PHILIPS

MicroDose

Mammography Solutions

Proven clinical effectiveness
at low radiation dose

Several studies provide evidence that Philips MicroDose Mammography* can provide outstanding image quality at 18% to 50% lower radiation dose than used on other digital mammography systems, with an average dose reduction of 40%.[1, **]

Figure 1: Philips MicroDose Mammography system

Summary of scientific papers

Author and study title	Year[a]	Key findings
Weigel, et al., "Digital mammography screening with photon-counting technique: Can a high diagnostic performance be realized at low mean glandular dose?"[2]	2014	The Philips MicroDose system enabled detection of small invasive cancers and DCIS above the desirable level of the European guidelines. Higher cancer detection rates of invasive cancers and DCIS compared with other screening areas of the state were reached for subsequent screening at a higher recall rate.
Venturini, et al.: Tailored breast cancer screening program with MicroDose Mammography, US, and MRI imaging: Short term results of a pilot study in 40-49-year-old women"[3]	2013	A tailored breast cancer screening program that uses MicroDose mammography in 40-49 year old women is feasible and effective.
Cole, et al., "Comparison of radiologist performance with photon-counting full-field digital mammography to conventional full-field digital mammography."[4]	2012	Radiologist performance with Philips MicroDose Mammography was equal to that of GE Senographe DS at an average 40% lower MGD.
Keavey, et al., "Comparison of the clinical performance of three digital mammography systems in a breast cancer screening programme."[5]	2011	The cancer detection rate with the Philips Micro-Dose Mammography was at least equal to that of GE Senographe Essential and Hologic Selenia.
Oduko, et al., "A survey of patient doses from digital mammography systems in the UK in 2007 to 2009."[6]	2010	Philips MicroDose Mammography has 18% to 53% lower mean glandular dose (MGD) compared to mammography systems from Hologic, GE, Siemens, and Giotto.
Baldelli, et al., "Comprehensive dose survey of breast screening in Ireland."[7]	2010	Philips MicroDose Mammography had the lowest MGD for both CC and MLO views. The average examination dose for the MicroDose Mammography was 36% lower than Hologic Selenia, and 39% lower than GE Senographe Essential.
Leitz W, Almén A. "Patient doses from X-ray examinations in Sweden – trends from 2005 to 2008."[8]	2010	The average MGD for Philips MicroDose Mammography was about half that of the other FFDM systems in the survey.

[a] Publication year

Introduction

Because breast tissue is sensitive to radiation, it is crucial that the radiation dose used in mammography is as low as possible,[9] particularly in mammography screening, in which a large number of healthy women are examined on a regular basis. Recently, the scientific guidance from the International Commission on Radiological Protection (ICRP) concluded breast tissue is more than two times more radiosensitive than thought earlier.[10, 11]

Doctors should always strive towards exposing patients to the lowest dose possible when performing X-ray scans. Authorities such as the American College of Radiology (ACR) and the Radiological Society of North America (RSNA),[12] as well as the U.S. Food and Drug Administration's Center for Devices and Radiological Health (CDRH), have all launched initiatives intended to reduce unnecessary radiation exposure from medical imaging.[13]

Given the value of mammography screening, as well as the exposure to radiation it involves, it is very important for mammography system manufacturers to provide systems that enable low radiation dose exams without sacrificing clinical image quality.

This white paper summarizes data from scientific publications, and shows that the MicroDose Mammography can provide outstanding image quality with 18% to 50% lower radiation dose than used on other digital mammography systems, with an average dose reduction of approximately 40%.[1, **]

Review of scientific papers comparing MicroDose Mammography with other FFDM systems

Weigel, et al.: Digital mammography screening with photon-counting technique: Can a high diagnostic performance be realized at low mean glandular dose?

Weigel, et al. assessed the screening performance of a Digital Radiography (DR) photon-counting system (Philips MicroDose Mammography) versus statewide screening units that use different digital technologies. The retrospective study examined data from 1,007,134 women, age 50 to 69 years old, who underwent the screening program in the state of North Rhine-Westphalia (NRW) from January 2009 to December 2010. It compared data from 13,312 exams performed with MicroDose Mammography to 993,822 exam performed on statewide screening units (37 CR systems and 55 conventional DR systems).

Results:

- The Philips MicroDose system enabled a higher overall cancer detection rate for subsequent screening compared with the statewide rate. MicroDose studies resulted in a higher recall rate; the authors could not distinguish whether this was due to the technique or reader factors.
- The Philips MicroDose system demonstrated a higher detection rate of ductal carcinoma in situ (DCIS) for subsequent screening compared to the statewide rate with computed radiography and DR technology, as well as for a subgroup of only DR technology.
- MGD of the MicroDose system was significantly lower than that of the subgroup of conventional DR systems (0.60 vs. 1.67 mGy) even thoug the mean compression thickness was higher (61 mm vs. 59.4 mm).

Screening performance for prevalent screenings

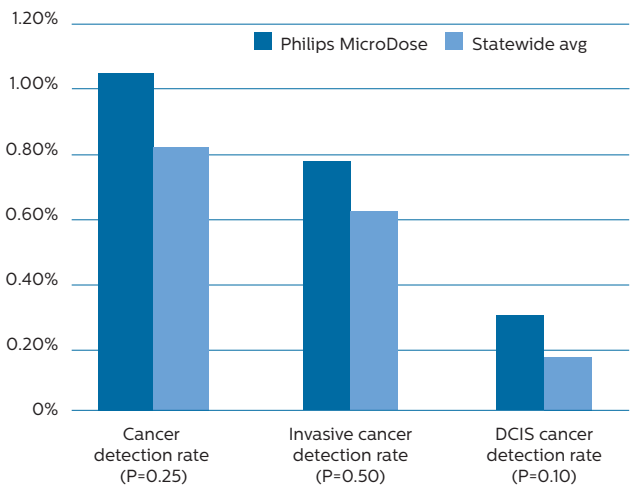

Figure 2: Screening performance for prevalent screenings in comparison to Statewide average

Screening performance for subsequent screenings

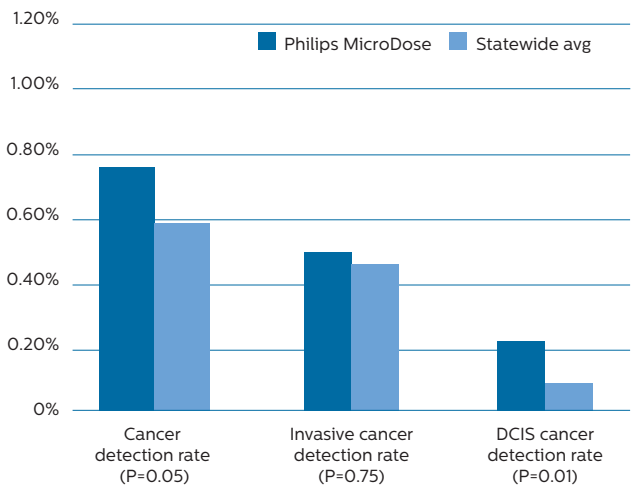

Figure 3: Screening performance for subsequent screenings in comparison to Statewide average

Screening performance for prevalent screenings

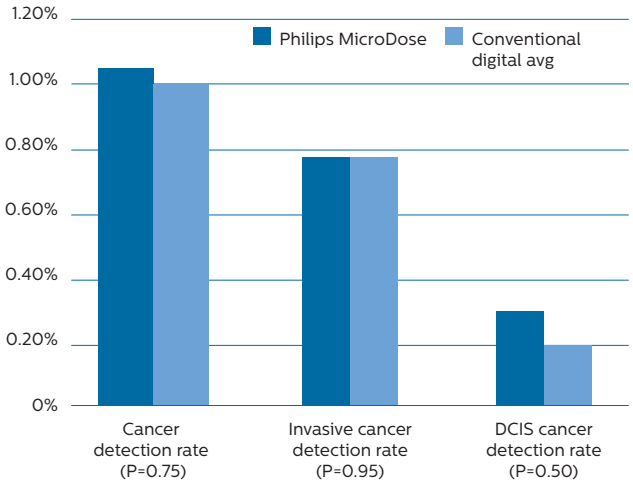

Figure 4: Screening performance for prevalent screenings in comparison to Conventional digital average

Screening performance for subsequent screenings

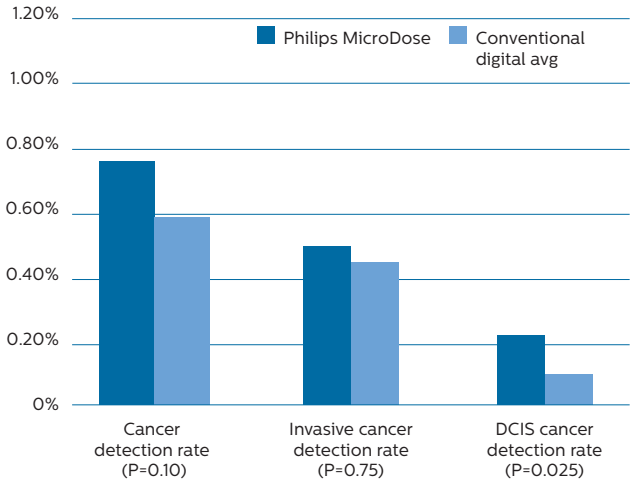

Figure 5: Screening performance for subsequent screenings in comparison to Conventional digital average

Mean glandular dose

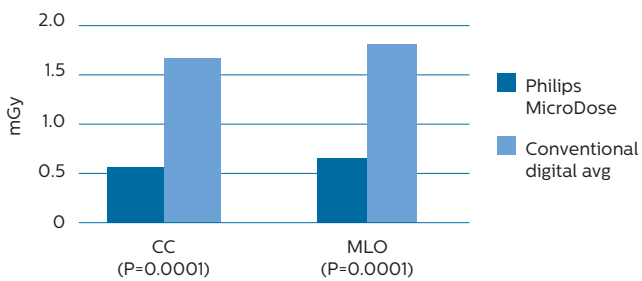

Figure 6: Comparison of Mean MGD with Conventional digital average

Venturini, et al.: Tailored breast cancer screening program with MicroDose Mammography, US, and MRI imaging: short term results of a pilot study in 40-49-year-old women

Venturini, et al. implemented a screening program of women age 40-49 years that was tailored to individual risk profile and breast tissue density, using mammography with further assessment by ultrasound and MRI. The 1,666 women underwent low-dose, photon counting digital mammography (Philips MicroDose) performed in two views (CC/MLO) and blind-reviewed by two dedicated radiologists. The US and MRI were performed according to the BIRADS density score and the risk group of each patient.

Results:

- Most cancers were diagnosed by MicroDose Mammography (12/14) and mostly in high density breasts (10/12) with a low average glandular dose of 1.49 mGy per examination for a mean breast thickness of 50 mm.
- The authors stated that a tailored breast cancer screening program in 40-49 year-old women yielded a greater-than-expected number of cancers, most of which were low-state disease.

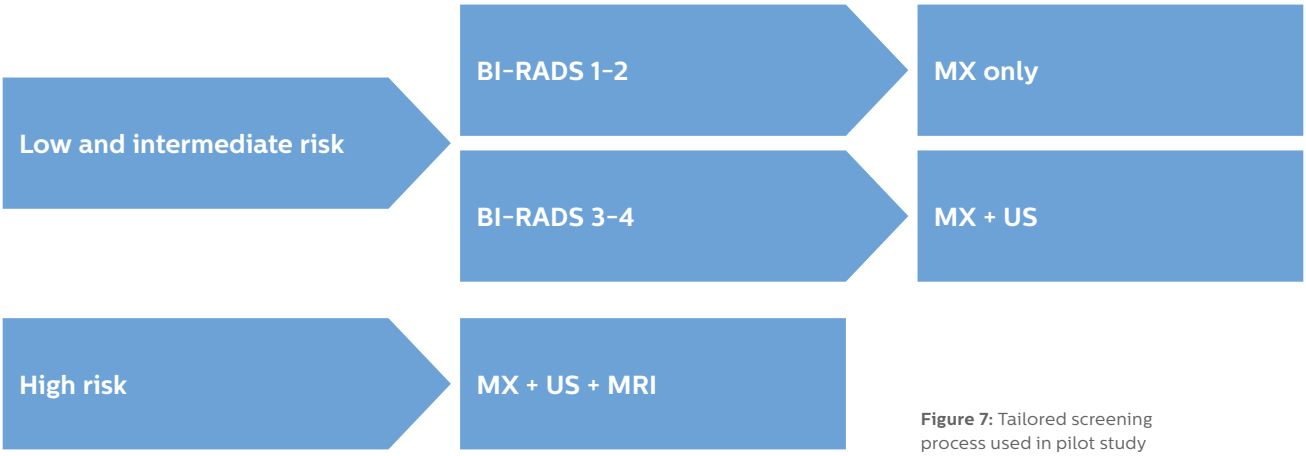

Figure 7: Tailored screening process used in pilot study

Cole, et al.: Comparison of radiologist performance with photon-counting full-field digital mammography to conventional full-field digital mammography

Cole, et al. assessed the performance of the MicroDose Mammography system in comparison to another FFDM system (GE Senographe DS) for women presenting for screening mammography, diagnostic mammography, or breaast biopsy.[4] A total of 133 women were enrolled in this study at two European medical centers. Sixty-seven women who were tested using a conventional FFDM 10 to 36 months earlier were tested using MicroDose Mammography. Another 66 women had screening tests with MicroDose Mammography and within 90 days after that underwent diagnostic tests with a conventional FFDM. Mean glandular dose was recorded for all cases. Sixteen U.S. radiologists were recruited to participate in the reader study, which took place at the American College of Radiology Image Metrix Core Laboratory in Philadelphia.

	Philips MicroDose Mammography	GE Senographe DS
Average AUC	0.947	0.931
Sensitivity per case	0.936	0.908
Specificity per case	0.764	0.749
The average MGD	0.74 mGy	1.23 mGy

Table 2: Radiologist performance with MicroDose Mammography system compared to a conventional FFDM

Results:

- Radiologist performance with MicroDose Mammography was equal to that of conventional FFDM, at an average 40% lower MGD.

Keavey, et al.: Comparison of the clinical performance of three digital mammography systems in a breast cancer screening program

Keavey, et al. conducted a study that compares the clinical performance of three digital mammography systems used in BreastCheck, Ireland's national breast screening program, from April 2007 to April 2010.[5] (BreastCheck data on dose had been investigated by Baldelli,[7] as described later in this white paper.)

Twenty-eight digital mammography systems from three different vendors were included in the study: GE Senographe Essential, Hologic Selenia, and Philips MicroDose Mammography systems. The retrospective analysis included 238,182 screening examinations of women aged between 50 and 64 years. Cancer detection rates were calculated separately for the initial and subsequent screening cohorts, and a total of 1,632 cancers were diagnosed. All images were double-read and assigned a result according to a five-point rating scale (R1-R5) to indicate the probability of cancer. Women with a positive result (R3-R5) were recalled for further assessment workup.

Results:

- The cancer detection rate with the Philips MicroDose Mammography was at least equal to that of GE Senographe Essential and Hologic Selenia.
- In all the comparisons, there was a trend in favor of MicroDose for invasive cancer detection rate and ductal carcinoma in situ (DCIS), both for prevalent and subsequent screening **however there was not a statistically significant difference** (Figures 8 and 9).

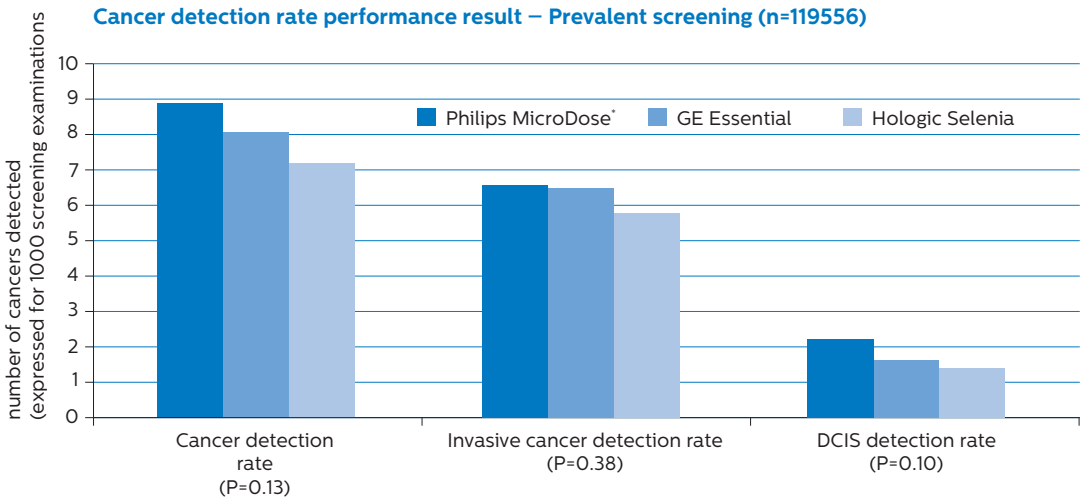

Figure 8: Comparison of cancer detection rate for prevalent screening for three FFDM systems (Confidence Interval 95%)

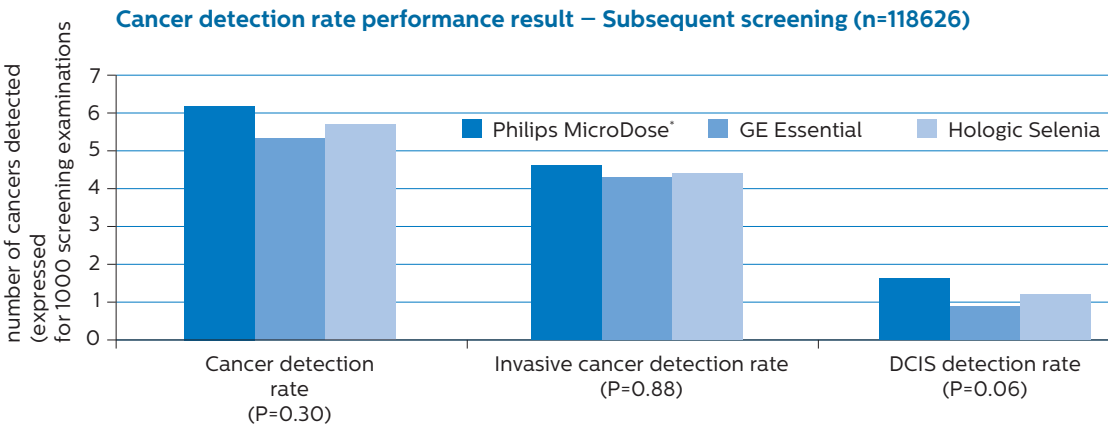

Figure 9: Comparison of cancer detection rate for subsequent screening for three FFDM systems (Confidence Interval 95%)

Oduko, et al.: A survey of patient doses from digital mammography systems in England in 2007 to 2009

Oduko, et al. analyzed patient dose data collected as part of the quality system for the United Kingdom's nationwide breast screening program (NHSBSP) run by the National Health Service (NHS).[6] Data was collected for a sample of fifty or more women for each mammography system used from 2007 to 2009. Dose data from more than 28 digital mammography systems and more than 4,100 images were analyzed. Radiographers who performed the mammography examinations supplied the exposure parameters for individual patients to the physicists working with the NHSBSP for the calculation of mean glandular dose (MGD). All physicists used the same program to calculate the MGD, according to Dance, et al.[14]

Results:

- The average MGD levels of the MicroDose Mammography system ranged from 18% to 53% lower than other digital mammography systems, with a comparable average breast thickness (Table 3, Figure 10).

Manufacturer and model	Number of systems	Number of main images	Average and range of Mean MGD* to breast (mGy)	Mean thickness (mm) ± 2 SEM	Percent difference
Philips MicroDose Mammography	4	316	0.95 (0.93 - 0.97)	63.5 ± 0.6	–
GE Senographe 2000D	2	200	1.3 (1.26 - 1.34)	57.0 ± 0.8	27%
GE Senographe DS	7	1139	1.59 (1.56 - 1.62)	53.9 ± 0.3	40%
GE Senographe Essential	4	805	1.44 (1.41 – 1.47)	58.1 ± 0.4	34%
Hologic Selenia	3	356	2.00 (1.93 - 2.07)	53.1 ± 0.5	53%
Hologic Selenia W	3	616	1.44 (1.40 – 1.48	52.2 ± 0.8	34%
Siemens Inspiration	1	128	1.21 (1.14 – 1.28)	58.8 ± 1.1	21%
Siemens Novation	3	483	1.16 (1.11 – 1.21)	56.9 ± 0.6	18%
IMS Giotto	1	118	1.78 (1.68 - 1.88)	55.5 ± 0.9	47%

Table 3: MGD and thickness for oblique views, for all breasts, for different types of digital mammography systems

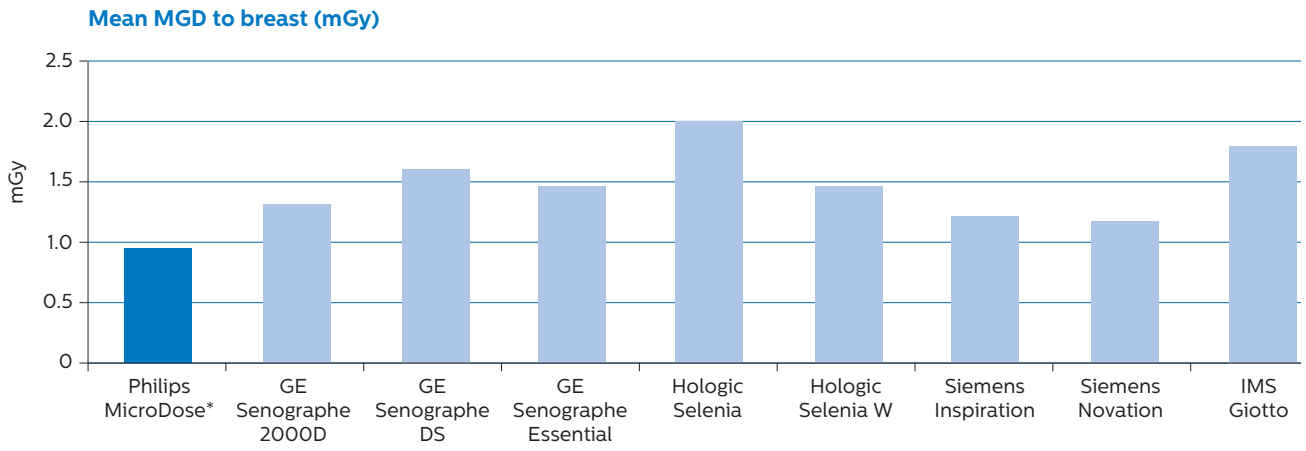

Figure 10: Comparison of Mean MGD to breast for Oblique Views for different mammography systems

Baldelli, et al.: Comprehensive dose survey of breast screening in Ireland

Baldelli, et al. examined the dose impact of breast screening by digital mammography systems by analyzing BreastCheck (Ireland's national breast screening program) clinical dose survey results.[7] Data acquired over a one-month period in 2009 included 2,910 examinations compromising 12,110 images from three different FFDM models: GE Senographe Essential, Hologic Selenia, and Philips MicroDose Mammography systems.

Results:

- The study found that the MicroDose Mammography system demonstrated the lowest average MGD. The average examination dose for the MicroDose Mammography was 39% lower than that of GE Senographe Essential and 36% lower than that of Hologic Selenia.

	Philips MicroDose Mammography	GE Senographe Essential	Hologic Selenia
Average MGD for an exam	1.86 mGy	3.03 mGy	2.91 mGy
Average MGD in the CC view	0.90 mGy	1.39 mGy	1.36 mGy
Average MGD in the MLO view	0.88 mGy	1.52 mGy.	1.44 mGy
Average MGD	(0.90+0.88)/2=0.89	(1.39+1.52)/2=1.455	(1.36+1.44)/2=1.4

Table 4: Radiation dose comparison based on BreastCheck 2009 data

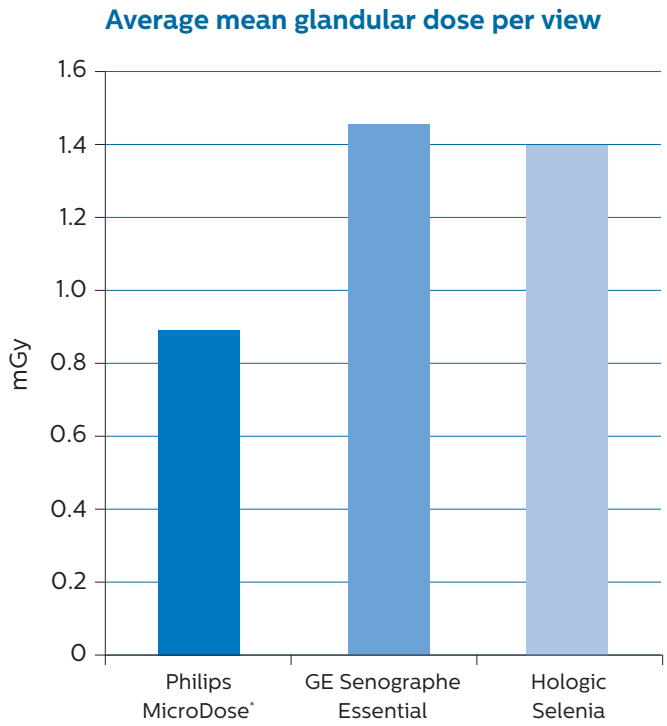

Figure 11: Comparison of overall MGD for Philips MicroDose, GE Senographe Essential, and Hologic Selenia, based on BreastCheck 2009 data

The Swedish Radiation Safety Authority report on patient doses from X-ray examinations in Sweden – trends from 2005 to 2008

The Swedish Radiation Safety Authority (SSM) controls the screening program, sets the standards for permitted X-ray doses, and controls the quality of the mammography systems used in Sweden. The report issued from SSM contains data from 150 mammography systems used in clinics from 2006 to 2008.[8,**]

Because many new FFDM units have been installed since 2008, a follow-up analysis of SSM data was conducted in 2010.[15] Dose data was collected from 62 clinics with a total of 175 mammography units. Figure 10 notes the variation in average MGD among different FFDM systems. As in the earlier study, the average radiation dose for MicroDose systems was about half that of the other FFDM systems in the survey.

Results:

- MicroDose Mammography systems used approximately half of the radiation dose of the other FFDM systems and less than half the dose of screen-film mammography systems.
- Between 2006 and 2008, the patient-related standard dose for mammography in Sweden decreased by 12% on average. The report notes that a significant part of this reduction can be attributed to the introduction of MicroDose systems.

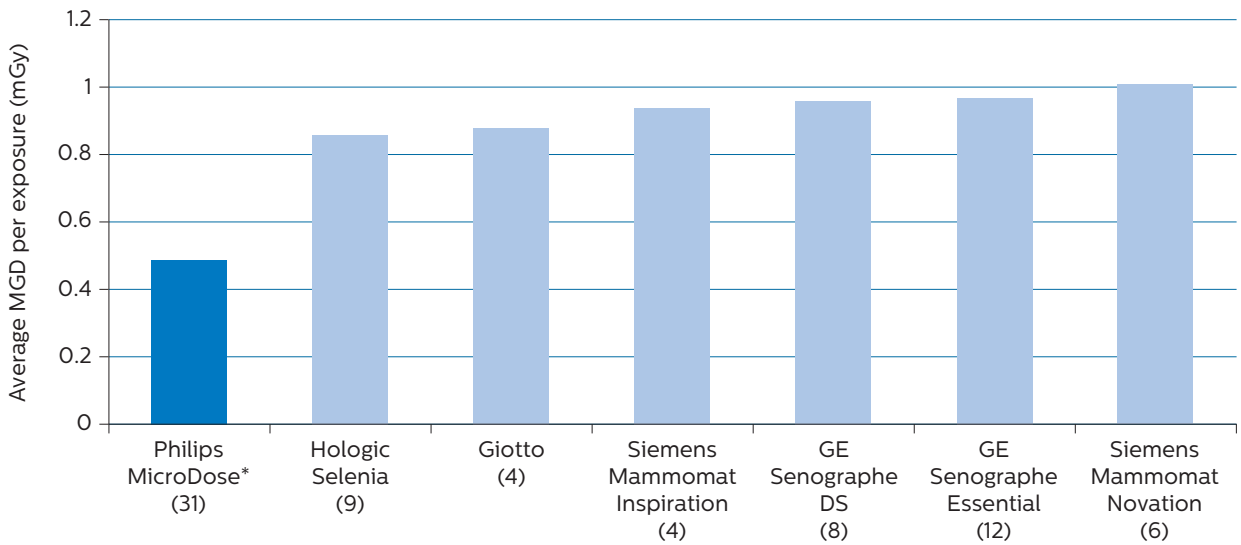

Figure 12: The average MGD per exposure for different FFDM systems, including both screening and clinical mammography (The number of units for each model is shown in parentheses)

Conclusion

The scientific studies reviewed in this paper demonstrate the significant dose efficiency of Philips photon counting detector technology in comparison to other FFDM systems used in the studies.[2,3,4,6,7,8,15]

Most recently, the study by Weigel, et al. supports and expands upon the Keavey et al. findings about the cancer detection capabilities of photon counting systems. While Keavey's comparison of the clinical performance in terms of overall cancer detection rate shows no statistically significant difference among the three different mammography systems employed in that study,[5] Weigel found a higher overall cancer detection rate for subsequent screening with photon counting technology at a higher recall rate.[2] The Venturini, et al study suggests that MicroDose mammography could reduce the dosage and preserve high diagnostic image quality, which is essential to decrease the lifetime exposure of young women participating mammographic screening.[3]

This complements an earlier study from the Irish BreastCheck by Baldelli, who reported the examination dose for MicroDose to be 36% to 39% lower than that for the other models in the survey.[7]

In addition, Philips calculated an average weighted dose reduction using the data from the UK nation-wide breast screening program published by Oduko, et al.[6] Using the range of mean MGD for each system, dose was weighted by the number of images per FFDM model using the data summarized in Table 2.2. The weighted average dose reduction is approximately 40%.[1]

These studies show that the cancer detection rate using the MicroDose Mammography was equal to that of other FFDM systems while using 18% to 50% lower radiation dose, with an average dose reduction of approximately 40%.** [1,2,3,4,5,6,7,8,15]

References

1. White paper, 2012. Comparison of Dose Levels in a National Mammography Screening Program, Philips Healthcare.
2. Weigel, S. et al., 2014. Digital mammography screening with photon-counting technique: Can a high diagnostic performance be realized at low mean glandular dose? Radiology, Volume 271: Number 2—May 2014
3. Venturini, et al., 2013. Tailored breast cancer screening program with MicroDose mammography, US, and MRI imaging: short term results of a pilot study in 40-49-year-old women. Radiology, Vol. 268, Issue 2, pp. 347-355.
4. Cole, E.B., et al., 2012. Comparison of radiologist performance with photon-counting full-field digital mammography to conventional full-field digital mammography. Acad Radiol 2012, pp.1–7.
5. Keavey, E., et al., 2012. Comparison of the clinical performance of three digital mammography systems in a breast cancer screening programme. The British Institute of Radiology, 85(1016), pp.1123-7.
6. Oduko, J.M., et al., 2010. A survey of patient doses from digital Mammography systems in the UK in 2007 to 2009. Digital Mammogr. IWDM 2010, pp.365–370.
7. Baldelli, P., et al., 2010. Comprehensive dose survey of breast screening in Ireland. Radiation Protection Dosimetry, Vol. 145, No. 1, pp.52–60.
8. Leitz, W., Almén A., Patientdoser från röntgenundersökningar i Sverige – utveckling från 2005 till 2008. SSM 2010-14, ISSN 2000-0456, [online] available in Swedish at: www.stralsakerhetsmyndigheten.se.
9. Berrington de Gonzáles, A., Darby, S., 2004. Risk of cancer from diagnostic X-rays: estimates for the UK and 14 other countries. The Lancet, 363, pp.345-51.
10. ICRP, 1991. 1990 Recommendations of the International Commission on Radiological Protection. ICRP Publication 60. Ann. ICRP 21 (1-3). [online] available at: http://www.icrp.org/publication.asp?id=ICRP+Publication+60.
11. ICRP, 2007. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP Publication 103. Ann. ICRP 37 (2-4). [online] available at: http://www.icrp.org/docs/ICRP_Publication_103-Annals_of_the_ICRP_37(2-4)-Free_extract.pdf.
12. Brink, J.A., et al., 2010. Image wisely: A campaign to increase awareness about adult radiation protection, Radiology, 257, pp.601-602. http://pubs.rsna.org/doi/full/10.1148/radiol.10101335?queryID=63%2F1719157.
13. U.S. Food and Drug Administration, 2010. Initiative to reduce unnecessary radiation exposure from medical imaging, [online] available at: http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm200085.htm?sms_ss=email.
14. Dance, D.R., et al., 2009. Further factors for the estimation of mean glandular dose using the United Kingdom, European and IAEA breast dosimetry protocols. Physics in Medicine and Biology, 54(14), pp.4361–72.
15. Lindh & Partners GBG, 2010. Based on the data supplied by the Swedish Radiation Safety Authority.

* MicroDose Mammography was developed by Sectra, whose mammography operation was acquired by Philips Healthcare in September 2011.

** The actual result of the average dose reduction will vary based on variations of digital mammography systems.

\+ Mean MGD is the same as the Average MGD.

\++ Data for mammography systems in the report were collected between 2006 and 2008.

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