Breast-Feeding and Silicone Implants

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Background: Despite the overwhelming advantages of breast-feeding, there is a persistent concern that maternal exposure to chemical contaminants may result in contamination of breast milk and have an effect on the child's growth and development. A parallel concern regarding lactation in women with silicone implants over the past years has led to confusion and anxiety relating to the potential risks to the child.
Methods: The author reviewed the facts and issues as he knows them, including biomaterials, lactation toxicology, and a previous study where no difference was found in silicon (a proxy measurement of silicone) in women breast-feeding with silicone implants and those without.
Results: In the author's previous study, he compared women with implants to women without implants as controls and showed that mean silicon levels were not significantly different in breast milk (55.45 ± 35 and 51.05 ± 31 ng/ml, respectively) or in blood (79.29 ± 87 and 103.76 ± 112 ng/ml, respectively). However, silicon levels in alternative methods of infant nutrition were much higher. The mean silicon level measured in store-bought cow's milk was 708.94 ng/ml, whereas that for 26 brands of commercially available infant formula was 4402.5 ng/ml.
Conclusions: In this review, the author looked only at silicon/silicone and did not address other potential contaminants that may be associated with silicone gel or the elastomer shell. This report may provide plastic surgeons and other healthcare workers with information regarding silicon/silicone for discussion with women with gel implants who are contemplating breast-feeding. (*Plast. Reconstr. Surg.* 120 (Suppl. 1): 123S, 2007.)

It is estimated that millions of women worldwide have received silicone breast implants either for aesthetic reasons or as part of reconstructive surgery. Breast milk contamination with silicone or its breakdown products was one of the many issue raised at the U.S. Food and Drug Administration hearings on silicone gel–filled breast implants in 1992, but no data were presented.[1] Concerns were raised regarding the health of children of women with implants, especially those who were breast-fed. This question about silicone in breast milk arises because of the possibility of "silicone bleed" or rupture of the silicone implant. Silicone bleed from implants into periprosthetic tissue and silicone migration to more distant sites including regional lymphoid tissue are known to occur.[2–7] However, little is known of the silicone transport mechanisms or the modes of silicone breakdown.[8]

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In cases where the implant ruptures and releases silicone gel, the problem is magnified. A silicone-type substance has been detected in lactiferous breast ducts in nonlactating women who were found subsequently to have ruptured implants. Chemical identification of silicone, however, was not performed in these case reports.[9–12]

A published report has suggested that mother-to-child transfer of silicone or immune complexes in breast milk may cause childhood "rheumatoid symptoms" or "scleroderma-like" abnormal esophageal motility.[13,14] No attempt was made to identify silicone or immune complexes in the breast milk in these studies.

Breast-feeding is known to possess nutritional and immunologic properties superior to those found in infant formulas.[15,16] Breast-feeding seems to be particularly protective against some of the

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common childhood conditions such as eczema, otitis media, and iron-deficiency anemia, and is beneficial to neurodevelopment in premature infants. Also, there are substantial health benefits of breast-feeding for the mother and possibly for the whole family.[17]

Mothers with silicone implants may decide not to breast-feed because of the suspected risk of breast milk contamination.[18] The alternative source of nutrition for these infants is a variety of commercially available formulas. It is well known that there are sources of silicone in the everyday diet, including its use as an antifoaming agent in fruit juices and other types of food. Infants have been given silicone drops for colic for many years, with no identifiable problems [Mylicon drops (Merck Consumer Pharmaceutical, Ft. Washington, Pa.), used in the United States, have 67 mg of polydimethylsiloxane per milliliter and Miniform, as used in Europe, has 94 mg of polydimethylsiloxane per milliliter].[19]

BREAST MILK AND CHEMICAL CONTAMINATION

Human breast milk is a suspension of fat and protein in a carbohydrate/mineral solution. The nursing mother easily makes 600 cc of milk per day containing sufficient protein, fat, and carbohydrate to meet the nutritional demands of the developing infant. Bulk proteins are fully synthesized from substrate delivered from the maternal circulation. Major proteins are casein and lactalbumin. The role of these proteins in the delivery of chemicals into milk has not yet been completely elucidated. Chemical or contaminate excretion into milk may be accomplished by binding to the proteins or onto the surface of the milk fat globule.

There also exists the possibility of chemical binding to the lipid and to the protein components of the milk fat globule. It is also possible that lipid-soluble drugs may be sequestered within the fat globule. In addition to lipids and protein, carbohydrate is synthesized entirely within the breast. All of these nutrients achieve a concentration in human milk that is sufficient for the needs of the human infant for the first 6 months of life.

The transport of chemicals into the breast milk from maternal tissue and plasma may proceed by a number of different routes. In general, the mechanism that determines the concentration of chemical or drug in breast milk is similar to that existing elsewhere within the body. Drugs traverse membranes primarily by passive diffusion, and the concentration achieved will be dependent not only on the concentration gradient but also on the intrinsic lipid solubility of the drug or chemical and its degree of ionization and binding to the protein and other cellular constituents.[20,21] The pharmacokinetics of drug transmission into breast milk is dependent on plasma concentrations, often resulting in a ratio of plasma versus breast milk concentrations. The mechanism by which a large molecule such as polydimethylsiloxane in the interstitial space would make its way into the thick-walled ducts in the breast is not clear. The oncotic pressure within the ducts during lactation must be extremely high, and therefore the transport of such a large molecule as silicone against this gradient seems unlikely. The other possible mechanism would be that of circulating plasma levels of silicone in the maternal circulation acting as a mechanism of transport into breast milk.

Full lactation does not begin until 2 or 3 days after birth. A small amount of colostrum is secreted. The composition of colostrum is very different from that of mature breast milk. This is very high in proteins and very low in fat content. The production of colostrum and the possible concentration of chemical contaminants are not well known.

Mature milk also has a different composition even during one feeding session. The initial milk, which is secreted at the beginning of a "feed," is very dilute and has a very low fat content. At the end of the feed, the milk is then drawn from the more distal part of the duct system to the lactiferous sinuses, where it is a much more viscous fluid and very high in fat content. Because of the variation in milk composition from the beginning of the feed to the end of the feed, milk samples would have to be tested at the beginning and also well into the feeding session.

BREAST IMPLANTS IN THE LACTATING BREAST

The proximity of an implant to the milk-producing ducts in a lactating breast is also an issue. One mechanism for the transference of silicone to breast milk is the immediate proximity of the interstitial leaching into the duct network. Many breast implants will be found underneath the pectoralis muscle, which would likely preclude any contiguous relationship between silicone gel and the breast milk produced. Also, a thick capsule surrounding an implant would provide an extra barrier for the leakage of free silicone into the breast parenchyma.

The physiologic effects of the lactating breast on a given silicone implant are not well known or understood. Increased temperature, increased blood flow, and the mechanical and hydraulic ma-

nipulation of a hungry infant may play a role in the environment within and around the prosthesis.

Although migration of silicone to lymph nodes and other remote sites has been demonstrated, there is little quantitative information on rates of migration, local concentrations, or related sequelae. The biodegradation of silicone materials is controversial and the form of the silicon or silicone by-products is not known.

INFANT

A factor that has received relatively little attention, in drug interactions, is the infant. There are very few data on whether the infant can absorb chemicals from the intestinal tract. A drug given to an infant must be evaluated according to the infant's ability to detoxify or conjugate the chemical in the liver and/or excrete in the urine or stool.[21] Some compounds that appear in breast milk in very low levels are not well excreted by the infant and therefore accumulate in the infant's system to the point of toxicity. It is unclear—if silicone is introduced into the infant intestine—whether or not absorption will occur.[22–24]

BIOMATERIAL ASPECTS OF COMPONENTS OF GEL IMPLANTS

Silicone Oil

The available biological evidence confirms that liquid polydimethylsiloxane polymers are chemically inactive but may have some biological reaction. They may induce a fibrotic reaction in proportion to the amount dispersed in the tissues.[25–27] Silicone granulomas may form around these droplets. There is little information on the cellular mechanisms involved in the possible biological degradation and excretion of the silicone oil.

Silicone Gel

Newer generation cohesive gel implants have a higher cross-linked gel. In the older generation of implants, the tissue response to silicone gel appears similar to liquid silicone. The coherence and viscosity of the gel may localize an extravasation following rupture and may slow down the migration of the fluid component. Larger amounts of gel may become incorporated in the fibrotic tissue.[28] Calcification also may be associated with the presence of silicone gel in the tissues.[29]

Silicone Elastomer

It appears to be generally agreed on that in both animal and human studies only a mild inflammatory response occurs around solid implants or around the elastomer with the formation of a smooth-surfaced fibrous capsule.[30] Fatigue fracture in joint or tendon silicone prostheses may lead to particalization, which may result in some increased fibrosis and cellular reaction.[31–33]

ANALYTIC STUDIES

Currently, there is no satisfactory method for analysis of silicones. The best analysis for silicon content is usually performed using atomic emission or absorption spectroscopy.[34–38] Although this measurement includes related compounds, it is considered a reliable estimation of silicon.[39]

Silicon is the second most abundant element in the earth's crust, constituting approximately 28 percent by weight (oxygen is the most common at 47 percent[40]). Certain foods and beverages, notably vegetables, grains, rice, and beer, have been shown to contain significant levels of silicon.[41] A geographic variation in the silicon content of tap water has also been reported.[42,43]

In humans, silicon is found in significant concentration in hair, bone, epidermis, and dental enamel.[40] Silicon is considered an essential element in humans, although its physiology remains obscure. Currently, little information is available on the significance of elevated levels of silicon in human tissues.[44,45]

Silicone is a polymer, 40 percent silicon by weight, and is used in many prostheses, medical devices, and pharmaceutical products.[45,46] A recent study[46] revealed that there was no significant difference in the levels of silicone in breast milk and blood between two groups of women. One group of women was breast-feeding with silicone implants, whereas the group breast-feeding without silicone implants acted as a control group (Table 1). There was no association between silicon levels and age of the implants or duration of lactation. Perhaps one of the most interesting findings in this study was that silicon levels measured in samples of cow's milk and infant formula were higher than those found in any of the study groups, including breast milk from women with implants (Table 2).[46] Because the reliable determination of silicone levels in human body fluids with available technology is not feasible, the alternative is the precise measurement of elemental silicon. Both furnace atomic absorption spectroscopy and inductively coupled plasma–atomic emission spectroscopy[36,37] have been used to measure silicon in biological fluids, including human blood and breast milk. Although furnace atomic absorption spectroscopy also measures related

Table 1. Comparison of Lactating Women with and without Implants*

	Implanted Women		Control Women		
	No.	Mean ± SD	No.	Mean ± SD	*p*†
Foremilk silicon‡	15	53.50 ± 36.93	34	52.20 ± 35.88	0.9084
Hindmilk silicon	15	57.39 ± 44.91	33	53.13 ± 38.59	0.7377
Combined breast milk	15	55.45 ± 35.81	34	51.05 ± 31.02	0.6643
Blood silicon	13	79.29 ± 87.84	23	103.76 ± 112.12	0.5031
Age, years	14	34.21 ± 4.08	34	32.90 ± 3.95	0.3089
Duration of lactation, weeks	14	23.85 ± 21.55	34	14.88 ± 11.03	0.1584

*From Semple, J. L., Lugowski, S. J., Baines, C. J., Smith, D. C., and McHugh, A. Breast milk contamination and silicone implants: Preliminary results using silicon as a proxy measurement for silicone. *Plast. Reconstr. Surg.* 102: 528, 1998.
†*t* test.
‡Silicon is expressed as nanograms per milliliter (parts per billion).

Table 2. Silicon Levels in Infant Formula*

Brand	Silicon Levels (ng/ml)
A	2755.0
B	3639.0
C	1389.0
D	5333.0
E	2867.0
F	911.0
G	12,680.0
H	13,811.0
I	1603.0
J	875.0
K	6344.0
L	6265.0
M	4985.0†
N	13,796.0†
O	5721.0†
P	7376.0†
Q	746.0
R	915.0
S	1077.0
T	3287.0
U	2156.0
V	6072.0
W	2208.0
X	5663.0
Y	790.0
Z	1201.0

*From Semple, J. L., Lugowski, S. J., Baines, C. J., Smith, D. C., and McHugh, A. Breast milk contamination and silicone implants: Preliminary results using silicon as a proxy measurement for silicone. *Plast. Reconstr. Surg.* 102: 528, 1998.
†Soya based.

compounds such as silica and silicates, it offers a reliable estimate of silicone levels.[39,45] An increased burden of silicone is reflected in higher elemental silicon levels. Comparing implanted women with controls, mean silicon levels were not significantly different in breast milk [55.45 ± 35 and 51.05 ± 31 ng/ml (parts per billion), respectively] or in blood (79.29 ± 87 and 103.76 ± 112 ng/ml, respectively). Mean silicon level measured in store-bought cow's milk was 708.94 ng/ml, and that for 26 brands of commercially available infant formula was 4402.5 ng/ml.

DISCUSSION

Breast-feeding is known to possess nutritional and immunologic properties superior to those found in infant formulas. Breast-feeding seems to be particularly protective against some of the common childhood conditions such as eczema, otitis media, and iron-deficiency anemia and is beneficial for neurodevelopment in premature infants. Also, there are substantial health benefits of breast-feeding to the mother and possibly to the whole family.[23]

The potential for contamination of breast milk because of maternal exposure to drugs and chemicals has been well documented. In 1991, considerable controversy surrounded a report that summarized the rapidly accumulating scientific literature on the effects of chemical contaminates in women and their breast milk on a child's growth and development.[15–17] There have been parallel concerns regarding lactation in women with silicone implants that has led to confusion and anxiety related to the potential risks to the child.[14,19]

Despite the overwhelming advantages of breast-feeding, there is growing concern that maternal exposure to chemical contaminants may result in contamination of breast milk and have an effect on the child's growth and development.[47,48] A parallel concern regarding lactation in women with silicone implants has led to confusion and anxiety relating to the potential risks to the child.[13,14] Unfortunately, pediatricians and primary care workers have little evidence with which to properly advise mothers with silicone implants who wish to breast-feed. The Internet acts as an extensive source of information on almost any topic. Healthcare Web pages, news pages, advocacy sites, and chat rooms are all available and provide both incorrect and correct information to viewers. It is very difficult for women to navigate through the different sites with the ability to discriminate that which is extreme from that which is reasonable.

CONCLUSIONS

Some of the aspects of breast-feeding with silicone implants are reviewed. The scope of this article is based on the findings from a previous study in which my colleagues and I investigated the presence of silicon/silicone in breast milk. Other types of potential sources of implant contamination, such as platinum, were not addressed in the previous study and therefore are not discussed in this article. The literature specific to breast-feeding and silicone implants is based entirely on data from older generation implants (before 1992). There are no data regarding newer implants with improved elastomer envelopes or cohesive gel. However, my previous study indicated that there was no significant difference in silicon levels comparing breast milk from women with and without silicone implants.

Few devices or drugs have come under such intense scrutiny by the U.S. Food and Drug Administration as silicone implants with regard to comprehensive safety. This report may provide plastic surgeons and other healthcare workers with information for discussion with women with silicone implants who are contemplating breast-feeding and help to enable such women to make informed decisions.

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