



Continued Growth and Outcomes with Invenia ABUS (Automated Breast Ultrasound)

Background

The gold standard for breast cancer screening and detection is mammography; it is also the only screening test proven to reduce mortality from breast cancer. While mammography has been the mainstay of screening for decades, it also has shown limited efficacy when visualizing dense breast tissue. Over 40% of screening-age women in the United States have dense breast tissue and are at increased risk (4 – 6 times) for breast cancer.^{1,2} In fact, 71% of breast cancers are diagnosed in dense breasts.³ Research has shown that nearly one in two cancers are missed on standard mammography in extremely dense breasts.⁴ Furthermore, in women with dense breasts, cancer is more likely to be found in the interval between routine mammography screens (termed “interval cancer”), and interval cancers tend to have worse prognoses. Mammographic limitations are due in part to the masking effect caused by dense tissue on the mammogram.

On mammography, both breast cancer and dense breast tissue usually appear white, limiting the ability to differentiate between the two. Because of these limitations, an individualized multimodality approach is recommended to improve screening outcomes by increasing the detection of early invasive cancers and decreasing interval cancer rates. With ultrasound technology, dense tissue is white, while breast cancers usually appear black allowing for greater detection. Various studies support the use of automated breast ultrasound as an adjunctive tool to increase the sensitivity of screening for women with dense breast tissue.^{5,6}

Imaging for Women (IFW), located in Kansas City, Missouri, is a radiology group practice with expertise in women’s imaging that prides itself in offering the latest technology. In May 2014, they installed the somo•v™ ABUS (Automated Breast Ultrasound) from GE Healthcare. The installation of ABUS allowed them to offer more women with heterogeneously or extremely dense breasts the option to have a screening breast ultrasound. Imaging for Women has been informing women of their breast density since opening in 1997. After the Missouri density inform law passed (1/1/2015), they continued to experience increased demand for supplemental screening. Because of these factors, in August 2015, IFW upgraded their somo•v ABUS to GE Healthcare’s next generation system platform, the Invenia™ ABUS. During December 2018 and leading into January 2019, two more Invenia 2.0 units were added with an upgrade from 1.0 to 2.0 in the older unit. It was at this time that IFW began using ABUS as a diagnostic tool as well.

The objective of this study was to document the impact of ABUS on clinical and operational outcomes within a radiology group practice while offering same-day mammography and ABUS exams.

“Women with dense and heterogeneously dense breast tissue have a higher risk of developing breast cancer, and their cancers are more difficult to detect. Over the past 6 years, Imaging for Women has successfully utilized ABUS screening to help close the detection gap for these women. With ABUS, our goal is to find cancers at their earliest and most treatable stage.”

Allison H. Zupon, MD

maging for Women

Raising the standard of care

630 NW Englewood Road | Kansas City, MO 64118

Phone (816) 453-2700

www.imaging4women.com

About Imaging for Women

Dedicated to offering patients an exceptional experience in women's health care, Imaging for Women offers high quality imaging services at an affordable price for the patient and in a comfortable, service-oriented environment.

The goal at IFW is to offer women same-day services, providing women with convenience and peace of mind. IFW accomplishes this by utilizing the most advanced technology available, including 3D mammography, Profound AI, and 3D Automated Breast Ultrasound. IFW only hires certified technologists who were chosen for their skill at performing exams, while providing compassionate care. Imaging for Women is staffed by 2 breast fellowship trained radiologists, 4.5 mammographers, and 4 sonographers. All mammographers and sonographers have been trained to perform ABUS exams. This provides a smooth transition from mammography to ABUS by utilizing the next available technologist. Exams are read in real-time, so every patient leaves the office with a verbal result and a written letter in layman's terms.



Dr. Allison Zupon and Dr. Troy Voeltz

"Imaging for Women takes a little extra time to explain the risks of denser breast tissue and patients are grateful we offer ABUS."

Ronna Rowe, Senior Mammographer



Methodology

The study analyzed 60 months of data starting after the first installation of sono-v ABUS (January 2015-December 2019). The data included:

- Volume of mammography examinations
- Rate of mammography in women with dense breasts
- Volume of screening ABUS
- Volume of diagnostic ABUS
- Recall rates
- ABUS cancer detection rate with pathology
- ABUS payer mix
- Average reimbursement for ABUS examinations
- ABUS revenue as a percent of total breast ultrasound revenue

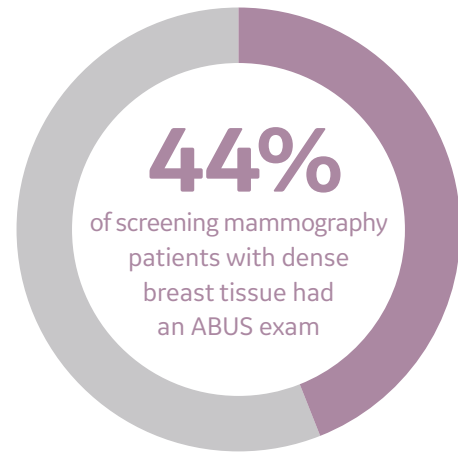
The study also included interviews with IFW clinicians and the administrator to provide insight on best practices and challenges.

Study Participants

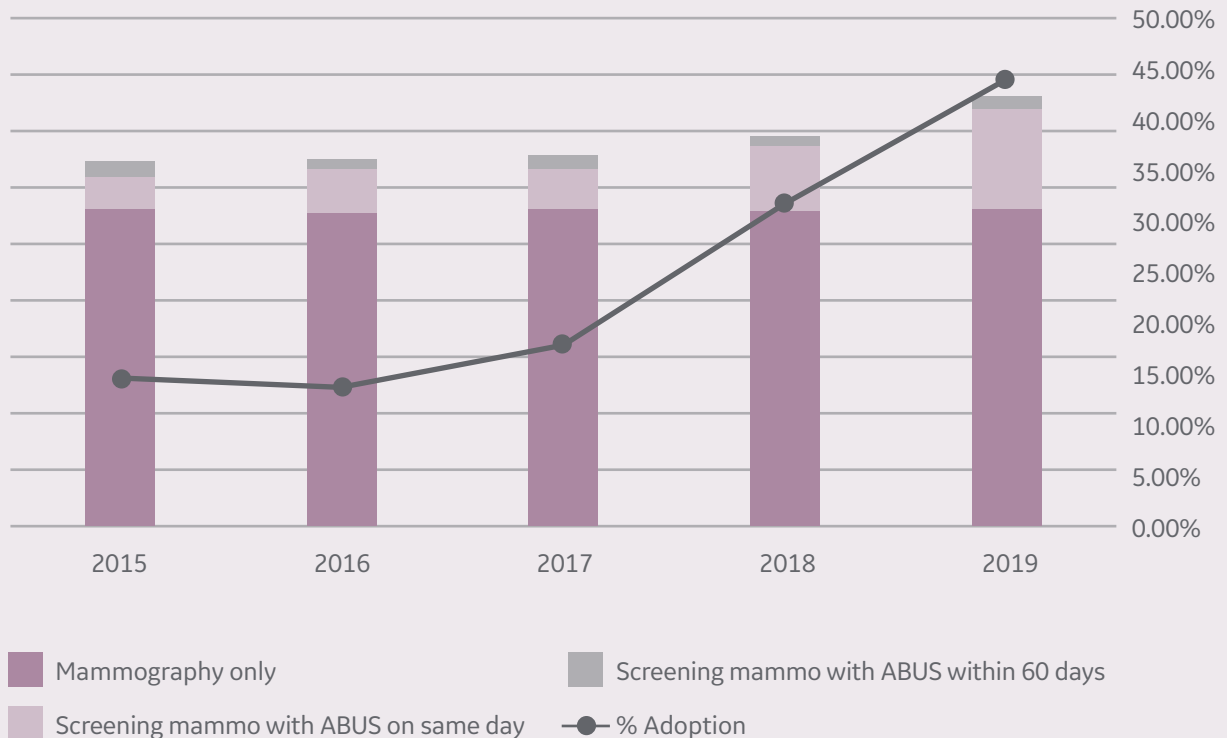
During the study period, 80,834 women underwent mammography. Of which, 47% were determined to have heterogeneously or extremely dense breasts. Among dense breast patients, 44% received an ABUS exam. Amongst those who chose to have an ABUS exam in 2019, 97% received the exam on the same day as their mammogram.

“Our patients love the convenience of the ability to choose ABUS the same day they receive their mammogram.”

Kristina Jones, IT Director



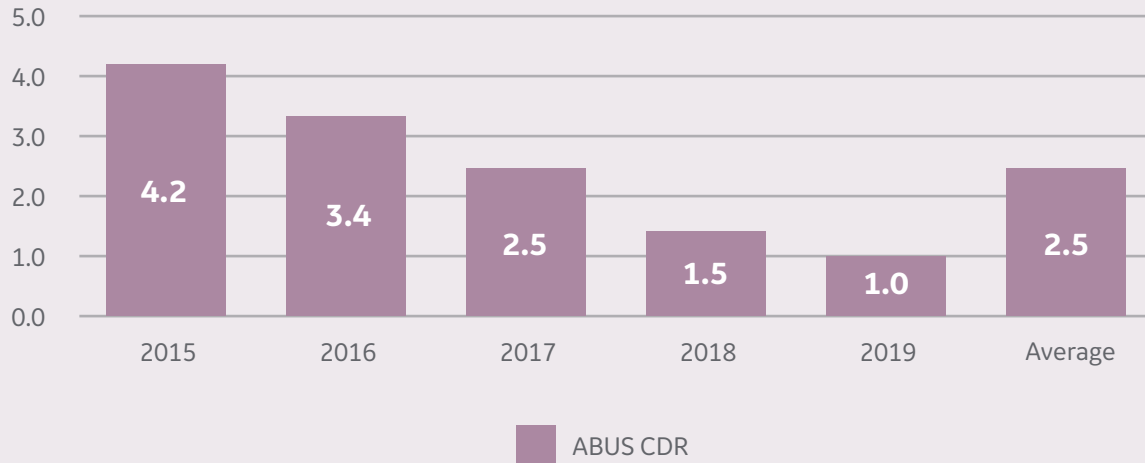
Dense Breast Screening Adoption



Cancer Detection and Recall Rates

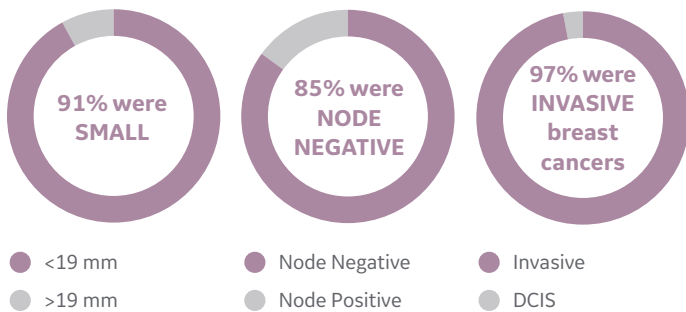
Over the entire study period, ABUS detected on average an additional 2.5 cancers per 1,000 women screened with majority of those cancers being invasive, small, and node negative.* The combined mammography and ABUS recall rate decreased over time to 9.5% and has remained consistently low over the past three years.

ABUS Cancer Detection Rate Per 1,000

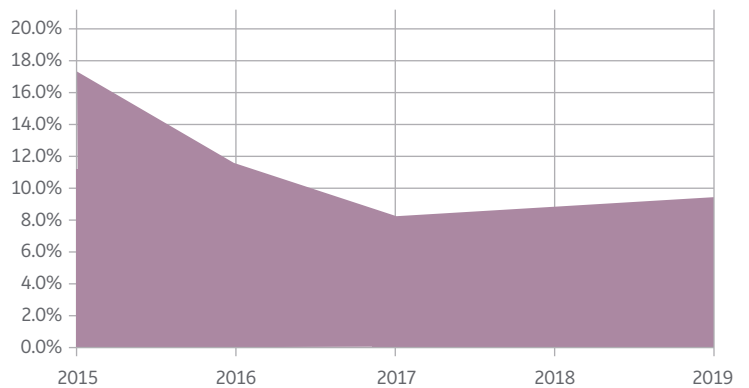


* It is noted that the CDR for ABUS decreased due to the uniform adoption of CC and MLO tomosynthesis imaging.

Pathology Results



Combined Mammography and ABUS Recall Rate



Economic Outcomes

Although IFW does not base care on patient financial status, revenue is an important consideration. Adding more ABUS units and without adding staff increased ultrasound revenue by 50% since 2017. The ABUS exam payer mix was 85%

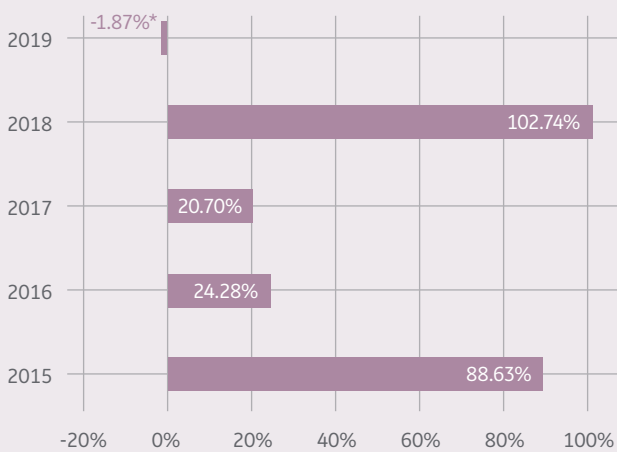
commercial and 15% Medicare. Average reimbursement (sum of plan paid plus patient out-of-pocket divided by total count of exams) across all payers was \$182.95 for a bilateral exam and \$102.18 for a unilateral exam.

Payer	Average Reimbursement†	
	Bilateral	Unilateral
Payer 1	\$212.94	\$182.95
Payer 2	\$178.50	
Payer 3	\$211.50	
Payer 4	\$162.81	
Payer 5	\$149.02	
		\$102.18

† Reported reimbursement rates are based on contract terms negotiated between Imaging for Women and individual insurance carriers. Reported reimbursement rates from this study are not a guarantee for other practices and settings.

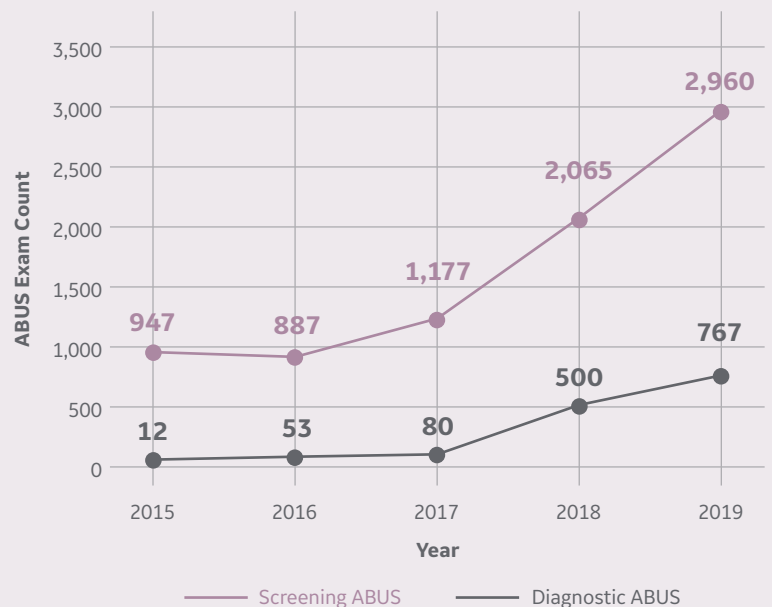
Based on a 60-month payment term and equipment purchase price of \$300K, on average, 3.6 ABUS procedures per day were needed to break even. Average procedures per day for IFW ranged from 5 to 10 with a median of 6.995. This resulted in a breakeven on equipment cost within the first 12 months.

Percentage of ABUS Revenue Increase Over Previous Year ABUS Revenue by Year



* Note: December 2019 ABUS Revenue Recorded in January 2020.

ABUS Volumes



“One of the great things that ABUS offers a radiologist is the versatility of the machine for either screening or diagnostic work up. It comes in particularly helpful when it is our busy season. Not infrequently all of my handheld ultrasound rooms are being used, but I need a diagnostic ultrasound work up on a patient. It is times like these that having another option to evaluate the patient is extremely helpful, especially considering the exam can be done by either a trained mammographer or ultrasound technologist. This allows us to not only work up the patient in a timely manner, but also gives us versatility to optimize staff and minimize their down time as well. It is a win-win for the patient and the practice.”

Troy D. Voeltz, MD

Best Practices

IFW's ABUS program success is due to the following factors set in place while implementing the program:

1. Patient and referring provider education and marketing
2. Referring provider on-boarding questionnaire
3. Engaged staff
4. Care coordination and operational efficiencies
5. Payer advocacy
6. Cash pay model with cost estimator tool

The primary aim of education is to drive demand for supplemental screening. According to results of a survey of 110 radiology facilities, the most common educational methods are informal discussions with referring physicians, followed by a referral to a website and formal educational lectures with referring physicians.⁷ These activities were the cornerstone of IFW's strategic plan, in addition to marketing initiatives (an annual survivor party, private screening events, community health fairs/senior events) and payer advocacy.

The role of education is an ongoing effort and does not reside with just one person. A table describing IFW's education initiatives, their targets and the personnel leading these efforts is outlined below.

IFW Lead	Target	Activity
Marketing Team	Referring Providers	Periodic office visits to provide marketing materials
		Send quarterly newsletters
		Provider onboarding questionnaires
Radiologists	Referring Provider Practices	Informal discussion of the role of ABUS and adding ABUS
Staff	Community	Survivor parties
		Private screening parties
		Community health fairs/senior events
Administrator	Payers	Outreach to share ABUS efficacy and outcomes data
Radiology Assistant	Patients	Discussion with each patient about their breast density

Referring provider education on density as a risk factor for breast cancer and the role of ultrasound in cancer screening and detection was paramount. Parallel to their efforts to obtain support from their referring provider base, IFW established practices to coordinate care and to improve operational efficiencies. Care coordination efforts consisted of referring provider surveys to understand their preferred method for sharing results and obtaining orders for additional testing. Operational efficiencies included EMR expansion to store patient breast density status that is used to facilitate scheduling, same-day scheduling of mammogram and ABUS in women known to have dense breasts, educational density inform letters printed and handed to women and explained on the same day as their mammogram, and insurance eligibility checks with estimated patient out-of-pocket (OOP) amounts shared at time of scheduling.

Prior to August 28, 2020, Automated Breast Ultrasound was not considered a preventative service and the challenge was exam cost for women seeking their ABUS exam early in the deductible year. Effective August 28, 2020, House Bill 1682 and Senate Bill 551 include additional or supplemental imaging such as breast MRI or ultrasound deemed medically necessary for women who have an above average risk for

breast cancer in accordance with ACR Guidelines for breast cancer screening with their annual mammogram. In this scenario, patient OOP expenses should be reduced. To overcome this limitation, IFW uses an electronic clearing house to assist with patient estimation and eligibility checks. This enables IFW to inform the patient of her OOP cost at scheduling. In addition, for patients not wishing to file insurance, IFW offers service packages that includes bundled services.

Cost was not always the barrier to supplemental screening with ABUS. In some cases, where women were found for the first time to have dense breast during their mammogram and the offer was made for additional screening with ABUS, women would decline due to lack of time. In these instances, patient breast density status was saved in the EMR and ABUS was offered to the patient when scheduling her next annual mammogram appointment.

After several years of providing ABUS as a supplemental tool, women now ask for ABUS at the time of scheduling. IFW has also found these patients educated their family and friends on the importance of knowing their breast density.

"In today's economic climate, every penny counts. ABUS is not yet considered a preventative screening and therefore not paid at 100% like screening mammography. Patients often must pay out-of-pocket expenses. We offer on-site education, special pricing to make it more affordable, and breast imaging packages. We strive to find ways to assist patients to afford the needed exam."

Phyllis Fulk, Administrator

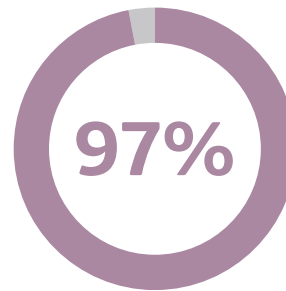
Conclusion

The addition of Invenia ABUS has positively impacted Imaging for Women's radiology group practice. Among these outcomes:



44%

of dense breast women who underwent mammography in 2019 also received a supplemental ABUS exam



97% of the women who chose ABUS received their ABUS exam the same day as their mammogram in 2019



Supplemental screening with ABUS in women with dense breast aided in early detection of otherwise mammographically occult breast cancer as IFW found 35 cancers in the first 60 months, equating, on average, an additional cancer yield of **2.5 per 1,000 women screened**



Combined breast ultrasound revenue **increased by 50%**



Combined recall rate for 2019 screening mammography and screening ABUS



Achieved an average bilateral reimbursement of **\$182.95** that resulted in a breakeven on equipment cost in year 1

1. Richard et al. N Engl J Med. 2005;353:275-285.
2. Kolb et al. Radiology. 2012 (October);265.
3. Arora et al. Ann Surg Onc. 2010; 17:S211-18.
4. Kolb et al. Radiology. 2002 (October);225(1):165-75.
5. Brem et al. Radiology.2015;274:663-673.
6. Kelly et al. Eur Radiol. 2010;20:734-742.
7. Nayak et al. Breast J. 2016;22(5):493-500.

© 2021 General Electric Company – All rights reserved.

GE Healthcare reserves the right to make changes in specifications and features shown herein, or discontinue the product described at any time without notice or obligation. Contact your GE Healthcare representative for the most current information. GE, the GE Monogram, Invenia, and sono•v are trademarks of General Electric Company. GE Healthcare, a division of General Electric Company. GE Medical Systems, Inc., doing business as GE Healthcare.

JB01169XX
ULT-0651-11.06-EN-US

