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Sentinel Node Biopsy Imaging in Breast Cancer

Scatter Reduction Using 3-Dimensionally Printed Lead Shields

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Background: Point of injection scatter (SPI) confounds breast cancer sentinel lymph node detection. Round flat lead shields (FLSs) incompletely reduce SPI, requiring repositioning. We designed lead shields that reduce SPI and acquisition time.
Methods: Two concave lead shields, a semioval lead shield (OLS) and a semispherical lead alloy shield (SLS), were created with a SICNOVA JCR 1000 3D printer to cover the point of injection (patent no. ES1219895U). Twenty breast cancer patients had anterior and anterior oblique imaging, 5 minutes and 2 hours after a single 111 MBq nanocolloid in 0.2 mL intratumoral or periareolar injection. Each acquisition was 2 minutes. Absolute and normalized background corrected scatter counts (CSCs) and scatter reduction percentage (%SR) related to the FLS were calculated. Repositionings were recorded. Differences between means of %SR (*t* test) and between means of CSC (analysis of variance) with Holm multiple comparison tests were determined.
Results: Mean %SR was 91.8% with OLS and 92% using SLS in early images ($P = 0.91$) and 87.2%SR in OLS and 88.5% in late images ($P = 0.66$). There were significant differences between CSC using FLS and OLS ($P < 0.001$) and between FLS and SLS ($P < 0.001$), but not between OLS and SLS ($P = 0.17$) in early images, with the same results observed in delayed studies ($P < 0.001$ in relation to FLS and $P = 0.1$ between both curved lead shields). Repositioning was required 14/20 times with FLS, 4/20 times with OLS, and 2/20 times with SLS.
Conclusions: We designed 2 concave lead shields that significantly reduce the SPI and repositioning with sentinel lymph node lymphoscintigraphy.

Key Words: breast cancer, lead shield, lymphoscintigraphy, scatter, sentinel lymph node, sentinel node biopsy

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Authors' Contributions: F.M.C.-S., X.L.E.B.-C., X.C., and P.J.M. contributed to the curved lead shield creation. All authors contributed to the design of the study. F.M.C.-S., X.L.E.B.-C., and P.G.Z. performed data collection and analysis. All authors discussed the results and implications and commented on the manuscript. All authors read and approved the final manuscript.
All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. An independent ethical committee for clinical research (Comité de Ética de Investigación con medicamentos de La Rioja, CEImLar) approved the study design (Ref. CEImLAR P.I. 460) in Spain.
The patients gave their written consent to our Healthcare Institute for use of data including anonymized pictures.
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The data sets used and analyzed during the current study are available from the corresponding author on reasonable request.
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A sentinel node is defined as the first lymph node receiving drainage directly from the primary tumor. The sentinel node concept establishes that when the primary tumor releases metastatic cells into the lymphatic circulation, the first lymph nodes receiving metastatic cells from the tumor will filter these and retain some of them internally. Therefore, if the sentinel node can be selectively extracted and studied, the metastatic cells will be detected. In the case that the primary tumor has not liberated metastases into the lymphatic circulation, the sentinel node will be free of metastases, and a complete lymphadenectomy will not be necessary. On the other hand, if the primary tumor has released metastases into the lymphatic circulation, the sentinel node will have metastases, and a complete lymphadenectomy is necessary. An accurate lymphatic or N staging is necessary for prognosis and treatment planning in oncological patients. The sentinel node biopsy technique provides an accurate lymphatic staging and reduces unnecessary morbidity associated with lymphadenectomies.[1–11]

The first step includes the injection of the radiotracer in the tumor or in the nearby tissue. The radiotracer migrates through the lymphatic vessels until it reaches the sentinel nodes. The point of injection (PI) presents a very high activity that makes it difficult to detect the sentinel node. To reduce the scatter, a flat lead shield (FLS) is used to cover the PI (emitter) and the detector (receptor).[3–7,12,13] This shield is generally designed in radiation oncology departments using a mold cutter, obtaining a circular shaped FLS.

Even after using these shields, there remains a lot of scatter radiation, making it difficult to acquire an adequate image. To reduce the impact of the scatter on the image, the technologist has to reposition the lead shield until the optimal position is identified and then acquires the image (Fig. 1). As a consequence, the acquisition time is increased, and visualization of nearby sentinel nodes can be hindered because of the use of lead shields. Therefore, some authors recommend not using lead shields in breast cancer.[14,15]

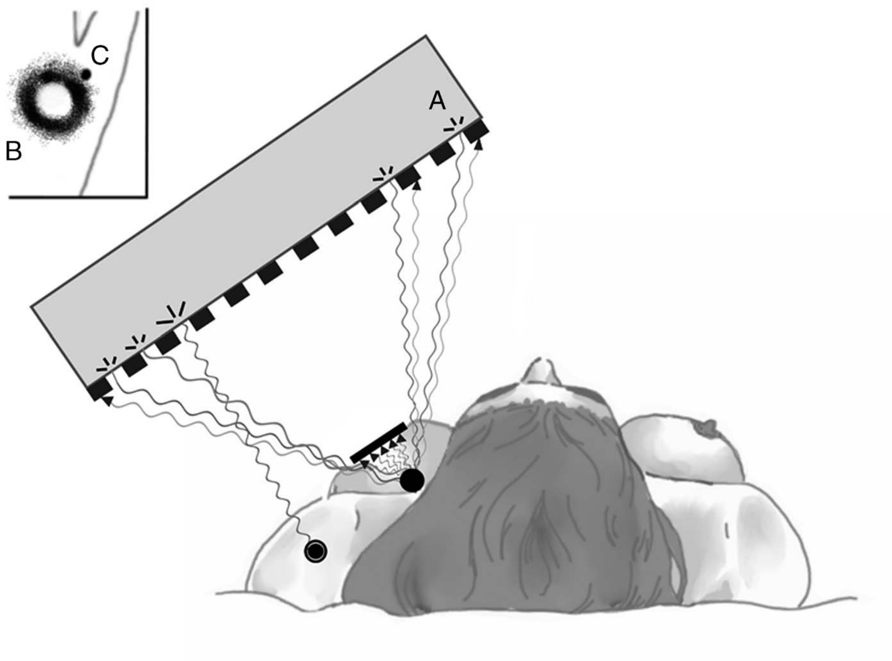

FIGURE 1. Figure shown the moment of image acquisition when using an FLS. The radiation reaches the detector (**A**) producing scatter (**B**) in the scintigraphy presented in the upper left corner of the figure. In the right axillary region, a sentinel node can be seen (**C**) that is near the scatter (**B**). Image is courtesy of Manuel Pedrero Gómez, reproduced with permission.

We have developed 2 innovative concave lead shields (CLSs) with a concave shape we have denominated CLS. One has a semispherical shape we have denominated semispherical lead shield (SLS), and the other has a semiellipsoidal or semioval shape we have denominated semioval lead shield (OLS). Both are designed to cover the breast while keeping the injection site inside of the concave part of the lead shield. The added value of the CLS compared with the standard FLS is that the CLS more effectively reduces the scatter reaching the detector, with the aim of improving the image and therefore improving the detection rate of the sentinel node (Fig. 2).

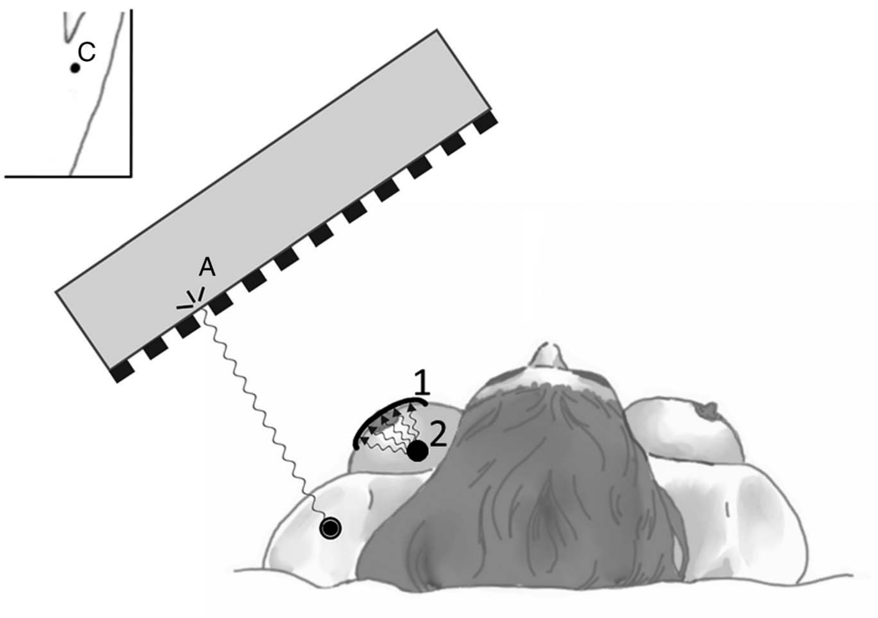

FIGURE 2. The CLS (1) is located around the PI (2), stopping the radiation and eliminating the scatter, detecting only the image of the sentinel node (**C**) in the scintigraphy, which is presented in the upper left corner of the figure. It can be seen how the detector (**A**) cannot detect the radiation emitted by the PI (2). Image is courtesy of Manuel Pedrero Gómez, reproduced with permission.

This invention was patented as a "scatter absorbing shield" (in Spanish "Escudo de absorción de radiación dispersa"). The patent was registered in the Spanish Office of Patents and Trade Marks (Oficina Española de Patentes y Marcas) with the number of patent ES 1 219 895 U, having been published in the official publication Boletín Oficial de la Propiedad Industrial de la Oficina Española de Patentes y Marcas on September 20, 2018.

OBJECTIVES

The main objective of the study was to quantify the scatter reduction obtained from the use of the 2 CLSs; (the semispherical and the semi ellipsoidal) compared with the FLSs. The second objective was to asses if the use of the CLSs reduced the need to reposition the lead shields during imaging acquisition compared with the FLSs.

MATERIALS AND METHODS

Design of the Curved Lead Shields

We designed 2 different CLS geometries, OLS and SLS, in order to position the injection site inside them and reduce the scatter.

The 3D printer SICNOVA JCR 1000 3D was used to create the polymer molds designed with AutoCAD (Figs. 3 and 4). Then, we generated sand molds, which in contrast to the polymer molds resist the high temperatures of molten lead. Then, the sand molds were filled with a pure lead alloy. Finally, once the lead alloy had solidified, the molds were withdrawn, and the edges of the lead shields were polished. The molds were painted with water-based white acrylic primer, appropriate for difficult-to-adhere surfaces, and then with 100% acrylic water-based paint.

Design of the Comparative Study

The design of the study was prospective, including 20 consecutive women (average age, 68.95 years; range, 51–84 years) with breast cancer. The pathology of the tumors was as follows: infiltrative ductal carcinoma (n = 14), intraductal carcinoma (n = 2), infiltrative lobular carcinoma (n = 2), tubule-lobular carcinoma (n = 1), and papillary carcinoma (n = 1). The T stage was as follows: "in situ" (n = 1), T1 or ≤2 cm (n = 11), and T2 or 2–5 cm (n = 8). Two of the 20 patients received induction chemotherapy (Table 1).

The sentinel node procedure included a lymphoscintigraphy following a single intratumoral injection (25% of patients) or periareolar (75%) of 111 MBq of ^{99m}Tc-nanocolloid of albumin in a volume of 0.2 mL, using a 25-gauge needle (0.5 × 16 mm). Early (5 minutes after injection) and late (2 hours after injection) images were acquired in anterior and anterior oblique projections. Two-minute images were acquired with each lead shield (flat, semispheric, and semiellipsoidal), obtaining 225 valid images.

We calculated the absolute and normalized subtracted background corrected scatter counts (CSCs) as well as the percentage of scatter reduction (%SR) related to the FLS in early and delayed studies (Fig. 5). We also estimated the need for repositioning the LS in each projection and with each LS. The differences between %SR means were evaluated with *t* test. For differences between means of CSC, repeated measures with an analysis of variance followed by Holm's multiple comparison tests were used. All analyses were

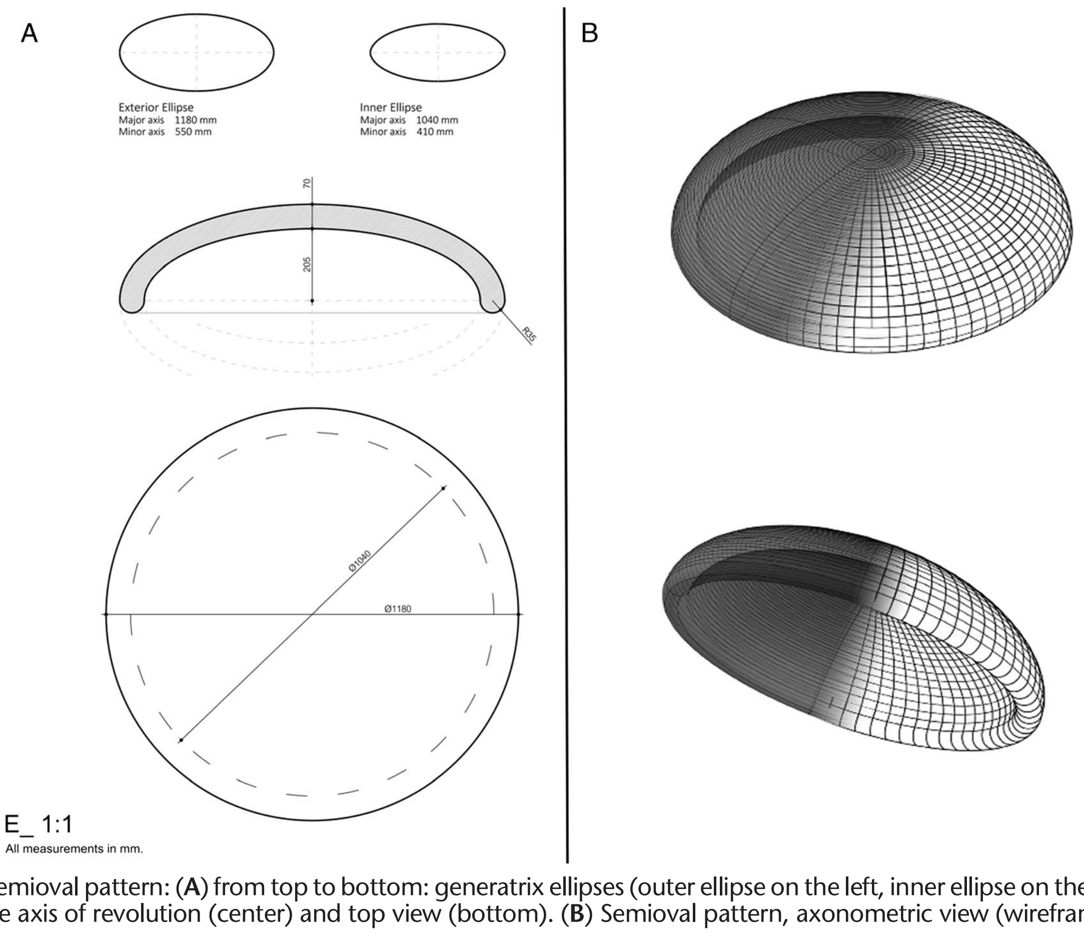

FIGURE 3. Semioval pattern: (**A**) from top to bottom: generatrix ellipses (outer ellipse on the left, inner ellipse on the right), cross section by the axis of revolution (center) and top view (bottom). (**B**) Semioval pattern, axonometric view (wireframe view).

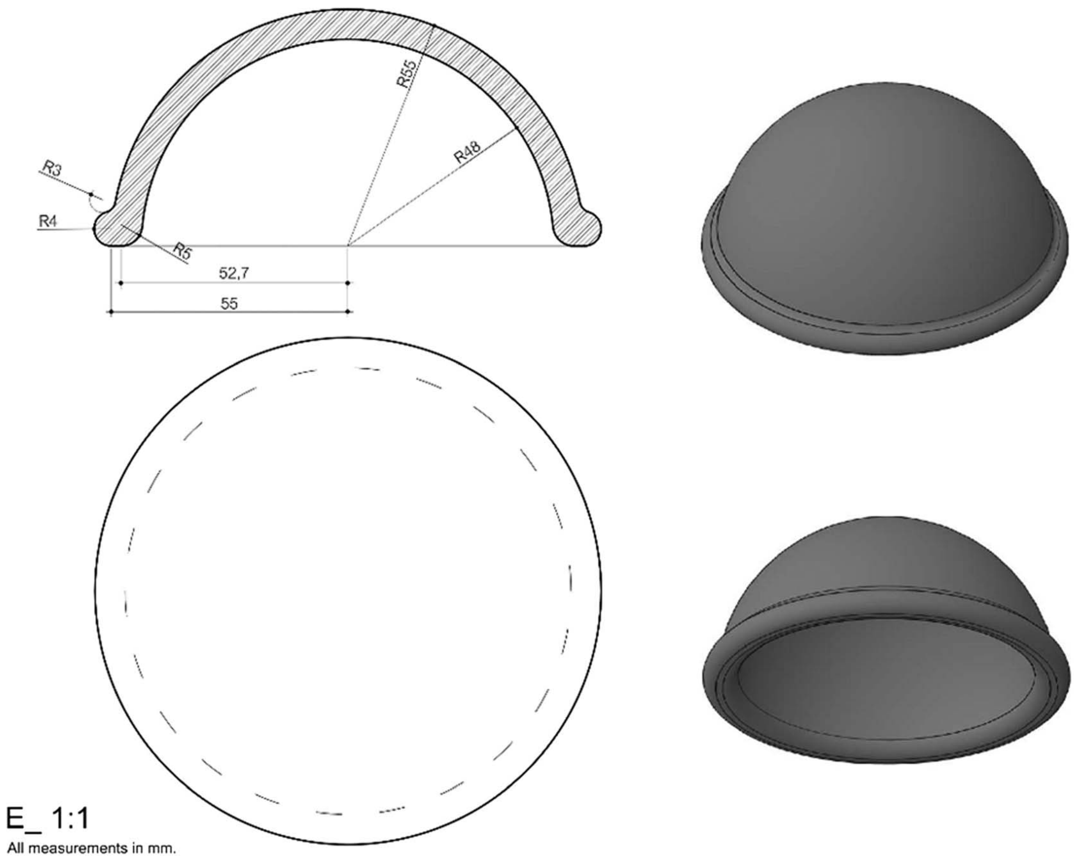

FIGURE 4. Semispherical pattern: cross section across the revolution axis (upper left), top view (lower left), and axonometric view (conceptual view, 2 images on the right).

conducted using R Commander. Two-tailed tests were used, and $P < 0.05$ was considered to be statistically significant.

In addition, the need for repositioning the LS in each projection and with each LS was estimated.

An independent ethical committee for clinical research (Comité de Ética de Investigación con medicamentos de La Rioja, CEImLar) approved the study design (Ref. CEImLAR P.I. 460) in Spain.

RESULTS

Mean absolute counts %SR of 91.8% with the OLS and 92% using the SLS in early images ($P = 0.91$) and 87.2% SR in OLS and 88.5% with SLS in late images ($P = 0.66$) were obtained. Furthermore, we found statistically significant differences between CSC using FLS and OLS ($P < 0.001$) and between FLS and SLS ($P < 0.001$), but no differences between OLS and SLS ($P = 0.17$) in early images, with the same results observed in delayed studies ($P < 0.001$ in relation to FLS and $P = 0.1$ between both curve shields).

Also, repositioning the lead shield in anterior oblique projection 6/10 times was necessary with FLS, 2/10 times with OLS, and 1/10 times with SLS and in anterior projection, 8/10 times with FLS, 2/10 using OLS, and 1/10 in SLS.

DISCUSSION

Efficacy has been defined as the probability that the individuals in a defined population will obtain the benefit of a medical technology when applied to a certain medical problem in ideal conditions; when the conditions in which it is applied are not ideal but common conditions, it is denominated effectiveness; moreover, when an economic analysis is included, it is called efficiency. The evaluation of the efficacy of diagnostic imaging has evolved since the 1970s with the development of several approaches. The conceptual

TABLE 1. Characteristics of the Population Included in the Sample

	n	%
Total included	20	
Sex		
Women	20	100
Pathology type		
Ductal infiltrative carcinoma	14	70
Intraductal carcinoma	2	10
Lobular infiltrative carcinoma	2	10
Tubular-lobular carcinoma	1	5
Papillary carcinoma	1	5
Local extent		
T “in situ”	1	5
T1 (<2 cm)	11	55
T2 (2–5 cm)	8	40
Induction chemotherapy	2	10
Point of injection		
Intratumoral	5	25
Periareolar	15	75

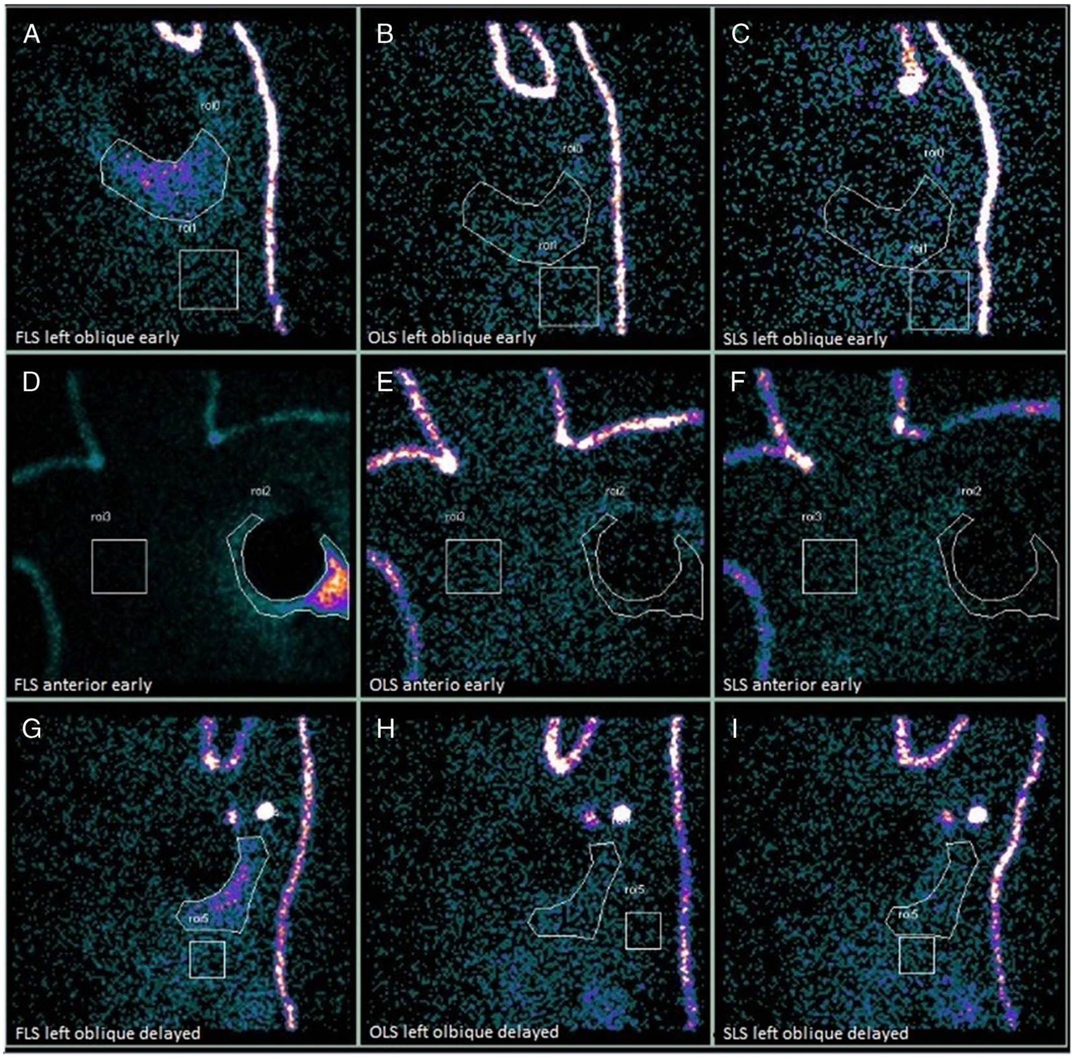

FIGURE 5. A 77-year-old patient undergoing a sentinel node procedure for breast cancer. The 3 lines are organized based on the projection and time of acquisition: early left anterior oblique projections are displayed in the first line (**A**–**C**); early anterior projections are displayed in the second line (**D**–**F**); and delayed left anterior oblique projections are displayed in the third line (**G**–**I**). The 3 columns are organized based on the lead shield used: images acquired using the FLS are presented in the first column (**A**, **D**, and **G**); images acquired using the OLS are presented in the second column (**B**, **E**, and **H**); and images acquired using the semispherical lead alloy shield (SLS) are presented in the third column (**C**, **F**, and **I**). Regions of interest (ROIs) with contours adjusted to the disperse radiation are indicated in all images. Rectangular ROIs for quantifying background activity were drawn as shown in the images: ROIs located in the contralateral breast in the anterior projections (**D**–**F**); ROIs located caudal to the disperse radiation ROIs in the anterior oblique projections (**A**–**C**, **G**–**I**). The images show there is less scatter using OLS (**B**, **E**, and **H**) or SLS (**C**, **F**, and **I**) compared with FLS (**A**, **D**, and **G**).

model described by Fryback and Thornbury provides a hierarchical model of efficacy for diagnostic imaging that can be used for the critical appraisal of diagnostic imaging research studies. The lower level of efficacy is called technical efficacy, including aspects such as the quality of the images.[16]

Regarding the state of the art of lymphoscintigraphy in sentinel node biopsy, several authors advise against using lead shields in breast cancer,[14,15] whereas others indicate that it improves sentinel node detection,[5,6,13,14] and others even recommend including images with and without the lead shield to adequately image the area and prevent from covering lymph nodes very close to the PI.[6] Perhaps, in the future, the reduction of the scatter radiation and the reduction of the acquisition time will be demonstrated with studies, and this will be the basis for the modification of the current recommendations, such as occurs with the current European Association of Nuclear Medicine guideline for sentinel node biopsy and melanoma, in which lead shields are recommended when the primary tumor is very close to the sentinel node.[3,7] Shielding the PI with lead may be useful to detect the sentinel nodes very close to the PI in melanoma and urological and gynecological tumors.[3,6,7,13] Concave lead shields are designed to partially introduce the breast inside its interior and provide the highest scatter reduction possible. We have compared CLS with FLS in a few melanoma patients, and the preliminary results showed scatter reduction, although not as evident as in breast cancer. Further studies are needed to adequately assess scatter reduction as well as evaluate higher efficacy levels, such as diagnostic efficacy and therapeutic efficacy.

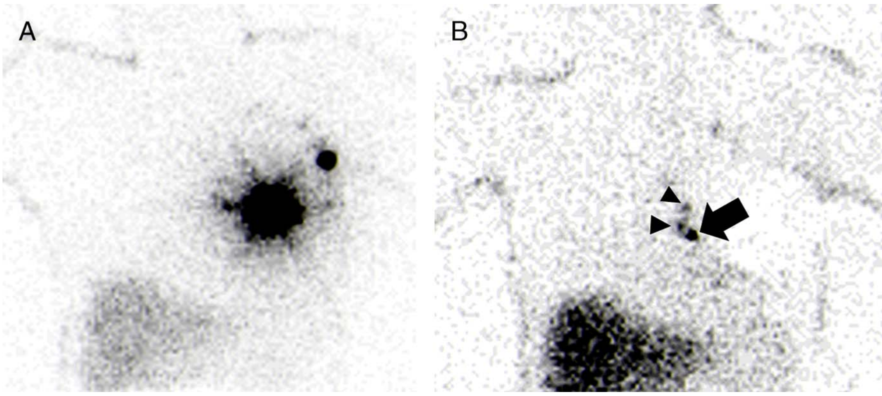

FIGURE 6. A 58-year-old woman undergoing a sentinel node procedure for breast cancer. Planar images in anterior projection are presented: (**A**) image without lead shield in which there is abundant disperse radiation; (**B**) image using the oval lead shield that eliminates the disperse radiation and allows an improved visualization of the sentinel node (arrow) and 2 secondary nodes (arrowheads) in the internal mammary chain.

Other methods have been developed to try to reduce scatter such as the graded shield, which uses 3 concentrically located leaded plastic shields that increment the attenuation from the periphery to the center.[17] However, if the sentinel node detection rate using the graded shield is compared with not using lead shield, it does not take into account scatter reduction with the FLS. Furthermore, the radiotracer used, which is different ([^{99m}Tc]-sulfur colloid), is applied with different doses and concentrations (11.1–22.2 MBq in 0.4 mL). Although in some cases we have detected sentinel nodes using the CLS that we could not detect without shielding (Fig. 6), this was not the aim of this study. Other authors aim at reducing scatter using a combination of shields and different energy windows[18] or try to improve image quality by eliminating the star artifact using medium energy[14] or high-energy[19] collimators or combining an energy window change with the collimator change.[14,20] This last method is an alternate for reducing acquisition time, although the results were obtained with only 3 phantoms and 1 patient,[20] concluding that the medium-energy collimator provides better image contrast when the sentinel node is located more than 3 cm away from the PI, although at a distance of 2 cm the image contrast is better using the FLS. At 3 cm, the acquisition time is the same for both methods, but at 5 cm, image contrast is better with the medium-energy collimator. The authors conclude that this method avoids obscuring the sentinel node with scatter artifact. They indicate that it will hopefully improve sentinel node detection rate and reduce acquisition time, although both aspects will have to be evaluated in further studies.

Another problem would be the existence of an intramammary lymph node that may be masked by the CLS covering the breast tissue near the PI. This problem may be solved using images with and without lead shields as has been proposed by some authors.[6]

Some authors do not describe the shape of the shielding,[3,13,15] whereas others relate small shield,[5] metal plate,[12,18] small metal plate,[7] and malleable lead shielding.[4] Three authors report more precisely the shape of the lead shield. Chen et al[17] used 3 concentric, leaded plastic pads, with diameters of 3, 5, and 7 cm, with each lead layer 0.25 cm thick with a measured attenuation factor of 3 for 140 keV gamma photons in the case of graded shield. Tsushima et al[20] reported a flat round shield that was 4 cm in diameter and 3 mm thick, which we consider would be very difficult to handle in clinical practice. Shoaib et al[12] report the application of a 1-cm-thick lead plate. The standard-of-care FLS that we were using had a thickness of 7 mm; thus, we created 2 curved lead shields with the same thickness to make the measurements comparable.

The intraoperative use of the lead shield has shown it helps reducing the “shine-through” problem, a phenomenon creating difficulty in differentiating between radioactive nodes and the PI when using the gamma probe, because of the scatter originating in the PI, typically seen in patients with melanoma and head and neck cancer. Guidelines indicate that, to reduce this phenomenon, a metal shield (lead or tungsten) should be positioned between the PI and the probe.[4,7,12] Reducing the scatter using CLS as compared with the conventional FLS indicates it could be useful in this scenario, although further studies are warranted.

Finally, an alternative approach to using lead shields is incorporating SPECT/CT imaging as part of the lymphoscintigraphy, which has already shown good results in improving sentinel node detection.[21,22] Because of this, SPECT/CT is already recommended, when available, in the sentinel node procedure in several tumors.[8–11,21,22] Therefore, future studies evaluating the role of lead shields in sentinel node procedure will have to compare their efficacy against the use of SPECT/CT imaging, in order to precisely estimate the added value of each of these procedures.

CONCLUSIONS

Two CLSs that significantly reduce the scatter from the PI and diminish the need for shield centering were created. These shields optimize the technical efficiency sentinel lymph node detection by lymphoscintigraphy in patients with breast cancer, with slightly better results using semispherical geometry.

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