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# Average glandular doses in contrast-enhanced spectral mammography (CEM)

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## Abstract

**Introduction:** Contrast-enhanced spectral mammography (CEM) is based on dual-energy breast exposure following intravenous administration of an iodinated contrast agent. Our study quantitatively assessed radiation dose from CEM for different breast thicknesses and compared it with doses from full-field digital mammography (FFDM) and with the dose limits set in the European Guidelines.

**Materials and Methods:** We studied 200,976 exposures from 59,438 examinations performed between January 2019 and December 2023 at the National Research Institute of Oncology, using a GE Healthcare Pristina Senographe mammography unit. Radiation exposure–related data, including average glandular dose (AGD) values, were obtained from the GE DoseWatch monitoring system. Doses for CEM exposure pairs (low- and high-energy exposure) were summed.

**Results:** Out of 176,700 FFDM exposures, the acceptable dose level was exceeded only in 11 cases (less than 0.01%). For combined CEM exposures, the acceptable dose level was exceeded in 965 out of 5481 cases (17.6%).

The doses in FFDM exposures and low-energy CEM exposures are similar. Average glandular dose for FFDM exposures and low-energy CEM exposures is clearly dependent on the breast thickness. In contrast, the dose for a single high-energy CEM exposure is about 0.7 mGy and shows no clear dependency on breast thickness.

Acceptable dose levels for combined CEM exposures were exceeded primarily with breasts with small thicknesses, most often (70% of cases) in patients whose breasts were less than 4 cm thick. For breasts from 6 cm and larger, no CEM exposures exceeded acceptable dose levels.

**Conclusions:** Although CEM exposures are a combination of two exposures (low- and high-energy), in most cases, the doses associated with CEM exposure do not exceed limits that were originally set for single FFDM exposures.

**Keywords:** mammography, AGD, dose, CEM

## Introduction

Breast cancer in women is now the most frequently diagnosed cancer in the world[1]. More than two million cases are diagnosed yearly[2]. According to current WHO data, "1 in 20 women worldwide will be diagnosed with breast cancer in their lifetime, and that if current rates continue, by 2050 there will be 3.2 million new breast cancer cases and 1.1 million breast cancer-related deaths per year"[3]. When it is available, mammography is the main technique for breast cancer diagnosis and the only screening technology that has been shown to help reduce breast cancer mortality.

However, the diagnostic accuracy of mammography is lower in women with so-called 'dense' breasts, meaning breasts with a high proportion of glandular tissue. The sensitivity can be as low as 65% in dense breasts, compared to 85–90% in mainly fatty breasts[4]. Sensitivity of mammography is especially low in the case of highly glandular breasts because X-ray absorption in glandular tissue is like that in tumors. Questionable diagnoses can be clarified using other imaging modalities such as ultrasound, magnetic resonance imaging (MRI), and contrast-enhanced spectral mammography (CEM).

CEM is a relatively new imaging technique (FDA approval in 2011) capable of detecting cancers that are not visible with standard mammography. This technique is based on dual-energy contrast-enhanced digital subtraction mammography. It is capable of detecting neoangiogenesis and can be used to assess multifocality or multicentricity in breast cancer. Applications of CEM include inconclusive findings in FFDM, preoperative staging, response monitoring, and CEM-guided biopsy[5].



Authors' contribution: A – Research concept and design, B – Collection and/or assembly of data, C – Data analysis and interpretation, D – Writing the article, E – Critical revision of the article, F – Final approval of the article.

Levin et al., in their first study (2003), found that CEM had 83% specificity with a sensitivity of 92%[6]. Dromain et al.[7] reported that in larger studies, sensitivity was 92% and specificity was 56%. In subsequent studies, Dromain et al.[8] found a sensitivity of 92% and specificity of 46% when they added CEM to ultrasound plus conventional mammography. CEM has been evaluated in numerous other studies[9-15] and has consistently shown improved results compared to full-field digital mammography (FFDM).

A 2018 meta-analysis reported CEM sensitivity of 89% and specificity of 84%, leading the authors to propose CEM as an alternative to contrast-enhanced MRI[14]. Furthermore, the lower specificity seen in earlier studies might have been due to operators not having enough experience. Rudnicki et al. showed that CEM could be used with confidence instead of MRI for cancer detection[16], but it is also important to remember that, unlike MRI, CEM results in X-ray radiation exposure.

CEM combines X-ray mammography with intravenous administration of an iodinated contrast agent, based on dual-energy breast exposure after contrast administration. Depending on the implementation, the tube voltage used for low-energy acquisition ranges from 25 to 34 kVp (depending on breast thickness and glandularity). For high-energy acquisition, the range is from 45 to 49 kVp[5]. This means that two exposures are performed for one projection during CEM, which results in a higher radiation dose received by patients in comparison with FFDM[5]. In FFDM, one exposure is performed for one projection.

The CEM literature reports average glandular dose (AGD) in both CEM and FFDM in different mammography systems[17], for a specific average breast thickness and for breast phantoms with different thicknesses[18]. Philips et al.[17] estimated that AGD for CEM exposure is between 1.2 and1.8 times higher than for FFDM exposure, depending on the mammography system used. James et al.[18] found that AGD ± standard deviation was 3.0 ± 1.1 mGy for CEM exposures and 2.1 mGy for FFDM for a mean breast thickness of 63 mm. According to Gennaro et al., the CEM dose is larger than the FFDM dose by 31.5% to 42.8%[19]. The data presented by Neeter et al. show a wider range of values (15% to 81%)[5].

AGD in CEM is higher than for FFDM but lower than for combined FFDM and DBT (digital breast tomosynthesis)[20,21]. Summed low- and high-energy dose from two CEM exposures in a single projection does not exceed the dose limit provided in the Mammography Quality Standards Act regulations (3.0 mGy per view), which was set for a single FFDM cranio-caudal exposure[5]. However, the MQSA limit is set only for an exposure of a phantom simulating a standard breast. In contrast, European recommendations provide acceptable dose levels for breast cancer screening using FFDM, which depend on the thickness of the compressed breast[22-24].

Our study quantitatively assessed radiation dose from CEM for different breast thicknesses and compared it with doses from FFDM and with acceptable dose levels set by European Guidelines.

## Materials and Methods

We studied exposures from examinations performed between January 2019 and December 2023 at the National Research Institute of Oncology using a GE Healthcare Pristina Senographe system (software version 7.70.51) capable of performing FFDM, DBT, and CEM. The system is equipped with an X-ray tube with two target materials (Mo and Rh targets) and three filtrations (0.03 mm Mo, 0.03 mm Ag, and 0.25 mm Cu) and a detector consisting of a caesium iodide (CsI) scintillator and an amorphous silicon photodiode array (100 μm pixel pitch). CEM examinations consisted of low- and high-energy exposures. For low-energy CEM exposures and FFDM exposures the system operates similarly. For the thinnest breast (and phantoms), a Mo/Mo target/filter combination and tube voltage of 26 kVp are used. For breasts with greater thickness, Rh/Ag and 34 kVp are used. For high-energy CEM exposures, the choice of target material is similar to that for low-energy exposures (Mo or Rh, depending on the thickness of the breast). However, filtration and tube voltage values are constant for all high-energy exposure (Cu and 49 kVp). In all types of exposure, the tube loading (mAs) value is automatically selected by the device depending on the thickness and structure of the breast.

Data on radiation exposure of examined women, including AGD, were obtained from the GE DoseWatch monitoring system and exported to an Excel file. A data set comprising 200,976 exposures and 59,438 tests was obtained. CEM was used in 5557 of these exposures. The data obtained included information on the cumulative average glandular dose for the entire study, the AGD for each breast, and exposure parameters (tube voltage, target/filter combination, and tube loading). Low-energy exposures were made at tube voltage values of 26-34 kVp and tube loading of 19-169 mAs (with a target/filter combination: Mo/Mo or Rh/Ag). High-energy exposures were made at 49 kVp and 52-163 mAs (with a target/filter combination: Mo/Cu or Rh/Cu). FFDM exposures were made at 26–34 kVp and 2-269 mAs (with a target/filter combination of Mo/Mo or Rh/Ag). The dataset included craniocaudal (CC) and mediolateral oblique (MLO) projections. AGD values were calculated automatically in the mammography computer system by multiplying the input air kerma and conversion factors taken from Dance[25-27]. The use of this method to determine AGD exposure in women is recommended by the European Guidelines[22-24].

Using Python software (v. 3.8.10) and the Pandas library (v. 1.4.0), doses were summed up for CEM exposure pairs, i.e., for low- and high-energy exposure in the same study and the same projection (omitting cases in which the number of exposures in the same projection differed from two). The obtained data were added to the Excel file.

AGD data on individual exposures, including summed CEM exposures, were compared with the acceptable dose levels indicated in the European Guidelines (**Table 1**)[22-24]. For breasts of thicknesses not listed in the table, the acceptable dose level was determined by interpolation using a second-degree polynomial.

**Table 1. Acceptable dose levels indicated in the European Guidelines[22-24].**

| Breast thickness (cm) | Acceptable dose level (mGy) |
|---|---|
| 2.1 | 1.2 |
| 3.2 | 1.5 |
| 4.5 | 2.0 |
| 5.3 | 2.5 |
| 6.0 | 3.0 |
| 7.5 | 4.5 |
| 9.0 | 6.5 |

In addition, the selection of exposure parameters in CEM mode for PMMA phantoms with different thicknesses ranging from 2 to 7 cm was checked. AGD values reported by the system for PMMA phantom exposures were compared with AGD values calculated independently. The calculations were based on the methodology described in the European Guidelines, using coefficients provided by Dance et al.[22-24,26-28]. Tube output values and HVL (half-value layer) values, which were necessary for calculations, were measured with a Piranha Black 657 multimeter (RTI Electronics AB).

**Table 2. Average glandular doses for four types of exposures (average ± SD).**

| Breast thickness range (cm) | Mean glandular dose in one exposure (mGy) | | | | |
|---|---|---|---|---|---|
| | FFDM | low energy | high energy | CEM | CEM to FFDM ratio |
| <2.0;3.0) | 0.81 ± 0.14 | 0.88 ± 0.11 | 0.59 ± 0.14 | 1.47 ± 0.23 | 1.81 |
| <3.0;4.0) | 1.00 ± 0.11 | 1.03 ± 0.10 | 0.70 ± 0.07 | 1.73 ± 0.14 | 1.73 |
| <4.0;5.0) | 1.14 ± 0.11 | 1.19 ± 0.12 | 0.70 ± 0.04 | 1.89 ± 0.13 | 1.66 |
| <5.0;6.0) | 1.29 ± 0.16 | 1.37 ± 0.20 | 0.68 ± 0.04 | 2.06 ± 0.19 | 1.60 |
| <6.0;7.0) | 1.53 ± 0.23 | 1.64 ± 0.27 | 0.67 ± 0.04 | 2.31 ± 0.27 | 1.51 |
| <7.0;8.0) | 1.88 ± 0.28 | 1.99 ± 0.28 | 0.69 ± 0.06 | 2.68 ± 0.31 | 1.43 |
| <8.0;9.0) | 2.25 ± 0.30 | 2.35 ± 0.35 | 0.73 ± 0.07 | 3.08 ± 0.40 | 1.37 |

**Table 3. Number of cases in which AGD in the CEM exposures exceeded the acceptable dose limit.**

| Breast thickness range (cm) | Number of CEM exposures | Exposures with dose exceedance | | Maximum dose (mGy) | Maximum dose exceedance (% of acceptable dose level) |
|---|---|---|---|---|---|
| | | Numer of cases | Percentage of cases | | |
| <2.0;3.0) | 210 | 144 | 69% | 1.91 | 39.5% |
| <3.0;4.0) | 767 | 574 | 75% | 2.17 | 33.8% |
| <4.0;5.0) | 1247 | 229 | 18% | 2.46 | 17.1% |
| <5.0;6.0) | 1508 | 17 | 1% | 3.10 | 19.3% |
| <6.0;7.0) | 1148 | 1 | 0% | 3.26 | 0.7% |
| <7.0;8.0) | 468 | 0 | 0% | 3.45 | 0.0% |
| <8.0;9.0) | 133 | 0 | 0% | 4.46 | 0.0% |
| **All cases** | **5481** | **965** | **17.6%** | | |

## Results

The results of average glandular doses for four types of exposures (FFDM, low-energy CEM, high-energy CEM, and summed CEM) for different breast thicknesses are presented in **Table 2**. The number of cases in which AGD in the CEM exposures exceeded the acceptable dose limit is presented in **Table 3**. **Figure 1** shows average glandular dose as a function

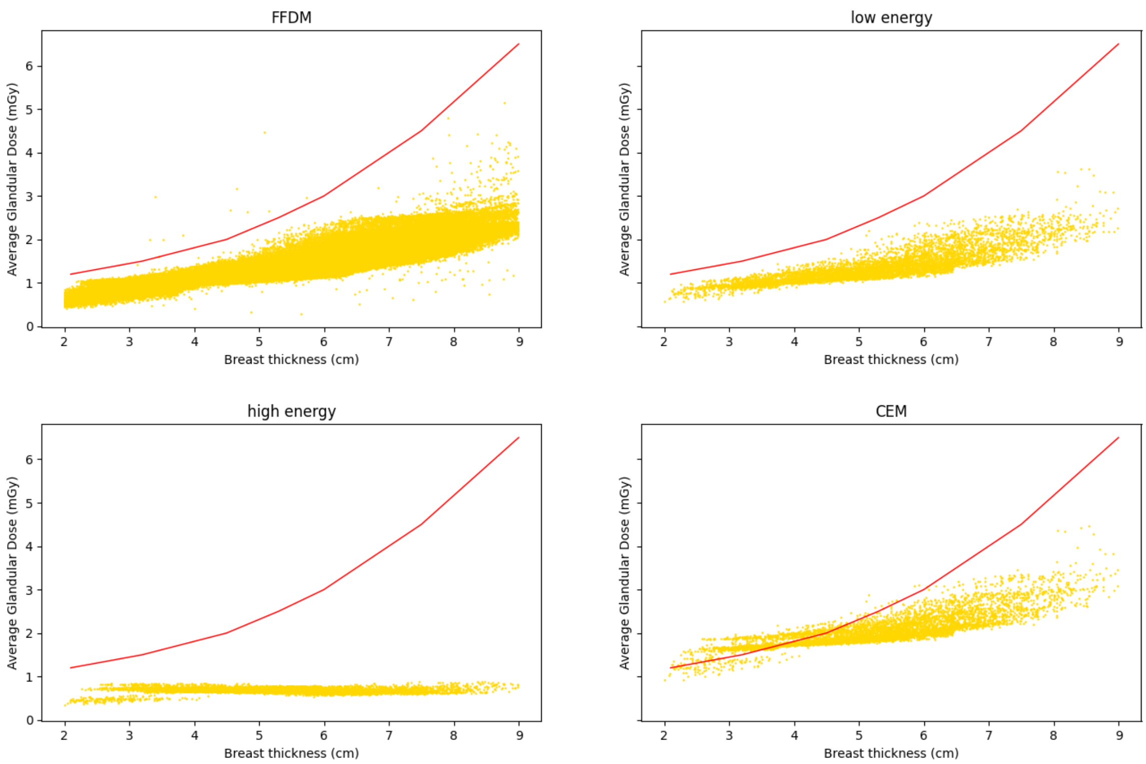


**Figure 1. Average glandular dose as a function of breast thickness for four types of exposures. The red line indicates an acceptable dose level.**

**Table 4. Exposure parameters in CEM mode for PMMA phantoms with different thicknesses ranging from 2 to 7 cm.**

| Thickness of PMMA (cm) | Equivalent breast thickness (cm) | Low-energy exposures | | | | High-energy exposures | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | target /filter | tube voltage (kVp) | tube loading (mAs) | displayed AGD (mGy) | target /filter | tube voltage (kVp) | tube loading (mAs) | displayed AGD (mGy) |
| 2.0 | 2.1 | Mo/Mo | 26 | 16.6 | 0.49 | Mo/Cu | 49 | 41.5 | 0.30 |
| 3.0 | 3.2 | Mo/Mo | 26 | 43.6 | 0.92 | Mo/Cu | 49 | 70.7 | 0.49 |
| 4.0 | 4.5 | Rh/Ag | 34 | 30.1 | 1.23 | Rh/Cu | 49 | 107 | 0.71 |
| 4.5 | 5.3 | Rh/Ag | 34 | 30.2 | 1.27 | Rh/Cu | 49 | 107 | 0.74 |
| 5.0 | 6.0 | Rh/Ag | 34 | 36.9 | 1.42 | Rh/Cu | 49 | 111 | 0.74 |
| 6.0 | 7.5 | Rh/Ag | 34 | 53.4 | 1.89 | Rh/Cu | 49 | 111 | 0.71 |
| 7.0 | 9.0 | Rh/Ag | 34 | 84.1 | 2.58 | Rh/Cu | 49 | 121 | 0.74 |

of breast thickness for four types of exposures. **Figures 2** and **3** present the average glandular dose for four types of exposures in different ranges of breast thickness. The label 'CEM' in figures and tables indicates the summed dose associated with low- and high-energy exposures in the CEM study. Table 4 presents exposure parameters in CEM mode for PMMA phantoms with different thicknesses ranging from 2 to 7 cm. Displayed values agreed with the independently calculated values within ±20%.

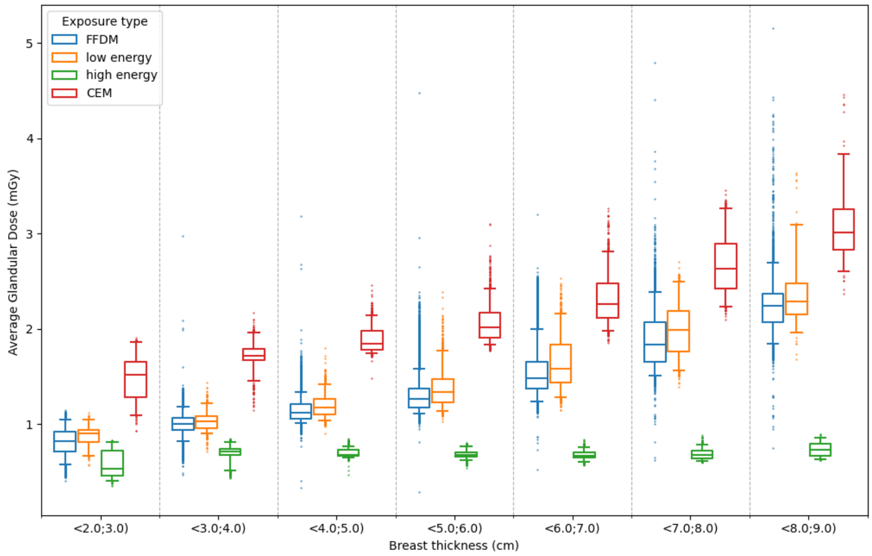


**Figure 2. Average glandular dose for four types of exposures in different ranges of breast thickness. The whiskers represent the 5th and 95th percentiles.**

## Discussion

The average glandular dose for FFDM exposures is clearly dependent on the breast thickness. The same is also true for low-energy CEM exposures. In contrast, the dose for a single high-energy CEM exposure is about 0.7 mGy and shows no clear dependency on the breast thickness (**Table 2**, **Figures 1-2**).

Out of 176,700 FFDM exposures, the acceptable dose level was exceeded only in 11 cases (less than 0.01%). For CEM exposures (summed low- and high-energy exposures), the acceptable dose level was exceeded in 965 out of 5481 cases (17.6%). Exceedances of the acceptable dose level for CEM exposures are mainly observed for breasts with small thicknesses (**Figure 1**).

The doses in FFDM exposures and low-energy CEM exposures are similar. The difference between doses in FFDM and CEM exposures is approximately equal to the dose in high-energy CEM exposure (**Figure 3**). For breasts with the smallest thicknesses, the addition of approximately 0.6-0.7 mGy from high-energy exposure may almost double the dose, resulting in an exceedance of the acceptable dose limit. When the same 0.7 mGy is added for breasts with the highest thicknesses, the relative change in dose is small, and the acceptable dose levels are not exceeded. The participation of AGD from high-energy exposure in the AGD from CEM exposure (summed low- and

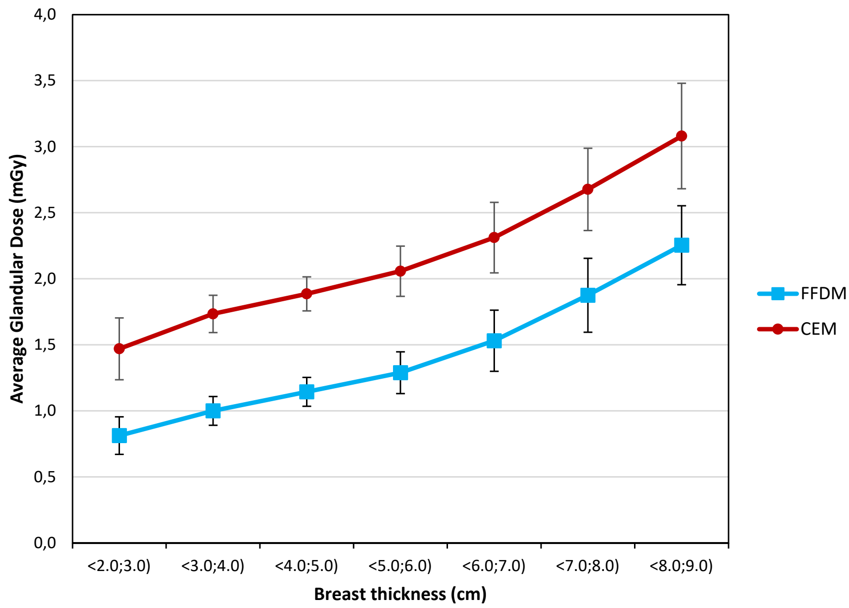


**Figure 3. Average glandular dose for FFDM and CEM exposures in different ranges of breast thickness (points represent mean, 'whiskers' – standard deviation)**

high-energy doses) decreases with breast thickness after compression. The ratio of mean AGD values from CEM exposure to mean AGD values from FFDM exposure for different breast thickness ranges after compression decreases with increasing breast thickness, as shown in **Table 2** and **Figure 2** – it changes from 1.81 to 1.37. The average AGD from high-energy exposure changes from 40% (for compressed breasts smaller than 3 cm) to 24% (for compressed breasts of 8 cm and larger) of the average dose for CEM exposure (**Table 2**). This is clearly seen in **Figure 2**, as well. This is because the AGD value from high-energy exposure is within a similar range of values for all breast thicknesses after compression. However, the AGD value from low-energy exposure increases with breast thickness.

For high-energy CEM exposures, the tube voltage value is constant (49 kVp), and the tube loading (mAs) value is automatically selected by the device. However, while for low-energy exposure the tube loading increases almost threefold when the phantom thickness changes from 4 cm to 7 cm, for high-energy exposure we observe an increase of only 13% (**Table 4**). In turn, the coefficients used to calculate AGD decrease with breast thickness[27]. As a result, the AGD value for high-energy exposure is almost constant across a wide range of breast thicknesses. The exposure parameters for flat, homogeneous phantoms made of PMMA do not have to correspond exactly to the exposure parameters selected by the device for real breasts. However, the relationships observed between phantom thickness and exposure parameters and AGD values are similar to those observed in examinations of women.

A comparison of AGD values for individual women's exposures with acceptable values shows that women examined using FFDM did not receive doses exceeding these levels (**Figure 1**). The same is true for doses from low- and high-energy exposure if we treat them as separate quantities. However, doses for the combined CEM exposure exceeded acceptable dose levels in 17.3% of cases. The vast majority (70%) of these instances were observed for breasts compressed with a thickness of 4 cm or less. In this group, 73.4% of exposures were made at a higher AGD value that exceeded the acceptable dose level. The fewest instances where the acceptable dose level was exceeded were for large breasts after compression (**Table 3**). In our study, 70% of CEM exposures were performed for breast thickness after compression ranging from 4 cm to less than 7 cm, and in this group, acceptable dose levels were exceeded in only 6.3% of cases. For breasts compressed from 6 cm and larger, no exposure exceeding the acceptable dose level was recorded (**Figure 1**).

For the thinnest breasts (range 2–3 cm), switching from FFDM to CEM means an 81% increase in dose, with the acceptable dose level exceeded by 39%. Nevertheless, the maximum dose observed for this thickness range (1.91 mGy) is lower than the acceptable dose level for breasts of average thickness (2.5 mGy for 5.3 cm). It is also lower than the average FFDM dose for breasts of greater thickness (2.25 mGy in the 8-9 cm range). The acceptable dose levels defined in the European Guidelines[22-24] should not be treated as safety limits, beyond which some specific radiobiological effect occurs. In general, there are no legal restrictions on the medical exposure of patients to ionizing radiation. However, there are rules requiring exposure to be justified and optimized in accordance with the ALARA principle (as low as reasonably achievable). Particular attention is paid to limiting exposure in screening mammography, which is performed on women without symptoms. The original acceptable dose levels for breast cancer screening using digital mammography were defined in 2006 with the assumption that average glandular dose levels in digital mammography systems should not be higher than for screen-film systems[22]. The values were based on AGD data acquired for screen-film mammography in the early 2000s. They were therefore not based on radiobiological knowledge but on the technical capabilities available at the time. The relationship between acceptable dose levels and breast thickness does not reflect any hypothetical relationship between breast thickness and its sensitivity to radiation. This relationship is due to technical reasons, namely the fact that with greater breast thickness, a higher radiation dose is required to obtain an image of adequate quality. Later, it was observed that for 2 cm of PMMA, the acceptable dose levels were difficult to comply with when using digital mammography systems. Therefore, the limiting values for the 2.1 cm breast and the 2.0 cm PMMA thickness were increased slightly in 2017. To support this decision, it was argued that the glandular dose for women with thin breasts is already lower than the dose for women with thicker breasts[24]. The risk of developing breast cancer caused by radiation associated with mammography screening is considered low, and the effectiveness of mammography screening program in terms of benefit-to-radiation risk ratio is high[28]. Of course, mammography screening is currently performed using FFDM, for which exposure is lower than with CEM. However, the increased exposure associated with CEM is considered justified in the case of abnormalities detected with FFDM[5,16]. The use of CEM in mammographic screening of asymptomatic high-risk patients is also being considered[21].

AGD values are approximately 19% lower than the values presented in the article by Philips et al.[17] and definitely lower (up to 4 times for thick breasts) than the values given in the article by Kisielewicz et al.[29]. These differences may be mainly due to the upgraded technologies used in the mammography unit in this study. It should be emphasized that the data presented refer specifically to CEM examinations performed using the GE Senographe Pristina mammography system. Dose values for other systems may differ[5,19]. For a similar GE Senographe Pristina system, Gennaro et al. have found a similar value of the high-energy dose (0.7 mGy) for the exposure of the CIRS Model 022 phantom (55-mm thick)[19].

The average glandular dose is defined as the average radiation dose absorbed in the exposed breast glandular tissue. AGD is not a directly measurable quantity. In practice, AGD is calculated by multiplying the air kerma by conversion coefficients[30]. The coefficients are determined based on Monte Carlo simulations, and their values depend on the simulation assumptions, including the breast model used. Different breast models are used in different studies[30,31]. That said, AGD is an operational quantity rather than a measure of the exposure of a specific woman. However, it should be remembered that the aim of the study was to compare the observed AGD values from CEM examinations with doses from FFDM and with acceptable dose levels set by European Guidelines. In this case, the most important thing is that all compared values were determined using the same methodology.

## Conclusions

The AGD values from FFDM exposures and CEM exposures have been analyzed in terms of compliance with the acceptable values specified in the European Guidelines[22-24].

The average glandular dose for FFDM exposures is clearly dependent on the breast thickness. The same is also true for low-energy CEM exposures. In contrast, the dose for a single high-energy CEM exposure is almost constant across a wide range of breast thicknesses. The ratio of mean AGD values from CEM exposure to mean AGD values from FFDM exposure for different breast thickness ranges after compression decreases with increasing breast thickness; it changes from 1.81 to 1.37. For the thinnest breasts (range 2–3 cm), switching from FFDM to CEM means an 81% increase in dose, with the acceptable dose level exceeded by 39% and the maximum dose being 1.91 mGy (lower than the acceptable value for thicker breasts).

Out of 176,700 FFDM exposures, the acceptable dose level was exceeded only in 11 cases (less than 0.01%). For CEM exposures (summed low- and high-energy exposures), the acceptable dose level was exceeded in 965 out of 5481 cases (17.3%). For breasts compressed from 6 cm and larger, no exposure exceeding the acceptable dose level was recorded. AGD values for CEM exposure exceeded the accepted levels mainly for breasts smaller than 4 cm after compression. Although CEM exposures are a combination of two exposures (low- and high-energy), in most cases, the doses associated with CEM exposure do not exceed the limits that were originally set for single FFDM exposures.

## Conflicts of interest

WS is editor-in-chief for Polish Journal of Medical Physics and Engineering. He was removed from all editorial processes relating to the handling of this submission.

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