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Towards personalized compression in mammography: A comparison study between pressure- and force-standardization

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ABSTRACT

Objective: To compare a conventional 14 decanewton (daN) force-standardized compression protocol with a personalized 10 kilopascal (kPa) pressure-standardized protocol.

Methods: A new add-on contact area detector, which enables pressure-standardized compression, is validated in a double-blinded intra-individual comparison study. Breast screening participants (433) received one craniocaudal (CC) and one mediolateral oblique (MLO) compression for both breasts. Three of these compressions were force-standardized, and one, blinded and randomly assigned, was pressure-standardized. Participants scored their pain experience on an 11-point numerical rating scale (NRS). Three experienced breast-screening radiologists, blinded for compression protocol, indicated which images required retakes.

Results: An unanticipated under-compression issue that occurred at forces below 5 daN was effectively solved with minimal extra radiographer training during the study. For pressure-standardized compressions obtained at 5 daN or more, the compressed breasts thickness increased on average 4.2% (MLO)—6.3% (CC), average pain scores were reduced by 10% (MLO)—17% (CC) and the proportion of women experiencing severe pain (NRS $\geq$ 7) was reduced by 27% (MLO)—32% (CC), compared with force-standardized compressions (all *p*-values <0.05). Average glandular dose (AGD) and proportions of retakes were similar for both protocols.

Conclusion: Pressure-standardized compressions resulted in AGD values and a retake proportion similar to force-standardized compressions, while pain was significantly reduced.

1. Introduction

In mammography, flattening of the breast reduces dose [1,2] and improves image quality [3–6]. However, these so called “breast compressions” are also associated with discomfort and pain [7,8]. The 2008 Cochrane systematic review found adverse effects [9–12] for several pain reducing strategies [11–14] and concluded that further research is called for [9]. There are also large variations in compression forces used between countries [15] [“this issue”] and between radiographers [16] (also called mammography technologists or breast imagers). One reason for these variations may be that mammography quality assurance guidelines worldwide [6,17] only mention subjective compression criteria such as “until the skin is taut at the sides” [18].

A recent observational study in a Dutch hospital [19] showed that women with small breasts significantly more often experienced severe pain than women with large breasts. We found that this is because the compression protocol of this hospital stated that the same target force should be applied to each breast, regardless the size of the breast. In this “force-standardized” approach, smaller

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breasts get much higher *pressures* (force per unit of contact area) than larger breasts. For that purpose, we developed a personalized compression protocol in which the same pressure is applied to each breast. This corresponds to applying forces that are proportional to the individual breast contact areas. Since women with smallest breasts experience most pain, it makes sense that less force is used for them, as is done in many countries and screening programs where there is no obligation to aim for a specified target force. What is new in our "pressure-standardized compression" approach is that we propose to *standardize* breast compression based on pressure, which at the same time may achieve pain reduction [19,20].

Pressure is expressed in the SI unit kilopascal ($1\,kPa = 1\,daN/1\,dm^2 \approx 7.5\,mmHg$). Since pressure is defined as "total force divided by contact area", it can be considered a breast "personalized" version of force. Pressure has the same physical dimension as tissue elasticity (Young's modulus) and blood pressure, whereas force itself is unrelated to any physiological parameter. Therefore, pressure may be more closely related to physiology than force. Since current mammography devices cannot measure the applied pressure in real time, we developed an add-on radiolucent contact area detector that enables compression to any desired target pressure.

The aim of this paper is to validate the use of a pressure-standardized compression protocol with a 10 kPa (75 mmHg) target pressure. This is done by comparing the compressed breast thickness, average glandular dose (AGD), pain experience, and the proportion of required retakes with respect to a strict implementation of the 14 daN target force compression protocol used in Dutch screening.

2. Materials and methods

2.1. Subjects and study design

This double-blinded intra-individual comparison study was performed in a breast cancer screening unit in Apeldoorn, the Netherlands. Approval was obtained from the Committee for Population Screening of the Health Council of the Netherlands [21]. We invited all women scheduled for a screening mammogram on 28 study days. Those who had previous breast treatment and those who did not understand the study information due to language or intellectual disability were excluded and received a regular mammogram. Participants ($n = 433$) aged 49–75 years (mean 60.2 ± 7.8 standard deviation), provided written informed consent. Each participant received a standard mammographic examination consisting of one craniocaudal (CC) and one mediolateral oblique (MLO) compression for both breasts. Of these four compressions, three were performed with the 14 daN force-standardized protocol, and one, blinded and randomly assigned, with the personalized 10 kPa (75 mmHg) pressure-standardized protocol. With the intention to maximize reproducibility (standardization), the radiographers aim to reach the target compression level as precisely and accurately as possible. However, less compression is used if the woman indicates that she considers the procedure too painful.

To prevent order-effect bias, a custom computer program provided a randomized order of compressions based on a predefined list; starting with the left breast as often as the right, starting with the two CC-compressions as often as with the two MLO-compressions and having the pressure-standardized compression equally often first, second, third and last. Since image quality and AGD of pressure-standardized mammography has not been validated before, the study was performed in two phases with a halfway evaluation of the available data. In the evaluation of phase 1, we identified an unanticipated technical issue leading to under-compression at low forces (explained in results). The cases with low forces will therefore be analyzed separately and presented alongside the complementary cases. To prevent this issue in phase 2, we implemented two measures: (i) a minimum force of 6 daN, and (ii) extra training for the radiographers. In the first phase ($n = 214$), the pressure-standardized protocol was always applied to one of the CC-compressions, and in the second phase ($n = 219$) always to one of the MLO-compressions. With this study design, each pressure-standardized compression has one force-standardized compression on the contralateral breast in the same view (CC/MLO), as well as two force-standardized control compressions in the other view (MLO compressions in phase 1 and CC compressions in phase 2).

2.2. Data acquisition

All compressions were performed on the same calibrated mammography device (Selenia S, Hologic Inc., Bedford, MA, USA). For performing the force-standardized compressions, we recorded breast thickness and applied force from the mammography device throughout each breast compression, as described in [19]. To enable pressure-standardized compressions, we also recorded the contact area by equipping both the small (18×24 cm) and large (24×30 cm) paddles with radiolucent and calibrated detector sheets (described in Appendix A). The ratio of applied force and contact area was continuously calculated to estimate the contact pressure at each moment of the compression. A custom display (see Fig. 1a) showed the compression level as percentage of the blinded target value, but not the actual values themselves. A team of five mammography screening radiographers, each with at least 2.5 years of experience, was instructed to compress the breast until the compression level was 100%. In this way, both the radiographers and the women were blinded for which protocol was used. All participants were instructed to hold their breath during X-ray exposure. After each compression, the radiographers asked the women to score their pain experience on a validated 11-point numerical rating scale (NRS) [22] with 0 indicating 'no pain' and 10 indicating 'unbearable pain'. We retrieved the AGD values calculated by the mammography device from the DICOM-headers. We also made video recordings ($n = 1732$) of all breast compressions for qualitative evaluation by a referent radiographer from the Dutch reference center for screening (LRCB, Nijmegen, the Netherlands).

2.3. Observer study

After the final inclusion, three breast-screening radiologists, who each have more than 9 years of experience and each have performed more than 100,000 mammogram readings, independently assessed all study images in randomized order. They were blinded for breast thickness, force, pressure, exposure settings and AGD, and they were asked to indicate for which image(s) they would require a retake in regular screening practice. If a retake was required, they had to indicate which of the following relevant ACR image quality criteria [23] were not met: breast positioning, image contrast, sharpness and/or parenchymal spreading. This observer study was performed without consensus reading.

2.4. Statistical analysis

To compare the differences between pressure-standardized and force-standardized compressions, five outcome measures were defined: (a) the average compressed breast thickness; (b) average glandular dose; (c) average pain score; (d) the proportion of women experiencing severe pain ($NRS \geq 7$), and; (e) the proportion of images for which one or more radiologists required a retake as part of the observer study. Based on Lilliefors tests