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Publication date	2019-04-01
Original Citation	Ugwah, J. A., Bennett, B., O'Donnell, B., O'Sullivan, M. and Moore, E. (2019) 'SMARTProbe -: An informative biopsy needle with bioimpedance sensing for real-time breast lesion screening', Smart Systems Integration; 13th International Conference and Exhibition on Integration Issues of Miniaturized Systems, Barcelona, Spain, 10-11 April, pp. 344-347. Available at: https://ieeexplore.ieee.org/abstract/document/8727824 (Accessed: 17 August 2021)
Type of publication	Conference item
Link to publisher's version	https://ieeexplore.ieee.org/abstract/document/8727824, https://www.vde-verlag.de/proceedings-de/564919053.html
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Download date	2026-11-01 21:35:50
Item downloaded from	https://hdl.handle.net/10468/11746

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SMARTProbe -: An informative biopsy needle with bioimpedance sensing for real-time breast lesion screening

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Abstract

Patients who present with a breast lesion require clinical and radiological examination for breast disease detection. For a definitive diagnosis, biopsy under ultrasound guidance is performed for histological assessment to determine if lesion is malignant or benign. The biopsy needle, currently a passive instrument, if integrated with impedance sensing, can give real time information for use as a tissue discriminating tool.

Bio-impedance is a technique which enables the use of three variables (resistance, reactance and phase angle) as indices of structural and functional biological variables. The frequency dependent electrical impulse gives the physiology and pathological information about the conductive and dielectric properties of cells. The differences in electrical properties of malignant and healthy tissues are associated with increased water and mineral content within tumor cells, the changes in membrane permeability, altered packing density as well as orientation of cells.

The prototype SMARTProbe, with bioimpedance sensing, is able to discriminate healthy tissue from malignant and benign lesions in ex-vivo clinical investigation. The fabrication process of sensors allows for defined and constant electrode distance, which enables small alternate current to be used, thus, decreasing variability as a result of tissue heterogeneity.

Keywords: Bio-impedance, Breast lesions, SMARTProbe

Introduction

According to the 2014 National Cancer Registry Ireland, 19,000 people are diagnosed with cancer every year, with over 8000 deaths reported yearly. It is estimated that

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breast cancer constitutes 22% of all female invasive cancer[1]. In Ireland, the annual average incidence for invasive breast cancer was 2,805 cases per annum between 2009 and 2011, which represents 31% of female invasive cancers (excluding non-melanoma skin cancer). The number of cases of female breast cancer is expected to increase by about 130% between 2010 and 2040 [2]. Cancer diagnosis, staging and treatment is a major health care challenge, which involves assessment by a multidisciplinary team that includes, breast consultants, radiology and histopathology experts One of the objectives for the rational for a national clinical guideline by the cancer control in Ireland include: improvements in the quality of clinical decisions. There is a need for a diagnostic adjunct technology which can give clinicians, real time information on a lesion presented at the breast clinic, this is the niche the SMARTProbe hopes to address.

The SMARTProbe is an informative biopsy needle with bioimpedance sensing for tissue-type differentiation. Bioimpedance, as a sensing technique, can provide rapid information regarding the cellular and architectural composition of tissue as a result of its electric properties. It's of interest to note that the highly insulating cell membranes limits electric current in living tissue, but the different tissue architecture such as cancer may impede current differently, to allow for normal and malignant tissue differentiation.

Materials and Method

Ethical approval was taken from the CREC, for the clinical investigation to be carried out at the Cork University hospital. Protocols that meet clinical standards were developed during the clinical investigation of the ex-vivo breast tissue and lesions.

The SMARTProbe was inserted into the tissue by direct puncture and this was held in place by the tissue and no bleeding noticed. A sinusoidal current is driven to the tissue to generate a voltage response for the bioimpedance measurements. . To do this the two electrode probe is connected to the potentiostat (PGSTAT204, Metrohm Autolab B.V., Netherlands) as seen in figure 1. The bioimpedance of healthy tissue is measured first with the SMARTProbe because of the heterogeneity of each individuals breast tissue which may be as a result of hormonal changes, menopause, ageing. The bioimpedance of the breast lesion is then done to compare with that of the healthy tissue. If two lesions are identified during the radiological assessment, the two different lesions are also measured and compared to tissues from other patients with the same histologically diagnosed cancer subtype. The data is then exported to excel and SPSS where it is analysed.

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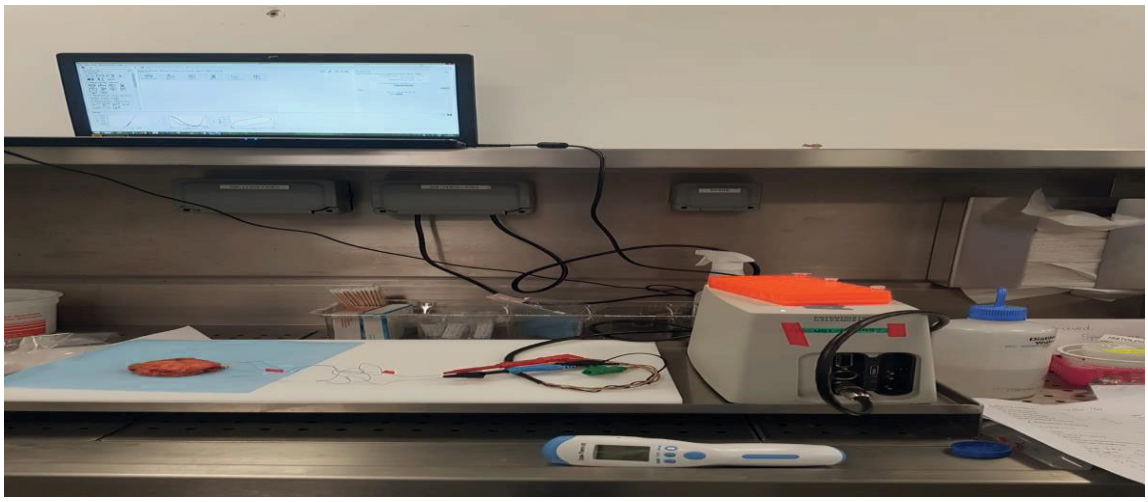


Fig 1a SMARTProbe in an excised breast lesion

Test FRA calibration of instrument is done on the dummy cell before each clinical investigation to ensure the equipment is calibrated and values are not out of range. The measurement in different concentration of saline (0.45%, 0.9% and 1.8%) is done at a fixed frequency, 10 kHz, to ensure sensors are working well. Three measurements are taken in the healthy tissue and also in the breast lesion and average of each tissue type used. The measurements taken are done within an hour of it being excised and then put into formalin to undergo the full processes required for pathological assessments. Temperature measurements are also taken during the measurements. A frequency band of 100Hz to 1MHz is used at an amplitude of 100nA to 1mA in 50 equal interval points. A frequency sweep is used as opposed to a fixed frequency as 50 impedance and phase angle measurements contains more information as a spectrum.

Discussion

The small distance between the current injecting and pick-up electrode was small enough that the impedance measurement is localized and only the dielectric properties of the tissue surrounding the needle tip was is obtained; thus, position error is avoided.

In our study, the impedance magnitude of Invasive ductal carcinoma, IDC is higher than the healthy tissue while the Invasive lobular carcinoma, ILC, it is lower. The SMARTProbe could significantly differentiate between healthy and cancerous tissue at frequencies between 100 Hz - 60 kHz.

Patient 25 has two malignant tumour subtype, IDC and ILC and has also had neo-adjuvant chemotherapy before excisional biopsy.

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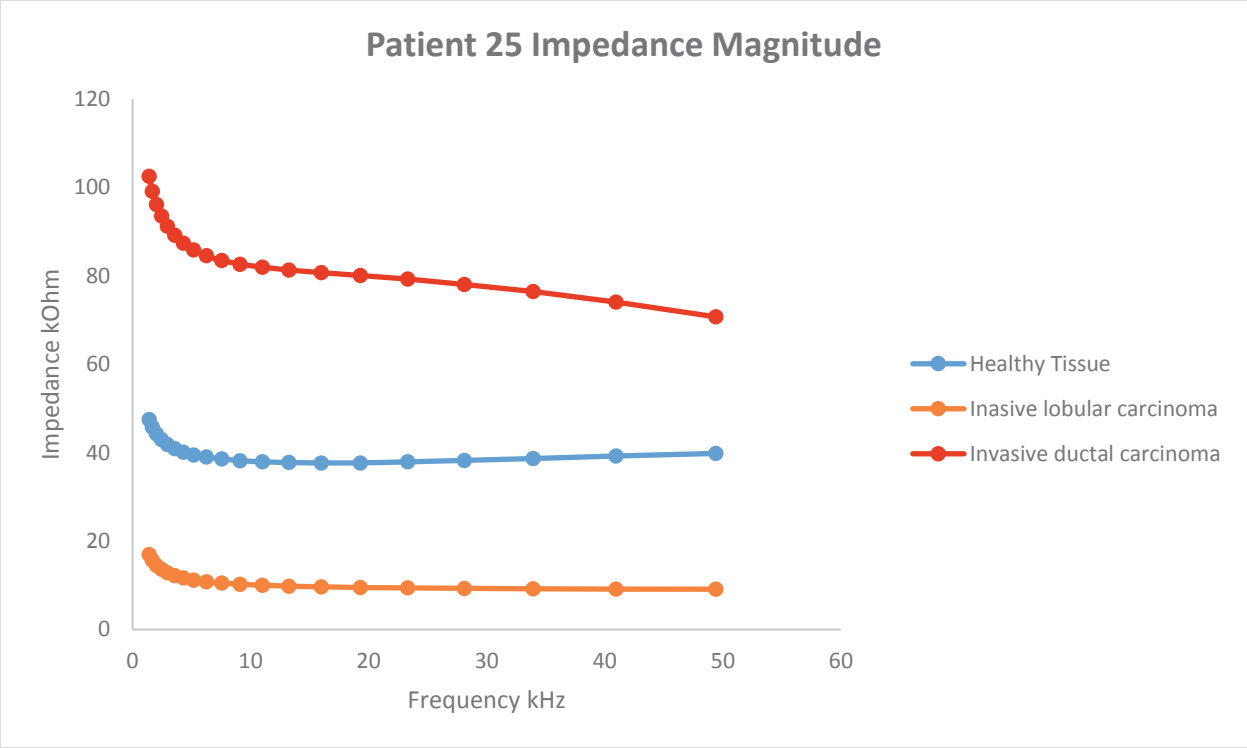


Fig 2 Impedance magnitude of patients 25

Conclusion

The SMARTProbe can discriminate between healthy and cancerous tissue and has shown sensitivity for differentiating between the Invasive ductal carcinoma and lobular carcinoma. It is presumed that similar results will be obtained in vivo, as measurements were carried out shortly after excision, before the onset of loss of tissue viability and function that can affect its dielectric properties. More data is required to be able to ensure sensitivity and specificity. Also more patients who have received neo-adjuvant chemotherapy will need to be investigated. No male patient was consented in this study to date and the bioimpedance of male breast tissue will be of interest.

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