The influence of pressure instead of force on the compression procedure of breasts during mammographic examinations.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON33632

Source
ToetsingOnline

Brief title
Pressure measurements during mammography

Condition

- Other condition
- Breast disorders

Synonym
pain and discomfort during compression of the breast in mammography.

Health condition

de meeste personen hebben geen aandoening

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W,Screeningorganisatie SVOB;SKE lening

Intervention

Keyword: mammography

Outcome measures

Primary outcome

Dynamic information of pain, pressure in Pascal, force in daN, Thickness in mm,

contact area in mm2, total surface of the breast on the mammogram in mm2,

breast density.

During upgraded compression:

Correlation between VAS and EDA-measurement of pain.

Pain-pressure correlation.

Pain-thickness correlation.

Pain-pressure gradient correlation.

Pain-thickness gradient correlation.

Pain-breast density correlation

Pressure

Pressure gradient

Force

Force gradient

Thickness reduction

Thickness reduction gradient

Contact area between paddle and breast

Contact area gradient

Secondary outcome

Multivariate analysis of study parameters

Study description

Background summary

There are many complaints concerning the compression procedure in mammography. Over 25% of the examined women experience moderate to severe discomfort and pain. At an estimated number of 500 millions compressions per year worldwide a disconcerting number of complaints. Nearly all interventions have failed to relieve the number of these complaints (Cochrane 2002). Much research has been done from the viewpoint that women have differences in pain thresholds and that could be the reason. But in general women are supposed to have a higher pain threshold than men. When they sit for example on a chair they experience no complaints. Whereas the forces they exercise on their rear end and upper legs are much larger than those that are applied at mammography. Everyone knows the logic of that; the force is divided over a much larger area. It is remarkable that this is not taken into account at mammography.

Mammographic paddle and force
At the routinely used technique in compression of the breast a so called 'paddle' is being used, which is down pressed by means of a motor. During the procedure an increasing force is measured. This force is a reflection of the counterforce which is experienced by the paddle-arm during the compression procedure. This force is expressed in dekaNewton (daN), approximately corresponding to 1 kilogram weight (1 kgf).
The compression is a rather standardized way of working which is, however, dependent on the experience and the impression of the technician concerning what the woman can tolerate. The applied force is being monitored and is maximized (maximum 20 daN). Because of this the desired goal (flatness of the breast) is realized. When reasoned from the apparatus, this is a reasonable approach.

Flattening and pressure
From the object which is compressed, however, this is an other story. During the compression, the breast experiences an increasing pressure. It is

eventually this pressure, which results in the desired flattening of the breast. The final effect depends on the exercised force and the area on which that force is exercised (N/m2, Pascal). The size of a woman*s breast can strongly differ as everyone knows. From a small sample of 50 patients it has become clear that the volume can differ a factor 10. That means that the contact area of the breast with the paddle can equally strongly differ during maximum compression; in this group a factor 4. In the current routine procedure we measured at the extremes in a number of woman a maximum pressure under 100 mmHg, but we found also women where this pressure can run up to 500 mmHg. It will be clear that this has large consequences for the desired flattening, and possibly also for the accompanying complaints.

Study objective

The aim of the research is during a period of three months, to examine a total of 500 participants referred for mammography to the AMC. The different parameters which are relevant to compression will be measured. Particularly the influence of pressure has never been systematically examined in this respect. By measuring the discomfort and pain complaints during the advancement of the compression by means of a visual analog pain scale (VAS) we hope to find a correlation between the different parameters, to confirm the hypothesis that the complaints have a relation with the maximum pressure (and no relation with the force) that is exercised. In addition the pain will be measured with the Electrical skin impedance (EDA) as an independent physiological parameter for pain. If the pressure indeed can be connected to a specific moment the pain arose we would also be able to estimate the total amount of flattening (in mm) which were reached hereafter by further compression. In this way we hope to be able to stipulate a cut-off value. The eventual aim is to provide the mammography machines with pressure sensors to prevent the observed extreme pressures in the future and as a result of which possibly a large number of complaints can be prevented. This would also have a positive influence on the compliance in the screening program.

Study design

The patients will be subjected to a normal routine mammographic investigation. During the research periode one type of paddle will be used.

Technical aspects of the method:
The mammographic machine will be equipped with an (optical) contact area meter. In the advancement to and during the maximum compression in same period of time the thickness reduction, incurring force, and the incurring contact area of the paddle with the breast is measured. These other parameters can are already measured in the machine itself. From the dynamic force and the contact area parameters the dynamic pressure range can be calculated.

Pain measurement:
First there is a short introduction and a hand out of the written information.
The radiologists performing the clinical mammography will not be aware if a woman has given her consent or not.
In advance of the investigation and after written informed consent, the woman receives a short instruction concerning the use of the continuous VAS-measurement. In addition the pain will be measured with the Electrical skin impedance (EDA) as an independent physiological parameter for pain. Directly after the procedure she is asked for her findings. These are noted.

The measured parameters will be stored directly in a database.

The pain scores will be correlated to the course of the different individual parameters and combinations of it.

At the informed consent, women will be asked if they are willing to comply to an telephonic interview which will take a couple of minutes and contains standard questions about her experiences at 14 days since the mammographic investigation.

The mammograms will routinely be scored according the clinical BI-RADS lexicon. The breast density will receive an ACR density score.

The number of prior mammograms will be taken in to account.

The size and thickness of the breasts will be compared to samples from anonymous data from digital screening units of various regions to trace a selection bias. This because of the specific profile of the academic population of the AMC.

Study burden and risks

Compared to a normal routine mammographic investigation, no extra risk can be identified.

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

Any referred woman for mammography, without a history of surgery.

Exclusion criteria

breast surgery (amputation or lumpectomie). Wheelchair patients.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2011
Enrollment:	500
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
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	NL25557.018.09