Cohort Study to Assess the Impact of Breast Implants on Breastfeeding

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Background: The objective of this study was to evaluate the impact of breast implant surgery and its approaches on lactation by comparing women with and without breast implants at the time of childbirth.

Methods: Between April of 2013 and July of 2014, in Rosario (Sanatorio de la Mujer and Centro Quirúrgico Rosario), Argentina, a prospective cohort study of women with and without breast implants was performed. Of a total of 3950 births that occurred during this period, 200 patients with similar anthropometric characteristics (maternal and newborn) were selected. Breastfeeding (exclusive or mixed) was compared with artificial feeding at 24 and 48 hours and 30 days in both groups, and the type of incision was also compared.

Results: Breastfeeding at 30 days showed a nonsignificant trend favoring the control group (OR, 7.39; 95 percent CI, 0.92 to 339.2). The percentage of women with implants who succeeded in establishing breastfeeding (exclusive or mixed) was very high (93 percent). In the control group, 99 percent of the women were breastfeeding at 30 days. In a comparison of the submammary and areola incision, breastfeeding showed odds ratios of 0.78 (95 percent CI, 0.33 to 1.87) at 24 hours, 1.10 (95 percent CI, 0.48 to 2.56) at 48 hours, and 0.18 (95 percent CI, 0.36 to 1.82) at 30 days.

Conclusions: This study shows that most patients with breast implants were able to establish breastfeeding. However, there is a higher number of women without implants that established exclusive breastfeeding. No significant difference was found between the different surgical approaches. (*Plast. Reconstr. Surg.* 138: 1152, 2016.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, II.

The exponential increase in the number of breast implant cosmetic operations worldwide in recent years is indisputable. In Argentina, according to the International Society of Aesthetic Plastic Surgery international survey on aesthetic/cosmetic procedures performed in 2013, breast implant placement is the most commonly performed plastic surgery procedure.[1] It should also be noted that the age range for this procedure has expanded, and many young and multiparous women undergo this type of procedure. The belief that pregnancy and lactation affect the aesthetics of the breasts influences the current cultural and working trend of delaying the age of first pregnancy.[2]

Therefore, a wide range of women likely to become pregnant consult plastic surgeons regarding the influence that the presence of breast implants and the approach to their placement could have on subsequent lactation. Some studies have suggested that breast cosmetic surgery reduction or implants interferes with lactation, either because of alteration in the innervation of the nipple-areola complex with the subsequent loss of the ejection reflex and a decrease in milk production or because of surgical section of the galactophorous ducts.[3–7]

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Breastfeeding is a vital function, with numerous psychological, physiologic, anatomical, social, and cultural factors. Breast milk is an optimal and complete food for newborns up to 6 months of age, not only because of the nutrients that it provides but also because of the antibodies transmitted by the mother and the affective bond created between the mother and child, which promotes sensory and cognitive development, in addition to protecting the infant against infectious and chronic diseases, according to the World Health Organization.[8]

The objective of this work was to demonstrate whether silicone gel breast implant cosmetic surgery influences breastfeeding in comparison with women without breast implants. Similarly, this work sought to analyze the influence of different surgical approaches (submammary versus those involving the nipple-areola complex) on lactation.

PATIENTS AND METHODS

Between April of 2013 and July of 2014, a prospective cohort study was conducted, performed by the plastic surgery services of the Sanatorio de la Mujer and the Centro Quirúrgico Rosario in collaboration with the Obstetrics and Childcare Services at the same hospital in the city of Rosario, Argentina. From a total of 3950 births that occurred in this hospital during that period, 210 women who met the inclusion criteria were evaluated and selected for this study and signed a written consent for participation. Of all the patients analyzed, 105 patients had, at the moment of hospitalization for child delivery, a history of breast implant surgery without previous abnormality or other associated breast surgery, and they formed the study group. It is worth mentioning that patients included in the study were not operated on by the authors of this study, as these women were patients of the obstetrics and childcare departments of the Sanatorio de la Mujer. Moreover, not all of them kept the identification cards of the implants from the manufacturer, and therefore it was impossible to present this information accurately.

The 105 women included in the control group were hospitalized in the same period as the study group. These women were chosen for similar anthropomorphic characteristics (both maternal and newborn), with no previous breast implants or

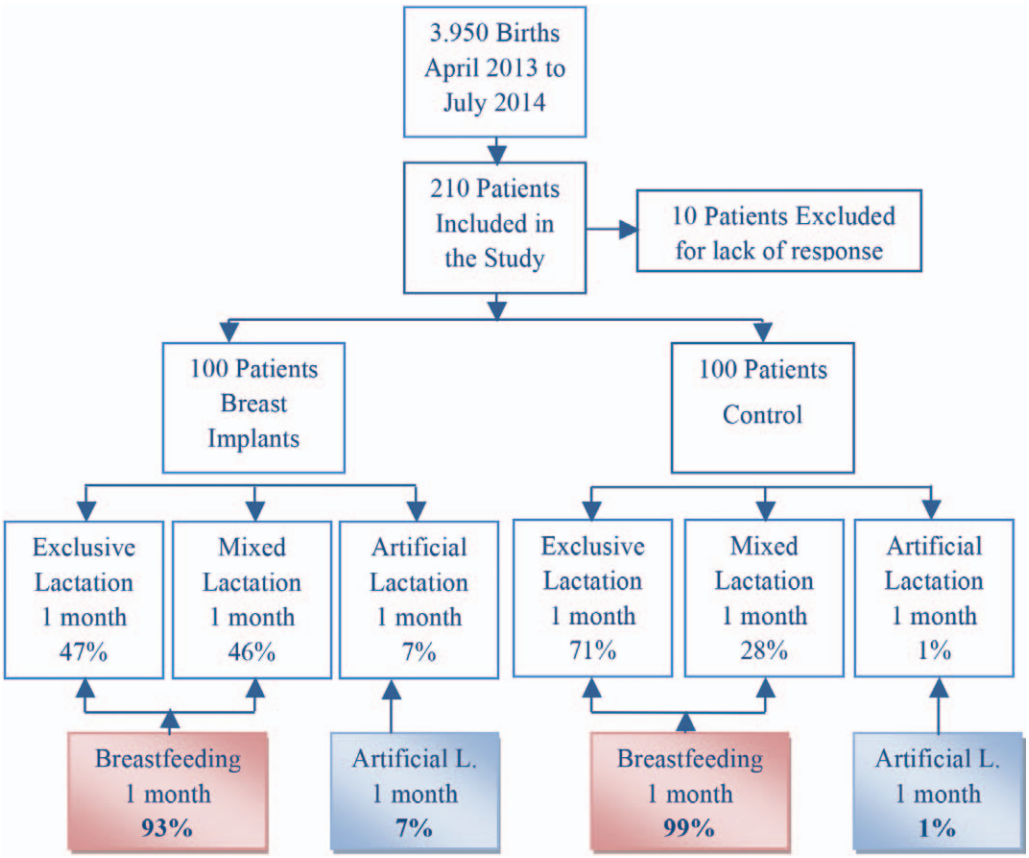

Fig. 1. Flow diagram. *L.*, lactation.

breast operations. In addition, similar birth dates, gestational age, weight, and modes of completion of the pregnancy were considered (Fig. 1).

No particular incentive was used to promote greater adherence of patients included in the study. The evaluation forms were designed exclusively for this study. The age, number of previous pregnancies, mode of delivery (i.e., vaginal or cesarean delivery), gestational age, weight of the child (i.e., at birth, 48 hours, and 30 days), type of lactation (i.e., exclusive breastfeeding, breast milk only; mixed lactation, breast milk supplemented with infant formula; and artificial lactation, infant formula only), type of incision for implant placement (i.e., submammary, periareolar, or transareolar), placement plane (i.e., subglandular, subfascial, or partially retromuscular), and implant volume were recorded for each patient. Records of the time from implant placement to pregnancy and breast feeding were inaccurate and therefore are not presented. The telephone numbers for the patient and family were recorded for contact at 48 hours and 30 days. All data were recorded in a Windows Excel (Microsoft Corp., Redmond, Wash.) spreadsheet (Fig. 2).

In the institution where the study was conducted, it is routine for nursing personnel of the childcare service to provide advice, information, and monitoring of the process and techniques of breastfeeding. Specialized nurses performed data collection during the first 24 hours of the hospitalization period. The data at 48 hours and 30 days were collected by means of phone calls made by physicians of the plastic surgery service.

The inclusion criteria for the breast implant group consisted of women with implant surgery whose children were born at term with adequate weight for their gestational age and without neonatal morbidity. The exclusion criteria consisted of women with a history of difficult lactation before the implant surgery. Difficult lactation is understood to be the sum of factors that could influence negatively the production of milk, such as physical, psychological, drug-related, and occupational. Patients with inverted nipples were excluded because that retraction and fibrosis might result in a decrease in breastfeeding.[9] Other factors of exclusion were patients with mastitis, tumors, and postoperative complications of implants (i.e., hematoma, seroma, infection, implant replacement, or capsular contracture), and any other type of surgery or previous mammary abnormality. Such factors were not recorded.

Because it was a cohort study, the decision was made not to explore variables that are either difficult to measure or very subjective, because they could lead to spurious conclusions. Therefore, qualitative variables such as breastfeeding desire or willingness or maternal request for cesarean delivery were not explored. Exclusion criteria for the control group were the following: women with a history of difficult breastfeeding in previous pregnancies, inverted nipple, mastitis, tumors and any other type of mammary abnormality, and previous mammary operations.

According to the World Health Organization, breastfeeding is an unequalled way of providing ideal food for the healthy growth and development of infants; it is also an integral part of the reproductive process with important implications for the health of mothers. "Predominant breastfeeding" means that the infant's predominant source of nourishment has been breast milk (including milk expressed or from a wet nurse as the predominant source of nourishment).[10] However, the infant may also have received liquids (water and water-based drinks, fruit juice); ritual fluids; and oral rehydration salts, drops, or syrups (vitamins, minerals, and medicines). "Exclusive breastfeeding" is defined as no other food or drink, not even water, except breast milk (including milk expressed or from a wet nurse) for 6 months of life, but allows the infant to receive

Data collection.

Mother's Name	Baby's Name	Birth Date	Mother's Age	Newborn's Weight	Gestational Age	Parturition Caesarean	Children Pregnancies
Implant Approach	Implant Pocket	Implant Volume	Weight 24h, 48 h, 1 month	Lactation 24 hours	Lactation 48 hours	Lactation 1 month	Telephone Number

Fig. 2. Data collection.

oral rehydration salts, drops, and syrups (vitamins, minerals, and medicines).[11] The volume of milk must be sufficient to maintain adequate growth of the newborn in accordance with usual pediatric evaluations.[3]

For the purposes of this study, we have defined partial breastfeeding or lactation as breastfeeding adding infant formula in different proportions. In 1990, Labbok and Krasovec classified lactation as complete, partial, or symbolic, and within partial lactation, subgroups of high, medium, or low were classified when the baby was breastfed over 80 percent, between 20 and 80 percent, or less than 20 percent of the time, respectively.[12] In all patients, the type of feeding and the progression of infant weight at 24 hours, 48 hours, and 30 days were evaluated.

The primary outcome measure considered for the study was patients with and without breast implants who breastfed (exclusively or partially) at 30 days. The last obstetric postpartum visit at the study settings is at 1 month after delivery. Thus, that moment was considered the best time to collect reliable data for the evaluation of the outcome measure.

The secondary outcome measures considered were patients with and without implants with exclusive lactation at 24 hours, 48 hours, and 30 days. Finally, we conducted a subgroup analysis according to the approach for the placement of the implants [submammary versus those involving the areola (periareolar or transareolar)] at 24 hours, 48 hours, and 30 days.

The incidence of the primary outcome (breastfeeding 30 days after delivery) was thought to be in the region of 90 percent at the recruiting hospital (Centro Quirúrgico Rosario). However, based on previous studies and expert opinions, it was estimated to be in the implant group in approximately 80 percent and in the control group in approximately 95 percent. These data indicated that the sample size needed to detect meaningful differences and allowing a margin for errors in estimation of outcome rates will be approximately 200 women.[13]

Assessment of the association of the risk factor with each outcome was performed. The outcome measures evaluated were all presented as categorical variables and were described using percentages. Statistical analysis calculated the risk of an outcome occurring in each group compared with the risk in the comparison. Results were expressed as odds ratio values with 95 percent confidence intervals with 80 percent power. Statistical analysis was carried out using free online software (Open Epi Software; Dean AG, Sullivan KM, Soe MM. OpenEpi: Open Source Epidemiologic Statistics for Public Health).

RESULTS

The average ages of the group of women with implants and the control group were 33 years (range, 19 to 42 years) and 32 years (range, 22 to 44 years), respectively. Both groups had the same number of vaginal births and cesarean deliveries (54 and 46, respectively), as this variable was used for selection of women in the control group. In the group of patients with implants, 57 women were primiparous and 43 women were multiparous. The control group included 49 primiparous and 51 multiparous women. The gestational age of the group of patients with implants was similar to that of the control group (average, 38.8 weeks; range, 37 to 41 weeks). The mean birth weight was similar for the two groups, 3206 g for the group with implants and 3229 g for the control group (Table 1).

Of the 210 selected patients, five patients who did not respond to phone calls were excluded from the final analysis of the study group; therefore, five similar patients were excluded from the control group (Fig. 1). Of the 100 women with breast implants, the incision was submammary in 59 cases, and the remaining 41 incisions were areolar (periareolar and transareolar). The mean implant volume was 300 cc (range, 240 to 450 cc) (Table 2).

For the primary outcome measure (breastfeeding at 30 days), a nonsignificant trend favoring the control group was observed (OR, 7.39; 95 percent CI, 0.92 to 339.2) (Table 3). It is noteworthy that the percentage of women with implants who succeeded in establishing breastfeeding

Table 1. Characteristics of Patients Studied and Control Patients

Characteristic	Patients Who Underwent Augmentation Mastoplasty	Patients Who Did Not Undergo Surgery
No.	100	100
Maternal age, yr		
Mean	32.98	31.82
Range	19–42	22–44
Type of birth		
Parturition	54	54
Cesarean	46	46
Parity		
Primiparous	57	49
Multiparous	43	51
Gestational age, wk		
Mean	38.80	38.86
Range	37–41	37–41
Birth weight, g		
Mean	3206.52	3229.42
Range	2370–4110	2490–4100

Table 2. Surgical Characteristics

Characteristic	Patients with Augmentation Mastoplasty
No. of patients	100
Incision	
Submammary	59
Areolar	41
Implant placement plane	
Subglandular	21
Subfascial	26
Complete submuscular	42
Unknown	11
Implant volume, cc	
Mean	300
Range	200–450

Table 3. Primary Result: Breastfeeding (Exclusive and Mixed) at 30 Days

	Implants	No Implants	OR (95% CI)
No. of patients	100	100	
Lactation at 30 days	93	93	7.39 (0.92–339.2)

Table 4. Secondary Results: Exclusive Lactation at 24 and 48 Hours and 30 Days

	Implants	No Implants	OR (95% CI)
No. of patients	100	100	
Lactation at 24 hr	69	90	4.02 (1.87–9.13)
Lactation at 48 hr	62	83	2.98 (1.55–5.87)
Lactation at 30 days	47	71	2.75 (1.54–4.98)

Table 5. Analysis of Subgroups: Exclusive Lactation According to Surgical Approach

	Submammary	Areolar	OR (95% CI)
No.	59	41	
Lactation at 24 hours	42	27	0.78 (0.33–1.87)
Lactation at 48 hours	36	26	1.10 (0.48–2.56)
Lactation at 30 days	29	18	0.81 (0.36–1.82)

(either exclusive or mixed) was very high (93 percent). Only seven of the 100 women included in the group with implants did not continue breastfeeding at 30 days. By comparison, in the control group, 99 percent of the women were breastfeeding (exclusive or mixed) at 30 days, and only 1 percent were using artificial feeding (Fig. 1).

For the secondary outcome measure (exclusive breastfeeding at 30 days), we found a statistically significant difference favoring the control group (without breast implants) (OR, 2.75, 95 percent CI, 1.54 to 4.98). Similar differences were observed when exclusive breastfeeding was assessed at 24 hours, where statistical significance was achieved in favor of the control group (OR, 4.02; 95 percent CI, 1.87 to 9.13), and at 48 hours (OR, 2.98; 95 percent CI, 1.55 to 5.87) (Table 4).

We found no significant differences in any of the outcome measures in patients with breast implants when the various approaches were compared. The difference between the submammary and areolar approaches regarding breastfeeding showed an OR of 0.78 (95 percent CI, 0.33 to 1.87) at 24 hours, an OR of 1.10 (95 percent CI, 0.48 to 2.56) at 48 hours, and an OR of 0.18 (95 percent CI, 0.36 to 1.82) at 30 days (Table 5).

DISCUSSION

Lactation after breast implant surgery is cause for great concern and extensive debate in both the scientific community and among pregnant women. Breastfeeding provides an optimal and complete food source for the newborns, as it provides the essential nutrients for growth, increases immunity to certain diseases, and stimulates an affective bond. Failure in achieving breastfeeding (either exclusive or mixed) can cause neonatal malnutrition, resulting in alterations in psychomotor development, in addition to psychological, affective, and social disturbances.[14]

The principal objective of our study was to evaluate the incidence of breastfeeding at 30 days in women with breast implants compared to women without implants. The results of this study showed that most patients with breast implants (93 percent) were able to establish breastfeeding in either an exclusive or a mixed manner. Compared to the control group without implants of whom 99 percent breastfeed, the incidence of breastfeeding was decreased by only 6 percent in the women with implants.

From the data published by studies conducted after 2000, included in the Cochrane database, approximately 90 percent of women successfully breastfed until postpartum week 8. Therefore, we assume that the percentage (99 percent) in our population compared with the general population will be higher for two reasons: first, our outcome was limited to 30 days after delivery and not 8 weeks and thus higher compliance with breastfeeding; and second, a 24-hour service dedicated to facilitating, teaching, and advising on breastfeeding was in place before the study began at our recruiting hospital.[15–17]

This study demonstrated that a large percentage of patients with implants naturally provide the infant's nutritional and immunologic requirements by breastfeeding, even when some of these patients add other types of supplements. In the evaluation of exclusive breastfeeding at 30 days, a greater difference between the groups was found (Fig. 1). It is understood that medium or high partial lactation provides benefits similar to those of exclusive breastfeeding.

We conducted a literature review and did not find any other prospective studies with cohorts similar in their maternal, newborn, or mode of delivery characteristics, nor have we found other studies with a sample size similar to or larger than ours. A systematic review and meta-analysis by Schiff published in 2014 concluded that women with breast implants that breastfed were less likely to have exclusive lactation compared with those without implants. Schiff's study included only small cohort studies with heterogeneous populations.[18]

Despite these facts and conclusions, it should be taken into account that this is an observational study with a potential bias in the data collection (recall bias), which depended largely on the memory, or lack thereof, of the patients of several surgical characteristics, such as the type and size of the implant, which prevents a more accurate comparison of the groups. We must determine the causes for the possible reduction that exists in exclusive lactation in breast implant patients. We could consider various hypotheses, including factors such as anatomical, surgical, physiologic, and psychological characteristics.

Regarding the anatomical factors, we conducted a search of the literature regarding breast volume and its relationship to breastfeeding and found only a few articles relevant to this issue. However, none of them was conclusive. Some authors suggest that the majority of women with breast implants are patients with primary or secondary hypomastia with inadequate development of the mammary gland. Therefore, this insufficient gland, characterized by small size, may result in a reduction in milk production capacity (per se).[19] One of the articles stated that breast size increases during human pregnancy on average by 96 ml regardless of the initial breast volume. However, although breast volume increases during pregnancy, not all women's breasts respond to pregnancy in the same way.[20] Another author assessed the increase in breast tissue volume from before conception until 1 month of lactation and concluded that breast volume was maintained for the first 6 months of lactation, in relation to the period of exclusive breastfeeding, and 24-hour milk production from each breast remained relatively constant. They say that there could be a relationship between 24-hour milk production and the storage capacity of the breasts, and that these both appeared to be responding to infant demand for milk.[21] Nevertheless, other authors acknowledged that there is no relationship between the amount of glandular tissue in the breast and either the storage capacity of the breast or milk production.[22] It seems that breast size alone does not determine the quality and quantity of milk produced.[23] To address this factor, women with similar anatomical mammary characteristics in both comparison groups should be evaluated in future studies.

We know that milk production is under the direct influence of the sucking reflex and neuroendocrine stimuli. Different authors, such as Hamdi et al., consider the surgical factor directly responsible for damage to these nerve pathways and the consequent altered sensation.[24] The latter would be the result of the distention of the fourth intercostal nerve because of the size of the implant in relation to the patient's thoracic capacity, as demonstrated in the study by Pitanguy et al.[25,26] Direct factors related to the surgical procedure, such as the type of implant, incision site, and placement plane of the implant, can lead to complications in the short and long term, which would compromise the future ability to breastfeed, as in the study by Michalopoulos.[7] Mofid et al. state that large implants in a small thorax can produce parenchyma compression by excessive pressure of the implant, resulting in atrophy of the cell wall of the alveoli and diminished milk production.[27] The U.S. Food and Drug Administration referenced studies that found a loss of nipple sensation in 8 to 10 percent of women at 3 years after surgery and in 10 percent of women at 5 years.[28] In a review of 36 publications, Ducic et al. confirmed the possibility of nerve injury during breast implant surgery, regardless of the approach, placement plane, and implant size.[29] Furthermore, Banbury et al. demonstrated a significant decrease in sensitivity at 3 months postoperatively with saline retropectoral breast implants, but with a normalization of the sensitivity at 6 months.[30] Other theories suggest that damage to the glandular tissue by way of the periareolar or transglandular approach could be another factor that affects lactation by directly damaging the galactophorous ducts, resulting in diminished milk drainage, leading to an inhibition of milk production.[31]

Nonsurgical factors that can temporarily inhibit the milk ejection reflex include sudden spontaneous pain when nursing, nipple fissures and injuries, sucking difficulty of the baby, maternal exhaustion, sudden physical and psychological stimulation, and stress.[7] Among the psychological factors, a great concern of women with breast implants is their aesthetics and the perception of how breastfeeding will affect the appearance of the breasts, which could have a significant influence on their breastfeeding. Many women think that breastfeeding can ruin the aesthetic outcome of their surgery and decide to discontinue lactation early, according to Cruz's report.[32] In contrast, Rinker et al. did not find that breastfeeding is a risk factor for mammary ptosis but that pregnancy and the increase in breast size alter the aesthetics.[33] Therefore, the maternal intention to breastfeed is another factor to consider. This factor could have affected the outcome of our study because women with implants have concerns regarding breast aesthetics.

CONCLUSIONS

The results of our study demonstrate that most patients with breast implants (93 percent) managed to establish breastfeeding, either exclusively or in a mixed manner, within 30 days. The control group evinced that only 6 percent of the implant patients did not achieve adequate breastfeeding. We have shown that breast implants decreased breastfeeding slightly, and these women can provide their children with the necessary nutritional, psychological, affective, and immune support. Plastic surgeons must perform correct evaluation and planning of the surgical technique, including incision type, placement site, and volume of the implant. They should advise and inform patients who are considering breast implant surgery about all the variables that can influence breastfeeding so that they can make a decision based on scientific studies.

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