Koning

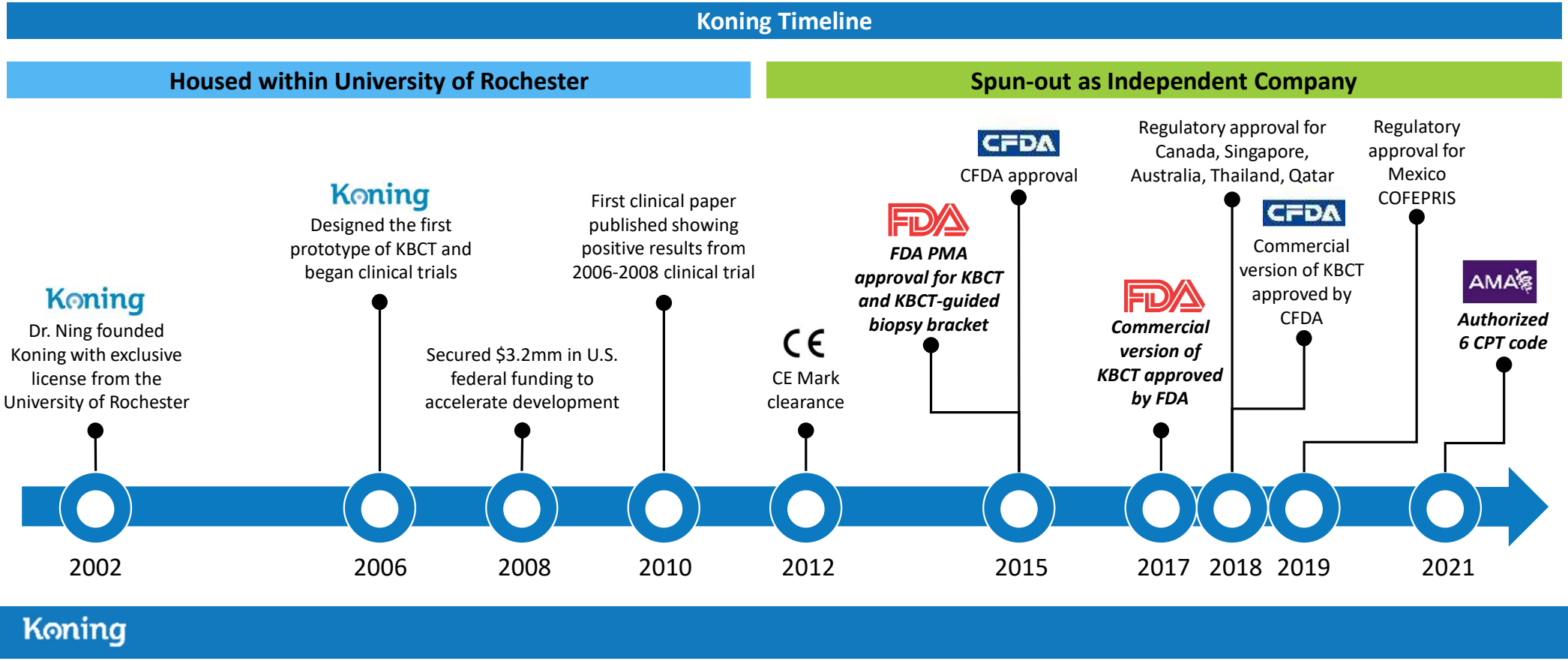
Koning Breast CT

2024

REVOLUTIONIZING THE BREAST IMAGING INDUSTRY

Overview of Koning's technology regulatory approvals timeline

Spun out of the University of Rochester, Koning is the only independent, commercial, dedicated breast CT company in the world



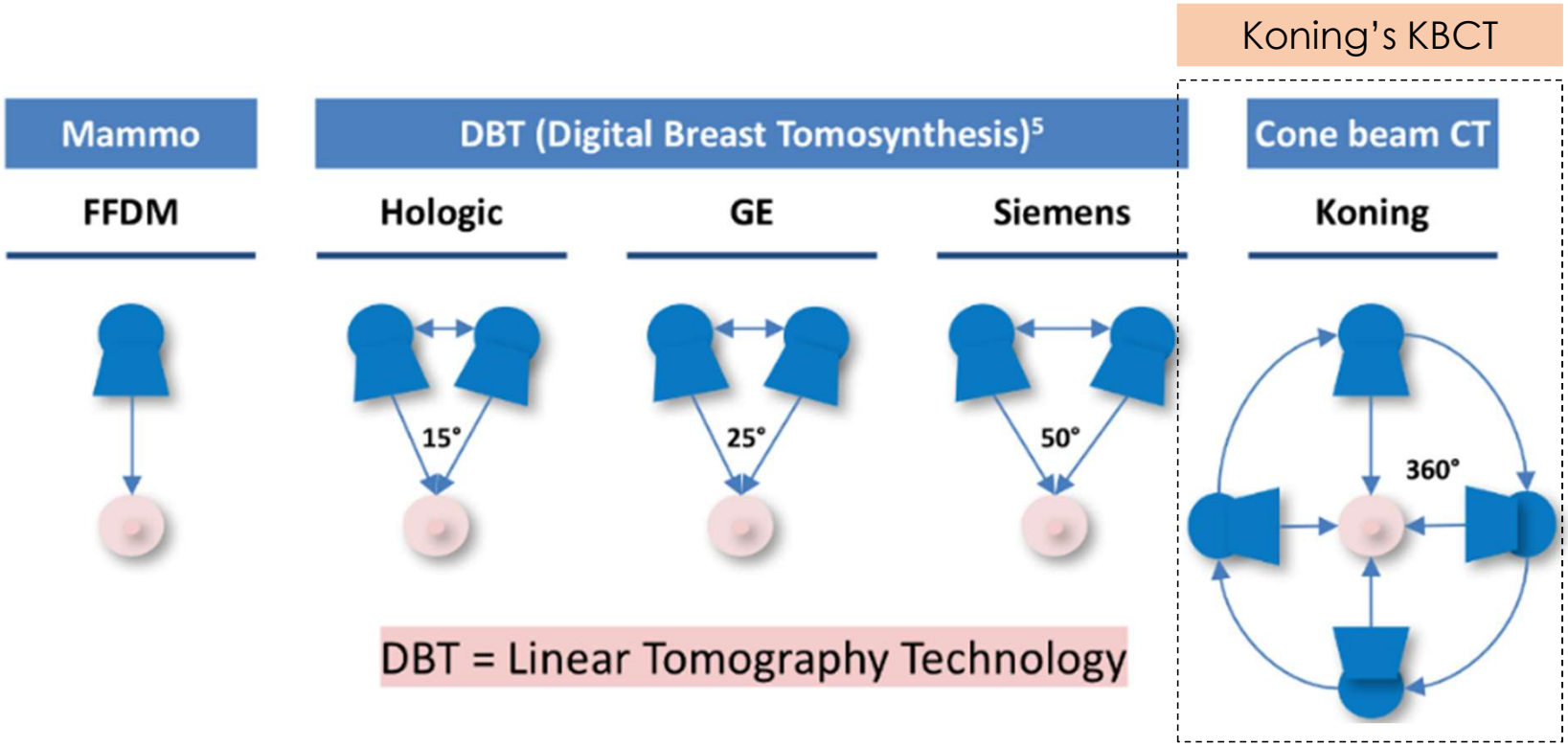
Comparison of devices: mammography (FFDM), digital breast tomosynthesis (DBT), Koning True 3D Breast CT (KBCT)

Full Field Digital Mammography (FFDM)

Digital Breast Tomosynthesis (DBT)

Koning True 3D Breast CT

Technologies Currently Available



Koning True 3D Breast CT (KBCT) provides significant clinical and economic benefits to all parties in health care ecosystem

Better patient experience	Better clinical insight	Better economics for providers …	… and payors
▪ No breast compression with comfortable prone positioning ▪ Fast scan time (7 sec) ▪ True 3D detects smaller, earlier cancers resulting in no recalls	▪ True 3D isotropic[1] imaging ▪ Superior detection ▪ Equivalent radiation dose to mammography ▪ Minimal training required	▪ Compelling economics ▪ Higher throughput ▪ Capital equipment efficiency – replaces multiple devices ▪ Small footprint, limited facility modifications	▪ Greater patient compliance ▪ Reduce cost per case ▪ Reduce total cost of breast cancer ▪ Less extraneous costs from false positives

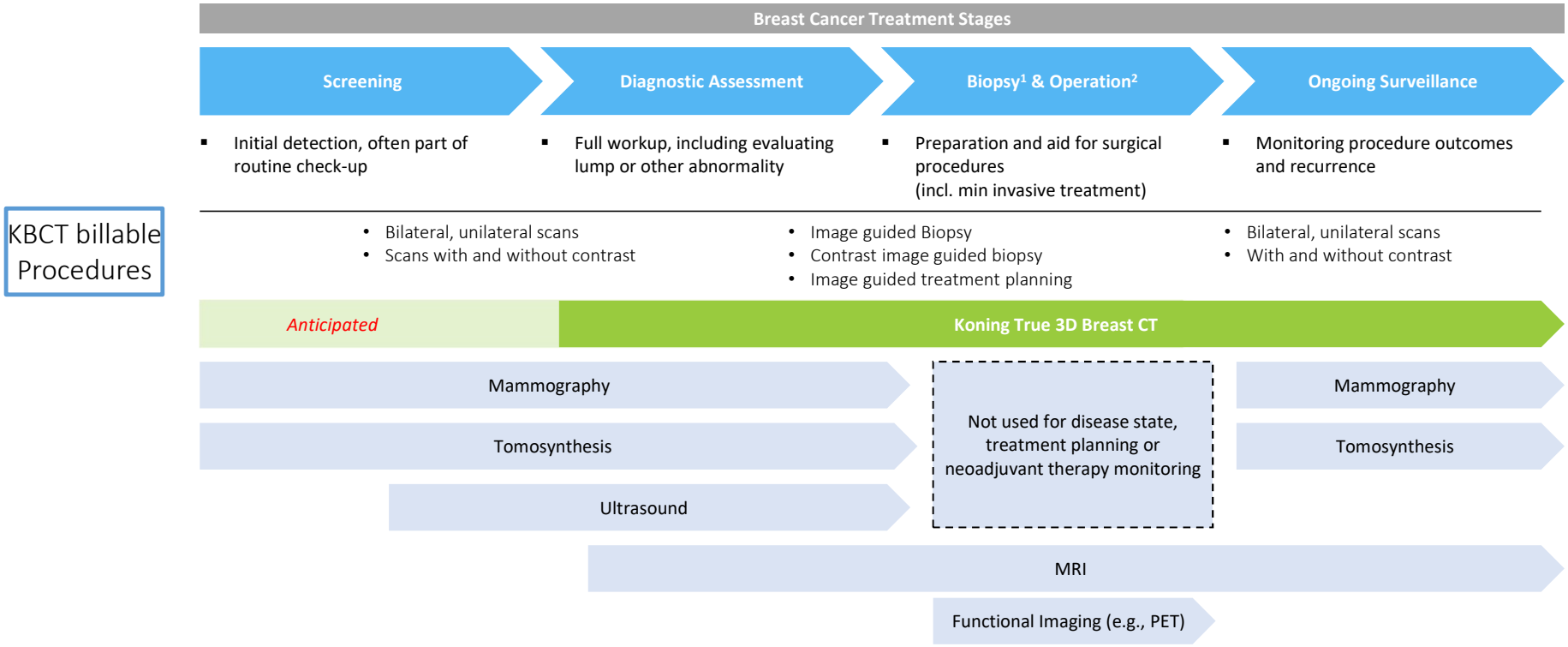
*1 – Typical volumetric imaging involves volumetric data described by a group of 2D image slices, stacked together to form a volume; **Isotropic** spatial **resolution** means that the spatial **resolution** in the transaxial plane (X–Y plane) and that in the longitudinal direction (Z direction) are equivalent.*

True 3D Breast CT has compelling advantages over existing modalities

	 KBCT	 FFDM	 DBT	 MRI	 Ultrasound	 CT
Real 3D – see through dense breast and overlapping structure	✓✓✓	✗	✗	✓✓✓	✗	✓
No Compression	✓✓✓	✗	✗	✓✓✓	✓✓✓	✓✓✓
Low radiation dose	✓	✓	✓	✓✓✓	✓✓✓	✗
Detects small tumors	✓✓✓	✓	✓	✓	✓	✗
Contrast enhancement of tumors	✓✓✓	✗	✗	✓✓	✓	✓
Low rupture risk on implants	✓✓✓	✗	✗	✓✓✓	✓✓✓	✓✓✓
Detection of calcification clusters (DCIS)	✓✓	✓✓✓	✓✓	✗	✗	✗
Density distribution measurement[1]	✓✓✓	✗	✗	✓✓✓	✗	✓
Ability to differentiate benign vs malignant masses	✓✓✓	✗	✗	✓✓✓	✗	✗
Spatial representation of other structures (e.g. vessels)	✓✓✓	✗	✗	✓✓	✗	✗
Low cost	✓	✓✓	✓✓	✗	✓✓✓	✗
High throughput	✓✓✓	✓	✓✓	✗	✓✓✓	✗

Estimated for the whole breast, but with True 3D, can be measured at a localized area

True 3D Breast CT will ultimately be the go-to imaging modality across the care continuum



[1] Biopsy currently requires stereotactic biopsy capabilities which incorporates FFDM with a table apparatus – limitation with this approach is that a 2D image is being used to locate the mass and place the biopsy needle. Additionally, this requires a separate capital purchase and procedure room

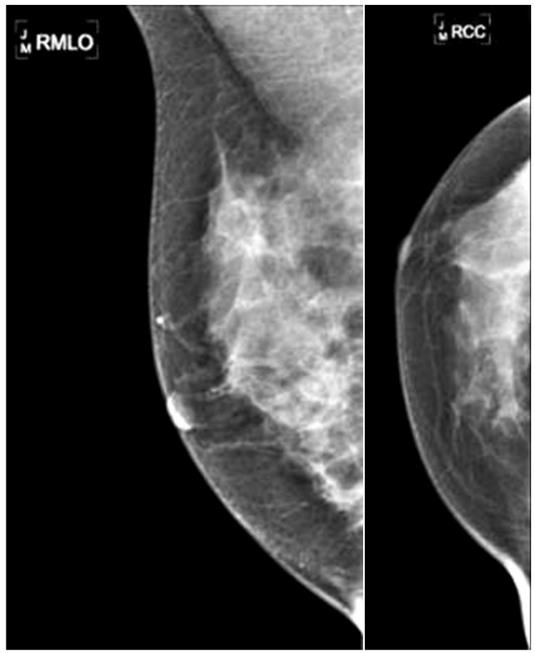
[2] MRI is used by surgeons to stage the disease and for operative planning

Mammograms can potentially miss lesions and cancers in dense breast

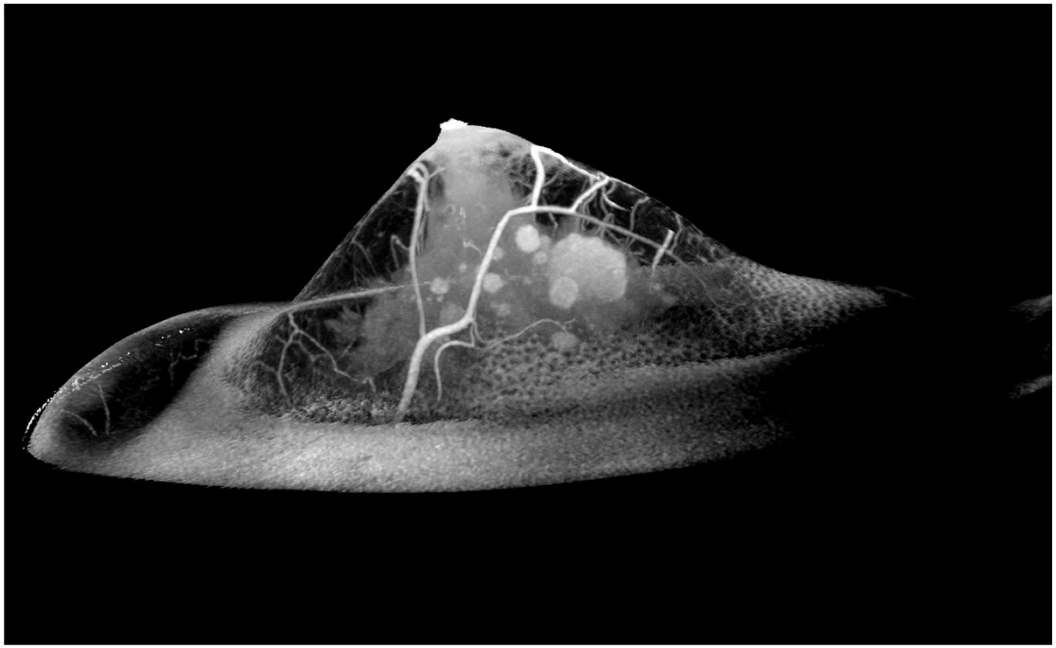
Case Study:

- 43 year old patient
- Extremely dense breast
- Prior annual mammograms showed no sign of disease
- Patient presented with rash on right breast

Full Field Digital Mammogram (FFDM)



KBCT

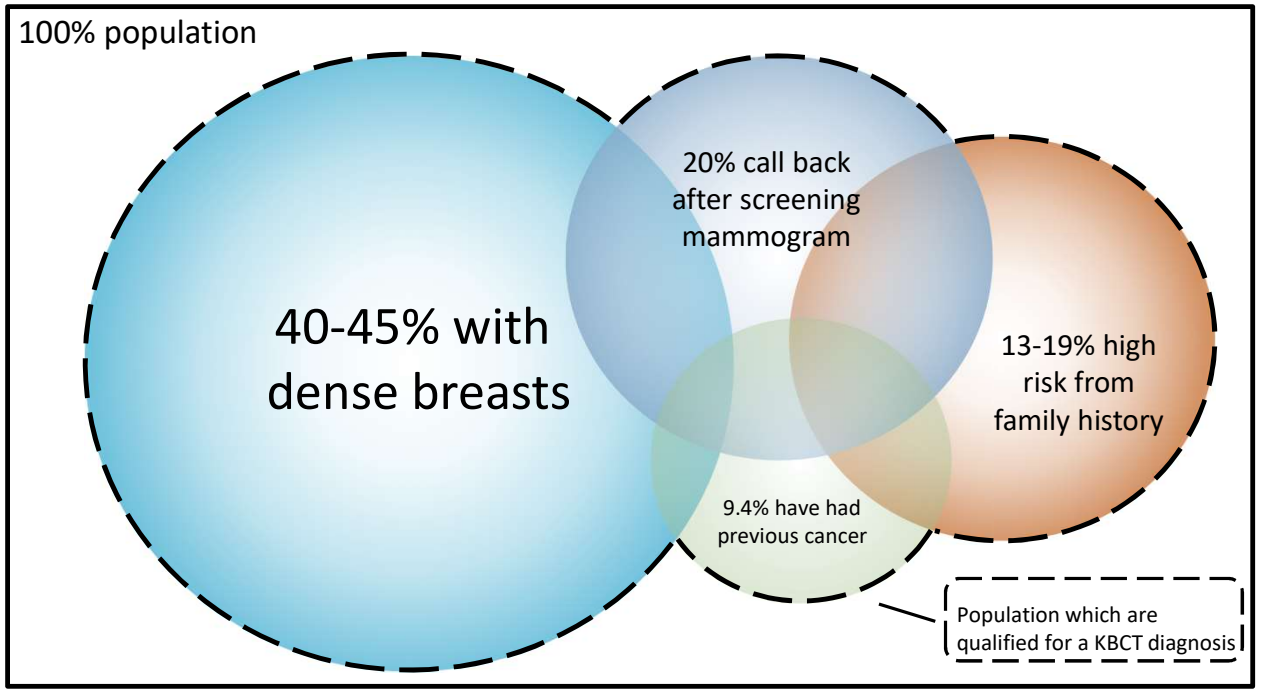


Drawback of Mammogram:

- 2D tomography imaging results in structural overlap of tissue and loss of resolution where images overlap
- Breast compression is painful for women
- Miss majority of cancers in women with small dense breasts

Source: Koning FDA and CFDA trial data, Marije F. Bakker, et. Al. Supplemental MRI Screening for Women with Extremely Dense Breast Tissue, N Engl J Med 2019; 381:2091-2102
Christopher C. Riedl, et. Al. Triple-Modality Screening Trial for Familial Breast Cancer Underlines the Importance of Magnetic Resonance Imaging and Questions the Role of Mammography and

>65% of the population are potentially qualified for KBCT diagnostic imaging workup



1 – Shiyanbola, O. O., Arao, R. F., Miglioretti, D. L., Sprague, B. L., Hampton, J. M., Stout, N. K., ... & Newcomb, P. A. (2017). Emerging trends in family history of breast cancer and associated risk. Cancer Epidemiology and Prevention Biomarkers, 26(12), 1753-1760.
2 – Calculated based on: https://en.wikipedia.org/wiki/List_of_cancer_mortality_rates_in_the_United_States, https://www.cancer.gov/about-cancer/understanding/statistics, https://www.breastcancer.org/symptoms/understand_bc/statistics, https://ww5.komen.org/BreastCancer/FamilyHistoryofBreastOvarianorProstateCancer.html

KBCT received 6 CPT codes in the US market in 1Q 2021

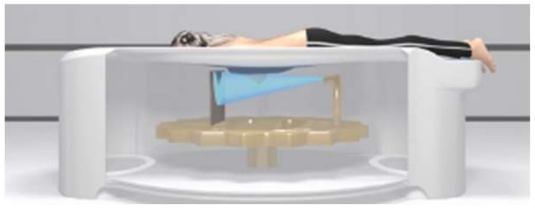
- 6 authorized CPT code went live in Q1 2021
- CMS has published national medicare reimbursement rates – dissemination to local MACs remains underway
- Rates range from 2x to 4x that of mammography

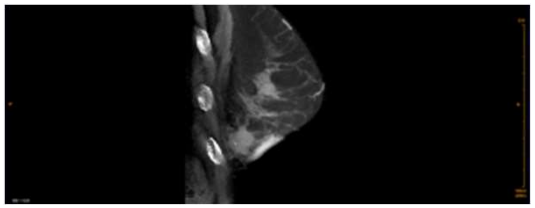
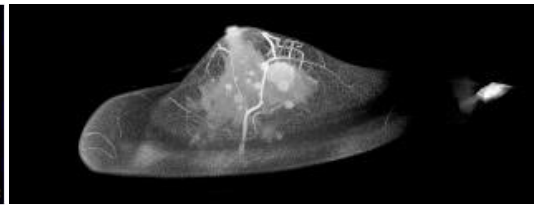
CMS national published rates for new CPT codes

Family 2 - CT and CTA with and without Contrast	
CY 2021 APC 8005 (CT and CTA without Contrast Composite)*	**CY 2021 Approximate APC Geometric Mean Cost = $218.53**
0633T	Ct breast w/3d uni c-
0636T	Ct breast w/3d bi c-
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74176	Ct angio abd & pelvis
74261	Ct colonography, w/o dye
CY 2021 APC 8006 (CT and CTA with Contrast Composite)	**CY 2021 Approximate APC Geometric Mean Cost = $423.88**
0634T	Ct breast w/3d uni c+
0635T	Ct breast w/3d uni c-/c+
0637T	Ct breast w/3d bi c+
0638T	Ct breast w/3d bi c-/c+
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye
70487	Ct maxillofacial w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye

KONING VERA BREAST CT

3 PROCEDURES, 3 OPTIONS TO FIND BREAST CANCER EARLY




NORMAL SCAN[1]

3 min from time patient enters exam room

CPT CODES
Unilateral without contrast: 0633T
Bilateral without contrast: 0636T

Avg private payor Reimbursement
$350

National Medicare Avg Reimbursement
$218.53

Onsite staffing requirement:
Radiology Tech
Nurse

CONTRAST-ENHANCED SCAN[2]

5-7 min from time patient enters exam room

CPT CODES
Unilateral with contrast: 0634T
Bilateral with contrast: 0637T

Avg private payor Reimbursement
$600

National Medicare Average Reimbursement
$423.88

Onsite staffing requirement:
Doctor or PA

BIOPSY SCAN[3]

15 min from time patient enters exam room

CPT CODES
First lesion: 19081
Each additional lesion: +19082

Avg private payor Reimbursement
$850

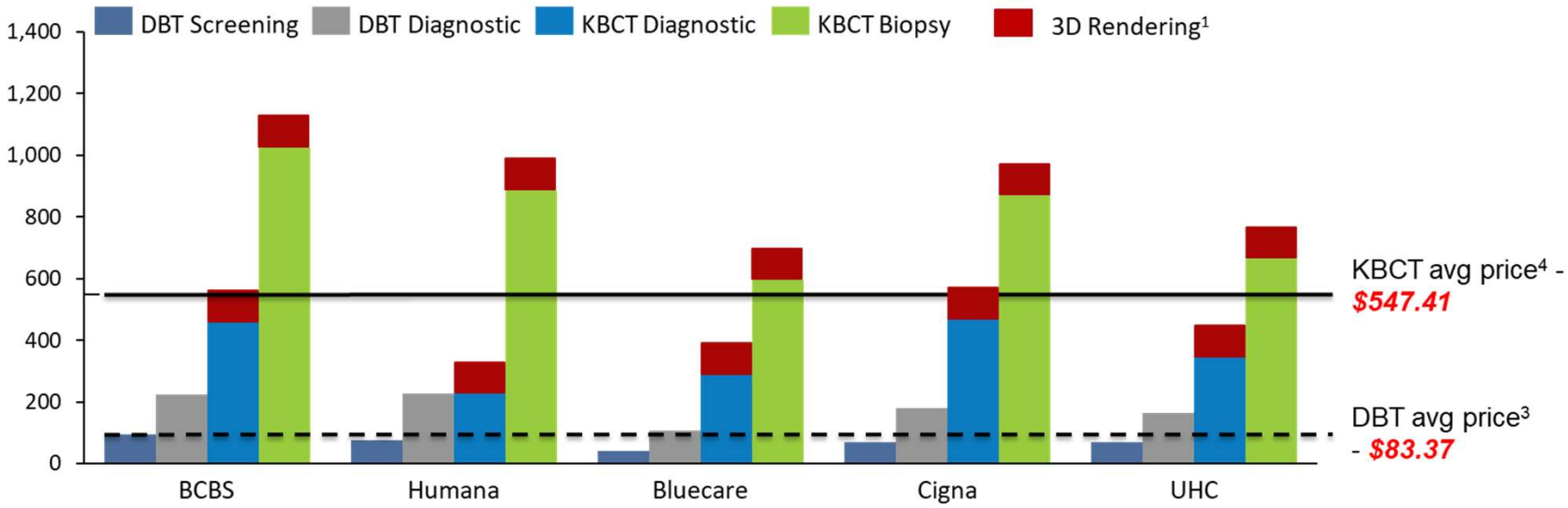
National Medicare Average Reimbursement
First lesion: $625.79
Each additional lesion: $504. 53

Onsite staffing requirement:
Specialist doctor (E.g. Breast radiologist, breast surgeon)

1 Primarily Bilateral
2 Either Unilateral or Bilateral
3 Predominantly Unilateral

CMS rates compare favorably to previous unlisted and chest CT reimbursement (US)

Reimbursement of Treatment of 5 Major Payers (prior to receiving dedicated breast CT CPT codes)



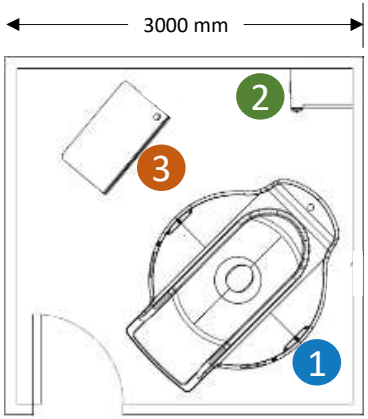
DBT breakeven point[2] is estimated at 7.6 patients per day, whereas KBCT could lower it to 1.2 patients per day

1 – Koning charge the 76377 3D rendering with all CT scans which adds $100 to the complete charge
2 – Assume equivalent equipment price of ~$450,000 for both DBT and KBCT
3 – Calculation of DBT treatment price is based on 80% volume on DBT Imaging and 20% on the average of DBT Diagnostic and DBT Diagnostic w. Addon
4 – Calculation of KBCT treatment price is based on 80% volume on KBCT and 20% on Biopsy

KBCT well suited for urgent care / OBGYN practices

KBCT SPECS

- **Electrical**: 220V – 35 Amp Sgl.[1]
- **Table Capacity**: 441 lbs.
- **Patient Table Height**: 27”
- **Shielding:** Self-shielded
- **Room Size**: 10 ft. x 10 ft.
- **Resolution**:
  - Standard mode = .273 mm^3 per Voxel
  - High Resolution mode = .155 mm^3 per Voxel



Item	Description	Weight Estimate	Height
1	Scanner	1000 kg	30’’-54’’
2	PDU	125 kg	24’’
3	Operator’s Console	100 kg	76’’

1. *Other electrical configurations available*
2. *3000 cm = 10 ft.*

FDA PMA clinical study of effectiveness between KBCT and diagnostic mammography

Retro double blind reader study

Non-contrast KBCT vs Full field digital mammography

KBCT vs. FFDM	CBBCT	Mammography	Difference
Average Sensitivity（%）	85.63	77.66	7.97
Average Specificity（%）	79.47	73.10	6.37
Average Accuracy（%）	82.03	75.00	7.03

Contrast Enhanced KBCT vs Full field digital mammography

CE KBCT vs. FFDM	CE-CBBCT	Mammography	Difference
Average Sensitivity（%）	92.73	76.10	**16.63**
Average Specificity（%）	75.24	71.43	3.81
Average Accuracy（%）	84.86	74.00	10.86

Modality	AUC
CE-CBBCT	0.9337
Mammography	0.8136
Difference	0.1201

AUC of CBBCT is higher than digital mammography. The difference is larger than 0.05 with statistical significance.

Note: AUC Difference Larger than 0.1 is considered a clinically super superior improvement.

Radiation dose – Diagnostic Mammo vs KBCT

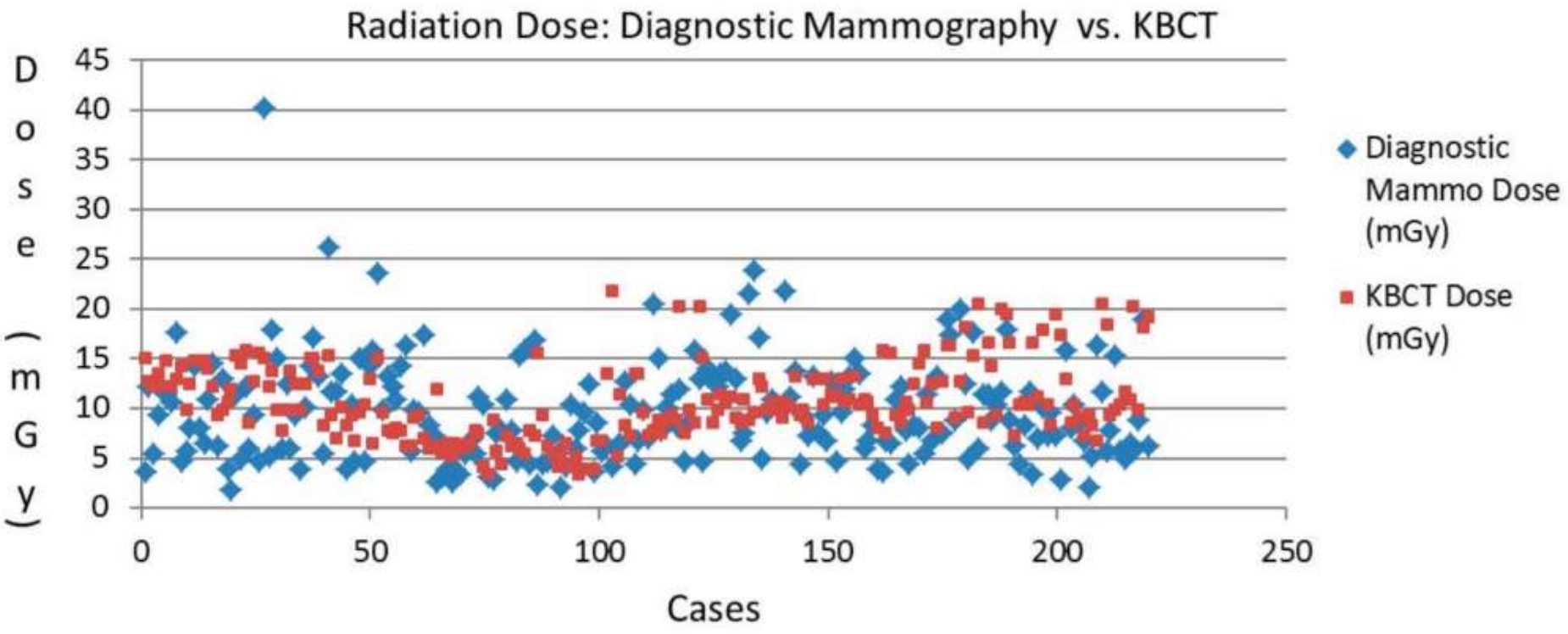
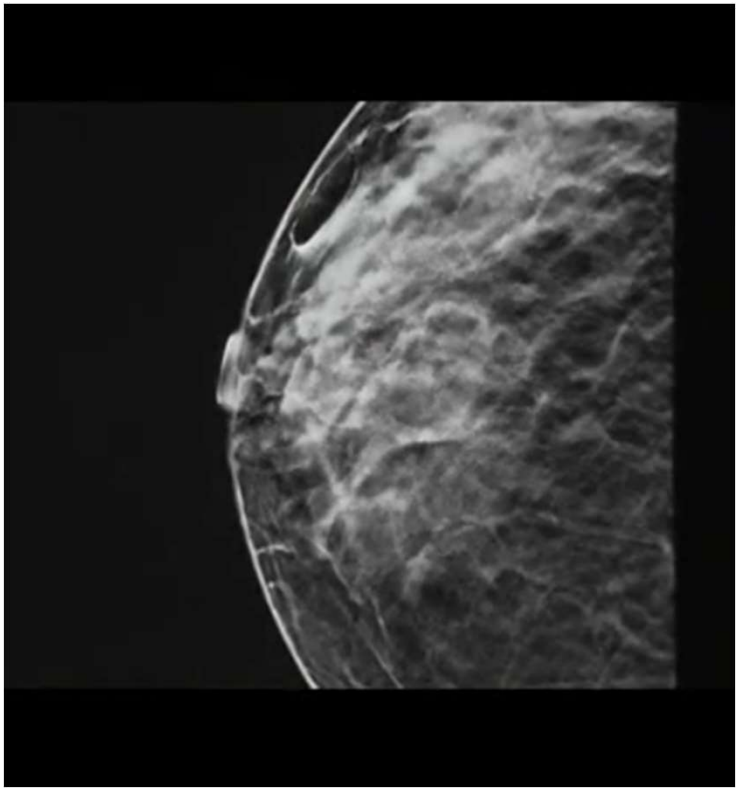


Figure D.2-1: Comparison of KBCT dose to diagnostic mammography dose for each patient.

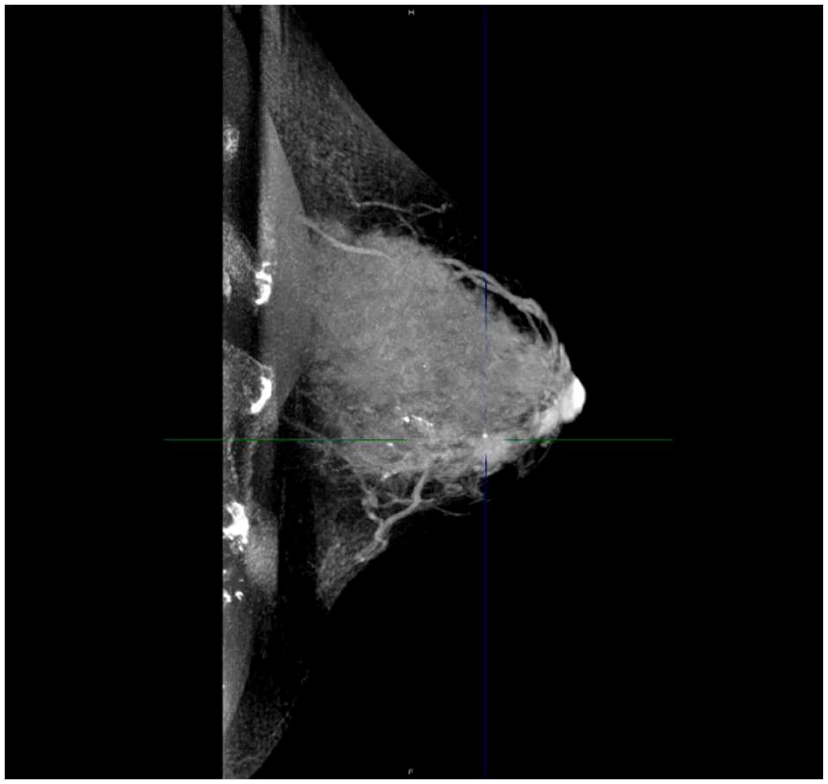
Comparison of Digital Breast Tomosynthesis (DBT) and Koning 3D Breast CT (KBCT) images

Tomosynthesis image



Tomo provides several slices of 2D images

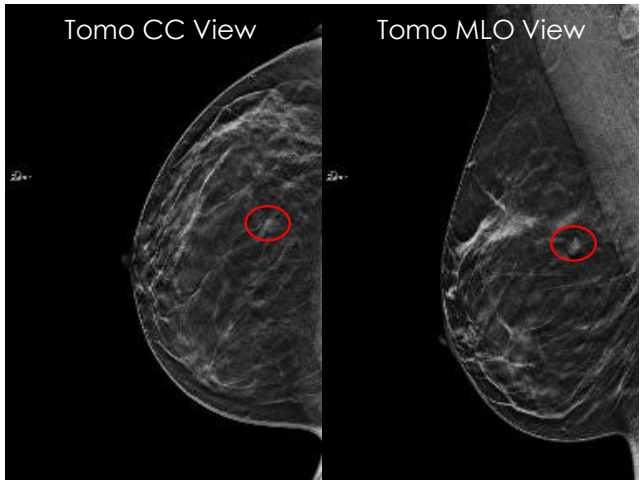
KBCT image

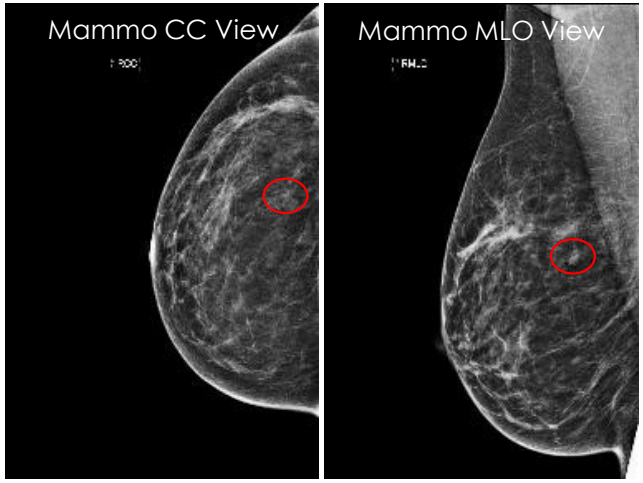


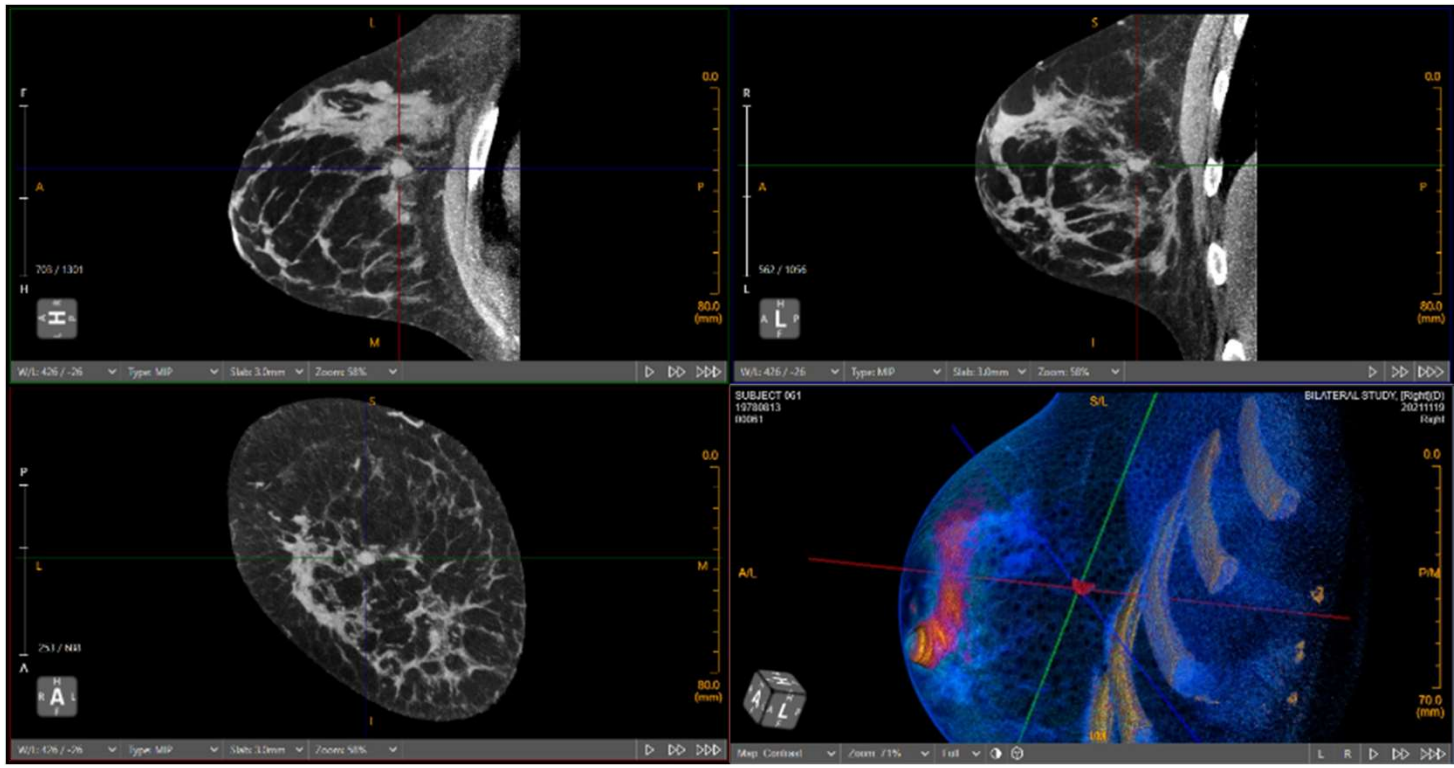
KBCT image provides full 3D images

Case 1

Masses clearly visualized on KBCT – another patient



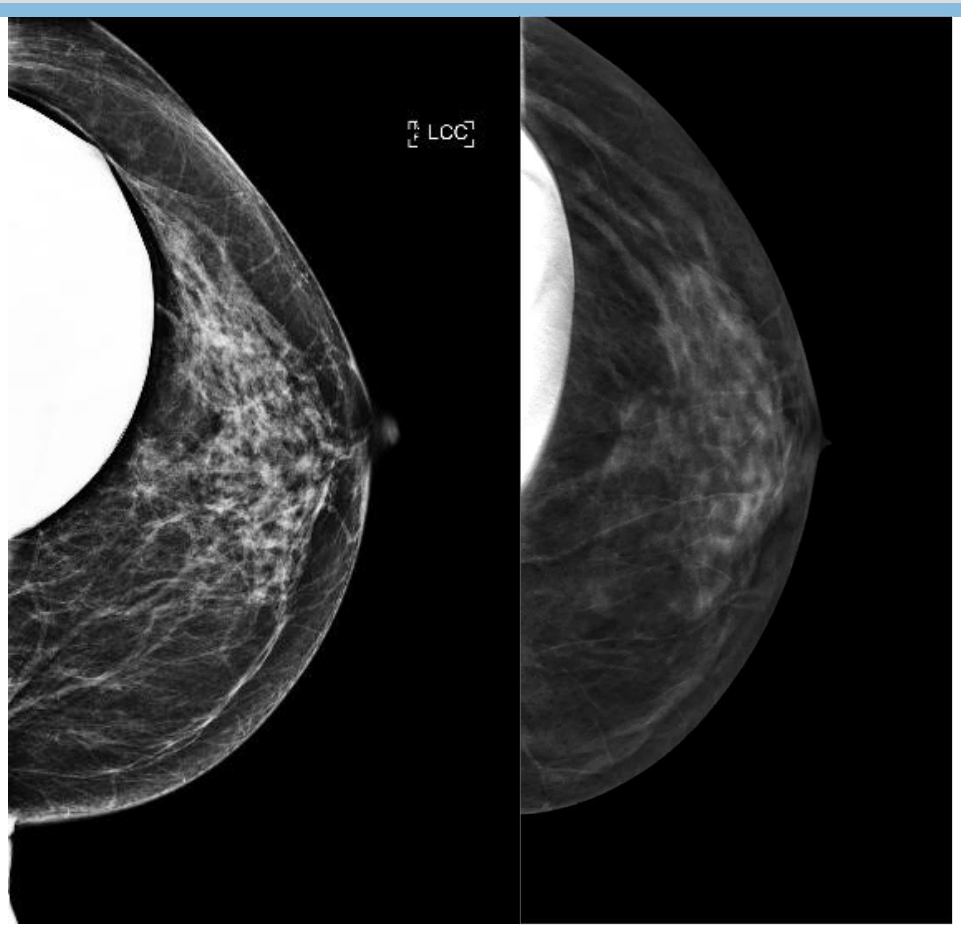




KBCT

Case 2

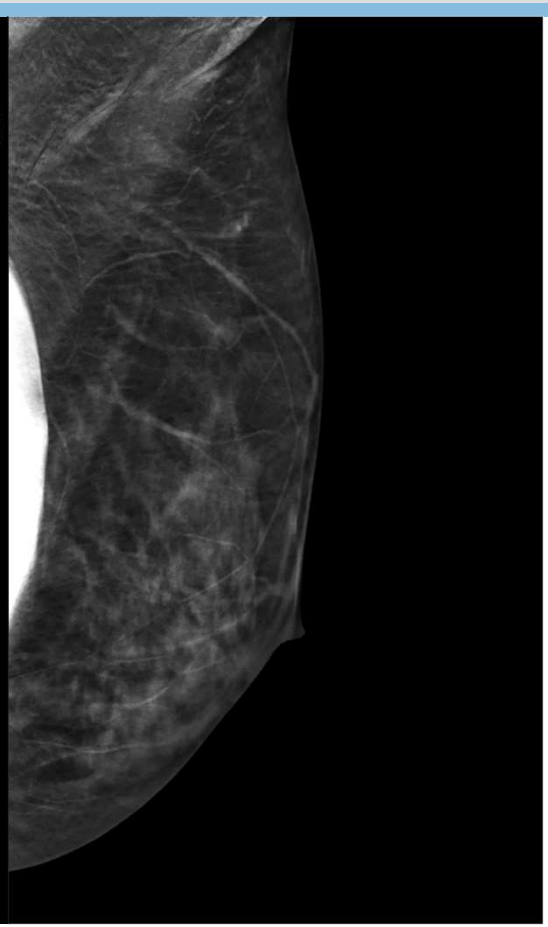
DBT/Mammo Implant view with poor chest wall coverage



Mammo LCC

Tomo LCC
(Implant Displaced)

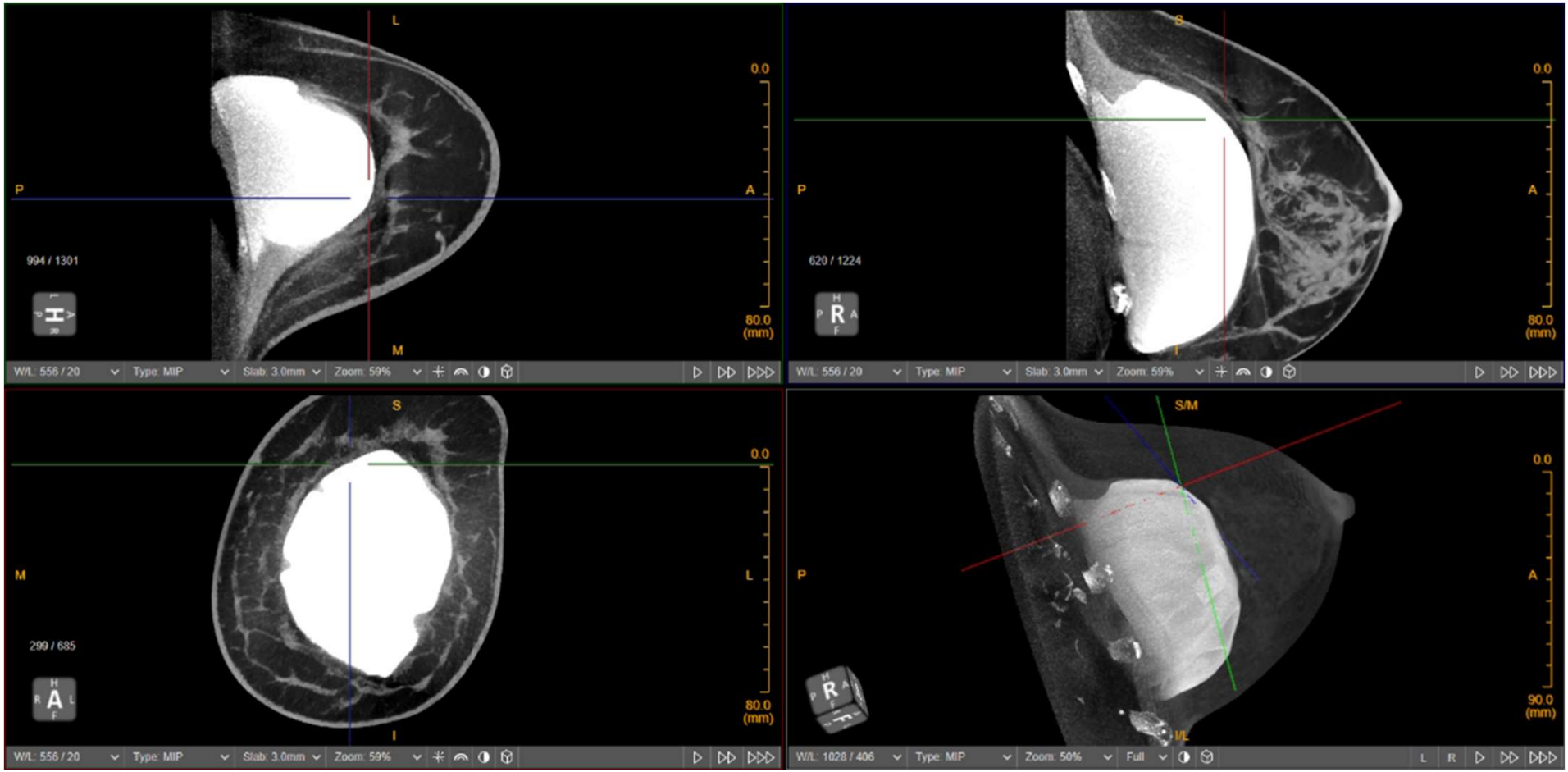
Mammo LMLO



Tomo LMLO
(Implant Displaced)

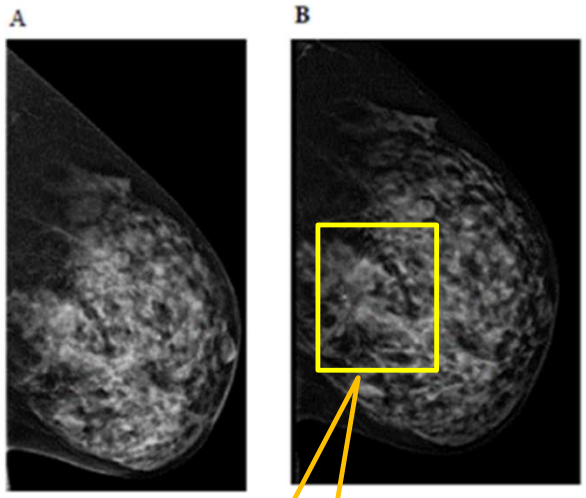
Case 2

KBCT clearly visualizes chest wall with no compression



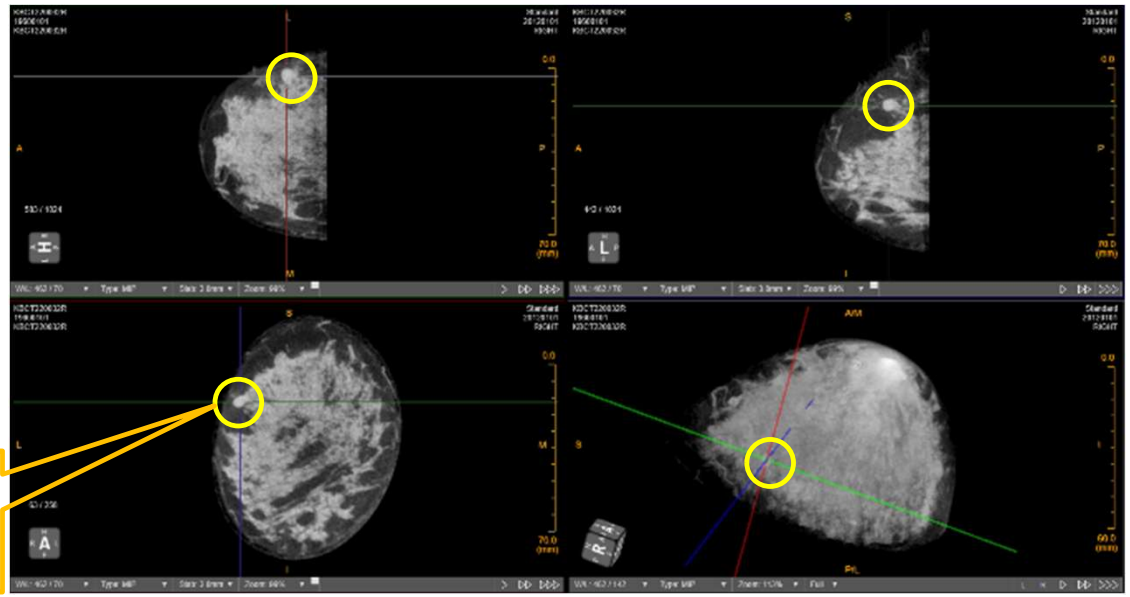
Case 3

Masses clearly visualized on KBCT



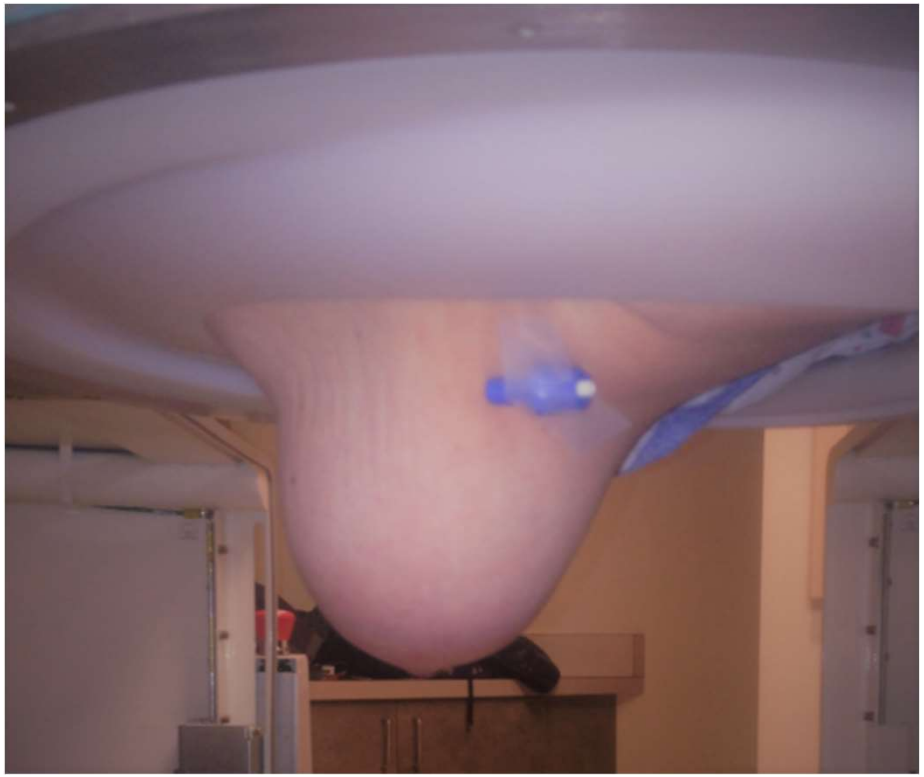
Patient Info:

- 45 year old
- Heterogenously Dense
- DBT: architectural distortion
- KBCT: Mass



Area of Coverage and Axillary tail

Marker placed on axillary tail



Marker as seen in imaging area of KBCT

Thank You – www. Koninghealth.com

- LOW DOSE – NO COMPRESSION – REAL 3D
- BREAST IMAGING AND BIOPSY