

SmartCurve™ Breast Stabilization System

Patient Experience in Routine Clinical Use

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Introduction

The SmartCurve™ breast stabilization system, which consists of a special curved paddle (see Figure 1) and accompanying processing software, was introduced to provide more uniform compression across the breast both laterally, anteriorly, and posteriorly and at the same time improve patient comfort.

The results of image quality, dose, and comfort as seen in a clinical trial¹ have been previously reported in a Hologic white paper.² In this paper we update the information learned from routine clinical practice of the SmartCurve™ system..



Figure 1. Hologic SmartCurve breast stabilization system paddle.

Patient Survey

Following its clinical introduction, Hologic surveyed women who had their mammograms performed using the SmartCurve system, to learn about their experience.

This white paper summarizes the results of the survey of 1066 women undergoing screening mammograms from 11 sites across the U.S. The women surveyed were reporting for their screening mammograms.* Their prior mammograms used conventional flat paddles whereas their mammogram on the day of the survey utilized the SmartCurve breast stabilization system.

The women surveyed ranged in age and history of mammography. As seen in Table 1, about half of the women reported that they had received more than 10 mammograms,

and about one quarter reported having had 1-5 prior mammograms and another quarter reported having had 6-10 prior mammograms.

The survey asked 7 questions about their previous and current experiences during mammography, including pain information. The survey also asked if the women might have delayed scheduling a mammogram due to discomfort, and if their current experiences with the SmartCurve system might change their behavior in the future.

How many mammograms?	Number	%
None	14	1%
1-5	236	22%
6-10	234	22%
10+	568	53%
Did not answer	14	1%

Table 1. Number of mammograms that the women reported that they have had.

Comfort Results

Respondents to the survey were asked questions about the pain that they experience during mammography, from their memory of their previous mammograms, and also from their experience during the current mammogram procedure using the SmartCurve system.

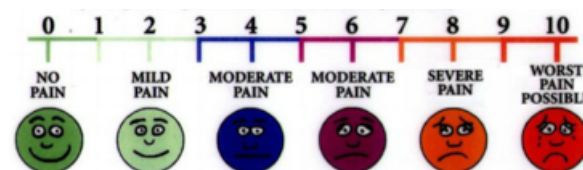


Figure 2. Pain score used in the clinical study.

The assessment of pain used the standard 10-point scale as seen in Figure 2.

The women were asked to circle on the response sheet the

pain they felt. Some of the respondents circled the numbers on the ruler having values from 0 to 10, whereas others circled the faces, which only had pain values of 0, 2, 4, 6, 8, and 10. In order to combine all the results, the pain data presented here averages the two sets of results, and we present pain data in the intervals of 0-1, 2-3, 4-5, 6-7, 8-9, and 10.

Pain versus Paddle Type

The histogram of reported pains from prior mammograms, performed using conventional flat compression paddles, is seen in Figure 3. About half of the respondents reported pain in the higher pain regions, colored in yellow and orange and red. About 10% of women reported severe pain, seen in the pain scores of 8 and higher.

In contrast, the pains reported using the SmartCurve system, as seen in Figure 4, show significant reductions in the higher pain regions

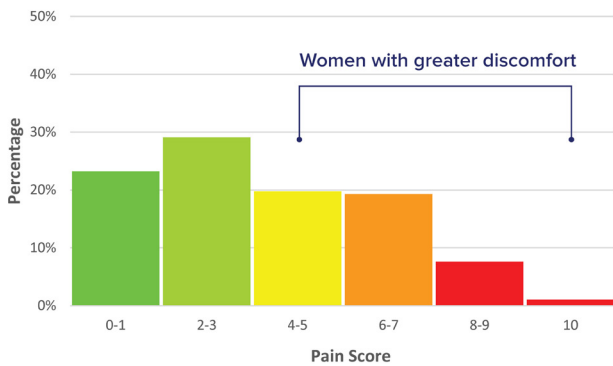


Figure 3. Pain reported from prior mammograms using flat paddles.

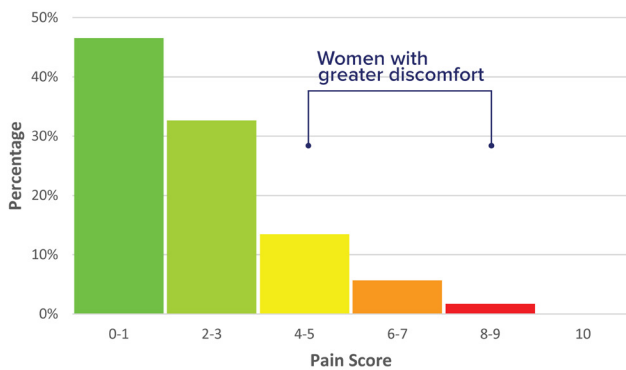


Figure 4. Pain reported from current mammograms using SmartCurve system.

The fraction of women reporting the higher pain scores decreases dramatically as the pain score goes to the higher pain values. This can be seen in Table 2. The fraction of women reporting conventional flat paddle pains of 6 or more was reduced by over 70%.

Pain Score	Reduction in % of women reporting this pain using SmartCurve compared to flat paddles
6-7	71%
8-9	78%
10	100%

Table 2. Reduction in % of women reporting higher pains using SmartCurve system compared to flat paddles.

Performance in women reporting high mammogram pain

The SmartCurve system was designed to improve patient comfort in women that experience high pain during mammograms.

About 1/3 of women self-reported high pain during mammograms using conventional flat paddles, defined here as having a pain score of 5 or higher. It is these women who will benefit the most from a reduction in pain using the SmartCurve system, and the following analysis will be restricted to this group. As seen in Table 3, the SmartCurve system showed an average reduction in pain of 3.3 points.

Paddle	Mean pain score
Previous mammogram(s)	6.6
SmartCurve system	3.3

Table 3. Pain reduction for women experiencing higher pain levels with flat paddles.

Table 4 shows the percentage of women reporting an increase, no change, or a decrease in pain when comparing the flat paddle to the SmartCurve system. 83% of women reported a reduction in pain using the SmartCurve system.

Figure 5 shows the histogram of pain differences between the conventional flat paddle and the SmartCurve system. Green colors represent comfort improvements using the SmartCurve

Protocol	Pain less with previous mammogram	Pain unchanged	Pain less with SmartCurve
Previous mammogram compared to SmartCurve	1.7%	15%	83%

Table 4. Comfort improvement with the SmartCurve system, for women experiencing higher pain levels with flat paddles.

system, i.e. higher pain scores with the flat paddle), yellow is where both paddle types resulted in the same pain score, and red indicates where the pain was lower with the flat paddle. There were a few cases where the pain was lower with the flat paddle, but this is perhaps not surprising because the women were comparing their SmartCurve experience today to a memory of years-past mammograms, involving possibly different technologists, and possibly changes in their breasts. In any case, there were almost 50 times as many cases where the pain was lower with the SmartCurve system. The large amount of green in Figure 5 shows that many women saw a reduction in pain.

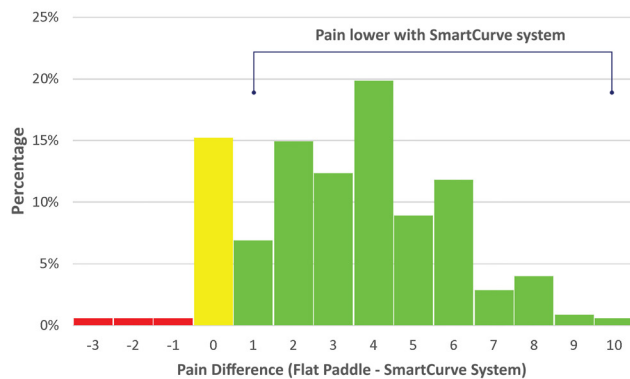


Figure 5. Distribution of pain difference between conventional flat paddle compression and the SmartCurve system, for women experiencing higher pain levels with flat paddles.

Significance of Pain in Mammography

It has been reported the discomfort that some women experience during mammography might make them reluctant to regularly return for screening mammograms³, which could result a delayed diagnosis of breast cancer.

During the survey, the women were asked questions related to pain and screening participation, with the goal of learning if the reduced pain using the SmartCurve system could demonstrate positive effects on screening attendance. The survey results are given in the tables 5-7. The total numbers in each of the tables vary slightly, as not all women replied to all questions.

The women were asked if the discomfort of mammography has ever caused them to delay scheduling their mammograms. As seen in Table 5, 8% of women self-reported delaying scheduling their mammograms.

Of the women who reported having delayed scheduling their mammogram, Table 6 shows that 80% of these women are now less likely to delay scheduling their future mammograms.** Finally, all the women were asked how likely it was that they would recommend the SmartCurve system to a friend or family member. As seen in Table 7, about 97% would recommend the experience to others.

The discomfort of mammography	Number	%
Has never impacted scheduling routine visits	959	92%
Has caused me to delay scheduling mammograms	85	8%

Table 5. Impact of Discomfort of Mammography.

If delayed, are you less likely now to delay?	Number	%
Yes	61	80%
No	15	20%

Table 6. Effect of SmartCurve experience on future mammogram scheduling.

How likely to recommend	Number	%
Definitely Would Recommend	663	63%
Very Likely to Recommend	174	17%
Probably Would Recommend	176	17%
Probably Would Not Recommend	22	2%
Very Unlikely to Recommend	6	0.6%

Table 7. Recommending the SmartCurve system to others.

** The 8 women who previously reported delaying scheduling are not included in Table 6 due to inconsistent answers in their questionnaires.

Summary and Conclusions

This survey of over 1000 women using the SmartCurve system reports on their real-life experience with the system. The results shown here indicate that many women reported reduced pain using the SmartCurve system than what they reported from their memory of their previous mammograms.

About 8% of women reported having delayed scheduling their mammograms due to discomfort, and the majority of these, 80%, would not delay future mammograms based on their SmartCurve system experience.

The survey also indicated that, based on their experience with the SmartCurve system, the women would recommend it to family or friends, which could lead to increased patient volume at these sites.

Not only does the SmartCurve system reduce pain, results from the survey indicated that it will increase compliance with mammography. If so, this would be a benefit to women's health.

References

* Date on file at Hologic, Inc. 2018

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