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A Ten-Year Experience Using Polyurethane-Covered Breast Implants

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Abstract. The purpose of this study is to disclose the low incidence (0.98%) of capsular contracture using polyurethane-covered silicone gel breast implants. Four hundred seven surgical interventions were performed during the 10-year period, 404 for hypomastia and 3 for breast reconstruction.

Key words: Hypomastia—Polyurethane-covered implants—Low capsular contracture

Introduction

History

In 1970, Ashley [1] started to use a new silicone gel breast implant covered with a thin coating of polyurethane, containing a Y-shaped septum. From then on, the new implant was called the ''Natural-Y.'' In 1972, Ashley [2] published a report covering 200 patients who had received such an implant with minimum complications and excellent results.

Capozzi and Pennisi [8], in 1981, and Capozzi [7], in 1982, reported the use of implants with a polyurethane cover manufactured by Heyer–Schultze. Of the 54 patients implanted, just one developed capsular contracture, another an infection, and a third a seroma.

In 1984, Schatten [35] reported the use of the Natural-Y in the breast reconstruction of 36 patients, with no capsular contracture, infection, or skin necrosis observed. Folds were palpated in the upper half of the mamma, immediately after the insertion of the implant following a subcutaneous mastectomy.

In 1984, Eyssen et al. [13] reported the use of the high-profile Natural-Y in 92 patients without any capsular contracture, although 14 developed an allergic reaction which disappeared in a week after specific treatment.

In 1984, Herman [17] reported the use of the new Natural White Même model implant made of polyurethane-covered silicone gel, differing from the Natural-Y in cover and density. A total of 81 patients was surgically implanted, with none presenting either capsular contracture or palpation at the polyurethane cover join. In 1985, of a total of 290 cases, only 2 presented unilateral infection.

In 1985, Dolsky [11,12] described 2.5 years of experience with Même implants used for augmentation mastoplasties, with the inclusion of 400 prostheses. The author described the caution to be taken regarding asepsis and antiasepsis to avoid infection and reported 7% Type II capsular contracture, according to the Baker classification.

In 1986, Jabaley and Das [24] reported two cases of unilateral pain some months after the procedure.

In 1988, Melmed [26] reviewed 6 years of experience with 416 implanted patients, reporting 15 capsular contractures, 6 infections, 3 allergic reactions, and 1 hematoma.

In 1988, Hester et al. [19,20] studied the performance of 1510 polyurethane-covered implants over 5 years, asserting that this prosthesis represented a great advance in avoiding capsular contracture.

In 1990, Melmed [27] reported the treatment of capsular contracture with capsulotomy and implant replacement with polyurethane-covered ones.

In 1990, Hoefflin [21–23] reported his extensive 8.5 years' experience with polyurethane prostheses, advising the use of different venues to ensure good results.

In 1990, Pennisi [28,29] reported 14 years of experience using polyurethane prostheses.

In 1990, Pitanguy [32] reported his experience using

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polyurethane implants in 73 patients, inferring its use both retro- and antepectorally, with a low rate of capsular contracture.

In 1991, Handel [16] carried out a comparative study on 250 patients with 439 smooth-surface implants and 279 with polyurethane-covered implants, reaching the conclusion that capsular contracture was significantly more frequent with the former.

In 1991, Cohney et al. [10] reported 19 years of experience with all retromammary implants.

In 1991, Pitanguy [31] reported 1% capsular contracture using polyurethane-covered implants in 156 cases. No cutaneous rash, infection, or extrusion was observed.

In 1992, Gasperoni et al. [15] reported 12 years of experience with 420 implants, reporting 3.3% capsular contracture. They used three types of polyurethane-covered implants.

In 1993, Rebello [33] analyzed the controversies regarding the use of polyurethane-covered implants.

Capsule Histology

In 1978, Zimman et al. [39] published their investigation about the fibrotic capsule around smooth-surfaced breast implants. They undertook a study of the capsule with light and electronic microscopy to observe the formation of collagen and fibroblasts in the presence of the implant.

Smahel [37] described the histological aspects found in seven capsules of polyurethane-covered breast implants. The polyurethane set up a body reaction and was slowly degraded, with some particles being found in the capsule.

In 1984, Brand [4,5] performed tests on mice using polyurethane-covered and textured surface implants. Histologically the studies on mice implanted with polyurethane covers revealed a lengthy antigen foreign-body reaction, with the mobilization of macrophages and multinuclear giant cells.

This response increased from the periphery, throughout the degradation of the polyurethane. The small fragments were phagocytosed by macrophages; the large ones were anchored and surrounded by macrophages and giant cells, later replaced by fibroblasts and collagen. The absence of capsular contracture is due to the slow fibrosis growth from the polyurethane structure foam toward the periphery, produced by the free polyurethane fragment microcapsules.

In 1992, Barone et al. [3] studied the biomechanism and histopathological effect of polyurethane-coated silicone gel implants and tissue expansion. They concluded that the polyurethane surface was more effective, creating capsules in the implants that were hard at the onset but started to soften in 4 weeks with the edema resolution. Eight months after the procedure, the polyurethane-covered implants become softer and less prone to contracture than the textured-surfaced ones.

In 1993, Sinclair et al. [36] researched the biodegradation of the polyurethane cover and produced convincing evidence that polyurethane is degradable. They used optical and electronic microscopy. In the patients studied, the foam underwent degradation for 3 years, then lost its structure completely and degraded further into small particles.

in 1994, Bucky et al. [6] presented a paper called ''The Capsule Quality of Saline-Filled Smooth Silicone, Textured Silicone, and Polyurethane Implants in Rabbits: A Long-Term Study.'' They concluded, after over a year of research, that

(a) the capsules around the textured saline-solution prostheses were significantly firmer and less distensible than those around implants with a smooth surface and polyurethane cover, and
(b) histologically a significant inflammatory response exists around the textured silicone implant, which does not exist around the smooth-surface version.

Although the capsule around the polyurethane implant has inflammatory cells, there is less fibrotic tissue deposited and a reduction in the proportion of type-3 collagen found around the capsule of the textured implant. Above all, the characteristic contraction of the rabbit's fibroblast differs from the standard contraction in humans.

Polyurethane Degradation

In 1991, Szycher et al. [38], based on risk statistics, concluded that the possibility of cancer was 1 woman in 400,000,000. Considering that 1 in 11 women runs the risk of developing breast cancer during her life, the risk of developing 2,4-TDA (toluenediamine) malignity should be considered insignificant.

In 1991, Amin [33] found no signs of TDA when polyurethane foam was treated under physiological conditions and concluded that the variety of the results published in vitro and the in vivo studies should be adapted to a nonphysiological treatment of the foam.

In 1992, Hum et al. [33] claimed that the hydrolysis of polyurethane foam occurring at 150°C and in the presence of water suffers an abnormal thermohydrolytic degradation that releases TDA. The experimental procedures used may not be applied to in vivo conditions.

On June 27, 1995, the U.S. Food and Drug Administration (FDA) [14] published an update on the TDA released by breast implants covered with polyurethane foam. They investigated the presence of TDA in urine and blood serum of women having Même and Replicon implants in a double-blind study on 61 patients and a similar number without implants as control. The presence of very small quantities (parts per billion) of free TDA was found in the urine of 80% of the implanted patients and in 13% of the women serving as controls. No free TDA was found in the implanted women's blood serum.

In 1998, during the 24th Annual Meeting of the Society for Biomaterials, San Diego, California (USA), held on April 22–26, Santerre et al. [34], concluded, ''Hence, in regards to material toxicity and carcinogenecity, TDA

(toluenediamine) may not be the clinically relevant product to be studied. . . .'' This paper confirms the FDA's statements on the subject of TDA.

Immunology

Many authors have dealt with the immunological issues triggered by the use of silicone gel breast implants [9], including the report published in March 1996 by Katzin et al. [25] in *Clinical and Diagnostic Laboratory Immunology*, where they studied the phenotype of lymphocytes in the different types of prosthesis, including the polyurethane-covered version.

This study typified the phenotype of the lymphocytes found in the exudate between the capsule and the prosthesis, as well as in the capsule itself and in the peripheral blood of 209 patients with removed implants because of some type of complaint (local pain, capsular contracture). The amount of T lymphocytes was much greater in the exudate and capsule in implanted patients compared with the amount found in the peripheral blood.

Materials and Methods

We started using polyurethane-covered silicone gel implants in 1988, with 404 surgical interventions for augmentation mammoplasty and 3 for breast reconstruction (Fig. 1). Of the 811 single implants inserted, 24 were National White model Même, 6 were Surgitex model Replicon, and 781 were Silimed.

Procedure

Complete presurgery examinations were requested, along with bilateral mammographies with axillary projection. Just before surgery, the anterior wall of the chest was washed with a povidone–iodine soapy solution. Antibiotics were administered orally 24 h before and 48 h after the procedure, and 1 g of cephalothin parenterally 30 min prior to surgery. In most cases local anesthetic was used, plus neuroleptic analgesics, with general anesthesia in the rest of the patients.

Placement of the prostheses was performed by the intrareolar approach (depending on the case, perimammary or semicircular transareolar) in hypomastias. For reconstructive surgery, the access used was the same as used by the surgeon who performed the mastectomy. A large pouch was made in all cases.

The sealed wrapping containing the breast implant was always opened immediately before the insertion. Formerly, we placed the implant with the appropriate appliance, but now we dip the implant in a solution of povidone–iodine and place it without the appliance, since its use made implant placement difficult. All the implants were placed in the retromammary position.

No drainage was left in any case. The bandages were removed after 72 h, with the inclusion mobilized after the seventh day.

Capsule Study

We studied the composition of the capsule in order to determine its histological composition and the immune reaction triggered by polyurethane, using the capsular lymphocytic typology. The material was sent to a pathological anatomy laboratory, an immunogenetic laboratory, and a biochemical laboratory. We also had echographs performed on many of the patients.

Histological Study. Macroscopy. A fiber-like tissue formation, whitish-red in color and 2 mm thick, was observed covering the breast implant but not firmly fastened to it. It presented both an inner surface of a tarnished appearance with hematic areas and in contact with the breast implant and an outer one of a fibrous appearance, whitish-pearl in color and in contact with the mammary tissue.

The capsule was firmly attached to the prepectoral fascia plane and to the mammary gland deep plane. Macroscopically, the capsule acted as an anatomic barrier isolating the implant. The tissue peripheral to the capsule was of normal appearance.

Light Microscopy. Microscopically, five layers can be distinguished in the capsule, arranged in concentric shape from the inner surface in contact with the implant, toward the periphery in contact with the surrounding tissue.

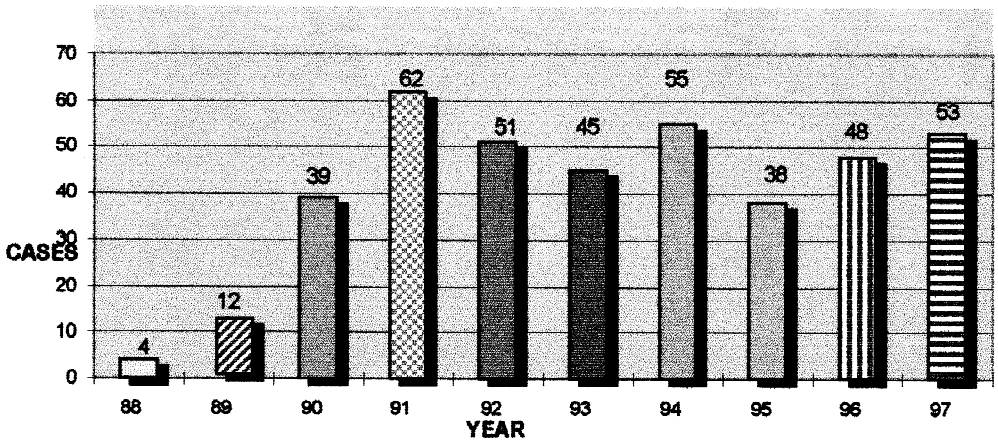
Each of the layers is characterized by its histological composition, as follows:

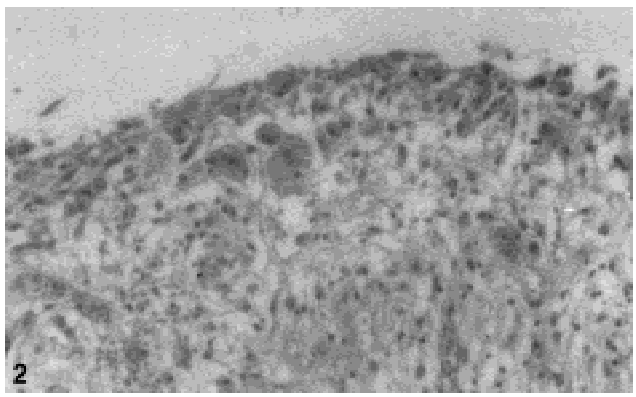
(1) A single layer of macrophages, epithelioid cells, and foreign body giant cells, with some of them containing phagocytosed foreign bodies in their cytoplasm (Fig. 2).
(2) A layer of subacute inflammatory tissue with edema, neoformation vessels, and lymphocyte, mononuclear infiltrate (Fig. 3).
(3) An infiltrate of plasmocytes (Fig. 4).
(4) A thick layer of fibrous connective tissue (Fig. 4).
(5) Loose connective tissue bordering the mammary parenchyma (Fig. 5).

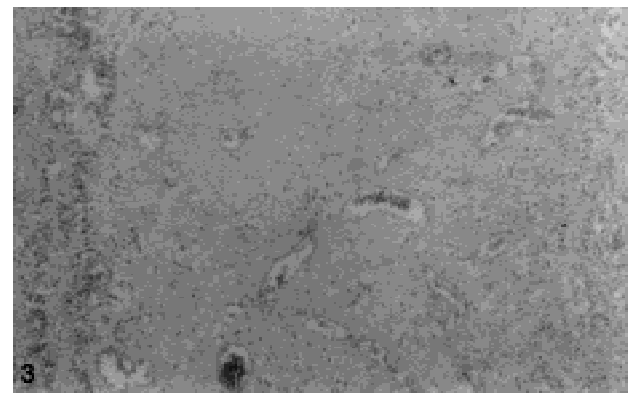
No macrophages were observed with a foreign body content, except in layers 1 and 2. No embolization of the macrophages was observed in the vessel neoformation. This led to the diagnosis of a chronic inflammatory reaction produced by lymphocytes and plasmocytes, with the presence of macrophages and foreign body giant cells.

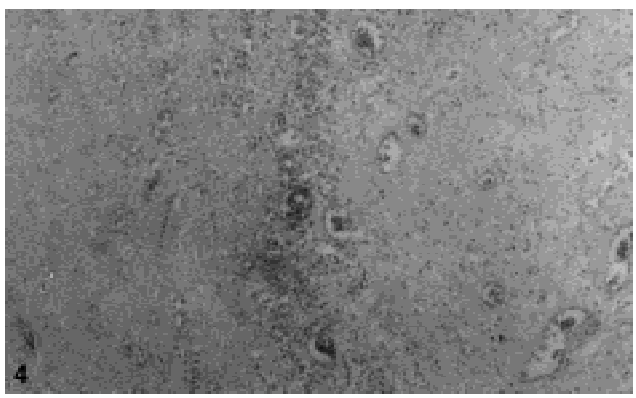
Exudate Study. An extension of the exudate was investigated by staining it with May Grunwald–Giemsa. Clusters of macrophages were observed, as well as abundant body cells (Fig. 6). Dark-field macroscopy indicated a macrophage intracytosolic content consisting of foreign bodies.

Electron Microscopy. The presence of foreign bodies in the phagocytosis phase was noticed inside the macro-









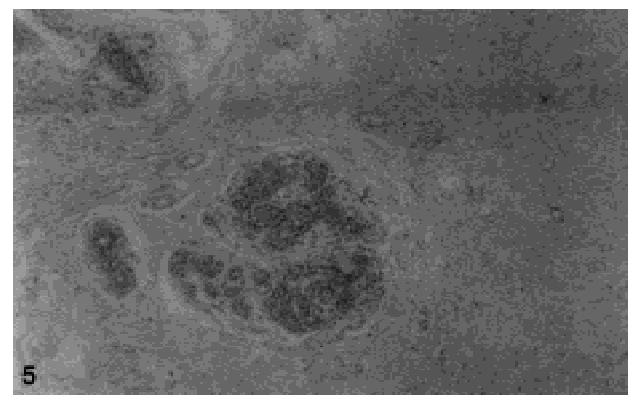


Fig. 1. Cases per year. Total, 407 patients.
Fig. 2. Light microscopy: layer 1 in contact with the implant, macrophages, epithelioid cells, and foreign-body giant cells.
Fig. 3. Layer 2: neoformation vessels and lymphocyte, mononuclear infiltrate.
Fig. 4. Light microscopy: layer 3, plasmocyte barrier and fibrous connective tissue.
Fig. 5. Light microscopy: layers 4 and 5, connective tissue and mammary parenchyma.

phages, which did not have cytological alterations. Plasmocytes were observed with active granular endoplasmic reticulum (Fig. 7).

Foreign Bodies. By enzymatic biodegradation we produced lysis of the capsule, establishing the existence of short- and long-chain polyurethane remainders, thus confirming that the polyurethane is digested in the capsule macrophage vacuoles, as observed under electronic microscopy.

Using atomic spectroscopy we confirmed the presence of silicone in the capsule as well, as is common in all silicone gel implants. We also noticed microexudates on all silicone gel implants.

Immunological Typing of the Lymphocytes in the Capsule. We identified the lymphocytes obtained in the capsule, with the following results: 55% T lymphocytes (anti-CD3), of which 61% are T helper (anti-CD4) and 39% T cytotoxic (anti-CD8); and 45% B lymphocytes

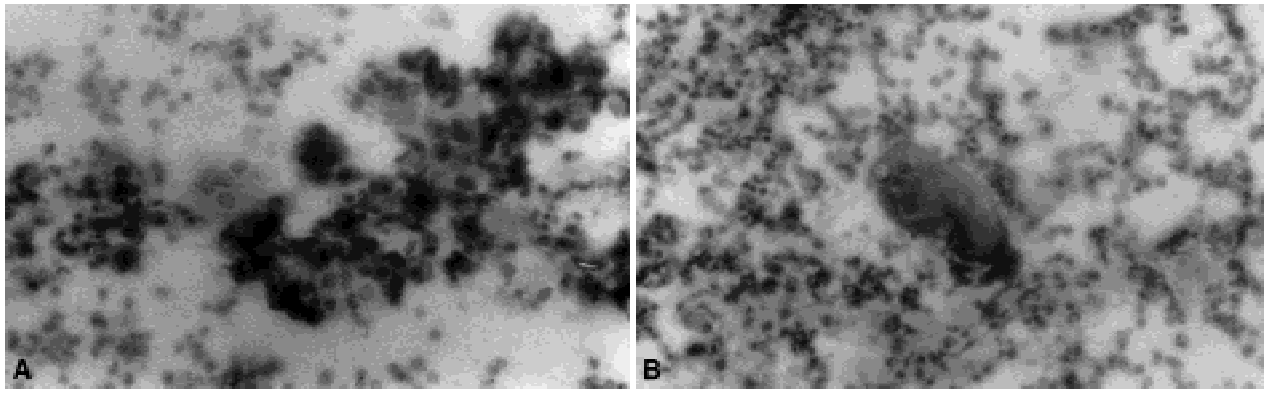


Fig. 6. Exudate study. **A** Clusters of macrophages. **B** Giant cell.

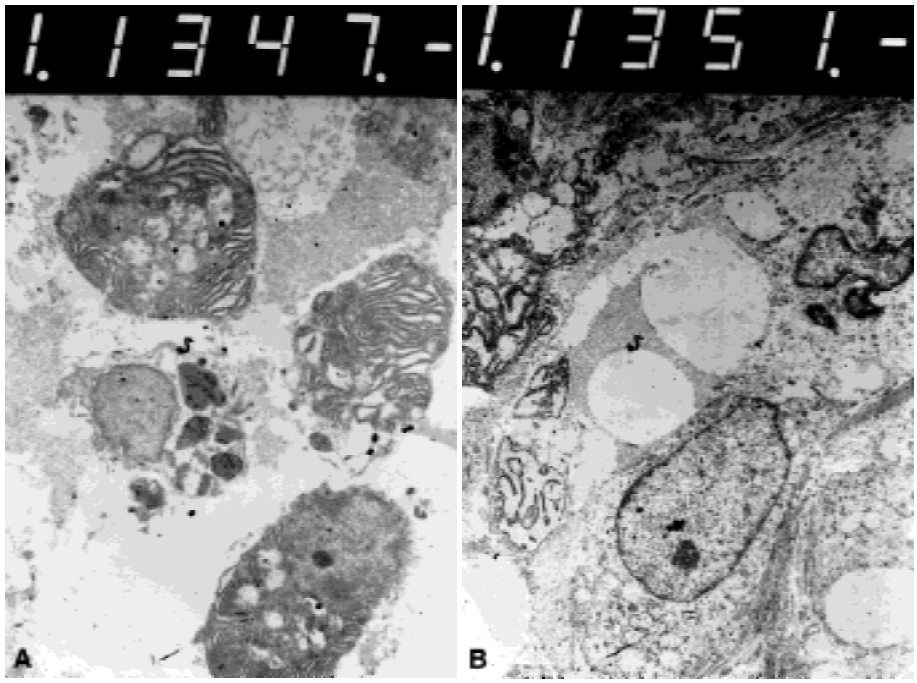


Fig. 7. Electronic microscopy: **A** A macrophage surrounded by plasmocytes. **B** Foreign bodies inside the macrophage.

(anti-CD19), of which 60% are Bκ and 40% Bλ. There is a predominance of T lymphocytes, characteristic of chronic inflammatory infiltrates.

Echographic Study of the Capsule. An echographic study of the capsule was performed, examining the pectoral is major muscle, the prepectoral fascia, the implant, and the mammary gland, as well as the capsule completely surrounding the implant. In most cases the surface of the capsule measured 1.1 times larger than the implant.

Table 1. Complications in 407 patients with 811 implants[a]

Complication	Quantity	%
Hematoma	5	1.22
Seroma	8	1.96
Skin rash	19	4.66
Capsular contracture	4	0.98
Skin folds	7	1.72

[a] The percentages were obtained from the total number of patients rather than the total number of implants, since the latter would have reduced the percentage by half.

Complications

Of the total 407 patients with 811 implants, we observed the complications listed in Table 1.

We noted by palpating thin patients that the polyurethane layers covering the implant adhered to each other in 84 patients, or 20.63% of the total sample. We do not consider this a complication, as it is somehow inherent to the implant. At present, with the new polyurethane cover design presented by Silimed we have not

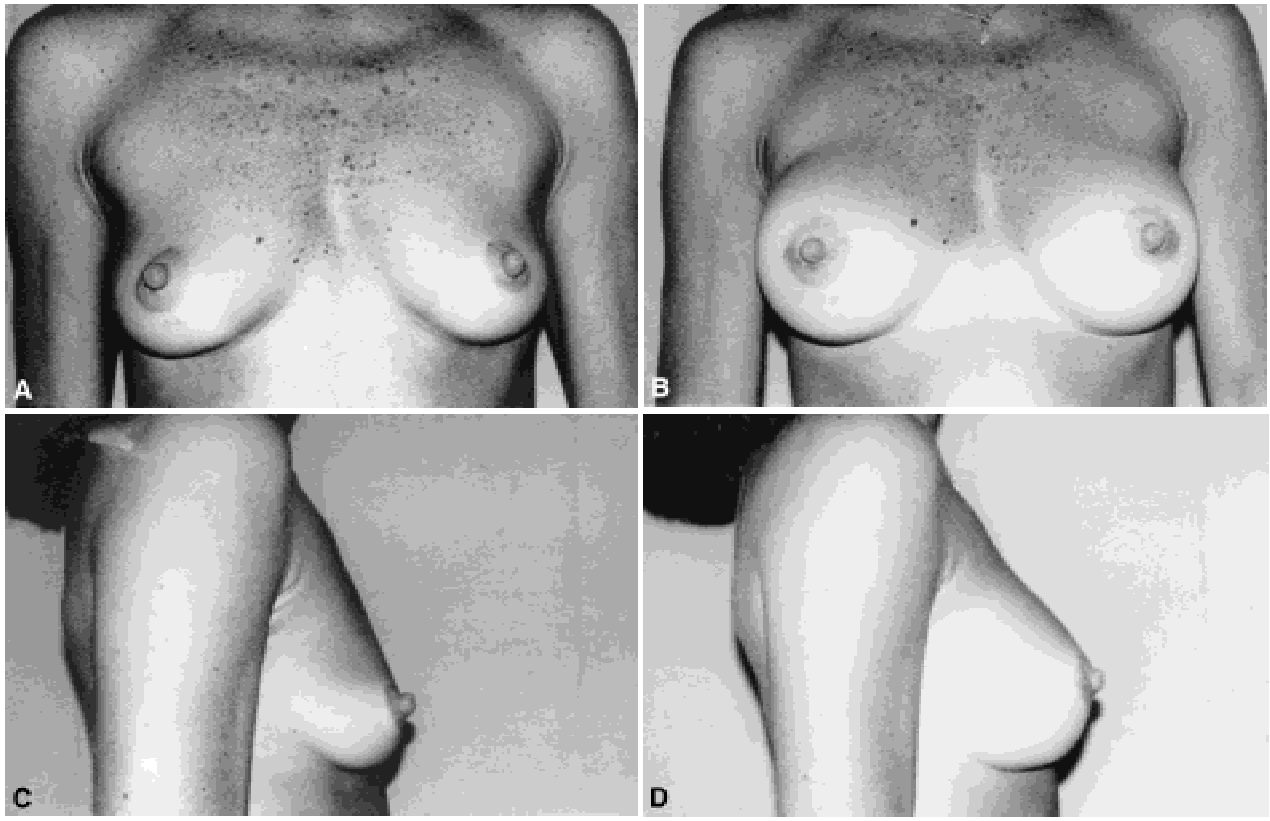


Fig. 8. Clinical cases: Frontal view, presurgery **(A)** and postsurgery **(B)**. Right profile, presurgery **(C)** and postsurgery **(D)**.

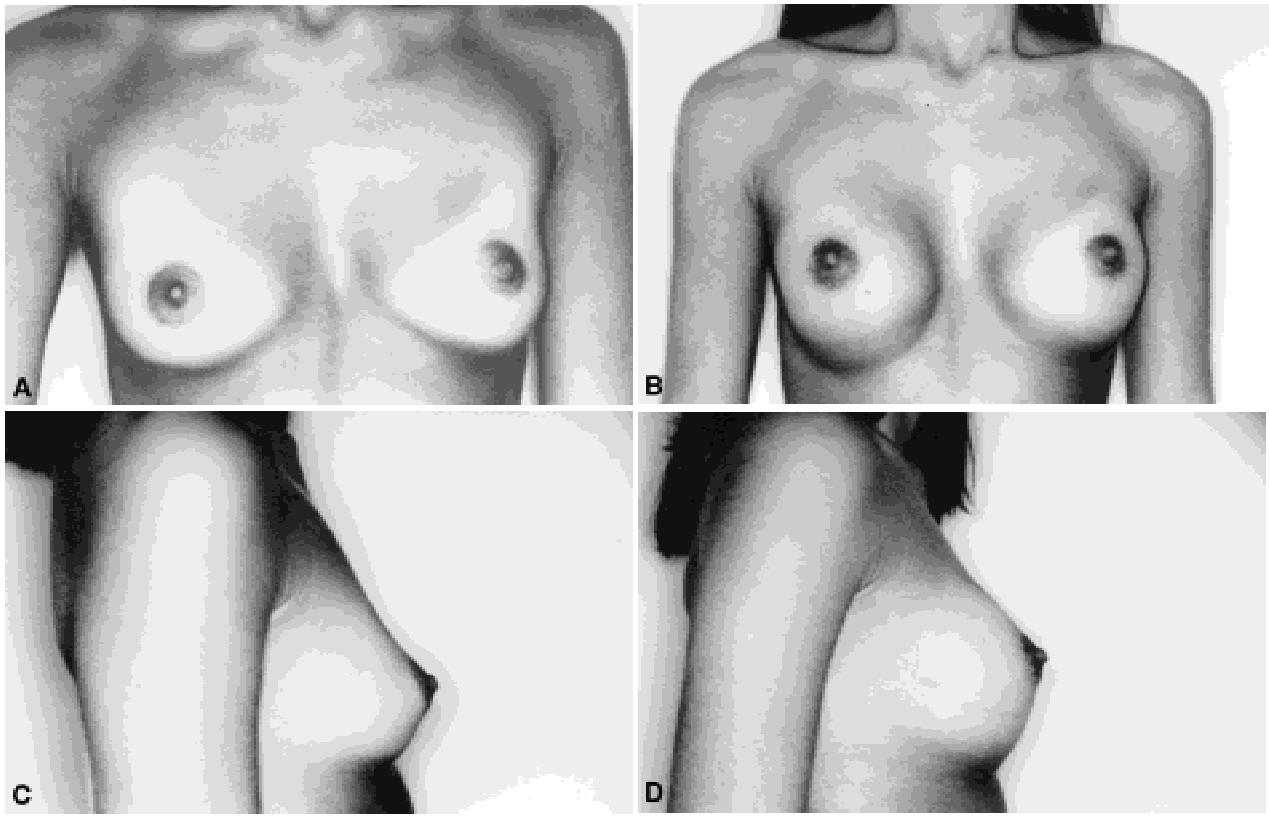


Fig. 9. Clinical cases: Frontal view, presurgery **(A)** and postsurgery **(B)**. Right profile, presurgery **(C)** and postsurgery **(D)**.

seen this again, as the polyurethane upper and lower layers' covers join at the base of the implant, inside the seam.

No infections, fistulas, or extrusions were observed. The hematomas, seromas, and capsular contractures have been always unilateral.

The four cases of capsular contracture were two Grade II and two Grade III, according to the Baker Scale.

Results

One of the main problems in breast implantation using silicone gel prostheses has been capsular contracture. Some studies described 30% or more capsular contracture when applying smooth-surface implants. The introduction of textured implants has lowered this percentage to 5–15%. The studies carried out on silicone gel polyurethane-covered implants showed the lowest percentage of capsular contracture.

Our experience with 407 patients provides a percentage of 0.98% considering the total number of cases, with just 0.49% (or half) if we refer to the total number of implants inserted.

Conclusions

After having used polyurethane-covered silicone gel implants in 407 patients, we are able to make the following comments:

For the first 6 weeks after implantation, the breast is tender. Later the edema disappears and it becomes completely pliable and supple in consistency (Figs. 8 and 9).

We believe that the best approach is the intrareolar incision, since the submammary, although it makes placement easier, is more liable to fistulas and extrusions.

The polyurethane-covered implant remains in the retroglandular position where it is first placed, shifting with the rest of the gland to conform to all the breast movements, whereas the smooth- and textured-surface implants move freely within the capsular space, stretching in many cases beyond the glandular area, to produce a very unpleasant appearance.

We strongly advise making a large pouch to avoid the folds that might otherwise appear in the implant.

To make implant insertion easier, we dip it in a povidone–iodine solution dispensed with the applicator provided. We consider it extremely difficult to introduce a dry-surfaced polyurethane-covered implant without the applicator, as the implant can break because it adheres to the host raw approach surface.

In thin patients with pure hypomastia, we use the new model designed by Silimed, which prevents touching the juncture of the two layers of polyurethane foam, as the join is at the base of the implant.

From the studies carried out, we conclude that the capsule produced by the polyurethane-covered implant presents a different architecture and cellular composition with a lower concentration of collagenous fibers, which causes less fibrosis and therefore less likelihood of capsular contracture.

The main debate regarding the use of polyurethane-covered silicone gel breast implants suggests the toxicity of 2,4-TDA (toluenediamine). Referring to the latest research [34], we conclude that patients implanted with these prostheses present no statistically significant differences compared with those who do not receive any implants.

Our experience of over 10 years with polyurethane-covered silicone gel breast implants has led us to conclude that this implant reduces capsular contracture to under 1%. Some authors have stated that after the polyurethane foam disappears, the implant behaves as a smooth implant and thus produces a significant contracture. We do not believe that this happens exactly as reported, because the polyurethane foam disappears within 1 or 2 years after the surgery is performed. We have not seen the onset of a contracture increase, because according to our experience the polyurethane remains in the capsule as we have shown by the enzymatic biodegradation. Furthermore, the histological architecture of the capsule is different from that of smooth implants.

We would also like to remark that when these implants first came out on the market, the polyurethane foam was glued to the implant, and it was common to see a double capsule, as the polyurethane foam became loose and a capsule was formed between the gland and the foam, with another one between the foam and the implant. Probably the latter one was too small to allow the implant to move freely in the cavity, producing an important contracture after the polyurethane foam had disappeared. Nowadays Silimed is the only company making these implants, and the polyurethane foam is not glued to the implant any longer, eliminating the problem.

Since capsular contracture is the most common complication that plastic surgeons have experienced with breast implants since they have become widely used, we believe that the above-mentioned percentage and the low incidence of other complications make the use of these implants one of the best options for augmentation mastoplasty.

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