

Technical Analysis of Radiolucent Breast Cushions

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Summary

This paper discusses the technical aspects of the use of radiolucent cushions in analog and digital mammography with regard to comfort, image quality, dose, tissue acquisition, and compression.

Introduction

Many women experience some degree of pain or discomfort during mammography; some women even avoid or delay mammograms because of the pain associated with the exam. Although numerous studies have been performed to assess the magnitude of this problem, the variability of the test instruments makes it difficult to reliably quantify the severity and incidence of mammography-associated pain. It is fair to say, however, that any technique successful in alleviating some of the pain or discomfort of mammography would be very beneficial to patients and could have a positive impact on compliance.

The most frequently reported source of pain in mammography is compression, followed by discomfort caused by the sharp edges of the image receptor, and contact with the cold surface of the breast support. Until recently, pain control was limited to the use of relaxation techniques and patient controlled compression, with no viable method for addressing pain caused by the physical structure of the mammography system.



Figure 1. Radiolucent breast cushion applied to image receptor. The low-tack adhesive in the pad does not leave residue on the receptor.

Radiolucent Breast Cushion

In February 2001 MammoPad received 510(k) marketing clearance from the US Food and Drug Administration for use in mammography exams. MammoPad is a soft, compressible, single-use foam cushion with a low-tack adhesive on the underside. The cushion is placed over the image receptor, providing a softer and warmer surface on which the breast can rest during the exam. A second cushion can also be placed on the underside of the compression paddle for additional comfort, if needed. Figure 1 illustrates application of the MammoPad radiolucent breast cushion on the image receptor.

To determine whether the use of breast cushions is a viable and effective aid to mammography, it is necessary to establish that the primary objective of the product, reducing pain associated with mammography, can be met and that there are no detrimental effects on the quality of the mammograms, as measured by: (i) image quality and dose; (ii) adequate tissue acquisition; and, (iii) achievement of acceptable levels of compression.

Comfort Assessments

Three large, independent studies^{1,2, 3} enrolled patients reporting for routine screening to evaluate whether use of radiolucent cushions resulted in increased comfort. In these studies, both the CC and MLO view for one breast was used as a control (uncushioned), while the other breast was cushioned. Following the exam, patients rated the level of pain for each breast using either a visual analog scale (VAS) or paired numerical rating scale (NRS). Statistically significant levels of pain reduction were seen in all studies, with 66.0% to 73.5% of patients realizing at least a 10% reduction of pain (the benefited group). The average reduction of pain ranged from 33.0% to 52.6%. Table 1 summarizes these findings.

The studies cited above were performed using cushions on both the image receptor and compression paddle. Today, most practices incorporating the use of breast cushions customarily use a single cushion on the image receptor only and report no discernable reduction in comfort levels.

In addition, these studies specifically excluded women with previous breast surgery or existing breast conditions. At least one study⁴, however, has shown that the use of breast cushions may reduce mammography pain by 25% to 50% for women who have previously undergone lumpectomy and radiation therapy.

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	n	Scale	BG	Pain Reduction, BG	Pain Reduction, All
Tabar, et. al.	838	VAS	555 (66.0%)	52.6%	37.2%
Markle, et. al.	505	VAS	371 (73.5%)	47.0%	33.0%
Dibble, et. al.	394	VAS 11-point NRS	NR	NR	$p < .0001$ $p < .0001$

Table 1. Summary of pain reduction in benefited group (BG) and all study participants

Image Quality and Dose

Two methods have been used to evaluate image quality with the use of breast cushions; (i) studies using blinded, side-by-side comparisons of images of cushioned versus uncushioned breasts^{1,2,3}, and (ii) evaluations involving contrast-detail phantoms and ACR phantom images^{5,6}. Both types of evaluations report no degradation of image quality or statistically or clinically significant increase in dose when the breast cushion was used. Table 2 summarizes the findings of the side-by-side evaluations for image quality.

Comparable image quality was achieved without an increase in dose in each of the studies cited above. The Tabar study found a strong correlation between cushioned and uncushioned views (0.853 for CC views and 0.808 for MLO views); the Markle study showed p-values of 0.030 for CC views and 0.876 for MLO views; and the Dibble study showed 0.6246 significance for CC views and 0.0015 for MLO views.

The study by Markle, et. al. also measured midglandular dose and found that average doses on the cushioned side for CC views was significantly lower (-4.0%) than the uncushioned view, but not significantly lower (-0.6%) for the MLO view.

Study	Images w/cushions	Images w/o cushions	Review	Differences Noted
Tabar, et. al.	1680	1680	Blinded	None
Markle, et. al.	1010	1010	Blinded	None
Dibble, et. al.	788	788	Blinded	None for 97.5% – 98.0%*

Table 2. Blinded comparison of images taken with and without breast cushions

* In this study⁸, retakes were required for a small subset (2%) of patients where cushions were used, with improper positioning as the predominant cause (53%) for retakes. Since no degradation of image quality has been noted in other studies, this difference may be an aberration linked to training.

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Contrast-detail Phantoms, ACR Phantom Images

Two evaluations led by Eric Berns, PhD and R. Edward Hendrick, PhD, FACR, Lynn Sage Comprehensive Breast Center, Northwestern Memorial Hospital, Northwestern University, Chicago, IL, evaluated contrast-detail images and ACR phantom images acquired on; (i) 12 analog systems and 4 digital mammography systems; and (ii) 4 digital mammography systems. Images were taken using the clinical site's standard technique factors at 2, 4, 6, and 8 cm thickness using no cushion, 1 cushion on the image receptor only, or 2 cushions. The study conclusions are outlined below:

- The evaluation involving both analog and digital systems found that the use of cushions has no effect on optical density or contrast and a minimal, clinically insignificant effect on average glandular dose, contrast-detail scores and ACR phantom scores. The authors found "no clinically significant difference in image quality or dose from the use of foam pads to increase the comfort of mammography." Table 3 shows average ACR phantom scores for this evaluation.

- The evaluation involving 4 commercially available digital mammography systems showed no significant effect on average glandular dose, contrast-detail scores, or ACR phantom scores. A slight decrease in signal-to-noise ratio was noted, but there was no clinically significant effect on image quality. Table 4 shows average ACR phantom scores for this study.

Hologic, Inc. conducted a similar study using its Selenia digital mammography system. The evaluation was done in December 2006 as part of Hologic's due diligence assessment of the technology. Key findings of that study include the following:

- With proper compression, use of the cushion produces equivalent ACR phantom scores when comparing images acquired without the cushion and there is no increase in image noise.
- There is a slight increase in patient dose and reduction in image signal (~3.5%) when the pad is used; however, these variations are not clinically significant.

Appearance of Compression Mark

Some facilities using breast cushions have experienced random, sporadic occurrences of films showing lighter, circular or oval-shaped areas of contrast within the breast tissue, a phenomenon known as a compression mark. These infrequent occurrences have been limited to large, fatty-replaced breasts. A compression mark may appear with or without breast cushions when uneven compression of the breast occurs (see Figure 2). Investigation of this anomaly when used with breast cushions links it to a combined effect of the cushion's grip-like surface, uneven breast thickness, and non-uniform compression of the breast, leading to a pooling or collection of tissue in the center of the breast. This thicker region is denser and absorbs more of

# of Pads	Fibers	Specs	Masses
0	4.88	4.38	3.53
1	4.94	4.47	3.38
2	4.84	4.25	3.41
Significant p<0.05	**	1 vs. 2	**

Table 3. Average ACR phantom scores for evaluation involving analog and digital mammography systems. Table provided courtesy of Eric Berns, PhD

# of Pads	Fibers	Specs	Masses
0	5.29	5.00	4.08
1	5.25	5.00	3.96
2	5.00	5.00	3.79
Significant p<0.05	None	None	None

Table 4. Average ACR phantom scores for evaluation involving 4 commercially available digital mammography systems. Table provided courtesy of Eric Berns, PhD

the x-rays, while the surrounding tissue is thinner and allows more x-rays to pass through the tissue and reach the film. When this occurs, optical density readings will show normal exposure for the central area, while the surrounding region will be slightly more exposed but within an acceptable range. Physicians have reported no difficulty reading these films and seldom feel retakes are necessary. Careful positioning and application of uniform compression can help to minimize the potential for occurrence in this particular breast type, with or without the use of breast cushions.

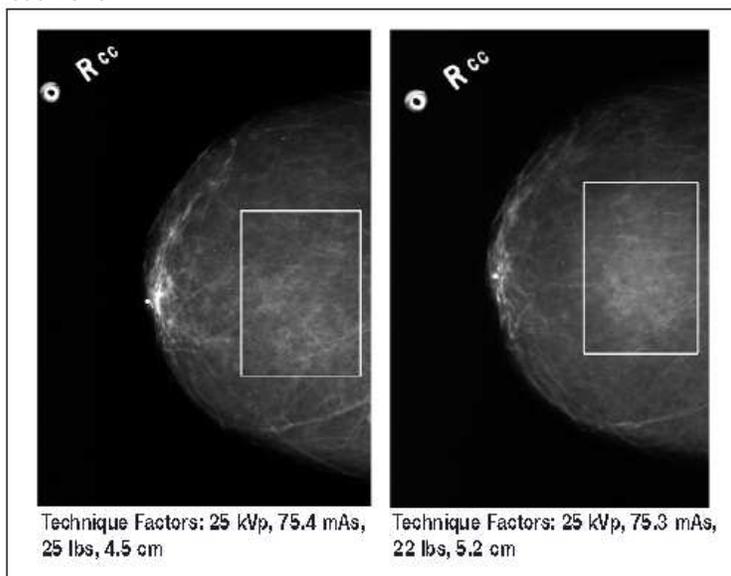


Figure 2. Appearance of compression mark in two consecutive years, without use of MammoPad (left) and with MammoPad (right)

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Study	Total Images	RCC	LCC	RMLO	LMLO	Average
Everett-Masseti and Watt	670	0.27	0.18	0.33	0.28	0.27
Coryell	844	0.67	0.57	0.65	0.56	0.61
Jaeger, et.al.	348	0.25	0.24	0.46	0.53	0.37

Table 5. Summary of additional tissue seen for each view of the screening exam performed with cushions, as compared to previous years exam performed without cushions. To determine tissue acquisition, the posterior nipple line was measured

Tissue Acquisition

Different case studies^{7,8,9} have shown average increases in tissue acquisition at the chest wall for all screening views ranging from 0.27cm to 0.61cm in side-by-side comparisons with images of exams from the previous year. These results are summarized in Table 5. A sub-analysis of these three studies looked at the percentage of views showing increased tissue acquisition of 1.24 cm or greater, a measurement felt by clinicians to have greater clinical relevance. The average percentage of views meeting this criteria was 15.4% of all views in the 3 studies, with ranges from 10.7% to 19.7%, as illustrated in Table 6.

In addition to increased tissue acquisition, researchers report increases of 20% or more in the amount of pectoral muscle visualized⁹ and openness of the inframammary fold⁹. Figure 3 provides a comparison of images for the same woman taken with (current exam) and without (prior year's exam) breast cushions.

While it is likely that some of the noted improvements in tissue acquisition in the above studies can be attributed to positioning workshops combined with cushion-specific training, researchers and technologists also credit the gripping ability of the cushion along with enhanced comfort and warmth, which leads to increased relaxation of involved muscles.

Study	Total Images	Image with >1.24 cm increase in tissue acquisition	Percent (%)
Everett-Masseti and Watt	670	74	10.7
Coryell	844	166	19.7
Jaeger, et.al.	348	51	14.7

Table 6. Percentage of images showing increased tissue acquisition of 1.24 cm or greater

Compression

The body of available published literature supports the fact that the use of breast cushions does not compromise adequate compression; in fact, it has shown that, for many patients, greater compression can be achieved with breast cushions. Research by Dibble, et. al.³ found significant improvement in compression (significance: $p < .0001$ in compressed breast thickness in both views); Markle, et.al.² found statistically significant improvement ($p < .0001$) in compression force in both views; and research by Jaeger, et. al.⁹ found an increase in mean compression force of 17.6%. Research by Tabar, et. al.¹ found strong correlation between compression force for cushioned versus uncushioned breasts (0.853 for CC views; 0.759 for MLO views).

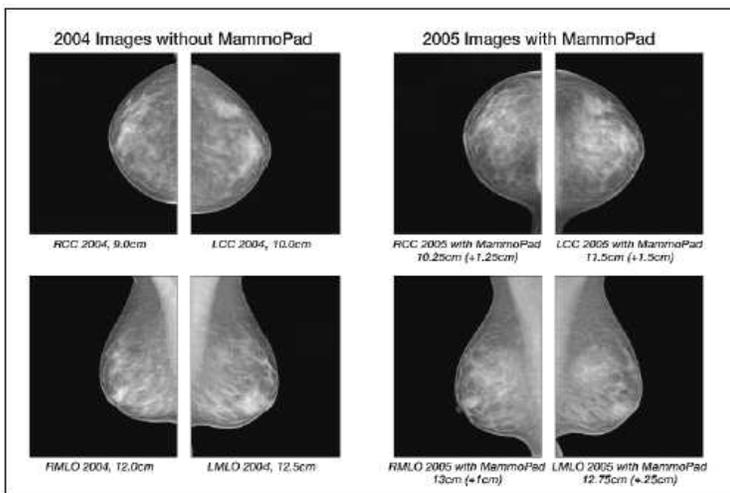


Figure 3. Screening exams with cushion compared to prior year's exam without cushion

Discussion

The use of radiolucent breast cushions has been shown to provide a significant reduction in mammography-associated pain for a majority of women. It has also been clearly demonstrated that this increase in comfort can be achieved without a trade-off in reduced image quality or increased dose. In addition, with appropriate training, tissue acquisition can be enhanced when the cushion is used and compression force can be increased without a resultant increase in discomfort.

Incorporation of radiolucent cushions in breast imaging practices should provide a more comfortable and positive experience for most women and may lead to increased compliance for women avoiding initial screening or returning for regular, periodic exams.

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