



UMC Utrecht

MAESTRO Interim Results

from 75 of the 200 Subject MAESTRO Study

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Purpose Study

To assess the diagnostic value in terms of sensitivity and specificity of additional Opto-Acoustics (OA) to conventional diagnostic ultrasound in masses classified as BI-RADS 4a and 4b.

Purpose Study

To evaluate BI-RADS 4a and 4b masses and reclassify BI-RADS category using OA feature scoring

- Downgrade benign masses (to BI-RADS 2 or 3)
- Upgrade malignant masses (to BI-RADS 4c or 5)

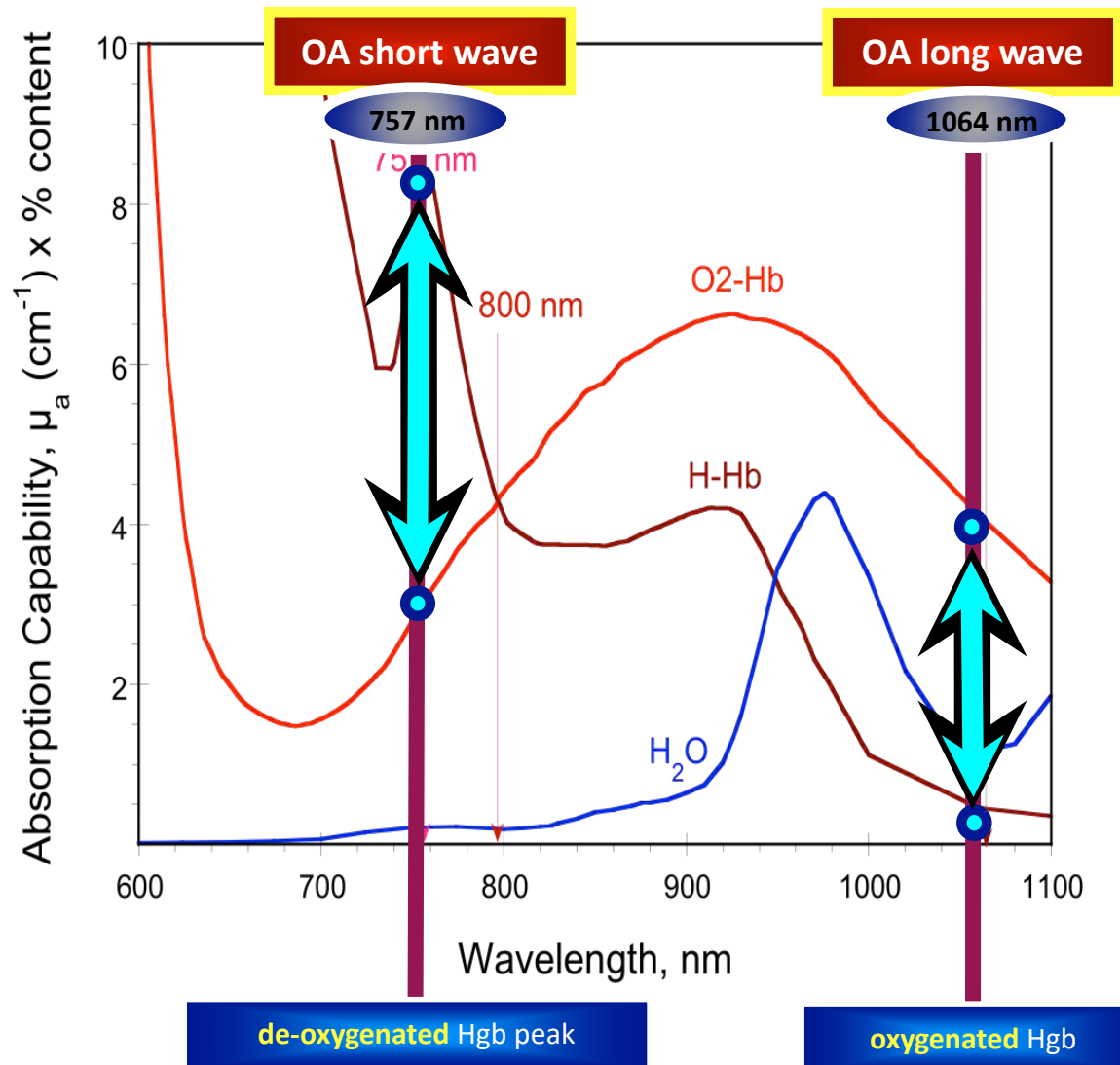
Materials and Methods

Used Seno Medical Instruments
Opto-acoustic imaging device, Imagio[®]



SENO IMAGIO[®] DEVICE

Seno Imagio[®] Device

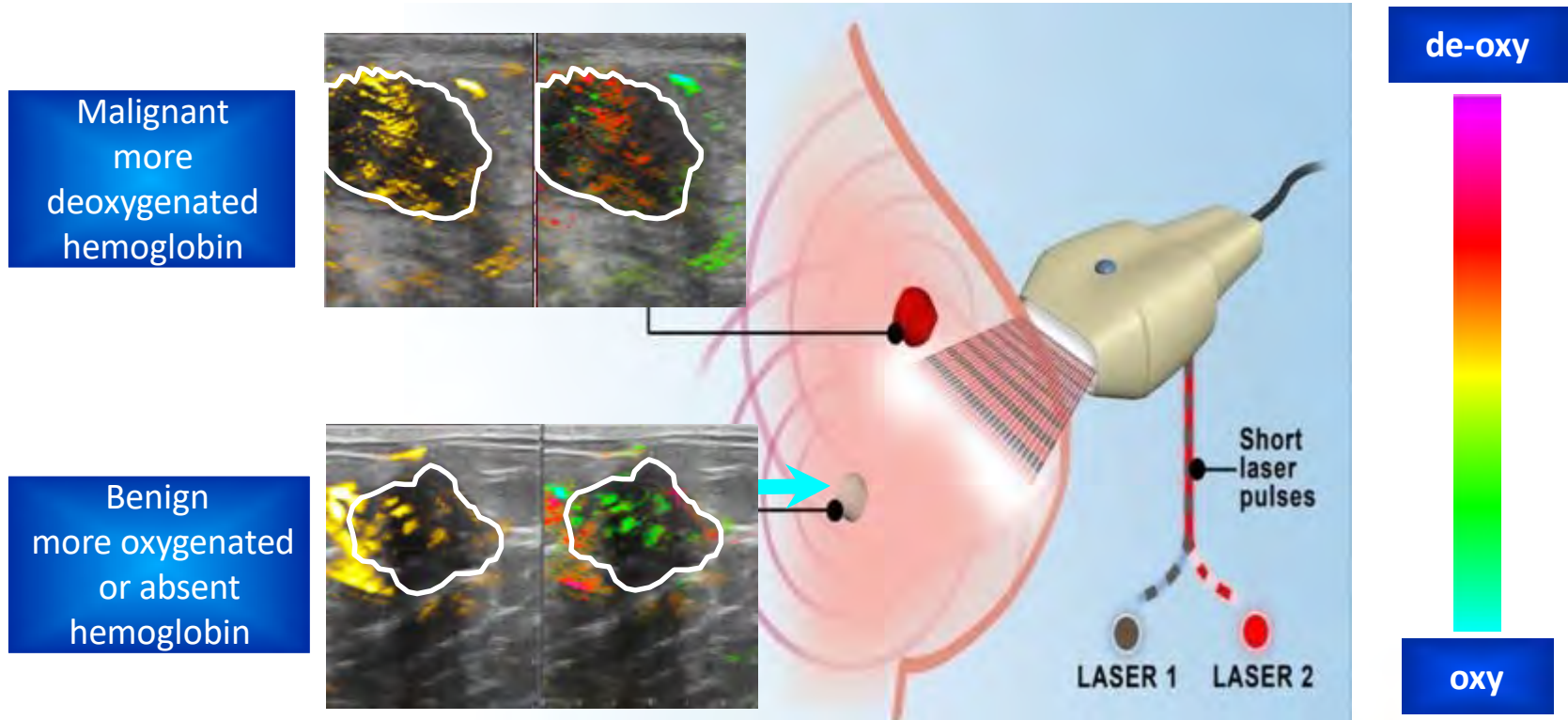


Optical Absorption within Breast Tissues

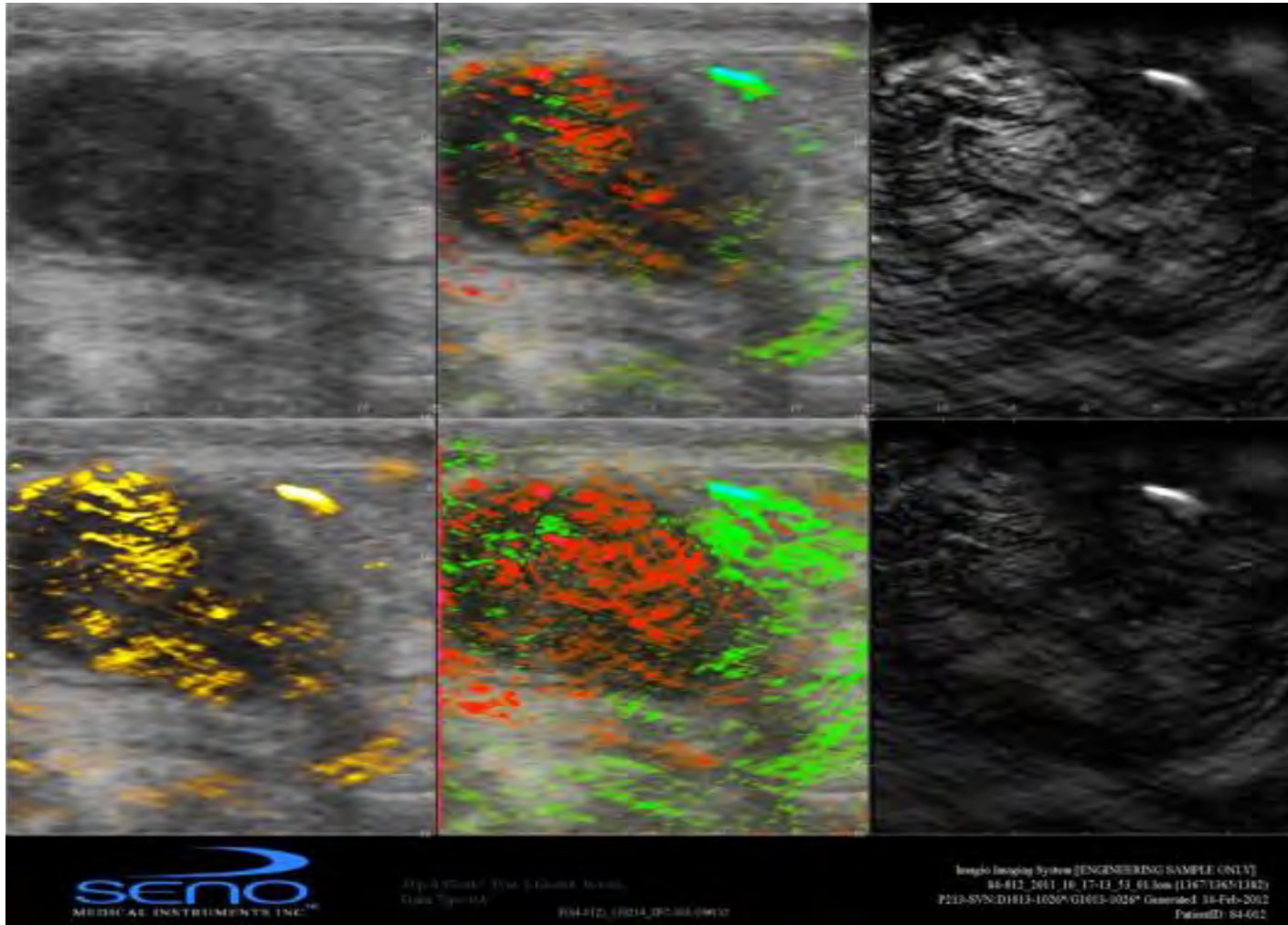
- at two laser wavelengths

Materials and Methods

Opto-Acoustic (OA) and Ultrasound Images Real-time hemoglobin map



Materials and Methods

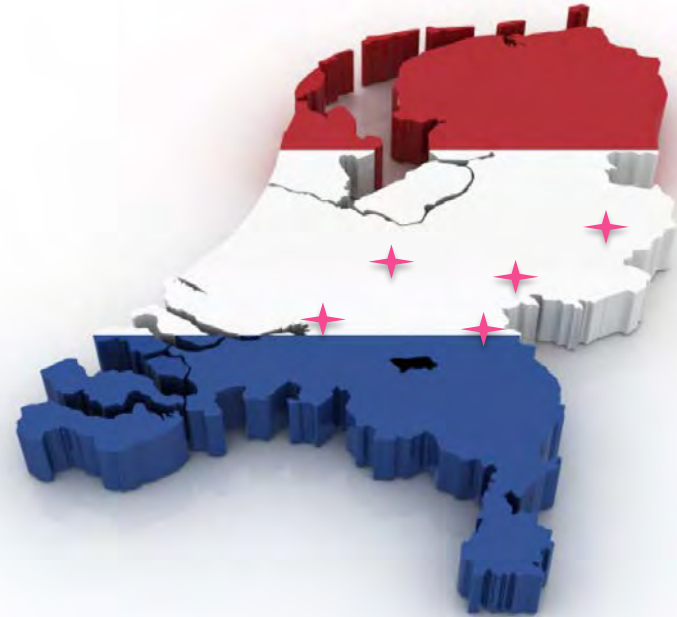


Invasive ductal carcinoma, grade 3

Materials and Methods

Multi Centre Study

- UMC Utrecht
- Radboud UMC
- Rijnstate Hospital
- ZGT Hospital
- Albert Schweitzer Hospital



Materials and Methods

- 78 masses with BI-RADS 4a or 4b
 - 44 benign
 - 34 malignant
- All underwent biopsy
- *Prior to biopsy; Radiologists (unlike previous PIONEER study)*
 - *Scored 5 OA features*
 - *Assigned percentage change of malignancy (POM)*
 - *Assigned and OA BI-RADS category*
- Central Pathology Review
 - Prof dr M. van de Vijver (AMC Amsterdam)

Results: Sensitivity and Specificity

MAESTRO: 78 Masses Sensitivity and Specificity

	CDU		Imagio®		
BI-RADS	Sensitivity	Specificity	Sensitivity	Specificity w/o nomograms	Specificity with nomograms
4a & 4b	100%	0%	97.1%	43.2%	68.2%

The nomenclature “nomogram” may change in future documentation.

Results: Downgrades and Upgrades

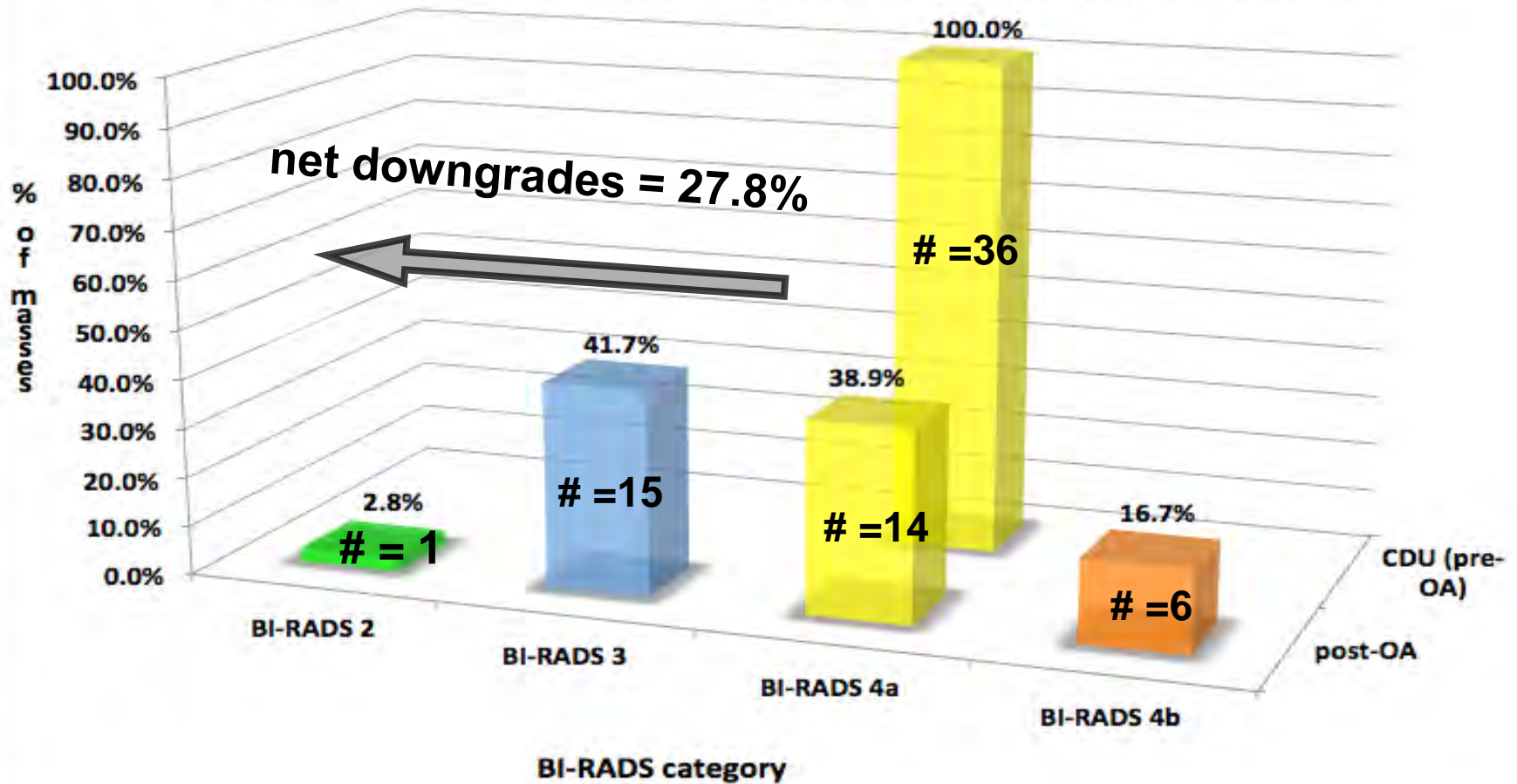
MAESTRO: 78 Masses - Downgrades and Upgrades

BI-RADS	Benign Mass Downgrades		Malignant Mass Upgrades	
	Overall	Using Nomograms	Overall	Using Nomograms
4a & 4b	43.2%	68.2%	47.1%	35.3%
4a	44.4%	75.0%	20.0%	20.0%
4b	37.5%	37.5%	51.7%	37.9%

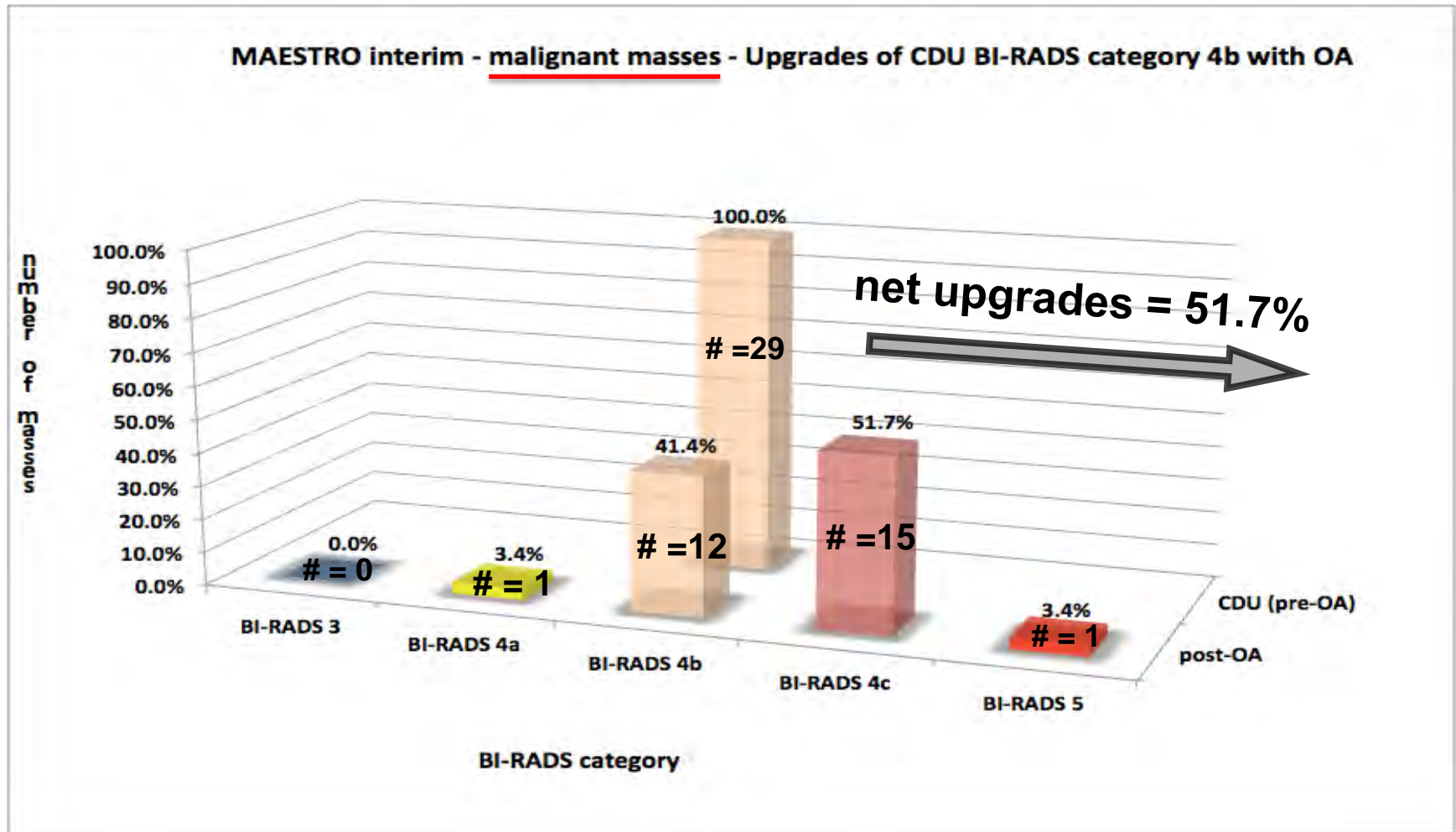
The nomenclature "nomogram" may change in future documentation.

MAESTRO interim - benign masses - CDU BI-RADS 4a downgrades

MAESTRO interim - BI-RADS changes of CDU BI-RADS category 4a with OA

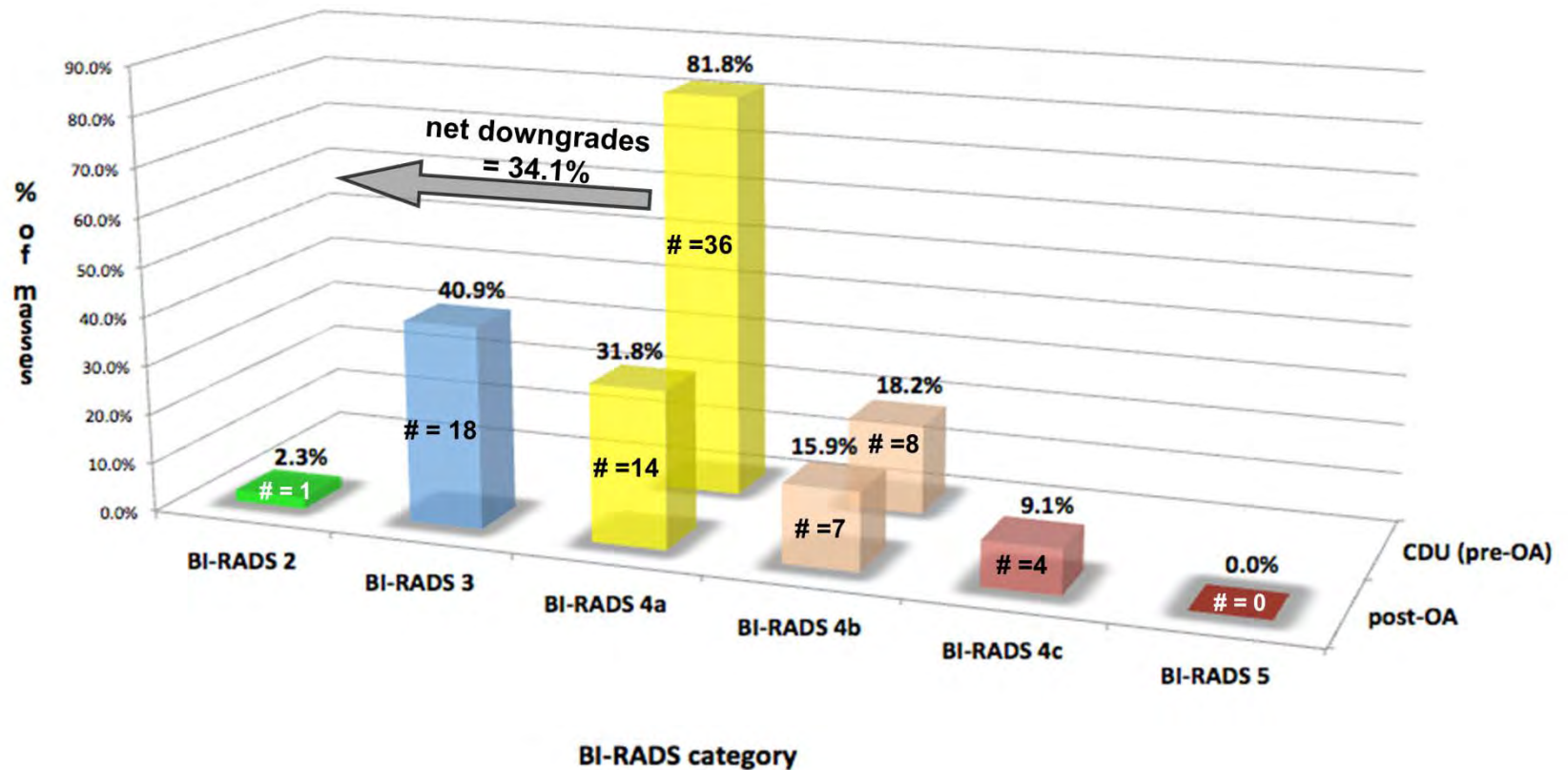


MAESTRO interim - malignant masses - CDU BI-RADS 4b upgrades



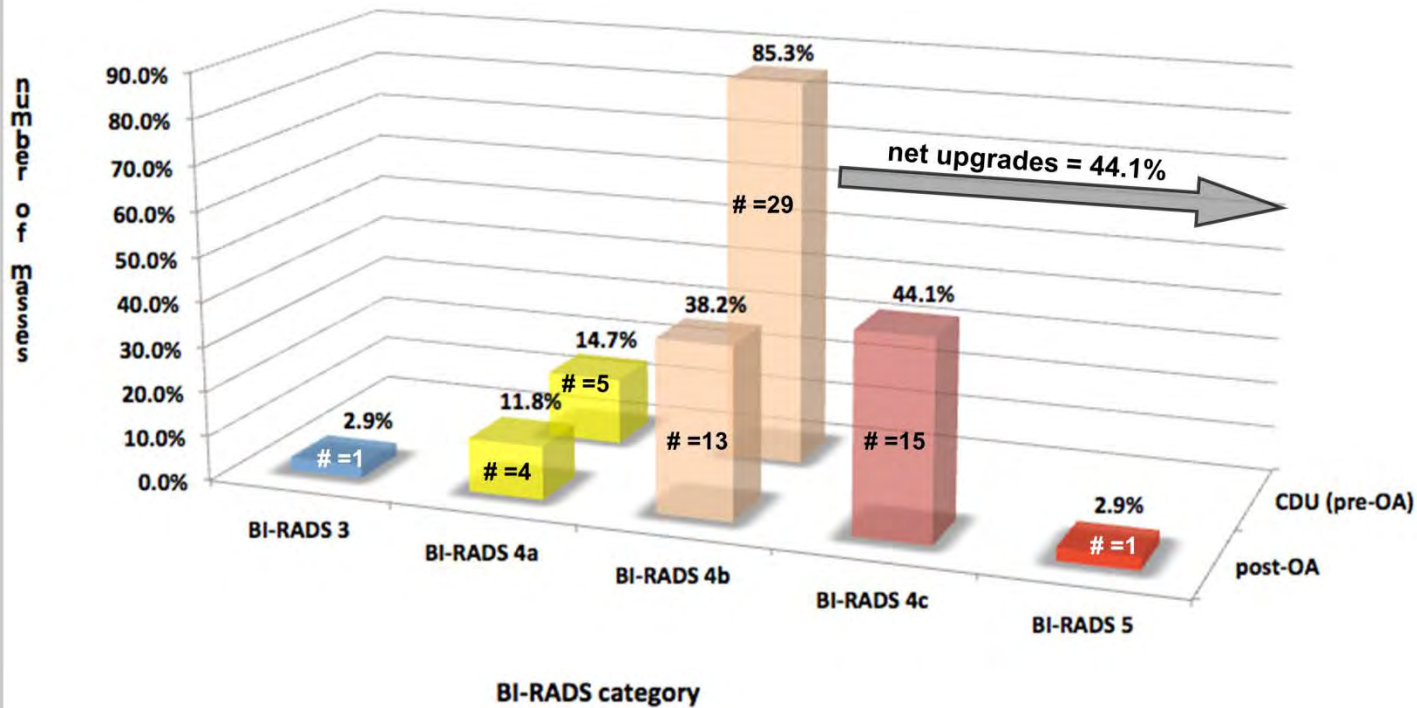
Results – Downgrades of Benign Masses

MAESTRO interim - benign masses - Downgrades of CDU BI-RADS categories 4a,4b with OA



Results – Upgrades of Malignant Masses

MAESTRO interim - malignant masses - Upgrades of CDU BI-RADS category 4a,4b with OA



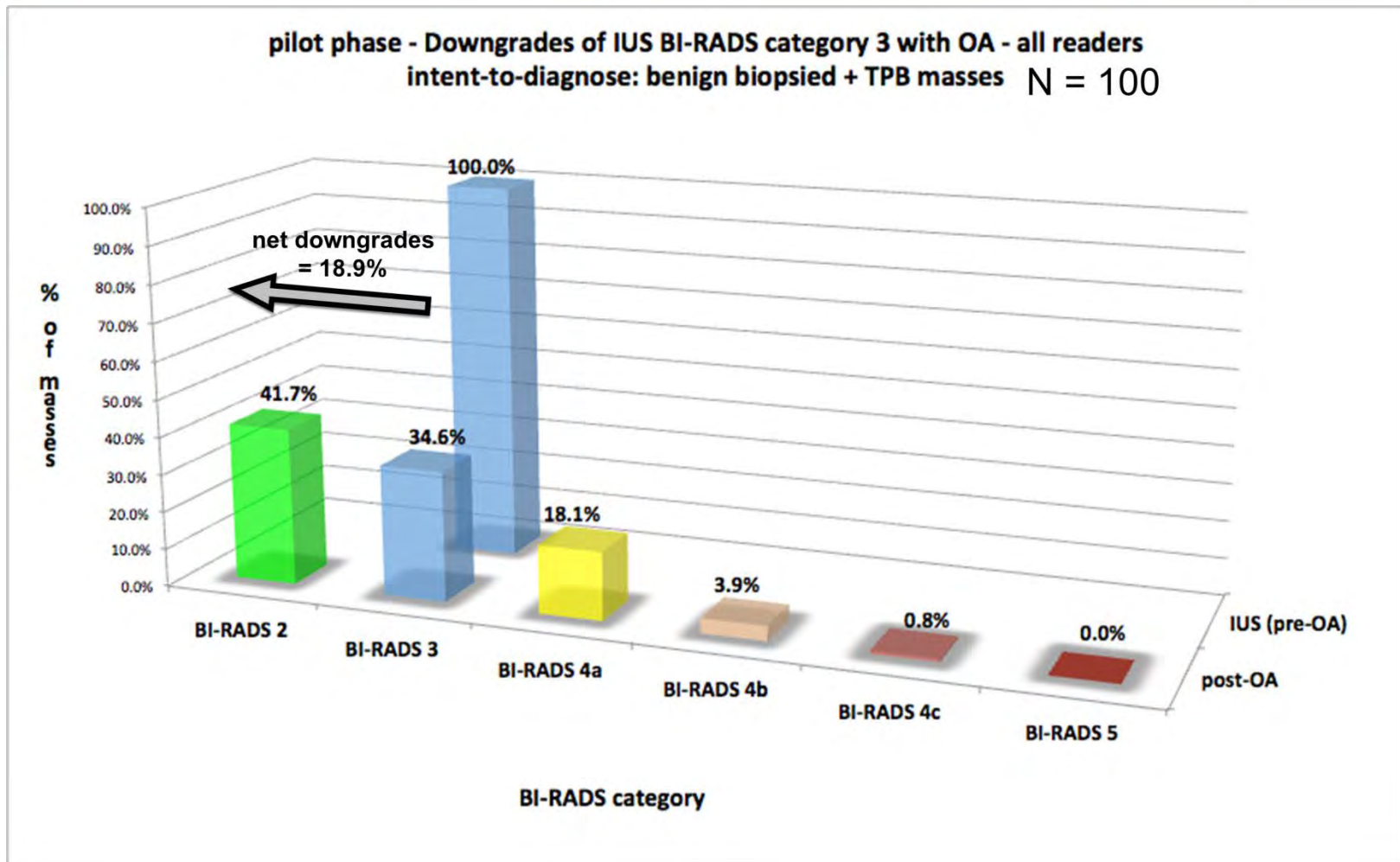
Results: Learning Curve

MAESTRO Learning Curve
Specificity Improved - False Positives Decreased

	BI-RADS	Benign	Cancer
All 78 Masses	4a	20 FPs	1 FN
	4b	5 FPs	0
Learning Curve	First 30	11 FPs (0.367)	0
	Last 48	14 FPs (0.292)	1 FN

20% absolute reduction in FP rate in last 48 cases

PIONEER - Pilot Downgrades from BI-RADS 3 to BI-RADS 2 can potentially obviate follow-up in addition to preventing biopsy



Conclusions

- OA appears to better distinguish between benign and malignant masses than does US.
- OA has the potential to decrease benign biopsies by downgrading.
- OA has the potential to upgrade BI-RADS category in malignant masses.
- The completed PIONEER Pivotal Study (N=2,095) and the MAESTRO Study (n=200) may further confirm these results.



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Thank you