**BACKGROUND**

- Breast cancer is the most diagnosed cancer in women in both high- and low-resource settings.
- 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.
- 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 a scarcity of resources for optimal diagnosis and treatment.

**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. Median age of participants was 54.5 years old and all breasts received 434 mammograms, 317 received both iBE exams and ultrasound exams.

**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.

**RESULTS**

- **Mammogram**
  - A positive mammogram was considered BIRADS 0, 3, and 4.
  - A positive US was considered BIRADS 3.

- **Ultrasound**
  - A positive mammogram plus US, the mammographic classification was considered the true status except for BIRADS 3, in which 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 iBE exams.

- **Sensitivity**
  - 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.

- Noteable, 15 of the 17 cases missed by iBE were classified as BIRADS 0.

**CONCLUSIONS**

- 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.