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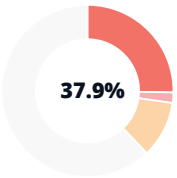

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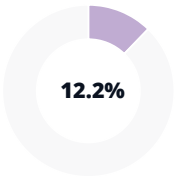

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Software Tools for Simulating 2D-mammography and Breast Tomosynthesis Images

1. Introduction

Planar 2D X-ray mammography is generally accepted as the preferred screening technique used for breast cancer detection. Breast cancer in western countries is characterized by high incidence and mortality rates *(Parkin & Fernandez 2006)*. As a result, nationwide breast screening programs have been implemented in many countries to aid early detection and improve outcome *(Karim-Kos et al. 2008)*. While mammography is a widely used and effective screening tool for breast cancer, there are some limitations and potential disadvantages associated with the procedure. False Positives: Mammograms can produce false-positive results, indicating an abnormality that further testing reveals not to be cancerous. This can lead to unnecessary anxiety, additional tests, and sometimes even unnecessary biopsies. False Negatives: Despite being effective, mammograms can miss some cancers, resulting in false-negative results. This can occur due to factors like dense breast tissue, tumor characteristics, or the positioning during the mammogram. Discomfort: For some individuals, mammography can be uncomfortable or even painful due to the compression of the breasts required to obtain clear images. This compression is necessary for better imaging but can cause discomfort, particularly for women with sensitive breasts. Radiation Exposure: Mammograms use low doses of radiation to capture images. While the level of radiation exposure is considered safe, repeated mammograms over time might contribute to a cumulative radiation dose, although the risk is generally minimal. Dense Breast Tissue Challenges: Dense breast tissue can make it more difficult to detect abnormalities in mammograms, as dense tissue appears white on the image, similar to tumors or masses. This can lead to reduced sensitivity in detecting cancers in women with dense breasts.

Digital Breast Tomosynthesis (DBT) is an advanced imaging technique used in mammography for breast cancer screening and diagnosis. It's often referred to as 3D mammography. Traditional mammography captures two-dimensional (2D) images of the breast tissue, which sometimes may make it challenging to detect abnormalities due to overlapping tissue. DBT works by taking multiple low-dose X-ray images of the breast from various angles, creating a three-dimensional image of the breast tissue. This technique allows radiologists to examine the breast in thin slices or sections, making it easier to identify abnormalities, such as tumors or lesions, and reduce the impact of overlapping tissues that might obscure findings in traditional mammography.

However, the introduction of any new technology demands clinical evaluation studies to establish any potential superiority over established methods before widespread adoption. Furthermore, the pace at which image technology can be developed now outstrips the rate at which clinical trials can be reasonably conducted, motivating the need for more efficient forms of technological assessment. For studies involving screening populations, an even greater challenge is presented because of ethical issues of repeated radiation exposure of asymptomatic subjects needed to establish statistical significance. One possible solution is to conduct virtual trials to evaluate and compare modalities using validated modelling tools.

2. Materials and Methods

In this work, we introduce a collection of modelling tools that facilitates simulation of the image acquisition process of 2D-planar mammography and DBT systems. Two simulation methodologies have been developed. The first simulation methodology, total image simulation (TIS) uses a 3D mathematical description of the object to be imaged. This may be used to simulate images of simple geometrical test objects or quite complex mathematical models representing breasts. This approach can be used to study various image related parameters associated with a particular system design, and may provide useful information to developers, as well as users of a particular imaging system. The second simulation methodology, inserted lesion simulation (ILS), involves inserting simulated pathology into clinical images in order to conduct human observer studies. If an accurate physics based approach is used for insertion, then the inserted structures should have the correct contrast, blur

and noise, and would ideally be indistinguishable from real lesions in clinical images. Once validated, this methodology can be used to conduct observer studies by inserting pathology that is representative of mass-like lesions *(Rashidnasab et al. 2013a, Rashidnasab et al. 2013b)* and micro-calcifications *(Shaheen et al. 2011)* into normal clinical patient images. Such an approach would then serve as an efficient alternative or pre-cursor to clinical evaluations with real subjects.

A model should be developed for a specific purpose (or application) and its validity determined with respect to that purpose. If the purpose of a model is to answer a variety of questions, the validity of the model needs to be determined with respect to each question. Numerous sets of experimental conditions are usually required to define the domain of a model's intended applicability. A model may be valid for one set of experimental conditions and invalid in another. A model is considered valid for a set of experimental conditions if its accuracy is within its acceptable range, which is the amount of accuracy required for the model's intended purpose.

In order to validate the methodologies presented, measurements of the sharpness and contrast-to-noise of test objects obtained with a Hologic Selenia Dimensions 3D system (Hologic Inc., Bedford, Massachusetts, USA) were compared with measurements on simulated images simulated using the two methodologies and the same exposure conditions. However, this approach can be readily extended to simulate other system designs, provided the acquisition parameters are known and processing and reconstruction software are available.

Development of the TIS and ILS approaches required characterisation of the imaging system's acquisition process via physical measurements. Following this, a collection of modelling tools was designed to simulate the various system acquisition and image degradation processes. Finally, the modelling tools were used to construct the TIS and ILS simulation chains.

3. Conclusion

The performance evaluation and comparison of X-ray imaging systems poses a number of practical challenges within a clinical environment. To address the above issue, two simulation chains constructed using a set of modelling tools have been developed and validated. The first methodology, total image simulation, is based around defined virtual geometric objects used alongside a virtual representation of the image acquisition process. This is suitable for understanding the impact of technical factors such as dose and beam quality on the image formation process. The second methodology, inserted lesion simulation, is suitable for conducing observer studies by inserting objects representative of lesions and micro-calcifications into clinical patient images. Both methodologies have been validated by simulating test objects and comparing the results with real authentic images acquired in the system under study. Measurements performed on the simulated images such as contrast and blur are in good agreement (<9% error) with the physical data measured from counterpart real images. The methodologies presented can be used for rapid evaluation and comparison of 2D-mammography and tomosynthesis systems.

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Ciatto S, Houssami N, Bernardi D, Caumo F, Pellegrini M, Brunelli S, Tuttobene P, Bricolo P, Fantò C, Valentini M, Montemezzi S, Macaskill P 2013 Integration of 3D digital mammography with tomosynthesis for population breast-cancer screening (STORM): a prospective comparison study Lancet Oncology ***14*** *583-589.*

AI content detector report

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