

Comparison Study: Impact of Thin Protective Coverlets on Positioning and Tissue Acquisition in Breast Imaging

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OBJECTIVE

To determine whether the use of thin protective coverlets (Bella Blankets® protective coverlets, Beekley Medical™, Bristol, CT) on the mammography unit image receptor helps to increase tissue acquisition when compared with prior mammographic exams where no coverlet was used.

METHODOLOGY

All patients received a standard 4-view screening mammogram utilizing a thin protective coverlet on the image receptor in a single center observational study. The current year (CY) mammogram was compared with the previous year (PY) mammogram utilizing the following criteria:

1. Posterior nipple line (PNL) measurements of craniocaudal (CC) and mediolateral oblique (MLO) views
2. Maximum visualized width of the pectoralis muscle on the MLO view (rated as generous, moderate, or minimal)
3. Amount of visualized retroglandular tissue
4. Presence of an “open” inframammary fold (IMF)

A total of 58 female patients were evaluated. To ensure that any imaging improvements were due solely to the use of protective coverlets rather than year-to-year changes to the breast, the study eliminated patients who gained or lost more than 10 pounds during the past year. Those who began hormone replacement therapy, breast implant recipients, and patients who had breast surgery within the past year were also excluded.

RESULTS

The addition of a thin protective coverlet enabled increased tissue acquisition in 77% of the patients in the study. The average PNL increase was 0.4 cm per image (0.16 in), with a 95% confidence interval of 0.30-0.52 cm. The overall visualization of the pectoralis muscle on the MLO view was improved in 48% of the images. Visualization of retroglandular tissue improved from 86% to 96%. Instances of visualization of the IMF described as “open” improved from 67% to 87% (Table 1).

Table 1. Summarization of study results

Women with increased tissue acquisition	77%
Average increase in PNL in both views	0.41 cm
Patients with improved visualization of pectoralis muscle	48%
Visualization of retroglandular tissue	from 86% PY to 96% CY
Visualization of IMF as “open”	from 67% PY to 87% CY

CONCLUSION

The study results demonstrate that the use of thin protective coverlets appear to be useful in capturing more breast tissue during mammography. The collected data had a statistically significant impact in terms of increased acquisition of breast tissue based on the PNL measurement increase. There were also favorable improvements in other American College of Radiology (ACR) positioning criteria such as ensuring an open IMF, improved visualization of retroglandular fat, and adequate pectoralis muscle captured.

BACKGROUND

Screening mammography significantly reduces breast cancer mortality in women aged 50 to 74 years. Proper breast positioning during mammography is a key factor in achieving optimal image quality for breast cancer detection. As technologists capture more tissue, the likelihood that malignancies will go undetected—and undiagnosed—decreases. However, several impediments can interfere with optimal breast positioning. These include patient resistance or intolerance to adequate compression, complications secondary to body habitus, and difficulty in maneuvering the breast into proper position when perspiration causes the skin to stick or slide on the image receptor.

Breast centers that utilize thin protective coverlets have observed an overall improvement in capturing more posterior breast tissue during mammography.

Protective coverlets, designed primarily to offer a protective underlay between the breast and the image receptor, may be an important adjunct to overcoming these obstacles. The use of coverlets may ease the required breast manipulation and allow for improved breast positioning.

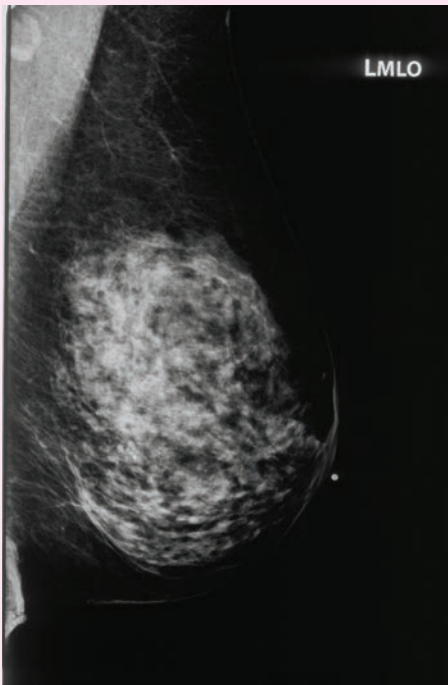
For example, coverlets absorb perspiration and instances of breast tissue sticking to the image receptor are reduced. As a result, manipulation of the breast becomes easier, enhancing the technologist's ability to better position the patient and capture more breast tissue. Incidence of skin folds is also reduced as technologists can easily slide their hands out from under the breast after placing it in position.

The coverlet's textured material may also help improve the technologist's ability to properly position breast tissue by reducing the possibility of the breast tissue slipping posteriorly during compression. The result is that more breast tissue may be visualized, creating a mammogram with more information for the radiologist to interpret.

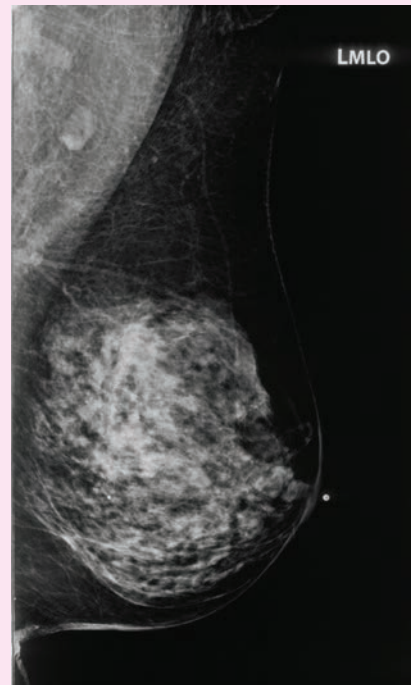
To confirm the findings reported by breast centers, a study was commissioned that compared current year mammograms with prior mammograms involving the same patients with the difference being the addition of a thin protective coverlet.

The study evaluated whether using thin protective coverlets during breast imaging allows more tissue to be acquired than imaging women without coverlets.

Example of improved visualization of IMF with use of coverlet:



Left MLO 2012 without coverlet



Left MLO 2013 with coverlet

2013 shows improved visualization of the pectoral muscle and open IMF compared to 2012.

MATERIALS / METHODS

An ACR accredited imaging facility with a demonstrated history of low patient turnover was chosen for this study to ensure data availability between current and previous studies. All mammograms were performed by one qualified technologist using ACR positioning guidelines.

All patients received a screening mammogram utilizing a thin protective coverlet on the image receptor. The current year (CY) mammogram was compared to the previous year (PY) mammogram.

A total of 58 female patients who did not have an image receptor cover used during their PY mammogram were evaluated. To ensure that any imaging improvements were due solely to the use of thin protective coverlets rather than year-to-year changes to the breast, the study eliminated patients who gained or lost more than 10 pounds during the past year. Those who began hormone replacement therapy, breast implant recipients, and patients who had breast surgery within the past year were also excluded.

Generalized estimating equations (GEE) with identity link function and exchangeable correlation structure were used to account for possible correlation of within-subject

measurements. This approach allowed investigators to calculate the sandwich variance estimator and obtain consistent standard errors. The significance level for all tests was set at 0.05, or a 5% margin. All data was analyzed by an independent qualified biostatistician⁽¹⁾.

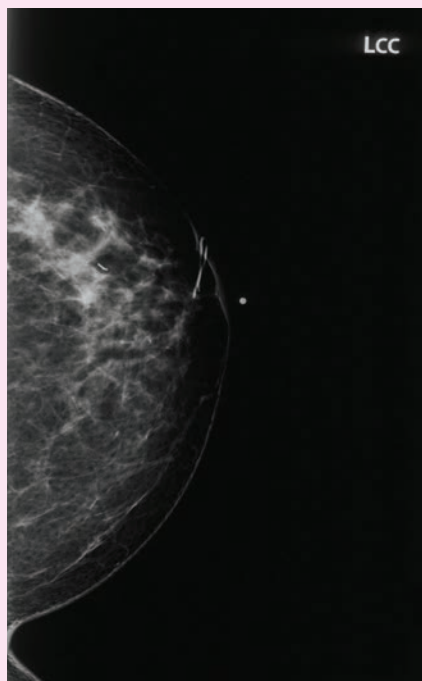
Bella Blankets® (Beekley Medical™), market-cleared by the FDA in March 2008, was used in this study.

DATA

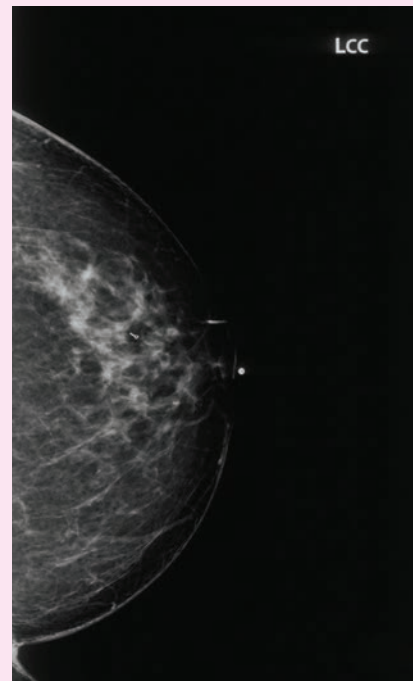
- Patient age, ethnicity, and breast size
- CC and MLO PNL measurement for the current year (CY) and for the prior year (PY)
- Observed maximum width of the visualized pectoralis muscle on the MLO view for the CY and for the PY (rated as generous, moderate, or minimal)
- Visualization of retroglandular tissue for the CY and for the PY
- Presence of an open inframammary fold on the MLO view for the CY and for the PY

The average age of subjects engaged in this study was 56 years; the patient population included 52 white (90%) and 6 African-American (10%) women.

Example of PNL increase with use of coverlet:



Left CC 2012 without coverlet



Left CC 2013 with coverlet

2013 shows that the PNL increased from 7.0 cm to 8.0 cm and improved visualization of retroglandular tissue

¹ Aniko Szabo, PhD, Associate Professor, Division of Biostatistics, Director, Biostatistics Consulting Service, Medical College of Wisconsin

The patient breast size ranged from A to DD: A=6 patients, B=16, C=17, D=11 and DD=8.

FINDINGS

PNL Measurement

Posterior nipple line measurement was completed for all 58 patients and an overall increase in PNL measurement was shown. The average increase was 0.41 cm per image (0.16 in), with a confidence interval of 0.30-0.52 cm.

An increased amount of breast tissue was captured in 69% of images, excluding a small subset of women whose images showed more tissue captured on the MLO view despite a shorter PNL as evidenced by pectoralis muscle pattern and length.

This subset involved 12 patients and 18 views and reflected the variance between prior year studies, when MLO positioning may have been marginal, and the current exam where improved positioning showed the anterior margin of the pectoralis muscle as convex and extended inferiorly to the level of the nipple. In these women, the PNL line extended from the nipple skin junction to the anterior margin of the pectoralis muscle rather than the edge of the image. This resulted in a shorter PNL measurement while allowing more tissue to be captured.

When this subset of patients is included, the percentage of patients who showed an increase in the amount of tissue imaged improved to 77%, an 8% increase.

Pectoralis Muscle

The study also evaluated the maximum visualized width of the pectoralis muscle on the MLO view, which was rated as generous, moderate, or minimal. Overall, improvement in the visualization of the pectoralis muscle was observed in 48% of images.

The change in the frequency of each pectoralis description (generous, moderate, or minimal) from prior to current

Table 2. Proportions of changes in pectoralis visualization PY vs. CY

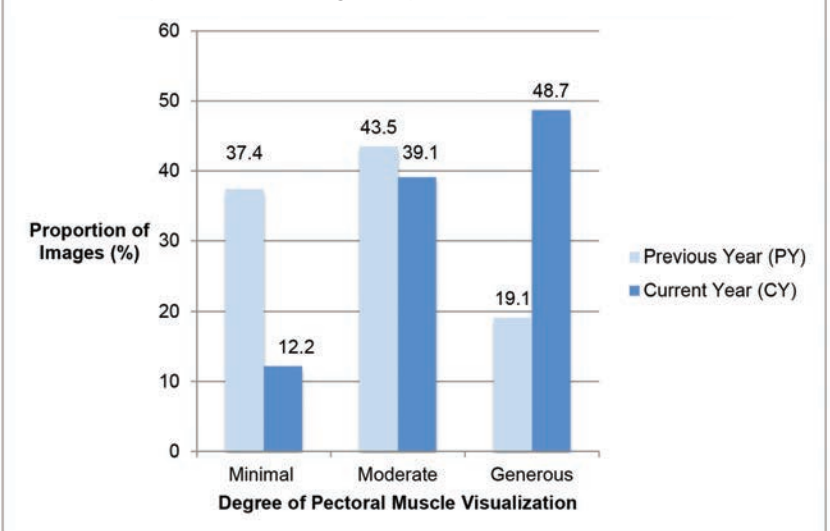


Table 3. Percentage of tissue visualization PY vs. CY

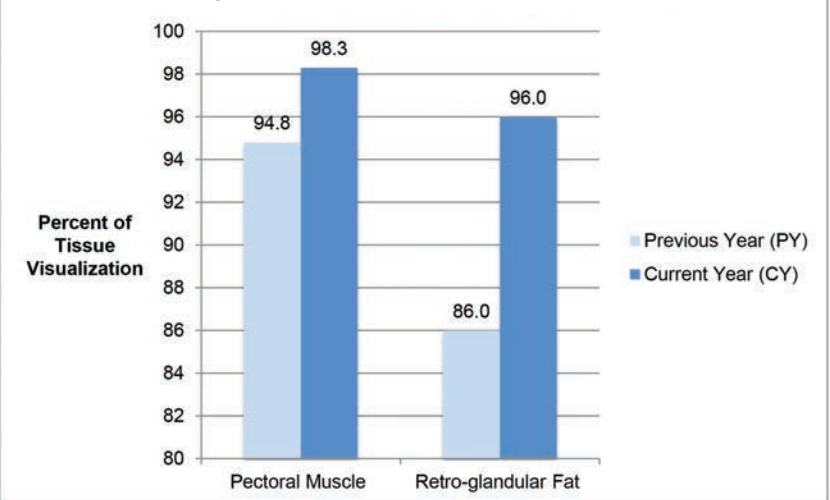
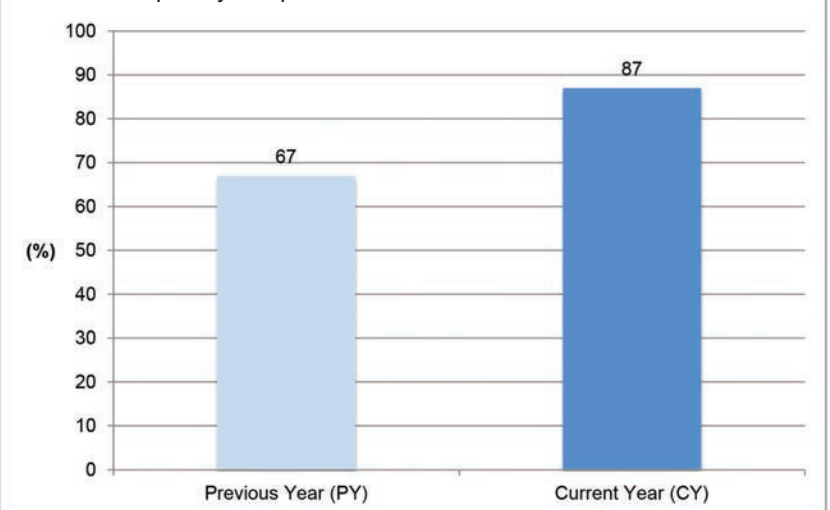


Table 4. Frequency of open IMF PY vs. CY



years was considered significant. 72% of the image pairs improved from minimal to moderate/generous visualization. Of 43 image pairs involving minimal visualization of the pectoralis muscle during the previous year, 12 remained unchanged while 20 improved to moderate and 11 improved to generous visualizations in the current year (Table 2).

Retroglandular Tissue

Visualization of retroglandular tissue was evaluated and showed improvement from 86% to 96% year over year (Table 3).

Open IMF

Visualization of the IMF on the MLO view and the ability to “open” the IMF were evaluated. The frequency of visualization of the IMF described as “open,” indicating additional benefit in visualization of the inferior/posterior tissue and allowing optimal compression by the technologist, improved from 67% to 87% year over year (Table 4).

Other Covariates

Also evaluated were the effects of breast size, patient age, and the two screening mammographic views (4 total views bilaterally) to determine if there was any correlation. All three covariates were found to be statistically insignificant despite the overall improvement that was identified based on the parameters discussed above. The greatest increases in each of the three categories involved women under 50 years of age and those with breast sizes D and DD.

RESULTS

Each of the following variables showed statistically significant positive changes in terms of improved breast tissue acquisition during the current year with use of coverlets when compared with the previous year when coverlets were not used.

- **The average increase in PNL was 0.41 cm per image (0.16 in):**
 - 69% of patients showed an increased amount of breast tissue captured
 - The total number of patients with increased breast tissue views rose to 77% with the inclusion of a small subset of patients (P=12) whose PNL was shorter but showed increased breast tissue acquisition as evidenced by more pectoralis muscle visualized
- **48% of the images showed overall improvement in the visualization of the pectoralis muscle on the MLO view:**
 - 72% of the image pairs with minimal visualization improved to moderate/generous visualization
 - The proportion of images showing generous views of the pectoralis muscle increased from 19.1% to 48.7% with coverlets, resulting in a decrease of moderate visualization from 43.5% to 39.1%
 - Minimum visualization of the pectoralis muscle dropped from 37.4% to 12.2%, reflecting an increase in generous visualization over the previous year. The percentage of visualization increased from 94.8% the previous year to 98.3%
- **Visualization of retroglandular tissue improved from 86% to 96%**
- **Visualization of the IMF described as “open” improved from 67% to 87%**

SUMMARY

This study demonstrated that thin protective coverlets appear to be useful in capturing more breast tissue during mammography. This data was found to be statistically significant based on PNL measurements. There were also favorable improvements in other ACR positioning criteria such as ensuring for an “open” IMF, and visualization of both retroglandular fat and adequate pectoralis muscle captured.

