Automatic decision support system for contrast enhanced spectral mammography (Tel Hashomer)
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Automatic decision support system for contrast enhanced spectral mammography

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Background

Mammography is a well-established, cost-effective imaging technique for breast cancer detection that has been clinically available since 1970. It is the only screening technology that was proved to reduce mortality and the only one with FDA clearance.

In the last decade full-field digital mammography has progressively replaced the film-based mammogram. Solid-state detctors directly converts X-rays into a high resolution digital image.

The lack of visibility in dense breasts remains a major limitation of mammography even in its digital form. In a dense breast mammography (Figure 1, left), most of the breast may appear opaque, totally masking the presence of a malignant lesion.

40 to 50% of women below 50 years have dense breasts as well as a significant proportion of women older than 50 years. The overall sensitivity range of mammography is 63%-98% and drops to 30%-58% for dense breast.

In the last decade, MRI proved to be a very sensitive tool in breast cancer detection even with dense breast by leveraging the complementary information provided by contrast adminstration. In particular, contrast-enhanced MRI is extremely sensitive to angiogenesis. Unfortunately, breast MRI remains very expensive in comparison to digital mammography, with limited availability thereby limitating its usage.

Contrast enhanced digital mammography (CEDM) was developed in the very recent years as a low cost technique for the detection of abnormal focal areas with increased microvessel density.

Clinical feasibility and initial experiences with CEDM have been reported; **Dual energy**, mammography performed following injection of iodine , and acquisition of pairs of low and high energy images and recombined subtraction images are computed. In Figure 1 (right) the subtraction image for a dual energy CEDM is compared with the corresponding digital mammogram for the same breast (left). The contoured area in the subtraction image is a large malignant lesion that was totally occluded by dense breast tissues in the digital mammogram. The added value of CEDM is very clear in this case as it provides an excellent visibility of the lesion, comparable to contrast enhanced MRI.

Good lesion visibility, however, is merely the starting point for the diagnosis process to be performed by the expert radiologist. For this purpose, he shall mentally integrate the information provided by the visual analysis of the CEDM pixels together with context information defining the medical background of the patient. Age, genetic background (BRCA gene), previous/family history of disease, lesion palpability, etc, are some of the background variables needed to build the *big picture* in the radiologist mind.

In many cases, however, clear-cut diagnosis is hard to reach even with CEDM, and a biopsy is performed for final assesment by the pathologist. About 60%-70% of the biopsies are benign findings. indicating a lot of room for specificity improvement.

Computer assisted diagnosis (CAD) has been used for many year with mammography but it did not improve the situation with dense breast as it inherently suffered from the lesion visibility problem. Also, the analysis relied exclusively on pixel information, virtually ignoring valuable cues from the patient medical background. In the field of CEDM, automatic image analysis systems are not yet available as the imaging technique is still relatively young.

We propose to develop an automatic decision support system that will help the radiologist reach a confident classification of CEDM breast lesions as benign or malignant. The goal is to increase the radiologist diagnostic specificity so that a significant amount of unnecessary biopsies will be avoided without compromizing sensitivity. In a unique approach, the developped system will integrate both visual data (pixels) and patient background information (risk stratification system)into a joint supervised learning scheme.

The Need

Breast cancer screening has become big business, starting with the multi-billion dollar goliath, mammography. No other medical screening has been as aggressively promoted. Yet, there are risks and benefits to mammograms: Thirty years of US government data studied found that as many as 1/3 of cancers detected by mammography may *not* have been life threatening, and that **over 1 million women have been over-diagnosed; leading to unnecessary treatments involving disfiguring surgeries; radiation and chemotherapy.**

Mammogram screenings have increased from about 30 percent of women 40 and older in 1985, to about 70 percent of women screened, proving how effective we have been. The Industry is looking for solution to improve the early screening:

Innovations in the field include 3D TOMOSYNTHESIS mammogram, a digital method for creating 3D images by x-rays from the breast tissue, and requirs mechanical compression, and **30 percent more radiation!** The technology may provide more efficacy, reduce patients' anxiety, and will may reduce the costs of health care system.

The Technology and Innovation

The developed technology should benefit over the years from several important factors:

With high sensitivity and low cost, CEDM has an excellent growth potential that will benefit to any decision support systems relying on it.

Using an "online" learning approach (see section 5.1.2), the performances will benefit from the increasing number of processed cases over time.

The technology is easily applied to the characterization of MRI lesions.

Therefore, we can expect the developed technology to survive the major part of a patent

protection period depending.

The developed technology can be applied to other breast imaging techniques such as MRI that would also benefit from the contextual patient information in obtaining a higher diagnostic confidence and potentially reduce the amount of unnecessary biopsies.

Also, the developed technology may be applied to other organs where contrast enhancement MRI is performed for the detection of malignant lesions such as the prostate.

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The Market

The global breast imaging market is segmented into ionizing breast imaging technologies and non-ionizing breast imaging technologies. The ionizing breast imaging technologies segment is subsegmented into analog mammography, full-field digital mammography (FFDM), 3D breast tomosynthesis, positron emission tomography/computed tomography (PET/CT), molecular breast imaging/breast-specific gamma imaging (MBI/BSGI), cone-beam computed tomography (CBCT), positron emission mammography (PEM), and electric impedance tomography. The non-ionizing breast imaging technologies segment includes breast MRI, breast ultrasound, optical imaging, automated whole-breast ultrasound (AWBU), and breast thermography.

Growth in the breast imaging market is driven by factors such as the rising incidence of breast cancer globally; growing government investments and funding for breast cancer treatment and related research; increasing awareness about early detection of breast cancer; rising geriatric population; technological advancements in breast imaging modalities; and launch of advanced breast imaging systems capable of detecting cancer in women with dense breast tissues. In addition, the growing demand for breast imaging in emerging Asian countries, and technological advancements in breast cancer detection are expected to offer high growth opportunities for market players. However, factors such as high installation cost of breast imaging systems, side-effects of radiation exposure, and errors in breast cancer screening and diagnosis are restricting the growth of the global breast imaging market.

North America is estimated to be the largest regional segment in the global breast imaging market in 2016, followed by Europe. However, the Asia-Pacific market is expected to grow at the highest CAGR of 9.5% from 2016 to 2021. A number of factors, such as the growing patient population, increasing healthcare expenditure, improving healthcare infrastructure, growing government spending on breast cancer research studies, and implementation of several initiatives to create awareness about the early detection of breast cancer are expected to drive the market in the Asia-Pacific region.

Hologic, Inc. (U.S.), GE Healthcare (U.K.), Siemens Healthcare (Germany), Philips Healthcare (Netherlands), Fujifilm Holdings Corporation (Japan), Gamma Medica, Inc. (U.S.), Toshiba Corporation (Japan), Sonocine, Inc. (U.S.), Aurora Imaging Technology, Inc. (U.S.), and Dilon Technologies, Inc. (U.S.) are some of the key players operating in the global breast imaging market.

The medical recommendations are that every woman should have a test every second year.

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