# Silicone gel mammary prostheses: immune pathologies and breastfeeding

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**Summary**

Augmentation mammoplasty is the most frequent request among esthetic surgery procedures but numerous controversies have been raised about the security of the silicone gel prostheses. Today a new question needs an answer: is the prosthesis a risk factor for pregnancy? In this paper the results of a hematochemical study performed on a group of patients with term pregnancies and silicone gel breast implants (group A) compared with a control group without implants (B) are described. For laboratory screening the valuation of antibody (TRIM) and silicone concentrations in blood and maternal milk and in neonate blood was performed.

*Key words:* Augmentation mammoplasty; Mammary prostheses; Autoantibody; Silicone; Immune pathologies; Breastfeeding.

## Introduction

Augmentation mammoplasty has been the object of numerous controversies: could mammary prostheses be considered as a risk factor for women during pregnancy, lactation or fetal development? Could silicone during the puerperium contaminate the milk and predispose the newborn to immune pathology? [1-11]. The clinical trials present in the literature have attempted to answer these questions, but have often been affected by errors in the sampling. They often result without statistical significance or are contradictory [1-6].

Studies with small groups have little statistical significance whereas larger groups can determine immune pathology in an independent way from mammoplasty. The latter has statistical significance but often is contradictory and not reproducible.

The aim of our study was to attempt to answer these questions: the safety of silicone gel prostheses for the mother, the effects of eventual contamination of maternal milk and if this condition is associated with elevated concentrations of silicone in the blood of the neonate and, if silicone presence is correlated with immune pathology in the newborn.

## Materials and Methods

The study was conducted jointly by the Department of Plastic and Reconstructive Surgery and the Department of Gynaecology and Obstetrics of L'Aquila School of Medicine (Italy). From January 1995 to December 2005, 15 women near term pregnancy with mammary silicone gel prostheses, (Group A) were selected. Exclusion criteria were fibrocystic mastopathy, mastitis, immune pathology determined before mammoplasty and all women with saline prostheses. Pregnancies secondary to assisted fecundation were excluded.

Revised manuscript accepted for publication July 16, 2007

A control group (B) included 15 women near term pregnancy without breast implants.

Group A had a mean age of 27.9 ± 4.1 years old. The mean time of implant permanence was 62.1 ± 32.3 months. Eleven patients (73.4%) had the prostheses in the subglandular plane and four (26.6%) in the submuscular plane. Mean pregnancy time was 39.3 ± 1.2 weeks and breastfeeding duration was 26.15 ± 4.1 weeks. Group B had a mean age of 26.8 ± 3.6 years old, a pregnancy rate of 39.4 ± 1 weeks and the mean duration of breastfeeding was 26 ± 4.7 weeks (Table 1).

Table 1. — *Clinical data.*

| Patients | Group A (n = 15) (with prostheses) | Group B (n = 15) (without prostheses) | p |
|---|---|---|---|
| Age | 27.9 ± 4.13 | 26.8 ± 3.60 | 0.443 |
| Gestation time | 39.3 ± 4.12 | 39.4 ± 1.04 | 0.812 |
| Duration of breastfeeding | 26.1 ± 4.12 | 26.0 ± 4.71 | 0.937 |
| Implant permanence | 62.1 ± 32.3 | | |

At prepartum admission, evaluation of ESR, CRP, RF, Ig A,G and M classes and ANA/ENA antibody tests were performed in all patients.

The same laboratory parameters were carried out for the infants of our patients at the start and end of breastfeeding. We also evaluated silicone concentrations in the whole blood of the mothers and infants, and in the maternal milk.

The typical instruments were used to evaluate the concentration of antibodies, whereas silicone concentrations were evaluated by spectroscopic analysis with silicone-free devices [12, 13].

The results were statistically analyzed to verify the relation coefficient between the prosthetic inserts and the values of tests by the chi-square test, one-way analysis of variance and t-test.

## Results

Values of inflammatory proteins are shown in Table 2. Antibodies in all groups were compared by the chi-square test and the difference was not significant (Table 3). Sil-

Table 2. — *Inflammatory proteins.*

| | Group A | Group B | p |
|---|---|---|---|
| ESR | 5.9 ± 3.32 | 6.2 ± 3.39 | 0.788 |
| C-RP | 86.8 ± 19.91 | 85.4 ± 21.56 | 0.855 |
| RF | 0.142 ± 0.03 | 0.135 ± 0.03 | 0.588 |

ESR: erythrocyte sedimentation rate; C-RP: C-reactive protein; RF: rheumatoid factor.

Table 3. — *Antibody profile.*

| | No. of patients | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | ANA | ANA | ENA | ENA | (+) | (–) | (+) | (–) | (+) | (–) |
| Group A | 3 | 12 | 2 | 13 | 7 | 8 | 7 | 8 | 5 | 10 |
| Group B | 3 | 12 | 2 | 13 | 5 | 10 | 6 | 9 | 4 | 11 |
| $\chi^2$ | 0.208 | | 0.288 | | 0.139 | | 0.000 | | 0.000 | |
| p | 0.648 | | 0.591 | | 0.709 | | 1.000 | | 1.000 | |

Table 4. — *Silicone concentration.*

| | Group A | Group B | p |
|---|---|---|---|
| Whole blood | 83.0 ± 41.50 | 80.9 ± 35.25 | 0.881 |
| Maternal milk | 51.1 ± 22.91 | 51.1 ± 18.60 | 0.998 |

Table 5. — *One-way analysis of variance of silicone concentrations in the blood.*

| Variation source | Degrees of freedom | Variance |
|---|---|---|
| Between groups | 1 | 33.07 |
| Within groups | 28 | 1482.41 |
| Total | 29 | |
| p | 0.882 | |
| F | 0.02 | |

Table 6. — *One-way analysis of variance of silicone concentrations in the milk.*

| Variation source | Degrees of freedom | Variance |
|---|---|---|
| Between groups | 1 | 0.00 |
| Whitin groups | 28 | 435.41 |
| Total | 29 | |
| p | 1.000 | |
| F | 0.02 | |

icone concentrations in the whole maternal blood and milk are reported in Table 4; to compare and establish the significance level we performed one-way analysis of variance (Tables 5 and 6).

Silicone in maternal blood was more concentrated in patients in Group A, but the difference was not statistically significant. Silicone concentrations in the maternal milk of both groups were superimposable. Thus no correlation between mammary implants and silicone values in the milk were found.

Evaluation of the concentration of inflammatory proteins in newborn blood was performed both at the start and end of breastfeeding.The results were compared by the Student's t-test (Tables 7 and 8).

Antibody rates were studied in the newborns of both groups in the same mode as the other tests and the statistical significance was evaluated by the chi-square test (Tables 9 and 10).

Table 7. — *Comparison between concentration of inflammatory proteins in newborns at the start and end of breastfeeding.*

| | T test | p |
|---|---|---|
| ESR start | –0.386 | 0.702 |
| ESR end | 0.288 | 0.776 |
| CRP start | 0.000 | 1.000 |
| CRP end | –0.078 | 0.938 |
| RF start | –0.130 | 0.897 |
| RF end | –0.091 | 0.928 |

ESR: erythrocyte sedimentation rate; C-RP: C-reactive protein; RF: rheumatoid factor.

Table 8. — *Comparison between blood silicone concentrations in newborns at the start and end of breastfeeding.*

| Hematic silicone concentration | T-test | p |
|---|---|---|
| Start | 0.417 | 0.680 |
| End | 1.321 | 0.197 |

## Discussion

Silicon (Si) is one of the most common elements on the earth crust and traces can be found in food, make-up, drugs, clothes and also in the hair of some people [10, 14-18].

Numerous compounds in nature have a basis of Si but only the crystalline form has been able to define the pathogenesis because it is the cause of lung fibrosis and pleural mesothelioma [10, 14-18].

The organic form of Si, like silicone, is used to prepare prosthetic implants used in medicine [19].

Controversies on the safety of mammary implants made of silicone gel have been ongoing since 1980. Numerous case reports on patients with immune pathology were considered to be a consequence of augmentation mammoplasty. Conseguently the FDA forbid the sale of silicone gel breast prostheses in February 1992 [1-6, 20].

In that period augmentation mammoplasty by silicone gel implants had been reserved only for patients undergoing mastectomy or volunteers enlisted in experimental trials [15-18].

This phenomenon brought about the start of numerous studies that affirmed or negated the relation between local and/or systemic illness and silicone gel prostheses.

Today exactly how silicone interacts with biologic tissues is not completely understood and how it acts as a trigger for immune pathology is even less understood [20, 21].

All prostheses, independent from the other substances added to silicone, induce a fibrous reaction in periprosthetic tissue thus indicating non tolerability to the silicone [15, 16, 22, 23].

Cases of lymph-node biopsies reported in the literature show that the presence of silicone depends on the phagocytosis process of silicone molecules by macrophages and the successive transport of the material to the lymphatics [20, 24-26].

Silicone captured by the macrophages could derive from premature prosthetic failure to the capsule formation or bleeding of the gel through the prosthesis envelope [16, 17, 27-29].

The aim of our study was to attempt to define the relation between silicone gel filled implants and the onset of immune pathology in carriers as well as their offspring.

Our results are in accordance with those found in the literature. Investigation of hematochemical and antibody markers, while helpful in the diagnosis of immune pathology, does not put in evidence any particular cause-effect relation and it is absolutely non specific for other clinical implications [4, 8, 31]. The same result was observed in the analysis of newborn antibody rates in Group A which did not have statistical significance in any test.

As for silicone concentrations in maternal whole blood we observed higher values in patients with prostheses. However this difference did not appear to be due to the silicone gel. Instead silicone concentrations in maternal milk and in the blood of newborns were the same in all groups suggesting a different mode of contamination.

Critical analyses of our cases are in agreement with the international literature [11, 13, 30-32].

Silicone is surely not the ideal material, but today it appears to be the best synthetic product available to plastic surgeons and for the safety of female recipients and their offspring.

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