Integrating a New Breast Screening Modality Into a High-Volume Mammography Program

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Abstract

SoftVue™ was recently approved by the FDA as an adjunct to screening mammography for women with dense breasts. SoftVue can be performed at the same visit as mammography - before radiologist interpretation; it is the only automated ultrasound device with this indication. Our facility tested this workflow in a prospective study. By reviewing the data collected, we aimed to evaluate the workflow efficiency, cost-effectiveness, patient experience impact, and to determine the maximum number of SoftVue scans that can be performed in clinical setting.

Data collected from 21-Aug-2017 to 18-Jan 2019 were retrospectively reviewed. Daily, weekly, and monthly SoftVue scan volumes were counted, as well as time to perform each step in the workflow, compensation rates of involved staff members, and the results of patient surveys rating several experience variables as positive, neutral, or negative.

A total of 1520 subjects were consented and received SoftVue on the same day as their screening mammogram. SoftVue completed as many as 10 patient scans in a day, 37 in one week and 135 in one month during this clinical study. A >90% positive patient experience remained stable on high volume days, weeks, and months, compared to those with lower volume.

Two study coordinators worked 80 total hours per week and 25% of that time was performing SoftVue scans at a rate of up to 2 exams per hour. The remaining 60 hours were consumed by research-specific activities, not required in routine clinical practice. The average daily screening volume while operating 3 mammography units was 60, and an average of 25 potentially eligible participants were identified daily, based on their density only.

Given that the additional workload imposed by study-only activities, eligibility criteria limitations, and other research related barriers to SoftVue would not be factors in routine clinical practice, it is feasible for a comparable breast imaging center to employ the same workflow and achieve daily volumes of 12 SoftVue scans or more per day, and 60 SoftVue scans or more per week, with 1 additional full-time equivalent (FTE), who is a non-technologist.

Introduction

Delphinus Medical Technologies, the developer, manufacturer, and sole distributor of SoftVue™ 3D Whole Breast Ultrasound Tomography, sponsored a multi-center prospective case collection registry (NCT03257839) in which 7500 asymptomatic women were consented nationwide and, of that, 7439 eligible subjects with BI-RADS Composition Density C or D were enrolled to receive a SoftVue scan on the same day as their screening mammogram. Our facility, Ascension St. Elizabeth Hospital in Appleton, Wisconsin, contributed to 20.43% of the total enrollment volume across the 10 participating sites. All SoftVue scans and study procedures were performed by two research coordinators, one of whom entered the project with no prior breast imaging training. A total of three radiologists were contracted as co-investigators to oversee the conduct of the project and interpret the screening exams.

The SoftVue procedure is automated, requiring minimal intervention by the system operator. Coronal plane images are acquired by a unique ring transducer as the patient rests in the prone position with her breast immersed in a warm water bath. The nipple engages with gentle suction under the water with an acoustically transparent gel pad (Sequr™ Breast Interface) to center and stabilize the breast during the scan, also optimizing the angle of incidence at which the 3mHz sound waves enter the tissue. As the transducer moves from the nipple to the chest wall and axillary tail, reflection data is captured together with transmission signals (sound speed and attenuation) as they propagate through the breast. Each breast is scanned in approximately 3 minutes, with a total exam-room time of 12-20 minutes, varying by the size of the breast, as larger cup sizes require more 2mm image slices than smaller breasts.

The three datasets are reconstructed and analyzed by the system software to produce detailed volumetric images of the tissue and glandular architecture, including a colorized overlay indicating relative stiffness, which is used by the radiologist to characterize lesions. Images are available for review in as soon as 20 minutes from the time the scan was initiated, and interpretation is completed on any workstation with 4MP color monitor in 2 ½ minutes.

Materials

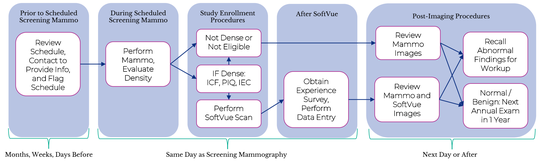
After the SoftVue scan was completed, each participant was given questionnaire about their SoftVue experience, on which they were asked to rate their agreement with each of the following statements about factors that affect satisfaction on a 5-point Likert scale:

Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree

1. The SoftVue experience was comfortable.
2. I did not feel pain during the SoftVue exam.
3. I was not anxious or nervous during the SoftVue procedure.
4. I found the SoftVue exam easy for me to complete.
5. The SoftVue procedure progressed quickly.
6. The SoftVue experience was private and discreet.
7. The SoftVue exam was calming and relaxing.
8. Comparing all breast imaging exams I've had, SoftVue was the best experience.
9. The way Sequr™ contacted my breast during the SoftVue exam was acceptable to me.
10. I will recommend the SoftVue exam to other women.

Methodology

The total protocol workflow is summarized as follows: In the process of being recruited to enroll, patients with a known history of qualifying breast density, as well as those with unknown history, were contacted by study coordinators before their scheduled annual mammography exams and provided with written informational materials about SoftVue and participation requirements. These potential subjects were flagged by study staff on the daily screening mammography schedule so that the radiologic technologists (RTs) performing those exams knew to evaluate breast density at the time of mammographic imaging to determine eligibility. A full set of digital 2D images in addition to 3D images were captured per the normal screening imaging workflow. Those patients with dense breast tissue were then referred to one of two research coordinators for informed consent (ICF), assessment of additional inclusion/exclusion criteria (IEC) and obtain additional clinical data (PIQ) about their relevant health history and demographic information. SoftVue was performed immediately thereafter and then the subjects completed a post-exam survey to collect information about their experience and satisfaction with SoftVue. Exams were batched for review the following day by one of three co-investigators (radiologists). Mammography and SoftVue were sequentially interpretated and any BI-RADS 0 findings on either exam were recalled for diagnostic workup. Subjects with normal or benign findings were scheduled for their next annual exam in one year and instructed to self-monitor for any breast changes or symptoms. The research coordinators performed data entry, study records management, and follow-up.



Survey responses were categorized as Positive (Strongly Agree or Agree), Neutral (Undecided) or Negative (Disagree or Strongly Disagree) for each statement subjects rated on the survey. Next, subject datasets were sorted into cohorts according to the total number of SoftVue scans performed on their same date of enrollment, as well as that by week, and by month. The median enrollment values were used for the cut point between high and low volume.

The total time required to perform each step in the workflow by the involved staff members was evaluated together with hourly wages and compared to current reimbursement levels using the current Medicare payment rates for the technical portion of the service.

Results

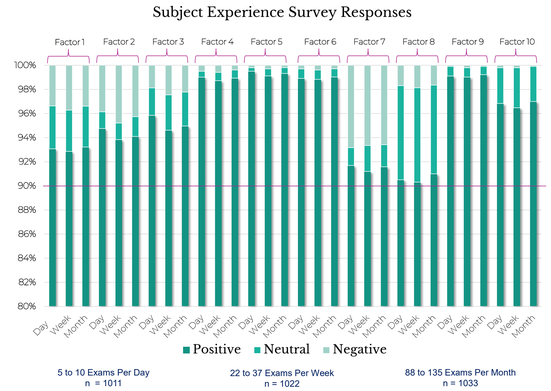
Of the total 1520 subjects who were consented and received SoftVue, a complete set of Experience Survey responses were available for 1517 (3 skipped one or more questions). The overall survey response results for n=1517 participants is as follows:

Experience Factor	Agree	Strongly Agree	Positive	Undecided / Neutral	Disagree	Strongly Disagree	Negative	Positive	Neutral	Negative
1. Comfortable	693	725	1418	51	47	1	48	93.47%	3.36%	3.16%
2. No Pain	404	1029	1433	22	58	4	62	94.46%	1.45%	4.09%
3. Not Anxious/Nervous	409	1037	1446	40	30	1	31	95.32%	2.64%	2.04%
4. Easy	341	1160	1501	10	5	1	6	98.95%	0.66%	0.40%
5. Quick	343	1163	1506	8	2	1	3	99.27%	0.53%	0.20%
6. Private/Discreet	239	1263	1502	11	3	1	4	99.01%	0.73%	0.26%
7. Calming/Relaxing	457	926	1383	35	89	10	99	91.17%	2.31%	6.53%
8. Best Experience	424	948	1372	120	24	1	25	90.44%	7.91%	1.65%
9. Sequr™ Acceptable	357	1148	1505	10	1	1	2	99.21%	0.66%	0.13%
10. Will Recommend	462	1004	1466	45	3	3	6	96.64%	2.97%	0.40%
Overall	**4129**	**10,403**	**14,532**	**353**	**262**	**24**	**286**	**95.79%**	**2.32%**	**1.89%**

During the study, a maximum of 10 SoftVue scans were performed in a day, with a median value of 4 scans throughout the 339 days participants were enrolled. The survey results were available for 1011 of the 1013 subjects who had SoftVue on any of the 162 days where more than 4 scans were performed.

A total of 1023 participants were scanned during the 76 weeks where the total enrollment volume exceeded a median value of 21, with a maximum of 37 subjects. 1022 data sets were available from this cohort of 22 or more scans performed weekly.

For a total of 9 consecutive months, the total number of SoftVue scans performed was greater than a median value of 87.5, reaching a monthly high of 135 total subjects enrolled and representing a total of 1035 participants, 1033 of which had complete survey data.



Conclusion

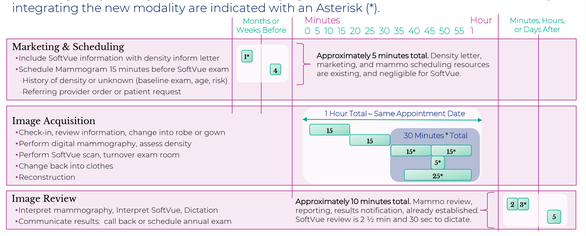
For each subject who was recruited, consented, screened and enrolled, the total protocol enrollment workflow averaged 2 hours per subject, only 30 minutes of which was attributed to steps directly related to performing SoftVue. Depending on individual clinical outcomes, up to an additional 1 hour of data entry per subject, as well as time performing administrative protocol tasks such as attending monitoring visits, complying with IRB requirements, and managing project records could be added to the study coordinators' workloads when they were not interacting with participants on the day of enrollment. It was these study-specific dynamics of the workflow that were accrual-rate limiting, not the SoftVue procedure itself.

In routine clinical practice, without any study related tasks and at an average hourly rate of $20/hour for a single medical assistant or equivalent staff member to operate the SoftVue device, the labor cost per image acquisition could be as low as $10 per exam during an 8-hour workday with a full SoftVue schedule, while also allowing for sufficient employee breaks and patient cancellations. Utilizing AMA CPT 76641 (Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete) with modifier 50 for a bilateral exam, the National Medicare reimbursement rate for the technical component (equipment and technician performing the test) is nearly $110 per procedure. Therefore, at a facility performing more than 50 screening mammography exams per day, it is both possible and profitable to perform 12 or more SoftVue scans daily implementing an efficient workflow.

In our high-volume practice, while there is an emphasis on productivity and streamlining workflow to optimize efficiency and reduce operational costs, the quality of care delivered to our patients and their satisfaction with our provided services must not be sacrificed. The demand on study personnel and the resulting workflow impact was a concern during times of high enrollment, so it is reassuring to conclude that this did not have negative ramifications on the participants' SoftVue exam experience, based on a >90% positive rating across the 10 factors of satisfaction that were surveyed immediately following their SoftVue scans.

Recommendations

Below is our proposed workflow for integrating SoftVue as an adjunct to screening mammography in a high-volume breast imaging center. The additional tasks introduced by integrating the new modality are indicated with an Asterisk (*).



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