

Improving Patient Comfort During Breast Imaging: *The SoftVue™ Solution*

Screening mammography has made a significant impact in the early detection of breast cancer, demonstrated in research across several decades, yet many women find the procedure to be unpleasant and difficult. Delphinus Medical Technologies, Inc. has gained insight into women's perceptions of breast imaging exams based on a study conducted during the investigation of a new innovative technology, SoftVue™ 3D whole breast ultrasound.

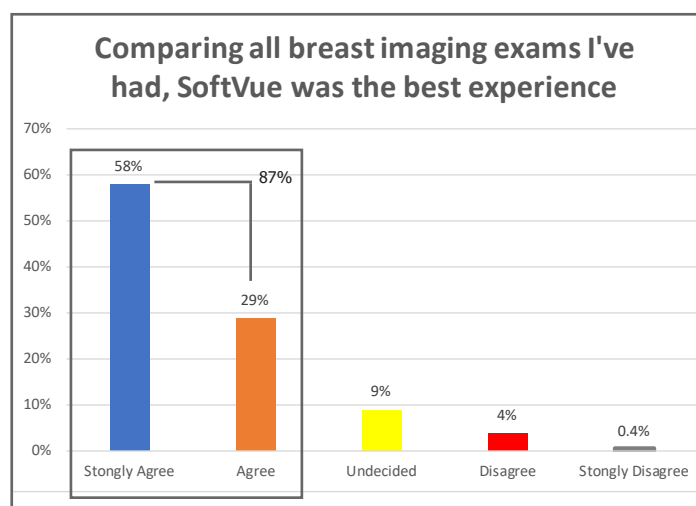
In a survey conducted of women who have experienced the SoftVue™ exam, **more than 87%** strongly agree, or agree, that **SoftVue™ was the best imaging experience comparing all other imaging exams** (see Figure 1).

Over the course of 30 years, while mammography technology has evolved remarkably, the patient experience has not shown the same level of improvement. Looking at a study published in *Radiology*² in 1988, of 356 women who completed a survey after mammography:

- 38% reported mammography to be uncomfortable, but tolerable
- 11% indicated mammography was very uncomfortable
- 3% found the examination to be intolerable
- 4% of women indicated that they would not return for mammography

In a paper published in *The New Zealand Medical Journal*¹ in 1998, almost half of women reported that they do not get regular screening mammograms due to discomfort. And a recent survey conducted in 2017 with registered mammography technologists, published in the *International Journal of Women's Health*³, respondents reported that **91% of women indicated having some degree of pain** during a mammogram with the primary variables being *pain during*

Figure 1



the last mammogram and *high breast density*. In addition, the article indicated that **fear of pain impacted compliance with 36% of women**.

In today's healthcare environment, a positive patient experience is central to providing excellent patient care. The paradigm of consumer experience has been integrated into the CMS program of value-based reimbursement, constructed with quality domains that evaluate performance, with patient experience carrying a significant weight at 25% of the overall evaluation. The scoring impacts CMS reimbursement and financial incentives paid to providers.

The SoftVue™ Solution

Recognizing the significance that pain has on patient satisfaction and mammography screening compliance, and the acknowledged impact patient experience may have on provider reimbursement, as new imaging modalities are being investigated, astute developers now consider experiential factors into design and function. One of the primary objectives is to improve the patient encounter during breast imaging exams by providing greater comfort and overall satisfaction, while supporting and promoting adherence to screening recommendations.

Stepping up to these challenges, Delphinus developed SoftVue™, a 3D whole breast ultrasound system. SoftVue™ introduces a new approach to imaging the entire breast, particularly for women with dense breasts.



Comfort & Design



The SoftVue™ technology incorporates a first-ever circular ultrasound transducer that captures not only reflected echoes in a 360-degree array, but also quantifies speed of sound and attenuation signals passing through the tissues. The exam is comfortable with no compression or radiation, unlike mammography, which has shown to cause anxiety among women. Lying prone on a memory foam table top with a flexible membrane providing support, women lower one breast at a time into warm water.

Once in the water, the breast rests on a soft, anatomically-formed gel guide, Sequor™, to center, shape and secure the breast during the imaging process. Using the circular transducer, SoftVue™ scans the entire breast in 2 mm increments. Moving from the nipple to the chest wall and making no contact with the breast, the SoftVue™ ring transducer creates full-volumetric images. The exam takes 2-4 minutes per breast and when the exam is complete, a woman simply lifts up and dries off.

Currently, Delphinus Medical Technologies, Inc. is sponsoring a large, nationwide project investigating the SoftVue™ system's ability to increase cancer detection in women with dense breasts compared to 2D and 3D mammography alone. This project also captures perceptions of the imaging experience for women undergoing the SoftVue™ exam. While data collection for the comparative study is ongoing, research has produced conclusive evidence that SoftVue™ is considered a more comfortable imaging experience for women who have undergone the exam.



Patient Response to SoftVue™

To gauge the impact of SoftVue™ on patient comfort, each patient completed a survey following the SoftVue™ exam. Preliminary results, in which more than 800 patients underwent a SoftVue™ procedure and completed the post-exam survey, indicates the majority of women have favorable opinions about SoftVue™ in comparison to standard mammography and other imaging modalities. In fact, many of them would recommend SoftVue™ to other women and **feel it was the best breast imaging exam they had experienced.**

The survey queried patient demographics, as well as the SoftVue™ exam experience. Questions focusing on experience asked women to rate the SoftVue™ exam in comparison to other imaging exams, if they would recommend SoftVue™ to other women, as well as rank the level of comfort and pain experienced during the exam. The ranking scale in the survey ranged from strongly agree to strongly disagree. The analysis of post-exam survey results is depicted in figures 1-4.

Summary of Statistics

These statistics are calculated by combining participant responses of strongly agreed or agreed to the questions presented in the post-exam survey.

- **87%** rate SoftVue™ as the best breast imaging experience in comparison to other imaging modalities
- **91%** of women found the exam comfortable
- **94%** of women would recommend SoftVue™ to other women
- **95%** did not feel pain during the SoftVue™ exam

Figure 2

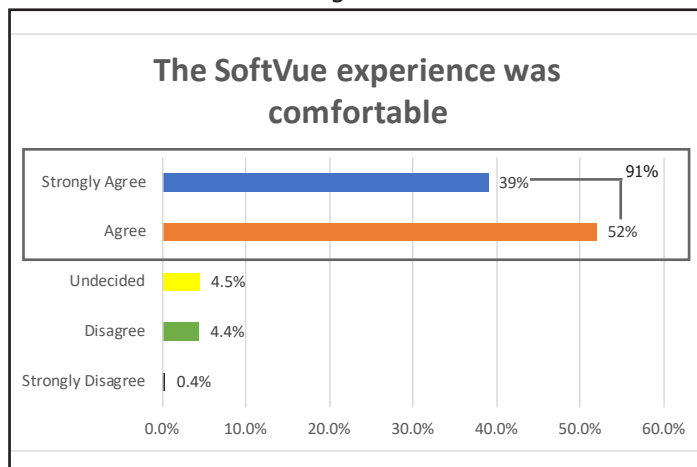


Figure 3

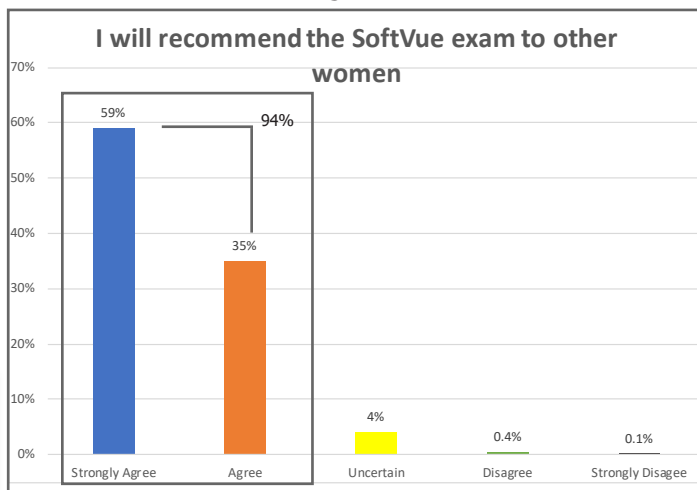
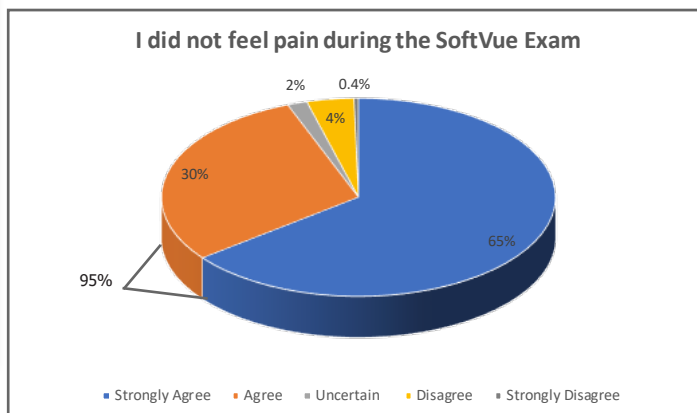


Figure 4



Patient Demographics



Average statistics of patients who experienced the SoftVue™ procedure and completed the post-exam survey:

- 52 years of age
- 155 lbs in weight
- 65 inches tall
- B or C bra size

Summary

While mammography is the standard-of-care for the detection and diagnosis of breast cancer, for the majority of women the degree of discomfort experienced with mammography is concerning. Results of the post-exam survey indicate SoftVue™ 3D whole breast ultrasound significantly improves the breast imaging experience for women.

Clearly, the vast majority of women who experienced SoftVue™ and responded to a post-exam survey found the procedure to be pleasant, replying that SoftVue™ offers the best breast imaging experience, they would recommend the exam to other women, found the exam comfortable, and did not feel pain. These results provide a strong indication that women have an extremely positive perception of SoftVue™, and this is very encouraging. When the imaging experience is affirming, it is generally found that compliance with screening recommendations improves. As research on the use of SoftVue™ progresses, it is anticipated the technology will be integrated into the portfolio of breast imaging particularly for the underserved population of women with dense breasts, supporting and assisting breast screening compliance, and ultimately, saving more lives.

SoftVue™ has received 510(k) clearances from the FDA for diagnostic breast ultrasound imaging and is not intended for use as a replacement for screening mammography.

Currently, the technology is in use at research sites. For more information about SoftVue™ visit <http://www.delphinusmt.com/technology/>.

Comments offered by patients about the SoftVue™ Experience

(Due to patient privacy concerns, patient's names are excluded)

"Much better than a mammogram."

"It is my preferred method for future breast exams."

"If approved, this will be a major improvement in terms of comfort for many women undergoing breast imaging."

"When compared to mammogram, SoftVue™ was gentle and an overall pleasant medical experience."

"Quick, relaxing and calming experience."

"Great to have a screening process that is non-invasive, not painful, with little anxiety."

"It is my preferred method for future breast exams."

"It's better because there is no pain from compression."

"Better option than MR"

"Hope this technique for imaging gets approved."

References

1. Jackson, V. P., Lex, A. M., & Smith, D. J. (1988). Patient discomfort during screen-film mammography. *Radiology*, 168(2). doi:<https://doi.org/10.1148/radiology.168.2.3393659>
2. Elwood, M., McNoe, B., Bandaranayake, M., & Doyle, T. C. (May 1998). Once is enough--why some women do not continue to participate in a breast cancer screening programme. *The New Zealand Medical Journal*. Retrieved from <https://www.ncbi.nlm.nih.gov/pubmed/9640316>.
3. Mendat, C., Mislan, D., & Hession-Kunz, L. (May 18, 2017). Patient comfort from the technologist perspective: factors to consider in mammographic imaging. *International Journal of Women's Health*. doi:10.2147/IJWH.S129817