

# Performance of Opto-acoustic Ultrasound with an Artificial Intelligence-based Decision Support Tool Versus Ultrasound Alone to Classify Benign Versus Malignant Breast Masses: A Pivotal Reader Study

Session ID: **BR03-D7**

Speaker: **Stephen Jacob Seiler, MD**

Date: **Tuesday, November 30**

Time: **4:30 – 5:00 PM CST**

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## SESSION INFORMATION:

**Purpose:** To evaluate the gain in specificity using opto-acoustic and ultrasound fused images (IUS+OA) and an artificial intelligence-based decision support tool (AI-DST) versus ultrasound (IUS) alone, controlling for sensitivity.

**Methods and Materials:** Randomly selected 480 BI-RADS 3–5 masses (0.33–3.89 cm, mean diameter  $1.45 \pm 0.77$  cm) that underwent IUS+OA scanning as part of the multi-site PIONEER-01 trial were evaluated by 15 readers trained in IUS+OA interpretation. Readers first assigned probability of malignancy (POM) and BI-RADS category based on clinical history, mammogram and IUS. Readers then evaluated IUS+OA images, assigning IUS and OA feature scores and viewed a likelihood of malignancy (LOM) prediction score derived from a machine learning AI-DST before issuing a final POM and BI-RADS category. Mean specificity at fixed sensitivity of 98% (fSp), negative likelihood ratio (NLR), positive likelihood ratio (PLR) and partial area under the curve (pAUC) (95–100% sensitivity) of IUS+OA vs. IUS were calculated.

**Results:** The study demonstrated a statistically significant gain in fSp of 9% (averaged over all readers) for IUS+OA compared to IUS ( $p=0.027$ , 95% CI: 1.03%, 16.9%). The mean NLR was 0.047 (95% CI: 0.032, 0.062) for IUS+OA and 0.053 (95% CI: 0.037, 0.070) for IUS alone. The mean PLR was 1.959 (95% CI: 1.870, 2.051) for IUS+OA and 1.548 (95% CI: 1.498, 1.597) for IUS alone. The pAUC was 0.0244 (95% CI: 0.0230, 0.0258) for IUS+OA and 0.0205 (95% CI: 0.0191, 0.0219) for IUS alone, a difference of 0.0039.

**Conclusions:** IUS+OA plus an AI-DST has a statistically significantly better fSp than IUS alone. The IUS and OA feature scores can be used as combined qualitative diagnostic and predictive imaging biomarkers.

**Clinical Relevance/Application:** IUS+OA provides useful diagnostic information and, with AI-DST, has the potential to reduce false positives, and thus biopsies of benign masses, versus IUS alone without sacrificing sensitivity.

