Evaluation of The Pink Luminous Breast LED-Based Technology Device as a Screening Tool for the Early Detection of Breast Abnormalities

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ABSTRACT

Breast cancer is the leading cause of sex-specific female cancer death in the United States. Detection at earlier stages contributes to decrease the mortality rate. The mammography is considered the gold standard for breast cancer screening with an estimate sensitivity of 86.9% and a specificity 88.9%. However, these values are negatively affected by the breast, which is consider a risk factor for developing breast cancer. Herein, we validate the novel LED-based FDA Class I medical device Pink Luminous Breast (PLB) by the comparison of two breast screening imaging-based tests using a double blinded approach. The PLB works by emitting a LED red light with a harmless spectrum of 640-800 nanometers, the trans-illuminated breast tissue allows the observation of abnormalities represented by darker or shadowing areas. In this study, we evaluated the sensitivity and specificity of the PLB device as a screening tool for the early detection of breast abnormalities when compared with the mammography as the gold standard. Our results showed that PLB device has a high sensitivity (89.6%) and specificity (96.4%) for detecting breast abnormalities comparable to the

adjusted mammography values: 86.3% and 68.9% respectively. Importantly, the percentage of positive dense tissue findings from a total of 340 events was 266 (78.2%) using PLB vs. 248 (72.9%) detected by the mammography. A 100% of the participants responded in a survey that they feel comfortable using the device and visualizing their breast without feeling pain or discomfort during the examination. The PLB positive validation vs the mammography brings the potential to be recommended for routinely breast screening at non-clinical settings. The PLB provides a rapid, non-invasive, portable, and easy-to-use tool for breast screening that can complement the home-based BSE technique or the CBE. In addition, the PLB can be conveniently used for screening breasts with surgical implants. PLB provides an accessible and painless breast cancer screening tool. The use of this device is not intended to replace the mammography as the gold standard for breast screening but rather to use it as an adjunct or complement tool as part of more efficient earlier detection strategies and contribute to decrease this health disparity.

Competing Interest Statement

The authors have declared no competing interest.

Funding Statement

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Author Declarations

I confirm all relevant ethical guidelines have been followed, and any necessary IRB and/or ethics committee approvals have been obtained.

Yes

The details of the IRB/oversight body that provided approval or exemption for the research described are given below:

This study was approved by the Ponce Health Sciences University Institutional Review Board, Ponce, Puerto Rico as protocol #1911024753.

All necessary patient/participant consent has been obtained and the appropriate institutional forms have been archived.

Yes

I understand that all clinical trials and any other prospective interventional studies must be registered with an ICMJE-approved registry, such as ClinicalTrials.gov. I confirm that any such study

reported in the manuscript has been registered and the trial registration ID is provided (note: if posting a prospective study registered retrospectively, please provide a statement in the trial ID field explaining why the study was not registered in advance).

Yes

I have followed all appropriate research reporting guidelines and uploaded the relevant EQUATOR Network research reporting checklist(s) and other pertinent material as supplementary files, if applicable.

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