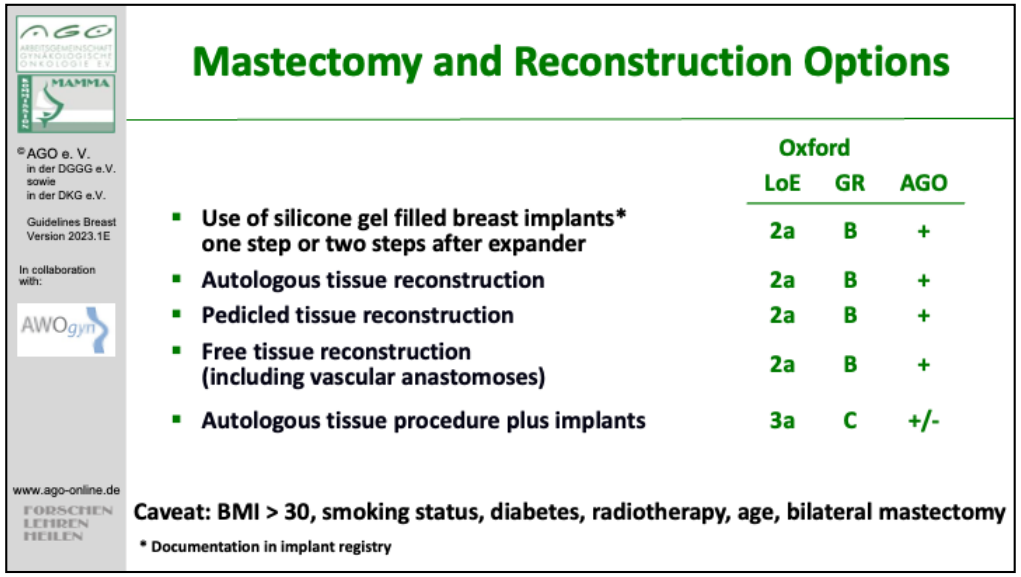

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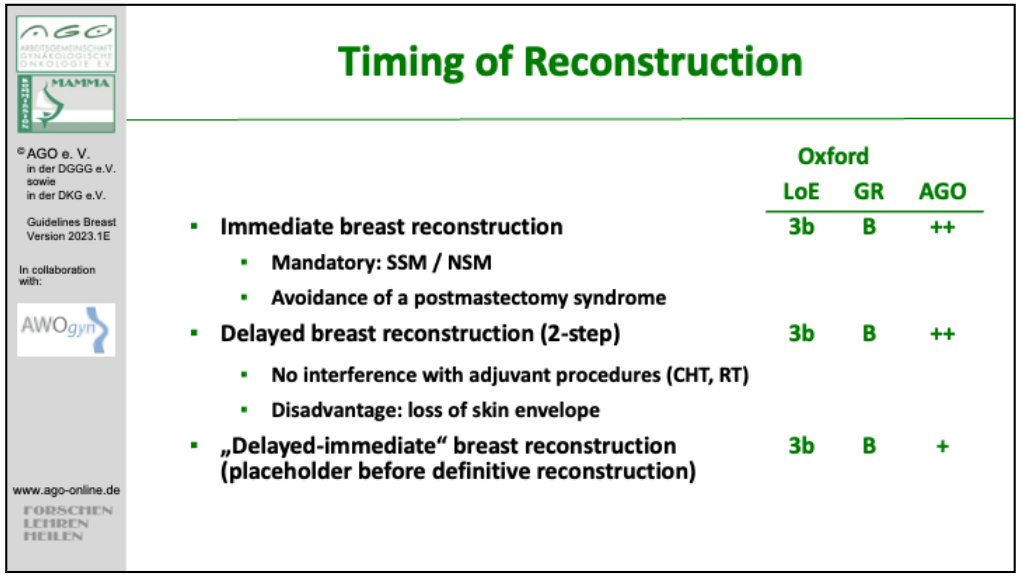

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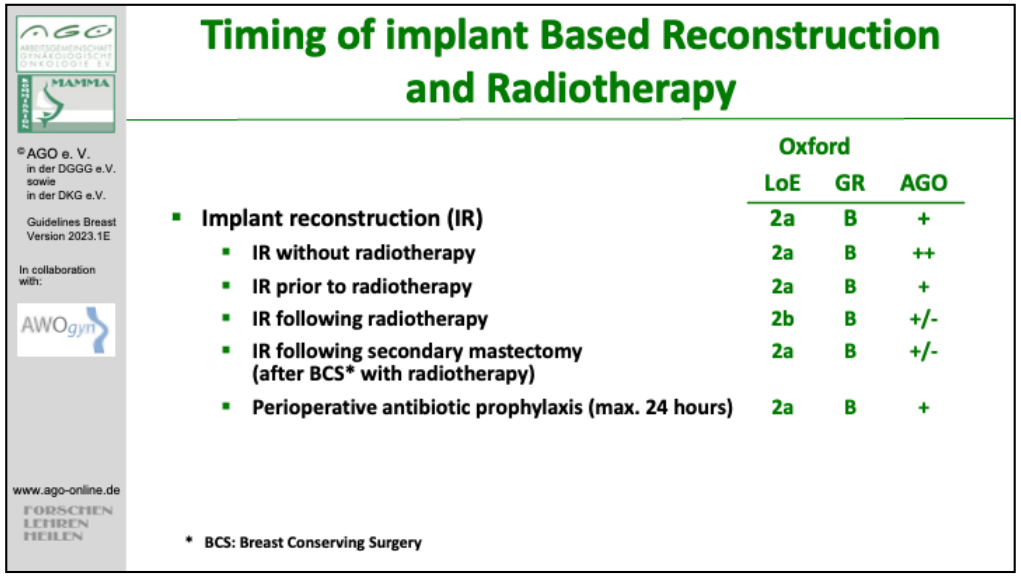

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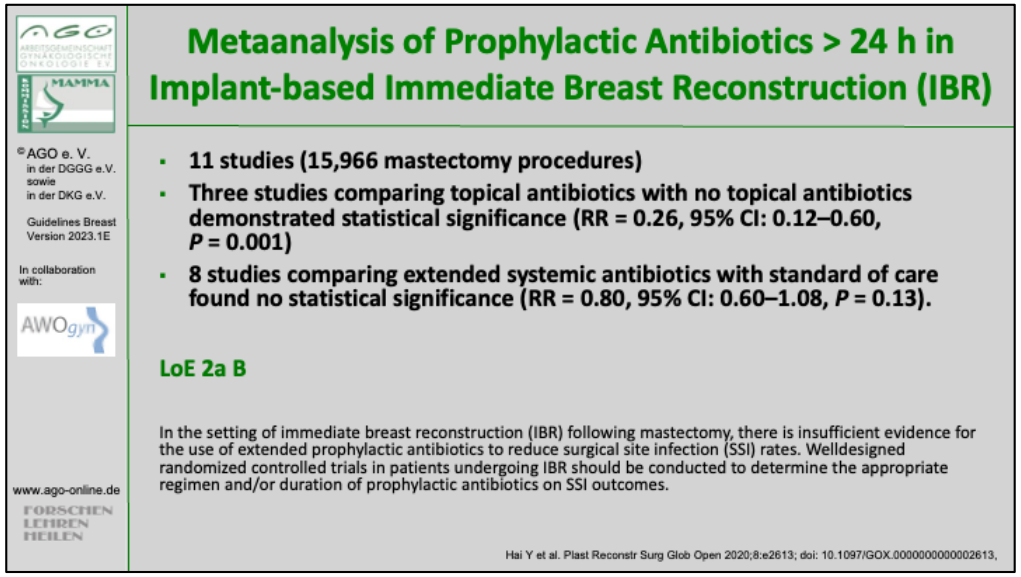

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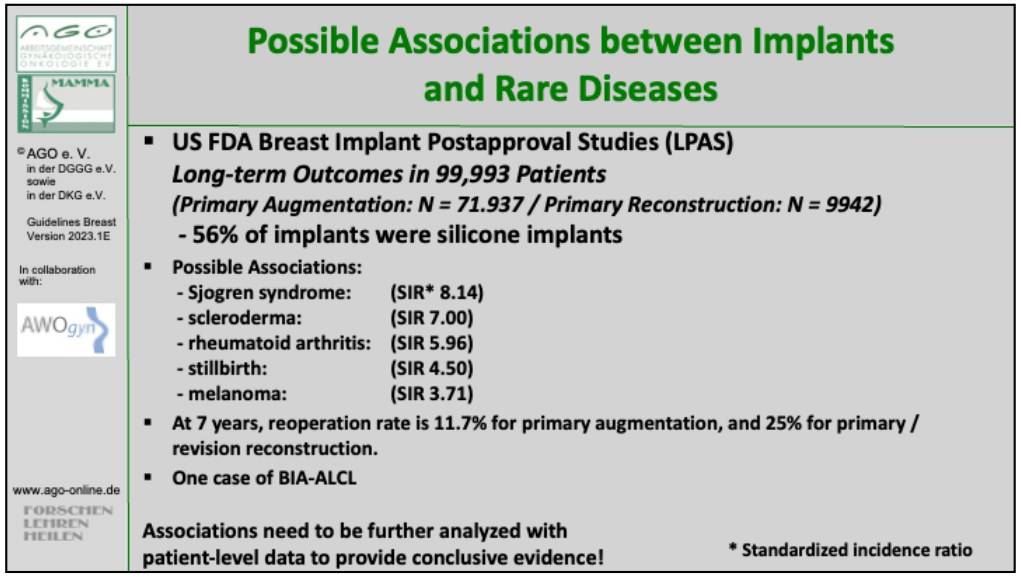

Statistical Analysis:

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.

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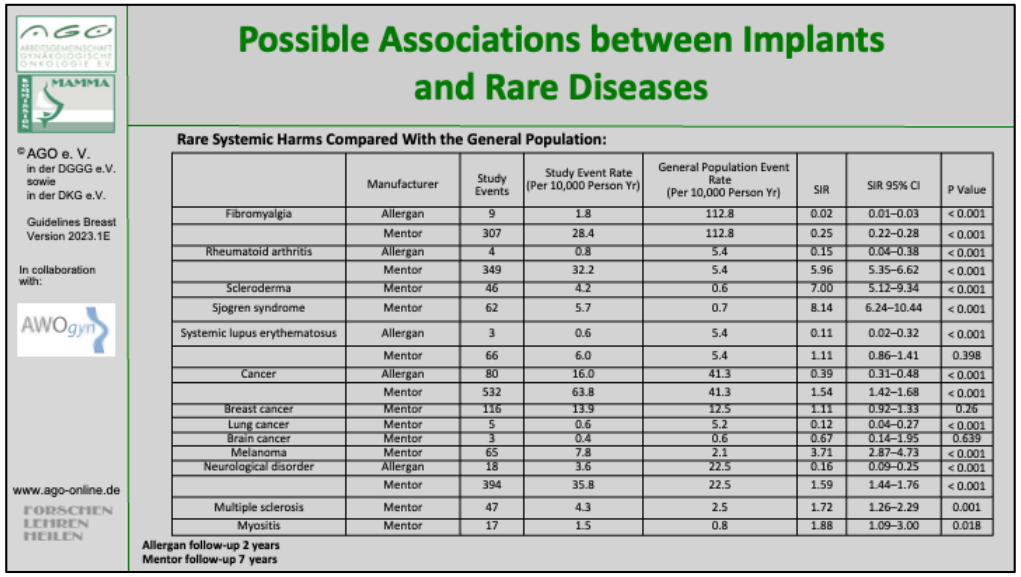

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Possible Associations between Implants and Rare Diseases

Rare Systemic Harms Compared With the General Population:

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

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

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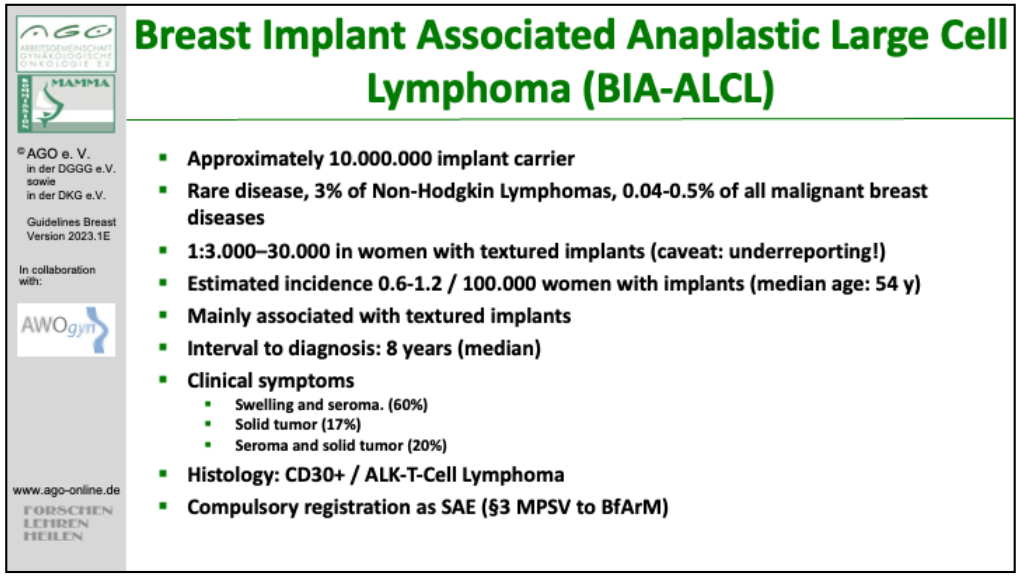

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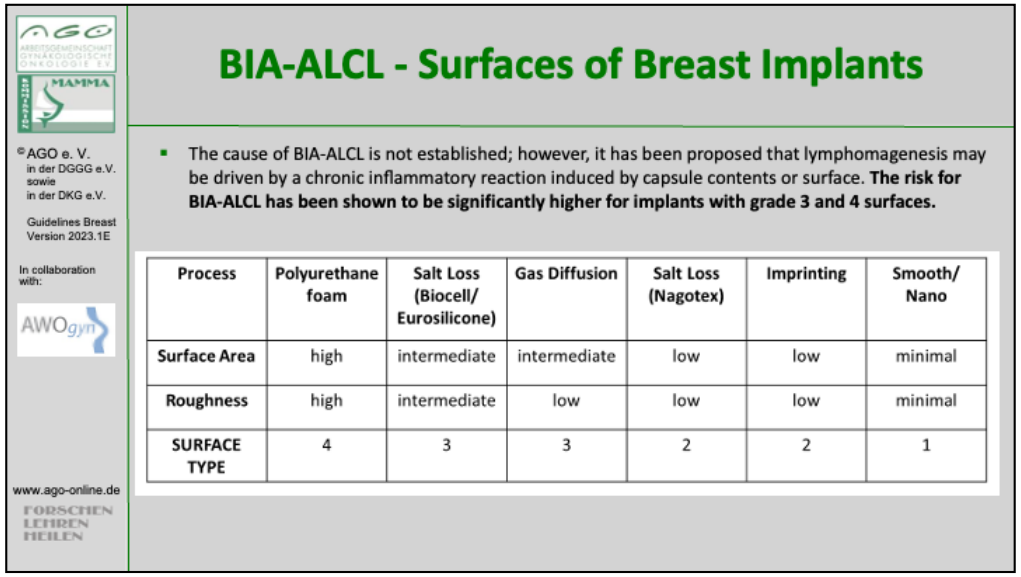

BIA-ALCL - Surfaces of Breast Implants

- 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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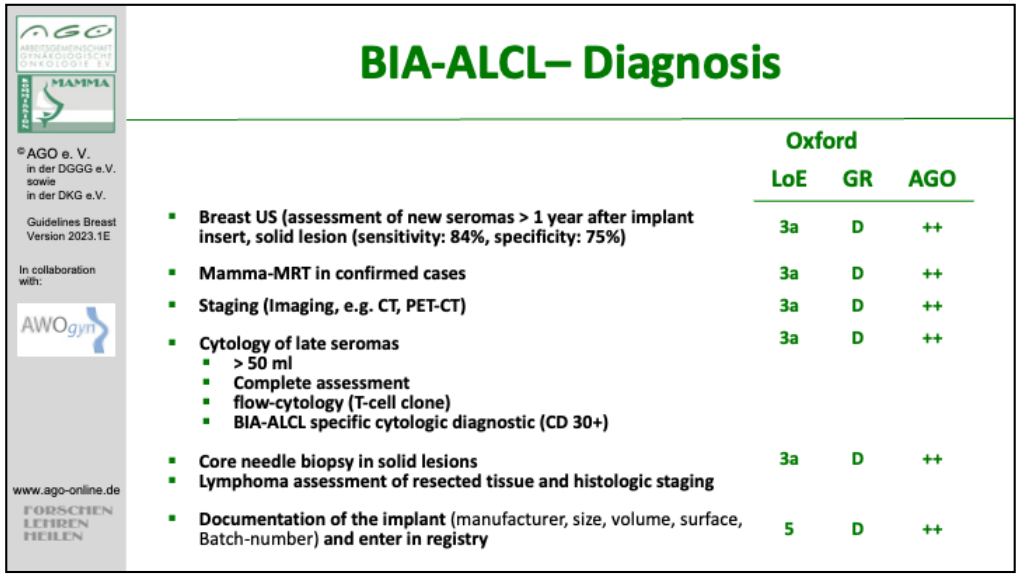

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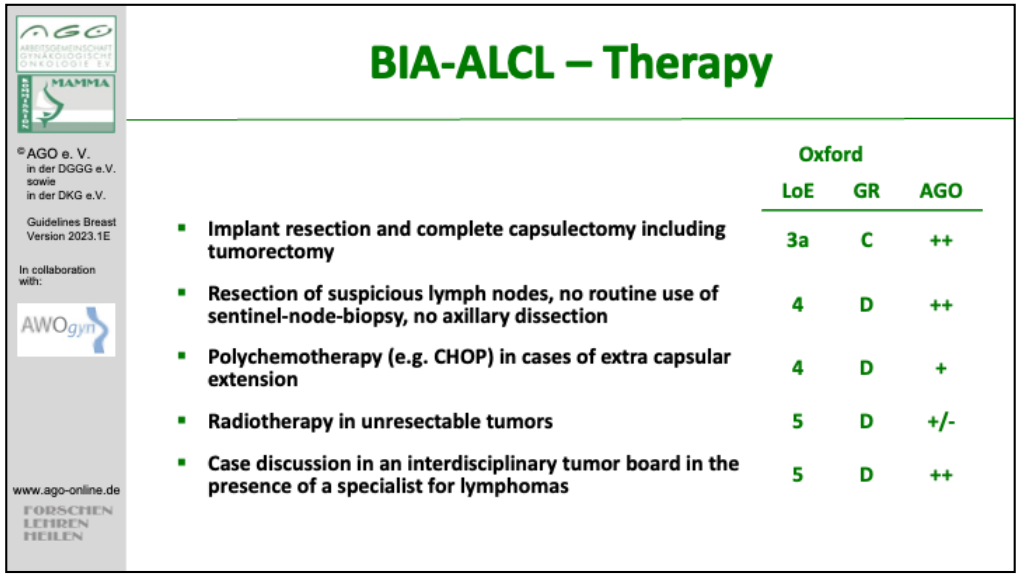

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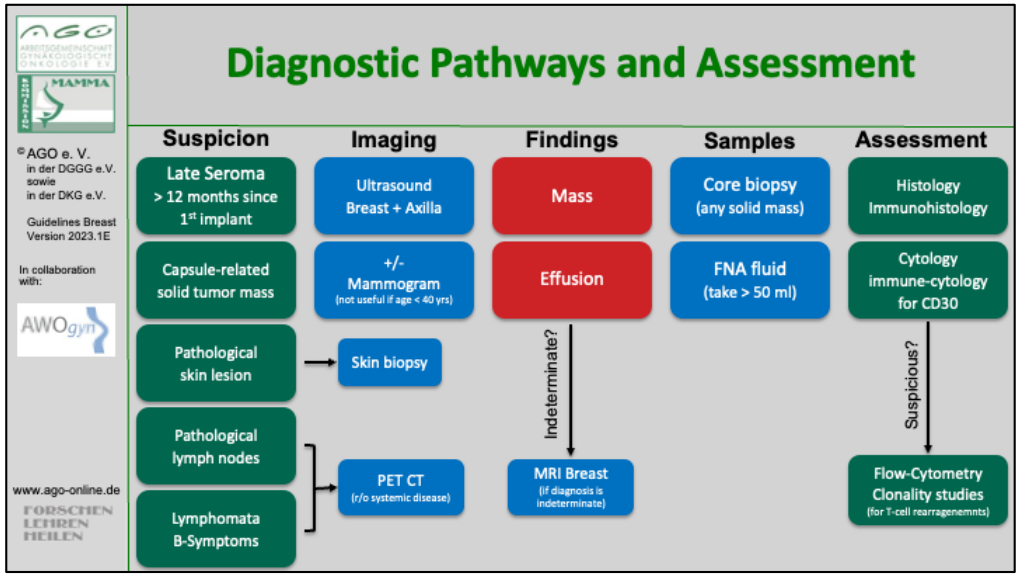

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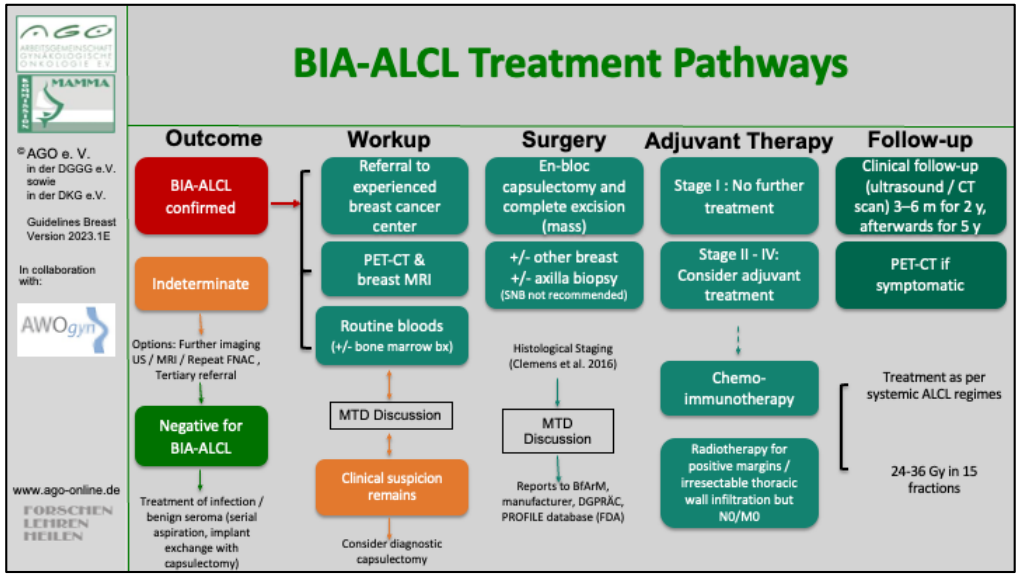

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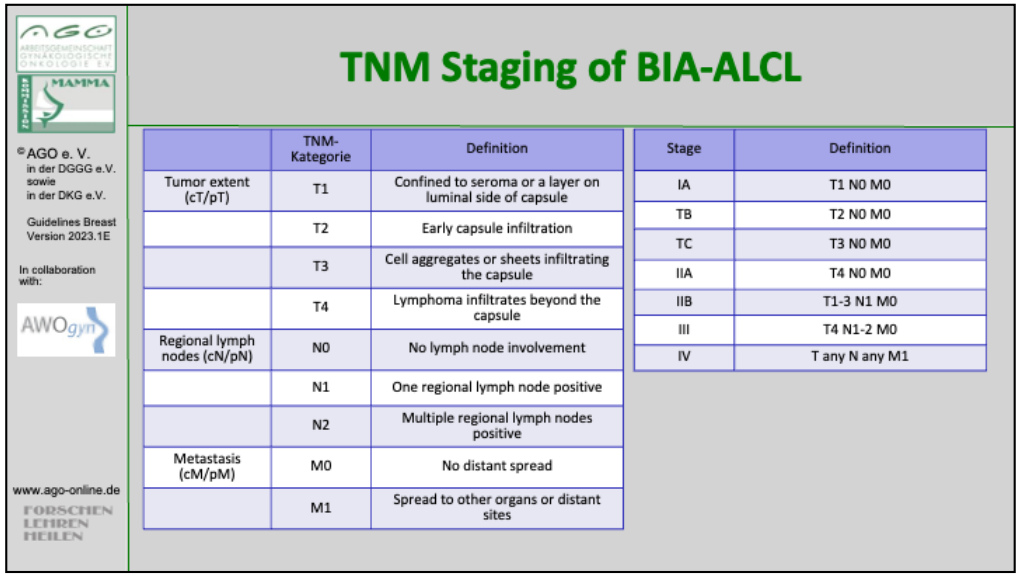

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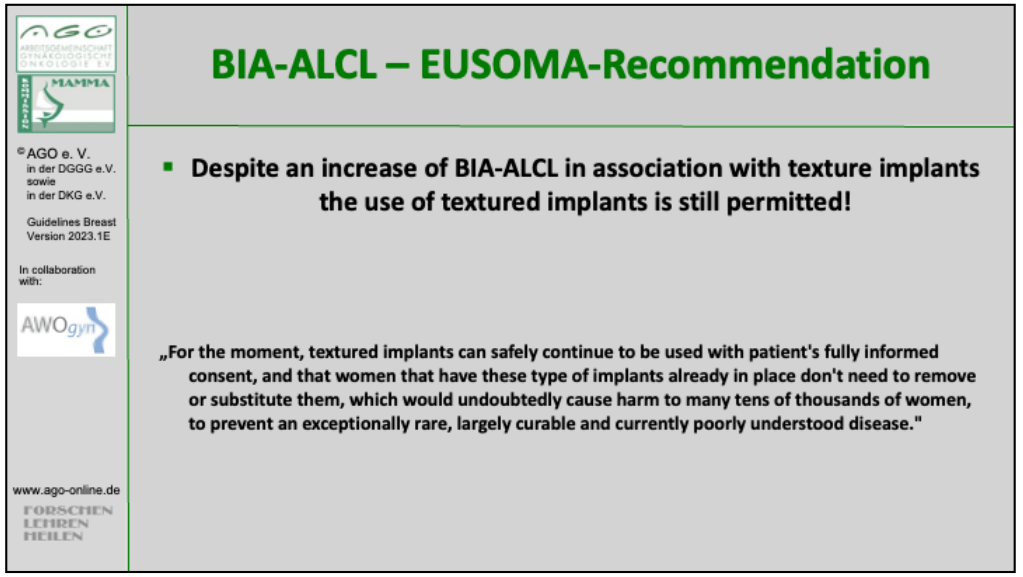

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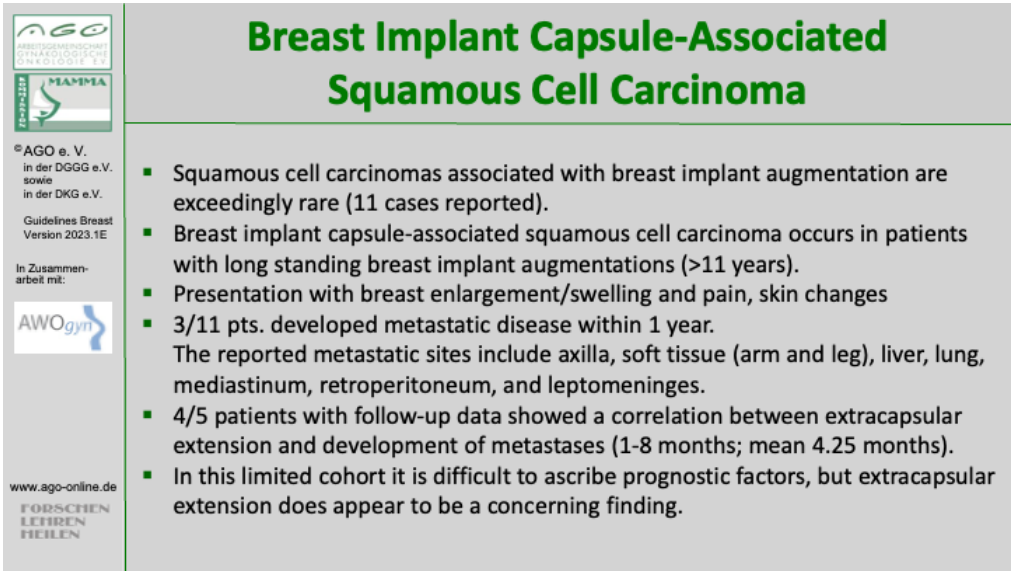

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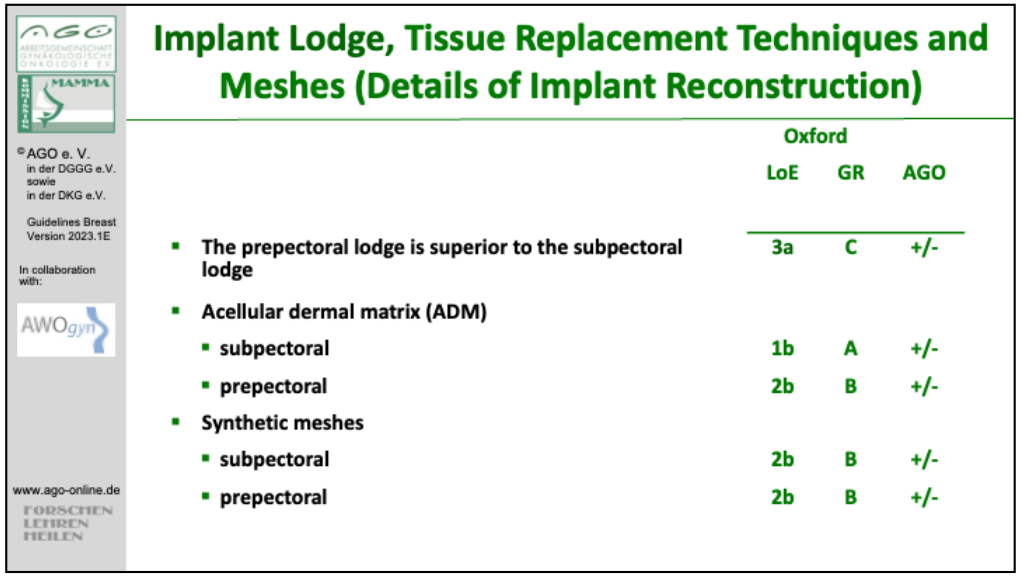

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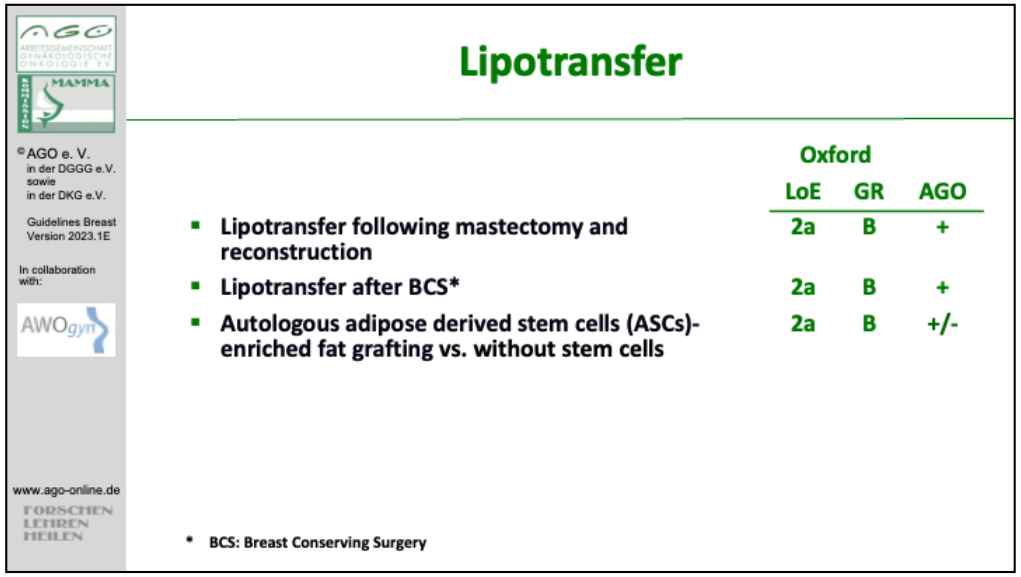

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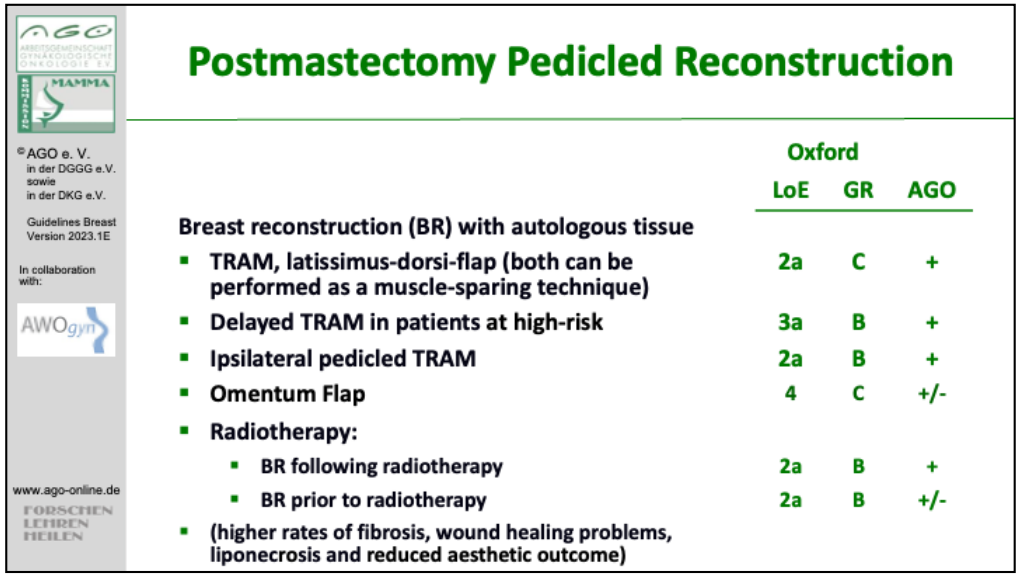

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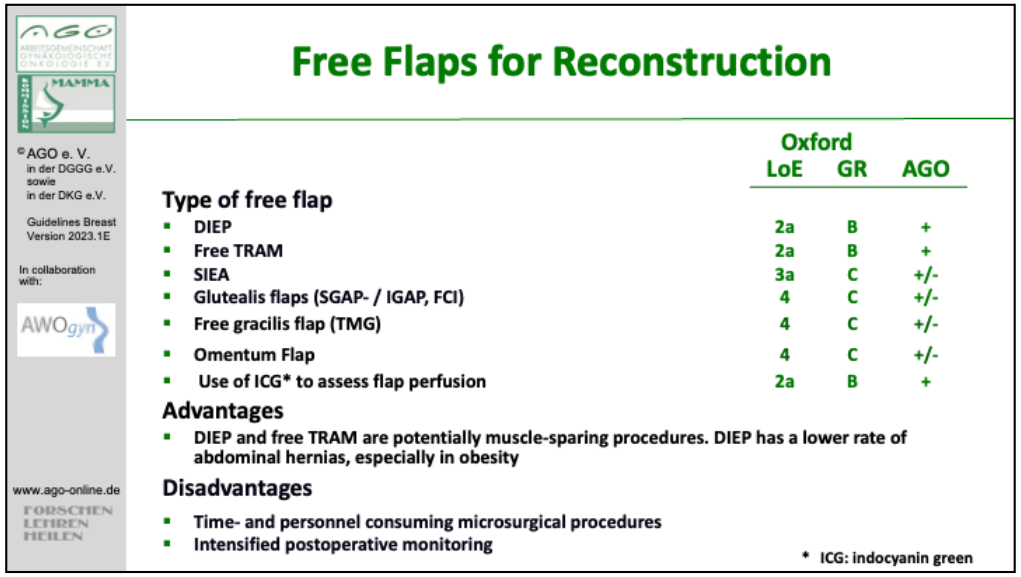

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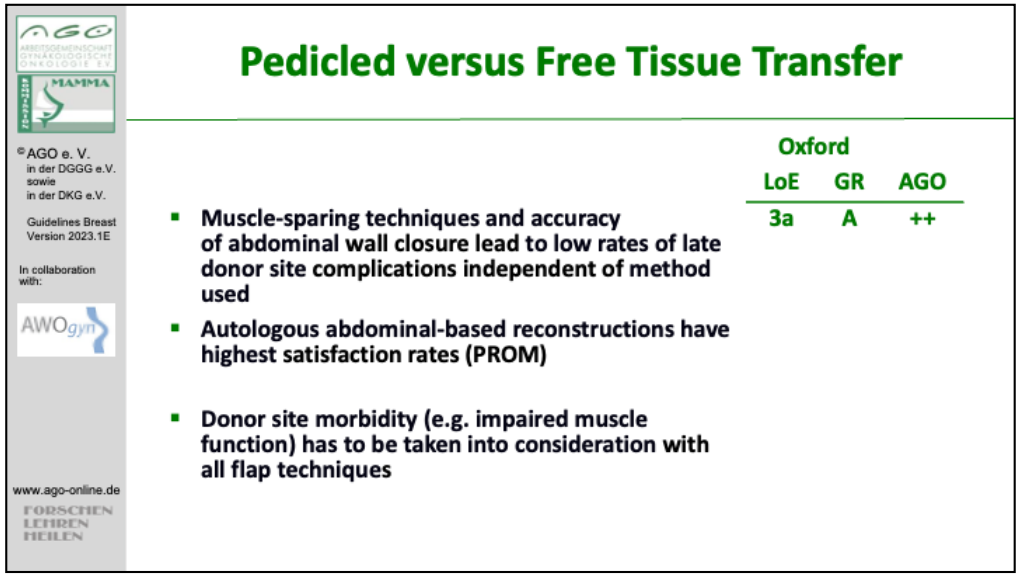

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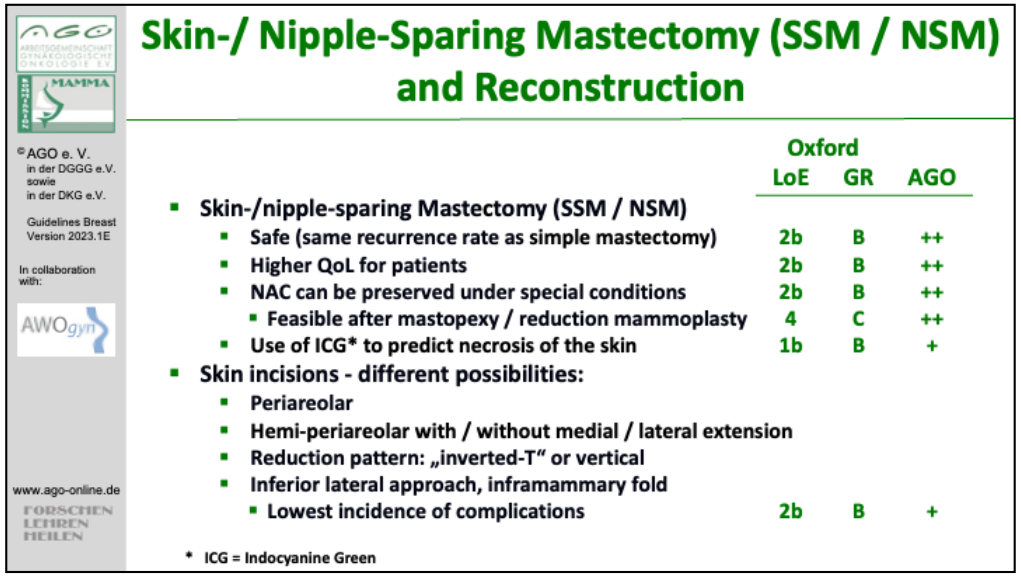

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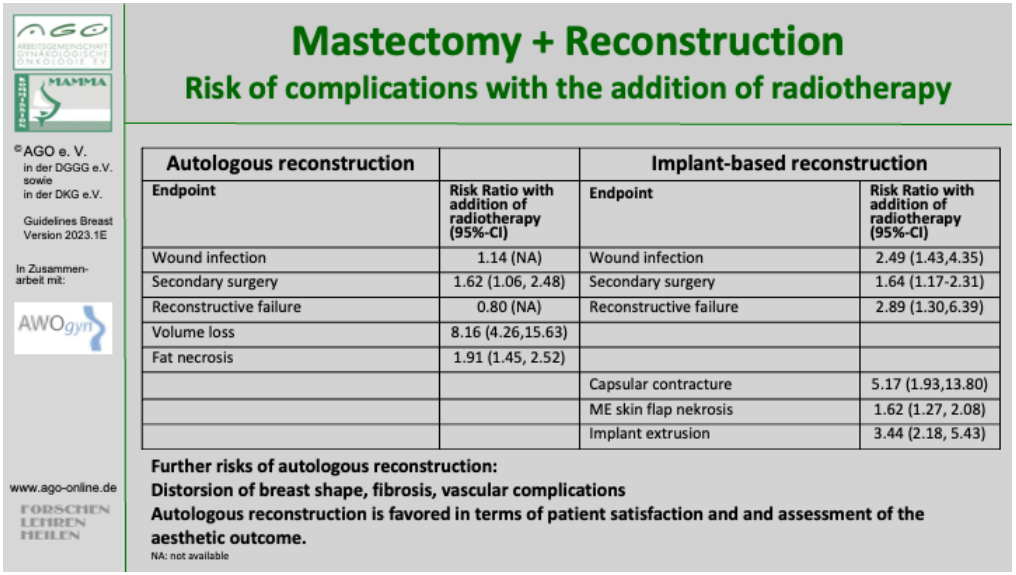

Mastectomy + Reconstruction

Risk of complications with the addition of radiotherapy

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

Further risks of autologous reconstruction:
Distorsion of breast shape, fibrosis, vascular complications
Autologous reconstruction is favored in terms of patient satisfaction and and assessment of the aesthetic outcome.

NA: not available

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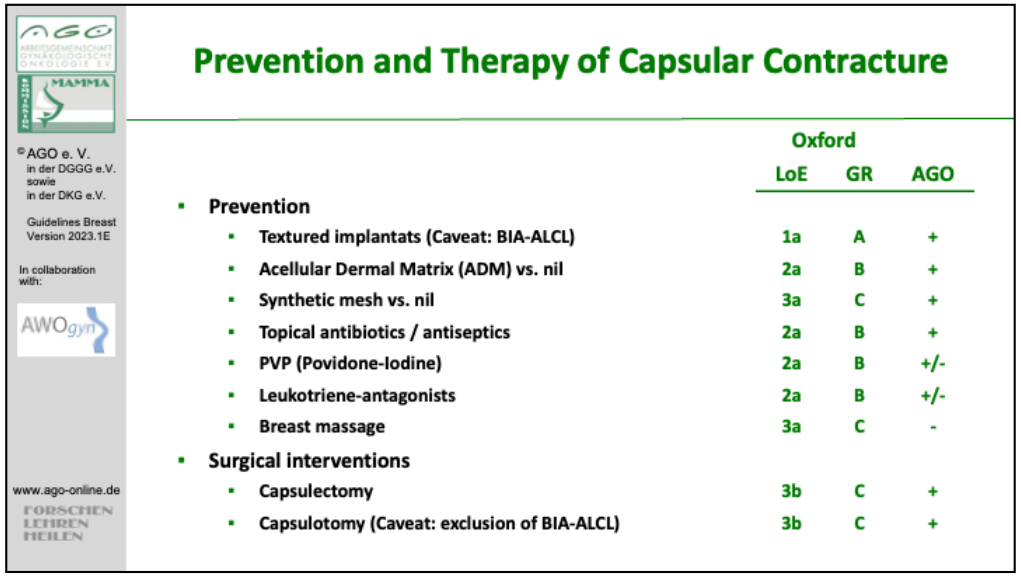

Prevention and Therapy of Capsular Contracture

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

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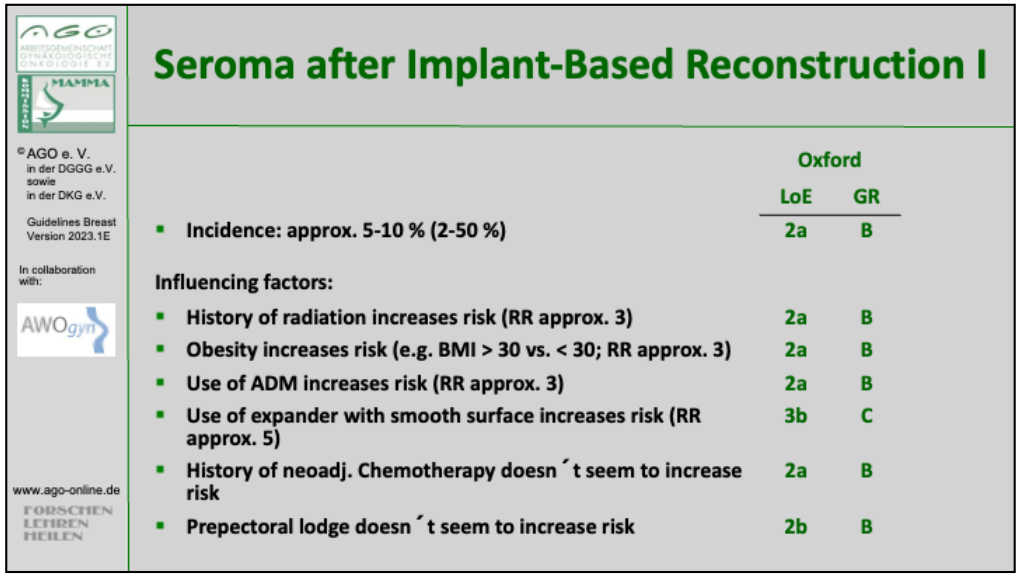

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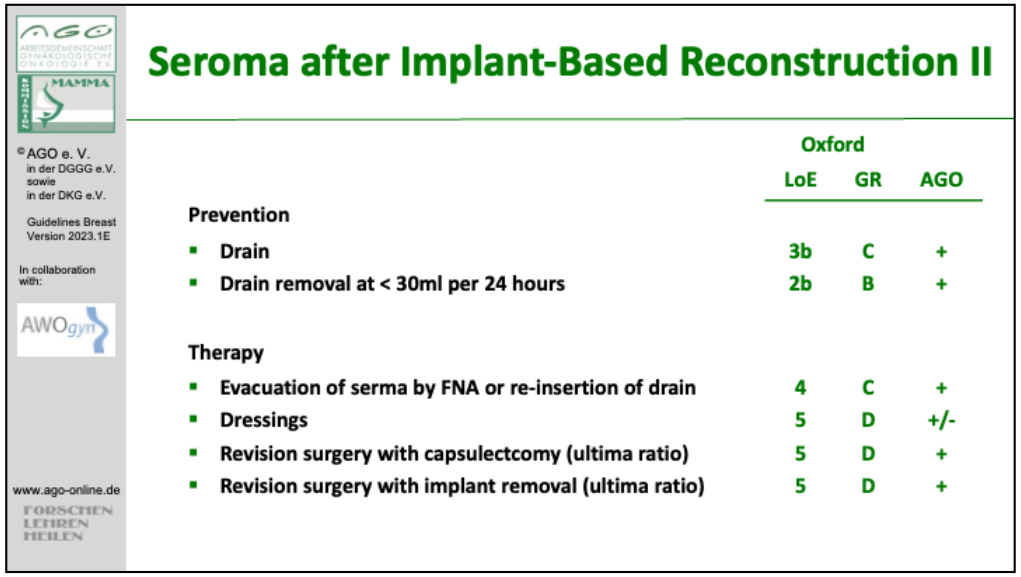

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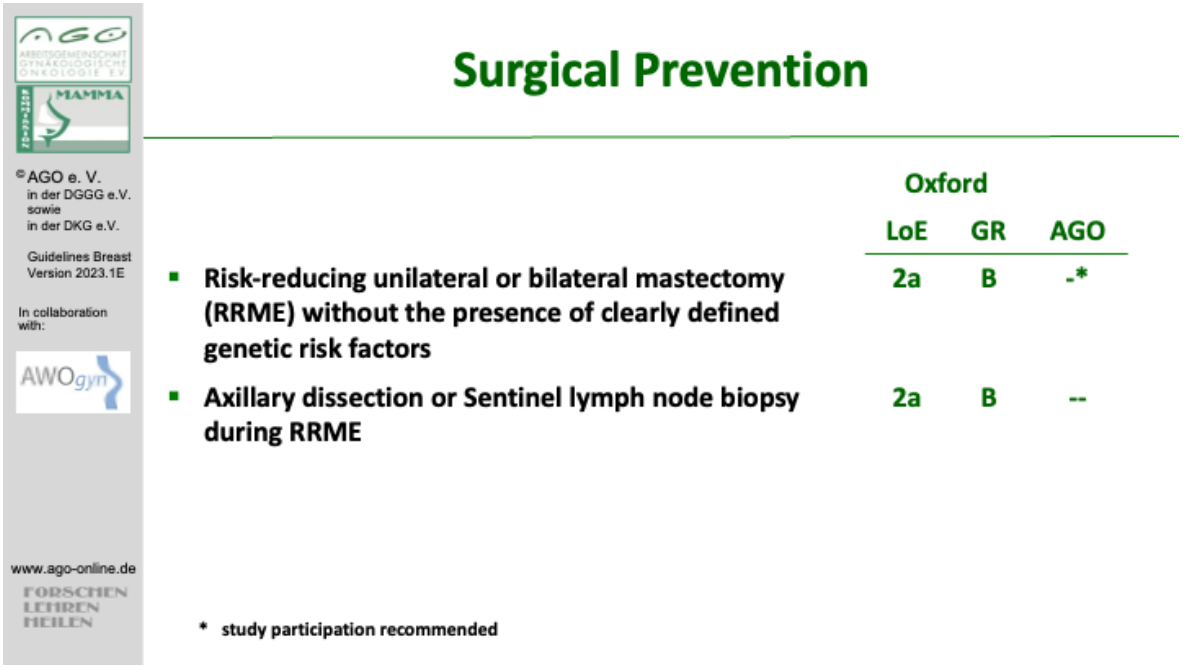

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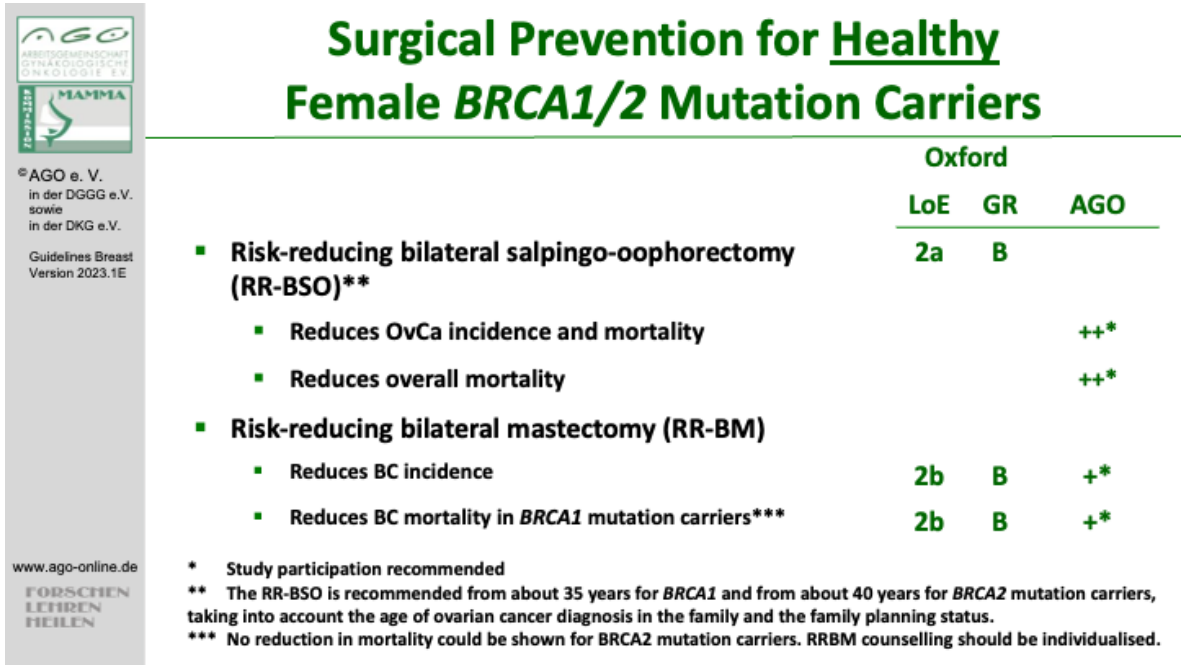

Surgical Prevention for Healthy Female *BRCA1/2* Mutation Carriers

	Oxford LoE	Oxford GR	AGO
▪ **Risk-reducing bilateral salpingo-oophorectomy (RR-BSO)****	2a	B	
▪ Reduces OvCa incidence and mortality			++*
▪ Reduces overall mortality			++*
▪ **Risk-reducing bilateral mastectomy (RR-BM)**			
▪ Reduces BC incidence	2b	B	+*
▪ Reduces BC mortality in *BRCA1* mutation carriers***	2b	B	+*

* Study participation recommended
** The RR-BSO is recommended from about 35 years for *BRCA1* and from about 40 years for *BRCA2* mutation carriers, taking into account the age of ovarian cancer diagnosis in the family and the family planning status.
*** No reduction in mortality could be shown for BRCA2 mutation carriers. RRBM counselling should be individualised.

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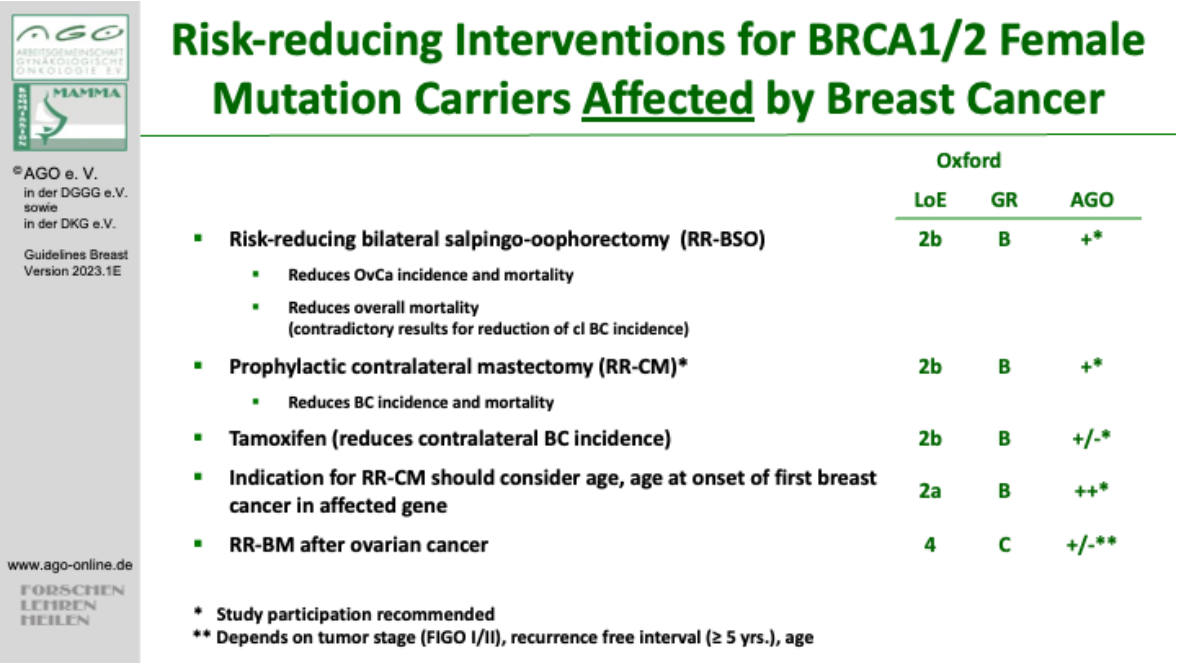

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