Non-invasive classification between benign and cancerous breast lesions via time-domain bioimpedance sensing: a first-in-human study.

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INTRODUCTION

- Breast cancer is the most common cancer in women worldwide. While mammography remains the standard for early detection, radiation, discomfort and cost warrant development of novel screening tools and diagnostic approaches.
- Bioimpedance scanning, a non-ionizing modality which measures electrical differences between healthy and cancerous tissue offers promise as a new cancer detection tool in the breast.
- In this study, a novel handheld device using time-domain bioimpedance sensing (TD-BIS) infers dielectric properties of tissue
- TD-BIS was deployed with machine learning methods to determine if breast lesions present in patients were either benign or cancerous in nature.

METHODOLOGY

- 62 participants undergoing routine mammography or breast ultrasound were enrolled post radiological review and diagnosed by biopsy. Prior to the biopsy, participants were scanned on each breast using the TD-BIS device at predefined locations on the breast.
- Varying patterns of capacitances were used as input for a random forest model to distinguishing between cancerous and benign lesions.
- F1 score, balanced accuracy (BA), false positive rate (FPR), false negative rate (FNR), positive predictive value (PPV) and negative predictive value (NPV) were calculated.
- Models were trained using either one scan per patient (single scan), all scans combined (combined scans), or all scan data that was within 8 cm of the known lesion (close scans).
- Mann-Whitney tests (with a Bonferroni correction) were used to evaluate the significance between models. Independent t-tests were used to compare the performance of each scan position relative a random permutation of the labels.

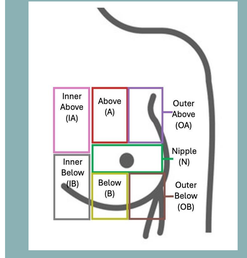


Figure 1:
Scans from 7 standard positions were recorded from each breast, starting with one taken directly on the nipple (N) and the remaining scans taken at clock-face positions 2, 4, 6, 8, 10, and 12, with the nipple at the centre. For the right breast, these positions were labelled 'inner above (IA), 'inner below' (IB), 'below' (B), 'outer below' (OB), 'outer above' (OA), and 'above' (A) respectively. OA/IA and OB/OB were swapped for the left breast.

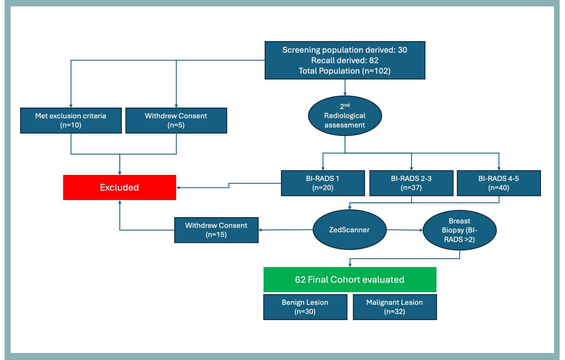


Figure 2:
Flowchart of patient inclusion of the clinical study. Participants were scanned with the TDBIS, post mammogram/Ultrasound. The final cohort for the analysis was 62 participants, 32 with malignant lesions.

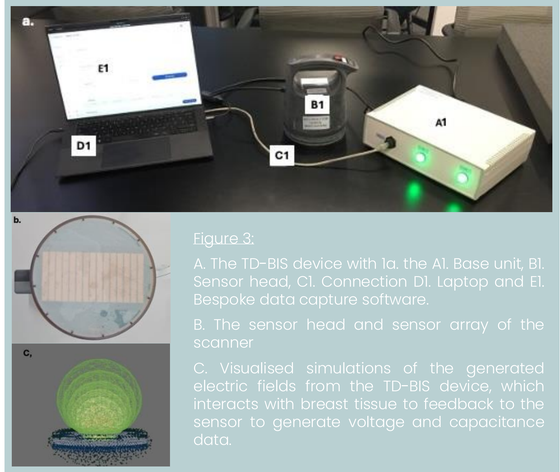


Figure 3:

A. The TD-BIS device with 1a. the A1. Base unit, B1. Sensor head, C1. Connection D1. Laptop and E1. Bespoke data capture software.

B. The sensor head and sensor array of the scanner

C. Visualised simulations of the generated electric fields from the TD-BIS device, which interacts with breast tissue to feedback to the sensor to generate voltage and capacitance data.

RESULTS

- 62 participants were categorized as cancerous (n=32) or benign (n=30) via radiological and biopsy evaluation.
- The most significant to BA and F1 performing models in cancer/benign distinction were 'Close', A, IA, IB, N, and B models.
- Using only one scan position resulted in high FNR.
- Close scan data, 13 of 30 benign lesions and 31 of 32 cancerous lesions were correctly identified, respectively.
- The performance for close scans was: BA:0.651, F1:0.623, FNR:0.039, FPR:0.660, PPV:0.609, NPV:0.895, all with p-value <0.05.
- When evaluating the combined data, 6/30 benign lesions and 31/32 cancerous lesions were correctly identified, with BA:0.567, F1:0.497, FNR:0.031, FPR:0.834, PPV:0.553, and NPV:0.828.

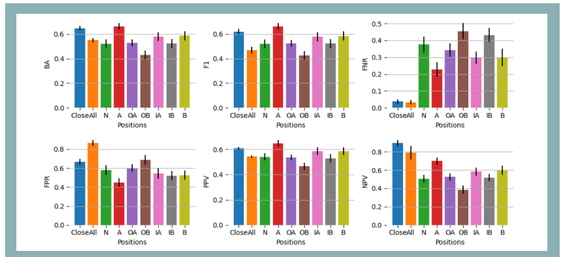


Figure 4: Data on the performance of individual scans, combined and close scans across a variety of statistical analyses.

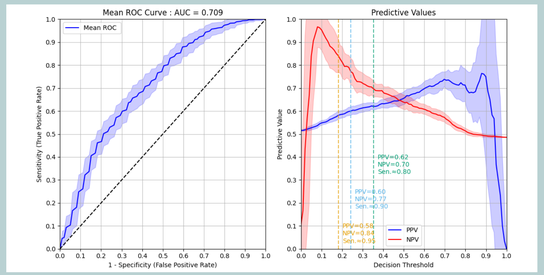


Figure 5: The devices AUC was 0.71 in distinguishing malignant lesions within the breast. Varying sensitivity values impacted the model's accuracy.

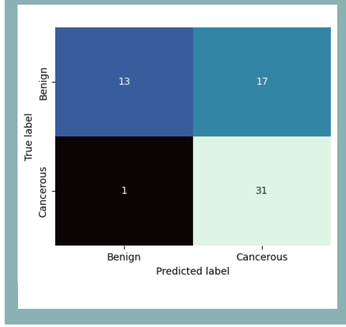


Figure 6:
The model's predictive power was weighted to detect malignant lesions, with 31/32 lesions being correctly identified. Classification of benign lesions showed the model provided an increase in false positives, indicating work is needed to accurately distinguish benign lesions within the breast.

CONCLUSION

- This initial evaluation of TD-BIS demonstrates its feasibility as a method for discriminating between benign and cancerous lesions. When evaluating spatially relevant data, the study shows that data closest to the lesion improves the cancer detection models when compared to non-spatial data.
- This implies that the TD-BIS device measures biologically relevant dielectric properties of the underlying tissue. The performance of the close model reveals an FNR less than 4%, suggesting this technology has the potential to be a non-invasive clinical tool to discriminate between benign and cancerous lesions. This conclusion is supported when the model input is expanded to include scans farther from the lesion site (e.g combined), which significantly reduces model performance.

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