# Radiolucent Prosthetic Gel

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The successful use of silicone breast implants is complicated by their interference with mammography. We have evaluated clinically available implant filling materials and found that a new Bio-Oncotic gel approximates the radiolucency of normal breast tissue. Silicone implants completely obscure areas of the breast in mammography. Recently proposed as a filler material, peanut oil is significantly more radiolucent than normal tissue. Physiologic saline solution compares favorably as a tissue-density-simulating substance. However, saline's lack of lubricating properties results in leakage, making it less than optimal. Bio-Oncotic gel is biologically compatible. We conclude that this gel is the most appropriate filler for breast prostheses. Clinical studies are indicated.

The purpose of this study is to compare various physical characteristics of three clinically available mammary prosthesis fillers, with particular emphasis on their relative x-ray transmission. There has always been a compelling desire for breast enhancement among patients with unilateral or bilateral micromastia, hypomastia, or breast deformity. Despite problems associated with prior breast augmentations, patients wish to feel normal and to have what they perceive to be a normal appearance. Thus breast augmentations or reconstructions continue to be among the most frequently requested surgical procedures.

Silicone-filled breast prostheses were first described by Cronin and Gerow in 1962.[1] Over the past two decades, approximately 2 million American women have undergone breast augmentation for cosmetic or reconstructive reasons, with over 200,000 such mammary prostheses implanted in U.S. patients yearly.[2,3]

One in 9 Caucasian women will eventually experience breast cancer. Recent studies have reported that cancer will recur in 1 of 3 of these women.[4] Many physicians have expressed concern that breast prostheses may interfere with the early detection of small masses forming in the breast.[5-7] Clearly, development of a radiolucent prosthesis is critical to early detection of tissue changes in patients with augmented breasts.[8]

All mammary prostheses currently in use are comprised of a thin silicone elastomer envelope containing a filling material. This study will concentrate on the x-ray transmission of the three types of breast implant filler materials that are clinically available: physiologic saline solution, cohesive silicone gel, and Bio-Oncotic gel.

Saline-filled implants are relatively radiolucent.[5] However, they are subject to fold-flaw fractures and valve leakage, resulting in a high percentage of implant deflations. The average spontaneous deflation rate of saline-filled breast prostheses implanted in patients is approximately 1 percent per year.[9,10] Nevertheless, saline-filled implants remain in use.

Cohesive silicone gel has a lower coefficient of friction than does saline. This prevents leakage due to fold-flaw fracture.[9,12] However,' silicone-filled implants have an extremely low x-ray transmission, which has been reported to interfere with the detection of small masses forming in the breasts.[2,10,13] Excessive radiation is required in special mammography procedures developed to detect tumors in the presence of silicone gel-filled mammary implants.[12]

In addition, when the shell integrity of a silicone-filled implant is compromised by outside trauma (such as an automobile accident), the migration of silicone gel results in significant diagnostic and reconstructive problems. The silicone gel is relatively inert and does not interact with the host chemically. However, the presence

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TABLE I
X-Ray Transmission of Mammary Prosthesis Filling Materials in Parallel-Sided (3-cm Inner Diameter) Tissue-Culture Flasks

| | Filling Material | Exposure (mR) | Transmission (%) |
|---|---|---|---|
| (A) | Silicone gel | 0.340 | 0.1 |
| (B) | Physiologic saline | 9.200 | 3.0 |
| (C) | Bio-Oncotic gel | 13.200 | 4.3 |
| (D) | Tissue-equivalent control | 19.800 | 6.4 |
| (E) | Peanut oil | . 53.700 | 17.0 |
| | Air | 308.000 | 100.0 |

of silicone gel in subcutaneous locations remote from the breasts not only creates a diagnostic challenge, but also causes chronic inflammatory foreign-body reaction—and occasionally requires extensive surgery for its removal.[14-16]

A recently introduced biologically compatible gel implant filler, Bio-Oncotic gel, has a lower coefficient of friction than does silicone gel and an x-ray transmission similar to that of tissue equivalent materials (see Tables I and II and Fig. 1).

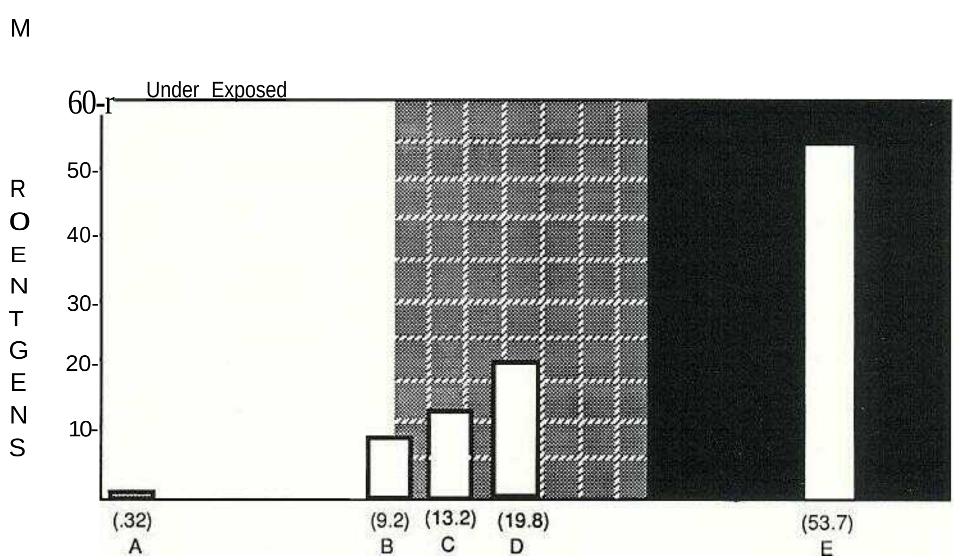
## MATERIALS AND METHODS

X-rays were generated using a Senographic 500T mammographic x-ray unit at 28 kVp. X-ray transmission measurements were made using 80 rnA-s and with a target-detector distance of 57 cm and a field size of 24 X 30 cm. Radiation exposure levels were measured by a Radcal Corporation Model 1015 x-ray monitor and a 10 X 5-6 m mammographic ion chamber. Images were obtained with the timer set on "automatic" using Kodak Min-R screen and Ortho M film. All x-ray films and measurements of transmitted x-rays were made as indicated in Figure 2.

TABLE II
Physical Constants of Mammary Prosthesis Filling Materials

| Matei'ials | Density (gm/cc) | Coefficient of Friction | pH | Viscosity (CP) |
|---|---|---|---|---|
| Silicone gel | 0.97 | 0.60 | — | 400.000 |
| Physiologic saline | 1.00 | 0.74 | 6.4 | 1.002 |
| Bio-Oncotic gel | 1.08 | 0.09 | 7.0 | 211.00 |

A phantom grid was made from 0.0035-inch-diameter monofilament nylon line strung at 90 degrees to 0.0065-inch-diameter monofilament nylon line to form a grid over the entire x-ray field of 0.5-inch squares. Containers of the filling materials (prosthesis envelopes and parallel-sided tissue flasks) were each placed on top of the nylon grid (see Fig. 3). Lucite, which has x-ray transmission properties similar to those of breast tissue,[17] was used as a tissue substitute for comparing x-ray transmission values.




(A) SILICONE GEL
(B) PHYSIOLOGICAL SALINE
(C) BIO-ONCOTIC™ GEL
(D) TISSUE EQUIVALENT CONTROL
(E) PEANUT OIL

FIG. 1. Relative intensity of transmitted radiation through 3 cm of mammary implant filling materials (in mR).

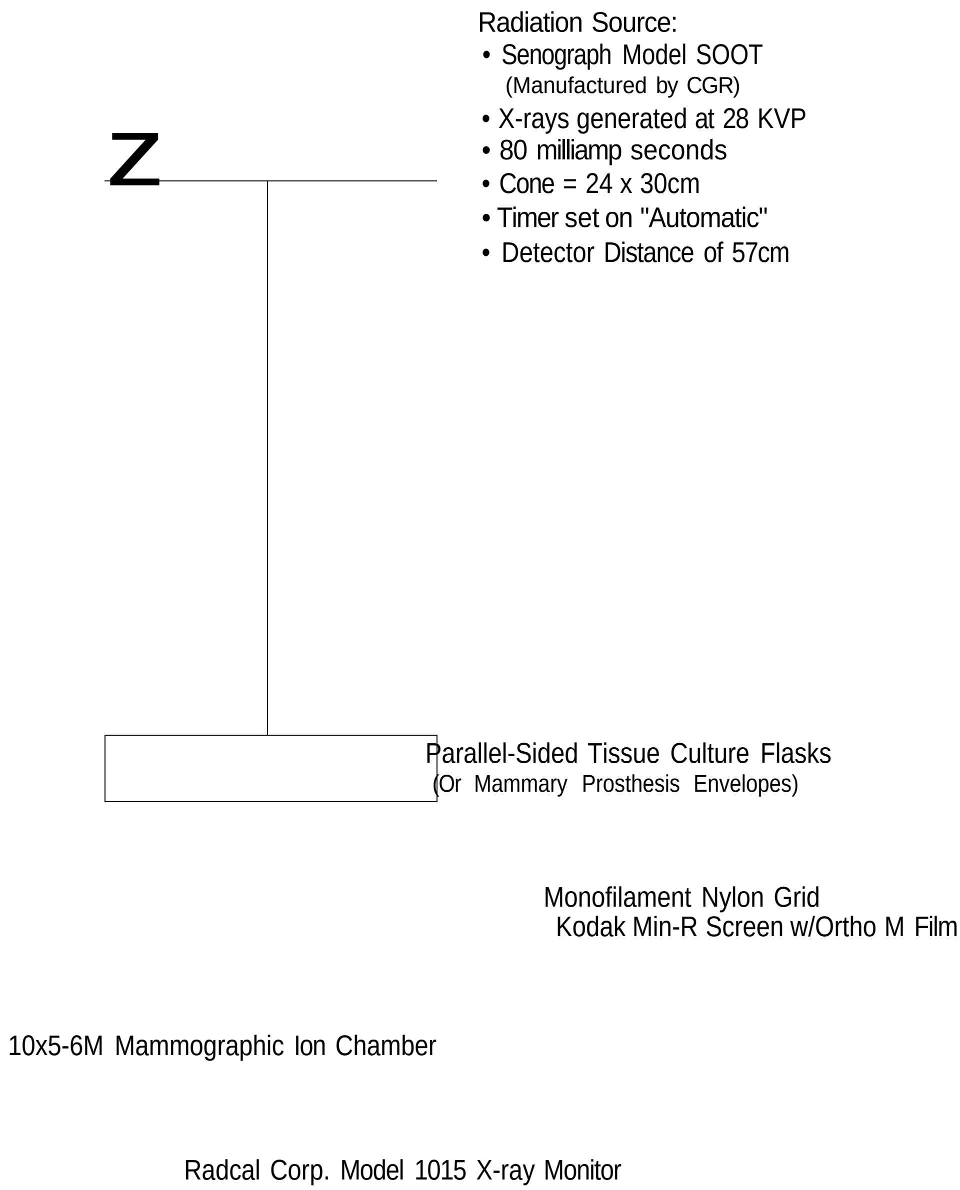



FIG. 2. X-ray setup.

Group I: A total of 275 ml of each clinically available filling material was placed into a polystyrene parallel-sided standard tissue culture flask (see Fig. 4).

Group II: The standard silicone breast prosthesis envelopes were all made from textured silicone elastomer, supplied by one manufacturer.* A total of 220 ml of each clinically available filling material was placed into an identical 220-cc silicone elastomer breast prosthesis envelope.

* Bio-Manufacturing, Inc., St. Paul, Minn.

The filling materials used in this study were as follows:

The standard clinically available silicone gel was supplied by one manufacturer.[T]
The sterile physiologic saline solution for IV infusion was supplied by one manufacturer.^
Bio-Oncotic gel was supplied by the manufacturer. §
The tissue-equivalent control was approxi-

[T] Applied Silicone, Santa Barbara, Calif.
t Kendall McGaw Laboratories, Inc., Boston, Mass.
S Bioplasty, Inc., Roseville, Minn.

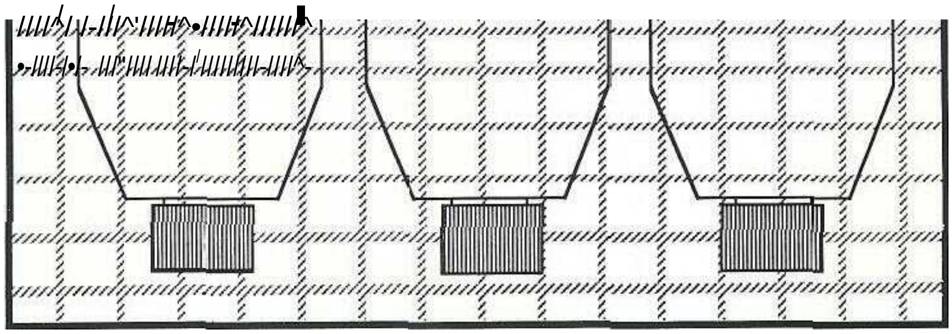


FIG. 3. Top view of empty flasks positioned on top of phantom nylon grid.

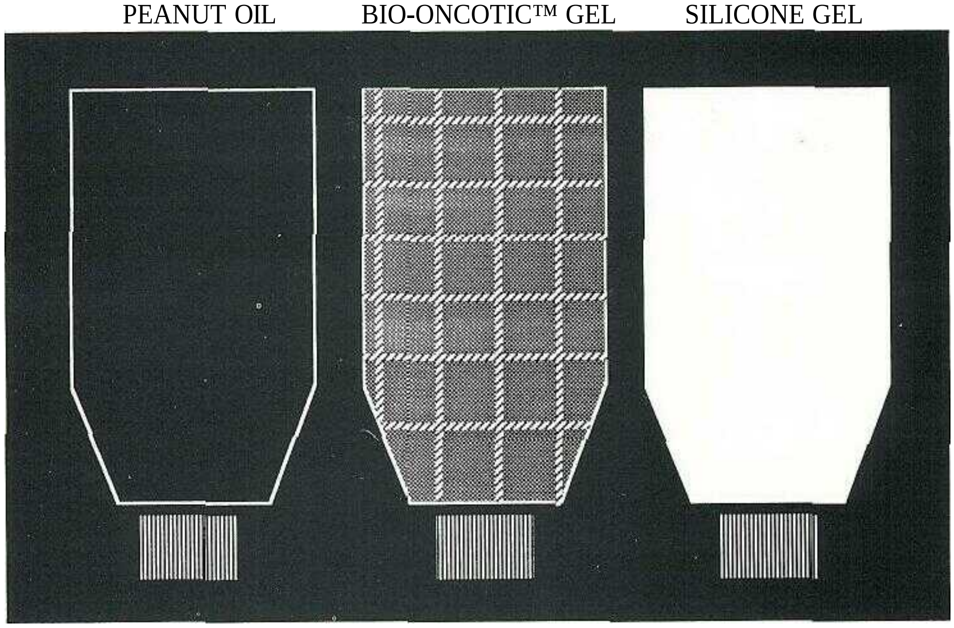



FIG. 4. Predicted view of x-ray film when radiolucent material is in the bottle on the left, tissue equivalent is in the center bottle, and radiopaque material is in the bottle on the right. This represents what a processed x-ray film would be expected to look like if tissue-equivalent acrylic were placed in the center flask, radiolucent material were placed in the flask on the left, and radiopaque material were placed in the flask on the right.

mately 30 mm of solid acrylic plastic.

Bio-Oncotic gel is a new osmotically and oncotically balanced gel that consists of a biologically inert polymer with an average molecular weight of 13,700. This material holds the trademark of Au24k. It is from a group of polymers that have been successfully used as binders and extenders, and in injectable and ingestible medications throughout the world since 1934. Prior research has shown that members of the family of polymers are safely dispersed from the body, having been taken up by the reticuloendothelial system and eliminated by the kidneys within a matter of a few days.[18]

This study utilized solid acrylic plastic as a tissue-equivalent x-ray transmission material. Standard tissue-culture flasks were selected as test receptacles for various filling materials because the flasks have flat parallel sides that provide a

75-cm$^2$ area of a uniform 3-cm thickness of filling material for comparison (Fig. 6).

The silicone envelopes were all made from clinically available prosthetic textured silicone elastomer, supplied by one manufacturer. A total of 220 ml of each clinically available filling material was placed into a silicone elastomer envelope.

## RESULTS

None of the clinically available mammary implant. filling materials lias x-ray transmission properties exactly equivalent to that of normal tissue (Table I and Fig. 1). Our studies show that the x-ray transmission of silicone gel at 28 kV is 0.1 percent that of air. Physiologic saline is 3 percent, Bio-Oncotic gel is 4.3 percent, and the tissue-equivalent control is 6.4 percent (or 10 percent when corrected for density differences). The x-ray transmission of peanut oil is 17 percent.

Because silicone gel is the most radiographically dense material of those materials clinically available, it is therefore the most disruptive to the detection of small masses on mammographic x-ray film (Fig. 1). Sterile saline solution has an x-ray transmission much closer to that of the tissue-equivalent material than does the silicone gel filler. However, Bio-Oncotic gel is approximately 40 percent more translucent than sterile physiologic saline solution (Fig. 1).

Optical density measurements of the exposed x-ray films were found to be in agreement with x-ray transmission values. The nylon grid is completely obscured by the silicone and is slightly obscured by the saline-filled mammary prosthesis (Fig. 7). The sterile physiologic saline solution in the parallel-sided tissue-culture flask (Fig. 6) and in the implant envelope (Fig. 7) also partially obscures the grid, whereas both the Bio-Oncotic gel-filled tissue-culture flask (Fig. 6) and the prosthesis (Fig. 7) allow for clearer visualization of the nylon grid than either the silicone or saline fillers (Fig. 8).

Folds, seams, or patches of the mammary prosthesis envelope clearly interfere with visualization of the grid. Although none of the clinically available implant filler materials studied offers the x-ray translucence of normal tissue, when x-rayed through the flasks, Bio-Oncotic gel is clearly superior to either silicone gel or physiologic saline. The more nearly tissue-equivalent x-ray transmission of the Bio-Oncotic gel gives rise to improved x-ray image contrast in regions behind a gel-filled implant, compared to implants containing either silicone or physiologic saline.

## DISCUSSION

The problem that results from using radiopaque silicone gel to fill mammary prostheses has been described by others.[3,7,11] The detection of tumors adjoining silicone gel-filled mammary prostheses requires employing special radiographic techniques.

The absorption of x-rays by normal breast

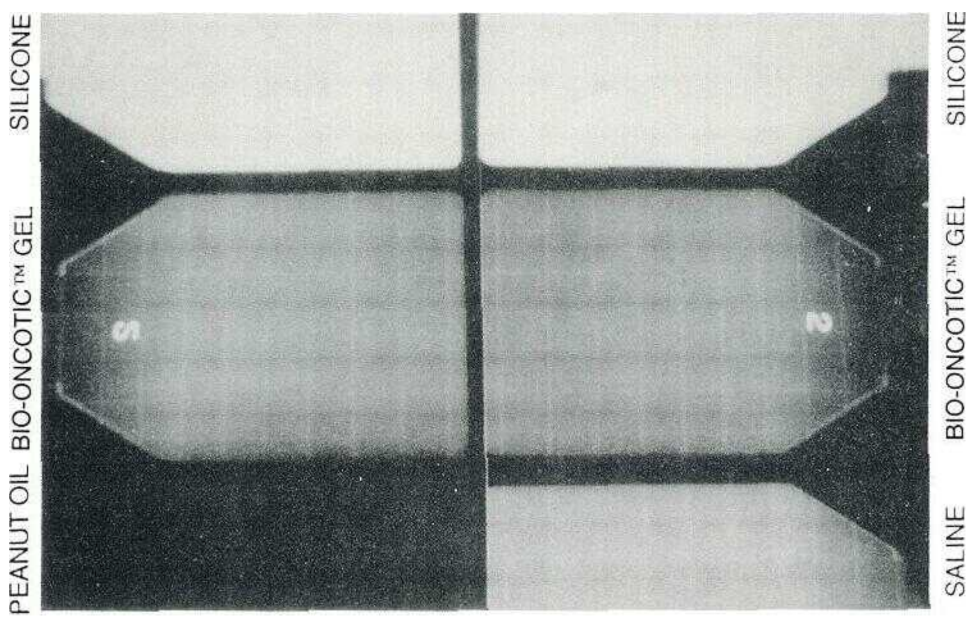
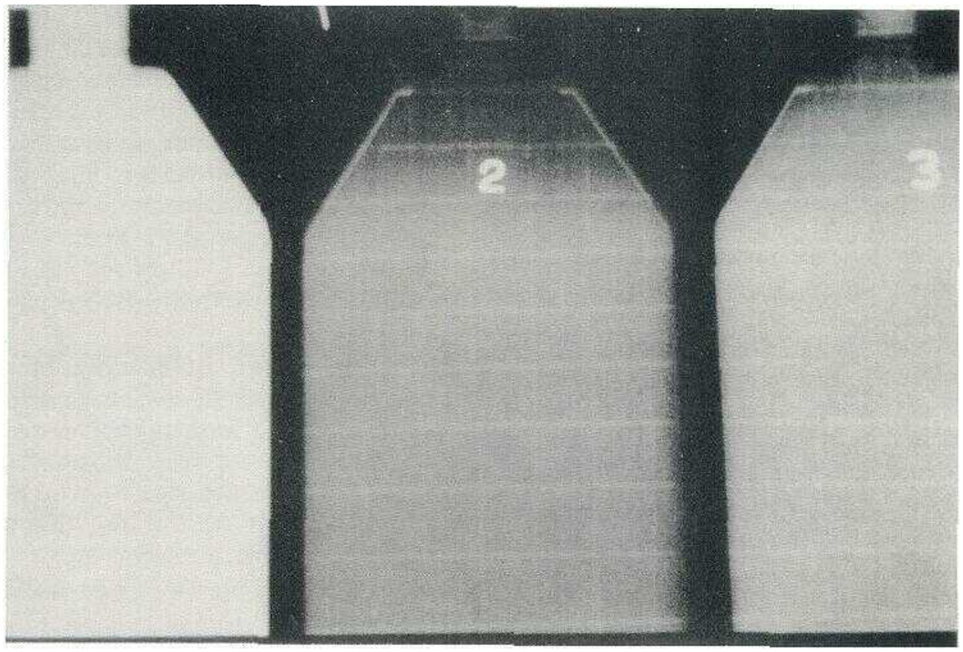
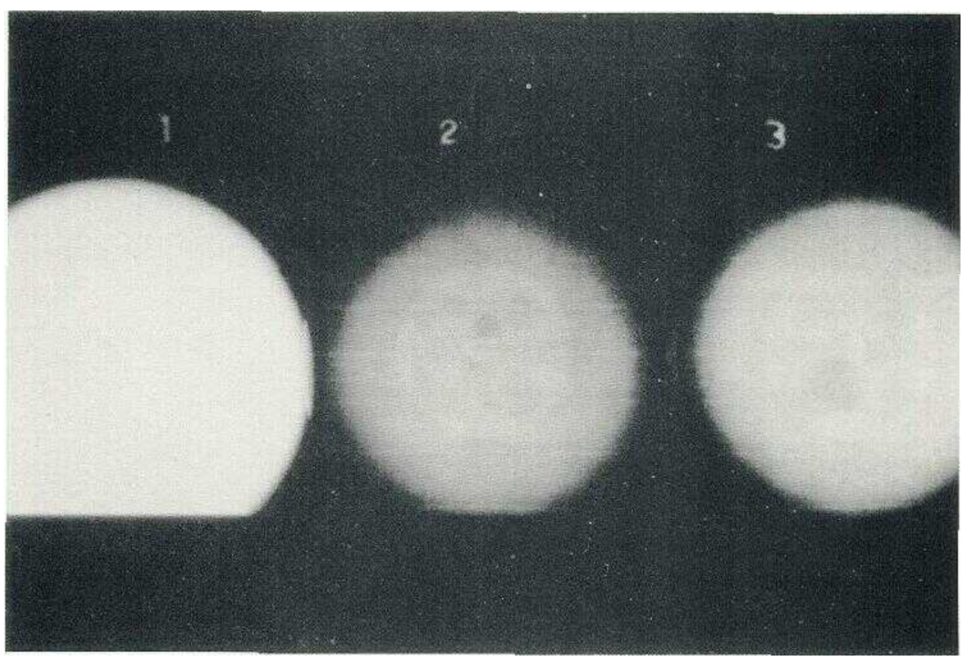



FIG. 5. Two exposed x-ray films. The material in the upper flasks is silicone gel. The flasks in the center hold Bio-Oncotic gel. The flask on the lower left contains peanut oil. The flask on the lower right contains physiologic saline.




**SILICONE GEL** **BIO-ONCOTtC™ GEL** **SALINE**

FIG. 6. An exposed x-ray film with Bio-Oncotic gel in the center flask, silicone gel in the flask on the left, and physiologic saline in the flask on the right.

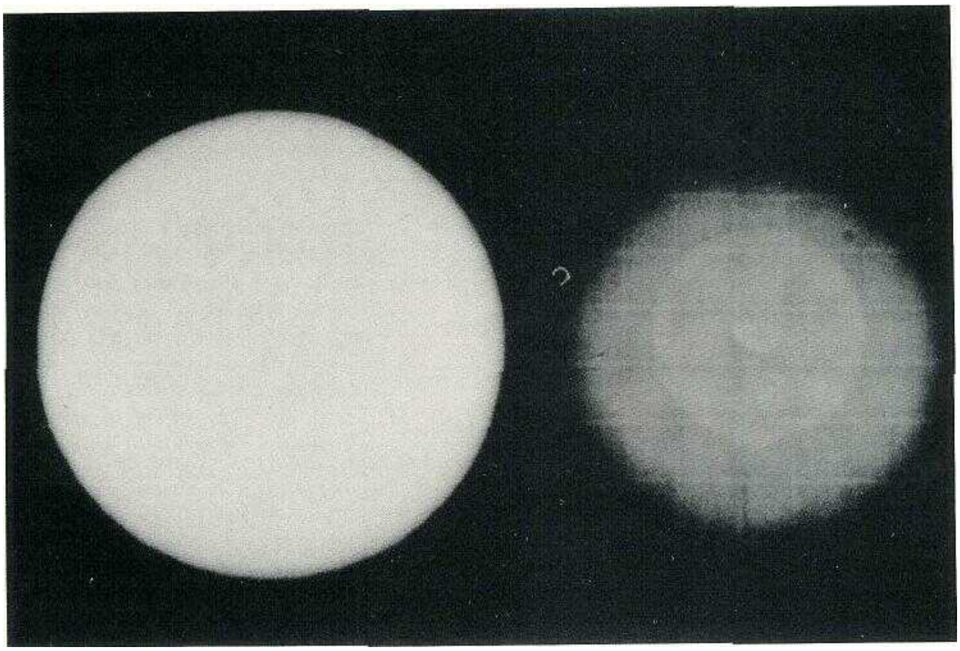



SILICONE GEL BIO-ONCOTIC™ GEL PHYSIOLOGIC SALINE

FIG. 7. An x-ray film of three silicone mammary envelopes of identical size, each containing 220 cc of fluid. The prosthesis on the left contains silicone gel. The center prosthesis contains Bio-Oncotic gel. The prosthesis on the right contains physiologic saline.

tissue must be closely approximated by the filling material used in mammary implants if normal mammographic techniques are expected to detect tumors adjacent to the mammary prosthesis.

The ideal mammary prosthesis would have an x-ray transmission close enough to normal tissue that the prosthesis would not interfere with the early detection of small tumors during mammographic screening. It is desirable that both the envelope and the filler be comprised of biocom-



SIL1CONEGEL BIO-ONCOTIC™ GEL

FIG. 8. Processed x-ray film of commercially available silicone mammary implant envelopes. The envelope on the left contains 220 cc of silicone gel. The envelope on the right contains 220 cc of Bio-Oncotic gel. Both envelopes have been placed over the same grid. Visualization of the grid is only possible through the Bio-Oncotic gel, which closely approximates the radiotransmission of normal breast tissue.

patible materials close to the x-ray transmission of normal tissue.

In this study, textured 220-cc silicone envelopes were used with each of the filler materials. Ideally, a biocompatible polymer less dense than this silicone elastomer could have been utilized as the prosthetic envelope. However, we utilized the silicone elastomer envelopes in this study because all implants currently available clinically are made from this material.

Effective mammography is dependent on many factors. These include radiologic materials and techniques, the position of the patient, location of the implant, and adequate flattening of breast tissues. While the presence of any prosthesis or contracture around such a prosthesis may alter the results of mammography, it has been the purpose of these studies to deal only with the tissue standard of radiotranslucency in breast prosthetics.

## CONCLUSIONS

When comparing saline-filled prostheses with silicone gel-filled prostheses, studies have noted an increased incidence of spontaneous deflation of the saline-filled implants.[11] This increased deflation rate has been associated with the fold-flaw fracture phenomenon owing to the high coefficient of friction of the saline implant filler.[6,12,16] Silicone gel has a sufficiently low coefficient of friction to avoid the spontaneous deflation problems associated with their saline-filled counterparts (Table II). Bio-Oncotic gel has a coefficient of friction superior to saline or silicone gel (see Table II).

Bio-Oncotic gel reacts with the body in a similar manner to that of physiologic saline. In case of shell rupture, saline is absorbed by the body tissues, and except for the damage that may be done by hydrodissection, it is physiologically innocuous. Bio-Oncotic gel is biocompatible and is eliminated through the kidneys, chemically unaltered, in a matter of days.

Bio-Oncotic gel has x-ray transmission properties superior to those of physiologic saline solution and is rapidly eliminated from the body. Therefore, Bio-Oncotic gel-filled prostheses appear to have the most desirable characteristics for compatibility with mammographic technology for detection of small tumors.

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