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Research article

Clinical validation of a pressure-standardized compression mammography system

D. den Boer[a,*,1], L.A.J. Dam-Vervloet[a,1], M.F. Boomsma[b], E. de Boer[b], J.A. van Dalen[a], L. Poot[a]

[a] Department of Medical Physics, Isala Hospital Zwolle, The Netherlands
[b] Department of Radiology, Isala Hospital Zwolle, The Netherlands

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ABSTRACT

Objectives: Validation of a pressure-standardized compression mammography (PSCM) system, which aims to reduce discomfort and pain by applying the same pressure to every breast, independent of breast size.

Methods: We retrospectively studied mammograms of 39 patients acquired with a conventional force-standardized compression mammography (FSCM) technique and intra-individually compared them to mammograms acquired on a checkup visit with PSCM technique. Patients received one craniocaudal (CC) and one mediolateral oblique (MLO) compression for both breasts. All images were processed to obtain the contact area between the breast and the compression paddle. The pressure was calculated by dividing the compression force by the contact area.

Results: A total of 150 FSCM and 150 PSCM images were analyzed. The mean pressure decreased significantly from 17.1 to 12.8 kPa ($p < 0.001$), when using PSCM instead of FSCM. The applied pressure hardly depended on the breast contact area with the paddle (-0.014 kPa/cm^2), while a clear dependency was observed using FSCM. Furthermore, the relative number of over-compressions reduced from 26% to 2%, benefitting patients with smaller breasts.

Conclusions: Our study suggests that using PSCM can reduce patient discomfort and pain during mammographic compression compared to conventional FSCM as a result of lower average pressure. Moreover, standardized pressure may provide a more constant image quality, which could improve diagnostic performance.

1. Introduction

As in every medical imaging modality, the ability to detect pathological conditions depends on the image quality. In mammography, one of the main challenges is to obtain a homogeneous contrast over the entire breast image. Compressing the breast between a compression paddle and the detector housing improves image quality [1] and results in a reduction of patients' radiation dose [2]. Moreover, it results in a more homogeneous exposure from nipple to chest wall which improves the dynamic range, the difference between the smallest and largest signal values of an image [3]. On the downside, mammographic breast compression is associated with discomfort and pain for the patient [4].

Current compression techniques are based on applying force-standardized compression, i.e. each breast is compressed within a range of recommended forces (130–200 N [5]). Breast size is not taken into account in this technique, which leads to a large variation in applied pressure on the breast during mammography [6]. Although guidelines exist to apply the appropriate compression force, there is a large variation in the amount of compression both between and within radiographers [7]. This means that the same patient would receive different compression forces with different compressions, which may lead to variations in discomfort and image quality.

Recently, a new technique was introduced which enables pressure-standardized compression mammography (PSCM) that aims to reduce discomfort [8] and to provide more constant image contrast by applying a constant pressure of 10 kPa, i.e. the same pressure in all compressions. The ratio of force and contact area is known as mean pressure, which implies that a constant pressure results in a breast-size dependent compression force. This pressure is intended to be enough to expel venous blood from the breast, but not to obstruct the inflow of arterial blood [9]. Additionally, a pressure between 9.2 and 10.7 kPa was shown to have the highest cancer detection rate[10,11]. The PSCM technique recognizes that the force that is exerted on the breast is distributed over the entire contact area. In this technique, both contact

Abbreviations: PSCM, pressure-standardized compression mammography; FSCM, force-standardized compression mammography

* Corresponding author at: Nieuwstraat 32C, 8011 TP, Zwolle, The Netherlands.
E-mail address: d.den.boer@isala.nl (D. den Boer).

[1] Both authors contributed equally.

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area and applied force are measured which allows for calculation of the applied pressure. This way, the same target pressure to the breast can be applied for each patient, which potentially provides a more objective and individualized compression. Women with smaller breasts typically have smaller contact areas and will thus benefit most, since by definition of pressure, these women will receive higher pressures when the same force is applied as in force-standardized compression mammography (FSCM).

In this study we compared the pressure-standardized compression mammography technique with the conventional FSCM technique. To our knowledge there is no literature on a validation of this new technique in clinical practice. Our primary aim was to validate that the pressure applied with PSCM does not depend on the breast contact area. Our secondary aim was to evaluate if variation in applied pressure to similar sized breasts was reduced. Furthermore, we aimed to assess the number of over-compressions with both techniques.

2. Materials and method

Fifty asymptomatic patients, scheduled for a standard mammography follow-up who received conventional FSCM mammograms between 2010 and 2015 were invited for this study, which was approved by our hospital's Medical Ethics Committee (IRB, 16.0241). The average age of the participants was 54 ± 10 years (range: 36–74). Follow-up mammograms were acquired in a period of three weeks. The time between both mammograms was 996 ± 491 days (range: 355–2124 days). We excluded 11 patients who had undergone breast interventions such as breast surgery, biopsy or radiotherapy treatment, because this potentially reduces breast volume and hence influences paired tests. This resulted in 39 patients that were included in the study. On the follow-up visit patients received PSCM mammograms. All compressions were performed on the same mammography device (Selenia, Hologic Inc., Bedford MA, USA) and PSCM was performed using a dedicated paddle (Sensitive Sigma Paddle, Sigmascreening BV, Amsterdam, NL). Using the traditional FSCM method, radiographers were instructed to compress between 100 N and 150 N, following international compression guidelines [5,12], or as much as the women could tolerate below 100 N. During both visits patients received one craniocaudal (CC) and one mediolateral oblique (MLO) compression for each breast.

To enable pressure-standardized compression both compression force (F) and contact area (A) were measured real time. Pressure (P) was then calculated by the following formula:

$$P\left[kPa\right] = 10\frac{F\ [N]}{A\ [cm^2]} \quad (1)$$

To measure the contact area the Sensitive Sigma Paddle system uses a plastic foil with a very thin conductive radiolucent layer inside the paddle (Fig. 1). The contact area between the breast and the compression paddle was measured using a capacitive sensor.

The ratio of the force and contact area was automatically computed and visualized on the paddle system using eight LED's to visualize pressures between 0 and 14 kPa, i.e. 2 kPa per LED. As pressure increased more LED's lighted up. A total of twelve radiographers were instructed to stop the compression once the target pressure was reached. However, they were allowed to deviate from the target pressure if the patient was in too much pain. The target pressure for the PSCM mammograms was 10 kPa, corresponding with the sixth LED. However, for smaller contact areas part of the applied force may be lost to compressing the pectoral muscle near the chest wall, leading to under-compression of the breast [7,13]. Therefore, for patients with a contact area smaller than 50 cm^2 a minimum force of 50 N was applied which allowed for higher pressures and prevent under-compression. For user consistency the paddle was configured such that for a contact area smaller than 50 cm^2 the sixth LED would light up at the target force of 50 N.

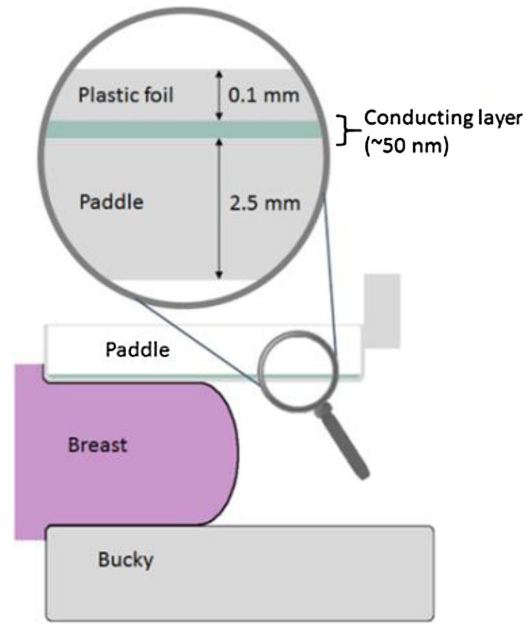

Fig. 1. Scheme of the capacitive-based Sensitive Sigma Paddle [15].

To obtain the contact area and subsequently the applied pressure, all images (PSCM and FSCM) were analyzed retrospectively using the algorithm described in the appendix of the paper by de Groot et al [14]. To assess whether the pressure was independent of the contact area with PSCM, we performed a linear regression for $A > 50\ cm^2$, because the relation between contact area A and pressure P is expected to be linear when using a constant pressure. For FSCM, however, the pressure is inversely proportional to the contact area. Hence, linear regression is not appropriate. The FSCM data were therefore fitted with the function $P = a/A$, with constant a. The CC and MLO sub-datasets were also fitted separately to assess a difference in trends. A paired samples *t*-test was performed to assess whether the mean pressure in PSCM decreased significantly with respect to conventional FSCM. Next, the relative error between the measured pressure (P_{meas}) and fit result (P_{fit}) was calculated for each data point, for both PSCM and FSCM data sets, using $(P_{fit} - P_{meas})/P_{fit} \times 100\%$. The Levene's test was used to assess if the standard deviation of the relative error distribution of both data sets differed significantly from each other. A difference would indicate a dissimilarity in applied pressure to similar sized breasts. Lastly, the number of over-compressions, defined as pressures > 20 kPa, was determined in both techniques. This threshold is chosen because serious over-compression will occur with forces of 180–200 N [15]. With a typical contact area of 100 cm^2 this implies an over-compression at pressures from around 20 kPa. A Fisher's exact test was performed to examine statistical difference in the occurrence of over-compression. The level of statistical significance was set at $p < 0.05$ for all tests.

3. Results

In both FSCM and PSCM data sets the same 39 patients were included. As all patients received a CC and MLO compression on both breasts, 156 images per dataset were acquired. The data of six images was corrupted, so pressure could not be calculated. These images were therefore excluded. As a result, 150 images were included in both datasets, resulting in 300 images. Using FSCM, the contact area was smaller than 50 cm^2 in 15 compressions, whereas with PSCM this was the case in 27 compressions.

In Fig. 2 the distribution of applied pressure versus contact area is shown. The PSCM data were split into two groups, because of the different target pressure/force that was used, 10 kPa for $A > 50\ cm^2$ and