

Complications in Breast Augmentation

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ABSTRACT

The authors present their 25-year experience assisting patients in their private clinic and in their Educational Service. The increasing number of silicone prosthesis implants has increased the incidence of complications related to this procedure, but a systemic complication such as autoimmune or neoplastic disease was never observed.

The most common local complications are studied and correlated to the different prostheses types manufactured over the years. The study of the prostheses coats and the organic fibrous capsules help to find the best decision in case of prosthesis replacement. These decisions may involve: perform a capsulotomy or a capsulectomy, the best prosthesis coat type, the need of a documented information to the patient, the risks and benefits related to the procedure.

Microscopic and macroscopic analysis of the local complications may help to decide the best prosthesis to be used: thin coat silicone gel prosthesis, textured lining coat prostheses, polyurethane overlapping coat prostheses, or inflatable saline-filled prostheses. There is no consensus about the ideal prosthesis.

In conclusion, the squeezing maneuver (non-invasive manual compression of the hardened breast) must not be performed, thin coat silicone gel prostheses are more associated to complications and should not be used.

INTRODUCTION

The number of silicone breast prostheses surgeries have significantly increased in the last 25 years. At the same time, the manufacture and the contents of the silicone breast prostheses have been modified.

Prostheses manufacturing development could be summarized as follows:

- ◆ Phase 1: Thick coat prostheses with a Dacron patch.
- ◆ Phase 2: Thin coat prostheses without patch.
- ◆ Phase 3: Double lumen prostheses.
- ◆ Phase 4: First inflatable coat prostheses.
- ◆ Phase 5: Textured lining coat prostheses.
- ◆ Phase 6: Polyurethane overlapping coat prostheses.
- ◆ Phase 7: Inflatable saline-filled prostheses.

Breast augmentation surgeries usually achieve good results (Figs. 1a and 1b), but the following questions are frequently made when a patient decide to make a breast prosthesis implant:

- ◆ Is there any risk related to the silicone?
- ◆ Does silicone cause cancer?
- ◆ Or any other disease?
- ◆ Why some breasts harden?
- ◆ Is it possible to breastfeed after the surgery?
- ◆ Is there any sensibility changes?
- ◆ What is the ideal prosthesis type?
- ◆ How long does the result last?
- ◆ When should I change the prostheses?

TECHNICAL DISCUSSION

The silicone (dimethyl-polysiloxane) is a very peculiar polymer: it is not biodegradable and is only dissolved in silicone itself. The silicone viscosity can be variable: from a very thin liquid to a gelatinous or solid consistency. The silicone viscosity is measured

in **centistokes**. For example, silicone gel breast prostheses are constituted of a silicone coat having a higher **centistoke** (solid) than the inside gel.

The old thick coat prostheses with Dacron did not provide a natural esthetic result and the Dacron was also related to complications such as foreign body inflammatory reaction. In order to solve these problems, the prostheses manufacturers began to make thin coat prostheses. It created a different kind of complication: the silicone gel inside of the prosthesis would dissolve the thin coat and make it rupture over the time. When the covering of the thin coat prosthesis was ruptured or dissolved, the silicone gel inside the organic fibrous capsule could migrate to the contiguous tissues and cause: granuloma, skin inflammation with rash, urticaria, chronic pain, and calcifications. The extravasated silicone gel could also migrate to lymph nodes, along a peripheral nerve course, or into the chest. The silicone infiltrating the chest can simulate tumors and can require an exploratory thoracotomy (Fig. 2). There are also several cases of ruptured or dissolved coats that caused no symptoms. Abramo⁽¹⁾, Brandt⁽⁶⁾, Brinton⁽⁷⁾, Ferreira⁽¹⁰⁾ and Shah⁽²⁴⁾ have studied the most common causes of periprosthetic breast capsules contraction since 1982.

The thin coat prostheses should be improved, thus the manufacturers began to produce a double lumen prostheses (a silicone gel inside, an aqueous layer and a silicone coat). It was manufactured for a short time because it was not practical. At that time, the first inflatable prostheses were described^(4, 14) and manufactured^(20, 22, 24). Their valves were not very safe and the manufacturer recommended to fill those prostheses with macromolecular solutions (dextran). As in any type of prostheses, if the barrier between the prosthesis content and the body tissues is not effective, there will be exchanges between them, which can cause capsular contractions. In addition, the prosthesis could empty due to the poor quality valve.

Prostheses with a coat that would resist to the silicone gel were developed. They were called textured lining coat prostheses with a traditional silicone gel filling, a treated silicone gel (cohesive) filling, or other fillings such as castor oil and others. These last ones were not very well accepted by the physicians.

In order to protect the patient body, a product that would cover the silicone coat and minimize the capsular contraction should be developed. The polyure-

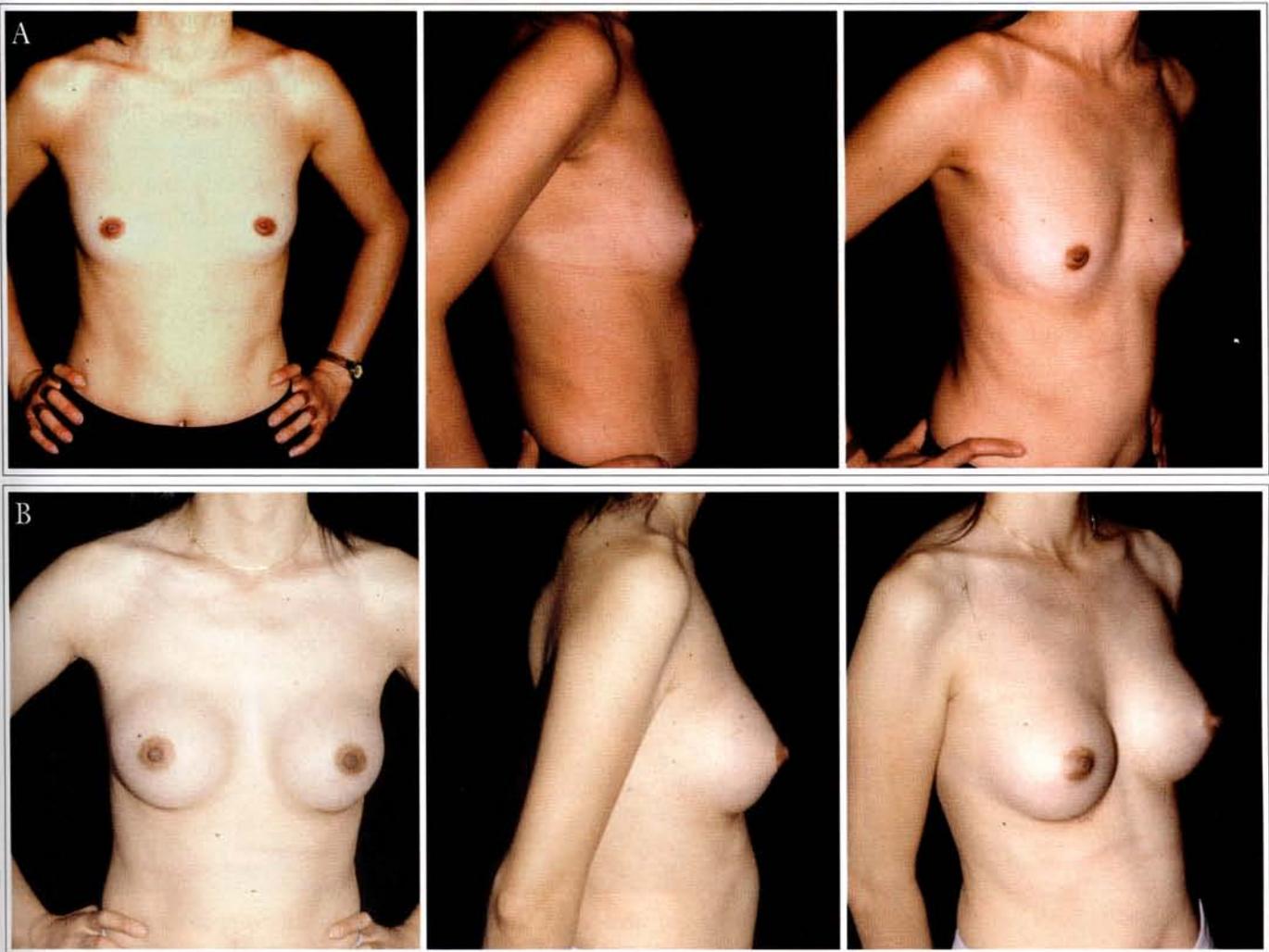


Fig. 1 - A: Hypomastia preoperative. B: Postoperative.

Fig. 1 - A: Pré-operatório de paciente com hipomastia. B: Pós-operatório.

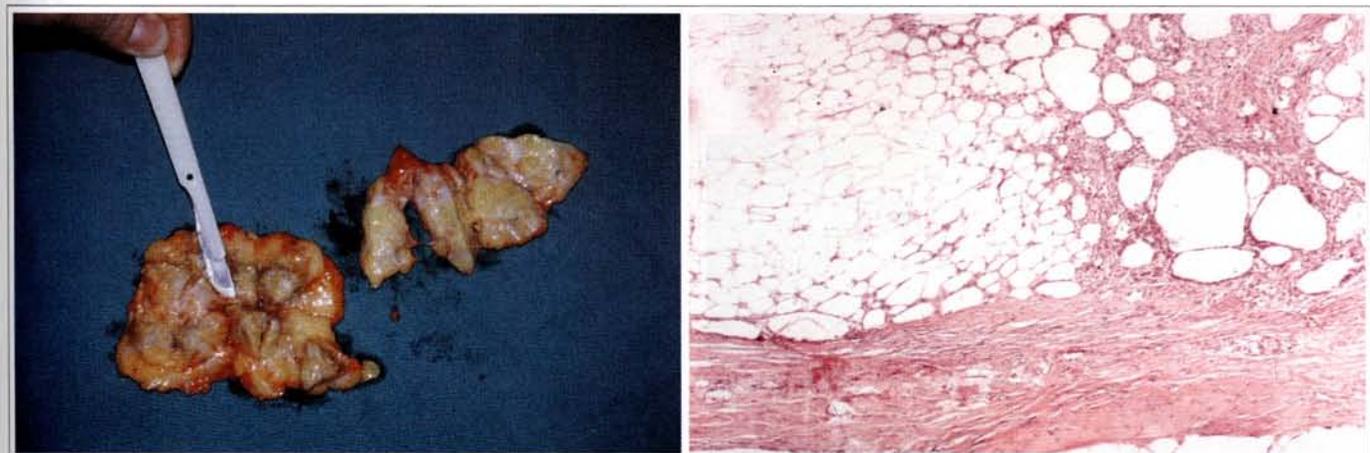


Fig. 2 - Aspect of a 12 y. o. silicone implant. A: macroscopic view (siliconoma) of the breast. B: Microscopic view of the surrounding tissue infiltrated by silicone (silicone gel prosthesis rupture). Bilateral granulomas with exuberant fibrosis and foreign body type reaction caused by silicone. Inflammatory process with lymphocytes. Breast parenchyma with ductal hyperplasia without atypia.

Fig. 2 - Siliconoma, em imagens de paciente portadora de prótese gelatinosa lisa operada há 12 anos. A: Aspecto macroscópico da peça (siliconoma). B: Aspecto microscópico de tecido vizinho à mama, infiltrado de silicone (ruptura de prótese gelatinosa lisa). Granulomas de silicone bilaterais com exuberante fibrose e reação tipo corpo estranho (siliconoma). Processo inflamatório linfocitário. Parênquima mamário com hiperplasia ductal sem atipias.

thane⁽¹⁸⁾ showed to be the best product and the polyurethane overlapping coat prosthesis is still in use. Simultaneous to the polyurethane and textured coat prostheses development, the inflatable prostheses began to be studied again. The advent of tissue expanders helped to develop the inflatable prostheses. The safety of several types of valves was determined and an isotonic saline solution was recommended as the filling of these prostheses^(20, 22).

As in any other silicone prostheses, the inflatable prosthesis coat is not absolutely impermeable. A “bleed-

ing” phenomenon (transudation from the prosthesis) may occur. Two causes are involved in this phenomenon: the pressure inside the prosthesis and the osmotic concentration of the liquid that fills it. If the pressure inside the prosthesis is high, the filling liquid may transude and the prosthesis may deflate. The filling liquid also needs to be isotonic to avoid ions and water to exchange.

MATERIAL AND METHOD

Four hundred twenty primary or secondary patients



Fig. 3 – Baker grade VI capsular contraction.

Fig. 3 - Retração capsular grau VI de Baker.

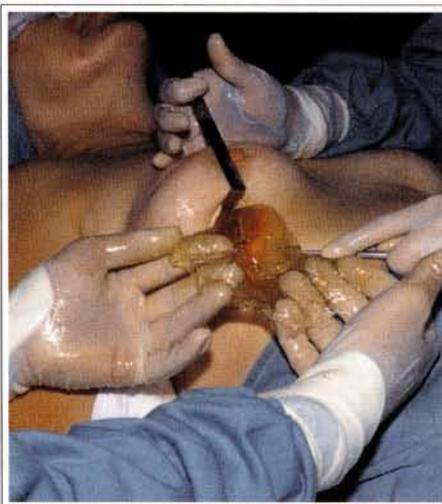


Fig. 4 – Ruptured silicone gel prosthesis. The prosthesis coat residues may be observed.

Fig. 4 - Prótese lisa gelatinosa rompida. Notam-se resíduos do envoltório da prótese.



Fig. 5 – Total disappearance of the silicone prosthesis coat. The material corresponds to the filling gel.

Fig. 5 - Desaparecimento total do envoltório da prótese gelatinosa lisa. O material que está sendo retirado corresponde ao gel de preenchimento.



Fig. 6a – Organic fibrous capsule calcification around a silicone gel prosthesis placed 18 years ago.

Fig. 6a - Calcificação da cápsula orgânica de prótese gelatinosa lisa colocada há 18 anos.

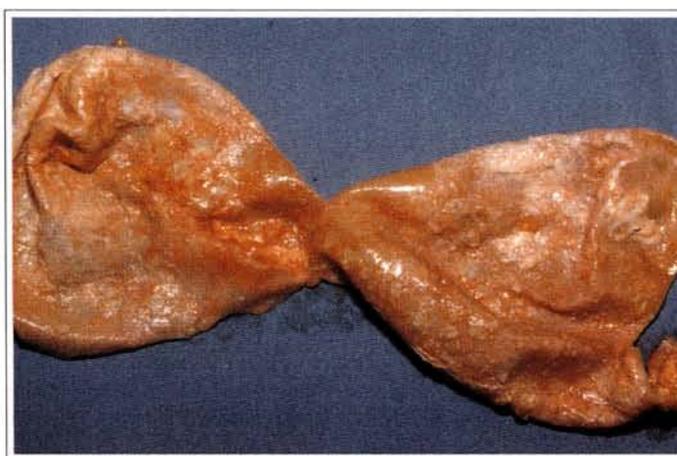


Fig. 6b – Another capsule with microscopic calcification.

Fig. 6b - Outra cápsula, com calcificação em visão microscópica.

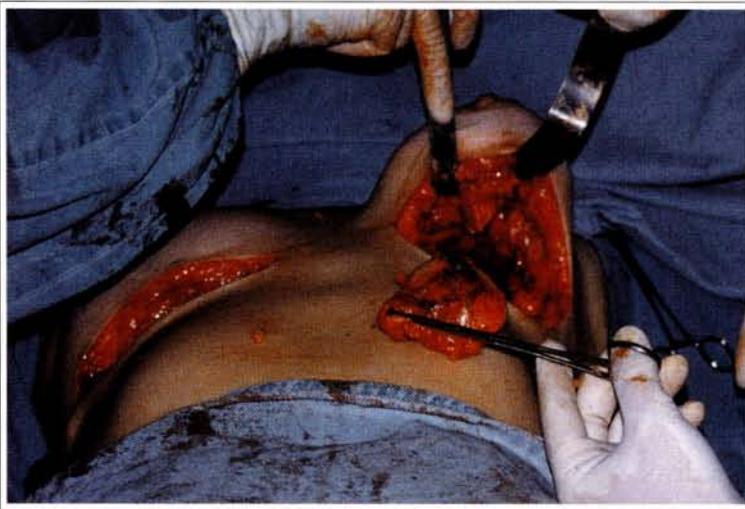


Fig. 7 - Silicone gel migration to the breast surrounding tissues. Note the large and hard tumors after a 15 years old prosthesis removal.

Fig. 7 - Migração do gel para a glândula e tecidos vizinhos. Notar as grandes tumorações duras (retirada de próteses incluídas há 15 anos).



Fig. 8 - Postoperative dysmorphism and prosthesis dislocation.

Fig. 8 - Dismorfia pós-operatória e deslocamento da prótese.



Fig. 9 - Prosthesis elimination due to infection.

Fig. 9 - Eliminação da prótese por infecção.

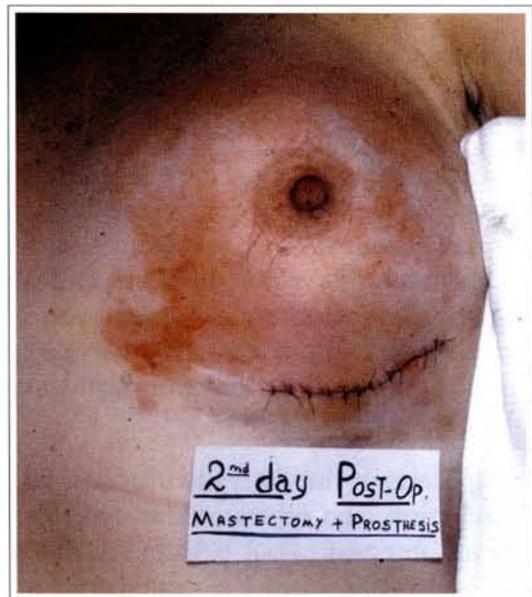


Fig. 10 - Inflammatory reaction 48 hours after the surgery. Rejection type reaction late characterized as a immunocomplexes phenomena due to chemotherapy treatment.

Fig. 10 - Fenômeno inflamatório nas 48 horas de p.o., com aspectos de "rejeição", o que foi caracterizado como sendo um fenômeno por imunocomplexos (paciente sob tratamento quimioterápico).

with breast prostheses implants in the last 25 years were reviewed. The patients studied could present any type of complain or complication related to the prosthesis. The most common local complications observed were:

- ◆ Capsular contraction and breast hardness (different degrees) (Fig. 3)
- ◆ Prosthesis rupture (Fig. 4)
- ◆ Prosthesis's coat disappearance (Fig. 5)
- ◆ Fibrous capsule calcification (Figs. 6a and 6b)
- ◆ Prosthesis rupture with gel migration to the surrounding glands and tissues (Fig. 7)
- ◆ Postsurgery dysmorphia and prosthesis dislocation (Fig. 8)
- ◆ Chronic pain and discomfort
- ◆ Prosthesis elimination (Fig. 9)
- ◆ Infection
- ◆ CAM sensibility change
- ◆ Cicatricial changes
- ◆ Volume changes

In addition to the complications above mentioned, an extensive medical literature review revealed several other local complications such as: granulomas formation, skin inflammation with rash, urticaria, and silicone gel migrating to lymph nodes, along a peripheral nerve course, and into the chest. The silicone gel migrating into the chest simulate tumors and may require exploratory thoracotomy^(3, 8, 9, 11).

Systemic complications (lupus erythematosus, scleroderma, rheumatism, and others) due to breast implant were never observed in our patients. In the literature, there is no data relating silicone breast implants to systemic complications. In our service, a prosthesis replacement due to its dislocation was performed in a patient with subcutaneous mastectomy and retromuscular breast implant. Fourty eight hours after the surgery there was an inflammatory reaction and the prosthesis was removed. This seemed to be a rejection type reaction, but immunocomplexes due to chemotherapy treatment were later identified as the cause. Six months later the prosthesis was implanted

again and no complication was observed (Fig. 10).

Among the patients studied, the age varied between 26 and 50 years. In most patients the surgery was performed for esthetic reasons. There was also a significant number of patients submitted to a subcutaneous mastectomy and silicone breast implant that presented breast hardness due to the exiguous amount of tissue over the prosthesis. This was also observed in patients with retromuscular prostheses.

In patients with capsular contraction grades I to IV (Baker) and breast complaints, we observed that:

- a) There was a predominance of grades III and IV in patients using a Phase 2 thin coat silicone gel prostheses (very thin coat prostheses).
- b) Approximately 20% of the patients with severe contractions had the prosthesis coat ruptured or totally dissolved (Figs. 4 and 5).
- c) Textured prostheses causes less contraction, usually II and III.
- d) In the last seven years, inflatable prostheses filled with saline solution caused only a grade I capsular contraction that happened in 2% of the total patients.
- e) Saline filled inflatable prosthesis emptied up to 10% of its volume in 15% of the cases. It happened in the first cases due to the prostheses over filling, but practically disappeared when we reduced the filling volume.

We have never used a polyurethane overlapping coat prosthesis, thus we could not determine the capsular contraction grade caused by this prosthesis type.

Chronic breast pain or breast discomfort were common complaints, mainly in patients with grades III and IV capsular contraction.

Among patients with thin coat prostheses, there have been a increasing number of patients with prosthesis rupture or prosthesis coat dissolution (Figs. 4 and 5). We began to systematically perform a capsulectomy in all patients undergoing prostheses replacement because the histological studies have shown that several capsules may have little amounts of silicone. In addition, silicone gel migration to the surrounded breast tissues create silicone tumors (siliconomas) (Figs. 2a and 2b).

The Food and Drugs Administration prohibited the silicone gel prosthesis use in the United States in 1992. Nowadays, only the inflatable saline filled prosthesis has been utilized. The silicone gel prostheses may be still used in the United States, in special cases, but this requires extensive documentation and approval. We have been using inflatable saline filled prostheses since 1993.

COMMENTS

During the last ten years, there have been an increasing number of breast implants and as a result, an increasing number of complications related to this procedure. These complications are most related to the kind of prosthesis utilized.

Some procedures had to be reviewed such as: whether the fibrous capsule around the implant should be left or not in case the prosthesis needs to be replaced and what type of prosthesis should be used for the replacement. The Baker's procedure was abandoned. It consisted of squeezing (non-invasive manual compression of the hardened breast). Several patients attributed the prosthesis coat rupture to that procedure and have sued their physician.

During old prosthesis removal surgery, it is not rare to observe that the prosthesis coat disappeared and silicone gel inside is restricted by the fibrous capsule or is infiltrating the surrounding tissues.

The prostheses coat and fibrous capsules studies by optical microscopy, electronic microscopy and scanning microscopy have helped the physicians and the patients to choose the best product to be used. Fibrous capsule and prosthesis surround tissues histological studies also helped to define the prosthesis type that should not be used.

CONCLUSIONS

During the first consultation, the physician should inform the patient the types of prostheses available and their advantages and disadvantages. He should also document the mutual option providing the patient an explanatory form and an authorizing form that must be signed. This will avoid a lawsuit in case of complications related to the prosthesis. If other complications occur, the informative document may attenuate the physician responsibility in case of a law-

suit. However, the most important aspect of this documentation is to improve the relationship between the physician and the patient, thus eventual problems may be solved with mutual cooperation.

The complications related to the breast implants allow us to conclude:

1. The silicone coat prosthesis is semi-permeable.
2. The filling gel dissolves the prosthesis coat over the time.
3. Prostheses with textured coat are more resistant to capsular contraction.
4. The organic fibrous capsule is thicker when non texturized silicone gel prostheses are used.
5. The organic fibrous capsule is very thin if saline filled prostheses are used.
6. The capsular contraction is more severe with non texturized silicone gel prostheses.
7. The capsular contraction is less intense with saline filled prostheses.
8. Inflatable saline prostheses can empty if over filled.
9. Patients should be clarified about the available prosthesis and their advantages and disadvantages.
10. The physician should give technical information to the patients and have the patient's consent signature before the procedure.
11. The squeeze procedures (non-invasive manual compression of hardened breast) must be avoided.

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