By Prof. K Grimbergen & Prof. A den Heeten

Pressure controlled compression of the breast in mammography

Current mammography procedures require compression of the breast by a compression paddle. Such procedures involve application of a certain force with generally no account being taken of the size of the breast. The process can result in various levels of pain and discomfort.

This article describes the rationale behind the development of a pressure-based compression system, i.e. one that takes into account the contact area of the breast with the paddle. Validation studies of the new system show that the use of standardized pressure-based compression not only provides high quality images at the same radiation dose but also significantly reduces the pain and discomfort reported by the women undergoing mammography examinations.

Recent results show that the performance of mammography, in terms of detectability of cancerous lesions can be affected by the compression pressure at which the examination is carried out.

Mammography is a widely used diagnostic modality in radiology and is the starting procedure in almost every work-up in breast imaging whether this is diagnostic, i.e. initiated by clinical signs or in asymptomatic subjects in screening programs.

Screening mammography is widely considered as one of the major medical successes of the past decades, and the decline in breast cancer mortality that has been observed in many countries throughout the world has been attributed at least in part to screening programs. Each year, an estimated 125 million women throughout the world are imaged using mammography, a process which involves each woman routinely undergoing two compressions of each breast.

A certain level of compression of the breast is required in mammography for several reasons:

- Immobilization of the breast is needed to avoid movement and the consequent blurring of images.
- Flattening of the breast enables a more homogeneous exposure and a better dynamic range of luminance.
- Superimposing structures at different depths and those with different degrees of stiffness can be better depicted in a compressed breast
- Last but not least, compression enables a quality image at a lower radiation dose.

However, despite the key role of compression, attempts to standardize the procedure have to date been limited to either the subjective judgement of the radiographer ("compress until skin is taut") or the use of a set amount of force ("apply 130N of force"), which does not take into consideration whether the breast is small or large. Compression which is too great can lead to a painful experience with the woman being less likely to continue to participate in the screening program.

To date, efforts to help radiographers achieve the optimal compromise between the pain felt by the woman and image quality have not been successful [1].

In this article we describe the advantages of introducing a more objective, scientific approach to breast compression with the ultimate aim of maintaining high image quality, low radiation dose and at the same time ensuring the most comfortable experience for the woman.

The Authors

Prof. Kees Grimbergen

Professor of Medical Technology, Biomedical Engineering & Physics Department, Academic Medical Center, University of Amsterdam, The Netherlands. email: c.a.grimbergen@amc.uva.nl

&

Prof. Ard den Heeten

Professor of Radiology, Radiology Department, Academic Medical Center, University of Amsterdam, The Netherlands.

email: denheeten@gmail.com

COMPRESSION BASICS

The word compression itself suggests that the breast can somehow be made smaller in volume, which is not the case. A recap on some basic features of compression may be required:

- The human breast is deformable but is "compressible" in the strict sense of the word only to a very limited extent. What is generally achieved during the compression procedure in mammography is breast flattening
- Flattening is achieved by applying a force (1) by mechanical means to the upper surface of the breast. The effect of this force is

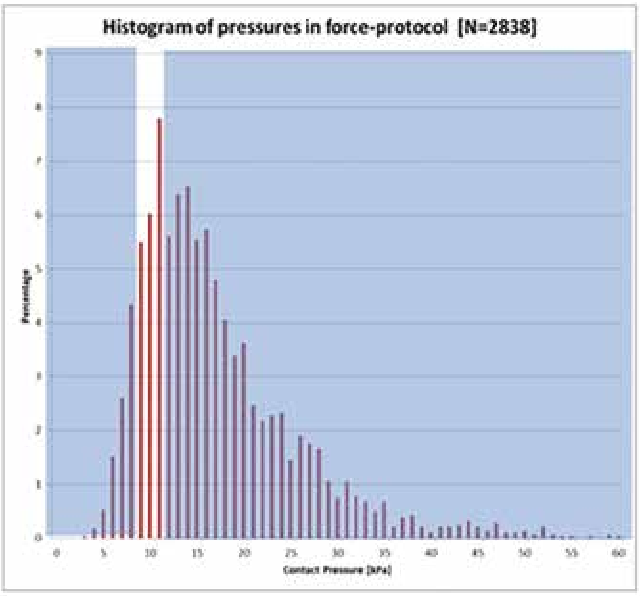

Figure 1: Histogram of pressure in standard force mammography (In our protocol we aim at 10 kPa).

determined by the viscoelasticity (2) and the volume (3) of the breast. These three factors determine a dynamic contact area (4) which increases as the compression increases, until it reaches a level which can be quantified by the mean contact area pressure (5), namely the force/contact area.

- The concept of force (expressed in the SI unit newton (N), as used in standard mammography is not suitable to describe or quantify the degree to which a body is affected by mechanical stress (which is what in fact causes the pain).
- Stress is a measure of the average amount of force exerted per unit area of a surface within a deformable body on which internal forces act. The SI-unit for stress is the pascal (Pa) which is also the unit of pressure (in medicine the unit of millimeter mercury (10 kPa = 75 mm Hg) is often still used).

Therefore, what standard mammographic procedures exert on the female breast is a force and what the female experiences is deformation of her breast. Since the breast has elastic properties, the contact area will vary in size during the increasing phase of the compression process. There are many factors influencing the viscoelastic behavior of the breast, but in the process of flattening the breast only the force can be controlled externally, since the other confounders, namely size and viscoelastic properties of the breast are individually determined. Since the breast can be flattened but only a little compressed, there is a limit to what can be achieved by increasing the force.

Some people have the misconception that the higher the force, the flatter the breast and thus the better the image.

A (more or less) standardized range of force between 12 and 18 daN (18 decanewtons = 180 N) as described in European and US guidelines will result in totally variable levels of the mean contact area pressure [Figure 1], depending on the individual properties of the breast. Ideally, to achieve a standardized and rational effect for an optimal mammographic image, individually determined amounts of force should be applied depending on the breast size and properties.

OPTIMIZING THE "COMPRESSION" PROCESS

In mammography, the acquisition of images of sufficient quality at

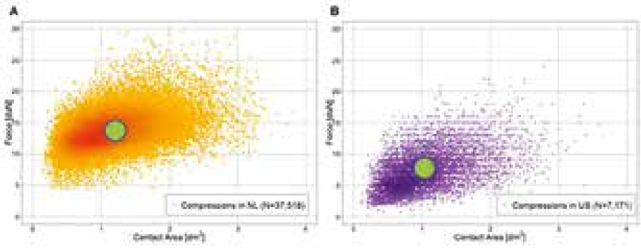

Figure 2: Graphical display of the range of forces between the contact area of the paddle and the breast in mammography. There is a large variation in forces applied within both the Dutch site (left panel) and the US site (right panel) and between Dutch and US sites. The green dots represent the center of the data.

the lowest radiation dose, requires compression of the breast. Since, as shown above, the amount of force applied is basically meaningless and in fact is the incorrect parameter to monitor, we defined the following research questions:

1. Can we develop a new method of compression that can be introduced in every currently commercially available mammographic unit and those of the future?
2. Can the frequent individual complaints from women regarding pain during and after mammography be correlated with and explained (at least in part) by large differences in applied pressure?
3. Is there an optimal pressure in mammography which not only allows optimal imaging and detection of lesions at a low radiation dose, but which is also comfortable for the woman.

INVESTIGATION

A multi-site study was carried out using data from a site in the USA and a larger sample from the Dutch breast screening program [2]. In the study, software from Volpara Analytics was used to record average force, pressure, breast thickness, breast volume, volumetric breast density and average glandular dose as a function of the size of the contact area between the breast and the compression paddle

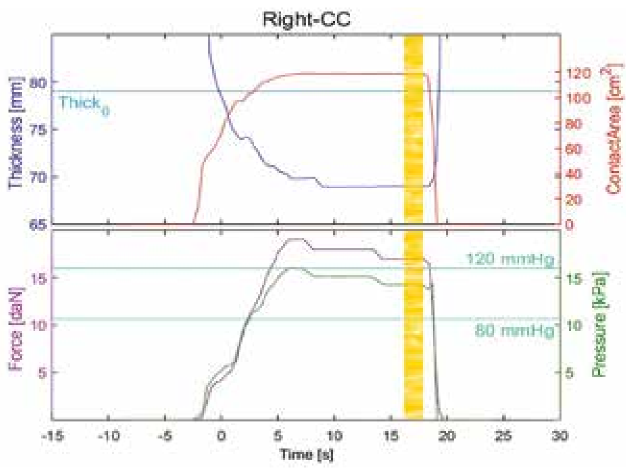

Figure 3: Real time recorded parameters versus time (thickness, contact area, force, pressure) during a single compression procedure. For comparison average blood pressure is indicated (80 – 120 mmHg). The vertical yellow bar indicates the image acquisition and radiation exposure

so that differences between sites and within individual sites could be quantitated. It was found that there was a large variation in the mean tissue force used during imaging [Figure 2].
These variations covered the range from the level of venous pressure up to several times systolic blood pressure and can be explained by the large individual differences in breast dimensions and elasticity. These in turn lead to differences in the size of the contact area between the breast and the paddle, which can vary by as much as a factor of 10 and consequently may result in differences in pressure of a factor of 10.

In an observational study we analyzed the standard compression procedure used in mammography [3]. We plotted the time course of the compression against the breast thickness, measuring the contact area and the force as a function of time [Figure 3]. By dividing the force by the contact area, the mean pressure can be derived and plotted versus time. The particular compression example shown in Figure 3 took about 5 – 10 seconds followed by a hold period of 10 – 15 seconds to allow the radiographer to reach the control desk and make the X-ray image acquisition. It can be seen that the compression is nonlinear, i.e. the rate of thickness reduction is reduced at higher forces. Since the parameters were measured during the whole compression period, these data enabled the breast tissue thickness, contact area (as well as the pain level reported by the woman) to be modelled. This model allows estimates of pain for any force and pressure to be made.

VALIDATION

The validation of our new compression procedure based on guidance by pressure rather than force was carried out via an intervention study performed within a unit of the Dutch national screening program and involving 500 women [4]. In this study, the pain experience as reported by the women, diagnostic image quality and dose were all recorded. Two compression protocols were used for each woman, one based on force with a target force of 14 decanewton (daN) and the other on pressure with a target pressure of 10 kilopascal (kPa). The different protocols were carried out in a random order for each woman and the technicians were blinded to the protocol. The majority of women considered the pressure-based protocol to be less painful than the one using 14 daN of force. One third of the women reported the same level of pain, and a relatively small group of women with large breasts (10%) reported more pain with the pressure-based protocols.
Four radiologists blinded to the protocol scored the diagnostic image quality. No statistically significant difference was found in image quality and the number of retakes between the force- and pressure-based protocols. In the pressure-standardized compression protocol, the average glandular dose (AGD) was reduced by 4,2% in Cranio Caudal view and 0,5% in Media Lateral Oblique MLO, as a result of filter switching and of a slightly harder energy X-ray beam.

Altogether these positive results were not really surprising to us since we anticipated that the introduction of a pressure-standardized procedure would improve quality. In fact the current lack of standardization throughout the world [Figure 5] results in many different local guidelines and differences in positioning training without taking into account quantitative breast sizes.

EFFECT OF PRESSURE ON SCREENING PERFORMANCE

The recent availability of Volpara Analytics software [5], enables the estimation of the contact area of the breast under compression during image acquisition. Hence the pressure can be computed retrospectively, opening up the possibility of analyzing established databases containing DICOM information and unprocessed images. Such analysis enabled the establishment of a relation between compression pressure and screening performance in a series of 113,464 screening exams [6]. The exams were categorized into five equal groups of increasing applied pressure, in such a way that each group contained 20 % of the exams. Pressure thresholds between the groups were 7.7, 9.2, 10.7 and 12.8 kPa. Measures of screening performance were then determined for the exams in each group. It was found that PPV and the cancer detection rate varied significantly within the five groups .There was a clear indication that the group with a moderate pressure (around 10 kPa) had a better performance than those in lower and higher pressure categories [Figure 4].

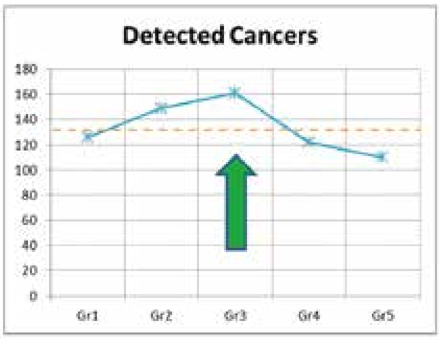

Figure 4. The difference in the number of cancers detected at different pressures in a total 113.464 examinations, split into five groups of different pressure. Each group contained the same amount of investigations. Group 3 (ca 10 kPa) has the highest detection rate.

DISCUSSION

We propose the use of a new compression procedure in mammography, based on a standard mean contact area pressure. To achieve this, we measure in real time the contact area which is related to the volume of the breast and the stiffness. The target pressure we aim for is 10 kPa (75 mmHg), the rationale behind this being that very little additional flattening of the breast can be expected at or above arterial blood pressure, as was shown in our prospective observational study [3].
It is not easy to show how our pressure-based compression relates to the conventional way of working because there is no single, conventional way of working. But we can compare our procedure to the most extreme compression protocols. In protocols with high target force (18-20 daN) serious over-compression will occur even if the technicians take,to some extent breast size into account. At the other extreme, a low target force (8-10 daN) protocol will produce serious under-compression in the larger breast.
The most fundamental difference with a pressure-based protocol is

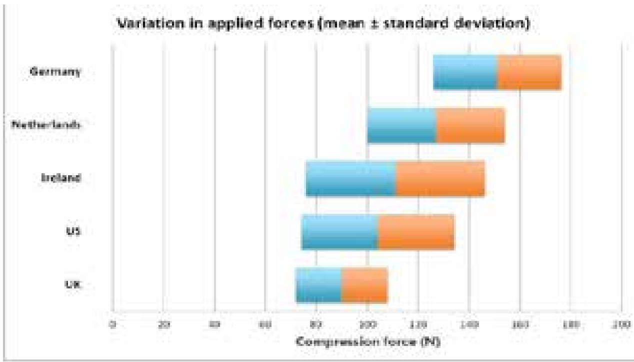

Figure 5 : Examples of the diversity of the mean force used in mammography compression throughout the world.

that every woman receives a personalized amount of force related to the contact area and stiffness and so makes mammographic compression predictable and repeatable.

Over-compression may result in unnecessary pain and discomfort, but the question is not if there is unnecessary pain in a 10 daN or a 18 daN protocol, but to what extent. It is obvious that in a country where the norm is to use a mean force of 10 daN, the number of complaints will be lower than in a country with a mean of 18 daN force.

But with the use of a pressure-based protocol, the extremes namely over-compression in small breasts and under-compression in large breasts will be avoided.

If it is possible to image the breast with pressures varying between 5 and 20 kPa, it may be asked if there is an optimal pressure. From a large study that was carried out, it appears that such an optimal pressure lies somewhere around 10 kPa.

Compression appears to be a "black hole" in mammography without any underlying rationale or standardization. This has resulted in completely different ways of carrying out mammography throughout the world [Figure 5] In some countries, even the guidelines for machine or phantom testing (between 10-20 daN) have been simply transferred into guidelines for the female population. Under-compression has an obvious effect on image contrast and will play a role in diagnostic performance. That over-compression plays a role not only in pain and discomfort but also in diagnostic performance, might surprise some readers but was already anecdotally known to many radiologists who were used to use cone down views, with disappearing distortions and tumors.

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A commercially available pressure-based compression paddle system

The new Sensitive Sigma Paddle uses multiple sensors to enable optimal breast compression for every breast, every time. Clinical trials of the system have shown positive clinical results and improved patient experience. In practice, the operation of the system is carried out in a few, simple steps::

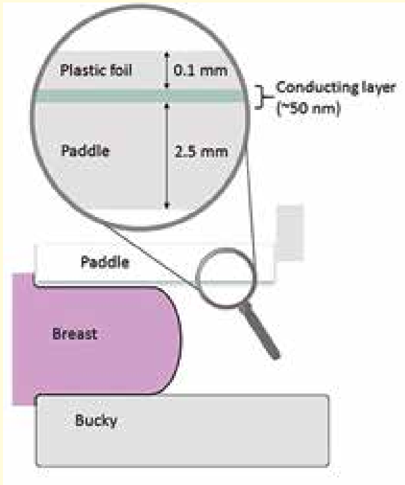
• The mammography technologist positions the breast and starts the compression;
• During compression, the real time pressure value is calculated automatically by the system and can be visualized from the built-in LED monitor lights;
• At the start of the procedure, i.e. with no breast compression, only the first LED is lit;
• As the pressure increases, additional LED's will light up;
• When the target pressure of 75 mmHg is reached the sixth LED will light up;
• The target pressure is chosen as being the optimal compression for this particular breast in this position;

The Sensitive Sigma Paddle from the Dutch company, Sigmascreening incorporates the new proprietary compression technology based on pressure standardization rather than force. The new unit is compatible with all current mammographic systems and can be easily retrofitted.

HOW DOES IT WORK?

In mammography a C-arm of the X-ray source and a x-ray detector is used to acquire mammograms. A plastic paddle is used for compression of the breast tissue during exposure in order to immobilize and flatten the breast so as to produce an optimal image and a minimal dose. The compression force is automatically measured in the C-arm of the mammography machine and is displayed, together with other parameters including the thickness of the breast tissue between the paddle and the detector cover.

To calculate the mean pressure — which is the basis of the new system—, the force



To automatically measure the contact area of the breast with the compression paddle, the Sensitive Sigma Paddle incorporates a proprietary thin (0.1mm) film containing silver nano-wires to measure capacitance. The film is fitted in the paddle and has minimal effect on X-ray transmission and scattering.

has to be expressed as a function of the area of the breast in contact with the compression paddle (contact area).

Thus, a method is needed to measure the contact area in real time.

The Sensitive Sigma Paddle system uses a capacitance-based method for which a conductive layer is needed in the paddle and which is transparent for light and x-rays. For this an innovative plastic foil covered with a layer containing very thin (~ 30 nanometers diameter) silver nanowires is used. This foil is similar in principle to those used widely nowadays in transparent touch screens.

The homogeneous foil (0.1- 0.2 mm) adds only approximately 4 – 8 % to the absorption and scatter of X-rays which already occur from the approx.. 2.5 mm thick paddle material. Repercussions on the image quality have been shown to be minimal.

The retrofittable paddle contains proprietary load cells and electronics to measure the force and the contact area. The ratio of the force and contact area is then automatically computed and visually portrayed on the rear of the paddle by LEDs, with each LED representing a mean pressure of 2 kilopascal (15 mmHg).

Sigmascreening
Amsterdam, The Netherlands
www.sigmascreening.com