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Analysis of whole breast ultrasound image sequence reading time with a new FDA approved automated whole breast ultrasound tomography system for supplemental screening in women with dense breasts

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INTRODUCTION

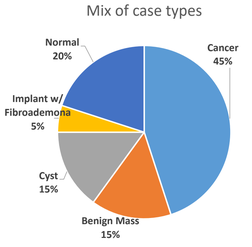
- In the United States, over 40% of women ages 40-74 have dense breasts. [1]
- Dense breasts are associated with a 2.9-to-4.6-fold increase in the risk for developing breast cancer. Women with dense breasts may benefit from supplemental ultrasound (US) screening since dense breasts can mask a cancer making it harder to identify on the mammogram. [2,3]
- Ultrasound technology as a supplement to mammography for screening women with dense breasts increases cancer detection.[4-6]
- However, automated whole breast ultrasound technologies have been shown to substantially increase radiologist reading time.[5]
- SoftVue (SV), a 3D automated whole breast US tomography technique, is an efficient, accurate, radiation-free, and operator-independent supplemental screening for women with dense breasts.

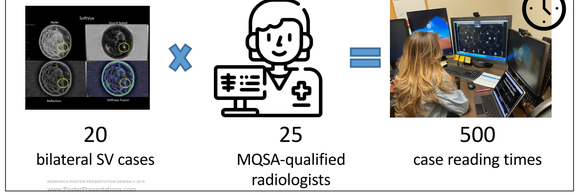
OBJECTIVE

- To assess how quickly and accurately radiologists could interpret images from a new automated whole breast ultrasound prior to launching a prospective case collection registry

MATERIALS & METHODS

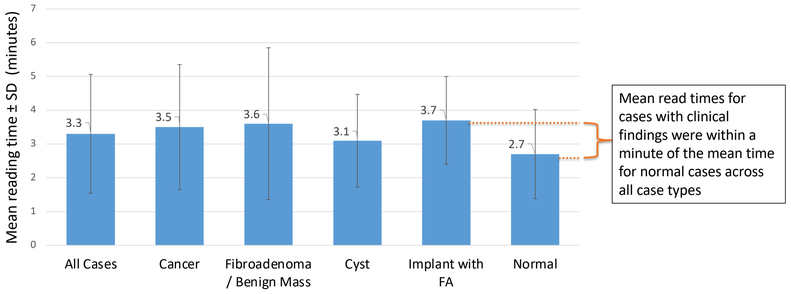
- Proctored reading validation program
- Recorded reading times of bilateral screening breast ultrasounds obtained from SoftVue Automated Whole Breast Ultrasound (SV) (Delphinus Medical) in women with dense breasts
- 20 bilateral screening ultrasound cases were selected.
- 25 MQSA-qualified radiologists with varying experience from 9 institutions across the United States each read the 20 cases.
- The same hanging protocol was used, beginning with sequences of Wafer and Sound Speed (SS) to identify an area of interest, Reflection to determine if the area persists, and then Stiffness Fusion for further confirmation and characterization.
- The primary outcome was reading time per bilateral ultrasound.
- Reading times were compared using linear mixed effects models for findings in neither, one, or both breasts and for subgroups of cancer and benign findings





RESULTS

Reading time: Mean reading time was 3.3 ± 1.76 minutes (n=498, median 2.9 min) per case.

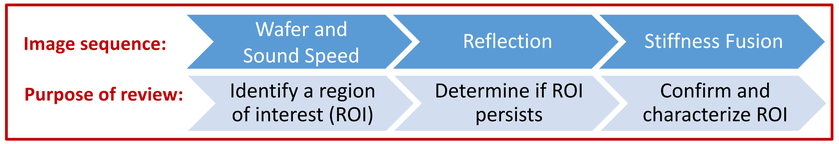


Bilateral SV reading time in minutes	All cases (n=498)	Cancer (n=224)	Fibroadenoma (FA) / Benign Mass (n=75)	Cysts (n=74)	Implant with FA (n=25)	Normal (n=100)
Mean ± SD	3.3 ± 1.76	3.5 ± 1.85	3.6 ± 2.25	3.1 ± 1.37	3.7 ± 1.30	2.7 ± 1.32
Median (Q1, Q3)	2.9 (2.1, 4.2)	3.0 (2.1, 4.4)	3.0 (2.1, 4.5)	2.8 (2.2, 3.7)	3.4 (3.0, 4.2)	2.3 (1.8, 3.3)

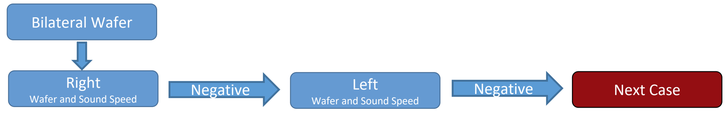
Reading time: Cases that were negative in both breasts tended to have faster read times compared with those with findings in one breast or findings in both breasts (p<0.001).

Bilateral SV reading time in minutes	Bilateral findings (n=149)	No findings (n=100)	Findings in only one breast (n=49)
Mean ± SD	3.8 ± 2.14	2.7 ± 1.32	3.2 ± 1.57
Median (Q1, Q3)	3.1 (2.3, 4.9)	2.3 (1.8, 3.3)	2.9 (2.1, 4.1)

READING PROTOCOL : SV IMAGE SEQUENCES

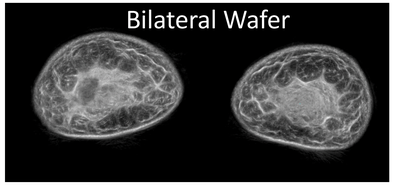


READING PROTOCOL: NEGATIVE CASE

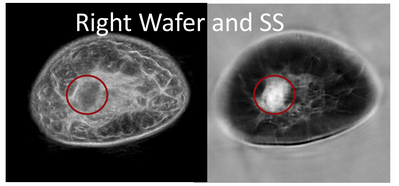


READING PROTOCOL: CANCER CASE EXAMPLE

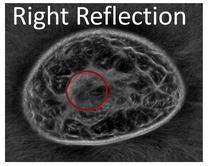
Invasive ductal carcinoma in right breast, Normal left breast:
Mean read time across 25 radiologists was 3.08 minutes



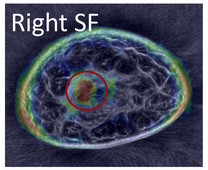
Begin case reviews with bilateral Wafer. Wafer (WAveForm Enhanced Reflection) suppresses fat signals to boost the visibility of masses.



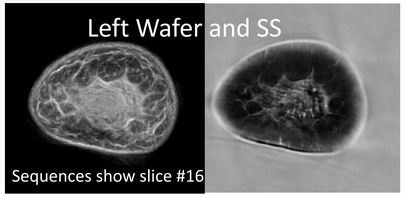
A region of interest was identified on right Wafer, shown here on slice #16. It is dark on Wafer and bright on Sound Speed, which measures the speed of sound moving through tissue.



Looking at Reflection, the region of interest is dark and persists.



Stiffness Fusion (SF) uses transmission properties of Sound Speed and attenuation, fused with Reflection. Color indicates stiffness of tissue/masses. In this case, the region of interest is focally stiff (orange/red).



Left Wafer and SS confirmed as negative ending the case review. By reviewing breast image sequences in order specified by the reading protocol, reading time is optimized.

TAKEAWAYS

Mean read times for bilateral SV automated whole breast ultrasound tomography cases with clinical findings were within a minute of the mean time for normal cases across all case types.

CONCLUSION

Breast image sequences of Wafer, Sound Speed, Reflection, and Stiffness Fusion from SV ultrasound tomography facilitate bilateral ultrasound mean reading times of less than 4 minutes per case.

CLINICAL RELEVANCE STATEMENT

SV, used as an adjunct to mammography in screening women with dense breasts, offers the benefits of increased cancer detection with supplemental ultrasound with little increase in radiologist reading time.

REFERENCES

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