Overview

• Regulatory Status: The Imagio® breast imaging system, a diagnostic opto-acoustic (OA) imaging device bearing the CE Mark, is in the U.S. FDA Premarket Approval process.

• Principle: OA provides both functional (relative oxygenation/de-oxygenation) and anatomic (angiogenesis) information that is co-registered and temporally interleaved in real time with gray-scale ultrasound that may improve distinction between benign and malignant masses.

• Goals: OA imaging pathology correlation was performed to elucidate the histologic features of OA features of breast cancers.

Methods and Materials

• A multicenter post-market surveillance study was conducted in five Dutch sites in which 209 women with breast masses underwent OA prior to biopsy.

• Histopathology examination of the biopsies revealed 146 benign masses (mostly fibroadenomas) and 67 malignant masses (mostly invasive ductal carcinomas).

• For invasive ductal carcinomas, histologic grade and the features used to assess histologic grade (nuclear pleomorphism, tubule formation, and mitotic count) were assessed.

• For each mass, 5 pre-determined OA features, 3 internal features, and 2 external features were evaluated.

• Three internal scores (vessels, blush, and hemoglobin) and 2 external scores were separately and collectively summed for testing relationships with traditional histopathology measures using a one-sided Jonckheere-Terpstra test of ordered outcomes reflecting experience.

• Distribution differences between benign and malignant masses were statistically significant for internal vessels (p=0.0009), internal blush (p=0.0085), external boundary zone (p=0.0001), and external peripheral radiating vessels(p<0.0001), but not internal hemoglobin (p=0.340).

Results

Table 1: Mean Total Internal Score, Total External Score, and Total Score were all significantly higher (all p<0.01) for malignant vs. benign.

Table 2: Among invasive carcinomas, Total Internal Score and Total Score were significantly higher for higher histologic tumor grade (p=0.050, 0.034).

Table 3: Higher Total External Score and Total Score for higher tubule score (p=0.072, 0.068).

Table 4: Higher Total Internal Score and Total Score for higher nuclear pleomorphism score (p=0.059, 0.065).

Table 5: Significantly higher Total Internal Score for higher mitotic score (p=0.026).

Conclusions

• OA feature summary scores appear to differentiate between benign vs. malignant and correlate to histologic grade and scoring components of histologic grade.

• The PIONEER pivotal study (n=2,095) may further confirm these results.