Optimal contact-pressure for Digital Breast Tomosynthesis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast disorders
Study type	Interventional

Summary

ID

NL-OMON49000

Source
ToetsingOnline

Brief title
Optimal pressure for DBT

Condition

- Breast disorders

Synonym
breast cancer, mamma carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Sigmascreening B.V., spin-off van het AMC,Sigmascreening B.V.;spin-off van het AMC

Intervention

Keyword: Compression, Mammography, Optimalisation, Tomosynthesis

Outcome measures

Primary outcome

We study the influence of the level of contact-pressure on three parameters: lesion conspicuity, absorbed glandular dose and pain experience. The primary analysis consist of two balanced one-way ANOVA tests, one for untreated and one for BCT-treated breasts. From this we determine whether one of the five levels of contact-pressure is significantly optimal for DBT.

Secondary outcome

The secondary objective is to assess the diagnostic value of compression-blinking and x-ray elastography. The research questions for this objective are radiologists* opinions on whether:

- these techniques improve the diagnosis (sensitivity, specificity)

- they reduce the need for follow-up diagnosis (ultrasound, biopsy)

- they are easy to integrate in the workflow (time needed)

- they are intuitive to interpret

Study description

Background summary

In conventional mammography, one of the reasons for breast compression is lateral spreading of the tissue to reduce overprojection. Because Digital Breast Tomosynthesis (DBT) combines multiple projection images from various angles into a pseudo 3-dimensional image, overprojection is less of a concern. It has therefore been hypothesised that less compression may be sufficient, however, all results in literature are based on reducing the target force. A

2015 PhD dissertation from the University of Amsterdam shows that pressure-standardized compression is preferred because it adjusts the compression force to the size and firmness of the individual breast. This is shown to reduce pain experience without compromising the image quality or increasing the absorbed glandular x-ray dose (AGD). Therefore, the AMC standard-of-care compression protocol since 2014 is to use a contact area average pressure of 10 kPa (* 75 mmHg) for all women. For DBT, it is however not yet known which level of contact-pressure (compression force divided by the breast-paddle contact area) is optimal.

Study objective

The objective of this study is to statistically identify the optimal level of contact-pressure for DBT. *Optimal* is defined as a weighed sum of three clinical interests: as high as possible lesion conspicuity, as low as possible absorbed glandular x-ray dose and as low as possible pain experience.

Study design

The objective is most directly achieved by using a within-women comparison study. Each breast will get a customized two-in-one DBT-recording whereby two DBT image sets are acquired at two different levels of contact-pressure without repositioning the breast. Three radiologists will compare lesion conspicuity, the absorbed glandular dose is retrieved from the DBT image information header (DICOM) and the participants are asked to rate their pain experience directly after each of the two DBT image-acquisitions. The ANOVA test will be used to select which level of contact-pressure is optimal: (rounded) 6, 8, 10 or 12 kPa.

Intervention

One of the DBT-recordings per included breast is replaced by a custom *two-in-one* DBT-recording. Instead of releasing the breast immediately after the x-ray exposure, the mammography technologist will apply slightly more pressure and make a second DBT-recording.

Study burden and risks

Participants will receive one extra DBT-recording per included breast on top of two routine recordings per breast. The extra DBT-recording will increase the total absorbed glandular dose per included breast but has the advantage of providing a second image set in which the breast is exactly in the same position but slightly more compressed. Differences between these two image sets will be visualized by blinking, which highlights the deformability of internal structures. Combined with the pressure-levels, we will calculate the strain map, which quantifies the elasticity of internal structures. Both can increase

the conspicuity of malignant lesions.

For obtaining the two-in-one DBT-recording, the breast will be flattened and immobilized approximately twice as long (60 to 90 seconds instead of 30 to 45 seconds). This could be more painful, however, all compression levels are based on the contact-pressure: the forces are therefore already adjusted to the size and firmness of the individual breast. The study will add two to five minutes to a total of 10 to 15 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. female
2. older than 30 years of age

3. receives DBT as standard procedure or as indicated by the responsible radiologist on site

Exclusion criteria

1. unable to understand the patient information folder
2. has or previously had breast endo-prostheses (implants);as breast treatment grouping criterion:
underwent any form of breast surgery or therapy, with the exception of Breast Conserving Therapy with radiotherapy

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-12-2018
Enrollment:	935
Type:	Actual

Medical products/devices used

Generic name:	Pressure-guided compression paddle
Registration:	No

Ethics review

Approved WMO

Date:	28-02-2018
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO Date:	28-02-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL63445.018.17