Evaluation of the Effects of Silicone Implants on the Breast Parenchyma

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Abstract
Background: Despite being the cosmetic procedure most performed worldwide, there are still few objective measurements of postoperative volumetric analysis of breast augmentation available in the literature.
Objective: The aim of this study was to evaluate volumetric changes in the breast parenchyma after the placement of silicone implants in the subglandular plane.
Methods: Thirty-four women were randomly allocated to the intervention group (n = 24), who underwent breast augmentation in the subglandular plane, or to the control group (n = 10), who received no intervention. Volumetric magnetic resonance imaging was performed at inclusion, and after 6 and 12 months in all participants. The non-parametric Friedman’s test was used for statistical analysis.
Results: There was a significant reduction in glandular volume (mean, 22%) at 12 months postoperatively in patients who underwent breast augmentation.
Conclusions: Breast augmentation caused reduction in the volume of the breast parenchyma.

Level of Evidence: 3

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Breast augmentation has evolved not only technically, but in the quality and diversity of implants, in order to address specific needs including different types and sizes of the chest. Variables such as type of incision, plane of insertion of the implant, and implant characteristics have previously been addressed in the literature. Much has been written about the ideal type of implant for each patient. However, the evaluations of the cosmetic surgical outcome performed by the surgeon and patient are subjective. There is a lack of objective measurements to analyze cosmetic surgical outcomes in the short and long-term.

There remains controversy over the best type of implant for breast augmentation as information on preoperative factors are inaccurate and subjective. Although plastic surgeons are concerned with preoperative anatomic factors, other factors may be more important to the outcome than the anatomical factors evaluated before surgery. Knowledge of potential changes in the breast after augmentation mammoplasty is not only useful in choosing the most suitable implant, but also for managing patient expectations.

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Patients have sought breast augmentation at younger ages and with increasing size of implants, leading to early changes in the breast parenchyma, and requiring increased prospects for long-term success. It is imperative that breast augmentation be performed based on well-established volumetric parameters and measures, allowing accurate assessment of asymmetries and volume changes. Therefore, the aim of this study was to evaluate changes in breast parenchyma after insertion of implants in the subglandular plane.

METHODS

This longitudinal, prospective, analytical, interventional, single-center, and randomized clinical trial was conducted between January 2012 and August 2014. The study was approved by a Research Ethics Committee (Brazil Platform System, approval number CAAE 14299213.2.0000.5259) and performed in accordance with the ethical standards of the 1964 Declaration of Helsinki and its subsequent amendments. Written informed consent was obtained from all patients previous to their inclusion in the study and anonymity was assured.

Thirty-four women who expressed a desire to undergo breast augmentation were selected from the plastic surgery outpatient clinic of a university hospital in Brazil. Inclusion criteria were that age ranged from 18 to 30 years, body mass index (BMI) was between 19 and 25 kg/m², and contraceptives were in use. Exclusion criteria were breast ptosis, family history of breast cancer, breast cancer, previous breast surgery, co-morbidities, regular use of medication except contraceptives, pregnancy, breastfeeding, history of obesity, and significant weight changes. Patients lost to follow-up were also excluded from the study.

The patients were randomly allocated to two groups using the Research Randomizer software. The intervention group (n = 24) underwent subglandular breast augmentation performed through an inframammary incision. Patients from the control group (n = 10) were not operated on. Both groups were followed up for at least 12 months.

Radiological Examination

The radiological examination was performed at a diagnostic center. All patients underwent magnetic resonance imaging (MRI) with a 1.5-T MRI unit (Siemens Vision, Erlangen, Germany), using a sagittal T1 fat-suppressed sequence. Volumetric analysis of breast parenchyma was performed using the AW Server 2.2 Workstation (GE Healthcare, Waukesha, WI) always by the same radiologist. This software performs the analysis through identification of the breast parenchyma boundaries in all the slices. Volumetric analyses were performed by adding up all the slices volumes in cm³.

Patients in the intervention group underwent MRI at three time points: preoperatively (baseline) and at 6 and 12 months after surgery. Similarly, controls underwent MRI at inclusion (baseline) and 6 and 12 months later. Volumetric measurements were necessarily performed between days 3 and 14 of the menstrual cycle; every patient underwent all three MRI on the same day of her menstrual cycle, calculated from the first day of contraceptive use.

All patients were weighed at every radiological examination so that weight changes were not a bias factor in volumetric analysis. Volumetric differences in the breast were calculated for the intervals 0 to 6 months, 6 to 12 months, and 0 to 12 months. Similarly, the breast volume to BMI ratio was calculated for the three time points, as well as their differences for the intervals 0 to 6 months, 6 to 12 months and 0 to 12 months. The percentage differences between the ratios (breast volume/BMI) and volumetric measurements for each time interval should be equal or very close, otherwise they were considered discordant and the patient was withdrawn from the study.

Surgical Procedure

Patients in the intervention group underwent breast augmentation and received a textured silicone implant with a round base, spherical profile, high projection, and with a volume ranging from 225 to 335 mL (model Maximum, Silimed, Rio de Janeiro, Brazil), inserted in the subglandular plane. For every patient, the implant volume was chosen based on breast measurements (base width and nipple-to-inframammary-fold distance) assessed according to the manufacturer’s instructions.

Statistical Analysis

The non-parametric Friedman’s test was used to compare preoperative glandular volume with those measured at 6 and 12 months postoperatively.

The GraphPad Prism version 5 for Windows (GraphPad Software, San Diego, California) was used for data analysis. All statistical tests were performed at a significance level α of 0.05 (P < .05).

RESULTS

Twenty-four patients underwent preoperative radiological examination and breast augmentation. One patient withdrew and twenty-three patients completed all phases of the study. All patients received high projection implants. Mean age in the intervention group was 23.7 years old (range, 18-30 years), and 22.4 years old in the control group (range, 18-26 years). Mean BMI in the intervention group
was 21.44 kg/m² (range, 19.3-24.8 kg/m²) and in the control group was 20.53 kg/m² (range, 19.5-21.8 kg/m²). Implant volumes ranged from 225 to 335 mL (mean, 273 mL). The mean operative time was 65.3 minutes. The patients were observed in the hospital for 24 hours. No major complications occurred; one patient developed a seroma that resolved spontaneously without the need for surgical intervention. No case of capsular contracture occurred by the end of 12 months. All patients in the control group underwent the three radiological examinations and were submitted to breast augmentation after they completed a year of analyses.

No significant differences in BMI and age were found between groups. MRI results revealed a volumetric reduction in breast parenchyma of 27% at 6 months after surgery ($P = .0002$) and a volume regain at 12 months, but still with a reduction of 22% of the initial volume ($P = .0008$) (Figures 1-3). There was a significant difference in parenchymal volume from baseline at 6 and 12 months postoperatively, but no significant difference was found between 6 and 12 months ($P = .1699$) (Figure 4).

No significant difference in breast volume was observed in the control group at the three time points ($P = .9685$) (Figure 5).

Postoperative follow-up time ranged from 12 to 18 months (mean, 15 months).

**DISCUSSION**

With the increasing number of breast augmentation procedures being performed, it is necessary to understand that the aesthetic results depend not only on the inherent characteristics of the implant, but also on morphological changes in the breast tissue associated with the use of implants. The increased volume of the breasts after augmentation mammoplasty is attributed to a biomechanical interaction between the implant and the breast. If, on the one hand, the implant leads to an increase in breast size, on the other hand, it exerts pressure on the mammary gland and chest wall causing morphological changes in the breast tissue.9

Since the beginning of the use of silicone implants, manufactures have been changing their designs. Changes have been made in implant shell, filling material, and shape to minimize risks, increase safety to patients, and ensure long-term aesthetic results.10 The first generations of silicone breast implants were associated with a high rate of capsular contracture. Today, postoperative changes in breast shape are the main focus of study. The most common questions are related to implant size and projection, vascular impairment that may occur postoperatively, and changes in the breast parenchyma caused by the implant.

Some authors11,12 have observed that the higher the projection of an implant, the higher is the pressure exerted on the overlying tissues, resulting in atrophy of the breast parenchyma, impaired lactation, sensory and vascular impairment, chest wall deformities, and aesthetic changes, including implant rippling, bottoming-out deformity, and loss of upper pole projection. However, no studies were found comparing breast volume before and after surgery, and determining volume reduction due to extrinsic compression. Some studies13-17 have described changes in breast contour caused by the use of silicone implants, but these are...
based on anthropometric parameters, for example nipple-to-inframammary-fold distance, increase in the upper pole projection, and changes in the anteroposterior projection. But little or no attention has been paid to changes in the glandular tissue caused by the pressure exerted by the implant on overlying tissues.

Fat-suppressed noncontrast MRI was effective in quantifying breast volume. MRI is an imaging technique that, with the aid of software, provides a detailed 3-dimensional (3D) volumetric analysis of the breast without involving radiation. It is not a dynamic examination, allowing data acquisition and later analysis of multiple sequences without the presence of the patient. MRI is a method of analysis that accurately differentiates the implant from breast tissue and provides the volumetric analysis of other organs and tissues. Its advantage over a 3D scanning technique is the accurate visualization of the posterior borders of the breast (between the breast and the chest wall) through axial slices. Although the 3D body scanning system is a fast and comfortable examination for the patient, it only scans the breast surface. Liu et al demonstrated the influence of respiration on measurement of breast volumetric change.

CT and mammography are examinations that use radiation and would therefore not be the best choices for repeated examinations. The 3D scan is a very good examination technique for evaluating breast surface, but is a new method and there some issues remain to be resolved (including the facts that it does not evaluate breast posterior border and it is very sensitive to movement) so that MRI remains the more precise method. Besides, we always ask the patient to undergo a breast image exam before surgery and 3D scanning is not a diagnostic exam.

In addition, studies have shown that MRI is the most accurate technique for breast volumetric analysis, providing

Figure 2. (A, C, E) Preoperative photographs of a 24-year-old woman (the same patient featured in Figure 1) who underwent subglandular breast augmentation. (B, D, F) Postoperative photographs of the same patient at 12 months postoperatively after the insertion of 270-mL textured silicone implants with high-projection.
a volumetric measure more representative of breast composition than mammography, especially in dense breasts.

Because the breast is an organ influenced by hormonal changes, knowledge of the cyclic variations of the breast parenchyma becomes essential to prevent bias in volumetric analysis. The volumetric study was performed always on the same day of the menstrual cycle because some authors have observed low metabolic activity and reduced inflammatory response in the first phase of the menstrual cycle (days 3-14), whereas a significant increase in the percentage of fibroglandular tissue occurs in the second phase of the cycle.28 The use of oral contraceptive ensures regularity in the menstrual cycle and little influence of hormonal action on the breast parenchyma,29 and therefore the eligibility criteria included the regular use of oral contraceptive.

The volume reduction in the breast parenchyma after implantation may be attributed both to mechanical compression and parenchymal atrophy. Tepper et al13 found using 3D images an increase in projection of 20.9% less than expected based on implant dimensions and variations in the expected total breast volume at 6 months after surgery. We found a significant reduction in parenchymal volume at 6 months after surgery, with some volumetric regain at 12 months, but with significant differences from baseline at the two postoperative time points ($P < .001$). This may be attributed to a mechanical compression, including a “sponge effect”, where a decrease in total breast volume occurs due...
to a reduction in the area occupied by the mammary gland. However, after tissue accommodation, there is a distention caused by the expansion of structures, especially the skin and dermis, resulting in the remodeling of the mammary gland but with reduction in glandular volume even after the increase in the breast size. In this study, the mean volumetric reduction in the breast parenchyma was 22% of the initial volume at 12 months after surgery. Eder et al\textsuperscript{30} described breast measurement changes after breast augmentation until the sixth 6 month after the procedure, which is consistent with our findings (of no statistical difference between breast volume at 6 and 12 months).

One hypothesis for this volumetric reduction is atrophy of the mammary gland caused by vascular compression and reduced blood flow. The control group in this study did not show significant changes in breast volume at the 6 or 12 month follow-up. Patients in the control group underwent breast augmentation after the evaluation period. Because it was more difficult to maintain a patient in the control group than in the study group, we decided to keep it to a smaller number than the study group without interfering in the statistical analysis. After conducting statistical analysis, it was determined that the number of patients in the control group was enough for comparison without compromising the study.

This study aimed to evaluate the effects of implants on breast parenchyma. Because of the small sample, there were no subgroups to evaluate different types of implant projections and their effects on the breast, or effects due to implant size and volume loss. Another difficulty in correlating implant size and projection to volume loss are patient’s measures. Larger volumes were implanted in women with larger chests because we use chest measures and nipple areolar sulcus distance to select implant size. To avoid bias, we created a pattern to choose implant sizes.

No inference was made about capsular contracture and its effects on whether this causes additional parenchymal volume loss because we did not have any case of this complication. This fact is due to the small sample and the short term postoperative period of analysis.

The present study evaluated the effects of textured high projection silicone implants on breast parenchyma. Further studies are needed to evaluate whether implant type and projection influence breast volume loss. We do not use saline implants and few plastic surgeon still use smooth implants. Polyurethane is however used by a considerable number of plastic surgeons.

**CONCLUSION**

The results suggest that breast augmentation with silicone implants inserted in the subglandular plane causes an average volumetric reduction of 22% in the breast parenchyma.

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