THE LANCET
Global Health

Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Appendix
Table 1: Breast Imaging-Reporting and Data System (BI-RADS) assessment categories [26]

BI-RADS Category	Description
0	Incomplete- need additional imaging evaluation and/or prior studies for comparison
1	Negative
2	Benign
3	Probably benign
4	Suspicious
5	Highly suggestive of malignancy
6	Known Biopsy-Proven Malignancy

Table 2: 273 symptomatic women were included in this study and reported a variety of breast symptoms.

Breast Symptom	Number of women (%)
lump	88/273 (32%)
pain/discomfort	181/273 (66%)
nipple discharge	51/273 (19%)
axillary swelling	9/273 (3%)
itching	8/273 (3%)
tingling	1/273 (0.4%)
skin changes	1/273 (0.4%)

Table 3: Positive exam rates for clinical breast exam and iBreast Exam.

	Clinical breast exam	iBreast Exam
Overall positive studies	84/424 (20%)	226/424 (53%)
Symptomatic women positive	75/273 (28%)	160/273 (59%)
High risk women positive	9/151 (6%)	66/151 (44%)

Table 4: The joint use of iBreast Exam and clinical breast exam considered positive if either exam was positive.

Combined use of iBreast Exam and clinical breast exam	(95% CI)
Sensitivity for suspicious masses	92% (77.4–98.3)
Specificity for suspicious masses	49% (44.0–54.1)
Accuracy for suspicious masses	53% (47.7–57.6)

Table 5: Sensitivity of clinical breast exam and iBreast Exam for smaller breast lesions (≤ 2 cm) compared with larger breast lesions (>2 cm).

	lesions >2 cm	lesions ≤ 2 cm	p value
Clinical breast exam sensitivity	26%	8%	0.021
iBreast Exam sensitivity	42%	29%	0.093

Table 6: iBE and CBE sensitivities and specificities for detection of suspicious breast findings in dense vs. non-dense breasts. Note breast density was available for 399 women.

	Dense Breasts	Non-Dense Breasts	p value
iBE sensitivity	80% (59.3%, 93.2%) (20/25)	100% (69.2%, 100%) (10/10)	0. 30
iBE specificity	40% (33.5%, 46.8%) (88/220)	63% (54.8%, 71.1%) (91/144)	<0.0010
CBE sensitivity	80% (59.3%, 93.2%) (20/25)	100% (69.2%, 100%) (10/10)	0.30
CBE specificity	83% (77.1%, 87.5%) (182/220)	92% (86.7%, 96.1%) (133/144)	0.013

Table 7: Patient age (≤50 years or >50 years) did not significantly affect sensitivity or specificity of suspicious breast lesions with clinical breast examination or iBreast Exam.

	p value
Clinical breast exam	0.34
iBreast Exam	0.79

Table 8: Percentage of false-positive iBE evaluations (false positive iBE/total negative patients as defined by imaging) before (n=192) and after (n=232) the iBE device upgrade.

	Any Finding	Suspicious Findings
Before Upgrade	49% 37/75	61% 109/179
After Upgrade	35% 39/111	41% 83/204
	p = 0.053	p < 0.0010
Overall	41 % 76/186	50% 192/383