Diagnostic Accuracy of a Novel Palpation Device to Improve Early Detection of Breast Cancer in Low-Resource Settings

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BACKGROUND

- **Breast cancer is the most diagnosed cancer in women in both high- and low-resource settings[1]**
- The absolute burden of breast cancer and rate of increase is higher in less developed countries and by 2020, over 1 million new cases per year are projected in low- to middle-income countries (LMICs) alone[1,2]
- Mortality rates in LMICs remain disproportionately high due to late-stage presentation
  - Indicating a variety of barriers to early detection and diagnosis of breast cancer as well as scarcity of resources for optimal diagnosis and treatment [3,4]
- iBreastExam (iBE) is a novel, quantitative and low-cost elastic modulus (E) sensor that can measure tissue compression and stiffness by top down touching of the skin surface with patented tactile sensors using Piezoelectric Sensor Array
  - **iBreastExams ability to apply a gentle force and measure the subtle displacements electrically, all within the sensor, makes for an ideal 'electronic palpation' sensor for in-vivo breast imaging.**

Although incidence continues to increase in low- to middle-income countries, access to early detection in these high burden areas remain limited, in part due to lack of low-cost efficacious tools where mammography isn't feasible. Therefore, the aim of this study is to evaluate the diagnostic accuracy of the lower cost, non-invasive, portable device iBreastExam in the detection of clinically relevant breast lesions.

METHODS

- **A prospective non-randomized trial** was conducted in Nova Iguaçu and Rio de Janeiro, Brazil with women seeking routine screening or follow-up breast diagnostic evaluation, respectively.
  - Each woman received an iBE palpation test and then mammography, ultrasound (US), or both, each by a different blinded clinician.
- Each breast was considered an independent result for the sake of analysis for a total of 449 breasts (n=226 women) .
- Non-pregnant women aged 18 and older were eligible to enroll after providing informed consent.
- **To assess accuracy of iBE to detect lesions, the sensitivity and specificity were calculated compared to mammography alone, ultrasound alone, or mammography plus ultrasound**.
- A random subset of women (n=57) were invited to complete a one-minute assessment on the acceptability of iBE after their examination.

EXAMINATIONS

iBreastExam

- Trained technicians scanned each breast fully using the iBE in a clock-wise manner.
- The number of required positions to image the whole breast was determined by the patient's breast size and ranged from 4 to 9 scans per breast
- Individual scans took about 3 to 4 minutes and generating an automatic reports

Mammogram

- In patients in which a mammogram was performed both breasts were imaged in the craniocaudal and mediolateral oblique views by digital mammogram.

Ultrasound

- US exams were performed by 3 radiologists, one specialized and two nonspecialized in breast imaging.
- Variable ultrasound systems were used equipped with a linear-array transducer with a bandwidth of 7.5–13.5 MHz and interpreted according to the current ACR BI-RADS.

For the sake of determining true lesion status for calculations:

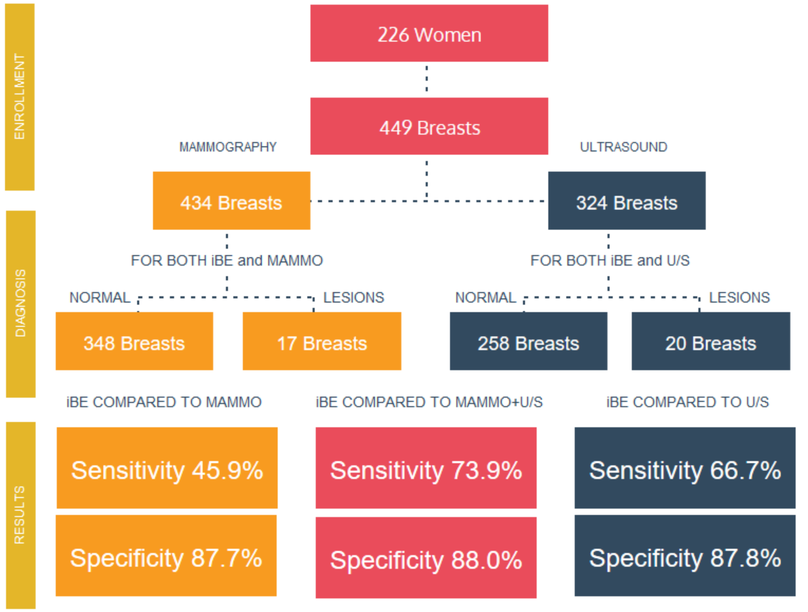
- A positive mammogram was considered BIRADS 0, 3-6
- A positive US was considered BIRADS 3-6.
- For mammography plus US, the mammographic classification was considered the true status except for BIRADS 0, in which case the US classification was considered the truth.

- 226 women were enrolled for a total of 449 breasts. Median age of participants was 54 years old and all breasts received iBreastExams exams
  - 434 received mammograms
  - 324 received ultrasounds
  - 317 received both

RESULTS

Results	Mammography (n=434)	Ultrasound (n=324)
BIRADS 0	15	0
BIRADS 1	85	222
BIRADS 2	312	73
BIRADS 3	10	13
BIRADS 4	10	13
BIRADS 5	1	2
BIRADS 6	1	1

RESULTS



CONCLUSIONS

- The relatively high specificity highlights the tools' ability to reduce the pool of women warranting further evaluation but the sensitivity of iBE compared to mammography alone was relatively low.
- Notable, 15 of the 17 cases missed by iBE were classified as BIRADS 0.
  - When these cases underwent US, the net sensitivity increased to 74%.
- Based on the acceptability survey, iBE shows extreme promise and demonstrates high approval among women
- **These data highlight the potential for iBE to strengthen breast cancer early detection programs in LMIC's and support the need for next generation sensors with improved sensitivity.**

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