



Real World Experience 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, seventy-one percent 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 to provide patient care. 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 the option to have a screening breast ultrasound for women with heterogeneously or extremely dense breasts. 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.

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 supplemental screening with ABUS added to mammography.

“Imaging for Women acquired ABUS to assist women with heterogeneously dense and extremely dense breast tissue to find breast cancers earlier. Finding earlier cancers means less treatment, lower cost to the patient, and a higher cure rate.”

– Dr. Mark J. Malley, Senior Radiologist



630 NW Englewood Road Kansas City MO 64118

Phone (816) 453-2700

www.imaging4women.com

About Imaging for Women

Dedicated to offering patients a new experience in women's health care, Imaging for Women (IFW) offers high quality diagnostic imaging services in a comfortable, service-oriented environment.

The goal at IFW is to offer women the best possible experience while at the facility. IFW accomplishes this by both utilizing the best technology currently available, including 3D mammography and whole breast ultrasound, and using certified technologists who were chosen for their skill at performing exams, while providing compassionate care. Exams are read in real-time by board certified physicians who are specialized in breast imaging. IFW offers same day services which provides women with convenience and peace of mind.



"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 30 months of data starting after the first installation of sono•v ABUS (May 2014). The data included:

- Volume of mammography screening examinations
- Rate of mammography screening in women with dense breasts
- Rate of supplemental screening with ABUS
- 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.

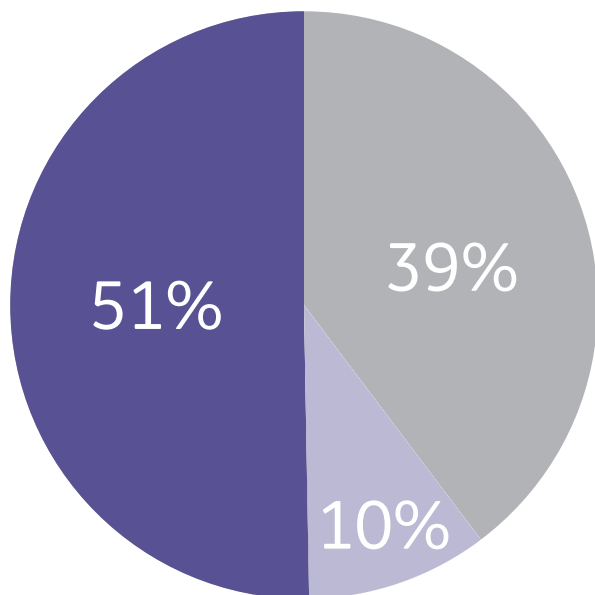
Study Participants

During the study period, 41,791 women underwent mammography screening. Of which, 49% were determined to have heterogeneously or extremely dense breasts (39% of patients were asymptomatic; 10% were symptomatic). Among dense breast patients, 21% received an ABUS exam (99.5% received a bilateral screening exam; 0.5% received a unilateral diagnostic exam). Amongst those who chose to have an ABUS exam, 32% 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.”

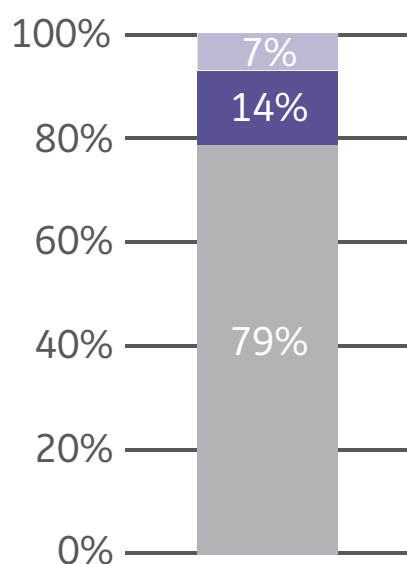
– Kristina Jones, IT Director

Study Participant Profile



- Dense Breast, Asymptomatic
- Dense Breast, Symptomatic
- All other

Mammography + ABUS Distribution



- Mammogram
- Mammogram + ABUS (same day)
- Mammogram + ABUS

21%
of mammography
patients with dense
breast return for an
ABUS exam

Clinical Outcomes

Among dense breast patients that chose to receive an ABUS exam, the cancer detection rate was 2.6 per 1,000 screened women (11 of 4,270). These cancers were all mammographically occult. The cancer yield of supplemental screening in this retrospective study was consistent with results seen in other real world settings and even clinical reader trial settings.^{5, 6, 8-13}

Comparison of Cancer Yield from Supplemental Screening Studies (Per 1,000 Screened)			
Study Type	Author/Study	Additional Cancer Yield	Modality
Retrospective, Real World	Imaging for Women	2.6	ABUS
	Hooley et al, Radiology ⁷	3.2	HH U/S
	Philpotts et al, RSNA 2015 ⁸	2.6	HH U/S
	Bae et al, Radiology ⁹	4.0	HH U/S
Clinical Reader Trials	Brem et al, Somolnsight ⁵	1.9	ABUS
	Kelly et al, European Radiology ⁶	3.6	ABUS
	Berg et al, ACRIN 6666 ¹⁰	4.2	HH U/S
	Ohuchi et al, J-START ¹¹	2.5	HH U/S
	Tagliafico et al, ASTOUND ¹²	7.1	HH U/S

Legend: ABUS – automated breast ultrasound; HH U/S – handheld ultrasound

The majority of the cancers detected with ABUS at IFW were node negative with lesions ranging in size from 0.2 cm to 1.9 cm.

Imaging for Women ABUS Findings							
Patient	Age	BI-RAD Breast Density	Other Risk Factors	Lesion Size (cm)	Pathologic Findings	Staging	Lymph Node Status
1	70	D	family hx	0.8	invasive ductal	pT1b, pNO {i-}{sn}	negative
2	53	C	family hx, benign bx	1.3	invasive ductal	pT1c, pNO (sn)	negative
3	55	D	family hx	1.6	invasive ductal	pT1c, pNO	negative
4	65	D	hx of cysts	0.2	invasive ductal	pT1c, pNO (i-)	negative
5	61	D	hx of cysts, 2° family hx	0.6	invasive lobular, LCIS	pT1b, pNO, pMX	negative
6	47	D	hx of cysts, 2° family hx	1.4	invasive ductal, DCIS	pT1c, pN1a	positive (1 of 12)
7	54	D	hx of cysts	0.3	invasive ductal, DCIS	pTX NX MX	negative
8	57	D	hx of ovarian CA	1.9	invasive ductal, DCIS	pT1c, pNO {i-}{sn}	negative
9	47	D	none	1.0	invasive ductal, DCIS	pT1N0M0	negative
10	65	D	none	n/a*	invasive lobular	pTX NX MX	n/a
11	70	C	family hx, benign bx	n/a**	invasive ductal, invasive lobular	pT1c, pN1a	negative

Legend: BI-RAD C – heterogeneously dense; BI-RAD D – extremely dense; bx – biopsy, CA – cancer, hx – history, n/a – not available

* In process of shrinking prior to excisional biopsy;

** Mets to nodes bilateral mastectomy

Economic Outcomes

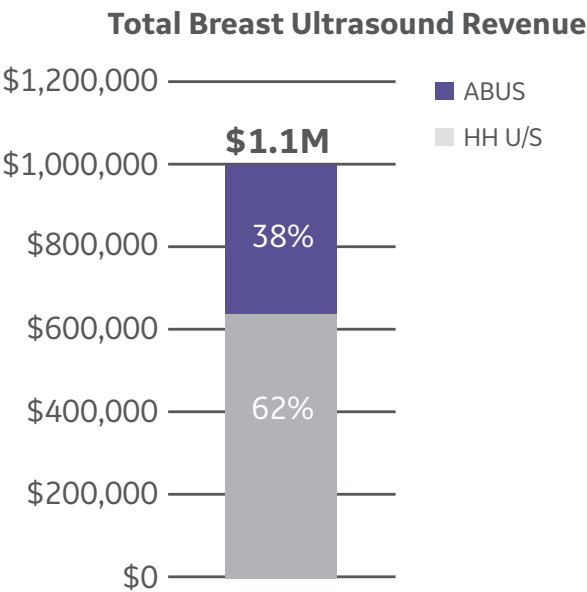
Although IFW does not base care on patient financial status, revenue is an important consideration. Addition of ABUS increased breast ultrasound revenue by 61% and totaled \$1.1M (38% from ABUS; 62% from handheld ultrasound). The ABUS exam payer mix was 85% commercial and 15% Medicare. Average reimbursement (sum of plan paid plus patient out of pocket

divided by total count of exams) for a bilateral ABUS examinations was highest for Blue Cross Blue Shield (\$208.69), followed by Medicare (\$206.21) and Cigna (\$191.33). Average ABUS reimbursement across all payers was \$202.84 for a bilateral exam and \$98.96 for a unilateral exam. Average patient out-of-pocket (OOP) ranged from 5% to 54% of total.

Payer	Average Reimbursement†		
	Bilateral		Unilateral
Blue Cross Blue Shield	\$208.69	\$202.84	\$98.96
Cigna	\$206.21		
Medicare	\$191.33		
United Healthcare	\$183.47		
Aetna	\$181.52		

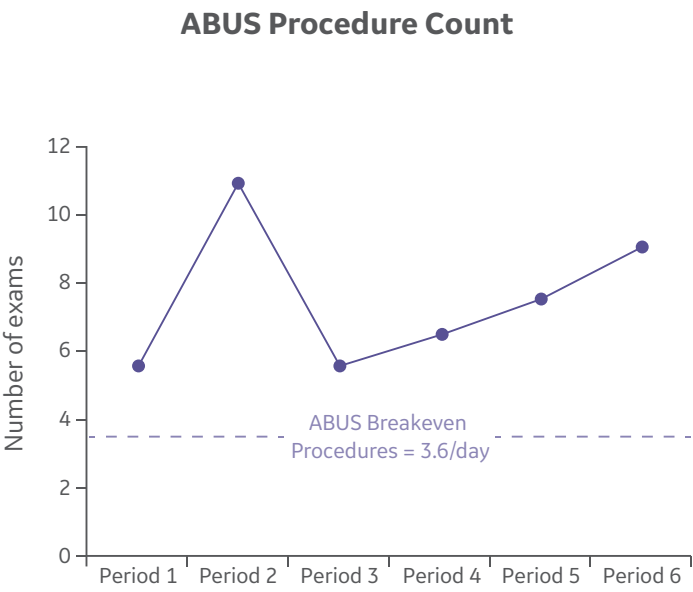
† Reported reimbursement rates are based on contract terms negotiated between Imaging for Women and individual insurance carriers. Reported reimbursement rates from this study are not a guarantee for other practices and settings.

Based on a 60-month payment term and equipment purchase price of \$300K, on average, 3.6 ABUS procedures were needed to breakeven. 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.



30 Months, Post somo•v ABUS Installation

Legend: ABUS – automated breast ultrasound; HH U/S – handheld diagnostic breast ultrasound



Legend: ABUS – automated breast ultrasound
Period 1: 06/01/14 – 07/31/15; Period 2: 09/01/15 – 12/31/15;
Period 3: 01/01/16 – 03/31/16; Period 4: 04/01/16 – 06/30/16;
Period 5: 07/01/16 – 09/30/1; Period 6: 10/01/16 – 12/31/16

Best Practices

Success of IFW’s ABUS program was largely attributable to a three-prong strategic plan targeting.

- 1) education
- 2) care coordination and operation efficiencies
- 3) payer advocacy

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.¹³ 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 Physicians	Periodic office visits to provide marketing materials
		Send monthly newsletter
Radiologists	OBGYNs Family Practice MDs	Informal discussion of the role of ABUS in screening
Staff	Community	Survivor parties
		Private screening parties
		Community health fairs/senior events
Administrator	Payers	Outreach to share ABUS efficacy and outcomes data

Referring physician 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 buy-in from their referring physician base, IFW established practices to coordinate care and to improve operational efficiencies. Care coordination efforts consisted of referring physician 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.

Challenges

The success of IFW’s ABUS program did not come without challenges. Automated Breast Ultrasound is not considered a preventive service and therefore is not covered 100%. As such, the biggest challenge was exam cost for women seeking their ABUS exam early in the deductible year. In this scenario, patient OOP expenses are applied towards their deductible. To overcome

this limitation, IFW uses Zirmed 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 IFW staff would look to schedule ABUS with the subsequent year’s mammogram.

“In today’s economic climate, every penny counts. ABUS is not 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

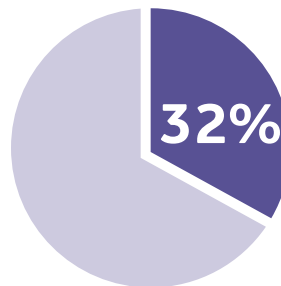
Conclusion

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

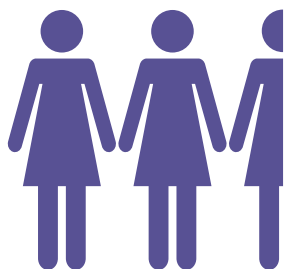


21%

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



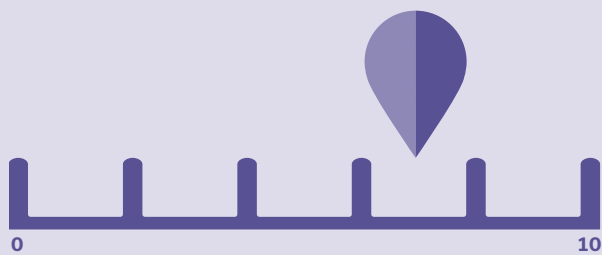
32% of the women who chose ABUS received their ABUS exam the same day as their mammogram



Supplemental screening with ABUS in women with dense breast aided in early detection of otherwise mammographically occult breast cancer as IFW found 11 cancers in the first 30 months, equating an additional cancer yield of **2.6 per 1,000 screened women**

↑ 61%

Breast ultrasound revenue **increased by 61% and totaled \$1.1M** (38% from ABUS; 62% from handheld diagnostic breast ultrasound)



Fast ramp up in average amount of daily ABUS exams
(5 to 10, median 6.995)



Achieved an average bilateral reimbursement of **\$202.84** that resulted in a breakeven on equipment cost in year 1



About Invenia ABUS

Invenia ABUS (Automated Breast Ultrasound System) is the only ultrasound system approved by the FDA for breast screening. It is a comfortable, non-ionizing alternative to other supplemental screening options for women with dense breast tissue. When used in addition to mammography, Invenia ABUS can improve invasive breast cancer detection by a 55 percent relative increase over mammography alone.⁵

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. Hooley et al. Radiology. 2012;265:325-336.
8. Philpotts et al. RSNA. 2015.
9. Bae et al. Radiology. 2014;270(2).
10. Berg et al. JAMA. 2008;299:2151-2163.
11. Ohuchi et al. Lancet. 2016 (January);387.
12. Tagliafico et al. J Clin Oncol. 2016;34(16):1882-1888.
13. Nayak et al. Breast J. 2016;22(5):493-500.

Imagination at work

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