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Abstract

Objectives: Compression is used in mammography to reduce breast thickness, which is claimed to improve image quality and reduce radiation dose. In the Norwegian Breast Cancer Screening Program (NBCSP), the recommended range of compression force for full field digital mammography is 11-18 kg (108-177 Newton [N]). This is the first study to investigate the compression force used in the program.

Methods: The study included information from 17,951 randomly selected women screened with FFDM at 14 breast centres in the NBCSP, January-March 2014. We investigated the applied compression force on left breast in craniocaudal (CC) and mediolateral oblique (MLO) view for breast centres, mammography machines within the breast centres and for the radiographers.

Results: The mean compression force for all mammograms in the study was 116N and ranged from 91 to 147N between the breast centres. The variation in compression force was wider between the breast centres than between mammography machines (range 137-155N) and radiographers (95-143N) within one breast centre. Approximately 59% of the mammograms in the study complied with the recommended range of compression force.

Conclusions: A wide variation in applied compression force was observed between the breast centres in the NBCSP. This variation indicates a need for evidence-based recommendations for compression force aimed at optimizing the image quality and individualising breast compression.

Advances in knowledge: There was a wide variation in applied compression force between the breast centres in the NBCSP. The variation was wider between the breast centres than between mammography machines and radiographers within one breast centre.

Introduction

Breast compression is used in mammography to reduce breast thickness with the intention of decreasing radiation dose and improving image quality [1-3]. However, breast compression might lead to discomfort and pain for the women who undergo mammography [4] and this might affect the woman's experience, leading to reduced screening participation [5, 6].

There are currently no evidence-based recommendations regarding optimal breast compression in mammography. The European guidelines for quality assurance in breast cancer screening and diagnosis state that "the breast should be properly compressed, but no more than is necessary to achieve a good image quality" [1]. The guidelines from the National Health Service Breast Screening Programme in the UK state that "the force of the compression on the x-ray machine should not exceed 200 Newtons or 20 kilograms" [7]. The lack of precise and objective recommendations for breast compression might lead to variations in applied compression between radiographers and breast centres. Studies by Mercer *et al* [8-10] and Branderhorst *et al* [11] have reported large variations in compression force between radiographers [8-10] and screening sites [10, 11] and that compression force is highly dependent on the radiographer rather than the screened women. These findings have been reported both for screen film [8-10] and full field digital mammography (FFDM) [11].

The quality assurance manual of the Norwegian Breast Cancer Screening Program (NBCSP) recommends that the compression force for FFDM should be between 11 and 18 kg (1 kg = 9.81 Newton [N]; 11-18kg = 108-177N) [12]. As the first step towards establishing evidence-based guidelines for compression force in mammography, we investigated the applied compression force for the breast centres, mammography machines within the breast centres and for the radiographers in the NBCSP.

Materials and methods

This study received ethical approval from the Data Protection Official of the Cancer Registry of Norway (Reference 2014/15279).

The NBCSP started in 1996 and expanded gradually to become nationwide in 2005 [13]. Women aged 50-69 years are invited biennially to two-view mammography, including craniocaudal (CC) and mediolateral oblique (MLO) views. About 300,000 women were invited in 2015. The program includes 26 stationary and four mobile mammography machines administered by 16 breast centres. The breast centres cover different geographical areas corresponding to the counties. The Cancer Registry of Norway is responsible for administration and quality assurance of the program [14]. The National Radiation Protection Authority is responsible for regularly technical quality control of the mammography equipment in the screening program [15]. This work is performed in collaboration with a dedicated quality assurance radiographer at each breast centre. The specification for compression force is that the compression force indicated on the machine should be within ± 10N of the measured value [15].

Data collection

An e-mail with information about the study and a request to participate was sent from the head of the NBCSP to all the leaders at the 16 breast centres in the program. Employees at the Cancer Registry performed the randomization for 1,550 screening examinations performed in the period January-March 2014. The number of examinations was based on power analyses. A list was sent to each breast centre including a running number and the 11-digit personal identification number (PIN) given to all inhabitants in Norway. The PIN was used to identify the images.

The quality assurance radiographers at the breast centres used the PIN to identify the examinations in the *picture archiving and communication system* (PACS). Information about compression force, compressed breast thickness and initials of the radiographers who performed the examinations was manually extracted and registered into Excel. Fifteen breast centres returned data to the Cancer Registry together with the running number. However, data from one breast centre was excluded as digital breast tomosynthesis was used for screening during the study period [16]. We received information from 19,114 examinations, varying from

297 to 1,550 per breast centre. Each breast centre had 1-3 stationary and mobile mammography machines, typically staffed by the same radiographers.

In this paper, ‘breast centre’ refers to one of the 14 breast centres, while ‘mammography machine’ refers to the mammography machines used for screening within one breast centre (26 mammography machines in total). The breast centres were anonymized with letters (A-N) and the mammography machines with a letter, indicating the center, and a number indicating the different machines (ie. A1).

We excluded screening examinations with less (n=143) or more (n=670) than four standard mammograms (left and right breast in CC and MLO view); examinations on women with breast implants (n=163); pacemakers (n=7); physical or psychological disorders (n=2); or other reasons (n=27). Further, examinations with single mammograms registered with an extreme value of compression force (outside range 20-200N) or compressed breast thicknesses (outside range 10-110mm) were considered as typographical errors and were therefore excluded (n=151 examinations). This left 17,951 screening examinations for analysis.

There was no statistically significantly difference in the compression force of left and right breast. Therefore, information only from the mammograms of left breast was used in the analyses to avoid double values from the same women. Information from 35,902 mammograms were available in total, 17,951 CC and 17,951 MLO. Descriptive results from the right breast are shown in Appendix 1. The mammograms were acquired using FFDM systems from Siemens (Mammomat Inspiration; n=7,282 examinations), General Electric (GE; Senographe Essential; n=6,215 examinations [3,336 on stationary mammography machines and 2,879 on mobile mammography machines]), Philips (Microdose Mammography L50; n=1,492 examinations / Sectra Microdose Mammography L30; n=1,502 examinations) or Hologic (Hologic Selenia Dimensions; n=1,460 examinations) (Table 1).

Data analysis

All data regarding compression force was analysed in Newtons. As data were normally distributed, means and 95% confidence intervals (95% CI) were used for investigating compression force, by breast centre, mammography machines within breast centres and in total. The observed values of compression force were compared to the recommended level of compression force (108-177N) indicated within the Quality Assurance Manual of the NBCSP [12]; the percentage of mammograms below, within and above the recommended values were calculated. This was performed by breast centre.

A total of 200 radiographers were involved in the imaging, ranging from 8-28 radiographers within each breast centre. Information from mammograms without initials of the radiographer who performed the examination (n=39 mammograms) or mammograms acquired by radiographers who had performed less than 20 examinations (n=69 mammograms), were excluded from analysis for radiographers. Analyses related to the individual radiographer who fulfilled the inclusion criteria were therefore based on 35,794 mammograms. Mean and median number of mammograms acquired by the radiographers were calculated. Mean and range of compression force were calculated for each radiographer.

Information about the radiographers, such as age and years of experience within mammography was obtained by e-mail correspondence with the quality assurance radiographers at the breast centres. This information was available for 154 radiographers (77%). Mean compression force was calculated by age groups (25-34, 35-44, 45-54, 55-69 years) and years of experience in screening and/or clinical mammography (<5, 6-10, 11-15, 16-20, >20 years) of the radiographers.

Linear regression was used to explore variation in compression force by breast centre, mammography machines within breast centres, radiographer, age and experience of the radiographer, machine vendor and woman body mass index (BMI: weight in kilograms / height in meters^2). Information regarding weight and height was reported by the women in a questionnaire, which all women received at the same time as the invitation to attend breast screening. This information was available for 60.3% (n= 10,830) of the women. Backward elimination and Akaike information criterion (AIC) were used for selection of the appropriate multivariate linear regression model.

Pearson correlation coefficient (r) was used to identify the correlation between compression force and compressed breast thickness. We also used Pearson correlation coefficient to estimate the accuracy of the manually reported data for two centres where Volpara software (VolparaDensity version 4, Matakina, Wellington NZ) is installed (breast centre D and H). The manually reported information on compression force and compressed breast thickness at the two breast centres (n= 6226 mammograms) were compared with information for the same examinations given by Volpara. We assessed correlation according to the following distribution: 0-0.3, negligible correlation; 0.3–0.5, low correlation; 0.5-0.7, moderate correlation; 0.7-0.9 high correlation; 0.9-1, very high correlation [17].

Analysis of variance (ANOVA) and Tukey's Honestly significant different (HSD) pairwise comparisons were used to test statistical significance. All statistical analyses were conducted using Stata Statistical Software (version 14, *Stata* Corp, College Station, Texas, USA).

Results

Mean compression force for the mammograms performed in the NBCSP during the study period was 116N (95% CI: 116.0-116.6) (Table 1). It was 108N (95% CI: 117.6-118.4) for CC and 125N (95% CI: 124.2-125.0) for MLO (Table 1). The range of mean compression force was wider between the breast centres than between mammography machines within one breast centre (Figure 1). Mean compression force varied from 91N (breast centre E) to 147N (breast centre M) between the breast centres, while mean compression force between the mammography machines within one breast centre varied from 137N to 155N (breast centre M). Mean compression force differed statistically significantly for five breast centres when compared to each of the other breast centres ($p < 0.05$), while it differed statistically significantly between mammography machines in six breast centres ($p < 0.05$).

A total of 58.9% (21,161/35,902) mammograms performed in the NBCSP during the study period complied with the recommended compression force range (108-177N) (Figure 2). We identified 38.2% mammograms (13,706/35,902) to be below, and 2.9% (1,035/35,902) to be above the recommended range. The lowest percentage of mammograms with compression force within the recommended values was observed at breast centre E (16.5%, 505/3,058), while the highest at breast centre L (95.5%, 2,788/2,920).

Compression force by radiographers

Mean and median number of mammograms acquired by the radiographers who fulfilled the inclusion criteria were 304 and 284, respectively. Mean compression force ranged from 83N to 164N for the radiographers, while it ranged from 95N to 143N for radiographers working at the same breast centre (breast centre N) (Figure 3). Mean compression force decreased slightly as the radiographer's age and experience increased ($p < 0.05$). The slight decrease was statistically significant for all groups of experience, and between the two youngest age groups compared to the two oldest age groups ($p < 0.05$). The decrease in compression force was non-linear for radiographer experience.

Univariate linear regression showed that radiographer (r^2: 0.358), mammography machines within breast centres (r^2: 0.269), breast centre (r^2: 0.261), machine vendor (r^2: 0.073), BMI (r^2: 0.042), years of age (r^2: 0.001) and years of experience within mammography (r^2: 0.002) for the radiographer were significant predictors of the compression force used in the NBCSP (p

<0.001). We could not include all the significant predictors of compression force in a multivariate linear regression model due to collinearity. Backward elimination and AIC identified radiographer, BMI and mammography machines within breast centres as the strongest predictors of compression force in a multivariate linear regression model. The overall fit of the model was 39.7%.

The correlation between compression force and compressed breast thickness was negligible (r= 0.186). The estimated accuracy of the manually reported data compared with the data given from Volpara was high for the two counties tested: r= 0.93 for compression force and r= 0.99 for compressed breast thickness.

Discussion

A moderate percentage (58.9%) of the mammograms in the NBCSP were performed with a compression force within the recommended range (108-177N). Almost 40% of the mammograms were performed with a compression force below the recommended values. A substantial variation in compliance with the recommendations was observed between the breast centres.

There are several factors that might affect the applied compression force in mammography; the woman [18-20], the equipment [21, 22] and the radiographer [8-11, 22, 23]. Factors related to the screened woman include differences in breast volume [18], breast stiffness and compressibility [19, 20] and acceptance of pain. Characteristics of the breast compression paddle [24], positioning of the compression paddle [22, 23], positioning of the detector plate [21], and use of automated compression force methods [22] are factors related to the equipment. The positioning of the breast compression paddle and detector plate will affect how the pressure from breast compression is distributed across the breast [21-23]. Studies have indicated that pressure is often concentrated to the firmer juxtathoracic structures of the breast, rather than on the breast itself [22, 23]. Whether the breast compression paddle is rigid or flexible might also affect the distribution of pressure in the breast. However, Broeders *et al* reported no difference in mean compression forces when flexible and rigid breast compression paddles were compared [24]. Presence and use of automated compression force methods (such as Siemens proprietary OPCOMP), where the machine holds further compression force application when the ratio between thickness reduction and applied force drops below a threshold, might also have an impact on the applied compression force. We did not have information about the paddles or the use of automated compression force methods in our study. However, we found that the machine vendor was not of great influence for the applied compression force.

Previous studies have suggested that radiographers or screening centres might have their own preferred compression force levels [10, 11]. The compression force might be influenced by the radiographers' age, experience, and attitudes towards compression force for the radiographer and screening centre. The women's BMI, the radiographer who performed the examination, and the mammography machines within the breast centres were the strongest predictors of compression force in our study. The women's BMI might be related to the breast volume and thereby affect the applied compression force [18]. A sub analysis showed that the compression force decreased slightly by increasing age and years of experience in mammography of the radiographers. However, the correlation was not linear and further investigation is needed before any confident conclusion can be stated. The overall prediction of the multivariate model for compression force in our study was low (39.7%) as we were unable to include other factors to increase the prediction for the compression force. This suggests that application of compression force is an action influenced by several factors unavailable in this study, or is even random. Prediction of compression force is thus challenging.

The variation in applied compression force in the XBSCP might have consequences for the quality of the program, such as image quality [25, 26], radiation dose [27-29], the woman's experience of the examination [4] and re-attendance [5, 6]. Contradictory results have been reported regarding the effect of compression force on visually assessed image quality. A study by O'Leary *et al* [25] concluded compression force to be of significant effect on image quality, while Mercer *et al* [26] reported no difference in visually assessed image quality with different applied compression force. Further studies investigating the effect of compression force on image quality including both visual and physical measurements of image quality are needed. Regarding radiation dose, studies have reported increased radiation dose with increased compressed breast thickness [27-29]. Further, the compression force might influence re-attendance [5, 6]. However, subsequent re-attendance is complex and is affected by several factors rather than simply the level of pain experienced during the screening examination [5]. Studies exploring these factors are important for the quality of a screening program.

While the UK guidelines [7] for breast compression only specifies the recommended maximum compression force (200N or 20kg), the Norwegian recommendations [12] specify a range of accepted compression force (11-18kg). Both guidelines accept a large range of compression forces and this might be one of the reasons for the observed variation in compression forces in this study and Mercer's *et al* [8-10] from the UK.

A more specified or narrow interval of accepted compression force might reduce the variation between radiographers and breast centres. As compression force has a different impact on different breast sizes and densities, there would still be differences in the level of breast thickness reduction for the individual woman. This highlights the difficulties with the current compression force standardized guidelines. This explains why, in 2004, Poulos and McLean required a new perspective on breast compression in mammography [20]. However, today, twelve years later, compression force is still used in clinical practice. Several studies have asserted that compression force might not be the best measure for breast thickness reduction [11, 20, 22, 30]. The negligible correlation between compression force and compressed breast thickness ($r = 0.186$) observed in our study confirms this suggestion. Recently, compression pressure (force divided by contact area, $N/m^2 = Pa$) has been suggested as a better parameter for reducing breast thickness [31, 32]. This work is promising as breast size might be a factor to take into account when moving towards individualised breast compression. There is a need for increased knowledge about optimal breast compression in mammography, which takes into account different breast characteristics. Such knowledge will allow us to establish evidence-based and individualised recommendations for breast compression.

The strength of our study is the large number of mammograms included. There was a very high correlation between the information extracted from the radiographers and from the outcome of Volpara ($r = 0.93$-0.99), which indicate a strong validity of the data collected. Information about image quality or radiation dose was not available for this study, which would have provided valuable insight of effects of the variation in compression force in mammography.

Conclusion

This is the first study to investigate the compression force used in the Norwegian Breast Cancer Screening Program. Mean compression force varied substantially between the breast centres, mammography machines used at screening within the breast centres and between the radiographers. Six out of ten mammograms were performed with a compression force within the recommended range. The correlation between compression force and compressed breast thickness was negligible. The findings highlight the need for increased knowledge about optimal levels for breast compression in mammography. Future recommendations for breast compression should be evidence-based and aimed at individualising the breast compression without compromising image quality.

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Table 1: Number of screening examinations (n), radiographers (n), machine vendor, mean compression force (Newton, N) with 95% confidence interval for craniocaudal (CC) and mediolateral oblique (MLO) view, by breast centre and mammography machines within the breast centres

Breast centre	Mammography machine	Study population (n)	Radio-graphers (n)	Machine vendor	Mean (95% CI) Compression force (N) CC & MLO	CC	MLO
A		1506	16	Siemens	117.8 (117.0-118.6)	103.9 (103.2-104.6)	131.7 (130.6-132.8)
	A1	133		Siemens	113.2 (110.9-115.5)	99.0 (97.5-100.5)	127.4 (124.6-130.1)
	A2	462		Siemens	122.4 (120.9-123.9)	110.6 (109.1-112.1)	134.1 (132.0-136.3)
	A3	911		Siemens	116.2 (115-1-117.2)	101.2 (100.5-102.0)	131.1 (129.8-132.4)
B		1492	20	Philips	124.9 (123.7-126.1)	119.6 (118.1-121.0)	130.2 (128.5-132.0)
	B1	455		Philips	121.3 (119.3-123.3)	115.9 (113.6-118.3)	126.7 (123.6-129.8)
	B2	1047		Philips	126.4 (125.0-127.8)	121.1 (119.3-122.9)	131.7 (129.6-133.9)
C		931	9	Siemens/GE	107.3 (106.0-108.6)	94.5 (93.1-95.9)	120.1 (118.3-122.0)
	C1	737		Siemens	104.4 (102.9-105.8)	92.2 (90.8-93.7)	116.5 (114.4-118.6)
	C2[A,B]	194		GE	118.5 (115.6-121.3)	103.1 (99.7-106.4)	133.8 (130.4-137.3)
D		1493	16	GE	118.5 (117.8-119.1)	111.0 (110.2-111.8)	125.9 (125.0-126.8)
	D1[A]	1326		GE	118.7 (118.0-119.4)	110.8 (110.0-111.7)	126.6 (125.6-127.5)
	D2	167		GE	116.7 (114.8-118.5)	112.5 (110.1-114.8)	120.9 (118.2-123.7)
E		1529	16	Siemens	90.5 (89.7-91.3)	81.1 (80.5-81.7)	99.9 (98.7-101.2)
	E1	914		Siemens	90.3 (89.2-91.3)	78.6 (77.9-79.3)	102.0 (100.4-103.7)
	E2	615		Siemens	91.8 (89.7-92.0)	84.8 (83.8-85.8)	96.9 (94.9-98.8)
F		1466	8	GE	137.5 (136.5-138.5)	122.1 (120.9-123.2)	153.0 (151.7-154.2)
	F1	528		GE	142.8 (140.8-144.7)	125.2 (122.9-127.4)	160.3 (158.0-162.7)
	F2[A]	938		GE	134.5 (133.4-135.7)	120.3 (119.0-121.6)	148.8 (147.3-150.3)
G		1523	9	Siemens	114.8 (113.9-115.7)	105.9 (105.0-106.9)	123.7 (122.4-125.1)
H		1143	22	GE	124.8 (124.1-125.5)	121.1 (120.2-122.1)	128.4 (127.5-129.4)
	H1	533		GE	129.9 (128.9-130.9)	126.2 (124.8-127.6)	133.6 (132.3-134.9)
	H2	278		GE	118.0 (116.7-119.4)	115.9 (114.1-117.8)	120.1 (118.2-122.1)
	H3	332		GE	122.2 (121.0-123.4)	117-4 (115.7-119.0)	127.0 (125.4-128.6)
I		1502	8	Philips[C]	110.2 (109.0-111.4)	94.4 (93.2-95.6)	125.9 (124.2-127.6)
J		622	28	Siemens/GE	114.6 (113.4-115.8)	111.2 (109.7-112.8)	118.0 (116.2-119.8)
	J1	231		Siemens	113.7 (112.0-115.5)	109.1 (107.1-111.0)	118.4 (115.7-121.1)
	J2[A]	391		GE	115.1 (113.5-116.7)	112.5 (110.4-114.7)	117.4 (115.4-120.1)
K		1498	9	GE	93.2 (92.6-93.8)	90.0 (89.1-90.8)	96.4 (95.6-97.3)
L		1460	13	Hologic	138.9 (138.3-139.6)	134.4 (133.6-135.2)	143.5 (142.5-144.4)
M		278	18	Siemens/GE	146.8 (145.0-148.5)	143.9 (141.5-146.3)	149.6 (147.0-152.2)
	M1	134		Siemens	155.3 (152.9-157.7)	152.1 (148.7-155.5)	158.5 (155.2-161.8)
	M2	114		Siemens	136.9 (134.5-139.4)	133.8 (130.7-136.9)	140.0 (136.2-143.8)
	M3[A,B]	30		GE	146.0 (140.5-151.5)	145.7 (138.6-152.7)	146.3 (137.5-155.2)
N		1508	8	Siemens	112.6 (111.6-113.6)	109.8 (108.6-111.0)	115.4 (113.9-117.0)
Total		17951	200		116.3 (116.0-116.6)	108.0 (107.6-108.4)	124.6 (124.2-125.0)

[A]Mobile unit

[B]The same mobile unit, which the breast centres shares

[C]Philips represents Sectra Microdose Mammography L30

Figure 1: Mean compression force used (Newton, N) (diamond in the box), 25 and 75% percentile with adjacent values up to 1.5 intra quartile range (excludes values >1.5 IQR [1.9%]) for craniocaudal (CC) and mediolateral oblique (MLO) view combined, by mammography machines and breast centres in the Norwegian Breast Cancer Screening Program

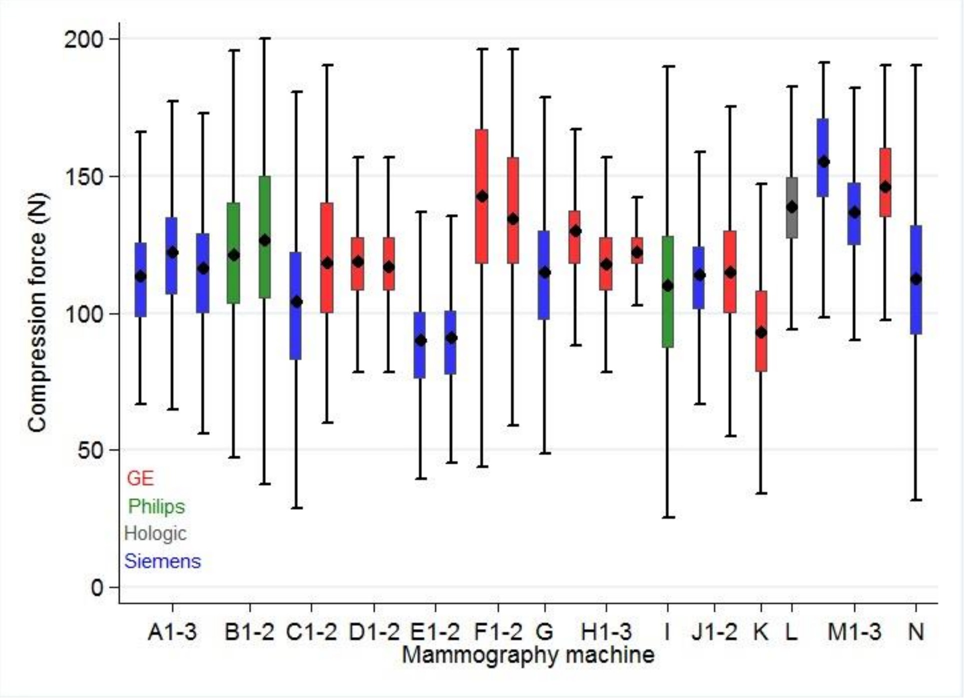

Figure 2: The distribution of compression force (Newton, N) within the recommended range of compression force from the Norwegian Breast Cancer Screening Program (108-177N; medium grey) and outside the recommended range (below: <108N, light grey; above: >177N, black), by breast centre and in total

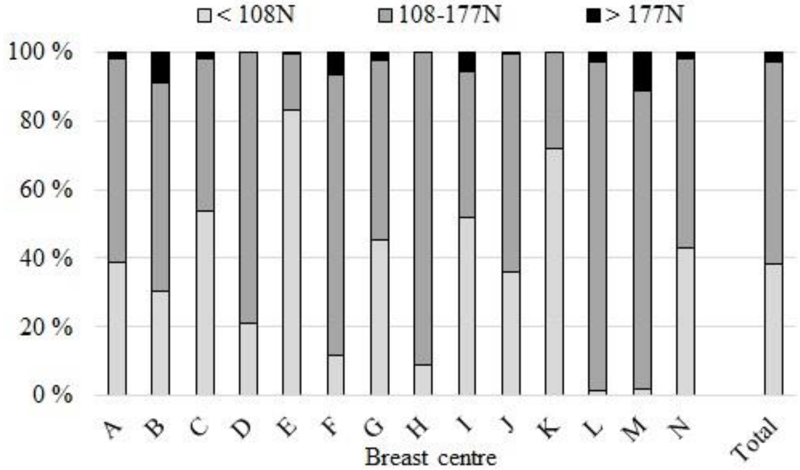

Figure 3: Mean (square) and range of compression force applied by the individual radiographers, by breast centre in the Norwegian Breast Cancer Screening Program. Each coloured square represents the mean compression force. Alternating red and blue squares have been used to enable easier visual differentiation between contiguous breast centres on the x-axis