Koning Breast Computed Tomography (CT)

May 2023

Device Overview

Breast imaging is an integral part in evaluating for diagnosis and clinical staging of breast cancer. [1] Mammography, ultrasound, and magnetic resonance imaging are standard breast imaging modalities; however, additional approaches are emerging to assist in diagnostic outcomes. [2] Cone-beam computed tomography (CBBCT) is an "isotropic tomographic imaging technique" that utilizes a cone shaped (versus a fan shaped) x-ray beam. [3,4] According to the manufacturer, the Koning Vera Breast CT "produces high contrast real three-dimensional (3D) images of the breast with exceptional spatial resolution." [5] Advantages listed include rapid seven-second exposure, radiation levels within the range of mammography, lack of need for breast compression, safe contrast enhancement, spatial representation of structures, and low cost. [5] It includes a biopsy device for 3D-guided biopsies as a "lower radiation" alternative to stereotactic guided biopsy. During the scan, the patient lies face down on the table and the breast being imaged is placed suspended into a hole in the table allowing the entire breast to be scanned in seconds. [5]

Actions for Consideration

PARTNER

ENGAGE SUBJECT MATTER EXPERTS

Key team members may include radiologists, interventional radiologists, radiation oncologists, radiology technicians, oncologists, imaging leadership, and quality.

CONSIDER GUIDELINES FOR USE

An interdisciplinary task force will be beneficial to evaluate evidence, guidelines, and benchmark within specialty including utilization for routine screening versus adjunct to mammography, ultrasound, and MRI.

UNDERSTAND CONCERNS

Leverage a physician champion as peer liaison to identify areas of concern and population limitations.

CONNECT

SEEK CLINICAL IMPACT

Include review of imaging specificity, comparison of outcome metrics, evaluation of patient satisfaction scores, and assessment of current evidence.

CONDUCT ANALYSIS

Compare cost versus other modalities. Evaluate outcomes potential, increased capacity (faster imaging), patient satisfaction, impact on necessity of repeat imaging, and reimbursement potential.

DETERMINE POPULATION

Consider specific population needs, varying risk levels, accessibility, and specialty guidelines.

COMMUNICATE

EDUCATE AND TRAIN

Ensure documented competencies for technicians. Include education on patient instructions (pre/intra/post) and device precautions for all touch points. Consider two tier interpretation for an initial period.

PLAN AHEAD

Communicate initiative with ample notice to allow for dialogue including concerns, questions, and rationales. Ensure supplier engagement for education, demonstration, and support.

FOLLOW-UP FOR FEEDBACK

Consider reconvening 90 days post implementation to discuss progress and barriers. Report metrics regularly.

Professional Society Statements & Clinical Practice Guidelines

The United States Preventive Services Task Force (USPSTF)

In their final recommendation statement, *Breast Cancer: Screening*, the USPSTF does not address dedicated breast CT specifically; however, it does state that for supplemental screenings to mammograms (in general): "The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of supplemental screening for breast cancer using breast ultrasonography or magnetic resonance imaging (MRI) in women identified to have dense breasts on an otherwise negative screening mammogram." [6] Found here.

American College of Radiology (ACR)

In their *Appropriateness Criteria® Supplemental Breast Cancer Screening Based on Breast Density* the ACR provides recommendations for criteria supporting when to consider supplemental screenings. Of note, dedicated breast CT is not included in the supplemental modalities. Found here.

Clinical Evidence

There are multiple studies on the diagnostic and prognostic capabilities of CBBCT. A sample of the available evidence is provided below.

A 2022 retrospective study by Aidi et. al. aimed to compare CBBCT to digital mammography (DM) in the ability to detect malignant breast calcifications. A total of 115 paired exams were compared and analyzed by three radiologists in separate sessions separated by four weeks. The combined sensitivity of CBBCT in calcification detection was 98.43% with specificity at 98.85%. They concluded that CBBCT "comparable to DM in the characterization of calcifications" and that it was sufficient in detection of calcifications which could lead to breast cancer diagnostic improvement. Limitations of this study were the lack of benign lesions with suspicious calcifications, limited cohort size, limited cohort complexity, and small number of reviewers. Additional studies were recommended. [8]

See Reference section for complete listing of research sources.

Clinical Evidence cont'd

A 2012 prospective study by O' Connell et al. aimed to compare visibility of proven lesions, radiation dose, and patient comfort between mammography and CBBCT. They included 36 patients (37 breasts) that had confirmed abnormal mammogram and/or ultrasound, subsequently administering CBBCT. Radiation dose was calculated for all modalities, images were compared qualitatively, and patients were surveyed for comfort levels. CBBCT radiation dose was equal to or less than mammography, scored equally or better for visibility in 33 of 34 mammographic lesions, and patients reported greater comfort with CBBCT. They concluded that CBBT offered a "promising modality for diagnostic evaluation of breast lesions" due to its radiation dose profile, high degree of correlation to mammography, improved patient comfort, and "more anatomical evaluation of breast lesions." [9]

A 2018 prospective study by Shakeri et al. aimed to compare dedicated breast CT (contrast enhanced and non-enhanced) to mammography for visibility of ductal carcinoma in-situ (DCIS) versus benign calcifications.

The study included 42 women with category 4 or 5 micro-calcifications (according to Breast Imaging and Reporting Data System score). Prior to biopsy, they had breast CT which two radiologists independently scored for conspicuity. DCIS was more conspicuous on contract enhanced CT (CEbCT) than benign calcifications, equally visible on mammography and CEbCT, and more apparent on both when compared to non-enhanced. Radiologists also had a higher discrimination performance with CEbCT over enhanced values alone. They concluded that "CEbCT may have an advantage over mammography by reducing false positive examinations when calcifications are analyzed". [10]

FDA Approval

Koning obtained PMA approval (#P130025) in 2015 as follows: "Koning Breast CT (CBCT1000) is a cone beam computed tomography system intended to provide three dimensional images for diagnostic imaging of the breast. Koning Breast CT should be read along with standard 2-view mammography (CC and MLO views)." Found here. [13]

Clinical Insights: Healthtrust Physician Advisors

A panel of radiologists, gynecologists, and plastic surgeons within our HealthTrust Physician Advisor Network offered the following insight with regard to Koning [11]:

Physician Insights

- **Has a potentially higher detection rate.**
- **May lead to earlier diagnosis.**
- **Published data supports its advantage for use in dense breast tissue.**
- **Artificial intelligence integration may solicit skepticism, slowing clinical adoption.**
- **There is a need for further long-term clinical studies.**

Clinical Insights: HealthTrust Huddle

Members within our HealthTrust Member Network offered the following insight (via survey within Healthtrust Huddle) with regard to Koning [12]:

HealthTrust Huddle Insights

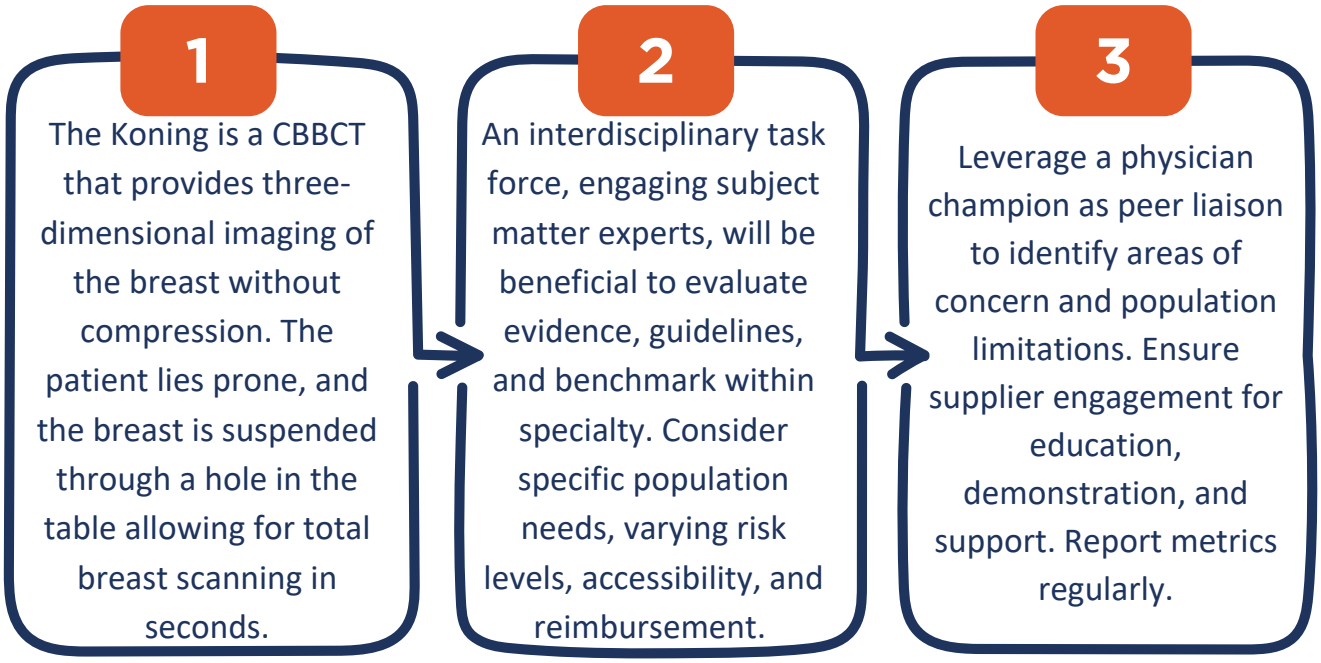
Advantages:

- **No painful compression**
- **Faster scanning**
- **Accommodates all breast types**
- **Potentially earlier detection**
- **Possibly more thorough exam**
- **May increase compliance to screenings**

Disadvantages:

- **Cost**
- **Possible reimbursement issues**
- **Large size may be issue if space is limited**
- **Potentially high cost of replacement parts/maintenance**

Summary



HealthTrust Clinical Resources

Allow us to connect you with the resources you need. Examples for this category include resources on value analysis and product trials. [14,15]

ASK A QUESTION | PROVIDE YOUR FEEDBACK | SHARE YOUR VOICE | NETWORK WITH PEERS

PERSONALIZED REQUEST SERVICE & RESOURCE LIBRARY

www.hpginsights.com

PEER NETWORKING

www.huddle.healthtrustpg.com
App store: "HealthTrust Huddle"

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