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Toxicity and cosmetic outcome after IOERT to the partial breast during breast conserving surgery of breast cancer patients in early stages: First results of a prospective single-center registry trial (415-E/2464/5-2019)

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Background

- ❖ **Partial breast irradiation (PBI) is established as viable treatment option for early staged breast cancer**
 - ❖ ESTRO/ACROP recommendations 2022 [Meattini I et al, Lancet Oncol, 2022]
 - ❖ ASTRO recommendations for PBI 2024 [Shaitelman SF et al, Pract Radiat Oncol 2024]
 - ❖ St Gallen consensus 2023 [Curigliano G. et al, Ann Oncol 2023]
- ❖ **Recommended techniques by int. Guidelines (ESTRO, ASTRO, DEGRO*)**
 - ❖ External photons (IMRT, 3-D CRT)
 - ❖ (Single-) Multi-catheter Brachytherapy
 - ❖ IOERT in clinical trials or multi-institutional registry
- ❖ **For IOERT as one stop PBI exist:**
 - ❖ European practical guidelines [ESTRO/ACROP 2020, Radiother Oncol 2020]
 - ❖ Comparable recurrence rates to other techniques in a low risk scenario [Cernusco NLV et al, Clin Breast Cancer, 2021]

* Strnad V et al STRONK 2020

Clinical endpoints

❖ Early ad late toxicity

- ❖ CTCAE RTOG toxicity score [Trott et al, IJRBP 2000]
- ❖ LENTSOMA Score [Rubin P et al, Pavay JJ et al Radiother Oncol 1995]

❖ Cosmetic outcome (subjective (patients) and objective (doctors))

- ❖ Van Limbergen Score [Van Limbergen E Radiother Oncol 1989]

❖ Local control (within the breast)

❖ Locoregional control (breast and regional nodes)

❖ Disease free survival (any event according to breast cancer)

❖ Overall survival

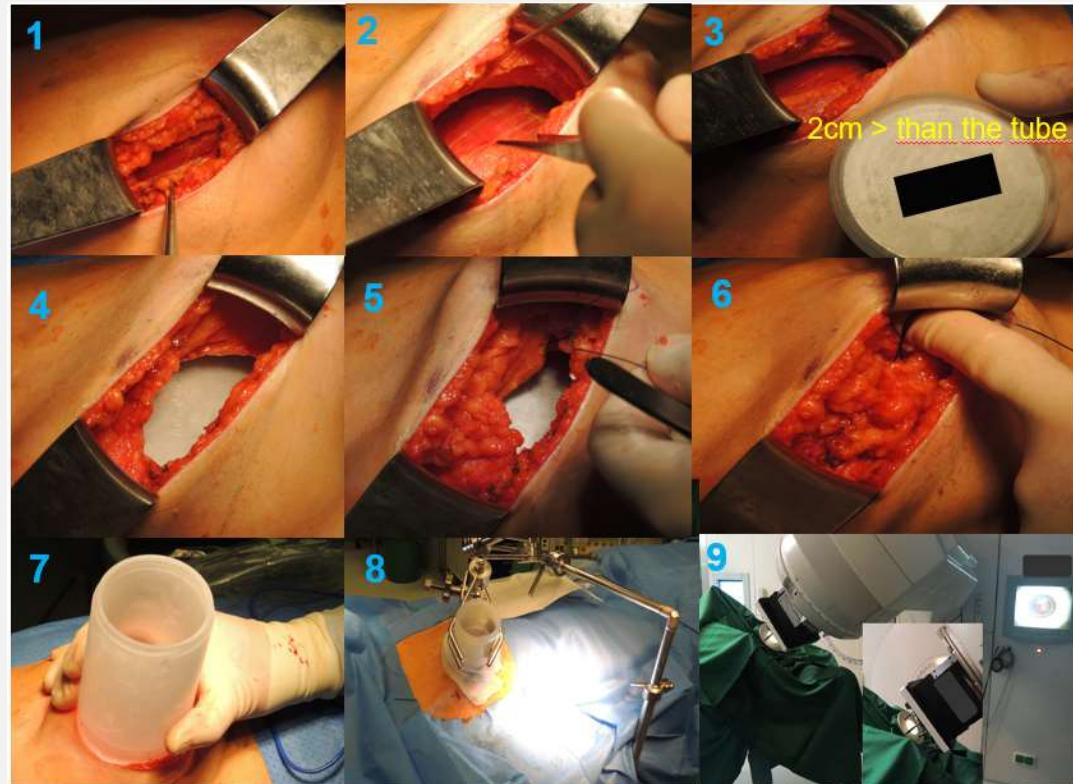
Inclusion criteria

- Inv. breast Carcinoma
- Age: ≥ 50
- T-status: T1 (<2 cm)
- N-status: N0
- R0-Resection
- Grading: G1-G2, KI 67 $\leq 25\%$
- Luminal A

Method: IOERT as PBI – „ELIOT – like“

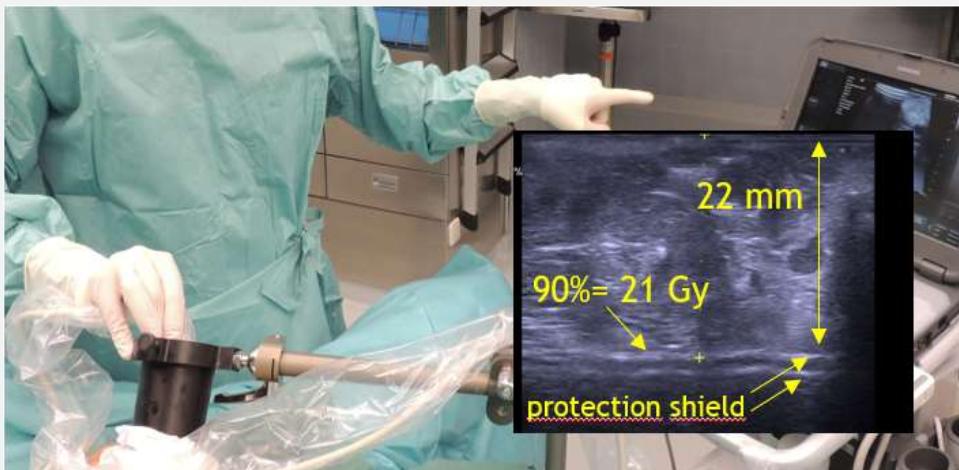
Procedure:

- 1: Lumpectomy
- 2: Prepect. pocket
- 3-4: Protection shield
- 5-6: tissue approximarion
- 7-8: tube positioning
- 9: patient positioning

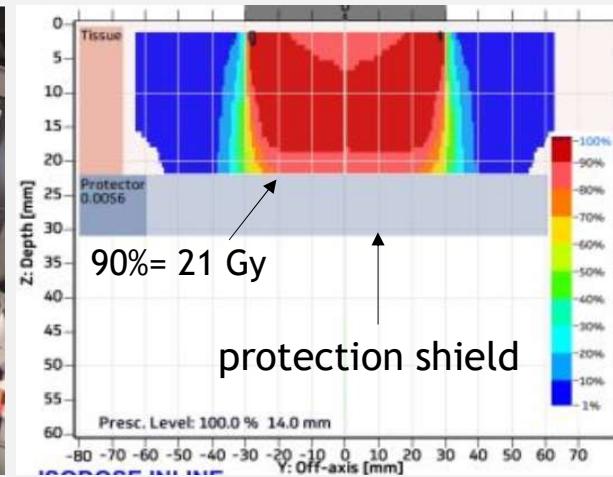


Method: IOERT-PBI

intraop. ultrasound

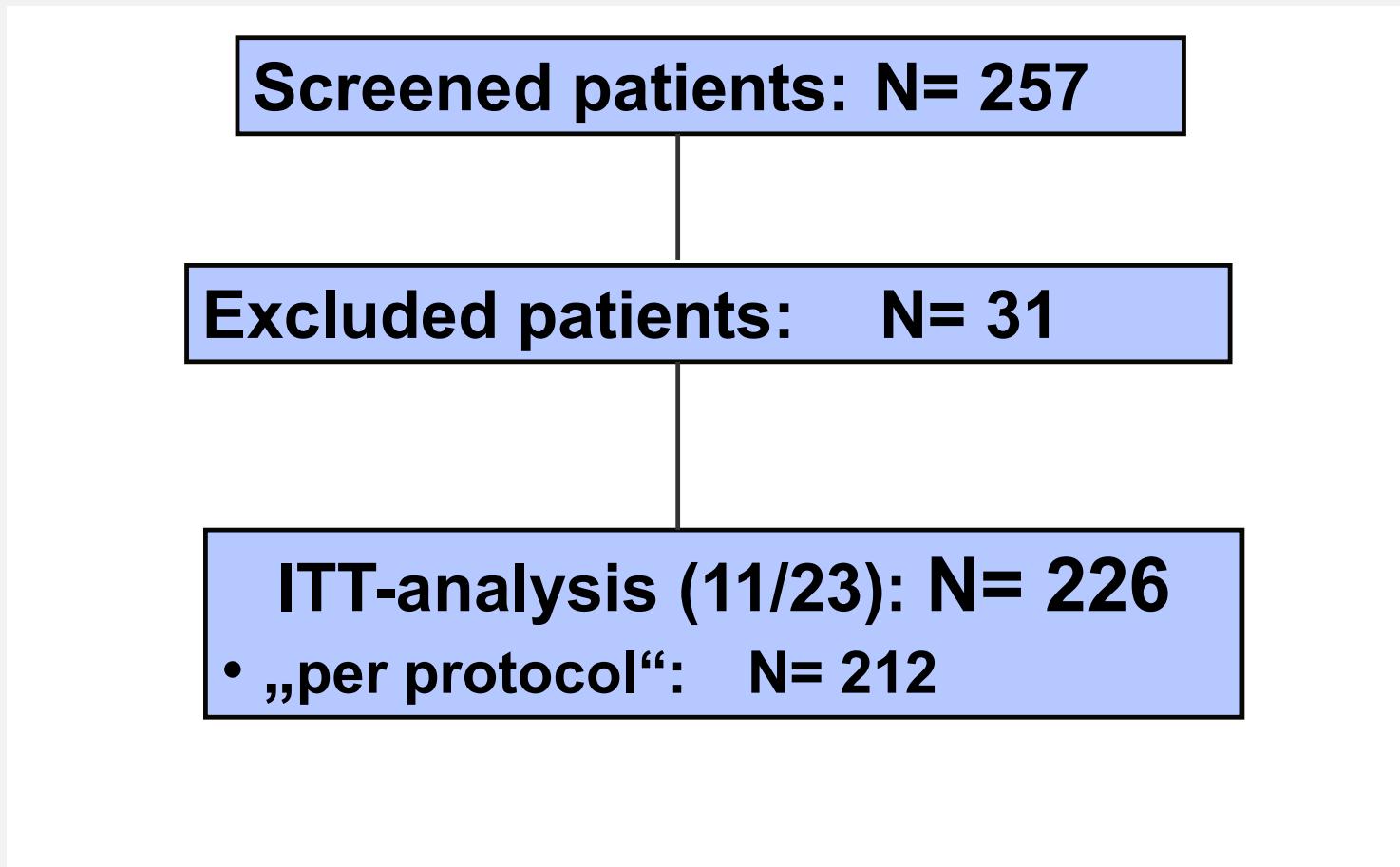


Electronprofile



- Electron energy MeV: 6 – 12, Tube diameter cm: 5 – 7 (8)
- Dosage: 21Gy (90%), 23.4 Gy D max, V90 ml: $V=\pi r^2 \cdot h$ (zylinder) or
 $V=(4/3)\pi a^2 c$ (ellipsoid)

CONSORT-Diagram: 11/23



Patients in FUP: N= 222

- Patients in FUP: **222**
- week1 : 222
- week 4: 215
- month 4/5: 204
- 1 year: 177 80 %
- 2 years: 135
- **3 years: 91 41%**
- **4 years: 47 21%**
- 5 years: 5
- FUP (Months): Median **25 (0.7 – 61)**



Characteristics

pT-Stage	n	Histology	n
1	212	IDC/NST	163
2	9	ILC	30
x	1	others	19
		mixed	10
pN- Stage		EIC-status	
0	203	negative	206
1	18	positive	16
3	1		
R-status		Grading	
R0	219	G1	90
R1	3	G2	131
		G3	1
Multifocality		KI67 (%)	
no	214	<20%	203
yes	8	≥20%	17
HER2-status		ns	
neg	218		2
pos	0		
low	3		

Characteristics

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R1	3	G2	131
		G3	1
			0.4%
Multifocality		KI67 (%)	
no	214	<20%	203
yes	8	≥20%	17
		ns	2
HER2-status			
neg	218		
pos	0		
low	3		

Adjuvant treatment

Adjuvant systemic treatment

ET:	N=210, 95%
CTX or ITX:	N=3, 1.5%
ET+CTX/ITX:	N=3, 1.5%

Adjuvant RTX

WBI:	N=5, 2.3%
RNI:	N=2, 1%
WBI/RNI:	N=7, 3%

} 6%

Technical parameters

Tube diameter cm:	Med. 6 (5-8)
Electron energy MeV:	Med. 9 (6-15)
Depth of 90% (21Gy) mm:	Med. 25 (11-40)
V 90 ml:	Med. 36 (5-95)
Lead shielding cm:	Med. 8 (7-9)
Resected tissue (g):	Med. 31 (7-181)

Acute Toxicity

<i>Evaluation:</i>	222	215
<u>CTCAE</u>	<i>1wk postop</i>	<i>4 weeks postop</i>

0 (no reaction):	62 %	71%
I (faint reaction):	25 %	20%
II (moderate):	0.4%	1.4%
III (pitting edema):	0.9 %	0.5%
ND	12 %	7%

Σ CTCAE 0/I	87%	91%
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LENTSOMA G0/I reaction

LENT-SOMA scale	4-5 M % of n=204	13 M % of n=177	24 M % of n=135	36 M % of n=91	48 M % of n=47	60 M % of n=5	Σ mean %
Pain	95.4	98.2	98.4	97.6	97.6	100	97.8 (95.4- 100)
Edema	98.4	100	100	100	100	100	99.7 (98.4- 100)
Fibrosis	85.5	87.5	88	87	81	100	88.2 (81- 100)
Teleangiectasia	100	100	100	100	98	100	99.6 (98 - 100)
Retraction	100	100	100	100	100	100	100
Σ mean %	96	97	97	97	95	100	97

Acute and late G3/4 reactions ?

CTCAE G3 (no G4 was observed)

CTCAE G3	1wk postop	4 weeks postop
Pats	2*	1**

* significant postop. hematoma with edema

** prolonged woundhealing

LENT-SOMA G3 (no G4 was observed)

LENT-SOMA scale	4-5 M % of n=204	13 M % of n=177	24 M % of n=135	36 M % of n=91	48 M % of n=47	60 M % of n=5	Σ mean %
Pain	1	0	0	0	0	0	0.16
Edema	0.5	0.6	0	0	0	0	0.18
Fibrosis	0.5	0.6	0	0	0	0	0.18
Teleangiectasia	0	0	0	0	0	0	0
Retraction	0	0	0	0	0	0	0
Σ mean %	0.4	0.24	0	0	0	0	0.1

Seroma / Liponecrosis

Seroma

FUP	% of observed pats	Seroma ml (mean)
10-14 days	49% (n=109)	70 (15-270)
4 weeks	37% (n=80)	63 (10-210)

Liponecrosis

liponecrosis score*	3y % (n) of n=82	4y % (n) of n=43	5y % (n) of n=5
No liponecrosis	32 (35)	25.6 (11)	40 (2)
asymptomatic (radiologic)	39 (32)	44.2 (19)	60 (3)
symptomatic (without medication)	24.4 (20)	28 (12)	0
symptomatic (with medication)	1.2 (1)	2.3 (1)	0
ns	11 (9)	9.3 (4)	0

* Lovey K et al al; J Radiat Oncol Biol Phys 2007; 69:724-31

Cosmesis evaluation:

Rep. Photodocumentation, Double evaluation: Doctor/Patient

Qualitative 5-Point-Score Van Limbergen E 1989

E₀: Excellent

E₁: Good

E₂: Moderate

E₃: Bad

E₄: Complications

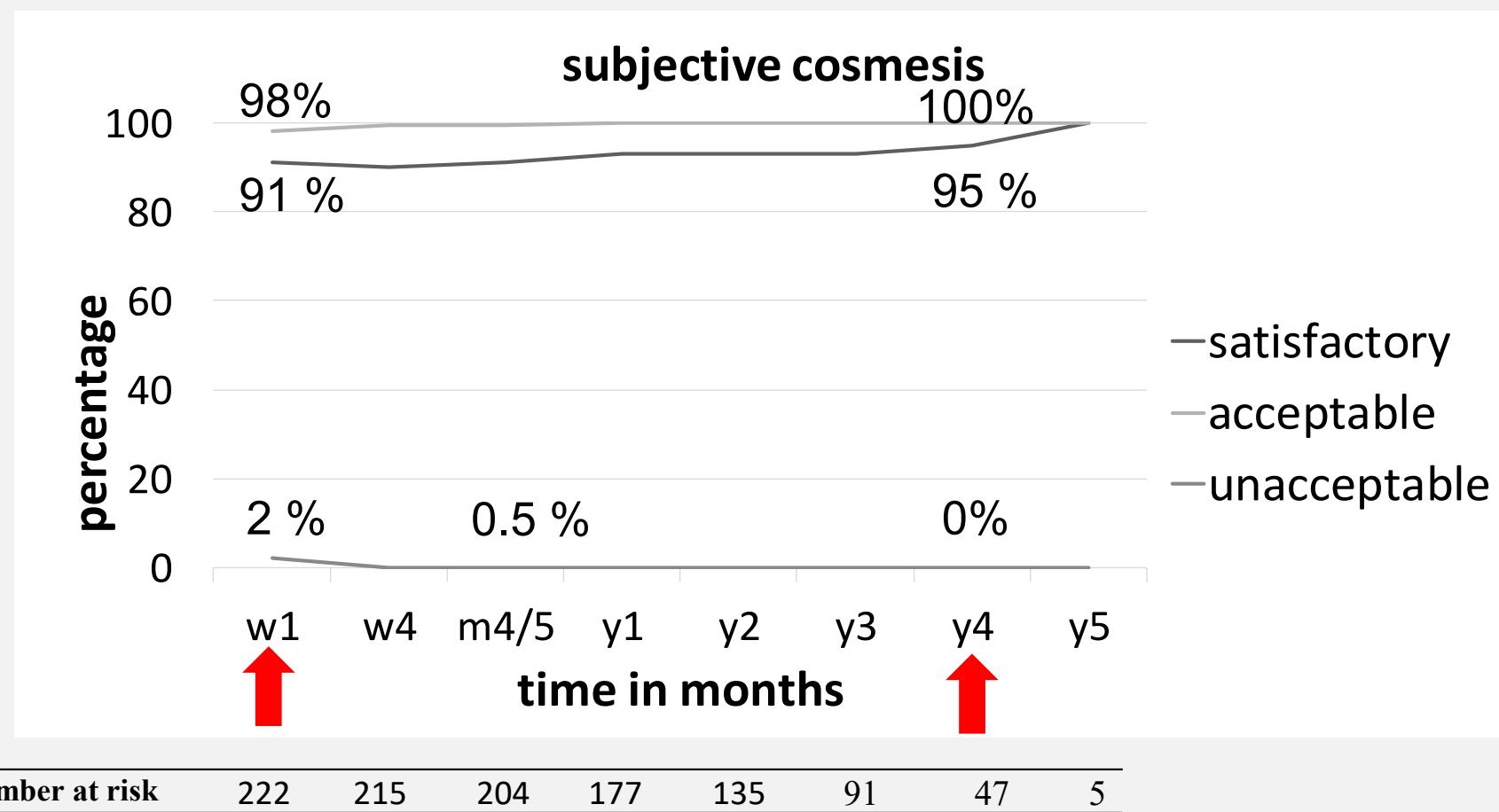
E₀-E₁: Satisfactory

E₀-E₂: Acceptable

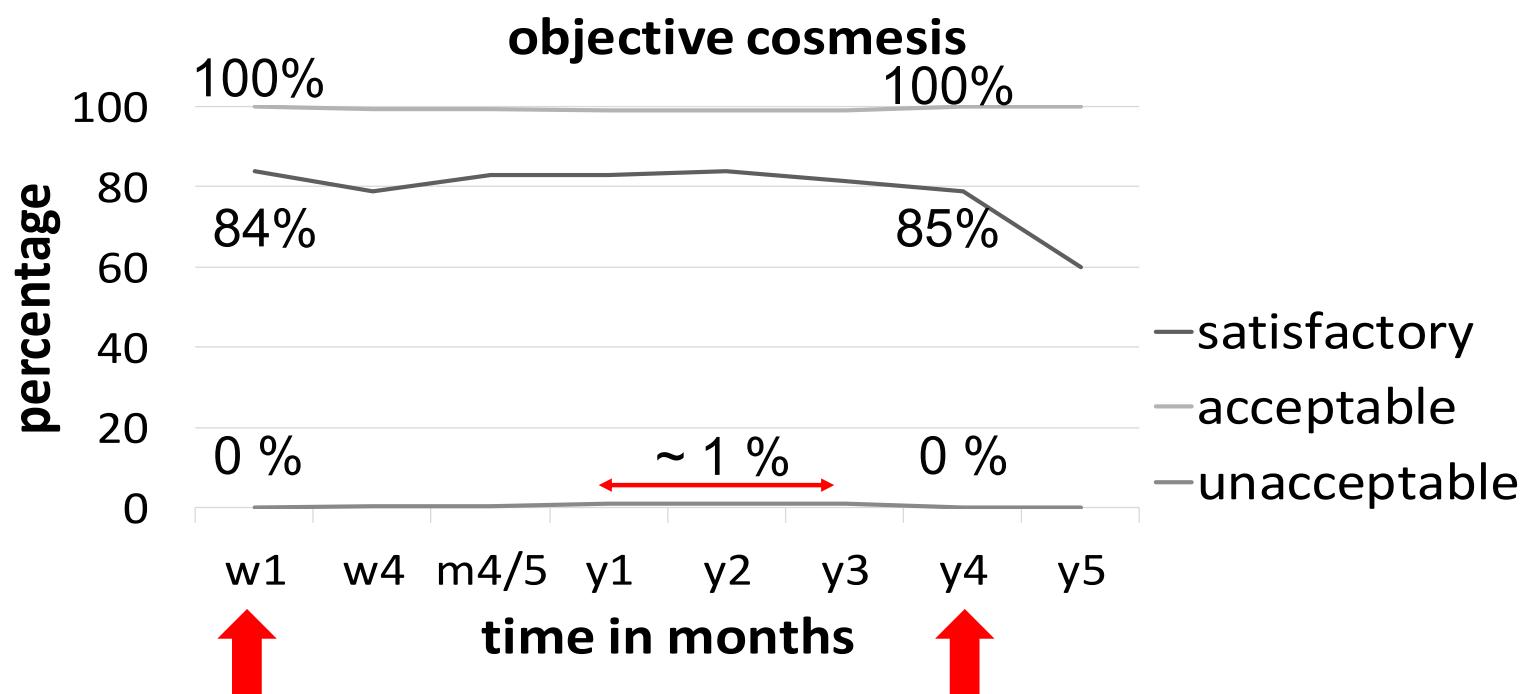
E₃-E₄: Unacceptable



Subjective cosmesis



Objective cosmesis



Number at risk	222	215	204	177	135	91	47	5
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Clinical Results:

FUP (Months): Med. 25 (0.7 - 61)

- ***No In Breast recurrence***
- ***No Reg. recurrence***
- ***Metastases: n=2***
- ***Died: n=2***
 - *of disease: 1*
 - *other reasons: 1*

Conclusion

- First interim analysis 11/2023:
 - Acute and late toxicity: (very) mild
 - Subjective /objective cosmesis: No difference of baseline vs. y4
 - No local / regional recurrence short term FUP
- Acknowledgement:
 - IOERT staff of radiation oncologists
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