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# Efficacy of the Breast-I® Device as a Screening Tool for Breast Cancer among Premenopausal Women in Sub-Saharan African

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***Abstract***

*Previous studies have shown that breast cancer can be detected early by translumination of red light rays through the breast tissue. There are few studies conducted to assess the usefulness of red light examination of the breast among dark skin population as previous clinical trials were mainly on Caucasians. This study thus presents our experience with red light examination of the breast using Breast I-device®. This prospective experimental observational study was carried out among female patients attending general surgery clinic, and women attending a seminar on breast cancer awareness. The patients were made to undergo self- breast examination, clinical breast examination and re-examined using Breast-I device®. The findings were then compared with the histological diagnosis.*

*One hundred and sixty-one women were enrolled, and three hundred and twenty breasts were examined. The mean age of the participant was 41.23(±6.7). Forty-seven (61.3%) patients had breast complaint. Thirty-five lumps were detected on self-breast examination while clinical examination detected extra 22 lumps and when combined with Breast-I device examination extra 14 lesions were detected. Nineteen out of the 23 lesions that had positive findings on the device were confirmed to be malignant giving Breast-I® device positive predictive value of 86.3% in predicting a malignant lesions with sensitivity and specificity of 82.6% and 91.8 % respectively*

*Breast-I device examination of the breast is simple to perform and can serve as complementary tool in routine breast examination.*

***Keywords****: Red light examination, breast cancer. Breast-I device and south western Nigeria.*

## Introduction

Breast cancer is one of the major health challenges facing women globally, [1] and the leading cause of cancer related death among women.[2] the incidence is increasing globally including areas that previously enjoyed low incidence. [3] Breast cancer patients suffer significant morbidity and mortality in most developing nations, due to delay presentation with subsequent increased cost of care and overall poor survival.[4-7] early presentation and prompt treatment interventions will improve breast cancer outcome. Though many factors are responsible for delayed presentation such as poor awareness and wrong misconceptions regarding breast and breast cancer; one other factor that needed to be addressed in most low- and middle- income countries is lack of well-organized screening programmes. Though, mammography is considered as the gold standard for breast cancer screening, however relying on mammography in low- and middle-income countries may not be sufficient due to high cost, unavailability, and even when available they are not in functional state all the time, and were ordered mainly for diagnostic purposes.[8] Forrest, in his report suggested the need for continuous search for non-invasive screening modality for younger women with dense breast tissue who may not benefit from mammography or where mammography may not be effective. [9,10] This recommendation by Forrest is of utmost importance, especially in places where breast cancer occurs relatively more among younger premenopausal women- a

situation in Nigeria, and many other low- and middle- income countries,[11-15] with peak incidence of about 10 years lower when compared to peak incidence in western countries [15,16] This device seems to be a promising tool for detecting breast cancer in all age groups.[17] The device is a handheld device that produces non harmful red light at a wave length of 617nm. The device works on the principle that red light at a wave length in the range of 617 – 620nm will be absorbed by haemoglobin when passed through a tissue, and an area with relatively high concentration of haemoglobin will cast a visible shadow on the opposite surface (superior aspect of the breast). The extent of light absorption thus depends on the number/density of red blood cells in the region illuminated, which in turn is also affected by the tissue vascular flow.[18] Thus regions without increased vascularity will appear as homogenous pinkish red surface. (Figure 1a and 1b) while area with cancer focus with increased neovascularization would cast optic shadow on the opposite surface. (Figure 2) Previous studies on red light examination of the breast were carried out among Caucasians who have lighter skin, with Edinburgh and Aberdeen clinical study trials quoting a sensitivity in the range of 70-90%.[19] This study was thus conducted to determine the efficacy of the Breast-i device as a breast cancer screening tool among the premenopausal women in Nigeria as there is paucity of such study among African population, and the authors are not aware of a similar study in Nigeria.

# Methods

## Study design

This was a prospective experimental observational study that was carried out in Ladoke Akintola University of Technology Teaching Hospital, Ogbomoso.

## Setting

A tertiary medical centre.

## Patients

Adult female patients with or without breast complaint attending general surgery outpatient clinic and general out-patients clinic that consented to participate in the study following counseling and explanations about the nature of the study. The verbal consent of each participant was obtained and it was explained that entering into the study is by free will and they could opt out of the study at any point without affecting their treatment. The participants were also made to know the implications of positive findings and possible need for further evaluation. The participants were also told that the device is not a substitute for breast ultrasound examination or Mammography.

## Inclusion and exclusion criteria

The inclusion criteria are: consenting adult female patients older than 18 years.

The exclusion criteria are**:** Non consenting female patients, patients with fungating breast lesions or patients with recent history (less than six months) of invasive breast procedures or trauma to the breast (these were excluded because of associated hematoma or ongoing resolving hematoma which may affect the interpretations; as such areas may behave as vascularised tissue).

## Sampling and sample size

Consecutive sampling technique was used for the study. Using sensitivity of 80% at 95% confidence interval with at 5% error margin a minimum sample size of 246 breasts were required and using 30% attrition rate 320 breasts were examined in 161 patients (as 2 patients were women with previous unilateral mastectomy for breast cancers).

## The device “Breast-I®” Device

Breast-I device (Figure 3) was used for the study. The device produces a high intensity red light at a wave length in the range of 614-620nm. The device is a class I medical device.

## The Procedure

All the enrolled women underwent initial self-breast examination routine clinical evaluation followed by examination with breast-i by another clinician who is not aware of the clinical examination findings. The device examination was done in a semi-dark room with a female chaperon usually one of the attending nurses with or without patients’ spouse or patients’ relatives as the patients preferred. The examination was performed by switching-on the device and pressing it lightly against the skin on the inferior surface of the breast (figure 4a and b) while watching for any black/dark shadow on

the superior surface of the breast (i.e. the contralateral surface).

The light intensity setting (1 to 5) was chosen to optimize contrast. The lowest possible intensity consistent with achieving transillumination maximizes sensitivity to observing shadows due to small lumps. All patients with suspicious finding(s) were then counseled to undergo further evaluation that include biopsy and histology while patients with negative findings were counseled on breast health, breast cancer and breast cancer screening and informed that the examination done so far is not a substitute for routine breast screening examination.

## Data

The data obtained includes: patients' bio data, weight and height, BMI, skin colour tone using Thomas B. Fitzpatrick scale,[20] lactational status, breast complaint if any, previous pregnancy, previous breast screening examination, previous invasive breast procedure and when, scar on the breast, clinical breast examination findings, Breast-i device examination findings, gross estimation size of the lesions in mm while undergoing Breast-i device examination using a tape rule and after surgical excision using a venire calliper, breast imaging on USS or and mammography when available and final histological diagnosis for patients that were subjected to biopsy and histology with intention to treat.

The sensitivity, specificity, positive and negative predictive value, and accuracy of Breast-i device in detecting breast cancer were calculated using histological diagnosis as the standard.

## Statistical analysis

Statistical analysis was done using Statistical Package for Social Science (SPSS) version 20. Data were presented as proportions, ratio, and percentages while Chi-square was used for significance analysis with *P* value set below .05 for significant difference.

## Results

One hundred and sixty one women were enrolled into the study and a total of 320 breasts were examined of which 33(66 breasts, 20.6%) women drop out from the study. The mean age of the participants was 41.23± 6.7. The clinico-socio-demographic characteristics is as shown in table 1.

The breast illumination was not affected by the intensity of the skin pigmentation. (Figure 6)

Forty-seven (63.1%) patients had breast complaints and breast lump was the presenting complaint in 35 (74.5%) of them. Clinical breast examination further detected 22 lumps giving rise to 62.9% increment. When patients where then subjected to breast-i device examination extra 14 lesions were detected. Figure 7

Further assessment revealed that 13(92.8%) out of the 14 extra lesions detected by breast-i device were actually lumps buried deep within the substance of the breasts that were missed by both patients and clinician on initial clinical examination giving rise to a total of 70 lumps in the series. Analysis of the extra detected 13 lumps revealed that 12 (92.3%) were actually malignant.

The mean size of the lump following excision was 24mm (±3.4) while breast i device estimated mean size was 27mm (±1.1).

Seventy (98.6%) of the 71 lesion that were subjected to histology were lumps. Twenty-two (30.9%) of these 71 lesions were histologically confirmed to be malignant.

Further analysis revealed that 23 (16.5%) out of the 71 lesions that were subjected to histology had positive findings on breast-i device examination of which 19 (82.6%) were histologically confirmed to be malignant giving breast-i device a sensitivity and positive predictive value (PPV) of 86.3% and 82.6% respectively. Forty-eight breasts findings were in keeping with benign findings on the device examinations of which 3 (6.3%) were confirmed to be malignant on histology giving the device a specificity and negative predictive value (NPV) of 91.8% and 93.7% respectively. Figure 8.

Six breast findings were inconclusive as the device failed to transmit light in such breast and all were in lactating women whom were later diagnosed as cases of galatoceole.

Analysis of clinical breast examination and breast-i device in detecting malignant breast disease revealed that out of the 22 malignant lesions in the study clinical breast examination suspected 10 (45.5%) out of the 22malignant lesions compared to 19 (86.4%) malignant lesions suspected by breast-i device ($X^2$=0.8.1931, p=0.0042).

Fibroadenoma constituted 23 (51.1%) of the 45 lesions that were truly benign followed by fibrocystic changes 21 (46.7%) and a case of tuberculosis of the breast (2.2%).

Based on the findings the diagnostic accuracy of Breast-I® device in detecting breast cancer is 90.1%.

False positive results were seen in 4 (17.4%) patients of which 2(8.7%) were in patients with previous breast scar and 2(8.7%) cases of giant fibroadenoma.

## Discussion

Breast cancer is the most common cancer in women, [21,22] with significant burden on health care system in most low-resource countries [23,24] including sub-Saharan Africa with comparative higher incidence in premenopausal women. [25-27] Lack of organised screening programmes and facilities coupled with high cost of screening where available are recognised factors associated with late diagnosis in most low- and middle- income countries.[28] This thus call for more emphasis on programmes that will ensure early diagnosis through screening in developing countries. The hallmark of a good screening programme involves selection of population to be screened and use of appropriate screening instrument to detect the disease when asymptomatic thus allowing multiple treatment options with lesser cost and better overall survival. Screening population for breast cancer is bound to varies from region to region based on the group of women that bear the major burden of the disease and thus considering this fact, premenopausal women who suffered the major burden of breast cancer in Nigeria and many other countries in the sub-Saharan African [9,11,12,29-31] should always be taken into consideration when planning screening programmes and modalities. Currently the most popular consensus regarding breast cancer screening is to start screening from fifth decade of life for population based screening where breast cancer peaked at fifth decade of life [32] using mammography which is currently considered as the gold standard in breast cancer screening. Extrapolating this to Nigeria and many other countries in sub-Saharan African needs re- appraisal as most cases of breast cancer are seen in relatively younger premenopausal women whom may not benefit from mammography which has been shown to be less sensitive in younger premenopausal women with more dense breast tissue, and possibly require screening, a decade lower than that of the western countries cut off point. This study was thus conducted to determine the efficacy of a breast-i device in detecting breast cancer among premenopausal women who bear the major burden of breast cancer in our region.[11,12]

The mean age of our patient was about 41 years, an age group the study specifically interested in or target based on our selection criteria as they constitute the group of women that bear the major burden of breast cancer. Majority 147 (91.4%) of our patients were educated all are aware of breast cancer, however majority 122 (95.3%) had never undergone radiological screening and only about 23 (19%) practice SBE. This finding is consistent with previous report from sub-Saharan Africa that reported poor performance of breast screening among educated women including health care workers.[33,34]

The most (74.5%) common presenting symptom in our study was breast lump a finding in consistent with report from a similar study.[35]

The mean size of the lumps was overestimated by the device, such finding was probably due to magnification of the lumps as shadow was used for the measurement, this finding was in contrast to mammographic and USS that often underestimates the lump size while clinical examination tends to overestimate the lump size.

Clinical breast examination led to 63% increment in lumps detected which rose to 100% when combined with breast-i device examination.

Further analysis of breast-i and clinical breast examination revealed that breast-i was able to detect about 86% of the breast cancer as compared to about 46% detected by the clinical breast examination alone, the higher detection rate of the breast-i examination was due to ability of the device to pick smaller tumour as previously reported [36] which ordinarily will be difficult to pick by clinical breast examination more especially in premenopausal women with large dense breast as shown in our study. Previous study among African premenopausal women in Ghana have also shown superiority of the Breast-I device in detecting breast cancer compared to clinical examination alone with

reported sensitivity of about 73% and 92 % respectively for clinical breast examination and the Breast-I device. [17]

About 93% of missed lesions on clinical breast examination were actually breast lumps that were buried deep within the substance of the breast.

Though clinical breast examination detected a total of 57 lumps (compared to 23 lesions detected by the device) and detected other signs such as nipple discharge and breast distortion which cannot be detected by the Breast-I device; these were not seen as short coming of the device as the device is specifically designed to detect breast cancer and not lumps irrespective of other associated symptoms or signs which we believed the device has fulfilled because the hallmark of breast evaluation is to rule in or rule out breast cancer. Thus complementing the device with CBE will improve the diagnostic yield of the CBE.

About 17 % of the breast lumps that were subjected to histological examination were considered suspicious lesions based on the device findings of which about 83% were later confirmed to be malignant given the device a sensitivity and PPV of about 86% and 83% respectively which was comparable to results from other previous similar studies. [37, 38] the value obtained from our study was relatively higher than that of an Aberdeen study that quoted sensitivity of about 73%. [19] The study also found specificity, negative predictive value of about 92% and 94 % for the device respectively with diagnostic accuracy of about 92% in detecting breast cancer. The higher value in our study could be due to hospital based nature of our study with tendency to have higher number of patients with background breast disease and relatively larger tumour sizes as tumour size had been shown to give a positive correlation with lesion detection rate when using the device.[39], [40,]

About 17% of the lesions in our study were false positive in 2 patients with previous scar and 2 with giant fibroadenoma. The reason for such false positive results could be due to inability of the light to pass through a scar tissue in patient with scar and progressive decrease in light intensity in patients with giant fibroadenoma. Inflammatory breast lesion was known to cause false positive finding due to increased tissue vascular flow as previously reported from some studies.[41,42]

About 6% of the negative finding were false negative, and were seen in cases that the lumps were located on the inferior surface of the breast and closed to the skin on the same surface the device was placed in women with TFP scale II, and this could have been due to masking of the optic shadow by the surrounding normal breast tissue that trans-illuminate brilliantly. This false negative findings could have been avoided possibly if the examinations were repeated using both surfaces as examining and observing surface alternately thus suggest the need to do the breast-i examination from minimum of two surfaces.

Breast-i device has been shown to detect breast cancer in both palpable and non-palpable lesions [17, 36] as also observed in our study and when combined with clinical breast examination it improve the overall diagnostic yield as compared to clinical breast examination alone. Combination of breast-i device examination with self-breast examination will also improve the diagnostic yield of self-breast examination and it was also reported that women combining SBE with Breast-i device examination tend to have better sense of participation in their own health and tend to be more compliant with SBE.[44]

The device has the advantage of being cheap and easily combined with both clinical and self-breast examination. The device performance has also been shown not to be affected by breast density or the skin pigmentation which make it a valuable adjunct to CBE and SBE in screening for breast cancer. Lack of radiation also makes the device a good option for all age group with cumulative risk of radiation damages. Because of its non-compressive mechanism it will serve as good examination device in patients with painful breast conditions that may preclude or make palpation less thorough due to tenderness.

Though the device generates heat, however, none of the patients in the study complained about it and this could also be minimised when the device is not allowed to unduly be in contact with the skin for too long.

The present report was considered as preliminary report as the authors suggest the need for more large population based study and the need to compare the breast-i device

examination with currently existing other imaging modalities.

## Limitations of the study

The patients with negative findings on both clinical breast examination and device examination were not evaluated further in the research protocol and thus were not included in the data analysis.

## Conclusion

Breast i device is not a diagnostic tool for breast cancer however it can serves as complementary examination to both clinical and self-breast examination as it has the ability to detect some tumour that may be missed by both CBE and SBE thus picking tumour early as early detection is the key to good outcome.

**Table 1.** Clinico-socio-demographic characteristics

| | |
|---|---|
| **Age** (mean sd) | 41.23± 6.7 |
| **BMI** (mean sd) | 24.5± 4.5 |
| **Educational level** | |
| None | 11 (8.6%) |
| Primary and secondary | 46 (35.9%) |
| Tertiary | 71(55.5%) 91.4 |
| **Previous screening for breast cancer** | |
| Self-breast examination | 23 (19%) |
| Clinical-breast examination | 1 (0.7%) |
| Breast Ultrasound | 4 (3.1%) |
| Screening mammography | 2 (1.6%) |

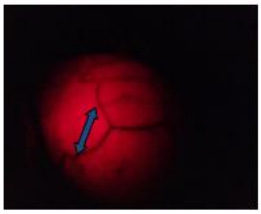


Figure 1a

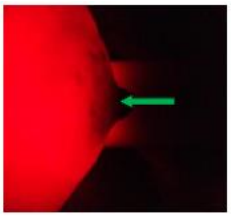


Figure 1b

**Figure 1a.** Showing a normal right breast in a 43 year old premenopausal woman undergoing examination with Breast-i: the superficial blood vessels casting black shadow (blue double headed arrowed) on a homogenous red background

**Figure 1b.** Showing homogenous red appearance of a benign finding and nipple areolar complex (green arrowed) in a 32 year old woman

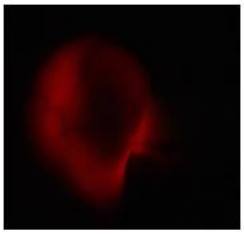


**Figure 2.** Showing a dark optic shadow (red arrowed) on homogenous red background on right breast of a 37 year old woman undergoing breast-i device examination that was later histologically confirmed to be malignant


**Figure 3.** Showing Breast-I®

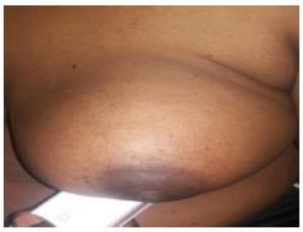


**Figure 4a**

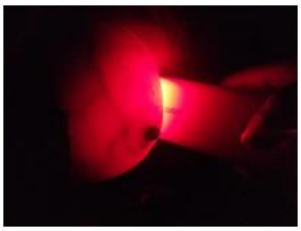


**Figure 4b**

**Figure 4a.** Showing the device (blue arrow) below the inferior surface of the left breast and figure 4b is showing the device after it was switched-on in a dark room.

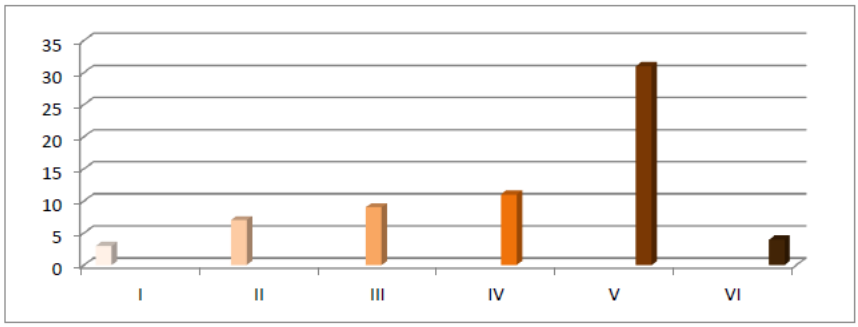
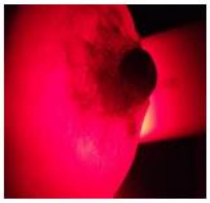
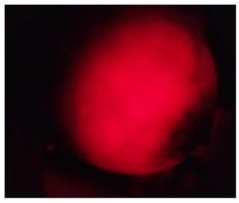



**Figure 5.** Showing distribution of intensity of skin pigmentation using Thomas B. Fitzpatrick scale.



II



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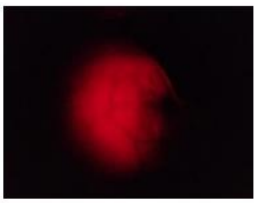

VI

**Figure 6.**showing breast illumination for different intensity of skin pigmentation using Thomas B. Fitzpatrick scale

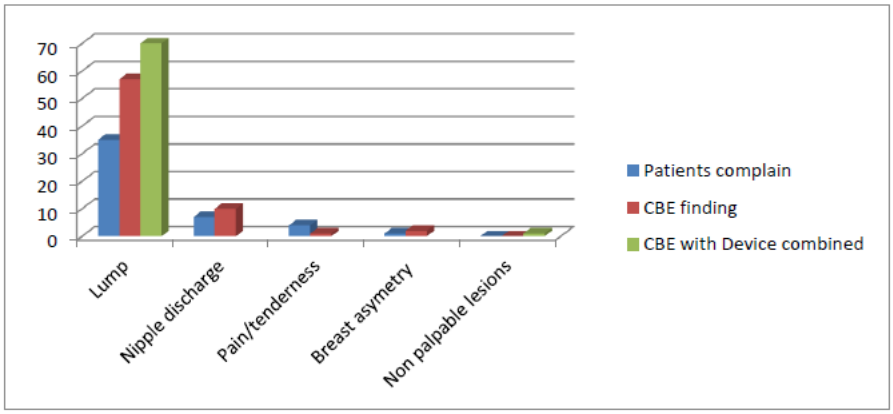


**Figure 7.** Showing patients' presenting complain, findings on clinical-breast examination alone and when combined with the device

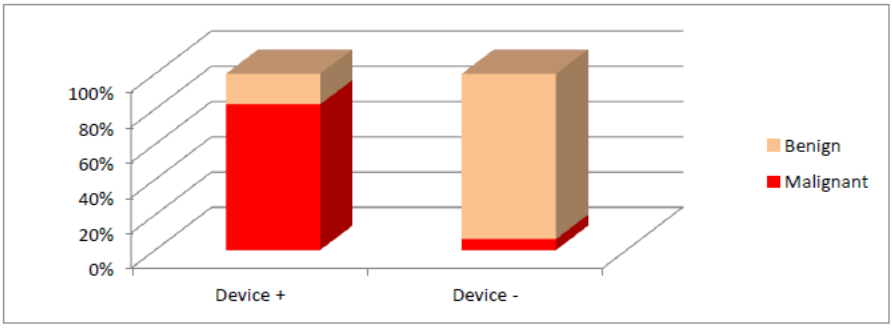


**Figure 8.** Showing concordance between the breast I device findings and histological diagnosis

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