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White paper

PRIME: Software-based scatter correction enabling gridless digital mammography

Lowering dose without compromise in image quality

PRIME: Software-based scatter correction enabling gridless digital mammography

By Dejan Danilovic, PhD, and Astrid Hamann

What is dose in digital mammography and why is it important?

In X-ray imaging, the term "dose" is employed in different contexts and has several definitions. From a patient's standpoint, "dose" is typically taken to mean organ dose, which refers to the radiation energy absorbed and deposited per unit mass of human tissue. In mammography, Average Glandular Dose (AGD) is a decisive quantity describing radiation energy deposition. The SI unit for dose is the gray (1 Gy = 1 J/1 kg).

Figure 1 illustrates the main dose parameters in mammography. An average breast is assumed to be composed of 50% adipose tissue and 50% glandular tissue. Since the risk of development of breast cancer in adipose tissue is minimal, radiation dosimetry is concerned only with the dose deposited in the glandular tissue. AGD cannot be measured and is calculated approximately from the specific tube output and tube load, using scaling factors based on Monte Carlo simulations to account for the irradiated X-ray spectrum, the breast thickness, and the signal-to-noise transfer performance of the imaging detector, often described in terms of detective quantum efficiency (DQE).

AGD is a frequently discussed issue in mammography, particularly in the context of screening, for the following reasons:

1. The majority of women undergoing screening are healthy and asymptomatic.
2. Low-energy (soft) X-rays are more readily absorbed by the tissue than other forms of radiation energy.
3. Glandular breast tissue has a relatively high sensitivity to radiation-induced cancer, particularly in young women.

Reducing patient dose is always an aim when working on technical improvements in mammography, but has to be weighed against the effects any such developments may have on image quality. Ideally, AGD should be as low as reasonably achievable (ALARA) without compromising image quality.

Average Glandular Dose (AGD) is an approximation of organ (i.e. patient) dose. AGD should be as low as reasonably achievable without compromising image quality.

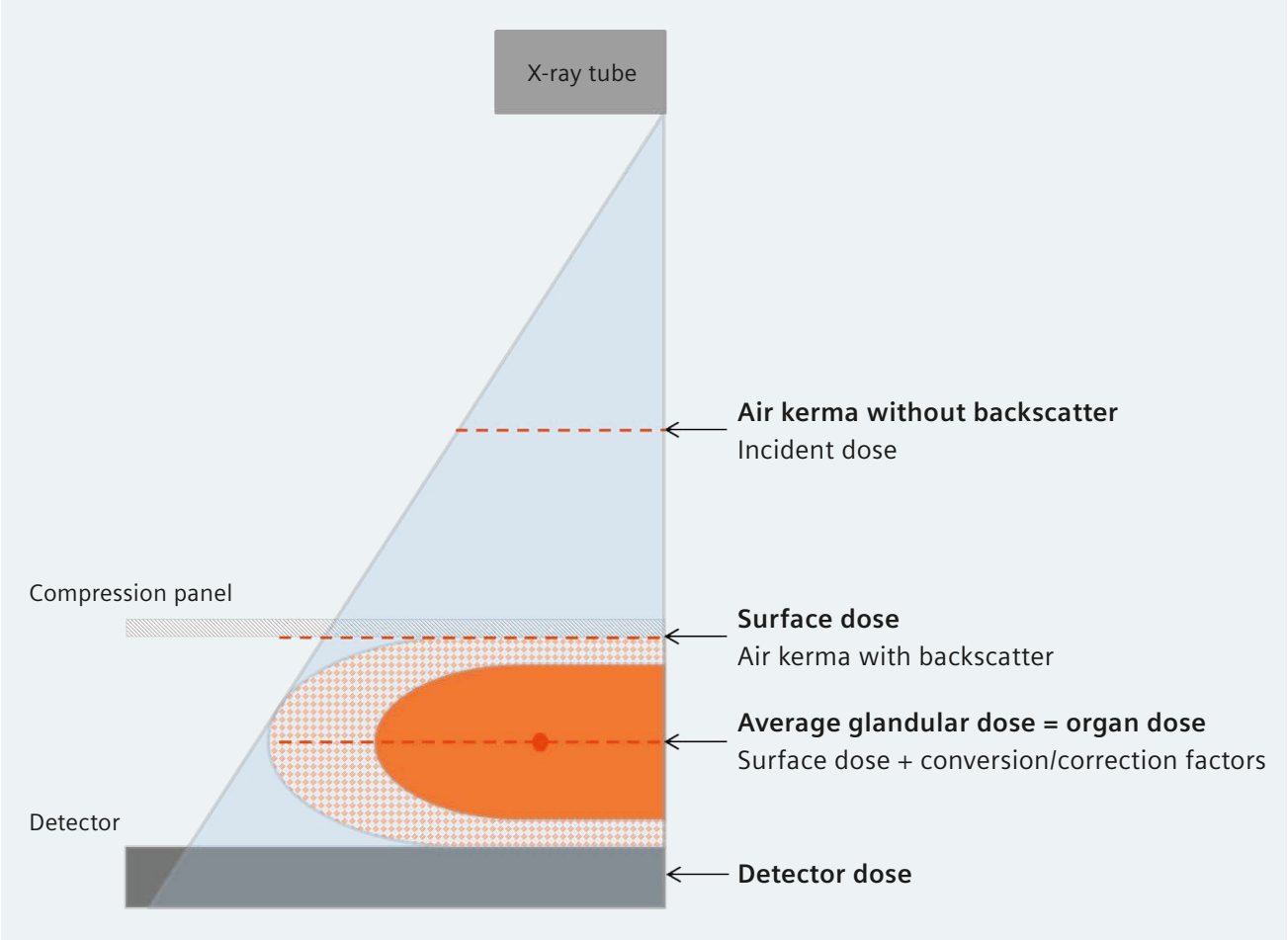

Figure 1: Overview of the main dose parameters in mammography.

1.1 X-ray scattering

Mammography generally requires a high image quality for the detection of microcalcifications, masses, distortions, and other subtle features indicating malignant tissue. X-ray scattering by the breast tissue is a physical process degrading image quality [1].

The scattered radiation can be modeled by a low-frequency and a high-frequency component. The low-frequency component reduces the relative image contrast by a smoothly varying additive offset to the intensity values in the image. The high-frequency component decreases the contrast-to-noise ratio (CNR) by the additive noise of stochastic nature.

X-ray scattering by the breast tissue is a physical process degrading image quality.

This paper describes a novel approach to reduce scattered radiation in the image, which permits the use of a lower incident dose and results in a lower AGD than in conventional anti-scatter solutions, without compromising image quality.

Methods to evaluate dose and image quality in mammography

According to European guidelines, the total radiation dose incurred during a single mammogram should not exceed 2.5 mGy for a standard breast thickness of 4.5 cm [2]. In full-field digital mammography (FFDM), the total AGD applied by a typical mammographic exposure is about 1 mGy per breast and lies below these regulations.

With regard to quality assurance, AGD is used to control and compare the performance of different mammography systems. When measuring and comparing doses, both dose and image quality measurements should be considered.

Three approaches are commonly used to compare dose and image quality in mammography: CDMAM phantom, PMMA phantom, and clinical data.

2.1 CDMAM phantom

Contrast detail mammography (CDMAM) phantoms, illustrated in Figure 2, are commonly employed for image quality assurance purposes in digital mammography and are also used by the National Health Service (NHS) in the United Kingdom for image quality comparisons [3, 4]. A CDMAM phantom consists of gold disks of varying thicknesses and diameters arranged in a 16 x 16 matrix. To be able to assess image quality, a "threshold thickness" is determined for the disks. This is the minimum thickness of the first gold disk of a certain diameter to be visible in an FFDM image. The dose needed to achieve visibility for a particular disk in a scan can then be used to compare the dose required for a given image quality with different mammography systems.

However, this dose cannot be directly related to the applied dose during mammography exams, as it merely represents a theoretical threshold value. The properties of a clinical image are dependent on many other factors, and the images themselves are intended to be suitable for diagnostic use. As such, the results of a CDMAM phantom measurement provide information about the dose required for given image quality under technical conditions, but not about the dose applied to a patient in a clinical setting.

2.2 PMMA phantom

To evaluate AGD in the course of quality assurance activities, European guidelines recommend polymethylmethacrylate (PMMA) phantoms made up of stacked PMMA plates (Figure 3) [2]. They absorb radiation in a manner similar to real breast tissue.

A PMMA phantom is imaged with different numbers of blocks in a stack, corresponding to thin and thick breasts, and the entrance air kerma (kinetic energy released per unit mass) is recorded for each thickness. AGD is calculated using the exposure factors selected by the automatic exposure control (AEC) for the given PMMA thickness and the measured entrance surface air kerma. The AGD values attained are then compared to the acceptable and achievable maximum AGD levels published by the European authorities. This method was also used by Dance et al. [5] to compare breast dose in tomosynthesis.

Although AGD calculated in this way comes close to the patient dose actually applied, the values are not completely consistent with each other. The applied patient dose is highly dependent on the AEC exposure parameters, which are adjusted according to the dense parts of an imaged breast. Since the PMMA phantom is homogeneous, the effects of AEC do not impact the applied dose and are not represented in the calculated phantom dose values. Furthermore, PMMA is slightly more dense than the compressed breast, necessitating the use of conversion factors in calculations (e.g. 70 mm PMMA is equivalent to 90 mm compressed breast).

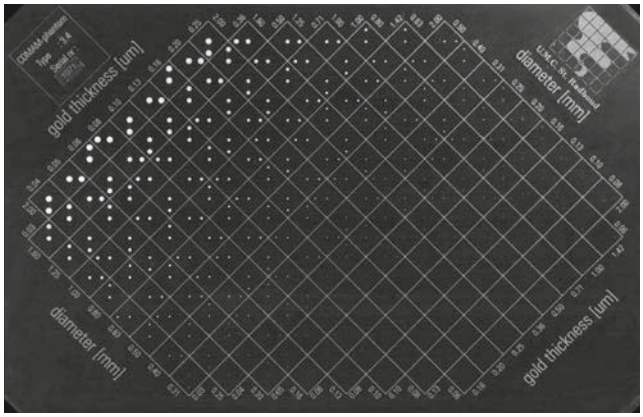

Figure 2: CDMAM phantom of Artinis medical systems used for image quality assessment in digital mammography.

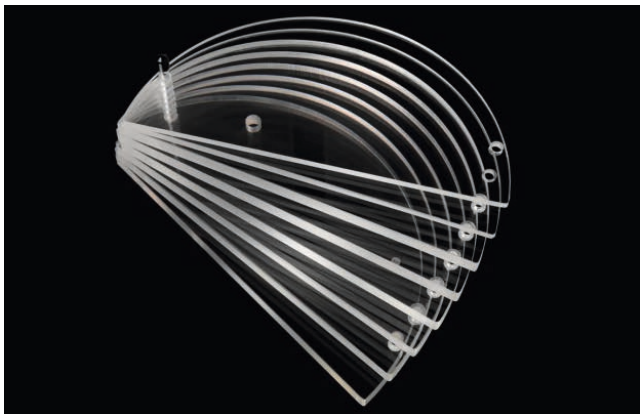

Figure 3: Example of a PMMA phantom.

2.3 Clinical data

The actual dose applied to a patient can be best approximated within the scope of clinical studies, optimally with >1000 cases [6-8]. AGD is recorded in the Digital Imaging and Communications in Medicine (DICOM) header of digital images, and it is therefore possible to analyze and evaluate large numbers of measurements. Equivalent populations should be selected for such analyses because patient population dose can differ across different screening regions.

The dose calculated during actual examinations includes the influence of breast density on the chosen AEC exposure parameters.

Although this method is not directly standardized for image quality, it is possible to measure diagnostic accuracy using benchmarks such as the detection rate and recall rate for mammography examinations. In this way, dose can be standardized for a clinical outcome rather than for a technical image quality.

Three approaches used to compare dose are: CDMAM phantom, PMMA phantom, and clinical data (Table 1).

	CDMAM phantom	PMMA phantom	Clinical study
Measured values	Dose required to display the threshold thickness of gold disks	AGD	AGD
Pro	+ Standardized for image quality	+ Breast thickness included	+ Measures dose applied to actual patients + AEC influence addressed + Standardized for diagnostic accuracy
Con	– Standardized for image quality: Breast anatomy not taken into account	– Homogenous material limits breast anatomy effect on AEC	– Not standardized for image quality (no phantom) – Large number of measurements (patients) required
Assessment of actual applied dose	– –	+	++

Table 1: Summary of measurement techniques for comparing dose in digital mammography.

PRIME Technology: Software-based scatter correction enabling gridless digital mammography at lower dose

3.1 Anti-scatter grid

Conventionally, an anti-scatter grid is placed between the breast and the detector to reduce the image degrading effects of X-ray scattering. However, the grid not only attenuates scattered radiation but also primary radiation reaching the detector: it lowers the detector dose (Figure 1) [9].

The lower detector dose due to the attenuation of the grid has to be compensated for by a higher incident dose, which in turn increases AGD (Figure 1).

3.2 Software-based scatter correction

If mammography is performed without an anti-scatter grid, software-based scatter correction (SBSC) as a novel strategy can reduce scattering effects [10-12]. SBSC algorithms estimate a low-frequency component of the scattered radiation and subtract it from the measured image [13]. Effects of a high-frequency scatter component are diminished indirectly by a larger amount of primary radiation reaching the detector without the grid.

3.3 PRIME algorithm

Siemens Healthcare developed PRIME (Progressive Reconstruction Intelligently Minimizing Exposure), a dedicated SBSC algorithm that enables gridless digital mammography at lower dose, without compromising image quality. PRIME Technology estimates a scatter field by using 2D scatter kernels [14, 15] generated via Monte Carlo simulations based on object properties, object geometry, and acquisition parameters (tube voltage and filter/anode combination). Figure 4 shows a simplified illustration of the PRIME algorithm.

PRIME (Progressive Reconstruction Intelligently Minimizing Exposure) algorithm corrects scatter and enables gridless digital mammography at lower dose, without compromising image quality.

Scatter correction takes only seconds longer than standard image post-processing in grid-based acquisition and will not affect the usual workflow during screening mammography.

In 2013, PRIME Technology was 510k cleared by the U.S. Food and Drug Administration. It is optionally available on the Mammomat Inspiration FFDM systems (upgrade possible) in all countries.

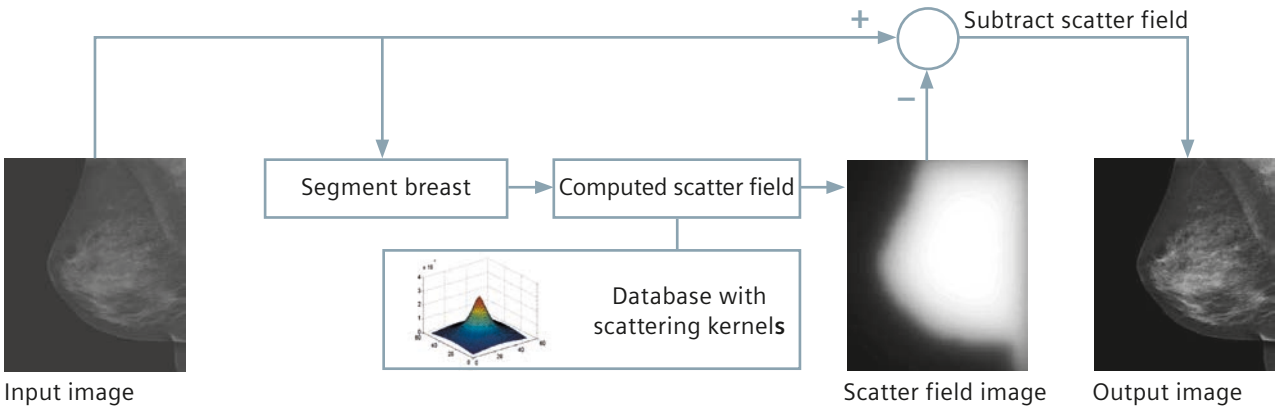

Figure 4: Simplified illustration of the PRIME algorithm for scatter correction [13]. PRIME Technology estimates and subtracts the low-frequency component of the scattered radiation in a process of convolution, using a database with 2D scatter kernels. Effects of the high-frequency component of the scattered radiation are reduced indirectly through a larger amount of primary radiation reaching the detector with gridless image acquisition.

Technical and clinical validation of PRIME Technology

4.1 Radiation dose reduction: Phantom and clinical study by Fieselmann et al. [13]

The **phantom study** assessed potential surface dose reduction with gridless acquisition and PRIME Technology versus standard acquisition with a grid, while providing the same CNR. The study also examined a difference in contrast-detail visibility [2] for gridless acquisition at this reduced dose level compared with grid-based acquisition.

Methods: To study dose reduction, PMMA phantoms (20-70 mm thick, in 10 mm steps) were placed on the detector of Siemens Mammomat Inspiration and were covered partly by a 0.2 mm aluminum foil. Sets of images were acquired using AEC with a grid, or using varying exposure times without a grid for the same beam quality (i.e. tube voltage and filter/anode combination) as for AEC. The CNR was determined for two regions of interest (1 cm^2 squares), one placed inside and the other outside the aluminum foil area [13]. Each PMMA thickness was converted to an equivalent compressed breast thickness (ECBT) [16]. Dose reduction factors were computed for gridless image acquisition (Figure 5).

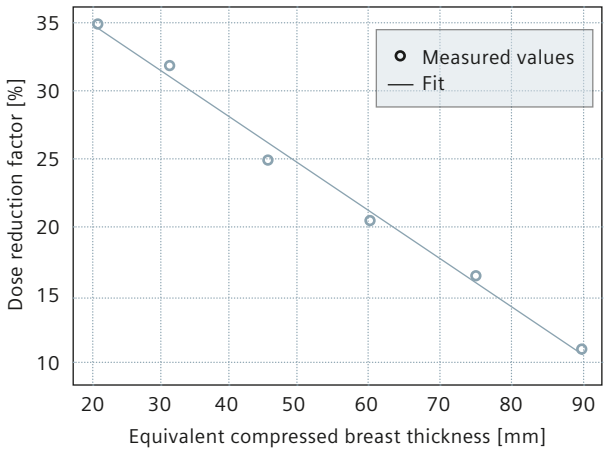

Figure 5: Surface dose reduction for gridless vs. grid-based acquisition ranged from 11% to 35% as a function of the ECBT (phantom study)* [13].

In a study of contrast-detail visibility, images acquired with 20-70 mm thick phantoms composed of PMMA blocks and CDMAM were evaluated using the automatic scoring software CDCOM [17]. The contrast-detail curves were constructed for each phantom thickness.

Findings: The dose reduction factor depended on the ECBT (Figure 5). Generally, with increasing breast thickness, the scatter fraction [18] and the additive noise increase, requiring more primary radiation (allowing less dose reduction) to achieve the same CNR as with a grid.

Figure 6 illustrates a contrast-detail curve comparison for grid-based versus gridless acquisition for a phantom thickness of 30 mm. The paired curves were similar to each other for all phantom thicknesses, suggesting that similar image quality can be obtained with both acquisition techniques despite dose reduction with gridless acquisition.

The **clinical part of the study** investigated dose-reduced gridless acquisition under realistic clinical conditions [13].

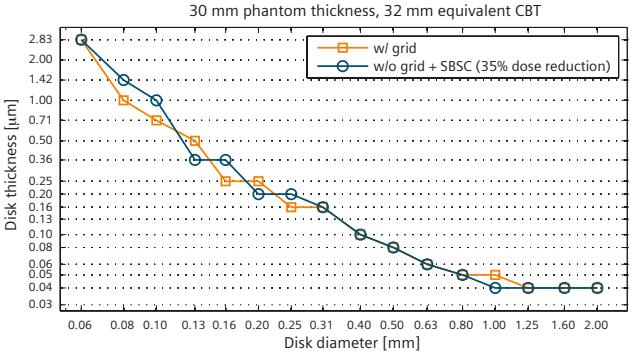

Figure 6: Pair of contrast-detail curves (log-log plots) illustrating similar image quality for grid-based acquisition and dose-reduced gridless acquisition plus PRIME Technology (phantom study) [13].

Methods: In 75 women recalled for further diagnostic mammograms after screening, two exposures were made during the same compression phase, first in the AEC mode with a grid, then without a grid and with a dose reduced by decreasing the tube current-time product according to the results of the phantom study, while keeping all other acquisition parameters constant. The images acquired without a grid were processed with PRIME Technology before their finalization using standard mammographic image processing algorithms [19].

* PRIME is used for a maximum breast thickness of 7 cm under compression

In a subsequent blinded reading of image pairs side-by-side, five experienced radiologists compared the two images on a 7-point scale (-3, -2, ... , +3) for several categories reflecting image quality. Based on biostatistical considerations, non-inferiority of the gridless technique for any category was assumed for a mean rating > -0.3 points on the 7-point scale, which was statistically tested by a one-sided t-test with the threshold set to -0.3.

Findings: The women (56 ± 5 years old) had compressed breast thickness (CBT) of 57 ± 15 mm (28 to 87 mm), with the breast density ratings: ACR 1 (4%), ACR 2 (53%), ACR 3 (33%), ACR 4 (10%). Mammographic findings were: masses (57%), microcalcifications (41%), and architectural distortions (20%) [13].

While the absolute AGD reduction with gridless acquisition plus PRIME Technology was similar across CBT ranges (Figure 7), the relative AGD reduction ranged from 12% (CBT: 85-94 mm) to 32% (CBT: 25-34 mm). The relative dose reduction factors were comparable to that in the phantom study [13], with minor differences attributable to the limited, discrete choice of exposure values available in the manual exposure mode, and to the variation of breast composition in the population. In principle, a higher dose is necessary for thicker breasts which – in combination with a smaller relative dose reduction for thicker breasts – leads to a similar absolute reduction.

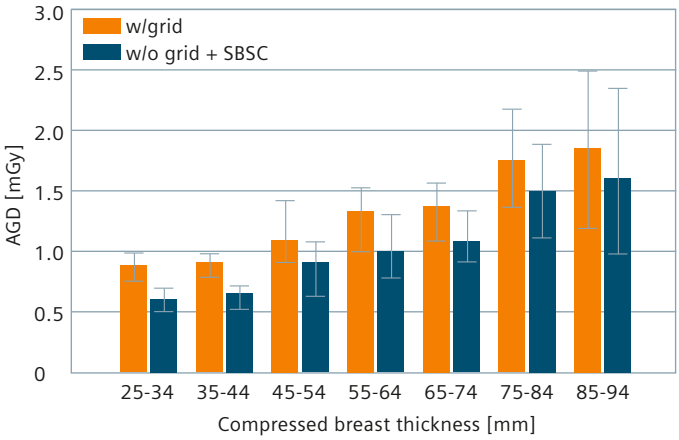

Figure 7: The absolute AGD reduction with gridless acquisition plus PRIME Technology was 0.26 ± 0.06 mGy (mean ± SD) and similar across CBT ranges (clinical study) [13].

The reading study results are shown in Table 2. P-values indicate highly significant non-inferiority of dose-reduced gridless acquisition combined with PRIME Technology.

Dose reduction with preserved image quality was confirmed in a first phantom and clinical study with PRIME Technology.

Category	Mean	SD	P-value
Overall image quality	0.07	0.31	$< 10^{-14}$
Visibility of			
• Tissue near the breast edge	0.00	0.16	$< 10^{-24}$
• Structures in the pectoral muscle	0.09	0.29	$< 10^{-10}$
• Noise	0.01	0.22	$< 10^{-17}$
Diagnostic certainty of			
• Mass	0.12	0.30	0.12
• Microcalcification	0.08	0.42	0.08
• Architectural distortion	0.18	0.28	0.18

Table 2: Results from the reading study comparing image pairs (clinical study) [13]. A positive mean value denotes a preference for dose-reduced gridless acquisition plus PRIME Technology over grid-based acquisition. Very low P-values indicate highly significant non-inferiority of the gridless option.

4.2 Image quality improvement: Phantom study by Binst et al. [20]

Methods: Images of 20-70 mm thick phantoms composed of PMMA blocks and CDMAM, acquired with Siemens Mammomat Inspiration, were evaluated for contrast-detail visibility using the automatic scoring software CDCOM [17]. As CDCOM was previously proven only for grid-based acquisition, the study validated CDCOM for gridless acquisition [20].

Images of the PMMA blocks were obtained in the AEC mode. For each phantom thickness, exposure parameters were recorded. The same exposure parameters were then set manually for the CDMAM configurations of corresponding equivalent thicknesses, while varying the tube current-time product (mAs) to ± 60% and ± 156% of the values with AEC [20].

Altogether, 960 CDMAM images were obtained for four scatter conditions (with a grid, without a grid, PRIME Technology without a grid with PMMA used as "breast thickness", and PRIME Technology without a grid with ECBT used as "breast thickness"), six phantom thicknesses, five dose levels, and eight images for each condition.

To assess AGD reduction for gridless acquisition (with and without PRIME Technology) versus standard acquisition with a grid, AGD for each exposure was calculated using the method of Dance [16].

Findings: PRIME Technology did not influence CDCOM readings compared with gridless acquisition without PRIME Technology, but image homogeneity [2] was improved (Figure 8), correcting the cupping artefacts, i.e. intensity bias. These artefacts can lead to serious misclassifications, especially when intensity-based segmentation algorithms are used to classify tissue on images [21].

Image homogeneity is improved with PRIME Technology.

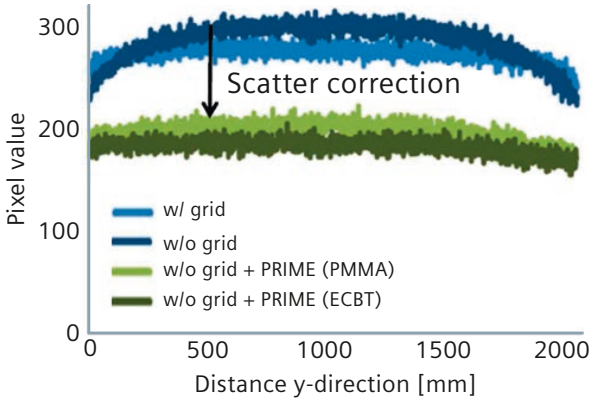

Figure 8: Improved image homogeneity with PRIME Technology has the potential to overcome cupping artefacts, i.e. intensity bias (phantom study) [20]. The Y-direction is parallel to the chest wall.

4.3 Clinical evidence: Large-scale clinical study by Larsen et al. [8]

Cancer detection rate, recall rate, and cancer detection specificity are three commonly used performance indicators (benchmarks) for screening mammography. A large population study presented by Dr. Lisbet Larsen at the European Society of Radiology (ECR) annual conference in 2015 compared these performance indicators for grid-based acquisition and dose-reduced gridless acquisition combined with PRIME Technology.

Methods: The study was conducted in Southern Denmark during 12 months before and 5 months after the complete change from conventional grid-based digital mammography to gridless acquisition with PRIME Technology. The PRIME algorithm was incorporated in one and the same Siemens Mammomat Inspiration system. For study purposes, population characteristics and the true breast cancer prevalence rates were considered to be equivalent for the two time intervals associated with the two screening methods.

Findings: The turning point was December 2013, before which 50,071 women received grid-based screening and after which 22,117 women underwent dose-reduced gridless screening combined with PRIME Technology. The study results are summarized in Table 3.

Screening performance indicators were equivalent for grid-based and gridless screening. In particular, the cancer detection rate was identical (0.55%). There was no statistical difference in the recall rate (2.59% grid-based vs. 2.44% gridless with PRIME Technology) or specificity (97.96% vs. 98.11%).

Performance indicators for screening mammography were equivalent for PRIME (22,117 women) and conventional grid-based screening (50,071 women) in terms of the cancer detection rate (5.5/1000), recall rate (2.5%), and specificity (98%).

Screening method	Number of women screened	Screening interval	Recall rate [NR /NW]	Cancer detection rate [NC /NW]	Specificity [1-(NR-NC)/NW]
Grid-based without PRIME Technology	50,071	12 months	2.59% (2.45-2.73)	0.55% (0.49-0.62)	97.96% (97.84-98.09)
Gridless with PRIME Technology	22,117	5 months	2.44% (2.23-2.64)	0.55% (0.45-0.64)	98.11% (97.93-98.29)

Table 3: Performance indicators (benchmarks) for screening mammography in Southern Denmark.[8] Data in brackets are 95% confidence intervals. Two-sided equivalence testing ($\alpha = 0.05$) performed on the cancer detection rate and specificity showed no statistically significant difference between the two screening methods.
(NC: Number of women with cancer, NR: Number of women recalled, NW: Number of women screened)

Conclusion

Especially in screening mammography, the radiation dose to the woman should be as low as possible for the required image quality.

An anti-scatter grid usually removes X-ray scattering that would have degraded the image quality, from the final image. This however requires an increase in incident and thus in glandular dose, as part of the primary radiation is removed with the anti-scatter grid and thus doesn't reach the detector.

The Siemens PRIME (Progressive Reconstruction Intelligently Minimizing Exposure) algorithm for scatter correction enables gridless image acquisition with uncompromised image quality. Technical and clinical validation of PRIME Technology showed up to 30% dose reduction in comparison to grid-based acquisition with Mammomat Inspiration, depending on breast thickness. In a large study of 72,188 women, the three commonly used performance indicators for screening mammography (cancer detection rate, recall rate, and cancer detection specificity) were equivalent for gridless dose reduced screening with the PRIME algorithm and conventional grid-based screening.

PRIME is a highly valuable development in digital mammography, enabling a significant dose reduction without compromising image quality or clinical performance.

Glossary

AEC	Automatic exposure control
AGD	Average glandular dose
ALARA	As low as reasonably achievable
CBT	Compressed breast thickness
CDCOM	Automated readout
CDMAM	Contrast detail mammography
CNR	Contrast-to-noise ratio
DICOM	Digital imaging and communications in medicine
ECBT	Equivalent compressed breast thickness
FFDM	Full-field digital mammography
Kerma	Kinetic energy released per unit mass
NC	Number of women with cancer
NR	Number of women recalled
NW	Number of women screened
PMMA	Polymethylmethacrylate
PRIME	Progressive Reconstruction Intelligently Minimizing Exposure
PRIME (PMMA)	Calculation using PMMA thickness as input parameter "breast thickness"
PRIME (ECBT)	Calculation using ECBT as input parameter "breast thickness"
SBSC	Software-based scatter correction
SD	Standard deviation
SI	The international system of units
vs.	Versus
w/	With (in figures)
w/o	Without (in figures)

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Siemens Healthcare Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen
Germany
Phone: +49 9131 84-0
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