National Call for Projects

French Hospital Research Program in Oncology PHRC Cancer 2012
Application Form


Project title:
ITACTs: Impact of self-compression on tolerance in the mammography experience

Keys words:

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<th>Project area :</th>
<th>Radiology</th>
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<td>Organ, tumor location :</td>
<td>Breast</td>
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<td>Other :</td>
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Sponsor:
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Budget planned over 4 years:
203 000 euros
Statistical analysis plan of ITACTs

Impact of self-compression on tolerance in the mammography experience

Funded by the French Hospital Research Program PHRC 2012, ITATCs
ClinicalTrials.gov Identifier: NCT02866591
Protocol version 5 du 20.04.2015

Principal Investigator : Dr Philippe Henrot, Radiologist

Written by Julia Salleron and approved by Dr Emmanuel Desandes

Signatures
Dr Philippe Henrot Dr Emmanuel Desandes Julia Salleron

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1 Introduction

a. Background and rationale
Mammography is the most effective method for screening, diagnosis, and follow-up of breast cancer. It is sometimes poorly tolerated by some patients who complain of uncomfortable or painful nature of the examination. This may compromise participation in mammographic screening campaigns. The goal of breast compression by the technologist is to reduce breast thickness during mammography. It is an important pain factor. It is also a key to achieve the best image quality of mammograms. That's why breast compression is required by Good Practice Referential.

b. Objectives
This study will compare self-compression to standard technique of compression by the technologist and will focus on the technical parameters such as compressed breast thickness, compressive force and on the image quality by performing a simple blind analysis of the blur by the radiologist on a 4-points scale. The global tolerance of mammography will be evaluated by the patient at the end of the exam and will be measured by a Visual Analogue Scale (VAS). The comparison will also focus on the patient's self-satisfaction by a score on the validated MammoGraphy Questionnaire (MGQ) and on the technologist self-appreciation.

2 Study Methods

c. Trial design
Randomized, multicentre and prospective with two parallel groups of patients

- experimental group : self-compression

- standard group: technologist-controlled compression

d. Randomization
Randomization in the self-compression technique or the standard-compression technique with an allocation ratio of 1:1 by computer-generated random numbers stratified by center.
e. Sample size
See research protocol.

3 Analysis

f. Level of statistical significance

As mentioned in the protocol, a one-sided 95% confidence interval will be computed for the primary outcome. For all other parameters, a two-sided 95% confidence interval will be computed and two-sided superiority test will be performed.

g. Primary endpoint

Definition

Value of the compressed breast thickness (millimetres) for each view: right/left craniocaudal (CC) and right/left mediolateral oblique (MLO)

Statistical analysis

Normality of the distribution will be investigated by the Kolmogorov-Smirnov test. In case of a non-normal distribution, a transformation of the primary outcome will be performed (square root transformation, reciprocal transformation...) in order to obtain a normal distribution.

The reproducibility of the four measures of the breast thickness measured in millimeter will be investigated by the intra-class correlation coefficient according to the Fleiss method (1).

If the intraclass correlation coefficient is greater than 0.8, the reproducibility of the four measures will be considered as a good reproducibility. In this case, for each patient, the mean of these four measures will be computed. This mean will be the primary endpoint. The primary outcome analysis will evaluate the non-inferiority by calculating the one-sided 95% confidence interval for the difference in breast thickness (standard compression minus self-compression). If the upper bound of the one-sided 95% CI for this difference is less than the inferiority margin (i.e., +3 mm), inferiority will be rejected. Two-sided superiority analyses were conducted on an intention-to-treat basis for the breast thickness of each view as secondary analysis.

If the intraclass correlation coefficient is less than 0.8, the analysis mentioned in the research protocol will be performed.

h. Secondary endpoints

Normality of the distribution will be investigated by the Kolmogorov-Smirnov test. In case of a non-normal distribution, Mann-Whitney U tests will be used and endpoints will be described
by median and inter-quartile range. Otherwise, endpoints will be described by mean with 95% confidence interval and Student T-test will be performed.

For qualitative parameters, Chi-squared test or Fisher Exact test will be used to compare the two arms.

i. **Analysis populations**

Analyses will be performed on the intention-to-treat sample (all randomized patients). A sensitivity analysis will be performed after removing patients who not completed the compression originally allocated.

j. **Statistical software**

Statistical analyses will be performed using SAS version 9.4 (SAS Institute Inc., Cary, NC, USA)

(1) Fleiss J. The design and analysis of clinical experiments. N. Y. NY Wiley 1986;1–31
# ITACTs Protocol

## ITACTs: Impact of Self-Compression on Tolerance in the Mammography Experience

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Abstract

**Title: Impact of self-compression on tolerance in the mammography experience**

**Abstract:**

Mammography is the most effective method for screening, diagnosis, and follow-up of breast cancer. Many patients report unpleasant experience after mammography and complain about pain at the time of the compression of the breast applied for each mammographic view. Breast compression is a key to achieve the best image quality of mammograms. That is why it is required in Good Practices Referential. By decreasing the breast thickness, compression allows reducing the scattering, and increases contrast. It also shortens the acquisition time so time for exposure and reduces the motion blur. At least it decreases the average glandular dose. According to the literature, a painful and uncomfortable mammography experience could compromise the adherence of mammographic screening campaigns.

Self-compression is currently not routinely used and only a few references report this technique in the literature.

Hypothesis of self-compression significantly reducing painful experience coupled to a radiographic image as good as that produced by means of technologist-controlled compression was proved on 109 women (1). 96% of patients were satisfied by self-compression. Another study evaluated mammographic tolerance according to reduced compression force. Compression pressure was decreased from 120 to 90 Newton. Consequently, the breast thickness with lower compression increased approximately by 3 mm. But Images quality was identical to that with standard (2).

We propose to evaluate the impact of self-compression on the result comparing to standard compression by the technologist, in a randomised prospective multicentric study in simple blind. 550 women aged from 50 to 75 years old having a breast-screen mammography or a distant survey following a treatment posterior to a breast lesion will be randomized in two groups:

- 275 experiencing self-compression (experimental arm)
- 275 having technologist-controlled compression (standard arm).

After signing free informed consent patient will be tested in a standardized pre-test to evaluate and validate their own ability to run self-compression. The percentage of women failing to the pre-test will be noted.

Process of mammogram views will be standardized. Two routine views of diagnosis - cranio-caudal (cc) and mediolateral-oblique (MLO) – will be done in the following sequence: CC on the right breast – CC on the left breast – MLO on the right breast – MLO on the left breast.

If necessary other views will be done at the end of the 4 routine views and radiologist motivation will be noted.

The comparison of self-compression to the standard will focus

- on breast thickness as the principal objective
- secondary on compression strength and images quality by simple blind appraisal of motion blur by the radiologist on a 4-points scale.

Patients will measure Global tolerance especially pain intensity of mammography on a Visual Analogue Scale (VAS).

Comparison will focus on Patient satisfaction by collecting the validated Norwegian MammoGraphy Questionnaire (MGQ) and on technologist appraisal.

A sample size of 550 patients (275 in each group) is necessary to demonstrate that a self-compression is at least not appreciably worse than standard compression in the non-inferiority study design, taking into account a 3 mm difference in the breast thickness between the two
compression methods (2) with an average breast thickness of 39 mm, a power of 90% and a type I error alpha of 5%.
Both techniques will be compared by a mathematical model taking into account the correlation between the measurements of the 4 views and using GEEs (Generalized Estimating Equations) methods on repeated measurements. The type I error alpha will be of 5%. Statistical analysis will be done by the SAS software, v9.3.
### Specific Informations

| Involvement of a clinical research structure. If yes tick the appropriate box | YES | NO |
| Data management center, approved by INCa | | |
| CIC-P Clinical Investigation Centre - plurithematic | | |
| CIC-EC Clinical Investigation Centre – Clinical epidemiology / clinical trial | | |
| CIC-BT Clinical Investigation Centre - biotherapy | | |
| CIC-IT Clinical Investigation Centre – technological innovation | | |
| Thematic Research and Health Care Centres / Networks (specify which ones) | | |
| Clinical research unit (specify if relevant) | Clinical Research Center labelled in 2011 by the French Minister of Health | |
| Other | | |

| Does the project involve the use or preparation of cell therapy, gene therapy or xenogeneic cell therapy products, or the implementation of such therapies or assessment of therapeutics, for therapeutics purposes, organs or animal tissues? | YES | NO |

| Biomedical research as in art. L.1121-1 of the French Public Health code | YES | NO |

| Non-interventional research as mentioned in articles L.1121-41 and R.1121-2 of the French Public Health code | YES | NO |

| Research related to current care as mentioned in art L.1121-41 and R.1121-3 of the French Public Health code | YES | NO |

### In the case where the therapeutic trial project deals with products mentioned in article L.5311-1 of the French Public Health code, specify the following items

| Trial on patients | YES | NO |
| Drug trial | YES | NO |
| Randomised trial | YES | NO |

| The risk is justified by: | YES | NO |
| - The expected benefit for the person participating to the research | YES | NO |
| - The expected benefit for other persons | YES | NO |
| Compensation for suffered damages | YES | NO |
| Accrual planned in the protocol | 550 | |

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<td>- cancer fight centres</td>
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<td>- French private, non-profit hospital participating in the public hospital sector</td>
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<td>- Professional physicians</td>
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| Multidisciplinary project, If yes, specify concerned areas | YES | NO |

## Co-funding

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<td>Other (indicate the requested amount)</td>
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<p>| Cooperation with research organisms (INSERM or other) |     |    |
| If yes, please specify                               |     |    |</p>
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<table>
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<tr>
<th>Team 1 (Coordination Team)</th>
<th>Pr / Dr / M. / Mme</th>
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<th>Function in the project</th>
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### Detailed Clinical Research Project

**Impact of self-compression on tolerance of the mammography experience**

#### SYNOPSIS

<table>
<thead>
<tr>
<th><strong>Title</strong></th>
<th><strong>Impact of self-compression on tolerance of the mammography experience</strong></th>
</tr>
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<tbody>
<tr>
<td><strong>Coordinator</strong></td>
<td>Dr Philippe HENROT</td>
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#### Rational

Mammography is the most effective method for screening, diagnosis, and follow-up of breast cancer. It is sometimes poorly tolerated by some patients who complain of uncomfortable or painful nature of the examination. This may compromise participation in mammographic screening campaigns.

The goal of breast compression by the technologist is to reduce breast thickness during mammography. It is an important pain factor. It is also a key to achieve the best image quality of mammograms. That’s why breast compression is required by Good Practice Referential.

This study will compare self-compression to standard technique of compression by the technologist and will focus on the technical parameters such as compressed breast thickness, compressive force and on the image quality by performing a simple blind analysis of the blur by the radiologist on a 4-points scale. The global tolerance of mammography will be evaluated by the patient at the end of the exam and will be measured by a Visual Analogue Scale (VAS).

The comparison will also focus on the patient’s self-satisfaction by a score on the validated MammoGraphy Questionnaire (MGQ) and on the technologist self-appreciation.

#### Study design

Randomized, multicentre, prospective and simple blind study:
- experimental group: self-compression
- standard group: technologist-controlled compression

Eligible patients who signed an informed consent will be randomized only after validation of their capability to run self-compression, thanks to a standardized pre-test. The percent of women who won’t validate this pre-test will be noted.

The order of mammographic views will be standardized for all the patients included in the study. The two mammographic views of the breast standard screening plan – face and oblique- will be used in the following order: craniocaudal right breast, craniocaudal left breast, mediolateral-oblique right breast and then mediolateral-oblique left breast. The realization of extra mammographic views at the end of the 4 views will be noted but not analysed.

#### Principal objective

To compare the impact of two breast compression techniques in mammography (self-compression against technologist-controlled compression) on the value of compressed breast thickness (millimetres)

#### Secondary Objectives

To compare the impact of both breast compression techniques (self-compression against technologist-controlled compression)
- For each mammographic view on:
  - Compression strength (Newton)
  - Breast thickness / compression strength ratio
  - Motion blur correlated with image quality and estimated by the blinded radiologist with a 4-point scale.
- All in all on:
  - Over-all pain evaluation by the patient at the end of the mammography on a Visual Analogue Scale (VAS)
- Patient’s self-satisfaction by using the validated Norwegian MammoGraphy Questionnaire (MGQ).
- Technologist’s assessment score

### Inclusion criteria

1. Women aged from 50 to 75 years old  
2. Performance status < 2  
3. Screening Mammography or mammography after a treatment-gap supervision for a breast lesion  
4. Signed informed consent  

Menopausal status and eventual hormonal treatments will be noted

### Non-inclusion criteria

1. Performance status ≥ 2  
2. Treatment for benign lesion by surgery within the last 3 years  
3. Treatment for cancer with surgery and / or radiotherapy within the last 3 years  
4. Breast macro biopsy for less than 1 year  
5. Persons deprived of liberty or under guardianship  
6. Breast implant  
7. Previous mastectomy  
8. Discovery of a suspected lesion at the inclusion  
9. Patient presenting active, symptomatic, painful lesions, which could affect the pain appreciation and the quality of breast compression (mastodynia)

### Method

Eligible patients who signed an informed consent will be randomized into 2 groups: self-compression against technologist-controlled compression after validation of a pre-test intended to uphold their capability to realize self-compression in standardized conditions.

If the designated group is “technologist-controlled compression”, the radiographer will realize the mammography with the standard practice.  
If the designated group is “self-compression”, the radiographer will lead the compression to the minimum threshold of 40 Newton and then will leave control of the compression to the patient. Then the radiographer will only deal with the breast positioning on the captor.  
Whatever the used technique, the process of mammographic views is the same for all the patients: cranio-caudal right breast, cranio-caudal left breast, medio-lateral oblique right breast and then medio-lateral oblique left breast.  
If need, extra mammographic views asked by the radiologist will be realized at the end of the 4 mammographic views of this study.

At the end of the 4 mammographic views, according to a standardized procedure, the radiographer explains to the patient the use-principle of the Visual Analog Scale (VAS) to evaluate the overall pain tolerance about the 4 mammographic views.  
The patient puts the scale cursor evaluating her pain and the radiographer carries forward the indicated value on the back of the scale in millimetres.  
The radiographer also writes the value of breast thickness (millimetre) and compression strength (Newton) for each mammographic view.

The radiographer sends all performed mammographic views to the PACS workstation, regardless of their quality, without informing the radiologist about the used technique.  
The radiologist evaluates in a simple blind methodology the motion blur from 1 to 4 for each mammographic view and each breast.

Any extra mammographic views are not analysed on the field of the protocol (additional mammographic views, spot compression or magnification views, echographic images or further investigations). The number of these extra mammographic views and the reason of a new examination will be written in the Case Report Form but are excluded of the statistical analysis. At the end of the mammography, the Norwegian self-questionnaire of...
satisfaction, the MammoGraphy Questionnaire (MGQ) will be proposed to the patient and will be completed before her departure of the imaging centre. The radiographer will also give his global appreciation of the study thanks to a specific score.

**Assessment criteria**

Main assessment criterion:
Compressed breast thickness (millimetres)

Secondary assessment criteria:
- For each performed mammographic view:
  - Value of compression strength (Newton) measured on PACS workstation
  - Calculation of breast thickness / compression strength ratio
  - Motion-blur score estimated by the radiologist in a simple blind methodology with a 4-points scale.

- Over-all mammographic tolerance with pain measurement by the patient on Visual Analogue Scale (VAS) (millimetres) at the end of the mammography.
- Evaluation of patient's satisfaction about the performed mammography by using the validated Norwegian MammoGraphy Questionnaire (MGQ)
- Radiographer’s assessment score for the study

**Patients number**

Calculation of the patient's number
In a non-inferiority study, supposing a compression mean of 39 mm [standard deviation 12 mm] (37) unchanged between self-compression and radiographer-compression with a maximum tolerance of 3 mm, an I type alpha risk of 5% and a power of 90%, the attended patient number in each group is 275. Altogether that comes to 550 patients.

**Statistical analysis**

Quantitative parameters will be reported in mean values more or less standard deviation; qualitative parameters will be presented in size and percentage.

Demographic and clinical parameters of the 2 groups will be compared by a Student t-test (quantitative parameters) or a chi-2 test (qualitative parameters).

To do over-all comparison between self-compression and technologist-controlled compression considering simultaneously the 4 performed mammographic views, assessment criteria for both techniques will be compared with Generalized Estimating Equations (GEEs) model on repeated measurements (37,38).

The I-type alpha risk to assess the significance of a difference is set to 0.05. All statistical analysis will be performed using Statistical Analysis Systems software, version 9.3.

**Investigation centres**

5 French centres

**Inclusion time**

18 months

**Study time**

24 months
Impact of self-compression on tolerance of the mammography experience

I. Synthesis of the literature and rational

1) Introduction

Mammography is the first-line examination for screening breast cancer, diagnosis of a breast abnormality, evaluation of locoregional treatment and post-treatment follow-up. Organized screening performed among women from 50 years reduces mortality from breast cancer by about 30% (1, 2). Women's participation is a parameter that determines the benefit of a screening campaign since studies showing participation rates close to 70% have reported the best results. There are several factors that explain the resistance of some women to perform a mammogram, that are socio-economic (geographic isolation, transportation difficulties, language barriers), psychological (fear of cancer, shame to undress), lack of compliance of their doctors to screening guidelines and the mammography technique itself (fear of radiation, discomfort or pain induced by the exam) (3-10).

Mammography is experienced as uncomfortable or painful for some women, to varying degrees, from 1 to 62% depending on authors (11-16). Stomper and al assessed the pain in 1847 women after mammography, and reported no discomfort or mild discomfort in 88% of women, moderate discomfort in 9%, severe in 1% and pain in 1% of women (12). Jackson et al. in 356 women reported experience of comfortable examination in 48%, uncomfortable but tolerable in 38%, very uncomfortable in 11% and intolerable in 3% of women (17). Rutter and al. among 597 women reported discomfort in 35% of women, pain in 6%, always disappearing after 10 minutes. The type of pain reported is mainly sensitivity or crushing (18).

Predictors of pain reported are the high socio-educational level, performing a clinical examination before mammography, fear of discomfort or pain before the test (18). Breast tension or premenstrual breast pain for premenopausal women, prior to the mammogram, are also reported as predictors of pain during the examination (19).

The discomfort and sometimes pain felt when performing a mammogram is associated with the mammography technique, detailed in guidelines, which strict compliance determines the diagnostic performance of the examination (20, 21). The North American Mammography Quality Standards Act published in 1997 identifies seven technical parameters conditioning the image quality mammography to be subject to periodic evaluation: positioning, breast compression, contrast, exposure, noise, sharpness, artifacts (21).

Breast compression is essential to achieve the best image quality and diagnostic performance of mammography. It consists in applying a force in order to reduce breast thickness during X-rays acquisition. Compression reduces the superposition of fibro-glandular structures that could create false images of abnormalities or that could occult actual lesions, it allows optimal spreading of fibro-glandular structures, ensuring good reproducibility of images over time, it reduces the scattered radiation which alters contrast, it reduces the irradiation of the breast, it reduces motion blur by immobilizing the breast and reducing the exposure time, then it reduces the geometric blurring by reducing the magnification ratio (22, 23, 24).

There is no recommendation setting the value of compression to apply to a patient. The European Guidelines indicates that compression should be performed "firm but tolerable" with a maximum value between 130 and
Compression is the main source of discomfort reported by women during mammography, however, there is no linear relationship between the value of compression and discomfort, nor between the value of compression and compressed breast thickness (25). The ratio of thickness / compression force seems better correlated to the level of discomfort than each sole parameter, according to Sullivan et al. (26). For Poulos and Sullivan, it is unnecessary to continue breast compression when the thickness has reached a minimum, because there is no benefit on the quality of the image, though the discomfort or pain are increased (25 26).

2) Rational

The aim of this study is to give the patient control of the compression of the breast during mammography and assess the impact of this technique on the tolerance of the examination.

Sharing control of the examination with the patient was suggested by Eklund who proposed patients with fear of having pain before the exam to reschedule their appointment and observed that these patients tolerate more compression when taking the decision to do further the examination (22).

Kornguth reported in 109 women's the interest to let the patient control the compression of one of the two breasts on the tolerance of the examination, assessed on an analogical scale of six points and on a satisfaction questionnaire. Tolerance was significantly improved on the side of self-compression in 71% of patients, and the satisfaction rate was 81% (27). To our knowledge, it is the only reference dealing with the self-compression of the breast.

The active participation of the patient during the examination could improve tolerance similarly to what has been reported on studies of self-inflicted pain (28).

There is a study which evaluates mammographic tolerance according to reduced compression force. Compression pressure was decreased from 120 to 90 Newton. Consequently the breast thickness with lower compression increased approximately by 3 mm. But Images quality was identical to that with standard (36).

We propose to evaluate on the result the impact of self-compression comparing to standard compression by the technologist, in a randomized prospective multicentric study in simple blind. A better tolerance of mammography is waited with a similar breast thickness after compression coupled with identical images quality.

3) Previous recommendations of the Scientific Committee

This project has not been previously selected in 2010 in spite of an interesting objective. The recommendations of the Scientific Committee were about methodology:
- an heterogeneous population very different from breast cancer screening population
- main assessment criteria not in accordance to the scientific question
- double blind design not understood

All these aspects were changed in this new project: homogeneous breast cancer screening population, simple blind study for radiologist appraisal of images quality and assessment criteria in accordance with objectives.
II. **Objectives of the study**

1) **Main objective**

To compare the impact of two breast compression techniques in mammography (self-compression against technologist-controlled compression) on the value of compressed breast thickness (millimeters).

2) **Secondary objectives**

To compare the impact of both breast compression techniques (self-compression against technologist-controlled compression)

- For each mammographic view on:
  - Compression strength (Newton)
  - Breast thickness / compression strength ratio
  - Motion blur correlated with image quality and estimated in blind by the radiologist with a 4-points scale.
- All in all on
  - Over-all pain evaluation by the patient at the end of the mammography on a Visual Analogue Scale (VAS)
  - Patient’s self-satisfaction by using the validated Norwegian MammoGraphy Questionnaire (MGQ).
  - Technologist’s assessment score

III. **Study design**

Randomized, multicentre, prospective and simple blind study:
- Experimental group: self-compression
- Standard group: technologist-controlled compression

Eligible patients who signed an informed consent will be randomized only after validation of their ability to run self-compression, thanks to a standardized pre-test. The percent of women who won’t validate this pre-test will be noted.

The order of mammographic views will be standardized for all the patients included in the study. The two mammographic views of the breast standard screening plan – face and oblique- will be used in the following order: craniocaudal right breast, craniocaudal left breast, mediolateral-oblique right breast and then mediolateral-oblique left breast.

The realization of extra mammographic views at the end of the 4 views after request by the radiologist will be noted but not analysed.

IV. **Patients selection**

1) **Inclusion criteria**

1. Women aged from 50 to 75 years old
2. Performance status <2
3. Screening Mammography or mammography after a treatment-gap supervision for a breast lesion
4. Signed informed consent
Menopausal status and eventual hormonal treatments will be noted

2) Non-inclusion criteria

1. Performance status \( \geq 2 \)
2. Treatment for benign lesion by surgery within the last 3 years
3. Treatment for cancer with surgery and / or radiotherapy within the last 3 years
4. Breast macro biopsy for less than 1 year
5. Persons deprived of liberty or under guardianship
6. Breast implant
7. Previous mastectomy
8. Discovery of a suspected lesion at the inclusion
9. Patient presenting active, symptomatic, painful lesions, which could affect the pain appreciation and the quality of breast compression (mastodynia)

V. Randomization of patients

Eligible patients who signed an informed consent will be randomized into 2 groups:
- Experimental group: self-compression
- Standard group: technologist-controlled compression

They will be randomized only after validation of a standardized pre-test intended to uphold their capability to run self-compression in standardized conditions.

The randomization will be done thanks to pre-established tables. One for screening-failure numbers (9XX) and another one for randomization number.

Whatever the technique will be attributed, the order of mammographic views will be standardized for all the patients included in the study.

The two mammographic views of the breast standard screening plan – face and oblique- will be used in the following order: craniocaudal right breast, craniocaudal left breast, mediolateral-oblique right breast and then mediolateral-oblique left breast.

The radiologist doesn't know which technique has been used for motion-blur score appraisal.

VI. Study progress

The patient identified on arrival at the imaging center to be eligible, is received by the radiologist who confirms eligibility, and if so, he explains the principles of the study and invites her to participate.

The radiologist explains the study and collects the signed informed consent.

Eligible patients who signed an informed consent do a standardized pre-test to assess their capability to realize self-compression in standardized compression.

The pre-test consists in a five-step process:
1. The radiographer explains to the patient why the pre-test is useful
2. The radiographer explains how breast compression works on the mammography device and invites the patient to test the compression
3. The patient is prepared for the first view by the radiographer
4. A breast positioning is made by the radiographer and the patient self-compressed it without using x-ray.

5. The radiographer validates the patient’s capability to use self-compression considering that the patient’s compression allows x-ray image capture.

If the patient fails, she won’t be randomized and will have a screening failure number. If she succeeds, then she will be randomized into 2 groups:
- experimental group: self-compression
- standard group: technologist-controlled compression

Thus, the patient will have a randomization number (given by pre-established table). Each centre will have its own pre-established randomization table to facilitate the inclusions process.

Fax of the screening failure number or of the randomization number will be sent to the Alexis Vautrin Centre to inform of the inclusion.

If the designated group is “technologist-controlled compression”, the radiographer will realize the mammography with the standard method (39).

If the designated group is “self-compression”, the radiographer will lead the compression to the minimum threshold of 40 Newton and then will leave control of the compression to the patient. The radiographer only deals with the breast positioning on the captor.

Regardless of the technique, the order of mammographic views is: craniocaudal right breast, craniocaudal left breast, mediolateral-oblique right breast and then mediolateral-oblique left breast.

At the end of the 4 mammographic views, according to a standardized procedure, the radiographer explains to the patient the use-principle of the Visual Analogue Scale (VAS) to evaluate the over-all pain tolerance about the 4 mammographic views.

The patient puts the scale cursor evaluating her pain and the radiographer carries forward the indicated value on the back of the scale in millimetre.

The radiographer records the values of breast thickness (millimeters) and compression strength (Newton) and calculates the breast thickness/compression strength ratio for each mammographic view.

He writes all data on the Case Report Form.

He sends all performed mammographic views to the PACS workstation, regardless of their quality, without informing the radiologist about the used technique.

The radiologist evaluates the motion blur from 1 to 4 on a 4-points scale for each mammographic view. He records these data in the Case Report Form.

Then he keeps on his interpretation of images and clinical management of the patient.

If necessary, extra mammographic views asked by the radiologist are realized. Any extra mammographic views are not analysed on the field of the protocol (additional mammographic views, spot compression or magnification views, sonogram scan or further investigation). The number of these extra mammographic views and reasons of a new examination are recorded in the case report form.

At the end of the mammography, the Norwegian self-questionnaire MammoGraphy Questionnaire MGQ is given to the patient and is completed before her departure of the imaging centre.

The radiographer also gives his global appreciation of the study thanks to a score.

A summary of the process is presented in the figure 1.
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Patient identified on arrival at the imaging center to eligible
Inclusion criteria checking

Study proposal
Informed consent sign in

Pre-test realization

Success
Randomization

Randomization N°
Randomization table

GROUP 1: SELF-COMPRESSION

Realization of the mammograms:
- Craniocaudal right breast
- Craniocaudal left breast
- Mediolateral-oblique right breast
- Mediolateral-oblique left breast

AT EACH MAMMOGRAPHIC VIEW
- Radiographer:
  - Recording of breast thickness and compression strength
  - Calculation of breast thickness/compression strength ratio
- Radiologist (simple blind): Motion blur rating

GROUP 2: RADIOGRAPHER-CONTROLLED COMPRESSION

AT THE END OF THE EXAMINATION
- Patient:
  - Over-all pain evaluation (VAS)
  - Self-satisfaction Questionnaire
- Radiographer: Examination appreciation

Fail

Out of the study

Screening failure N°
Screening-failure table 9XX

Normal follow-up care of the examination
If need, extra mammographic views

Fax the inclusion form

End of the study
VII. Evaluation criteria

1) Main assessment criterion

Value of the compressed breast thickness (millimetres)

2) Secondary assessment criteria

- For each performed mammographic view:
  - Value of compression strength (Newton) measured on PACS workstation
  - Calculation of breast thickness / compression strength ratio
  - Motion-blur score estimated by the radiologist in a simple blind methodology with a 4-points scale.

- Over-all mammographic tolerance with pain measurement by the patient on Visual Analogue Scale (VAS) (millimetres) at the end of the mammography.
- Evaluation of patient’s satisfaction about the performed mammography by using the validated Norwegian MammoGraphy Questionnaire (MGQ).
- Radiographer’s assessment score.

The evaluation of the blur (or sharpness) of the image is adapted from previous work published in the literature (32-35). Baines evaluates the image quality of 830 mammograms from the Canadian organized screening program by scoring from 0 to 3 respectively clichés "bad", "fair", "satisfactory" and "good" on the following quality criteria: sharpness, coaptation-screen film, screen artifacts or development, distortion and dust (34). Taplin compared the image quality of screening mammograms with 492 cancers detected with mammograms of 164 interval cancers by analyzing the following items the North American guideline Mammography Quality Standards Act (21): positioning, breast compression, contrast, exposure, noise, sharpness, artifacts and overall quality. Each item was initially rated from 1 to 5, but, considering that few films were scored at the very upper and very lower ends of the scale, the authors decided to collapse the rating to three points: pass (scores 1 and 2), borderline (score 3) and fail (scores 4 and 5) (35). Taplin rated the sharpness on the basis of the amount of blurring of edges of linear structures, tissue borders, and microcalcifications. He defines four levels of blur:

a. No blurring
b. Minimal blurring identified with a magnifying glass
c. Moderate blurring identified with a magnifying glass
d. Blurring identified capable of obscuring or creating lesions

We applied and adapted this model of evaluation in this study by rating the blurring of the image from 1 to 4:

1: absence of blurring
2: minor blurring visible mainly after magnification
3: blurring visible without magnification that could be responsible for a loss of information
4: major blurring that compromise interpretation

A model with illustrated examples of the four levels of blur is available in Appendix 1.

VIII. Determining of the number of patients and statistical analysis

1) Number of patients required

In a non-inferiority study, supposing a compression mean of 39 mm [standard deviation 12 mm] (36) unchanged between self-compression and radiographer-compression with a maximum tolerance of 3 mm, a I type alpha risk of 5% and a power of 90%, the attended patient number in each group is 275. Altogether that comes to 550 patients.
2) Statistical analysis

Quantitative parameters will be reported in mean values more or less standard deviation; qualitative parameters will be presented in size and percentage.
Demographic and clinical parameters of the 2 groups will be compared by a Student t-test (quantitative parameters) or a chi-2 test (qualitative parameters).

To do over-all comparison between self-compression and technologist-controlled compression considering simultaneously the 4 performed mammographic views, assessment criteria for both techniques will be compared with Generalized Estimating Equations (GEEs) model on repeated measurements (37,38).
The I-type alpha risk to assess the significance of a difference is set to 0.05.
All statistical analysis will be performed using Statistical Analysis Systems software, version 9.3.

IX. Data collection

Data will be collected by the investigators or their representatives in each center on Case Report Forms provided by the sponsor. A using guideline how to complete these documents will be at disposal in each centre.
Mammography images with digital display of parameters used (compressed breast thickness in mm, compression force in Newtons) will be archived on the PACS or dedicated archive to provide quality control of the collection of parameters, external checking or audit.

The data collected are:

- Names of the center and the radiologist that includes patient
- Informed consent signed by the patient
- Characteristics of the patient: initials of the name, date of birth, personal history of benign breast (treatment type and date), personal history of breast cancer (treatment type and date), family history of breast cancer, analgesic medication, current hormonal treatment, menopausal status
- Criteria for inclusion / non-inclusion validated
- Result s of the pre-test
- Screening failure number and randomization number

The examination data are:

- Over-all VAS measurement at the end of the 4 studied mammographic views
- Value of compressed breast thickness in mm for each view of each breast
- Value of compressive strength in Newton for each view of each breast
- Radiologist appraisal of the motion blur on images for each view of each breast
- Satisfaction questionnaire completed by the patient
- Radiographer's appraisal

X. Data Management

The data from this study will be validated and controlled concerning their exhaustiveness, authenticity, precision and coherence. Incorrect or incomplete date will need to be clarified. All data will be stores in a dedicated server.

The data base will be send as an ASCII file to the statistician methodologist of the study. During the study correction of data can be asked by the data management. Data will have to be complemented by qualified persons for completion of the case report Form

XI. Exit of study

Patients can leave the study to their request in case of

a. Withdrawal of consent
b. Refusal to continue the study
XII. Implementation plan of the study

1) Role of each team

Each principal investigator of the 5 participating centres insures the recruitment of patients and completes the Case Report Form. He is in charge of the studied patients' following. In each centre, a radiologist is in charge of the blind reading of images.

The Alexis Vautrin Centre as the promoter of this study will manage and organize the research, particularly the documents administration, monitoring, data management and statistical analysis.

2) Preliminary schedule and identifying key steps

The inclusion period lasts 18 months from the start of the study.

The preliminary schedule is as follows:
- Finalization of the protocol and submission of regulatory dossiers: 2nd half of 2012
- The first inclusion: 1st quarter 2013
- End inclusions: 3rd quarter 2014
- Analysis and Report: 1st half 2015

3) How the project coordination and quality control

In Alexis Vautrin Centre the coordination investigator will be supported by the Clinical Research Center recently labelled in 2011 by the French Minister of Health.

Study coordination
The coordinating investigator will be the link between the sponsor of the study, the French patients’ protective committee (Comité de protection des Personnes, CPP) and the participating centres. The coordinator will act as a medical reference for all participating centres and will be responsible for the eventual modifications and validating of documents.

Study follow-up – quality assurance
The sponsor will be responsible for a quality control system implementation to certify authenticity and credibility of the acquired data according to Good Clinical Practices (November, 24th 2006). The system comprises:
- management and follow up of the study according to CAV procedures
- quality control of the data by the monitor, who is responsible for:
  - control of respect of protocol issues, Good Clinical Practices and agreement with legal laws and decrees,
  - checking of eligibility and consent of each participating patient
  - checking agreement and cohesiveness of data in the Case Report Form comparatively to the sources
  - checking that participating patients are not included in another trial that would interfere with the current proposal. The monitor checks too that patients have not been previously enrolled in a study comprising a time wash-out for new participation.
- Quality assurance will be performed from the final database. The database will be forwarded to the statistical team (Datamanagement and biostatistics unit, ICL).
- Adverse events
  - All events must be managed and reported in compliance with all applicable regulations, and included in the final clinical study report.

Monitors responsible for the quality control will be designated by the sponsor. They have free access to all patients’ data that are mandatory to validate the quality control. They will be submitted to the
Professional secrecy according to the Penal Code (articles 226-13 and 226-14). A written report will confirm and validate monitoring visits.

Monitors responsible for the quality control and representatives of health authorities will have free access to the patients files.

Audits
As part of its audit program, the Sponsor may audit some centres Both the centre and Investigator agree that audits are conducted by the Promoter or any person duly authorized for at least until ten years after the study end.

More generally, the Centre and the investigator undertake to have all necessary time for audit or inspection procedures, and for additional information requested by the Promoter or by the Competent Authority or any official authority.

4) Ability to include patients
Investigators from the Alexis Vautrin Centre realize approximately 3500 mammograms each year, those of the Curie Institute 4400 and those of the Bergonie Centre 5000.
Investigators from the Rx 125 Imaging Centre perform 3600 mammograms per year, those of the Department of Radiology at the Majorelle Polyclinic 6500.

5) Data protection and confidentiality agreement
All the data and results obtained during the study belong to the Alexis Vautrin Centre and will be at its free disposal. All written or oral communication will necessitate consent from the promoter.

Until the trial results are published, the investigator is responsible for insuring the confidentiality of the global information provided by the Centre Alexis Vautrin, handled by herself/himself and all other individuals involved in the course of the trial till publication of the trial results.

This obligation holds neither for the information that the investigator may communicate to the patients within the context of the trial nor for the already published information.

The investigator will not publish, divulge or utilize directly or indirectly scientific or technical information concerning the study.

Nevertheless, in conformity with the article R 5121-13 of the Public Health Code, both the center and the investigator may communicate information relative to the trial:
- to the Health Minister,
- to the public health inspectors who are medical doctors.

6) Final report and publication
After the end of the study and statistical analysis, a final report will be delivered including data and results obtained.
All manuscripts or presentations concerning the study will have to mention financial support obtained by the PHRC program. The text will be communicated to INCA for information.
For the final publication, French or English, authors will have to include
- Study coordinator (first or last contributing author)
- Principal investigator of each participating centre
- Methodologist

XIII. Ethical and regulatory issues

1) Regulations
The clinical trial will be conducted in accordance with:
- the principles of ethics as stated in the last version in use of the Declaration of Helsinki,
- the Good Clinical Practices defined by the International Conference on Harmonization (ICH–E6, 7th July 1996),
- Huriet’s law (n° 88-1138), 20th December 1988, relative to the protection of persons participating in biomedical research and modified by the Public Health Law n°2004-804 of 9th August 2004,
- the law on ‘informatics and freedom’ (Informatique et Libertés n° 78-17) of 1978 January 6th, modified by the law n° 2004-801 of 6th August 2004, relative to the protection of persons with regard to the computerized processing of personal data,
- bioethic law n° 2004-800 of 6th August 2004
- the Good Clinical Practices, 24th November 2006

2) Ethic Committee (CPP) – competent authority - CNIL

Before starting a biomedical research on human patients, the sponsor must submit its project to the opinion of one of the competent Ethics Committee in the region where the principal investigator is practicing.
A request for opinion on the biomedical research project is addressed to the CPP (Comité de protection des personnes) by the sponsor.
Request of substantial modifications to initial projects are submitted for the CPP’s opinion by the sponsor as well.
Research related to current care is not submitted to the French competent authority.
The trial will be declared to the “informatics and freedom commission” (CNIL: Commission Nationale de l’Informatique et des Libertés) relative to the protection of persons with regard to the computerized processing of personal data. Personal data will be in an anonymous form before transmission to the promoter.
Sending of information and consent notes will be made in sealed envelope.

3) Information and patient consent

Prior to carrying out biomedical research on human patients, a free and written informed consent form must be signed by each individual participating in the trial after she/he has been informed by the investigator during a physician-patient consult and after sufficient time for reflection has been allowed.
Information given to the trial participants must cover all of the elements defined by the public health law of August 9th, 2004 and must be written in a simple and comprehensible patient-appropriate manner. Once the participant is acquainted with the information, she/he must sign all the pages of the information sheet. The original sheet will be kept in the investigator’s folder and the duplicate copy will be returned to the participant.
The consent form must be dated and signed by both the participant in research and the investigator.
The original document is archived by the investigator; a copy is given to the research participant.
The information sheet and informed consent form must be associated within the same document to insure that the whole information is given to the participant.

4) Responsibility of the sponsor

The sponsor of this trial is the Alexis Vautrin Centre. It takes the initiative of conducting this research and is therefore accountable for the research management and for verifying the financing schedule.
The main sponsor responsibilities are:
- to register the trial in the Afssaps data base and to get the identification number,
- to request the opinion of the ethical committee (CPP) on the initial project and the substantial amendments,
- to provide information on the trial to the heads of the health care centers and the appropriate investigators
- the declaration of the beginning and the end of the trial to the competent authority,
- patient’s randomization, monitoring, collect and data control
- statistical analysis
- editing the final report on the trial,
- communicating the information on the trial’s results to the CPP and the research participants,
- archiving the trial’s essential documents in the sponsor folder for a minimal duration of
15 years after the research is ended.

5) Responsibility of investigators

The main investigator of each concerned health care centre commits to conducting the clinical trial in compliance with the protocol and the French law, particularly according the Good Clinical Practices (24th November 2006).

It is the responsibility of the main investigator:
- to provide the promoter with its own curriculum vitae and co-investigators’ curriculum vitae,
- to identify the members of its team that participate in the trial and to define their responsibilities,
- to insure patient recruitment after the promoter has issued its authorization.

It is the responsibility of each investigator:
- to collect the informed consent form, dated and signed personally by each individual research participant before any selection procedure specific to the trial may start,
- to regularly fill in the case report form (CRF) for each patient included in the trial and to allow the clinical research assistant mandated by the sponsor to have direct access to the source-documents in order to validate the data collected in the observation handbook.
- to accept regular visits of the study monitor and possibly the auditors mandated by the sponsor or the inspectors of the legal competent authorities.
- to date, correct and sign the corrections brought to the Case Report Form for each patient included in the trial.

XIV. References


8. SA Fox, DS Klos and CV Tsou Underuse of screening mammography by family physicians. Radiology 1988;166:431-433


Appendices

Appendix 1: Information and Consent of the Patient

Impact of Self-Compression on Tolerance in the Mammography Experience

ITACTs - N° ID RCB: 2012-A00248-35
Version n°2 of 2013 May, 7

You are asked to read this information document carefully before making your decision. Ask your doctor to explain anything you could not understand. Keep this information form, it is proof of your participation in biomedical research.

Sponsor : Institut de Cancérologie de Lorraine
Avenue de Bourgogne
54511 VANDOEUVRE-LES-NANCY CEDEX

Principal Investigator : Dr Philippe HENROT
Institut de Cancérologie de Lorraine
Avenue de Bourgogne
54511 VANDOEUVRE-LES-NANCY CEDEX

Mrs Miss,

You must have a mammogram as part of annual breast screening or follow-up. We know that when performing a mammogram, breast compression is the main source of discomfort reported by women and that there is apprehension about this examination. That's why we propose in this study to give you control of the compression of your breast during mammography. This will evaluate the impact of this technique on the tolerance of the exam. We believe that your active participation in this examination could improve the tolerance of mammography.

What is the purpose of the research?
The purpose of this study is to evaluate the impact of the self-compression technique on the technical parameters, the tolerance and the quality of the image, during a complete bilateral examination. This will be measured on the thickness of the compressed breast and on a pain rating scale. We will also ask you to complete a satisfaction questionnaire to know your feelings at the end of the exam.

What is the methodology of the study?
As part of the annual screening for breast cancer or your mammography follow-up you will be received by a doctor who will suggest you participating in the study. He will explain all the details of the study. If you agree to enter this study, the radiographer will explain the self-compression technique and will invite you to perform an X-ray FREE pretest to verify that you are able to use this technique and to ensure that mammography will be carried out optimally.

If the radiographer thinks it is difficult for you to compress your breast alone, then he will do your mammogram himself as usual. The rest of the exam will run like a conventional mammogram and you will not have to answer the satisfaction questionnaire.

If the radiographer feels that you are compressing your breast properly, then there will be a draw (randomization) to determine which method will be used for your exam:

- group 1: Self-compression
- group 2: Compression by the radiographer

It is only after the designation of your group that the radiographer will actually perform the mammogram using X-rays.
As with any mammogram, the radiologist will study your images according to the usual practices, without knowing the group to which you belong so as not to influence the results of the study. Only the radiographer will know it.

No further examination to the usual practice will be required. As in a conventional examination, if the radiologist thinks it is necessary complete the exam with additional mammograms, they will be made with the current technique of a mammographic examination, that is to say a compression performed by the radiographer.

**How many patients participate in this study?**
This study will include 550 patients.

**What does your participation in the study entail for you?**
This study does not involve any additional cost for you. By participating in this study, you agree that the medical data concerning you will be collected and analyzed.

**What are the expected benefits?**
The pain and discomfort felt during mammography may increase your apprehension of the next mammogram and may result in discontinuation of screening or follow-up. By allowing you to participate actively in the exam, we plan to reduce pain and discomfort. In addition to the immediate benefit, this study will allow anyone who needs a mammogram to have access to a new, more tolerable method for.

**What are your rights as a participant in this research?**
You are under no circumstances obliged to take part in the study. A refusal to participate will in no way affect your relationship with the medical team that supports you, and the quality of your care will not be affected. According to the provisions of the law n° 2002-303 of March 4th, 2002 relative to the rights of the patients, you will be informed, at your request, of the overall results of the study by the investigator.

**Confidential aspect of the data**
Your information is strictly confidential and anonymous. Your medical file will remain confidential and can only be consulted under the responsibility of the doctor treating you. You can also consult your file, the health authorities and the persons duly mandated by the organizer of the research. All are subject to professional secrecy. In accordance with the provisions of the French Data Protection Act (Law No. 78-17 of January 6, 1978 amended by Law No. 2004-801 of August 6, 2004), you have the right of access, rectification of data concerning you and opposition to the transmission of such data. This right is exercised with your radiologist who knows your identity. This study is conducted in accordance with the provisions of the Public Health Code relating to biomedical research. In this context, it received the favorable opinion of the Committee for the Protection of Persons CPP EST III dated 2012 June, 5, and the authorization of the French Agency for Sanitary Safety of Health Products dated 2012 December, 18.

**Who do you contact if you have questions or problems?**
The study is conducted in your care facility under the responsibility of Dr. (Trial Investigator) Tel. It remains at your disposal to give you the additional information and explanations that you want during the scheduled consultations during and after the treatment period. Feel free to schedule an appointment if you need more information.
Patient Consent Form

Impact of Self-Compression on Tolerance in the Mammography Experience

ITACTs - N° ID RCB: 2012-A00248-35
Version n°2 of 2013 May,7

Sponsor: Institut de Cancérologie de Lorraine
Avenue de Bourgogne
54511 VANDOEUVRE-LES-NANCY CEDEX

Principal Investigator: Dr Philippe HENROT
Institut de Cancérologie de Lorraine

I, The undersigned:

Firstname, Name: _____________________________________________________________
Adress: ________________________________________________________________

declares having been informed by the Doctor _____________________________________
of the subject and modalities of the study which is proposed to me, and accepts, with full knowledge of
the facts and with complete freedom, to participate in it.

I received an information note regarding this study. Its purpose, its constraints and its duration of
realization were clearly explained to me, and I had the possibility to ask all the questions that I wished.

I understand that I am free to accept or not to participate in this study, and that I can ask at any time to
withdraw from it without having to specify the reasons, and without compromising the quality of the
care that will continue to me. to be lavished, nor my relationship with the health care team.

I also state that I am affiliated to a social security scheme.

My consent does not relieve the organizers of the research of their responsibilities. I keep all my rights
guaranteed by law.

The data that concerns me will remain strictly confidential. I authorize their consultation only by the
persons mandated by the person in charge of the study (the Cancer Institute of Lorraine of
Vandœuvre-lès-Nancy) and by the representatives of the Regulatory Authorities of Health.

I accept that the data concerning me is subject to computer processing by the promoter. I have a right
of access and rectification relative to these data envisaged by the law Informatique et Liberté of

Patient Name: Investigator Name:

Date: Date:

Sign : Sign :
Appendix 2: 4-point scale for the reading of motion blur

No blurring in particular on the edges of linear structures (arrows): blurring score = 1
Minimal blurring mainly identified with magnification: edges of linear structures appear less sharp and thicker (arrows): Blurring score = 2
Blurring identified without magnification: edges of linear structures and calcifications appear too thick (arrows): Blurring score = 3
Major blurring that could obscure or create lesions: Blurring score = 4
### Appendix 3: Performance Status – WHO Scale

<table>
<thead>
<tr>
<th>Performance status</th>
<th>Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capable of performing all normal activities without restriction</td>
<td>0</td>
</tr>
<tr>
<td>Intense physical activity reduced but able to move and provide easy work</td>
<td>1</td>
</tr>
<tr>
<td>Able to move and heal himself but unable to work; active more than 50% of waking hours</td>
<td>2</td>
</tr>
<tr>
<td>Able to take care of himself but only to a certain extent; bedridden or sitting more than 50% of waking hours</td>
<td>3</td>
</tr>
<tr>
<td>Total incapacity; can not take care of himself; bedridden or permanently seated</td>
<td>4</td>
</tr>
</tbody>
</table>
### Appendix 4: Mammography Questionnaire MGQ

<table>
<thead>
<tr>
<th>№</th>
<th>Items</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>I was surprised that I had to undress</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>2</td>
<td>The examiner was too rough with me</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>I felt free to ask about anything and everything</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>The examination made me feel embarrassed</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>The examiner seemed professionally capable</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>The examination made me uneasy</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>7</td>
<td>The staff told me all I wanted to know about the examination</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>8</td>
<td>The examination situation made me feel awkward</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>9</td>
<td>The staff used words that were easy to understand</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>10</td>
<td>I was worried in case the examination could injure my body</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>11</td>
<td>The staff did not explain what was to be done with me</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>12</td>
<td>Did you find the examination painful?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>13</td>
<td>I was able to undress undisturbed</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>14</td>
<td>I had to wait a long time before getting an appointment for the examination</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>15</td>
<td>The staff « pushed » me quickly through the examination</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>16</td>
<td>The examination room was unpleasant</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>17</td>
<td>I was treated worse than expected</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>18</td>
<td>The waiting room was pleasant</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>19</td>
<td>I sat too long in the waiting room before being examined</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>20</td>
<td>How long did you have to wait before being examined?</td>
<td>&lt;5 min</td>
<td>5-15 min</td>
<td>15-30 min</td>
<td>30-60 min</td>
<td>&gt;60 min</td>
</tr>
<tr>
<td>21</td>
<td>The examination was too expensive</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>22</td>
<td>Did the examination cause discomfort?</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>23</td>
<td>If the examination has to be repeated, I shall not dread it</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>24</td>
<td>The staff did anything they could to make me feel comfortable</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>25</td>
<td>I found nothing to complain about in connection with the examination</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>26</td>
<td>I would advise others not to have the examination</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>27</td>
<td>Certain things could have been done differently in connection with the examination</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>
Appendix 5: Radiographer-questionnaire about self-compression technique

For the study "Interest of the self-compression technique on mammography tolerance," you agreed to perform self-compression mammograms. We are interested in your experience of this practice.

Please respond personally to the following questions by indicating what best fits your situation. There is no "good" or "bad" answer. This information will remain strictly confidential.

<table>
<thead>
<tr>
<th>Question</th>
<th>Not at all</th>
<th>A little</th>
<th>Most of the time</th>
<th>Almost always</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is self-compression difficult to explain?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is your experience with the patient improved?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the exam more complex?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the examination time substantially increased?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is it difficult for the patient to perform self-compression?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Do you think self-compression could be routinely used?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 6: How to explain the realization of self-compression to the patient? Radiographer Information Form 1

Realization of the Pretest

ITACT Protocol – After information and retrieval of the Informed Consent by the Radiologist

Step 1: Welcoming patients
1. Identity verification (First Name, Family Name, Date of Birth)
2. Signed Consent verification
3. Patient’s Recording via the eCRF:  www.evamed.com/etude-itacts

Step 2: Explanations about the exam
4. Presentation of the exam
   « A mammogram is an X-ray of the breasts. It makes it possible to obtain images of the interior of the breast using X-rays and thus to detect possible anomalies. »
5. Usefulness of the breast compression
   « Breast compression is mandatory. The goal is to reduce the thickness of the breast when taking the shot. There is less tissue overlapping and all structures are spread out which reduces the dose of X-ray. The goal is also that the breast is fully IMMOBILE to prevent the image from being blurred. »

6. Presentation of the Trial
   « The purpose of this study is to let the women control the compression of their breasts and assess women’s experience at the end of the mammogram. Your compression group (Self-compression or Compression by the radiographer) will be designated by draw. »

Step 3: Explanations about the usefulness of the Pretest
   « I will be with you during the whole exam. I will position your breast on the sensor and you will step on the foot-controller. When you find that your breast is sufficiently immobilized, you will stop pressing the foot-controller. If I feel that your breast is compressed enough then I will validate your ability to perform self-compression and you will be able to participate in the study after drawing; otherwise you will leave the study and I will perform the exam as I usually do. As with any standard mammogram, know that the quality of the examination will be controlled »

Step 4: Explanations about the operation of the device
   1. To show the detector, compression paddle and the X-ray Tube.
   2. Press the foot-controller to show how the paddle is compressing.
   « The breast is exposed to a low dose of radiation to produce an image of the breast. The breast is first placed on a special platform and compressed using this paddle. »

Step 5: Test before positioning
   The patient puts her fist on the detector and compresses it by pressing on the foot-controller to become familiar with the mammogram.

Step 6: Test after positioning without X-ray
   Position the breast of the patient. The patient compresses it herself by pressing foot-controller. When she judges that it is sufficiently immobilized, she stops pressing and you check that the compression is sufficient.

Step 7: Validation of the efficacy of the compression
   To say to the patient if the test is successful or not.
   If the test is unsuccessful, say why.

Step 8: Stop compressing

Step 9: Pretest results recording and Randomization
   If the test is successful, complete the eCRF and start randomization at the following adress:
   www.evamed.com/etude-itacts
Appendix 7: Realization of the mammogram. Radiographer
Information Form 2

Realization of the Mammogram

ITACT Protocol – After information and retrieval of the Informed Consent by the Radiologist

The examination is conducted according to the results of the draw:

- Group 1: Self-Compression
- Group 2: Compression by the Radiographer

Whatever the image quality, indicate the following informations in the CRF:

- Breast Thickness (millimeter)
- Compression Force (Newton)
- Ratio Thickness / Compression Force

After performing the four mammographic views (right craniocaudal (RCC), then left craniocaudal (LCC), right mediolateral oblique (RMLO), and finally left mediolateral oblique (LMLO), evaluate the tolerance with the Visual Analog (see user manual of the Visual Analog Scale).

Do not forget to submit the Satisfaction Questionnaire MGQ to the patient and to have it filled in before she leaves.

Whatever the technique: only the initial four views are studied within the trial.

Any additional view is made after the four initial views on the demand of the radiologist.

If the mammogram is blurred despite a compression considered optimal, and if you feel necessary to redo them:

1. Tell the radiologist after performing the four initial views
2. Inform the patient the need for retake the unsatisfying mammogram after performing the first four views
3. Perform any additional mammogram with the standard compression method
4. Send ALL the mammographic views made to the radiologist even those you know bad.
Appendix 8: How to use the Visual Analog Scale (VAS)?

Assessing the intensity of pain is a fundamental time in pain management. Better to detect, quantify, and follow the evolution of the pain felt, subjective phenomenon par excellence, requires the use of validated and reproducible methods according to the characteristics of the person.

This implies good communication between the person who suffers and the carer, an opportunity for exchange and mutual understanding. It avoids the a priori judgment of the caregiver.

**What is the Visual Analog Scale (VAS)?**

This is a short plastic ruler of 10 cm. It is graduated from 0 to 10 cm on one side, it is about the "caring" face. On the other side, the patient sees a movable cursor that can move on a non-graduated horizontal line, from "no pain" to "maximum pain imaginable".

**Procedure of use:**

The patient must, along this line, position the cursor at the place that best situates his pain.

The position of the cursor mobilized by the patient allows the caregiver to read the intensity of the pain, which is measured in mm. This measurement is reported on the observation form.

First at all, it is necessary to explain to the patient the use of the scale, and to check the understanding of the tool (quantification of the pain, displacement of the cursor in the right direction, ...).