Patient-Assisted Compression – Impact on Image Quality and Workflow

Senographe Pristina

In 2017, GE Healthcare's Senographe Pristina™ ("Pristina") was approved by the FDA using the standard technologist-controlled (TC) compression mode. GE Healthcare sought to improve the features on the Pristina to include an optional patient-assisted (PA) compression mode. The patient-assisted feature enables the patient to personally refine breast compression using a hand-held remote control after the compression has been initiated by the technologist, which is required to ensure proper breast positioning.

To extend the compression modes available on Pristina, GE Healthcare conducted a single-blind prospective randomized research study that compared the acceptability of overall image quality in two-view (CC and MLO) breast images acquired using PA and TC compression modes. Clinical breast images were obtained from an Ethics Committee-approved clinical case collection study, where two-view (CC and MLO), unilateral PA and TC compression image sets were independently evaluated by two (2) MQSA-qualified readers who were blinded to the clinical care and histories of the patients, and the compression mode used during image acquisition. The results of the study clearly demonstrated that compared to images where compression was applied solely by the technologist, patient-assisted compression produces images of similar quality.

Image Acqusition and Procedural Data Collection

Consenting female patients presenting for screening exams with digital mammography were enrolled in this study and had one breast ("Breast of Interest") imaged with both PA and TC compression modes in standard CC and MLO views; the other breast was imaged with TC only, per standard of care.

Patients were randomly placed into two groups: a) the breast of interest (BoI) imaged first or b) BoI imaged second, so that approximately half the patients were assigned into each group.

For each patient's BoI, PA compression and image acquisition were conducted first, consisting of both CC and MLO views. No repeat imaging was administered using PA compression mode. Following PA compression image acquisition, TC compression and standard of care imaging were conducted on the same BoI.

Two (2) study-specific image sets of the BoI were collected for each subject. Image sets consisted of CC and MLO views obtained using PA compression and CC and MLO views obtained using TC compression. Study staff collected and documented the following workflow and procedural data on case report forms (CRF) for each subject: size of paddle used for imaging, amount of time required to educate subject on PA compression mode, laterality and order of imaging (first or second) for the BoI, start times for PA and TC compressions, technologist intervention(s) during PA compression, and incidence and reason for any repeat imaging. Compression force, breast thickness, entrance skin air kerma (ESAK), and acquisition parameters were acquired from the DICOM headers and recorded on CRFs by the study staff. (ESAK is determined on the mammography system and is used to calculate Average Glandular Dose.)

Image Attribute Reviews

Evaluable two-view (CC and MLO), unilateral PA and TC compression image sets were independently evaluated by two (2) MQSA-qualified readers who were blinded to the

clinical care and histories of the patients, and the compression mode used during image acquisition. A third reader provided adjudication when there was disagreement between the two (2) readers' evaluations of overall clinical image quality.

Images were displayed on mammography review workstations per the randomization scheme. Each reader evaluated each image set and documented acceptability ("acceptable" or "unacceptable") of overall image quality and image characteristics on CRFs. Readers indicated whether a repeat acquisition would be required in standard practice, and if yes, which view (CC, MLO, or both) would require re-imaging. Readers also specified the breast density for each image set.

Study Patients

A total of 30 patients completed the study, with ages ranging from 41 to 83 years old. Of the 30 patients, 16 completed the study from the BoI first group and 14 completed from the BoI second group.

A total of 60 image sets (30 PA and 30 TC image sets) were acquired from the 30 completed patients, thus representing the analysis set for all endpoint analyses, unless otherwise specified in the following sections.

Overall Image Quality

All 60 image sets (30 PA and 30 TC image sets) were evaluated for acceptability of overall image quality by two (2) readers. Both readers evaluated all image sets from all patients. Due to disagreement between Readers 1 and 2, Reader 3 provided adjudication for four (4) PA image sets and five (5) TC image sets. Including Reader 3, there were a total of 129 image evaluations included in the primary endpoint analysis of overall image quality (Table 1). Overall, 100% of image sets evaluated for both PA and TC compression were found to be of acceptable image quality by the readers (Table 1). When compared to TC image sets, 100% of the PA image sets were of equal or better acceptability for image quality (

Table 2).

Table 1 – Acceptability of overall image quality, both overall and by reader

		Overall Image Quality	
	Acceptability	**PA** [%(n/N)] [95% CI]	**TC** [%(n/N)] [95% CI]
Reader 1	Acceptable	100.0% (30/30) [88.4%,100.0%]	100.0% (30/30) [88.4%,100.0%]
	Unacceptable	0	0
Reader 2	Acceptable	86.7% (26/30) [69.3%,96.2%]	83.3% (25/30) [65.3%,94.4%]
	Unacceptable	13.3% (4/30) [3.8%,30.7%]	16.7% (5/30) [5.6%,34.7%]
Final, adjudicated	**Acceptable**	**100.0%** (30/30) [88.4%,100.0%]	**100.0%** (30/30) [88.4%,100.0%]
	Unacceptable	0	0

Table 2 –Patient-assisted (PA) versus technologist-controlled (TC) compression, overall image quality

	Acceptability of Overall Image Quality (PA vs TC)		
	PA equal or better than TC	**%(n/N)**	**95% CI**
Reader 1	Yes	100.0% (30/30)	[88.4%,100.0%]
Reader 2	Yes	96.7% (29/30)	[82.8%,99.9%]
	No	3.3% (1/30)	[0.1%,17.2%]
Final, adjudicated	**Yes**	**100.0% (30/30)**	**[88.4%,100.0%]**

Repeat Image Acquisition Results

Repeat imaging for PA and TC image sets were indicated by technologists during image acquisitions and by readers during image evaluations.

Technologists indicated only one (1) PA image set that would have undergone repeat imaging due to positioning and specified as "clipping

bottom of breast." For TC, however, four (4)

Technologist-indicated repeat acquisitions			Reader-indicated repeat acquisitions (Reader 2 only)		
Reason for repeat	PA	TC	View for repeat	PA	TC
Positioning	1	4	Both (CC & MLO)	1	1
Compression	-	-	CC	1	0
Other, specify	1	3	MLO	2	3
Total [n (%)]	1 (3.3%)	4 (13.3%)	Total [n (%)]	4 (13.3%)	4 (13.3%)

image sets were repeated by the technologists due to positioning (n=4) and other reasons (n=3), which were specified "opposite BoI skin fold." There were no repeats indicated due to compression (

Table 3).

Technologist-indicated repeat acquisitions			Reader-indicated repeat acquisitions (Reader 2 only)		
Reason for repeat	PA	TC	View for repeat	PA	TC
Positioning	1	4	Both (CC & MLO)	1	1
Compression	-	-	CC	1	0
Other, specify	1	3	MLO	2	3
Total [n (%)]	1 (3.3%)	4 (13.3%)	Total [n (%)]	4 (13.3%)	4 (13.3%)

Reader 2 was the only reader with unacceptable overall image quality evaluations, and therefore, was the only reader who was prompted to indicate if repeat imaging would be requested, and if yes, which view. There were nine (9) image sets that Reader 2 evaluated as unacceptable, but only eight (8) image sets were indicated for repeat imaging–four (4) PA and four (4) TC image sets. CC, MLO, and both (CC and MLO) views were indicated for PA image sets, whereas MLO and both were indicated for the TC image sets (

Table 3).

Table 3 – Summary of repeat imaging results

Image Attribute Review Results

Readers 1 and 2 evaluated all PA and TC image

sets for a pre-defined set of image attributes

Attribute Assessed	Image Attribute Review Final, Adjudicated	
	PA (% Acceptable)	TC (% Acceptable)
Breast positioning, assessing coverage of the breast on craniocaudal and mediolateral oblique view, separately	100.0%	96.7%
Exposure, assessing visualization of the adipose and fibroglandular tissues, and visualization of breast tissue underlying the pectoralis muscle, separately	100.0%	100.0%
Breast compression, assessing overlapping breast structures, uniformity of exposure of fibroglandular tissues, adequacy of penetration of thicker portions of the breast, exposure of thinner areas, and motion unsharpness	100.0%	100.0%
Image contrast for differentiation of subtle tissue density differences	100.0%	100.0%
Sharpness, assessing the edges of fine linear structures, tissue borders, and benign calcifications	100.0%	100.0%
Tissue visibility at the skin line	100.0%	100.0%
Noise, i.e., noise obscuring breast structures or suggestive of structures not actually present	100.0%	100.0%
Artifacts due to image processing, detector failure and other factors external to the breast on hard-copy and soft-copy displays	100.0%	100.0%

(Table 4). When there was disagreement between the readers for overall image quality, Reader 3 provided adjudication.
The final adjudicated results showed 100% of the PA image sets were acceptable for all eight (8) image attributes, as determined by the

readers. One-hundred percent (100%) of TC image sets were deemed acceptable for all attributes, except for the first attribute (see Table 4).

Imaging Duration Results

Prior to imaging, the study staff documented the amount of time it took to educate each subject on use of the PA compression mode. It took 1-2 minutes for 70% of patients (n=21) and 3-5 minutes for the other 30%.

Total image acquisition time was also collected for each image set. Image acquisitions using PA and TC compression modes lasted an average of 3.9 and 3.4 minutes, respectively (Table 5). Four (4) image sets were excluded from the TC analysis because the patients required repeat imaging per standard of care; repeat imaging was not allowed for PA compressions. One subject's PA and TC image sets were also excluded from the analysis due to a protocol deviation associated with the order of PA and TC imaging on the BoI. In total, one (1) PA image set and five (5) TC image sets were excluded from this analysis.

Table 5 – Summary of imaging durations by compression type

	Imaging Duration (minutes)	
	PA	**TC**
Mean (SD)	3.9 (1.0)	3.4 (1.0)
Median	4.0	3.0
Range	(3.0-6.0)	(2.0-5.0)

Table 6 – Summary of procedural characteristics

Procedural Characteristics

The mean compression force of PA compressions for CC and MLO views were 9.1 and 8.2 daN, respectively, versus 8.3 and 8.7 daN, respectively, for TC compressions. Breast thicknesses for PA and TC compressions were 52.0 and 53.2 mm, respectively, for CC views and 54.6 and 53.7 mm, respectively, for MLO views. Mean ESAK for PA compression was 4.5 mGy for CC views and 4.9 mGy for MLO views. ESAK for TC compression was 4.7 mGy for CC views and 4.8 mGy for MLO views (Table **6**). Acquisition parameters for each compression mode are presented in   Table **6**.

Conclusions

A total of 60 evaluable PA (n = 30) and TC (n = 30) two-view, unilateral image sets were collected from 30 distinct female patients using the PA and TC compression modes of Senographe

Parameters	Patient-Assisted (PA) Compression		Technologist-Controlled (TC) Compression	
	CC (N=30)	**MLO (N=30)**	**CC (N=30)**	**MLO (N=30)**
Compression Force (daN)				
Mean (SD)	9.1 (3.0)	8.2 (2.7)	8.3 (2.0)	8.7 (2.2)
Median	8.0	8.0	8.0	9.0
Range	(4.0-15.0)	(3.0-14.0)	(4.0-11.0)	(4.0-12.0)
Breast Thickness (mm)				
Mean (SD)	52.0 (14.3)	54.6 (16.1)	53.2 (14.0)	53.7 (15.1)
Median	50.9	53.7	51.1	52.9
Range	(29.4-96.0)	(29.8-98.7)	(29.5-95.7)	(29.4-93.5)
Entrance Skin Air Kerma (ESAK, mGy)				
Mean (SD)	4.5 (2.4)	4.9 (2.6)	4.7 (2.4)	4.8 (2.4)
Median	3.7	4.1	3.8	3.8
Range	(2.6-12.5)	(2.5-13.5)	(2.6-12.7)	(2.5-12.6)
Acquisition Parameters (kVp)				
Mean (SD)	33.3 (0.5)	33.3 (0.5)	33.3 (0.4)	33.3 (0.5)
Median	33.0	33.0	33.0	33.0
Range	(33.0-34.0)	(33.0-34.0)	(33.0-34.0)	(33.0-34.0)
Acquisition Parameters (mAs)				
Mean (SD)	35.7 (16.3)	38.5 (18.0)	36.9 (16.9)	37.6 (17.0)
Median	30.0	32.0	30.5	31.0
Range	(22.0-88.0)	(22.0-95.0)	(23.0-91.0)	(22.0-91.0)

Pristina in a clinical setting.

Mammography procedures were performed by qualified personnel, and independent image evaluations were conducted by two (2) MQSA-qualified readers, with adjudication performed by a third MQSA-qualified reader in cases of disagreement about overall image quality. The final overall clinical image quality was acceptable for 100% of the PA compression image sets evaluated in this study, and 100% of PA image sets were of equal or better image quality when compared to the TC image sets. Furthermore, 100% of the PA image sets were deemed acceptable for all image attributes. These cumulative results substantiate that compared to images where compression was applied solely by the technologist, patient-assisted compression produces images of similar quality.

In terms of workflow, the study demonstrated that patient education took 1-2 minutes in most cases, and the image acquisition time was minimally impacted by use of PAC. There was only one (1) instance of technologist intervention with PAC in this study, and subgroup analyses of patients with their BOI imaged first or second did not reveal significant differences between the two groups. These results confirm that the device is easily operable by patients, when guided by their technologist, and the education received from the technologist at the start of the exam and the guidance received during device operation were sufficient to achieve an adequate level of compression.