Original Research

Pressure-based Compression Guidance of the Breast in Digital Breast Tomosynthesis Using Flexible Paddles Compared to Conventional Compression

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Abstract

Objective: We investigated the effect of introducing a pressure-based flexible paddle on compression parameters and user and patient experience of digital breast tomosynthesis (DBT) combined with patient-assisted compression or technologist compression.
Methods: After institutional review board approval, women with a DBT appointment who gave informed consent received pressure-based flexible paddle breast compression. Eight lights on the paddle were illuminated (1.9 kPa per light) as pressure was applied, aiming for an 8–13.9 kPa target range. The compression level was applied by the technologist or the participant utilizing a remote control device. The participant's and technologist's experiences were assessed by a questionnaire. Compression parameters were compared to previous examinations. Comparative statistics were performed using *t*-tests.
Results: Pressure-based compression (PBC) was judged to be similar or more comfortable compared with previous traditional exams (80%, 83/103), and 87% (90/103) of participants would recommend PBC to friends. Pressure variability decreased for craniocaudal (CC) views (-55%, $P < 0.001$) and mediolateral oblique (MLO) views (-34%, $P < 0.0001$). Subgroup analysis showed a similar glandular dose for CC views, while breast thickness was reduced (-3.74 mm, $P < 0.0001$). For MLO views, both glandular dose (-0.13 mGy, $P < 0.0001$) and breast thickness were reduced (-6.70 mm, $P < 0.0001$). Mean compression parameters were similar for technologist compression and patient-assisted examinations.
Conclusion: Use of the pressure-based flexible paddle in DBT, with or without patient-assisted compression, improved participant and technologist experience and reduced compression pressure variability, mean breast thickness, and glandular dose.

Key words: mammography; breast compression; pressure; standardization; patient experience.

Introduction

In mammography and digital breast tomosynthesis (DBT), there are several reasons to minimize the thickness of and immobilize the breast to optimize image quality (1). However, in soft tissue mechanics, an internationally accepted rule or guideline to reach optimal breast flattening

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Key Messages
- Participant and technologist experience improved when using a pressure-based flexible paddle when compared with conventional breast compression in digital breast tomosynthesis.
- Digital breast tomosynthesis with pressure-based flexible paddle breast compression decreases compression pressure variability, mean breast thickness, and glandular dose, which helps standardization across visits and examination sites.

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and immobilization is nonexistent (2). Most procedures are performed utilizing local guidelines that aim for a target force or force range. However, technologist experience and patient feedback contribute to the final decision to stop breast compression. This nonstandardized practice of breast compression results in large variations in compression parameters within single departments, between countries (3,4), and between breast centers of the same screening program (5). In addition, many women report discomfort and pain during mammographic breast compression (6,7), which is also a common reason screening is avoided (8).

As there is a need for compression standardization (9), a different approach was recently reported in which the compression paddle of the mammography system was equipped with a conductive foil transparent to light and X-rays (10). The capacitance changes between the breast and the foil can be translated to a measurement of contact area (A, in cm^2). The ratio between the compression force and the breast contact area represents the mean contact pressure in that area (P = F/A). In prior studies, this approach was used in a double-blinded, intra-individual comparison study (10), in screening (11,12) and in clinical practice (13,14). In those studies, the pressure indicator was integrated on a rigid paddle and used in conventional two-dimensional (2D) mammography.

Mammography and DBT systems are regularly equipped with both rigid and flexible compression paddles, and the latter are currently used as the standard paddle in most clinics. Flexible paddles tilt during compression to adjust to the breast shape, consequently improving patient comfort. In countries where technologists are accustomed to relatively high compression force, it appears that the use of flexible paddles may sacrifice the total volume of tissue imaged, without necessarily improving the patient's pain experience (15). One could hypothesize that flexible paddles would better fit the needs of countries where compression force is moderate, such as in the United States (as compared with The Netherlands) (3).

Another suggested method to improve patient comfort is patient-controlled breast compression (16,17). Recently, a remote control device was introduced for women to finalize breast compression. Researchers reported that using this device resulted in higher compression levels, reduced breast thickness, and lowered the radiation dose while increasing the willingness of women to reattend screenings (18,19). The influence of this method on compression parameter variability was, however, not studied.

The use of pressure-based compression (PBC), flexible paddles, and patient-controlled compression as separate methods have their own positive impact on breast compression and patient satisfaction, but the impact of the combined use of these three methods on patient discomfort and compression variability is unknown. The primary aim of this study was to measure the effect of a pressure-based flexible paddle on compression parameters and its influence on the user's and patient's experience of DBT. Additionally, the second aim of this study was to assess the difference between remote controlled, pressure-based, patient-assisted compression and pressure-based, standard technologist-assisted compression.

Methods

The study was institutional review board approved and was compliant with the Health Insurance Portability and Accountability Act.

Participants

Female patients who had an appointment for screening or DBT between October 2018 and December 2018 were asked to participate in the study. The exclusion criteria for the study were the presence of breast implants, an inability to stand (ie, wheelchair dependent), an increased risk for falling, and enrollment in another study. All participants gave written informed consent to the procedure prior to inclusion.

Procedure

During the study period, a small (19 × 23 cm) and a large (24 × 29) pressure-based flexible paddle were used on a Senographe Pristina (GE Healthcare, Chicago, IL). The choice for paddle size was made per patient by the technologist and was based on breast size. The study procedure was performed by five trained and certified radiologic technologists with over five years of experience. Mean compression pressure (P) applied to the contact area between breast and paddle was calculated in real time by dividing the compression force (F) by the breast contact area (A), as follows:

$$P\,(kPa) = \frac{F(daN)}{A(cm^2)}$$

The compression parameters were obtained from different sources. The compression force (F) was delivered by the mammography system. The breast area (A) in contact with the paddle was measured by using a capacitance-based method for which the paddle tray was equipped with a thin conductive silver nanowire layer (50 nm) and protected by a transparent and radiolucent

layer (0.17 mm). The pressure (P) was calculated in real time by the paddle and was displayed to the technologist and patient by a progressive eight-light light-emitting diode (LED) indicator display located at the backside of the paddle. The eight lights were arranged in a sequence pattern, with the first LED light representing 0–1.9 kPa. As the compression pressure increased, the eight LEDs progressively illuminated, with each light representing an increase of 1.9 kPa. The lights provided a visual indication of pressure, as illustrated in Figure 1. The target pressure range (8–13.9 kPa) was achieved when LED lights #5–7 glowed pink. All other LEDs glowed white. Once the target range was reached, the indicator lights (present on the patient armrest) turned off (Figure 1). The PBC paddle was used in all mammographic exams throughout the study period. In one group, the compression was fully applied by the technologist, while in another group the participants participated in the compression by using a remote control. The participants were randomly assigned to one of two groups. In both groups, the technologist positioned the breast.

In the technologist compression group, the technologist was instructed to compress the breast within the target pressure range (LED lights #5–7). For the patient-assisted compression group, a remote control (Pristina Dueta, GE Healthcare, Chicago, IL [20]) was given to the participant. This device had a "+" button to increase the compression and a "-" button to decrease the compression by a maximum of two steps. After the participant was instructed about the procedure, the technologist positioned the breast and applied the initial compression force of at least 3 daN. The remote control was placed in the patient's hand contralateral to the breast being imaged. The participant was then asked to advance the compression to the target pressure range.

Experience Assessment

During and directly after the procedure, participants were asked to complete an experience questionnaire (Table 1). The survey assessed the participant's comfort and satisfaction, with the patients choosing one of five responses (strongly agree, agree, neither agree nor disagree, disagree, and strongly disagree). The survey consisted of three questions for all participants, nine questions for those receiving patient-assisted compression, and three questions for those receiving technologist compression. Directly after the image acquisition was complete, the technologist also answered a questionnaire (Table 2) using the same response options. The radiologists were asked if they rejected an image because of blur or bad patient positioning.

Compression Parameters

For all participants, DBT images of the full study examination, consisting of one craniocaudal (CC) and one mediolateral oblique (MLO) image per breast, were selected from the current study and matched to previous examinations. The participants' age and detector ID were obtained from the Digital Imaging and Communications in Medicine (DICOM) headers of the DBT images of all available mammographic views. Compression pressure and breast contact area were not stored in the DICOM header. The contact area (cm²) and
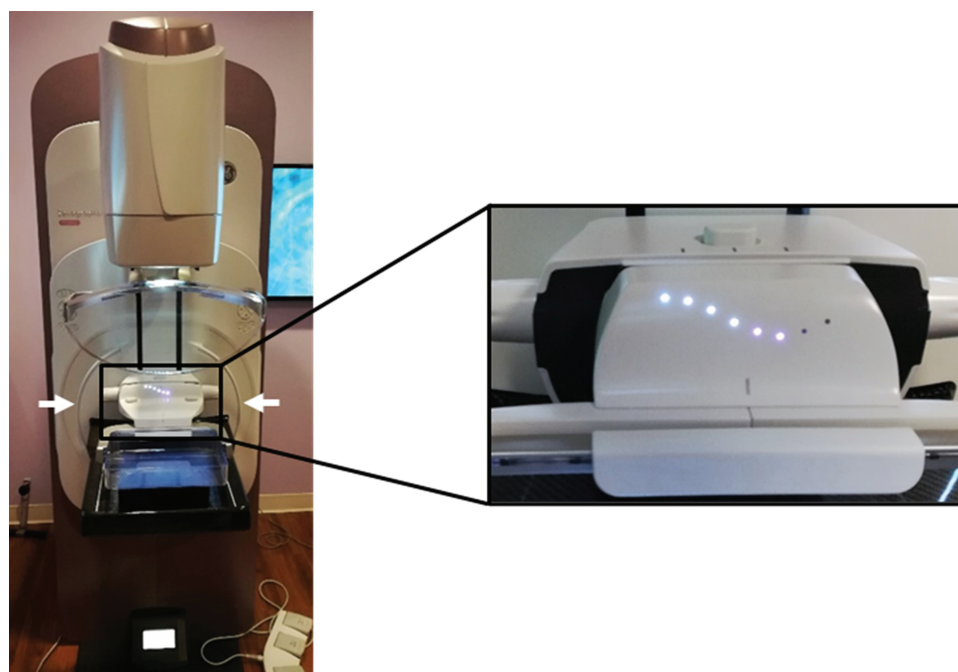

Figure 1. Research version of a flexible pressure-based compression paddle (Senographe Pristina, GE Healthcare, Chicago, IL). Eight light-emitting diode (LED) lights indicate the pressure level to the technologist and participant. LED lights #5–7 (pink) indicate the target pressure range (8–13.9 kPa). Once the target range is reached, the indicator lights, present on the patient handles (arrows), turn off. In this image, the lights are turned off.

Table 1. Participant Questionnaire Results

All participants (*N* = 103)	Questionnaire Answers					
	Strongly Agree	**Agree**	**Neither Agree/ Disagree**	**Disagree**	**Strongly Disagree**	***P*-Value**
Compared to your previous experience of mammography exams, would you say that the compression was less uncomfortable?	34 (33%)	25 (24%)	24 (23%)	19 (19%)	1 (1%)	<0.0001
Would you recommend PBC to your friends for their mammography exam?	63 (61%)	27 (26%)	9 (9%)	4 (4%)	0 (0%)	<0.0001
Would you look for a facility that offers PBC for your next mammography exam?	49 (48%)	34 (33%)	13 (13%)	7 (7%)	0 (0%)	<0.0001
PAC (*n* = 50)						
Compared to your previous experience of mammography exams, would you say that the compression was less uncomfortable?	18 (36%)	15 (30%)	10 (20%)	6 (12%)	1 (2%)	<0.0001
Would you recommend PBC to your friends for their mammography exam?	35 (70%)	12 (24%)	3 (6%)	0 (0%)	0 (0%)	<0.0001
Would you look for a facility that offers PBC for your next mammography exam?	24 (48%)	18 (36%)	7 (14%)	1 (2%)	0 (0%)	<0.0001
Were you able to see the patient handle lights for the CC views?	34 (68%)	12 (24%)	1 (2%)	2 (4%)	1 (2%)	<0.0001
Were you able to see the patient handle lights for the MLO views?	36 (72%)	13 (26%)	0 (0%)	1 (2%)	0 (0%)	<0.0001
Did you understand that when the patient handle lights turn off, the compression has reached the right level?	40 (80%)	9 (18%)	1 (2%)	0 (0%)	0 (0%)	<0.0001
Did you succeed in reaching the compression level to which the patient handle lights turn off?	39 (78%)	11 (22%)	0 (0%)	0 (0%)	0 (0%)	<0.0001
Would you recommend PAC to your friends for their mammography exam?	39 (78%)	10 (20%)	1 (2%)	0 (0%)	0 (0%)	<0.0001
Would you look for a facility using PAC?	28 (56%)	14 (28%)	8 (16%)	0 (0%)	0 (0%)	<0.0001
TC (*n* = 53)						
Compared to your previous experience of mammography exams, would you say that the compression was less uncomfortable?	16 (30%)	10 (19%)	14 (26%)	13 (25%)	0 (0%)	<0.001
Would you recommend PBC to your friends for their mammography exam?	28 (53%)	15 (28%)	6 (11%)	4 (8%)	0 (0%)	<0.0001
Would you look for a facility that offers PBC for your next mammography exam?	25 (47%)	16 (30%)	6 (11%)	6 (11%)	0 (0%)	<0.0001

Abbreviations: PAC, patient-assisted compression; PBC, pressure-based compression; TC, technologist compression.

breast volume (dm³) of both prior and study mammographic views were calculated by a digital image processing software tool (Volpara Enterprise v.3.3.2, Volpara Solutions LTD, Wellington, New Zealand). The same image processing software version was used for both prior examinations and the study's examinations. This software tool calculates the contact area at exposure from the mammographic image based on a software algorithm that models the geometry of the breast (21). The compression parameters—breast thickness (mm, distance between the detector and paddle), applied force (N), average glandular dose (mGy), and breast density (%)—of the participants were also taken from the user interface of the aforementioned digital image processing software tool.

The average glandular dose comparison was done on a subset of data, where both prior and current study examinations were acquired using the same Senographe Pristina and X-ray detector.

Statistical Analysis

The data is reported as mean ± standard deviation. Differences in compression parameters between the study and prior views were tested using a paired sample t-test. For the analysis of the differences between technologist compression and remote controlled, patient-assisted compression, an independent sample t-test was used. The difference in

Table 2. Technologist Questionnaire

All participants (*N* = 103)	Questionnaire Answers					
	Strongly Agree	**Agree**	**Neither Agree/ Disagree**	**Disagree**	**Strongly Disagree**	*P*-Value
PBC makes it easier to explain to patients the right level of compression.	69 (67%)	34 (33%)	0 (0%)	0 (0%)	0 (0%)	<0.0001
PBC helps involve the patient in the compression process.	68 (66%)	34 (33%)	1 (1%)	0 (0%)	0 (0%)	<0.0001
PBC impacts the compression time.	66 (64%)	35 (34%)	2 (2%)	0 (0%)	0 (0%)	<0.0001
Patient was at a normal anxiety level.	65 (63%)	37 (36%)	0 (0%)	0 (0%)	1 (1%)	<0.0001
PAC (*n* = 50)						
PBC makes PAC more acceptable	30 (60%)	8 (16%)	12 (24%)	0 (0%)	0 (0%)	<0.0001
All participants (*N* = 103)	Questionnaire Answers					
	Very Positive	**Agree**	**Neither Positive/ Negative**	**Negative**	**Very Negative**	*P*-Value
What is the impact of PBC with or without PAC on your interaction with the patient?	72 (70%)	20 (19%)	6 (6%)	4 (4%)	1 (1%)	<0.0001
What is the impact of PBC with or without PAC on your interaction with the patient?	70 (68%)	30 (29%)	3 (3%)	0 (0%)	0 (0%)	<0.0001

Abbreviations: PAC, patient-assisted compression; PBC, pressure-based compression.

variability was tested using Levene's test. A Wilcoxon signed-rank test was used for the Likert-type questionnaire results to test if the results differed from the midpoint. All tests were conducted in R statistical software (R v.3.6.2, R Foundation for Statistical Computing, Vienna, Austria). For all tests a *P*-value < 0.05 was considered significant.

Results

A total of 152 patients gave their informed consent for study participation. Different subsets were used for assessing the difference between the prior nonpressure-guided and current pressure-guided examination and between patient-assisted compression and technologist compression (Figure 2). Of the 152 participants, 103 participants (patient-assisted compression, n = 50; technologist compression, n = 53) successfully completed the questionnaire and had prior examinations available for data collection. This dataset was used to evaluate both participant and technologist experience. Of the 103 participants, 94 had a complete set of four DBT images (one CC and one MLO image of both breasts from prior examination and the current examination), resulting in 376 paired views, 188 CC views, and 188 MLO views. This dataset was used for compression parameters and examination time comparisons between the current study examination and the prior examination, and to assess differences between patient-assisted compression (176 views, 44 participants) and technologist compression (200 views, 50 participants).

The mean time between the study examination and prior examination was 466 days, with a standard deviation of 166 days. Of the 94 participants with complete DBT images, 25 participants (100 paired views) had both exams (prior and present) performed on the same mammography system. This dataset was used to analyze glandular dose.

Compression Parameters
In Figure 3, compression parameter scatterplots are given for the subset of 94 participants, with a complete set of mammographic examinations for both prior examinations (with conventional compression) and study examinations with PBC. In the CC views (Figure 3), differences between conventional compression and PBC were observed for force and pressure. The mean and standard deviation during conventional compression was 82.30 ± 20.85 N and was 86.35 ± 34.23 N during PBC (*P* = 0.11). The mean pressure decreased from 10.56 ± 4.60 kPa to 9.54 ± 2.29 kPa (*P* < 0.001).

For the MLO views (Figure 3) similar differences were seen as for the CC views. The paired comparison showed an increase in the mean applied force during the pressure-based study period. The force increased from 85.21 ± 21.85 N (conventional compression) to 103.05 ± 31.51 N during PBC (*P* < 0.0001). At the same time, the mean pressure increased from 7.50 ± 2.84 kPa during conventional compression to 7.98 ± 1.89 kPa during PBC (*P* = 0.02).

As observed in Figure 4, regression lines show a linear relation between force and contact area during pressure-guided
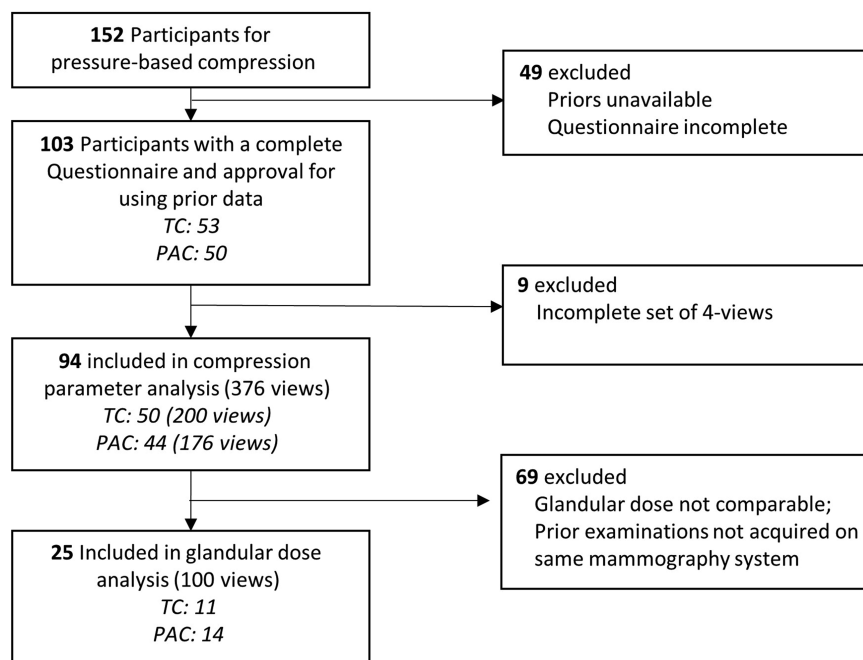
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┌──────────────────────────────────┐
│   152 Participants for            │
│   pressure-based compression      │
└──────────────────────────────────┘
                │         ┌──────────────────────────────────┐
                │────────▶│  49 excluded                      │
                │         │     Priors unavailable            │
                ▼         │     Questionnaire incomplete      │
┌──────────────────────────────────┐ └──────────────────────────────────┘
│  103 Participants with a complete │
│  Questionnaire and approval for   │
│  using prior data                 │
│      TC: 53                       │
│      PAC: 50                      │
└──────────────────────────────────┘
                │         ┌──────────────────────────────────┐
                │────────▶│  9 excluded                       │
                │         │     Incomplete set of 4-views     │
                ▼         └──────────────────────────────────┘
┌──────────────────────────────────┐
│  94 included in compression       │
│  parameter analysis (376 views)   │
│      TC: 50 (200 views)           │
│      PAC: 44 (176 views)          │
└──────────────────────────────────┘
                │         ┌──────────────────────────────────────────┐
                │────────▶│  69 excluded                              │
                │         │     Glandular dose not comparable;        │
                │         │     Prior examinations not acquired on    │
                ▼         │     same mammography system               │
┌──────────────────────────────────┐ └──────────────────────────────────────────┘
│  25 Included in glandular dose    │
│  analysis (100 views)             │
│      TC: 11                       │
│      PAC: 14                      │
└──────────────────────────────────┘
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Figure 2. Flowchart of study population. Abbreviations: PAC, patient-assisted compression; TC, technologist compression.

compression for both CC and MLO views, something that was absent during conventional compression. The force standard deviation increased by 66% for CC views ($P < 0.0001$) and 44% for MLO views ($P < 0.0001$).

Between pressure and the contact area, regression lines indicate a negative linear relationship during conventional compression (Figure 5). During PBC, pressure was no longer dependent on contact area. There was a reduction in pressure variability of 50% for CC views ($P < 0.001$) and of 34% for MLO views ($P < 0.0001$).

On average, breast thickness decreased by 4.5 mm for the CC view (from 53.19 ± 12.23 mm to 48.72 ± 11.32 mm, $P < 0.0001$) and decreased by 5.8 mm for the MLO view (from 58.08 ± 15.01 mm to 52.29 ± 12.41 mm, $P < 0.0001$). The MLO thickness variance reduced ($P = 0.02$). The mean breast contact area for the CC view increased from 90.83 ± 41.07 cm^2 to 94.47 ± 41.43 cm^2 ($P < 0.0001$) and for the MLO view increased from 122.82 ± 39.00 cm^2 to 132.17 ± 42.37 cm^2 ($P < 0.0001$). The breast volume decreased for both the CC view (0.77 ± 0.40 dm^3 to 0.70 ± 0.34 dm^3, $P < 0.0001$) and the MLO view (0.93 ± 0.47 dm^3 to 0.88 ± 0.43 dm^3, $P < 0.001$). Breast density decreased in the CC view from $8.00 \pm 6.76\%$ to $7.47 \pm 6.11\%$ ($P = 0.01$) and remained similar in the MLO view ($7.81 \pm 6.39\%$ to $7.65 \pm 6.67\%$, $P = 0.4$). Table S1 provides the compression parameters for prior conventional compression and current PBC.

In the subanalysis of 100 paired views, recorded with the same mammography system and the same detector, the average glandular dose was similar for CC views (conventional compression: 1.57 ± 0.30 mGy, PBC: 1.60 ± 0.39 mGy [$P = 0.38$]),

while the mean breast thickness reduced by 3.74 mm (from 53.89 ± 9.93 mm to 50.15 ± 10.61 mm, $P < 0.0001$). For the MLO view, the average glandular dose reduced from 1.72 ± 0.43 mGy to 1.59 ± 0.35 mGy ($P < 0.0001$), with a mean thickness reduction of 6.7 mm (from 60.32 ± 14.13 mm to 53.62 ± 12.08 mm, $P < 0.0001$). See Table S2 for an overview of all compression parameters for both CC and MLO views.

When comparing mammographic PBC between technologist compression (n = 50 participants) and patient-assisted compression (n = 44 participants), mean compression parameters were similar in both groups except for the average glandular dose in the CC view where the mean dose was higher in the patient-assisted compression group (1.57 ± 0.36 mGy) compared with the technologist compression group (1.48 ± 0.21 mGy, p = 0.04). A complete overview of the compression parameters is given in Table S3.

Participant Experience

The participant questionnaire results are shown in Table 1. The compression was judged as being similar or more comfortable compared with previous examinations by 83 out of 103 women. From all women, 87% (90/103) would recommend PBC to friends. A total of 98% (49/50) of the women receiving patient-assisted compression would recommend this to friends. While using patient-assisted compression, the LEDs on the compression paddle were seen by the participant in the MLO view (98%, 49/50) as well as the CC view (92%, 46/50). All participants (50/50) were able to compress until the target range was achieved.
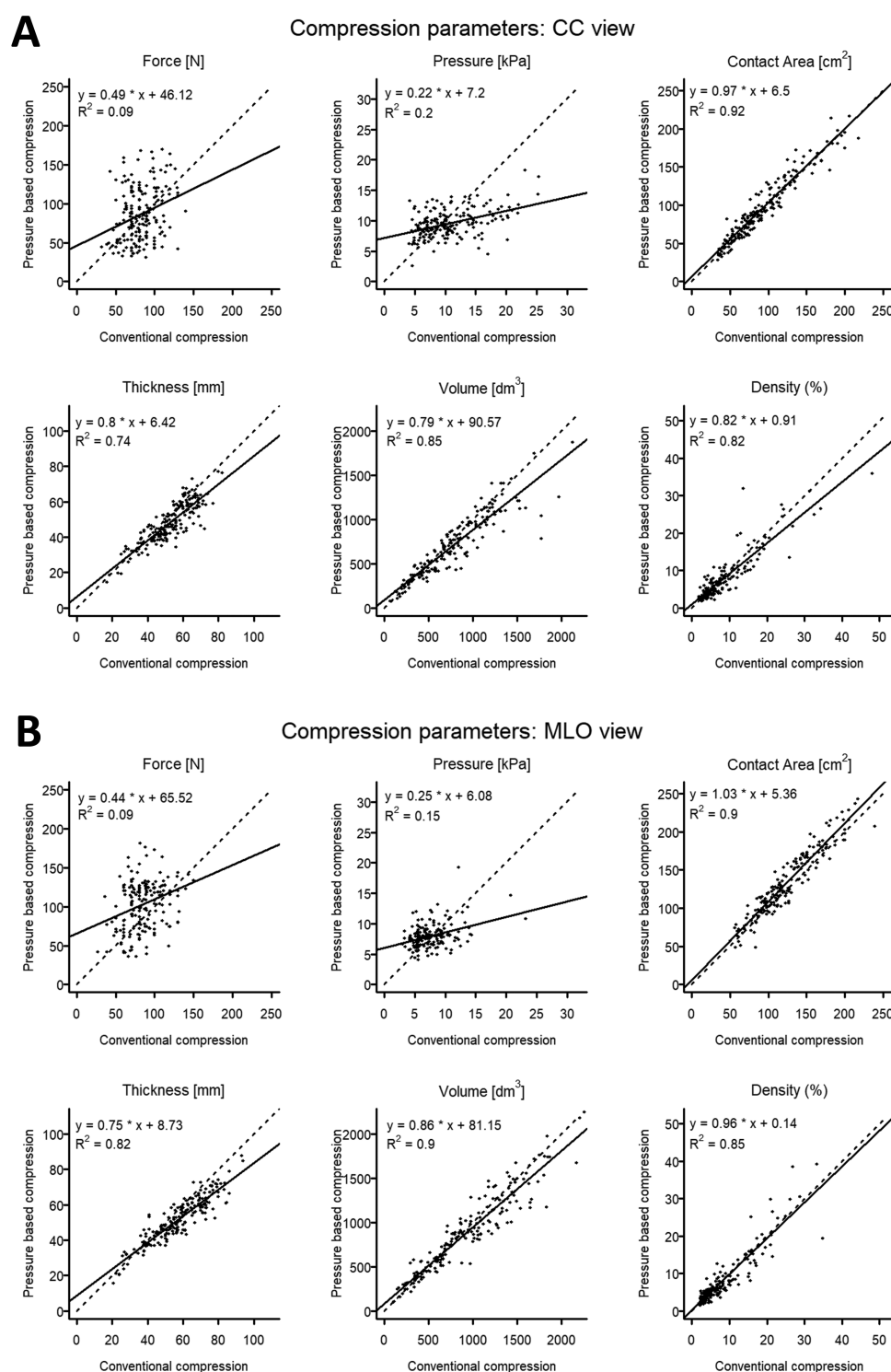
Figure 3. Compression parameter scatterplots for data obtained during pressure-based compression as a function of conventional compression for both CC (**A**) and MLO (**B**) views. Solid lines indicate the regression lines with the corresponding formula and R². Dashed lines indicate the line of identity.

Technologist Experience

As indicated in Table 2, technologists indicated that PBC eased explaining compression in all cases (103/103). In all except one case, PBC helped to involve the patient in the compression. In 98% (101/103) of the cases, technologists indicated that the compression time decreased. Radiologists indicated that for 2% (2/103) of the participants, they rejected an image because of blur or bad patient positioning.
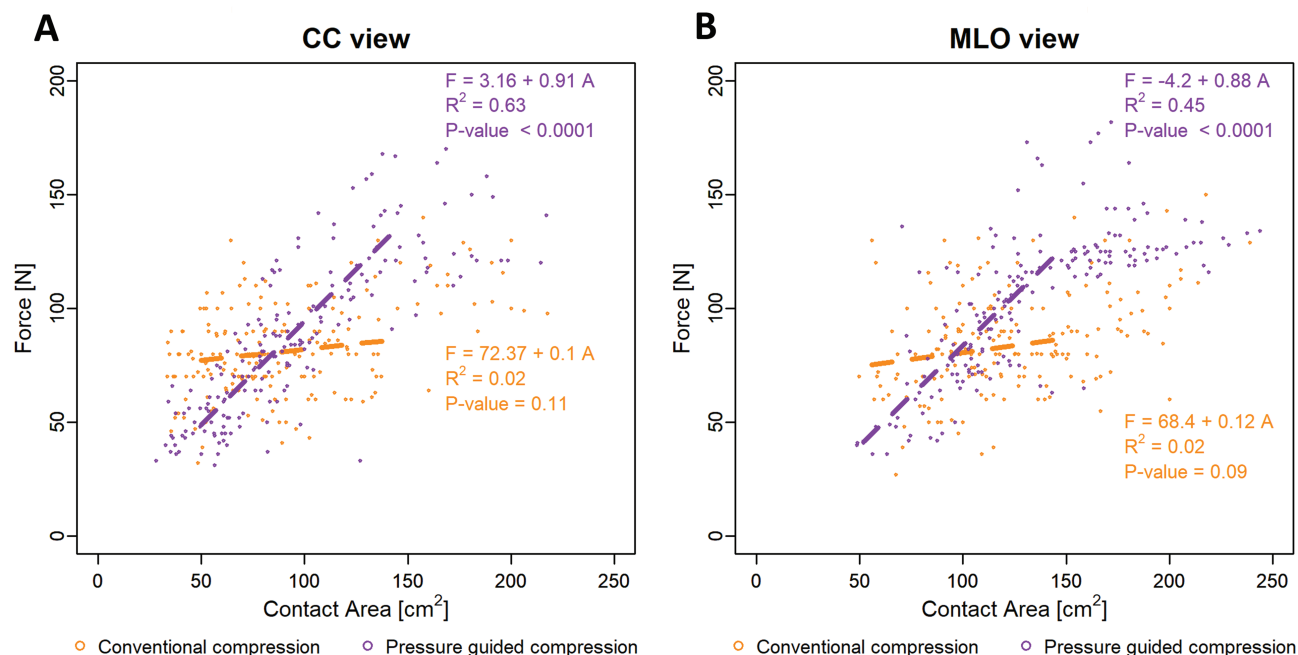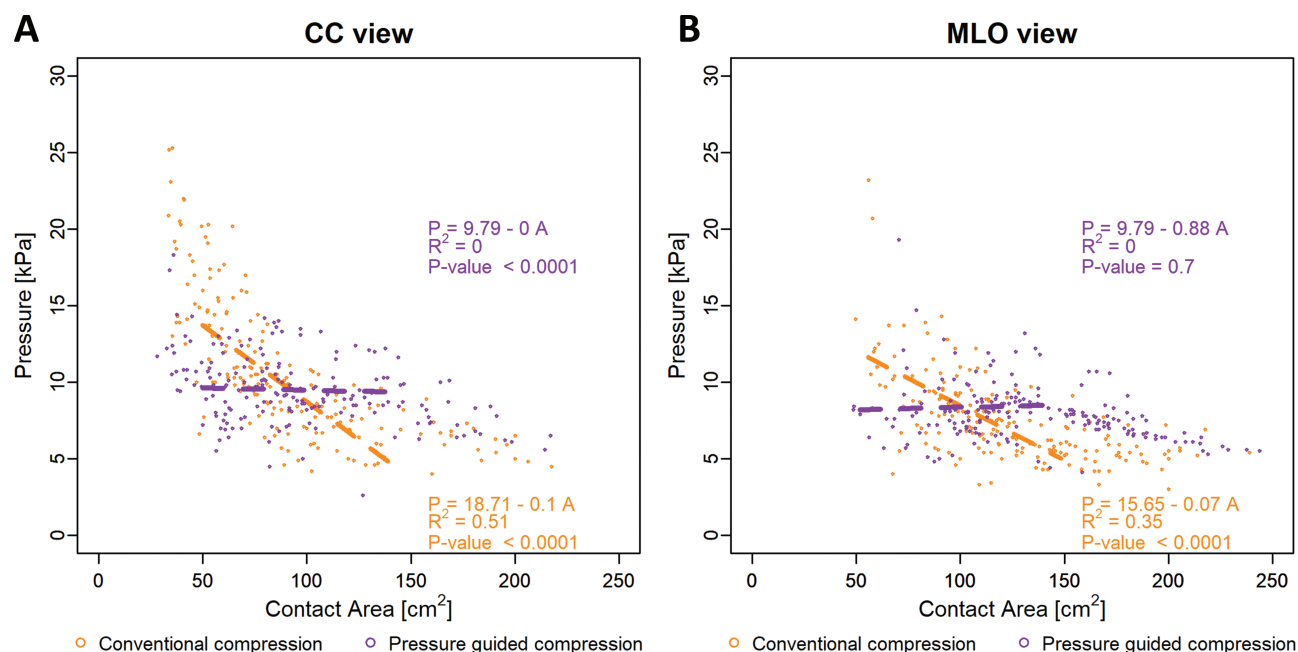
Figure 4. Compression force as a function of breast contact area for individual mammographic examinations during the conventional way of working (orange) and during pressure-based compression (purple) for CC (**A**) and MLO (**B**) views. Regression lines were added for both the conventional way of working (dashed orange lines) and pressure-based compression (purple dashed lines). For regression analysis, data with contact areas between 50 and 150 cm² (the range in which the paddle operates) were used.

Figure 5. Compression pressure as a function of breast contact area for individual mammographic examinations during the conventional way of working (orange) and during pressure-based compression (purple) for CC (**A**) and MLO (**B**) views. Regression lines were added for both the conventional way of working (dashed orange lines) and pressure-based compression (purple dashed lines). For regression analysis, data with contact areas between 50 and 150 cm² (the range in which the paddle operates) were used.

Discussion

In this study, we assessed the impact of introducing a pressure-based flexible paddle used in DBT. This paddle visualizes the mean pressure in real time during the progression of compression by the means of eight LED lights, with LED lights #5–7 indicating the target pressure range of 8–13.9 kPa (60–105 mmHg). This pressure range is similar to several physiological situations and conditions, such as normal diastolic blood pressure, the interface pressure between a chair and a sitting person (22), the safe pressure range for backpack strap pressure over the shoulder (23), and the average compression pressure as seen in conventional mammography (3).

We compared the compression parameters during the study examination with prior examinations of the same patients. For the MLO view, significantly higher forces were used with the pressure-based flexible paddle. This resulted in a slight increase in mean pressure. This can be explained by the fact that compression force becomes breast size-dependent when using PBC. Breasts with a smaller contact area (< 100 cm²) received, on average, a lower force compared to prior examinations; for larger breasts, the opposite was seen. In both CC and MLO views, mean breast thickness decreased by 3.74 mm and 6.70 mm, respectively, resulting in a significant reduction of radiation dose in the MLO view.

A strong increase of the force standard deviation and a corresponding decrease in the pressure standard deviation is inherent to PBC and contributes to the predictability and reproducibility of the procedure. In this study, a significant reduction in pressure variability of 50% for CC views and of 34% for MLO views was observed. This corresponds to previous studies using PBC in conventional 2D mammography (12,13,24), except for one study where the reported pressure was 2.5 times higher than intended (14), suggesting that the pressure protocol was not properly implemented. As it is the compression pressure that women feel, and not the amount of compression force, women's experience becomes more predictable when compression variability is reduced. Although screening reattendance depends on several factors, such as a previous false-positive screening results (25) and pain experience (8), the increased predictability of breast compression may contribute to a decrease in the negative perception of mammography and may improve continued breast cancer screening participation.

The breast volume decreased between prior examinations and the study examination. A possible cause may be that the model used to calculate breast volume deviates more from a real compressed breast when a higher compression force is used. The model, similar to the one described by de Groot et al (24), assumes that during compression the top contact area of the breast with the paddle is almost parallel to the contact area with the image receptor. As flexible paddles deflect more towards the nipple when a higher force is used, the volume from the pivot point towards the nipple may be underestimated and the volume towards the thorax may be overestimated. As the volume from the pivot point towards the thorax is much larger, there may be, on average, an underestimation of the total breast volume.

In a recent communication, the Food and Drug Administration (FDA) paid extensive attention to the role of breast compression in relationship to poor positioning and image quality (26). In 2015, the American College of Radiology (ACR) reported that poor positioning caused 92% of clinical imaging failures and 79% of all unit accreditation failures across ACR-accredited facilities. In 38% of poor images, inadequate compression played a role (27). Pressure-based compression, through a reduction in variability, has the potential to reduce the number of examinations with inadequate compression, and consequently provides more consistent image quality. Due to the importance of the patient experience, the FDA listed a number of innovations "to improve the overall comfort of mammography while maintaining image quality" (26). All these innovations have merits but lack clear guidelines on optimal compression, which ultimately lends to a compromise between patient experience and optimal mammography performance. The visual compression level feedback for technologists and patients appeared to be highly appreciated, and we showed that this improved the communication, interaction, and ultimately the overall patient experience.

The patient experience is related to more factors than pressure levels alone. Without being exhaustive, examples of these factors are the design of the mammographic machine itself, poor detector positioning resulting in unnecessary skin stretching (28), too high a position of the detector in the axilla in MLO views (causing intercostal pain and unwanted compression of the pectoral muscle), and suboptimal interaction between patients and technologists. With proper and repeated training of the technologist on breast positioning and communication, and with the help of the pressure-based paddle, the above-mentioned points may improve. This may be the reason that the technologists responded positively to the pressure-based paddle.

To improve patient experience, studies have shown that compression may be reduced in DBT because of the reduced issue of tissue superposition compared with conventional 2D mammography (29,30). In addition, studies suggest that excessive compression forces and pressures were associated with decreased screening performance (31,32). As shown in this study, when using PBC, the level of compression force becomes breast size and stiffness dependent, and a reduction of compression force is especially seen for small to medium breast contact areas.

The first types of pressure-based paddles were mainly evaluated in Europe, and they were of the rigid type (10,12–14). There are not many studies comparing rigid and flexible paddles (12,15). Broeders et al concluded that despite the slightly improved performance of the flexible paddle in the projected area, breast tissue was moved from the image area at the chest wall (15). But one should be aware that

the conventional compression practice described by Broeders et al, with a mean force of 128 N, reflects the compression practice of some specific countries in Europe and are, on average, much higher than the compression practice in the United States (3,4). Besides, differences in body weight, body mass index, breast size, and health status may differ between patient populations in different countries, so the results cannot be compared directly.

The study from Moshina et al comparing conventional rigid, conventional flexible, and a pressure-based rigid paddle showed significantly different pain scores between the conventional rigid and pressure-based rigid paddle, but no difference when comparing the conventional flexible paddle with the pressure-based rigid paddle (12). Our study suggests that a pressure-based flexible paddle could be the best of both worlds. Future studies may compare image quality and breast positioning when using a flexible or rigid pressure-based paddle.

We also studied the pressure-based flexible paddle when guided by the technologist solely and in combination with patient-assisted compression. In prior studies using self-compression, significantly higher forces were given in patient-assisted compression compared to technologist compression (17,18). In the current study, the compression parameters between technologist and patient-assisted compression did not differ significantly. This is probably related to the use of the LED light indicators that helped participants obtain a pressure range of 8–14 kPa, regardless of breast size.

Participants and technologists reacted very positively to the pressure-based flexible paddle with technologist compression as well as with patient-assisted compression. The vast majority of participants would look for a facility with the pressure-based flexible paddle and remote control combination. All technologists agreed that the explanation of the mammographic procedure was easier and helped to engage patients, which positively influenced stress levels and compression time.

There are some limitations to this study. This is a preliminary study with a small sample size, especially when comparing technologist and patient-assisted compression examinations. Besides this, the comparison between technologist and patient-assisted compression was a between-group comparison, which impacts comparability. In a future study, we suggest the inclusion of a within-person comparison to assess the possible differences between these compression methods in more detail. Due to various reasons we had to exclude a number of examinations, which resulted in group size differences. In addition, participant questionnaire results may be influenced (1) by the time between the current and prior examination, as the questionnaire was only used during the pressure-based flexible paddle examination, and (2) by the fact that the current and prior examination may be performed by different technologists. This study had a within-subjects study design and there was no control group included where both the prior examination and study examination was acquired using conventional compression. As a result, we cannot rule out the possibility that factors other than the explanation and subsequent use of a different compression paddle may have influenced the participant's satisfaction. This study focused on compression parameter comparison and patient and technologist satisfaction. A comprehensive analysis of image quality and breast positioning according to the Mammography Quality Standards Act was not part of this study and may have shown differences between groups. However, there was no indication of image quality deterioration, as the number of reported retakes (2%) was very low. These limitations should be taken into account in a future multicenter study. The pressure-based paddle may represent an additional cost compared to conventional compression paddles.

Conclusion

In conclusion, using the pressure-based flexible paddle in DBT improved participants' and technologists' experience and at the same time significantly reduced compression pressure variability, mean breast thickness, and glandular dose. Using pressure-based, patient-assisted compression showed a similar positive effect on compression parameters when compared with pressure-based standard technologist-assisted compression. The use of the pressure-based flexible paddle in combination with patient-assisted compression has the potential to decrease the negative perception of mammography due to breast compression and improve continued participation in breast cancer screening.

Supplementary Material

Supplementary material is available at the *Journal of Breast Imaging* online.

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Conflict of Interest Statement

M. van Lier is an employee and shareholder of Sigmascreening; J. de Groot is an employee of Sigmascreening; S. Muller is an employee of GE Healthcare; G. den Heeten is founder, scientific advisor, shareholder, and patent holder of Sigmascreening and is a medical advisor of and has stock options in Volpara Health Technologies Limited; and K. Schilling is a medical consultant and investigator for GE Healthcare.

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