# Improving Patient Comfort in Mammography

Andrew Smith, Ph.D.
Vice President, Image Research Breast Health, Hologic

## Introduction

This white paper will cover the history of breast compression and approaches Hologic employs to reduce discomfort during mammography imaging. In particular, it will discuss the newest product in the Hologic portfolio, the SmartCurve™ breast stabilization system, designed to greatly improve comfort during breast compression, especially for women who experience pain using conventional flat compression paddles.

## Mammography and Patient Comfort

Mammography screening reduces mortality from breast cancer.[1] Some portion of this success must be attributed to the dedication to creating proper techniques and high quality breast imaging. Proper breast positioning and breast compression are essential for optimal imaging. With recent advances in breast imaging, specifically breast tomosynthesis, Hologic is rethinking the classically held beliefs about breast compression, and has active research projects and product enhancements aimed at reducing the pain during breast compression and improving clinical outcomes at the same time. Hologic also feels that improving the patient experience in mammography may increase compliance to regular screening regimens.[2]

## Reasons for Breast Compression

It is useful to review the rationale for breast compression. There are many reasons why breast compression contributes to good mammographic image quality; however, some of these date back to the needs of analog imaging and are less relevant for breast tomosynthesis or 2D full field digital mammography (FFDM) imaging. Table 1 lists some of the reasons for breast compression and their relevance to current breast imaging.

## Breast Compression and Pain

Hologic has conducted research into patient discomfort in mammography, both from the technologist's perspective and from the patient's perspective. Hologic's goal is to make mammography more comfortable, in part to improve compliance, while improving clinical outcomes.

Hologic recently published a white paper, *Patient Comfort from the technologist perspective: factors to consider in mammographic imaging*, which highlights findings on discomfort in mammography.[3]

## Five Key Takeaways

- Advances in technology allow for new approaches to pain reduction, while still improving clinical outcomes compared to conventional 2D imaging.
- Tomosynthesis systems with fast scans and synthesized 2D imaging reduce compression time and can be expected to improve comfort compared to slower systems having longer compression times.
- Discomfort during mammography has a number of sources including breast compression.
- Pain reduction in mammography may encourage more women to comply with screening guidelines, resulting in earlier cancer detection.
- Clinical trials of the Hologic SmartCurve breast stabilization system show increased comfort for many women who experience the greatest pain using conventional flat paddles, while maintaining image quality and at no increase of radiation dose.

| Reason for Breast Compression | Relevance to Current Imaging Technology |
|---|---|
| To give the breast uniform thickness, so that the exposure on the image receptor is roughly constant across the breast image | This was a critical requirement of analog imaging. This requirement is of lesser meaning with FFDM or tomosynthesis imaging due to the wide dynamic range of digital detectors. |
| To make the breast thin, to reduce radiation exposure and to allow low kV imaging to increase image contrast | Again, a requirement of analog imaging. With digital detectors, the kV can be raised to keep the dose low, and the contrast can be optimized through image processing. |
| To make the breast thin to reduce x-ray scatter. | Image processing and/or anti-scatter grids can reduce this effect, so that the breast does not need to be extremely thin. |
| To reduce the effect of overlapping breast structures. | Breast tomosynthesis reduces overlapping breast structures, so this requirement is less important now for tomosynthesis imaging, but still a consideration for 2D FFDM imaging. |
| To pull and hold the breast away from the chest wall. | This requirement is important for tomosynthesis and FFDM imaging. |
| To hold the breast still during the exposure, reducing patient motion. | This requirement is important for tomosynthesis and FFDM imaging. |

**Table 1. Original reasons for breast compression and relevance to current technology.**

The reasons for discomfort in mammography are varied. The high compression forces lead to discomfort in some women. Some women who feel pain report that the sources of the pain are the hard edges of the paddle, such as pinching near the chest wall. Additional sources of discomfort are the length of time under compression and discomfort occurring during positioning. Hologic is addressing each of these points in different ways, including a shaped paddle that reduces localized pressure points by distributing the forces uniformly across the breast, very short tomosynthesis scan times to minimize compression time, and a reshaping of the breast platform housing to be more curved to reduce pinching at the chest wall.

Hologic conducted multiple trials comparing compression with standard paddles and experimental new paddle designs. After extensive interviews with the participants about how they felt pain, the locations of the pain and the reasons for the pain, these trials led to the development of a new system whose performance is described in more detail below.

## SmartCurve™ Breast Stabilization System*

Hologic has developed new compression paddles and software algorithms known as the SmartCurve breast stabilization system. The clinical testing reviewed in this paper will demonstrate that the new system reduces the pain of mammography in a large percentage of women, while at the same time maintaining image quality. The system includes software designed to adjust for the paddle curvature and ensure that the new images can be compared with priors. The new paddles are contoured to follow the shape of the breast along the lateral left and right sides of the breast and to follow the shape of the chest. The curves facilitate more uniform compression as compared with flat paddles, while at the same time reducing the pressure needed to immobilize the breast.

## Objectives of Research

These key criteria were considered in designing a new solution:

- Demonstrable reduction in pain for a large percentage of women.
- Compatibility with the spectrum of breast sizes, densities and shapes.
- Compatibility with 2D, tomosynthesis and synthesized 2D imaging.
- Minimal change in image appearance to facilitate comparison to priors.
- No negative effect on image quality.
- No negative effect on amount of tissue captured.
- No increase in radiation dose.
- Ease of use by the technologist or radiographer.
- Minimal or limited training needed.
- Suitability for high-throughput screening workflow.
- Robust product, with acceptable cost and usability.
- Easy to clean.
- Compatibility with Selenia® Dimensions® systems already in use.
- Compatibility with computer-aided-detection (CAD) and breast density software algorithms.

In a multi-year investigation, many designs were evaluated. A few met some of these requirements, but not all. The SmartCurve breast stabilization system proved to have the optimal design with features appropriate for high-volume screening usage and improved patient comfort.

## SmartCurve Stabilization System Solution

The system consists of hardware and software. The hardware consists of shaped compression paddles (see Figure 1) to better conform to and hold the breast shape, and the software is used to compensate for the varying breast thickness caused by the curved shape of the paddles. The initial paddle is 18x24 cm, analogous to the standard small flat compression paddle. A large 24x29 cm paddle, analogous to the standard large flat compression paddle is in development. The paddles are inserted and removed similarly to standard paddles. The system automatically identifies the paddle type through a radio frequency identification (RFID) tag on the paddle. The system also includes software, which performs a uniformity correction on the image to compensate for the variation in breast thickness due to the paddle's surface contours.

The mechanical design of the system has the following features:

1. The chest wall edge is curved – this shape allows improved comfort compared to conventional paddles that have a 90-degree edge at the chest wall. In addition, the paddle sometimes allows a reduction in breast tissue pushed out of the field of view, allowing for more breast tissue to be imaged.

2. The paddle is curved side-to-side (parallel to the chest wall) – this shape is also designed to more evenly distribute the compression force across the breast, decreasing patient discomfort, and it supports the breast in the medio-lateral oblique (MLO) position, decreasing the chance of patient motion.

**Figure 1. Hologic SmartCurve breast stabilization system paddle.**

## System Development History

Development of the SmartCurve Breast Stabilization System has been a multi-year project with imaging at six institutions under Investigational Review Board (IRB)-approved protocols with informed patient consent. The studies focused on optimizing tissue coverage, reducing discomfort, finding the optimal compression force and maintaining image quality. The study results presented here use compression to breast skin "tautness" similar to conventional imaging. Thus, the system can replace the standard compression protocol with no new training required for the technologists.

## Clinical Evaluation

A full multi-site clinical evaluation was performed. The following is a summary of the results of the women imaged with the small SmartCurve breast stabilization system.

The evaluation consisted of several components comparing the SmartCurve breast stabilization system to the standard compression protocol.

Among the items studied were:

- Patient's report of comfort or pain.
- Radiologist's blind evaluation of image quality.
- Evaluation of tissue coverage.
- Determination of patient dose.

## Comfort Evaluation

The most recently completed subject imaging used compression methods with the SmartCurve system that closely matched standard mammography compression methods. 68 subjects imaged for either screening or a diagnostic evaluation participated. Each subject was imaged with both a conventional flat paddle and a SmartCurve stabilization paddle (18x24 cm each). The order of the imaging for the two paddles was randomized. The subjects were asked to score the pain level for each paddle using a 10-point pain scale shown in Figure 2.

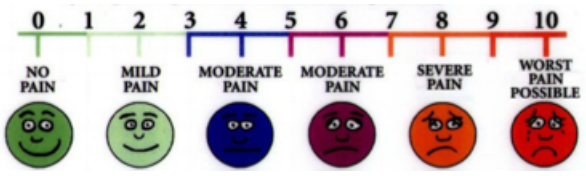


Figure 2. Pain score used in the clinical study.

## Pain Versus Paddle Type

The following two histograms show the distribution of reported pain values using the conventional flat paddle and the SmartCurve system for all 68 cases. The flat paddle histograms show women experienced a higher mean pain in the higher discomfort region of 5-10 with the flat paddle as compared with the SmartCurve system.

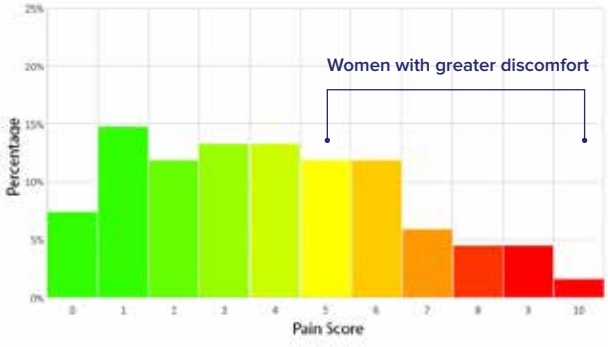


Figure 3. Pain reported using standard compression.

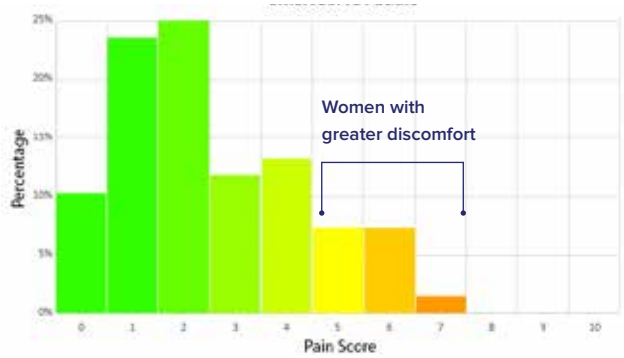


Figure 4. Pain reported using the SmartCurve system.

## Summary of Pain Reduction Using the SmartCurve System

Using the flat paddle, women reported pain scores ranging from 0 (no pain) to 10 (worst pain possible). The greatest need for pain reduction is in the subset of women that report higher pain; therefore, the following analysis focused on women who reported pain of at least 5 (moderate pain) using a conventional paddle. Of the 68 women imaged, 4 in every 10 women reported pain in the moderate to extreme category, and of these 93% saw comfort improvement when using the SmartCurve system.

Analyzing the data for cases where the flat paddle resulted in a pain score of 5 or higher, the SmartCurve system showed a reduction in pain, or equivalently, an increase in comfort of 3.2 points (see Table 2).

| Protocol | Mean pain score |
|---|---|
| Flat paddle | 6.6 |
| SmartCurve system | 3.4 |

Table 2. Pain reduction for women experiencing higher pain levels.

Another way to analyze this same data is to see in what percentage of cases there was an increase in pain, no improvement or a decrease in pain when comparing the flat to the SmartCurve paddle (see Table 3).

| Protocol | Pain less with flat paddle | Pain unchanged | Pain less with Smart-Curve system |
|---|---|---|---|
| Flat paddle compared to SmartCurve system | 0% | 7% | 93% |

Table 3. Comfort improvement with the SmartCurve system.

There was an improvement in comfort in about 93% of the cases. Figure 5 shows the histogram of pain differences between the flat paddle and the SmartCurve paddle. Green represents improvement using the SmartCurve system. Yellow means both paddle types resulted in the same pain score.

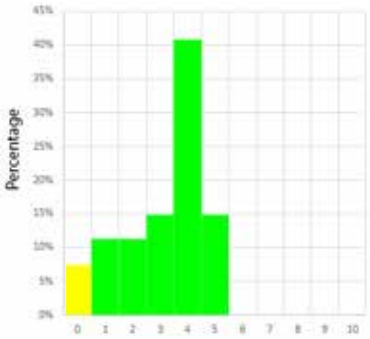


Figure 5. Distribution of pain difference between conventional compression and the SmartCurve system.

## Comfort in CC and MLO Projections

The improvement in pain with the SmartCurve breast stabilization system was seen in both the cranial-caudal (CC) and medio-lateral oblique (MLO) projections. Again, the analysis focused on cases in which there was a reported pain of 5 or higher with the standard flat paddle. There were eleven cases in the CC projection and 16 cases in the MLO projection that met this criteria (see Table 4).

| Projection | Mean pain improvement |
|---|---|
| CC Projection | 3.3 |
| MLO Projection | 3.1 |

**Table 4. Comfort improvement by projection type.**

Another way to analyze the data is to see in what percentage of cases there was an increase in pain, no improvement or a decrease in pain when comparing the flat to the SmartCurve paddle. In the CC projection, 91% saw an improvement in comfort, and in the MLO projection, 94% of cases showed an improvement with the SmartCurve system (see Table 5).

| Protocol | Pain less with flat paddle | Pain unchanged | Pain less with SmartCurve system |
|---|---|---|---|
| CC Projection | 0% | 9% | 91% |
| MLO Projection | 0% | 6% | 94% |

**Table 5. Comfort improvement with SmartCurve system by projection type.**

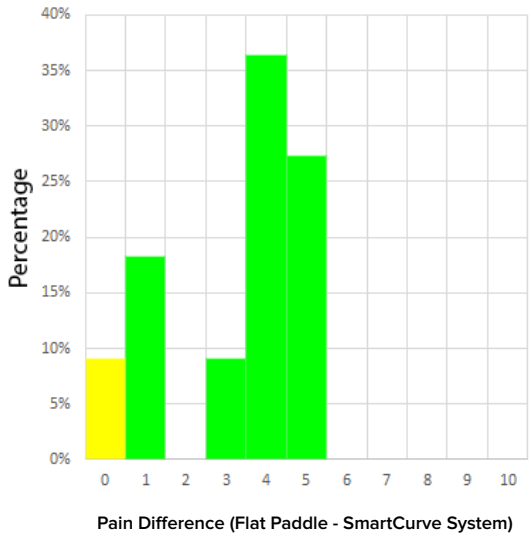


**Figure 6. CC projection: Differences in pain between standard compression and SmartCurve system.**

Figure 6 and Figure 7 show the histograms of pain differences between the flat paddle and the SmartCurve system in the CC and MLO projections, respectively. As before, the green color represents an improvement of pain with the SmartCurve system.

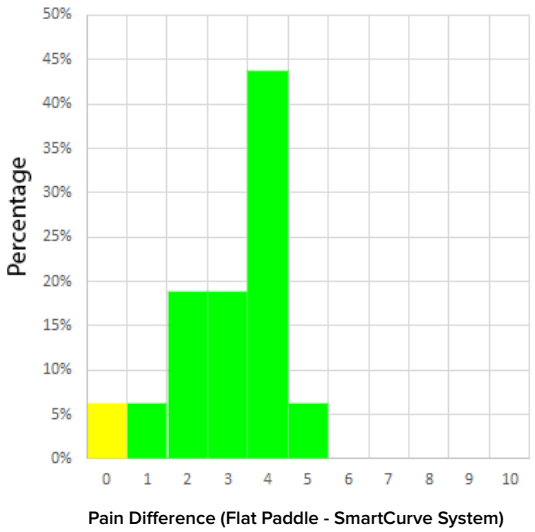


**Figure 7. MLO projection: Differences in pain between standard compression and SmartCurve system.**

## Patient Feedback

The clinical trial volunteers provided verbal feedback, comparing the flat and SmartCurve paddles, in addition to rating their numeric pain scores. 95% of women reported that they would recommend a facility that offered the SmartCurve system to their friends and family.

## Image Quality

Hologic conducted a reader study to compare image quality from a subset of the collected cases. The purpose of this reader study was to ensure that image quality was maintained using the SmartCurve system. 48 cases were selected for this reader study.

The cases came from three sites. There were 9 cancer cases, 15 benign cases and 24 negatives. Six radiologists read the 2D mammography studies and the tomosynthesis with synthesized 2D (C-View™ software) studies. A 7-point Likert scale (see Table 6) was used to compare each pair of images, and the radiologists scored overall image quality. The readers were blinded to which images were taken with the flat paddle

and which were taken with the SmartCurve breast stabilization system (paddle plus algorithm). The primary endpoint was to show non-inferior image quality using the SmartCurve system.

| Score | Left Image compared to Right Image |
|---|---|
| -3 | Left- Diagnostically inferior |
| -2 | Left - inferior |
| -1 | Left - slightly worse |
| 0 | Equal |
| 1 | Left - slightly better |
| 2 | Left - superior |
| 3 | Left - diagnostically superior |

**Table 6. 7-Point Likert Scale.**

The results of the study were as follows:

- For 2D mammography - image quality was non-inferior with the SmartCurve system.
- For C-View algorithm with tomosynthesis - image quality was non-inferior with the SmartCurve system.

The mean scores averaged over the six radiologists are shown below, along with the standard deviation of the scores. Note a positive score indicates that the SmartCurve breast stabilization system was better, a negative score indicates that the standard flat paddle compression was better.

For image quality, the differences are small, and there is essentially no difference in image quality for both 2D and for tomosynthesis plus C-View software images. This demonstrates that the improved comfort seen with the SmartCurve system is obtained while maintaining image quality.

| Image Type | Image Quality |
|---|---|
| **2D** | -0.10 ± .15 |
| **C-View algorithm plus tomosynthesis** | -0.03 ± 1.21 |

**Table 7. Mean scores for 48 cases read by 6 radiologists.**

## Radiation Dose

The mean glandular dose (MGD) delivered using Automatic Exposure Control (AEC) techniques were compared between the SmartCurve breast stabilization system and the standard flat paddle. The average MGD for the SmartCurve system was 98% of the conventional paddle dose, not statistically different. This demonstrates that the improved comfort seen with the SmartCurve system is obtained at no increase of radiation exposure.

## Evaluation With CAD and Quantra™ Breast Density Algorithms

Validation was performed to ensure that images taken with the SmartCurve breast stabilization system can be read using CAD and Quantra breast density assessment tools. Validation determined that the performance of these software offerings with the SmartCurve system was similar to performance seen when using the conventional flat paddles.

## Summary of Results Using SmartCurve Breast Stabilization System

The SmartCurve breast stabilization system was observed to offer increased comfort for women who experience the greatest pain using conventional flat paddles, while maintaining image quality and at no increase of radiation dose. The system met the design objectives of the new solution design.

- Positioning with the SmartCurve system regularly results in reduced discomfort and pain.
- Comfort improvement was seen in both the CC and MLO projections.
- Radiation dose and image quality are comparable between the SmartCurve system and conventional flat paddles.
- Tissue coverage was similar with the SmartCurve system and conventional flat paddles.

## Features of SmartCurve System

- Demonstrated improvement in comfort compared to flat paddles.
- Compatible with high-volume screening.
- No change in workflow or training required for the technologist.
- No increase of patient dose or loss of breast tissue compared to flat paddles.
- Robust mechanical solution.
- Compatible with existing Selenia Dimensions systems.
- Validated in 2D and tomosynthesis imaging modes.

- Validated with CAD and Quantra breast density software.
- Validated with C-View synthesized 2D images.

## Additional Products and Features Affecting Patient Comfort

Hologic has a number of other solutions that improve the patient experience.

### MammoPad® Breast Cushions

MammoPad breast cushions provide a thick, radiolucent, latex-free pink foam pad to cushion underneath the breast and along the chest wall. The pads do not leave visible structures on mammograms[4] and have been demonstrated to reduce patient discomfort due to the cushioning effect and to the thermally insulating characteristics of the material.[5] They have also been demonstrated to increase tissue capture.[6]

One of the SmartCurve system study sites routinely uses a MammoPad cushion as its standard of care and continued to do so during the study. The performance of the SmartCurve system was tested along with the MammoPad cushion. The clinical data indicated that the average pain scores of the participants imaged with a standard paddle and a MammoPad cushion were lower than with the standard flat paddle alone (confirming the value of the MammoPad cushion).

The pain scores were further reduced when a MammoPad cushion was used with the SmartCurve system. The use of the MammoPad cushion in conjunction with the SmartCurve system resulted in greater patient comfort than the use of the MammoPad cushion alone.

### Selenia Dimensions Design Features

As mammography gantries evolved, a number of additional design enhancements improved patient comfort and time-saving features have reduced the time under compression:

**Breast platform with curved front edge**
The breast platform includes smoother curves to avoid pinching points.

**Source-to-imaging distance (SID)**
Compared to older FFDM systems, the SID was increased to a full 70 cm to allow better access to the breast by the technologist and to facilitate upright biopsy of women with larger breasts.

**Retractable stationary tomosynthesis face shield**

A stationary tomosynthesis face shield is comfortable for the patient, as she can rest against it during the tomosynthesis scan, and there is less concern about the tube head hitting the patient. The ability to retract the shield makes it easier for the technologist to position the breast, which is more comfortable for the patient.

**Fast tomosynthesis scan time of 3.7 seconds**
The fast tomosynthesis scan reduces patient compression time and patient motion, leading to a decrease in retakes.

**Fast tomosynthesis reconstruction time of 1-2 seconds**
This enables a more compassionate tomosynthesis-guided biopsy procedure because the procedure is faster since the radiologist does not need to wait for the tomosynthesis reconstruction to proceed with the biopsy.

**Synthesized 2D algorithms**
The use of synthesized 2D images gives the radiologist a 2D image and tomosynthesis images without the patient needing to remain compressed for two separate images, thus reducing the time under compression (as well as reduced overall radiation exposure).

## Conclusion

Hologic has active research and business development activities dedicated to continuous improvement of patient comfort during mammography. With recent research indicating that discomfort during mammography can affect compliance with screening guidelines, it is critical that efforts are focused on comfort, as well as image quality, to ensure optimal cancer detection.

## References


* Upon FDA approval and/or commercial availability

1. American Cancer Society. Breast Cancer Facts and Figures 2015–1016. 2015. Available from: http://www.cancer.org/acs/groups/content/@ research/documents/document/acspc-046381.pdf. (Accessed June 14, 2017.)
2. Padoan M, Ferrante D, Pretti, G, Magnani C. Study of socio-economic characteristics, diagnosis, and outcome of women participating or not participating in mammogram screening. *Annals of Hygiene, Preventive Medicine and Community*, 26(6): 518-26 (2014).
3. Mendat CC, et al. Patient Comfort from the technologist perspective: factors to consider in mammographic imaging, *International Journal of Women's Health,* 2017:9 359–364.
4. Hendrick RE, Hall P. Technical Analysis of Radiolucent Breast Cushions. Hologic WP-00003 Rev 002 (2016).
5. Tabar L1, Lebovic GS, Hermann GD, et al. Clinical assessment of a radiolucent cushion for mammography. *Acta Radiol.* 2004 Apr;45(2):154-8
6. Coryell T. Increasing Mammography Tissue Acquisition through Positioning Training and Use of a Foam Breast Cushion. National Consortium of Breast Centers, 16th Annual National Interdisciplinary Breast Conference, Las Vegas, NV (2006).



**United States / Latin America**
250 Campus Drive
Marlborough, MA 01752 USA
Tel: +1.508.263.2900
Sales: +1.781.999.7453
Fax: +1.781.280.0668
www.hologic.com




HOLOGIC®