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Positron Emission Mammography Guided Breast Biopsy

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PURPOSE

To demonstrate the spatial accuracy and clinical utility of the Stereo Navigator* software guidance accessory of the PEMFlex PET scanner for targeting and accurately guiding biopsies of suspicious breast lesions identified with Positron Emission Mammography (PEM).

METHOD AND MATERIALS

Biopsy guidance was tested using a custom phantom with eight Na-22 point sources at known positions. The phantom was positioned between PEM detector heads with separations of 35-114mm. Success in targeting was defined if distance of the coaxial trocar tip to point source was ≤ 4.5 mm (across planes) and ≤ 2 mm (in-plane). Sponge & turkey breast phantoms with 3 to 5 mm FDG agarose lesions were used to test biopsy sampling when used in conjunction with commercial 9 to 11-g vacuum-assisted biopsy devices. A pilot patient study (n=20) is in process to confirm clinical utility of the Stereo Navigator accessory. Successful targeting & biopsy of these PEM identified lesions was measured by guiding a line source to ≤ 4 mm of lesion, alteration of the lesion in subsequent PEM scans and concordance between imaging and pathology.

RESULTS

For the 96 spatial accuracy measurements tests, the absolute difference between the physical locations of the Na-22 sources to the software calculated locations was $0.6 + 0.3$ (SD) mm in-plane and $1.0 + 0.9$ (SD) mm across planes. For the 81 point source targeting tests, the targeting success rate was 94% across plane and 98% in-plane. The success rate in targeting agarose lesions in 48 sponge and 49 turkey phantoms was 100% and the biopsy was successful in sampling 96% of agarose lesions. To date, six patients have completed successful biopsy of suspicious breast abnormalities (mean size: 6mm) with FDG uptake in an IRB approved multicenter study. The pathology results (IDC, DCIS, fat necrosis) were concordant with imaging.

CONCLUSION

The Stereo Navigator Accessory provides high spatial and targeting accuracy to guide the successful biopsy of breast abnormalities seen on PEM.

CLINICAL RELEVANCE/APPLICATION

The Stereo Navigator accessory provides a mechanism for physicians to biopsy suspicious breast lesions seen on PEM scans, adding a new tool in pre-surgical planning and breast cancer management.

*Investigational Device. Not available for sale.