Resolution 26-101

Advancing Diagnostic Visualization and Assessment Through Non-Compression Cone-Beam Breast CT Engagement

Physicians Society of Central Florida

Whereas, Breast cancer remains one of the leading causes of cancer-related morbidity and mortality among women in Florida and the United States, and early detection through effective screening remains the most powerful tool for reducing breast cancer deaths; and

Whereas, The U.S. Preventive Services Task Force recommends biennial screening mammography for women aged 40 to 74, concluding with moderate certainty that this strategy provides a moderate net benefit in reducing breast cancer mortality; and

Whereas, Despite the proven benefit of mammography, national data show that only approximately 75–80 percent of women aged 50 to 74 report receiving a mammogram within the past two years, with even lower participation among women aged 40 to 49, leaving millions of eligible women unscreened each year; and

Whereas, Pain, discomfort, and anxiety associated with breast compression during mammography have been repeatedly documented as barriers to screening participation, contributing to avoidable delays in diagnosis and reduced adherence to recommended screening intervals; and

Whereas, Dedicated cone-beam breast CT systems have demonstrated in peer-reviewed studies strong diagnostic performance for masses and architectural distortion, full-breast three-dimensional isotropic imaging without compression, radiation doses within the diagnostic mammography range, and feasibility for image-guided biopsy and preoperative planning; and

Whereas, Although cone-beam breast CT has demonstrated significant promise in diagnostic and preoperative settings, there remains insufficient evidence from large, prospective screening trials to define its role as a primary screening modality for average-risk women; and

Whereas, It is clinically plausible that a non-compression, three-dimensional breast imaging modality could increase screening uptake among women who currently avoid mammography due to pain or fear of compression, thereby improving early detection and potentially reducing mortality; and

Whereas, Modeling from the U.S. Preventive Services Task Force suggests that biennial screening from ages 40 to 74 prevents approximately eight breast cancer deaths per 1,000 women screened, indicating that even modest increases in screening participation among currently unscreened women could yield meaningful population-level mortality reductions; and

Whereas, For women who categorically refuse compression mammography, offering a reasonably performing, non-compression modality such as cone-beam breast CT is ethically analogous to preferring a parachute over no protection at all, even in the absence of randomized trials directly comparing that modality to the current standard; and

Whereas, Florida's diverse population, academic medical centers, and community health systems position the state as an ideal environment for clinical research, implementation studies, and technology evaluation in breast cancer screening; therefore, be it

RESOLVED, That the Florida Medical Association recognizes cone-beam breast CT as an emerging breast imaging technology with promising diagnostic capabilities and potential applicability to breast cancer screening, particularly for women who decline compression mammography; and be it further

RESOLVED, That the Florida Medical Association supports the A.D.V.A.N.C.E. – Breast Cancer Screening Initiatives to promote statewide awareness and physician education regarding the current evidence, capabilities, limitations, and appropriate clinical use of cone-beam breast CT; and be it further

RESOLVED, That the Florida Medical Association encourages and supports Florida-based research initiatives, including collaborations among academic institutions, community practices, and industry partners, to evaluate cone-beam breast CT as a supplemental or alternative screening option for women aged 40 to 75, assess its impact on screening uptake, stage at diagnosis, interval cancers, and patient-reported outcomes, and rigorously compare benefits, harms, and costs relative to digital mammography and digital breast tomosynthesis; and be it further

RESOLVED, That the Florida Medical Association advocates for state and federal funding mechanisms, including grants, pilot programs, and public–private partnerships, to support research and implementation studies evaluating cone-beam breast CT in Florida; and be it further

RESOLVED, That the Florida Medical Association affirms that mammography, including digital breast tomosynthesis, remains the current standard of care for population breast cancer screening for average-risk women aged 40 to 74, consistent with national guidelines, until and unless high-quality evidence demonstrates that cone-beam breast CT provides equal or superior outcomes; and be it further

RESOLVED, That the Florida Medical Association intends to use emerging evidence from Florida-based and national research to inform future advocacy with national specialty societies and guideline bodies, with the long-term goal of establishing cone-beam breast CT as a standard-of-care screening option for women aged 40 to 75 if and when evidence supports such a transition.

Fiscal Note:

Description	Amount	Budget Narrative
400 Staff hours Task force	$80,000 $ 5,000	Can be accomplished with current staff Meeting expenses
Total	$85,000	$5,000 added to the operating budget

Fiscal notes are an estimate of the cost to implement a given Resolution. All Resolutions that are adopted by the House of Delegates will be referred to the FMA Committee on Finance and Appropriations for fiscal consideration.

Reference Committee: I – Health, Education and Public Policy

<u>References:</u>

I. Patient Comfort & Experience

1. **Li H, Yin L, He N, et al.** *Comparison of comfort between cone beam breast computed tomography and digital mammography.* Eur J Radiol. 2019;120:108674.

II. Diagnostic Accuracy & Comparative Performance

2. **Yang L, Zhou Z, Wang J, et al.** *Head-to-head comparison of cone-beam breast CT and mammography in primary breast cancer: systematic review & meta-analysis.* Eur J Radiol. 2024;171:111292.
3. **Uhlig J, Uhlig A, Biggemann L, et al.** *Diagnostic accuracy of cone-beam breast CT: systematic review & meta-analysis.* Eur Radiol. 2019;29(3):1194-1202.
4. **He N, Wu YP, Kong Y, et al.** *Utility of breast cone-beam CT, ultrasound, and digital mammography for detecting malignant tumors: prospective study of 212 patients.* Eur J Radiol. 2016;85(2):392-403.
5. **Zhao B, Zhang X, Cai W, et al.** *CBBCT with multiplanar and 3D visualization vs mammography for differentiating breast masses.* Eur J Radiol. 2015;84(1):48-53.
6. **Wienbeck S, Fischer U, Luftner-Nagel S, et al.** *CE-CBBCT clinical performance compared to mammography and MRI.* Eur Radiol. 2018;28(9):3731-3741.
7. **Cole EB, Campbell AS, Vedantham S, et al.** *Clinical performance of dedicated breast CT vs diagnostic mammography.* RSNA Abstract.

III. Radiation Dose, Coverage, and Technical Performance

8. **O'Connell A, Conover DL, Zhang Y, et al.** *Cone-beam CT for breast imaging: radiation dose, breast coverage, and image quality.* AJR. 2010;195(2):496-509.
9. **Tseng HW, Karellas A, Vedantham S.** *Radiation dosimetry of a clinical prototype dedicated CBBCT system with offset detector.* Med Phys. 2021;48(3):1079-1088.
10. **Vedantham S, Shi L, Glick SJ, et al.** *Scaling-law for energy dependence of anatomic power spectrum in dedicated breast CT.* Med Phys. 2013;40(1):011901.

IV. Contrast-Enhanced CBBCT (CE-CBBCT): Tumor Characterization, Subtypes, NAC Response

11. **Wang Y, Zhao M, Ma Y, et al.** *Accuracy of preoperative CE-CBBCT vs MRI for residual tumor after NAC.* Acad Radiol. 2023.
12. **Ma Y, Liu A, Zhang Y, et al.** *Background parenchymal enhancement on CE-CBBCT vs MRI.* Eur Radiol. 2022;32(8):5773-5782.
13. **Ma WM, Li J, Chen SG, et al.** *CE-CBBCT features correlated with prognostic staging.* Br J Radiol. 2022;95:20210466.

14. **Ma Y, Liu A, O'Connell AM, et al.** *CE-CBBCT features correlated with IHC receptors & molecular subtypes.* Eur Radiol. 2021;31:2580-2589.
15. **Zhu Y, Zhang Y, Ma Y, et al.** *CBBCT features associated with HER2/neu overexpression.* Eur Radiol. 2020;30:2731-2739.
16. **Uhlig J, Fischer U, Surov A, et al.** *Optimal acquisition time for malignancy discrimination on CE-CBBCT.* Eur J Radiol. 2018;99:9-16.
17. **Uhlig J, Fischer U, Biggemann L, et al.** *Pre- and post-contrast vs post-contrast CBBCT for dose reduction.* Eur Radiol. 2019;29(6):3141-3148.
18. **Chen JT, Zhou CY, He N, et al.** *Optimal acquisition time to discriminate breast cancer subtypes with CE-CBCT.* Diagn Interv Imaging. 2020;101(6):391-399.
19. **Uhlig J, Fischer U, von Fintel E, et al.** *Contrast enhancement on CBBCT for discrimination of IHC subtypes.* Transl Oncol. 2017;10(6):904-910.

V. Calcifications, Density, and Morphologic Assessment

20. **Liu A, Ma Y, Yin L, et al.** *Comparison of malignant calcification identification between CBBCT and digital mammography.* Acta Radiol. 2023;64(3):962-970.
21. **Ma Y, Cao Y, Liu A, et al.** *Reliability of CBBCT for breast density assessment vs BI-RADS 5th edition.* Acad Radiol. 2019;26(6):752-759.
22. **Kang W, Zhong W, Su D.** *CBBCT characteristics of non-mass enhancement lesions.* Acta Radiol. 2021;62(10):1298-1308.

VI. Lesion Size, Pathology Correlation, and Surgical Planning

23. **Wienbeck S, Uhlig J, Fischer U, et al.** *Lesion size assessment: CBBCT vs DBT vs FFDM vs histopathology.* Medicine. 2019;98(37):e17082.
24. **Seifert P, Conover D, Zhang Y, et al.** *Evaluation of malignant lesions with non-contrast and CE-breast CT.* Breast J. 2014;20(4):364-374.
25. **Vedantham S, O'Connell AM, Shi L, et al.** *Dedicated breast CT for monitoring NAC treatment.* J Clin Imaging Sci. 2014;4:64.

VII. Biopsy & Interventional Applications

26. **Seifert PJ, Morgan RC, Conover DL, et al.** *Initial experience with CBBCT-guided biopsy system.* J Clin Imaging Sci. 2017;7:1.
27. **AJR 2017.** *Feasibility of vacuum-assisted breast CBBCT-guided biopsy vs prone stereotactic biopsy.* AJR. 2017;208:1154-1162.

VIII. Machine Learning, Reconstruction, and Future Technology

28. **Xie H, et al.** *Deep Efficient End-to-End Reconstruction (DEER) for few-view breast CT.* IEEE Access. 2020;8:196633-196646.
29. **Cong W, Shan H, Zhang X, et al.** *Deep-learning-based breast CT for radiation dose reduction.* Proc SPIE. 2019;11113:111131L.

IX. Reviews, State-of-the-Art, and Technology Evolution

30. **Zhu Y, O'Connell AM, Ma Y, et al.** *Dedicated breast CT: state of the art – Part I (technical).* Eur Radiol. 2022;32(3):1579-1589.
31. **Zhu Y, O'Connell AM, Ma Y, et al.** *Dedicated breast CT: state of the art – Part II (clinical applications).* Eur Radiol. 2022;32(4):2286-2300.
32. **Wienbeck S, Lotz J, Fischer U.** *Review of clinical studies and first European experiences with CBBCT.* Clin Imaging. 2017;42:50-59.
33. **O'Connell AM, Karellas A, Vedantham S.** *Newer technologies in breast cancer imaging: dedicated CBBCT.* Semin Ultrasound CT MRI. 2018;39(1):106-113.
34. **O'Connell AM, Karellas A, Vedantham S.** *Potential role of dedicated 3D breast CT: review & early clinical examples.* Breast J. 2014;20:592-605.

Domain / Question	Key Evidence (examples)	Approx. Level of Evidence*	Implication for Screening Use
Overall diagnostic accuracy vs pathology	Gong et al. 2023 systematic review & meta-analysis of 18 studies (1,792 pts) in women with suspected breast cancer; pooled sensitivity 0.95, specificity 0.72, AUC 0.92.	**Level 1a (diagnostic)** – systematic review of diagnostic accuracy studies	High diagnostic accuracy in referred populations; **supports diagnostic use**, not screening per se.
Head-to-head CBBCT vs mammography (MG)	Yang et al. 2024 meta-analysis: CBBCT sensitivity 0.92 vs MG 0.77; similar specificity; AUC 0.93 vs 0.83.	**Level 1a (comparative diagnostic)**	CBBCT outperforms MG in symptomatic / work-up settings; **suggests potential** but does **not establish screening benefit**.
CBBCT vs MRI	Gong et al. 2023: AUC CBBCT 0.88 vs MRI 0.96 in head-to-head diagnostic studies.	**Level 1a (comparative diagnostic)**	CBBCT somewhat inferior to MRI but still high accuracy; relevant for **diagnostic algorithms**, not screening trials.
Dense breasts / lesion characterization	Multiple prospective and retrospective diagnostic studies show improved mass visualization and characterization, especially with contrast-enhanced CBBCT, and good agreement with MRI for lesion type and enhancement patterns.	**Level 2 (individual diagnostic cohort studies)**	Supports CBBCT as an **adjunct diagnostic tool**, particularly in dense breasts; **indirect** for screening.
Radiation dose & technical feasibility	Early technical/clinical series show breast-limited dose comparable to mammography with full 3D coverage; ongoing work on dose reduction and reconstruction.	**Level 2–3 (technical + small clinical series)**	Dose appears acceptable for diagnostic use; **screening-dose optimization still evolving**.
Patient comfort / tolerability	Single-center comparative study shows higher comfort vs compressed digital mammography (no compression, prone positioning). (From your uploaded article set.)	**Level 2–3 (single cohort / survey)**	Favors CBBCT on comfort, which is **supportive but not determinative** for screening policy.
Screening outcomes (mortality, interval cancers, recall rates)	No randomized controlled trials or large prospective population-based screening cohorts of CBBCT vs MG or DBT.	**Level 4–5 (expert opinion, extrapolation)**	**No direct evidence** that CBBCT improves screening outcomes vs current standards. Any screening claim is extrapolative.

*Approximate mapping to Oxford Centre for Evidence-Based Medicine diagnostic levels:

- **Level 1a:** Systematic review of high-quality diagnostic accuracy studies
- **Level 1b:** Individual high-quality diagnostic accuracy study
- **Level 2:** Prospective cohort diagnostic studies
- **Level 3:** Retrospective / non-consecutive series
- **Level 4–5:** Case series, expert opinion, extrapolation