Pressure and breast thickness in mammography—an exploratory calibration study

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Objective: To perform a calibration study to provide data to help improve consistency in the pressure that is applied during mammography.

Methods: Automatic readouts of breast thickness accuracy vary between mammography machines; therefore, one machine was selected for calibration. 250 randomly selected patients were invited to participate; 235 agreed, and 940 compression data sets were recorded (breast thickness, breast density and pressure). Pressure (measured in decanewtons) was increased from 5 daN through 1-daN intervals until the practitioner felt that the pressure was appropriate for imaging; at each pressure increment, breast thickness was recorded.

Results: Graphs were generated and equations derived; second-order polynomial trend lines were applied using the method of least squares. No difference existed between breast densities, but a difference did exist between “small” (15×29 cm) and “medium/large” (18×24/24×30 cm) paddles. Accordingly, data were combined. Graphs show changes in thickness from 5-daN pressure for craniocaudal and mediolateral oblique views for the small and medium/large paddles combined. Graphs were colour coded into three segments indicating high, intermediate and low gradients [≤ -2 (light grey); -1.99 to -1 (mid-grey); and ≥ -0.99 (dark grey)]. We propose that 13 daN could be an appropriate termination pressure on this mammography machine.

Conclusion: Using patient compression data we have calibrated a mammography machine to determine its breast compression characteristics. This calibration data could be used to guide practice to minimise pressure variations between practitioners, thereby improving patient experience and reducing potential variation in image quality.

Advances in knowledge: For the first time, pressure–thickness graphs are now available to help guide mammographers in the application of pressure.

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In 2008, within the UK, breast cancer was the second most diagnosed cancer in females. Internationally, it accounted for nearly 11% of female cancer deaths [1]. For breast cancer detection, mammography plays an important role in screening symptomatic populations and rigorous quality assurance procedures are applied accordingly [2, 3]. There is a particular emphasis on equipment performance [4] and image reader ability to identify abnormalities [5]. By contrast, surprisingly little quality assurance emphasis is placed on the clinical image acquisition phase—especially the optimisation of pressure to reduce breast thickness.

Pressure is considered necessary to reduce breast thickness and for many years this reduction has been associated with image quality enhancement and radiation dose limitation [6]. Within the UK, there is no specific protocol for thickness reduction, but it is generally accepted that pressure should be applied

slowly and gently to ensure that the breast is held firmly in place and the skin is taut to touch or that blanching occurs [3, 7, 8]. The National Health Service Breast Screening Programme (NHSBSP) suggests that pressure should not exceed 20 daN. Limited literature exists about the application of pressure. However, Sullivan et al [9] demonstrated a relationship between pressure and thickness, and a maximum value of 16 daN was suggested. By contrast, Chida et al [10] used a standard compression force of 12 daN; if patients experienced pain a reduced force of 9 daN was suggested. Documented variation of opinion therefore exists.

Practitioner subjectivity associated with pressure application has been a concern for many years [11], and in 2004 Poulos and McLean [12] predicted that lack of attention to this could lead to large variations. In 2011, Mercer et al [13] concluded, from a cross-sectional clinical study of 500 females and 14 practitioners (radiographers and assistant practitioners), that large variations existed, and 3 categories of “compressor” were identified by their mean compression values: low—7.4 daN [standard deviation (SD) 1.5]; medium—8.8 daN

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(SD 1.5); and high—11.1 daN (SD 2.1). Importantly, Mercer et al concluded that the variation is highly dependent upon the practitioner. The study by Mercer et al raises concerns about the consistency of care, radiation dose and image quality, and suggests that more objective criteria for the application of pressure in mammography are required.

On reviewing the literature it is clear that little is published on the optimisation of pressure in mammography; for instance, almost no empirical data are available to describe how the *in vivo* female breast behaves when pressure is applied to it. This may partly explain why the NHSBSP guidance is lacking in detail and also why this aspect of practice is not adequately quality assured.

In this exploratory study we present a method and data to describe the relationship between pressure and female breast thickness. Because mammography machine and paddle combinations have readout thickness inaccuracies [14, 15], we have verified the relationship only for one machine by using a sample from its “typical” clinical population. It is worth remembering that Hauge et al [14] used a deformable breast phantom to determine how readout thickness varied from actual thickness; the experiment was conducted under clinically realistic conditions, which incurred bend and distortion across the paddle surface. These are not accounted for in standard medical physics quality control tests. With this in mind, it might be that, for the same pressure, thickness values will be different between mammography machines and different paddles. Similarly, there may be patient differences too, particularly between screening and symptomatic caseloads. Calibrating a mammography unit based on its local caseload would therefore seem an important first step.

Our study follows a similar design to work conducted by Hoflehner et al [16] and Poulos and McLean [12]. For one mammography machine, we outline a method to determine breast compression characteristics which include typical end points for pressure cessation and critical stages within the compression cycle. We conclude by proposing that our approach could be used to establish local pressure standards on which practice might be based and assessed.

Methods and materials

The mammography machine (Hologic™ Selenia; Hologic UK Ltd, West Sussex, UK, full field digital) served only a symptomatic female patient population, from which a sample of 250 patients was drawn. Three paddle sizes were used for imaging [1—small (15×29 cm), 2—medium (18×24 cm) and 3—large (24×30 cm)]. Routine medical physics quality assurance tests performed on the machine indicated it to be operating within expected manufacturer specifications. Owing to refusals (7) and exclusions (8), only 235 patients participated. Reasons for exclusion included breast implants and incomplete sets of pressure/thickness data. To minimise bias, computer-generated randomisation tables were used to select the patients. To meet ethics approval requirements, informed consent was established prior to commencement. Ethics approval was

granted by North Manchester General Hospital, Manchester, UK, and the University of Salford Ethics Committee, Salford, UK; the hospital in which the study was conducted considered the work to be “service evaluation”, and approval was granted accordingly. As part of the normal mammogram imaging routine, 940 compression sets were acquired, of which 470 were craniocaudal (CC) and 470 were mediolateral oblique (MLO), with left and right described as l and r, respectively.

Five practitioners who held recognised mammography qualifications conducted the mammograms. Prior to the study, to minimise practitioner technique and data recording variability, a 2-week training review was conducted. To help the practitioners, the same assistant was present in the room for all mammograms to record the pressure and breast thickness data. For the study, all practitioners followed the same technical and positioning procedures; these were in line with published techniques [7]. For rCC, rMLO, lCC and lMLO, automatic machine readouts for breast thicknesses were recorded along with the applied pressures (measured in decanewtons). For the most part, this recording procedure commenced at 5 daN and increased through 1-daN increments until the practitioner had reached the termination pressure and thickness for the patient's mammogram. Factors affecting termination of pressure included patient tolerance and the practitioner deciding that enough had been applied. These factors meant that the lower pressures had more data and the higher pressures had less data. Overall, per patient, the pressure and thickness recording process added to examination time by approximately 2–3 min. Breast density scoring was performed by two experienced observers using the Breast Imaging Reporting and Data System (BI-RADS) classification [17]. Their agreement was high (79%), and to resolve differences in opinion a third experienced observer arbitrated so that agreement was reached in 100% of the cases. Additional data collected on each patient included age and menstrual status.

Results

Each practitioner collected data on different numbers of patients (40%, 13%, 25%, 17% and 5%). Of the patients, 96% were attending the one-stop diagnostic clinic; for 58%, it was their first mammogram attendance. There was a fairly even distribution across the menstrual cycle [1–7 days (16%); 8–14 days (11%); 15–21 days (11%); 21–28 days (9%); 28+ days (12%); and unknown (1%)], with almost half of the patients being post menopause (40%). Age distribution demonstrates that there was close similarity to the previous 3 years' clients (Pearson's correlation indicates: 2008/study, $r=0.926601$; 2009/study, $r=0.923102$; 2010/study, $r=0.944200$); BI-RADS density distribution indicates that BI-RADS 4 was undersampled (2%) but BI-RADS 1, 2 and 3 were fairly well represented (20%, 59% and 19%, respectively). Paddles were used with the following frequencies: small, $n=19$ (8%); medium, $n=96$ (41%); and large, $n=120$ (51%).

Prior to generating graphs of pressure and breast thickness the data were examined for quality. As noted

Figure 1 Paddle comparison—craniocaudal view. Paddle 1, small (15×29 cm); Paddle 2, medium (18×24 cm); Paddle 3, large (24×30 cm).

earlier, it was observed that less sampling was performed at higher compression values. Because of this, to minimise error, for each pressure value, data were excluded that did not have adequate sample size. The cut-off sample size was $\sqrt{N}$, where N was the maximum number of patients acquired within the chosen group. As the pressure increased, the number of patients able to be sampled decreased, owing to either imaging requirements or patient tolerance. This meant that, as pressure increased, sample numbers decreased. A cut-off sample number was required and this was chosen to be the square root of N ($\sqrt{N}$), where N was the number of patients at the initial pressure, as this is the standard error value within a sample (assuming a normal distribution). Sample numbers lower than this value would mean that the sample was below the standard error, leading to high standard deviations. This meant that for all samples a value of 14 daN was the cut-off pressure value.

The initial thickness of breast tissue inevitably varied, depending on the patient size; therefore, the change in thickness (measured in millimetres) was evaluated to observe the effect the compression had on the deformation of the tissue. Using graphs, the data are therefore described as the absolute change in breast tissue thickness measured from the thickness at 5 daN in millimetres. Knowing that paddles may have different compression characteristics, data from the three paddles

were presented in graphical form (Figures 1 and 2). As can be seen for MLO and CC, Paddles 2 and 3 (medium and large) describe similar characteristics while Paddle 1 (small) is different. Graphs were generated for the BI-RADS categories (Figures 3 and 4). It is worth noting that no graph is presented for BI-RADS 4, as only four sets of patient data were available. Because the scatter plot of these four and all of BI-RADS 3 had similar distributions, we included the four into the BI-RADS 3 group to increase sample size.

In Figures 3 and 4, divergences in the graphs can be seen at around 11 daN. These divergences could be explained by the reduced sampling at the higher pressure values; this is illustrated in Figure 5a,b. For MLO and CC, little difference is noted until 11 daN; consequently, accepting that the divergence beyond this point is due to sampling error, all BI-RADS for the small paddle (Figures 6 and 7) and all BI-RADS for the medium and large paddles (Figures 8 and 9) were combined, and composite graphs were created. Error bars demonstrate the standard deviation of the data. Second-order polynomial trend lines were applied to the data using the method of least squares. These gave good correlation ($r^2 > 0.98$) for all data sets. Extrapolation of the data demonstrates the point at which further compression force no longer decreases breast tissue thickness (zero gradients). Maximum compression forces derived from the composite graphs

Figure 2 Paddle comparison—mediolateral oblique view. Paddle 1, small (15×29 cm); Paddle 2, medium (18×24 cm); Paddle 3, large (24×30 cm).

Figure 3 Breast Imaging Reporting and Data System (BI-RADS) comparison—craniocaudal (CC) view. LCC, left CC; RCC, right CC.

Figure 4 Breast Imaging Reporting and Data System (BI-RADS) comparison—mediolateral oblique (MLO) view. LMLO, left MLO; RMLO, right MLO.

are: small paddle, CC 18.4 daN, MLO 15.9 daN; medium and large paddles, CC 16.9 daN, MLO 17.3 daN.

Using the applied polynomial trendlines, the equations were differentiated to enable calculation of the gradient at various points. The gradient

demonstrated the amount of change of thickness of tissue, per unit of pressure applied. A higher gradient means a greater reduction in tissue thickness per unit of pressure applied. On this basis, we have colour coded the graphs into three gradient segments: ≤ -2 (light grey); -1.99 to -1 (mid-grey); and

Figure 5 (a) Craniocaudal compressions; (b) mediolateral oblique compressions. BI-RADS, Breast Imaging Reporting and Data System.

Figure 6 Small paddle—average craniocaudal.

Figure 7 Small paddle—average mediolateral oblique.

Figure 8 Medium and large paddles—average craniocaudal.

Figure 9 Medium and large paddles—average mediolateral oblique.

≥ -0.99 (dark grey). The use of this gradient calculation and the colour coding is described in the discussion section below.

Discussion

This study was carried out in a symptomatic unit where a larger proportion of younger females are imaged than in a screening setting; 63% of patients imaged were under the age of 50 years. While this may represent a study limitation, it does reflect the clinical norm for this machine's usage in symptomatic practice. Given that the intention was to propose a pressure calibration for the mammography machine using its own patient population, "oversampling" of BI-RADS 1–3 would seem to be appropriate, because BI-RADS 4 is likely to be associated with a much younger age.

Surprisingly, on reviewing Figures 3 and 4, there were almost no differences between the BI-RADS densities up to 11 daN (with some divergence beyond this, as explained earlier). This minimal difference may be because of the limited precision for the thickness measurements, suggesting that minor compressibility differences may exist but the machine cannot differentiate them. By contrast, differences did exist between the small and the medium/large paddles (Figures 1 and 2). Patient and paddle factors are likely to account for this. Firstly, the small paddle is used exclusively on small breasts and for these breasts there tends to be less mobility with a much smaller compression capability range. Secondly, the small paddle is non-tilting, unlike the medium and large paddles, which do tilt. Hauge et al [14] noted that larger thickness readout errors are associated with tilting paddles, so the differences could partly be owing to precision. Overall, the lack of difference between BI-RADS scores is helpful because it means that for this machine all BI-RADS scores can be combined for the small and medium/large paddles, allowing for a simpler process of calibration because only two composite CC and two composite MLO graphs would be required. Applying the data to the clinical setting would also be simplified.

Figures 6–9 demonstrate that SDs tend to increase with increasing pressures. This was explained earlier in relation to the reduced sampling for the higher-pressure values. Should this study be repeated, consideration should be given to how more data might be recorded for higher-pressure values, with due regards to patient comfort and tolerance. However, for all four graphs (Figures 6–9), extrapolation suggests that the NHSBSP maximum of 20 daN was not reached. This indicates that the machine's maximum average pressure falls within the NHSBSP recommendation; on the other hand, it might suggest that for this mammography machine a lower maximum absolute value could be proposed (e.g. 19 daN for small and 18 daN for medium/large paddles).

The colour-coded graphs (Figures 6–9) demonstrate areas of different gradients as described within the method. The gradient describes the amount of reduction in tissue thickness per unit of pressure, *i.e.* the rate of change of tissue thickness. In all cases the light-grey zone depicts a high rate of change, with average gradients of -2.0 and higher. The mid-grey zone depicts a medium

rate of change, with average gradients varying from -1.99 to -1.0 . Finally, the dark-grey zone depicts a low rate of change, with average gradients varying from 0 to -0.99 . On comparison with the light-grey zone, once the dark-grey zone has been entered the amount of breast thickness reduction is relatively small compared with the pressure required to effect that change. By contrast, in the light-grey zone there is a very high level of thickness reduction achieved for relatively small amounts of applied pressure. As the dark-grey zone is entered, resistance increases rapidly and the potential for pain and discomfort is also likely to increase quickly per applied decanewton. The thickness reduction in the dark-grey zone is low compared with the pressure required to effect that change; therefore, the benefit of applying additional pressure from the point of entering that zone ought to be questioned. On this basis, we propose that the practitioner enter the mid-grey zone and then attempt to reach but not necessarily enter the dark-grey zone before ceasing the application of pressure. Consideration for terminating compression for this machine would, therefore, on average, begin approaching 13 daN.

Practitioner latitude for the application of pressure would still be expected for patients who experience pain/discomfort and further research is required to assist the practitioners in using graphs of this type. At first presentation for mammography, the graphs could be used to help guide initial pressure and thickness values; for subsequent visits previous thicknesses and pressures should be noted but attention should still be paid to the graphs. It may be valuable to overlay a measure of pain/discomfort on Figures 6–9 and further research is proposed on this basis. It is also important to recognise that the selection of the critical gradients which differentiate the three shaded grey zones was arbitrary; it is likely that they will be redefined based on experience.

Conclusion

The lack of detail in national guidelines and published literature for the application of pressure in mammography can allow for variation to occur between and within practitioners. This variation may have consequences for mammographic image quality, radiation dose and patient experience.

Using female breast compression data for one mammography machine, we have proposed a method which may help minimise practitioner variability. Our method acknowledges that mammography machines have inherent differences and because of these each machine may require calibration. Additionally, we have acknowledged that different machines will serve different populations and those populations might also affect the calibration. We anticipate that our method and calibration data could be used to inform local practice and also serve as an audit standard. Consequently, we believe that our approach provides evidence for breast compression limits specific to the machine and its population and is therefore likely to have value within other mammography imaging centres. Finally, we would like to propose that our approach may be worth replicating on other mammography machines and paddles, because the resultant data could be used to help improve consistency in the application of pressure.

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