



Research article

Breast compression and experienced pain during mammography by use of three different compression paddles



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ABSTRACT

Objectives: We aimed to compare pain experienced during screening mammography, using three different compression paddles: a fixed paddle standardizing pressure (study paddle), a flexible, and a fixed paddle.

Material and methods: Using a numeric rating scale (NRS), ranged 0–10, we collected information on pain experienced during mammography from a questionnaire completed by 4,675 women screened in Stavanger, May–November 2017, as a part of BreastScreen Norway. The questionnaire also provided information on factors possibly associated with pain. Data on compression force, pressure and breast characteristics were extracted from the DICOM-header, and a breast density software. T-tests were used to compare mean values of the parameters between the types of compression paddles. Linear regression was used to determine the association of a score of ≥ 7 versus < 7 on NRS for experienced pain by compression paddle, adjusting for pressure, breast characteristics and associated factors.

Results: The mean of experienced pain did not differ for the study and flexible paddle (2.5 on NRS), and was lower for the study paddle compared to the fixed paddle (2.4 versus 2.6 on NRS, $p < 0.05$). Pain in shoulder(s) and/or neck prior to mammography was associated with 33% (RR 1.33, 95%CI 1.07–1.65) higher risk of a score of ≥ 7 versus < 7 for experienced pain.

Conclusion: The majority of women reported low scores of experienced pain during mammography, independent of compression paddle used. Further research on image quality is needed to fully understand which paddles should be preferred in a screening setting.

1. Introduction

During mammography, the breast is compressed between a compression paddle and a breast table to achieve high image quality and reduce radiation dose [1]. “Optimal” compression values are usually provided by mammography vendors, but these lack evidence related to image quality and women’s experience of discomfort and pain [2].

It is well known that some women experience discomfort and pain as a result of breast compression, both during and after mammography [3–5]. Because of this, some women do not want to undergo mammography or decide not to attend screening [3–6]. A systematic review has shown that 25–46% of the women who did not attend their next screening appointment due to pain related to breast compression [6].

Most studies on breast compression and experienced pain during mammography are based on screen-film mammography [3,4,7]. Digital mammography (DM) systems that are now used in most European countries, including Norway, are often equipped with different types of compression paddles, including fixed and flexible. Flexible compression paddles allow for various tilting angles and were introduced to decrease pain for women. However, no evidence exists to support this claim and the effect of these paddles on image quality has been questioned [8,9].

The majority of studies on pain during mammography consider compression in a general sense, without quantitative measurement [3–5,7,10]. Compression force, (newton, N) is one way to measure breast compression. Such data is easy to collect as it is visible to radiographers at the time of imaging and stored in the DICOM-header,

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however, there can be substantial variation in applied compression force between breast centers and between radiographers [11,12]. Compression pressure (kilopascal, kPa) at the time of imaging is currently considered a better metric related to experienced pain, than force [13–15]. Pressure can be estimated retrospectively by different types of software but is normally not visible for radiographers at the time of imaging, making it difficult to conduct prospective studies. However, recent developments in fixed paddle technology can help radiographers standardize compression pressure to 10 kPa in real time [15]. The variation of compression forces with the standardized compression pressure is dependent on the contact breast area, where higher forces correspond to larger compressed breast areas [15]. Studies have shown promising results, but there are still substantial knowledge gaps to fill before the overall effect of using pressure instead of force based compression in mammography can be estimated [14,15].

A previous study from Norway and studies from other countries showed that experience of pain and dissatisfaction with screening mammography was associated with breast compression [5,16]. We hypothesized that the real time pressure standardization will result in a less painful experience for the women. Therefore, a paddle, with means to indicate an optimal pressure of 10 kPa, was installed for clinical evaluation on one of two similar mammography systems in a screening unit in Stavanger, as a part of BreastScreen Norway. Using this paddle, hereafter referred as the study paddle, an ordinary flexible paddle (flexible paddle) or an ordinary fixed paddle (fixed paddle), we wanted to investigate experienced pain among women who underwent screening mammography.

2. Material and methods

This study was permitted under the Cancer Registry Regulations [17] and approved by the Data Protection Official at Oslo University Hospital (2017/6481).

2.1. BreastScreen BLINDED

The Cancer Registry of Norway administers the population-based breast cancer screening program, BreastScreen Norway, that serves about 600,000 women aged 50–69 years. These women are offered biennial mammographic screening that typically includes four DM images with craniocaudal (CC) and mediolateral oblique (MLO) views of each breast. The annual participation rate is about 75%. The program has been described in detail elsewhere [18].

2.2. Study groups – compression paddles

Women, who attended the screening unit in Stavanger, during the study period, May - November 2017 were directed to one of two screening rooms based on the principle “first come, first served”, according to the standard procedure [19]. Both rooms were equipped with GE Senographe Essential (GE Medical Systems, France).

Between May-June 2017, one screening room was equipped with the study paddle, while the other room was equipped with an ordinary flexible paddle. In the second part of the study, August-November 2017, the same study paddle was used in the same room, while an ordinary fixed paddle replaced the flexible paddle. All three paddles were available in sizes: 24×31 cm and 19×23 cm. The study paddle, a rigid Sensitive Sigma™ Paddle (Sigmascreeing, Amsterdam, the Netherlands), additionally included integrated force sensors, x-ray transparent foil with a conducting layer and controller with light-emitting diode pressure indicators to ensure that the pressure applied to each breast was measured individually [15,20]. The radiographers working with the study paddle were trained to use the light pressure indicator of the paddle to perform compression according to the level of compression pressure. While using the flexible and fixed paddles, the radiographers were recommended to apply compression force based on

the breast size and the recommendations from the Quality Assurance Manual (80–180 N) [19]. The compression paddles were used and further compared in pairs in two different periods: the study paddle versus flexible paddle between May-June and the study paddle versus the fixed paddle between August-November. For greater clarity, we refer to the study paddle as “study paddle 1” between May-June and as “study paddle 2” between August-November. No screening was performed during July.

During the study period, all attending women, except for women with breast implants, were invited to participate in this study at the standard prescreening interview, performed by the radiographers. These women received a questionnaire, which included a study identifier (running number) and questions about expected and experienced pain related to their screening examination. Women were not informed which paddle was used for their screening examination, however this information was available to the radiographers. In order to understand if this information had an effect on the radiographers’ imaging technique and if there was a general learning effect on the conventional compression practice during the study period we extracted data from the DICOM header and from Volpara (Volpara, version 1.5.1; Volpara Health Technologies, Wellington, New Zealand) [21] to estimate mean compression force and pressure used during at different time points of screening in Stavanger. We used data from four points: 6–10, 10–14, 24–18 and 50–54 weeks prior to the study period. Only the flexible paddle was used during this pre-study period.

2.3. The questionnaire

A continuous numeric rating scale (NRS) [22] was used for measuring expected and experienced pain. The women marked their response on a line, ranging from 0 to 10, indicated by 11 marks. A score of 0 indicated no pain while 10 indicated very strong pain. The women further reported information about presence of pain in shoulder(s) and/or neck prior to screening as well as weight and height, which were used to calculate their BMI as weight (kg) divided by squared height (m^2). The self-reported weight and height in Norway was shown to be consistent and reliable according to a recent study [23]. The questionnaire was completed immediately after the screening examination and submitted in a closed letter case at the screening unit. Responding to the questionnaire was considered an informed consent to using the data in this study.

2.4. Variables of interest

Response to the questionnaire was manually recorded at the Cancer Registry and linked to the characteristics of the women and compression parameters using a running number. Experienced pain was reported for the examination, not for each exposure/compression. Information about the women’s age was obtained from the Cancer Registry, while the information on compression force (N) and mean glandular dose (mGy) was obtained from the DICOM header. Data about compression pressure and breast characteristics, including contact breast area (mm^2), breast volume (cm^3), fibroglandular volume (cm^3), and volumetric breast density (%) were extracted using a fully automated software [21]. We present average values for each screening examination (four images), which was considered the unit of analysis.

2.5. Statistical analyses

Descriptive statistics were calculated using means with 95% confidence intervals (95%CI) and standard deviation (SD) both to describe the women’s characteristics and study parameters of interest. The reported pain was right-skewed, and the median values were also presented for the compression paddles. We used t-tests to compare mean values of the parameters between the types of compression paddles. We compared pain scores by compression paddles.

We used a cut point of 7 (< 7 versus ≥ 7) to categorize the experience: a score of < 7 corresponded to mild to moderate pain (low score), while a score of ≥ 7 included severe pain (high score) (22). This cut point was chosen to identify women who reported severe pain as the values ≥ 7 were considered a strong negative experience of mammography, perceived as a procedure causing significant and/or unbearable pain. The choice of the cut point was based on the previous study investigating pain due to breast compression in mammography [16]. Generalized linear regression models were used to determine the relative risk (RR) of a high pain score associated with the type of compression paddles [24]. Other covariates in the model included shoulder (s) and/or neck pain prior to screening examination (present versus absent), compression pressure [tertiles: low (4.3–9.9 kPa), medium (10.0–11.8 kPa) and high (11.9–32.6 kPa)], breast volume [tertiles: low (51.2–610.4 cm³), medium (610.5–984.5 cm³) and high (984.5–3076.5 cm³)], fibroglandular volume [tertiles: low (6.3–35.1 cm³), medium (35.2–52.4 cm³) and high (52.5–314.6 cm³)], age (50–54; 55–59; 60–64; 65–69 years) and BMI (low: < 18 kg/m², medium: 18–24 kg/m² and high: ≥ 25 kg/m²). Results from regression analyses, including continuous variables of compression pressure, breast volume, fibroglandular volume, age and BMI are shown in the appendix (Table A1). Box plots of observed pain by applied compression pressure (six groups: < 7.0 ; 7.0–8.9; 9.0–10.9; 11.0–12.9; 13.0–14.9; ≥ 15.0 kPa) was shown for study paddle 1, flexible, study paddle 2 and fixed compression paddles.

All analyses were conducted using STATA® 15.0 (StataCorp, Texas, USA).

3. Results

Among the 8,488 women attending the screening unit in Stavanger during the study period, 5,503 (65%) agreed to participate in this study. After exclusion, due to the unavailability of one or more parameters, data from 4,675 women were included (Fig. 1).

Mean age, BMI and volumetric breast density did not differ between the women in the four study groups, while mean contact breast area and mean fibroglandular volume were statistically significantly lower among women screened with the study paddle 1 versus the flexible paddle, as well as among women screened with the study paddle 2 versus the fixed paddle (Table 1). Mean glandular dose was significantly higher for the study paddles (1.42 mGy) compared to the flexible (1.37 mGy, $p < 0.001$) and fixed (1.33 mGy, $p < 0.001$) paddles.

Mean pain score did not differ statistically significantly for the study paddle 1 and the flexible paddle 2.5 (SD = 2.4) versus 2.5 (SD = 2.4) ($p = 0.83$) (Table 2). Median values were 2.0 vs 2.0. Mean pain score for the study paddle 2 versus the fixed paddle was 2.6 (SD = 2.5) versus 2.4 (SD = 2.4) ($p = 0.04$). Median values were 1.5 versus 2.0. For the study paddle, mean pressure was significantly lower compared to the fixed or flexible paddles ($p < 0.001$ for all). Means of compression force and pressure were statistically significantly lower for the study paddle 1 versus the flexible paddle and for the study paddle 2 versus the fixed paddle. NRS ranged from 0 to 10 for all paddles (Fig. 2). Relative risk of mild to moderate (< 7 on a NRS) versus severe (≥ 7 on a NRS) pain did not differ by the type of compression paddle (Tables 3 and A1). Shoulder(s) and/or neck pain prior to screening was associated with a 33% (95%CI 1.07–1.65) higher RR of severe pain compared to no pain prior to screening in adjusted analyses. Low breast volume was associated with a 26% (95%CI 0.56–0.98) lower RR of severe pain compared to medium breast volume in adjusted analyses.

For the study paddle 1, the highest median pain scores were shown for compression pressure of 7.0–12.9 kPa, while the highest median pain scores for the study paddle 2 were for compression pressure of 9.0–10.9 kPa (Fig. 3). Both the flexible and the fixed paddle showed increasing median pain scores with increasing pressure.

Compression force was significantly higher prior to the study period

compared to the force during the study, regardless of compression paddle used ($p < 0.001$). Compression pressure was significantly higher prior to the study period compared to the pressure during the study for the study paddle 1, flexible paddle and study paddle 2 ($p < 0.001$) (Table 4).

4. Discussion

Mean scores of experienced pain during screening mammography, given on an 11-point numeric rating scale, were low, varying from 2.4 to 2.6, for three different compression paddles. Mean experienced score did not differ statistically for women screened with the paddle designed to optimize breast compression pressure to 10 kPa and a flexible paddle but was higher for a fixed paddle. Shoulder(s) and/or neck pain versus no pain prior to screening was associated with a higher risk of severe pain related to the examination, while women with low breast volume – small breasts – had a lower risk of severe pain, compared to those with a medium breast volume – medium size breasts.

Despite higher compression force and pressure given to women screened with the flexible compared to the study paddle, no differences in reported pain were observed in the crude analyses. This was as expected as both paddles have been developed to reduce pain during breast compression by distributing the applied force differentially over the anatomical features of the breast [8,9,20]. Researchers from Malmö reported that compression force was mainly applied to the juxtathoracic structures in 42% of the imaged breasts [25]. Such compression might lead to pain. There is lack of knowledge about the distribution of the pressure during compression that needs to be addressed to understand if pressure distribution may affect women's experiences of pain, as well as image quality. The higher pain scores for the fixed versus the study paddle was an expected finding as both compression force and pressure were significantly higher for the fixed paddle.

Women screened with the flexible paddle had a larger contact breast area compared with those screened with the study and fixed paddles. Due to the flexibility of the paddle, the contact area of the breast was larger and the force was therefore distributed over a larger area. This might be of influence for the lower pressure and reported pain. Notably, we observed a higher contact breast area for both CC and MLO mammograms performed using the flexible paddle compared to the other paddles. Contrary, breast volume was highest for women screened with the fixed paddle. An optimal image includes the whole breast contour with all the breast tissue. However, this might be difficult to obtain due to individual variation among the women screened. A mammogram could also include a larger amount of the pectoral muscle [9,25], which could result in a large breast volume, but pushing a part of the breast tissue out the field of view and creating a blurred image. A study from the Netherlands concluded that flexible paddles were more likely to cut breast tissue close to the chest wall, and currently all screening units are required to use fixed paddles [8].

Despite the mean fibroglandular volume was lower for the study paddle compared to the flexible paddle, there were no difference volumetric breast density. This might be due to the fact that the fully automated software used a correction for the MLO-view to perform density estimations and, therefore, the difference in volumetric breast density between the paddles was minimal.

The radiographers individual preferences, lack of precise and evidence based guidelines and the volume of the breast could be the reason to increase or decrease the pressure from the point of 10 kPa in the study paddle. As far as we are aware, women with a very high breast volume need high forces and this could result in higher pressure. On the other side, compressions with a pressure lower than 10 kPa could be a result of women's experience of pain or discomfort, which made radiographers either to stop compressing or to lower the force and therefore pressure applied. Different pressure values for the highest pain score for the study paddle could be associated with the radiographer variability.

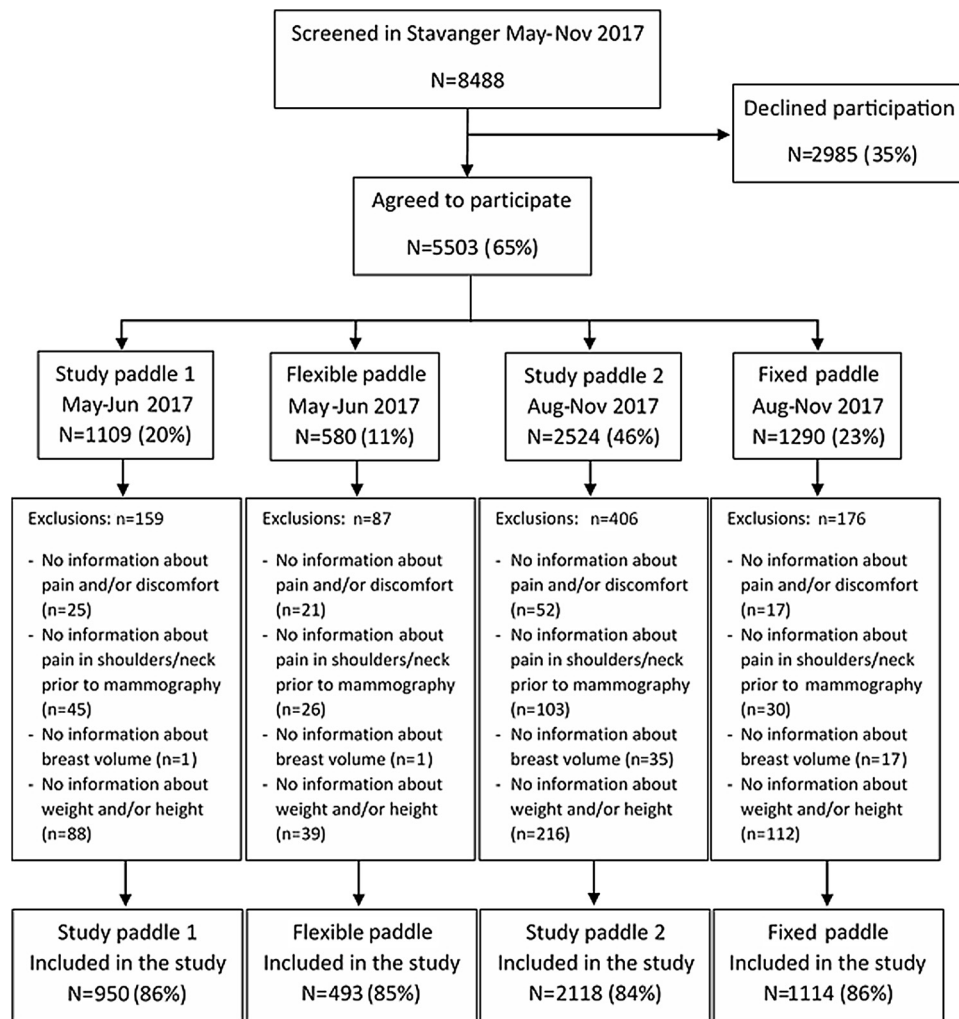


Fig. 1. Sample before and after exclusions in the study investigating pain experienced during mammographic screening using three different compression paddles (study, fixed and flexible) in BreastScreen Norway, May - November 2017.

Mean glandular dose was significantly higher for the study paddle compared to the flexible and fixed paddles. This might suggest that the optimization of pressure was associated with a higher dose needed to achieve a good quality image while adjusting the parameters of the automated exposure control. The higher mean glandular dose for the study paddle might be a result of the low compression force. Increasing the compression force and by that the compression pressure could be a means of lowering the dose.

Generalized linear model did not show any difference between mild to moderate versus severe pain for any of the compression paddles. Pain in shoulder(s) and/or neck prior to screening was associated with higher levels of pain during mammography and was an important confounder in this study. The results might indicate that such information should be available for the radiographers before the examination in order to personalize and/or lower the level of applied compression force. Using a compression paddle indicating the degree of

Table 1

Mean age, body mass index, breast volume, volumetric breast density, fibroglandular volume, contact area, mean glandular dose, by compression paddle among 4,675 women screened in BreastScreen Norway, May - November 2017.

	Study paddle 1 (n = 950)		Flexible paddle (n = 493)		Study paddle 2 (n = 2118)		Fixed paddle (n = 1114)	
	Mean	95% CI	Mean	95% CI	Mean	95% CI	Mean	95% CI
Age (years)	59.6	59.2-59.9	59.6	59.1-60.0	59.2	58.9-59.4	59.2	58.8-59.5
Body mass index (kg/m ²)	26.0	25.7-26.3	26.3	25.8-26.8	26.3	26.1-26.5	26.1	25.8-26.4
Contact area (mm ²)	11346	11072-11620	12514 ^a	12069-12959	11586 ^b	11392-11780	11045 ^{b,c}	10792-11299
Volumetric breast density (%)	7.0	6.7-7.3	7.1	6.8-7.5	7.1	6.9-7.3	7.1	6.8-7.3
Breast volume (cm ³)	827	800-854	821	784-858	857	838-877	881 ^{a,b}	854-907
Fibroglandular volume (cm ³)	46.3	44.8-47.8	50.8 ^a	48.5-53.1	48.4 ^a	47.3-49.5	50.6 ^{a,c}	49.0-52.2
Mean glandular dose (mGy)	1.42	1.41-1.43	1.37 ^a	1.34-1.40	1.42 ^b	1.41-1.43	1.33 ^{a,b,c}	1.32-1.34

^a Statistically significantly different from study paddle 1 (p < 0.05).

^b Statistically significantly different from flexible paddle (p < 0.05).

^c Statistically significantly different from study paddle 2 (p < 0.05).

Table 2

Mean values of pain reported on a numeric rating scale (NRS) ranging from 0 to 10, compression force and pressure by compression paddle among 4,675 women screened in BreastScreen Norway, May - November 2017.

	Study paddle 1 (n = 950)		Flexible paddle (n = 493)		Study paddle 2 (n = 2118)		Fixed paddle (n = 1114)	
	Mean (SD)	95% CI	Mean (SD)	95% CI	Mean (SD)	95% CI	Mean (SD)	95% CI
Pain (NRS)	2.5 (2.4)	2.3–2.7	2.5 (2.4)	2.3–2.7	2.4 (2.4)	2.3–2.5	2.6 ^c (2.5)	2.4–2.7
Compression force (N)	110 (27)	108–112	116 ^a (16)	115–118	115 ^a (25)	113–116	118 ^{a,c} (14)	117–118
Compression pressure (kPa)	10.3 (1.6)	10.2–10.4	11.3 ^a (4.4)	10.9–11.7	10.8 ^{a,b} (2.1)	10.7–10.9	12.8 ^{a,b,c} (4.6)	12.6–13.1

^a Statistically significantly different from study paddle 1 ($p < 0.05$).

^b Statistically significantly different from flexible paddle ($p < 0.05$).

^c Statistically significantly different from study paddle 2 ($p < 0.05$).

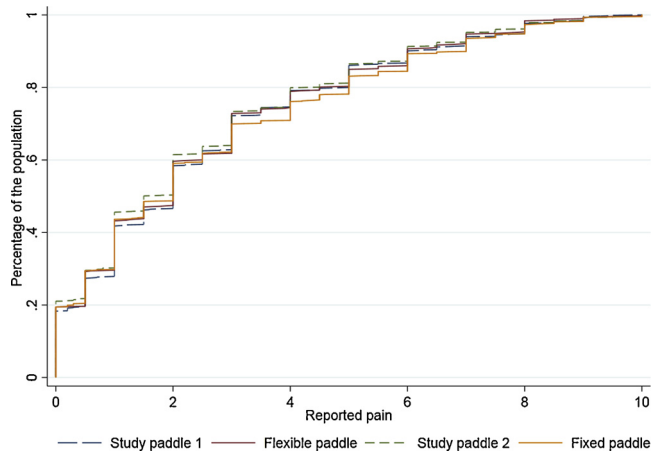


Fig. 2. Percentage of the study population by observed pain scores (on numeric rating scale) for the study paddle 1, flexible paddle, study paddle 2 and fixed paddle among 4,675 women screened in BreastScreen BLINDED, May - November 2017.

pressure monitored by the women during mammography can facilitate the communication between radiographers and women, and help women easier accept the applied force and/or pressure.

We observed a lower relative risk of severe pain among women with small (51.2–610.4 cm³) versus medium (610.5–984.5 cm³) breast volume. Use of higher compression force among those with medium breasts might be an explanation. Another explanation might be the reduction of compression force by request among those with small breasts, as the pressure increases faster by increased force, compared to women with large breasts.

Our results support findings from Broeders et al. (2013) and Dustler et al (2017) regarding no difference in experience of pain for fixed versus flexible paddles [8,9]. The results are difficult to compare with the conclusions of the studies by de Groot et al. (2015) and Branderhorst et al. (2014), indicating that standardization of compression pressure could lead to reduction of unnecessary pain [13,14]. Further, a previous study from Norway showed that a compression force of 130 N or higher and a pressure of less than 9.8 kPa were associated with more favorable results of performance indicators in the screening program [26]. The values could be considered an indirect measure of sufficient or even optimal image quality. Our results on mean compression force applied using the study paddle suggest that this paddle might be associated with reduced image quality.

4.1. Strengths and limitations

This study included information from 4,675 women screened in a population-based screening program. We used three types of compression paddles on two mammography units of a single type. The study included multiple well-known (compression force, age, BMI,

compression pressure, etc.) and less known (shoulder(s) and/or neck pain prior to screening) factors to investigate women's experience of discomfort and pain during mammography. However, factors as breast tenderness, menstrual status, education level, presence or absence of benign or malignant lesions, and anxiety level [27], were not considered, which represents a study limitation. The values of compression pressure were obtained from the fully automated software and might differ from the values the radiographers observed during compression. However, a previous study using the same type of the study paddle indicated that information on compression pressure could successfully be obtained from a similar software for quality assurance or evaluation [28]. It is also possible that one mammographic view was more uncomfortable or painful for the women. We were unable to investigate this because the questionnaire did not specify the experience of pain for each of the four images, but rather considered the examination as one event.

The substantially higher compression force and pressure used in the pre-study period indicates a study effect – the radiographers adapted the compression force needed to obtain 10 kPa also in the room without a pressure indicator. The pain scores for the flexible and fixed paddles might have been lowered due to lower compression forces used by the radiographers during the study. Further, the radiographers were better trained with the study setting in part 2, which might have influenced their skills and communication with the women. The numbers of women included in the groups of study paddle 1 and 2 were higher than the numbers of women in the flexible and fixed paddle groups, respectively. This might occur because the examinations were generally performed faster using the study paddle compared to the flexible and the fixed paddles. In addition, the radiographers, performing the examinations with the study paddle might be more experienced, which reduced the amount of time used for one examination.

The study did not provide data on image quality. We communicated with the radiologists regarding image quality during the study period and did not receive any comments indicating poor quality. However, this communication and opinions were not collected systematically.

5. Conclusions

The majority of women reported low scores of pain during mammography screening regardless of compression paddle used. Reported pain score did not differ between women screened with a compression paddle designed to optimize breast compression to 10 kPa pressure and a flexible paddle, while higher scores were reported for a fixed paddle. Optimized compression pressure was associated with a higher mean glandular dose compared to the dose for a flexible or a fixed paddle. Image quality including projected breast area and motion blur associated with applied compression force and pressure should be investigated in future studies aimed to compare breast compression paddles.

Table 3

Relative risk of mild to moderate (< 7 on a NRS) versus severe (≥ 7 on a NRS) pain associated with the type of compression paddle and associated factors among 4,675 women screened in BreastScreen Norway, May - November 2017.

Paddle type	Pain < 7 versus ≥ 7					
	Relative risk					
	Crude	95 % CI	p-value	Adjusted ^a	95 % CI	p-value
Study 1	1.00			1.00		
Flexible	0.94	(0.66-1.35)	0.74	0.90	(0.62-1.30)	0.57
Study 2	0.87	(0.68-1.13)	0.30	0.89	(0.69-1.15)	0.38
Fixed	1.17	(0.90-1.54)	0.25	1.14	(0.85-1.53)	0.38
Shoulder/neck pain prior to screening	1.35	(1.09-1.66)	0.005	1.33	(1.07-1.65)	0.009
Compression pressure						
Low (4.3-9.9 kPa)				1.07	(0.82-1.40)	0.60
Medium (10.0-11.8 kPa)				Ref	–	–
High (11.9-32.6 kPa)				1.09	(0.83-1.44)	0.52
Age						
50-54 years				Ref	–	–
55-59 years				1.32	(1.01-1.71)	0.039
60-64 years				1.05	(0.81-1.37)	0.71
65-69 years				0.96	(0.72-1.29)	0.80
Breast volume						
Low (51.2-610.4 cm ³)				0.74	(0.56-0.98)	0.001
Medium (610.5-984.5 cm ³)				Ref	–	–
High (984.5-3076.5 cm ³)				0.96	(0.56-1.20)	0.53
Fibroglandular volume						
Low (6.3-35.1 cm ³)				1.01	(0.90-1.13)	0.90
Medium (35.2-52.4 cm ³)				Ref	–	–
High (52.5-314.6 cm ³)				0.91	(0.81-1.01)	0.09
Body mass index						
Low (< 18 kg/m ²)				1.05	(0.92-1.19)	0.50
Medium (18-24 kg/m ²)				Ref	–	–
High (≥ 25 kg/m ²)				1.01	(0.89-1.14)	0.90

^a Adjusted for the paddle type, shoulder/neck pain prior to screening (yes/no) compression pressure (low, medium and high), age (50–54, 55–59, 60–64 and 65–69 years), breast volume (low, medium and high), fibroglandular volume (low, medium and high) and body mass index (low, medium and high).

Conflict of interests

The authors declare no conflict of interests.

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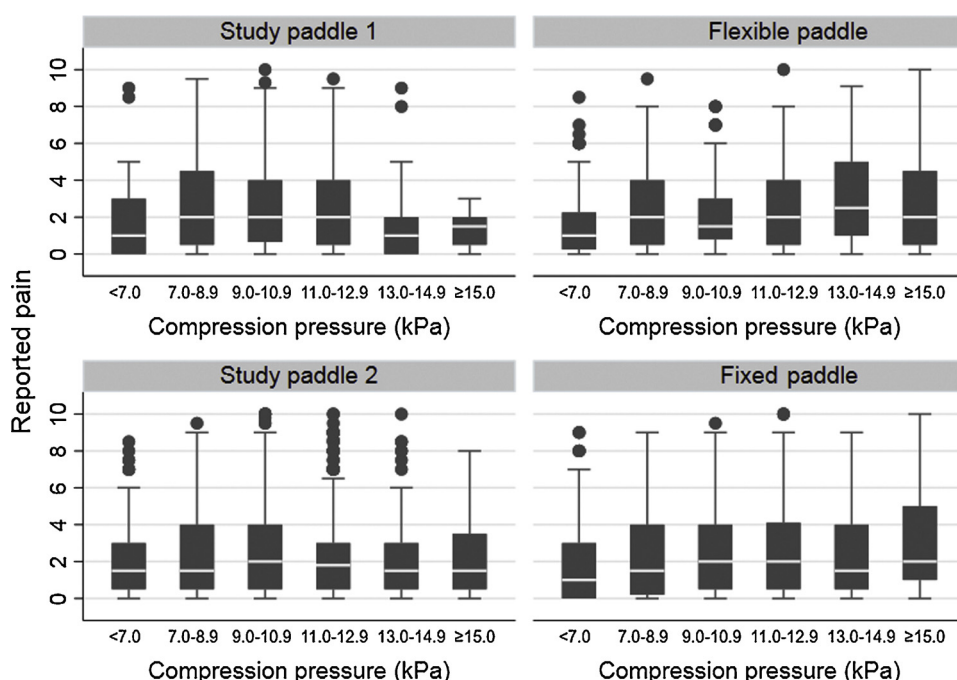


Fig. 3. Box plots of observed pain scores (on numeric rating scale) by applied compression pressure for the study paddle 1, flexible paddle, study paddle 2 and fixed among 4,675 women screened in BreastScreen Norway, May - November 2017. Each box contains 50% of the data (from the 25th to 75th percentile), and the horizontal white line represents the median value. The whiskers of the boxes represent the range of values of the remaining 25% in each direction. Extreme values are indicated with a grey circle.

Table 4

Compression force and pressure at four time points during a pre-study period and during the study among women screened in BreastScreen Norway.

	Compression force (N)		Compression pressure (kPa)	
	Mean	95% CI	Mean	95% CI
Pre-study period				
6–10 weeks prior study start (n = 1967)	121.7	(121.1–122.3)	12.6	(12.3–12.8)
10–14 weeks prior study start (n = 2175)	120.9	(120.4–121.5)	12.5	(12.3–12.7)
24–28 weeks prior study start (n = 2115)	122.9	(122.4–123.5)	12.8	(12.7–13.0)
50–54 weeks prior study start (n = 2019)	123.3	(122.7–124.0)	13.3	(13.1–13.5)
Study period				
Study paddle 1 (n = 950)	109.8 ^a	(108.1–111.6)	10.3 ^b	(10.2–10.4)
Flexible paddle (n = 493)	116.1 ^a	(114.7–117.5)	11.3 ^b	(10.9–11.7)
Study paddle 2 (n = 2118)	114.5 ^a	(113.4–115.5)	10.8 ^b	(10.7–10.9)
Fixed paddle (n = 1114)	117.5 ^a	(116.7–118.4)	12.8	(12.6–13.1)

^a p < 0.001 for mean compression force 6–10, 10–14, 24–28 and 50–54 weeks prior to the study start versus mean compression force for the study paddle 1, flexible paddle, study paddle 2 and fixed paddle.

^b p < 0.001 for mean compression pressure 6–10, 10–14, 24–28 and 50–54 weeks prior to the study start versus mean compression pressure for the study paddle 1, flexible paddle and study paddle 2.

Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.ejrad.2019.04.006>.

References

- [1] M.J. Yaffe, Basic physics of digital mammography, in: U. Bick, F. Diekmann (Eds.), Digital Mammography, Springer Berlin Heidelberg, Berlin, Heidelberg, 2010, pp. 1–11.
- [2] N. Perry, C. de Wolf, S. Tornberg, R. Holland, L. von Karsa, European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis, 4 ed., European Communities, Luxembourg, 2006.
- [3] A. Poulos, M. Rickard, Compression in mammography and the perception of discomfort, *Australas. Radiol.* 41 (3) (1997) 247–252.
- [4] D. Miller, I. Martin, P. Herbison, Interventions for relieving the pain and discomfort of screening mammography, *Cochrane Database Syst. Rev.* (4) (2002) Cd002942.
- [5] A.M. Myklebust, T. Seierstad, E. Stranden, A. Lerdal, Level of satisfaction during mammography screening in relation to discomfort, service provided, level of pain and breast compression, *Eur. J. Radiogr.* 1 (2) (2009) 66–72.
- [6] P. Whelehan, A. Evans, M. Wells, S. Macgillivray, The effect of mammography pain on repeat participation in breast cancer screening: a systematic review, *Breast (Edinburgh, Scotland)* 22 (4) (2013) 389–394.
- [7] A. Poulos, D. McLean, M. Rickard, R. Heard, Breast compression in mammography: how much is enough? *Australas. Radiol.* 47 (2) (2003) 121–126.
- [8] M.J.M. Broeders, M. ten Voorde, W.J.H. Veldkamp, R.E. van Engen, C. van Landsveld – Verhoeven, M.N.L. 't Jong – Gunneman, et al., Comparison of a flexible versus a rigid breast compression paddle: pain experience, projected breast area, radiation dose and technical image quality, *Eur. Radiol.* 25 (3) (2015) 821–829.
- [9] M. Dustler, Pressure Distribution in Mammography. Mechanical Imaging and Implications for Breast Compression, Lund University: Lund University, Faculty of Medicine, 2016.
- [10] S.L. Dibble, J. Israel, B. Nussey, J.W. Sayre, R.J. Brenner, E.A. Sickles, Mammography with breast cushions, *Womens Health Issues* 15 (2) (2005) 55–63.
- [11] G.G. Waade, N. Moshina, S. Sebuodegard, P. Hogg, S. Hofvind, Compression forces used in the norwegian breast cancer Screening program, *Br. J. Radiol.* (2017) 20160770.
- [12] C.E. Mercer, P. Hogg, R. Lawson, J. Diffey, E.R. Denton, Practitioner compression force variability in mammography: a preliminary study, *Br. J. Radiol.* 86 (1022) (2013) 20110596.
- [13] J.E. de Groot, M.J. Broeders, W. Branderhorst, G.J. den Heeten, C.A. Grimbergen, A novel approach to mammographic breast compression: improved standardization and reduced discomfort by controlling pressure instead of force, *Med. Phys.* 40 (8) (2013) 081901.
- [14] W. Branderhorst, J.E. de Groot, R. Highnam, A. Chan, M. Bohm-Velez, M.J. Broeders, et al., Mammographic compression—a need for mechanical standardization, *Eur. J. Radiol.* 84 (4) (2015) 596–602.
- [15] J.E. de Groot, W. Branderhorst, C.A. Grimbergen, G.J. den Heeten, M.J. Broeders, Towards personalized compression in mammography: a comparison study between pressure- and force-standardization, *Eur. J. Radiol.* 84 (3) (2015) 384–391.
- [16] J.E. de Groot, M.J. Broeders, C.A. Grimbergen, G.J. den Heeten, Pain-preventing strategies in mammography: an observational study of simultaneously recorded pain and breast mechanics throughout the entire breast compression cycle, *BMC Womens Health* 15 (2015) 26.
- [17] Forskrift om innsamling og behandling av helseopplysninger i Kreftregisteret (Kreftregisterforskriften), (2001).
- [18] S. Hofvind, Cancer in Norway 2016. Special Issue: The Norwegian Breast Cancer Screening Program, 1996–2016: Celebrating 20 Years of Organised Mammographic Screening, Cancer Registry of Norway, Oslo, 2017.
- [19] Quality Assurance Manual, Norwegian Breast Cancer Screening Program. Directions for Radiographers. Kvalitetsmanual. Mammografiprogrammet. Retningslinjer for Radiografaglig Arbeid: Cancer registry of Norway, Available from (2011) https://www.kreftregisteret.no/globalassets/mammografiprogrammet/arkiv/publikasjoner-og-brosjyrer/kval-man-radiograf_v1.0_innholdsfortegnelse.pdf.
- [20] SigmaScreening Products, (2017) Available from <https://www.sigmascreening.com/products>.
- [21] VolparaSolutions. VolparaResearch, (2017) [cited 2017 20.05.2017]. Available from: <http://volparasolutions.com/solutions/volpararesearch/>.
- [22] A. Williamson, B. Hoggart, Pain: a review of three commonly used pain rating scales, *J. Clin. Nurs.* 14 (7) (2005) 798–804.
- [23] K.M. Tsuruda, S. Sagstad, S. Sebuodegard, S. Hofvind, Validity and reliability of self-reported health indicators among women attending organized mammographic screening, *Scand. J. Public Health* 46 (7) (2018) 744–751.
- [24] J. Zhang, K.F. Yu, What's the relative risk? A method of correcting the odds ratio in cohort studies of common outcomes, *JAMA* 280 (19) (1998) 1690–1691.
- [25] M. Dustler, I. Andersson, H. Brorson, P. Frojd, S. Mattsson, A. Tingberg, et al., Breast compression in mammography: pressure distribution patterns, *Acta Radiol. (Stockholm, Sweden)* 53 (9) (2012) 973–980.
- [26] N. Moshina, S. Sebuodegard, S. Hofvind, Is breast compression associated with breast cancer detection and other early performance measures in a population-based breast cancer screening program? *Breast Cancer Res. Treat.* 163 (3) (2017) 605–613.
- [27] B. Davey, Pain during mammography: possible risk factors and ways to alleviate pain, *Radiography* 13 (3) (2007) 229–234.
- [28] M.G. van Lier, Jerry E. DG, Woutjan Branderhorst, Laura J. Schijf, Cornelis A. Grimbergen, Gerard J. den Heeten, Mammographic Compression Variability Increased After Removing Real-time Pressure Indicator: radiological Society of North America, [cited 2019 March 17]. Available from (2018) <http://archive.rsna.org/2018/18018352.html>.