Low Dose X-Ray Diffraction Imaging with Real Time AI Classification Distinguishes DCIS from Invasive Breast Cancer: Hardware and Interim Clinical Performance of the EosDx EoScan™ First-in-Human Study

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Background

Xray diffraction detects nanoscale structural alterations in collagen, lipid, and water that herald breast neoplasia. EoScan™ is a diffraction breast scanner that captures Bragg signatures through intact tissue and classifies malignancy using a convolutional neural network (CNN) trained on >12,700 spectra.

First-in-Human Hardware

The IRB-approved first-in-human unit ("Human-1", IRB #1381803, San Fernando Valley Cancer Center, Los Angeles, CA) comprises: (1) a micro-focus Xray source with liquid cooling, (2) a 80 μm slot collimator, (3) a 256×256-pixel photon-counting detector housed in a 2 mm Pb-equivalent shield. The system fits in <0.75 m², weighs 110 kg, runs standard 110V, without breast compression.

Methods

Ex-vivo cohort: Breast samples including malignant (n = 161) and benign (n = 131) obtained at Valley Breast Care (Los Angeles, USA) and Keele University (Keele, UK). A total of 12,730 diffraction patterns were collected at EosDx (Menlo Park, CA) and Queen Mary (London, UK) respectively. Malignant samples include infiltrating and in-situ types. Healthy control tissue was donated by patients undergoing reconstructive surgery performed by Dr. Daryl Hoffman (Campbell, CA); all samples were collected under the same IRB-approved protocol governing the in-vivo study. For all samples, pathology testing was conducted by the Valley Breast Care Pathology Department to confirm the disease status. Standard immunohistochemistry testing is conducted for information on hormone receptor status. FISH results are also reported.
In-vivo cohort: ongoing NOVA first-in-human trial (n = 150) using the Human-1 device at San Fernando Valley Cancer Center; patients are guided into exam room after completing IRB approved consent form and receive 3 scans on each breast. CNN outputs a malignancy index (0–100). Radiologic findings and pathology results are used to validate the malignancy index output and calculate performance metrics, such as Sensitivity (Se), Specificity (Sp), PPV, and ROC-AUC. DCIS versus invasive carcinoma performance is evaluated separately.

Results

Ex-vivo: Se = 95.9 %, Sp = 93.5 %, PPV = 95.1 %, AUC = 0.96; DCIS vs invasive accuracy = 90 %

In-vivo interim: Se = 85 %, Sp = 70 % across 150 participants; collected results are analyzed through previously trained machine learning models and cloud-based weekly model updates improve performance; no device-related adverse events. Patients report high satisfaction and a positive user experience.

Conclusions

EoScan delivers molecular level breast imaging at radiation doses ~25-fold below mammography. High ex-vivo accuracy and encouraging interim in-vivo performance, along with the ability to distinguish DCIS from invasive cancer, support its potential as a front line screening adjunct. Final NOVA results will be presented upon database lock.

Keywords

X-ray diffraction, breast cancer, DCIS, AI diagnostics, structural biomarkers, low-dose imaging

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