# COSMETIC

# Volumetric Evaluation of the Mammary Gland and Pectoralis Major Muscle following Subglandular and Submuscular Breast Augmentation

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THERAPEUTIC

**Background:** Besides being a procedure with high level of patient satisfaction, one of the main causes for reoperation after breast augmentation is related to contour deformities and changes in breast volume. Few objective data are available on postoperative volumetric analysis following breast augmentation. The aim of this study was to evaluate volume changes in the breast parenchyma and pectoralis major muscle after breast augmentation with the placement of silicone implants in the subglandular and submuscular planes.

**Methods:** Fifty-eight women were randomly allocated either to the subglandular group (n = 24) or submuscular group (n = 24) and underwent breast augmentation in the subglandular or submuscular plane, respectively, or to a control group (n = 10) and received no intervention. Volumetric magnetic resonance imaging was performed at inclusion in all participants and either after 6 and 12 months in the control group or at 6 and 12 months after surgery in the intervention groups.

**Results:** Twelve months after breast augmentation, only the subglandular group had a significant reduction in glandular volume (mean, 22.8 percent), while patients in the submuscular group were the only ones showing significant reduction in muscle volume (mean, 49.80 percent).

**Conclusions:** Atrophy of the breast parenchyma occurred after subglandular breast augmentation, but not following submuscular breast augmentation. In contrast, submuscular breast augmentation caused atrophy of the pectoralis major muscle. (*Plast. Reconstr. Surg.* 137: 62, 2016.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, II.

Breast augmentation is one of the most commonly performed cosmetic procedures.<sup>1</sup> Despite all the developments in surgical techniques and breast implants, reoperation rates are high, reaching 24 percent at 5 years and 36 percent at 10 years.<sup>2</sup> One of the main causes of reoperation is related to changes in breast volume and contour deformities.<sup>3</sup>

Compared with subglandular augmentation mammaplasty, breast augmentation with implants

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Received for publication May 28, 2015; accepted July 27, 2015.

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placed in the submuscular plane reduces contour deformities, decreasing implant edge visibility, traction rippling, and risks of capsular contracture.<sup>4</sup> However, this procedure has a higher risk of malpositioning of the implant and breast asymmetry.<sup>5</sup>

There are factors that participate in the postoperative course of these patients that may be as important to the outcome as the anatomical factors evaluated before surgery.<sup>6,7</sup> Knowledge of potential changes in the breast after augmentation mammaplasty is extremely useful not only in choosing the most suitable procedure, such as pocket plane selection and the appropriate implant volume to ensure long-term aesthetic results, but also for managing patient expectations.

**Disclosure:** None of the authors has a financial interest in any of the products or devices mentioned in this article.

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Muscle tissue is more susceptible to damage when subjected to pressure than other tissues; not only ischemia but also cell deformation plays an important role in tissue injury after prolonged compression.<sup>8–10</sup>

There are some comparative studies on subglandular and submuscular techniques available in the literature,<sup>11-13</sup> but no studies were found that evaluated and compared changes in the mammary gland and pectoral muscle after breast augmentation with silicone implants in the different pocket planes. The aim of this study was to evaluate and compare volume changes in the breast parenchyma after breast augmentation in the subglandular or submuscular planes as well as volume changes in the pectoralis major muscle following submuscular breast augmentation using the dual-plane technique.

#### PATIENTS AND METHODS

This longitudinal, prospective, analytical, interventional, randomized, single-center trial was conducted between January of 2012 and March of 2015. The study was approved by a research ethics committee (Brazil Platform System, approval no. CAAE 34307314.3.0000.5259) 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 prior to their inclusion in the study, and anonymity was assured.

Fifty-eight women who expressed a desire to undergo breast augmentation were selected from a plastic surgery outpatient clinic of a university hospital in Brazil. Inclusion criteria were age ranging from 18 to 30 years, body mass index between 19 and 25 kg/m<sup>2</sup>, and contraceptive use.

Noninclusion criteria were were breast ptosis, family history of breast cancer, breast cancer, suspicion of malignancy, comorbidities, chronic disease, pregnancy, breastfeeding, history of obesity, and smoking habit. The exclusion criterion was loss to follow-up.

The patients were randomly allocated to one of three groups using Research Randomizer software (http://www.randomizer.org/). Patients in the control group (n = 10) were not operated on. The subglandular group (n = 24) underwent subglandular breast augmentation and the submuscular group (n = 24) underwent submuscular breast augmentation. Patients in all three groups were followed up for at least 12 months. After completion of the study, all patients in the control group underwent breast augmentation.

#### **Radiological Examination**

The radiological examination was performed at a diagnostic center. All patients underwent magnetic resonance imaging with a 1.5-T magnetic resonance imaging unit (Siemens Vision, Erlangen, Germany), using a sagittal T1 fat-suppressed sequence. Volumetric analysis of breast parenchyma was performed in the three groups, and volumetric analysis of the pectoralis major muscle was done in the submuscular and control groups. The same radiologist carried out the volumetric analysis in all groups using the AW Server 2.2 Workstation (GE Healthcare, Waukesha, Wis.).

Patients in the intervention groups underwent magnetic resonance imaging at three time points: preoperatively (baseline) and at 6 and 12 months after surgery. Similarly, controls underwent imaging 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 magnetic resonance imaging examinations on the same day of her menstrual cycle, calculated from the first day of contraceptive use.

All patients were weighted monthly to ensure that their body mass index was maintained constant during the study period and therefore was not a bias factor in volumetric analysis.

Volumetric measurements of breast parenchyma were performed for the three groups at the three time points (baseline and 6 and 12 months). Volumetric measurements of the pectoralis major muscle were performed in the control and submuscular groups.

A variable volume difference of volume was created to compare the study groups to the control group. In this manner, postoperative volume was subtracted from the preoperative volume to obtain a variable that was used for between-group comparisons.

#### **Surgical Procedure**

Breast augmentation with silicone implants placed in the subglandular plane was performed with the patient under local anesthesia and monitored sedation. Submuscular breast augmentation using the dual-plane technique was carried out with the patient under general anesthesia. After visualization of the free lateral edge of the pectoralis major muscle, the lower edge of the muscle (mammary fold) was dissected in the lateromedial direction, without dissection in the retroglandular plane. Patients in both intervention groups received textured silicone implants with a round base, spherical profile, high projection, and volume ranging from 225 to 335 ml (model Maximum; Silimed, Rio de Janeiro, Brazil). 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. In both intervention groups, surgical approach was through a submammary incision. Patients were discharged from the hospital 24 hours after surgery.

#### **Statistical Analysis**

The assumption of distributional normality was tested using the Shapiro-Wilk test. The Friedman test was performed to compare three or more paired variables. Comparisons of two variables were carried out using the Wilcoxon test for paired groups and the Mann-Whitney test for unpaired groups.

The GraphPad Prism version 5 for Windows (GraphPad Software, San Diego, Calif.) was used for data analysis. All statistical tests were performed at a significance level  $\alpha$  of 0.05 (p < 0.05).

#### **RESULTS**

The mean operative time was 65.3 minutes in the subglandular group and 53.7 minutes in the submuscular group. The mean implant volume was 281.5 ml (range, 225 to 335 ml). No major complications occurred in either intervention group; one patient in the subglandular group developed a seroma and one patient in the submuscular group experienced difficult-tomanage pain, which ceased 7 days after surgery. Patients were allowed to return to work 15 days after surgery and to engage in physical activities involving carrying or lifting a load after postoperative day 60.

No significant differences in body mass index and age were found among the three groups. There was also no significant difference in implant volume between the intervention groups (Table 1).

In the subglandular group, one patient withdrew and 23 patients completed all phases of the study. In the submuscular group, six patients were lost to the 12-month radiological follow-up; therefore, 18 patients completed all phases of the study (Figs. 1 and 2).

Within-group comparisons of magnetic resonance imaging results for the subglandular group showed a volumetric reduction in breast Table 1. Characteristics of the Sample

	Gro		
Variable	Subglandular	Submuscular	<b>p</b> *
Age, yr (range) BMI, kg/m² (range) Implant	23.7 (18–30) 21.44 (19.3–24.8)	25.6 (18–30) 21.25 (19.3–22.6)	0.17 0.23
ml (range)	273 (225-335)	290 (245-335)	0.81

BMI, body mass index.

\*Mann-Whitney test. Statistical significance (p < 0.05).

parenchyma of 27.7 percent at 6 months (mean, 29.17 cm<sup>3</sup>) after surgery and a volume regain at 12 months, but still with a significant reduction of 22.8 percent (p < 0.0008) of the initial volume (mean, 24.52 cm<sup>3</sup> of loss) (Fig. 3). A significant difference in parenchymal volume was found between the subglandular and control groups at 6 and 12 months after surgery (Table 2).

For the submuscular group, within-group comparisons of magnetic resonance imaging results revealed a significant volumetric reduction in breast parenchyma of 23.08 percent at 6 months after surgery (p = 0.0006) and a volume regain and nonsignificant volumetric reduction (p = 0.06) at 12 months (Fig. 4). A significant difference in parenchymal volume was found between the submuscular and control groups only at 6 months after surgery (Table 3).

Significant reductions in the volume of the pectoralis major muscle of 46.38 percent and 49.80 percent were observed at 6 and 12 months after surgery (mean, 35.14 cm<sup>3</sup>), respectively (Fig. 5). When compared with the control group, there was a significant difference at 6 and 12 months after surgery.

#### **DISCUSSION**

Breast augmentation is associated with high satisfaction rates and significant improvement in patients' quality of life.<sup>14</sup> Nevertheless, changes in breast contour and implant volume have been the cause of reinterventions.<sup>15,16</sup> Handel et al.<sup>17</sup> showed that implant volume was the cause of reoperation in 21.8 percent of cases. According to Lui et al.,<sup>18</sup> volumetric changes following breast augmentation result from a biomechanical interaction between the implant and surrounding tissues and are not just limited to the volume of the implant. Some authors have identified the pressure exerted by the implant on surrounding tissues as the probable cause of aesthetic changes,

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**Fig. 1.** Fat suppression magnetic resonance imaging for volumetric analysis of the mammary gland in the submuscular group. (*Above*) Preoperative image; (*center*) 12-month postoperative image, lateral view of the mammary gland; (*below*) 12-month postoperative image, posterior view of the breast parenchyma.

such as rippling, contour deformities that are difficult to correct, and lack of upper pole projection. This pressure would lead to atrophy of the tissues around the implant.<sup>19,20</sup>



**Fig. 2.** Fat suppression magnetic resonance imaging density measure for volumetric analysis of the pectoralis major muscle in the submuscular group. (*Above*) Preoperative image, anterior view of the pectoralis major muscle (muscle volume, 84.07 cm<sup>3</sup>); (*below*) 12-month postoperative image, lateral view of the pectoralis major muscle, showing muscle volume of 39.50 cm<sup>3</sup> (loss of 46.98 percent of muscle mass).

In the present study, the sample population was composed of young nulliparous women, as structural changes in the mammary gland that occur after pregnancy and fatty degeneration following menopause may make the radiological evaluation of the breast parenchyma difficult.<sup>21</sup> Oral contraceptive use was an inclusion criterion of the study because hormonal alterations affect cell proliferation, causing changes in breast density.<sup>22</sup> The use of oral contraceptive not only ensures regularity of the menstrual cycle but also allows the precise determination of the cycle day. Some authors have observed low metabolic activity and decreased inflammatory response in the first phase of the menstrual cycle (days 3 through 14); therefore, we opted to perform the volumetric evaluation always in the first phase of the cycle.<sup>23–25</sup>

Breast Volume (Submuscular Group)



Fig. 3. Comparisons of glandular volume over time in the subglandular group.

Anthropometric parameters, such as body mass index and waist circumference, are directly related to changes in breast density, which is the proportion of fatty to fibroglandular tissue in the breast.<sup>26</sup> Patients in all groups showed no significant differences in body mass index between time points during the period of volumetric evaluation of the breast.

Magnetic resonance imaging is a radiationfree imaging procedure and the best method to differentiate the implant from breast tissue.<sup>27</sup> Furthermore, it allows the volumetric analysis of other organs and tissues,28-30 including muscle tissue. An advantage of the three-dimensional digital imaging is the accurate visualization of the posterior contours of the breast (between the breast and chest wall), through axial slices.<sup>31</sup> Klifa et al.<sup>32</sup> showed that magnetic resonance imaging provides more accurate measures of breast volume and breast composition compared with mammography, especially in women with high breast density.

The volume reduction in the breast parenchyma after implantation may be attributed to both mechanical compression and parenchymal atrophy.<sup>33</sup> Using three-dimensional images,

Table 2. Comparisons of Differences in Breast Volume over Time between the Subglandular and **Control Groups** 

Volumetric	Groups		
Time Points (cm <sup>3</sup> )	Subglandular	Control	þ
6 months – baseline	-28.19	6.54	0.0035*
12 months - baseline	-21.87	8.88	0.010*

\*Mann-Whitney test. Statistical significance (p < 0.05).

150 Breast Volume (cm<sup>3</sup>) 100



Fig. 4. Comparisons of glandular volume over time in the submuscular group.

Tepper et al.<sup>34</sup> found an increase in projection 20.9 percent less than expected at 6 months after surgery, but with no changes in the total breast volume. Kovacs et al.<sup>35</sup> observed an increase in projection 20 percent less than expected at 6 months after surgery with the use of round implants inserted in the submuscular plane, but no mention was made of the breast volumetric measures.

Our results show a significant reduction in parenchymal volume from baseline at 6 months after surgery in both intervention groups, but the volume loss was 16.6 percent lower in the submuscular group compared with that in the subglandular group. There was also a significant regain in parenchymal volume in both groups at the 12-month follow-up, but a significant volume loss was still observed in the subglandular group (p < 0.001). No significant volume loss in breast parenchyma was found in the submuscular group at 12 months after surgery. The decrease in the initial parenchymal volume may be attributed to a mechanical compression, such as a "sponge effect," in which a decrease in total breast volume occurs due to a reduction in the area occupied by the mammary gland. However, after tissue

Table 3. Comparisons of Differences in Breast Volume over Time between the Submuscular and **Control Groups** 

Volumetric Differences hotseen	Groups		
Time Points (cm <sup>3</sup> )	Submuscular	Control	þ
6 months – baseline 12 months – baseline	-24.86 -14.48	$-6.99 \\ -8.88$	$0.037* \\ 0.168$

\*Mann Whitney test. Statistical significance (p < 0.05).

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**Fig. 5.** Comparisons of muscle volume over time in the submuscular group.

accommodation, there is a distention caused by the expansion of structures, especially the skin and dermis, resulting in remodeling of the mammary gland but with reduction in glandular volume even after the increase in breast size. In this study, there was a significant decrease in parenchymal volume in the subglandular group but not in the submuscular group. One hypothesis for this volume reduction is atrophy of the mammary gland caused by vascular compression and reduced blood flow.<sup>19,20</sup>

Muscle tissue is more susceptible to injury when it is under constant pressure. Studies<sup>8-10</sup> have shown that external compression results in tissue damage, mainly by mechanical deformation of muscle cells. The use of orthoses and prostheses is a compression factor that may lead to muscle cell damage.<sup>36–38</sup> Gur et al.<sup>39</sup> showed by light and electron microscopy that the placement of tissue expanders under the pectoralis major muscle leads to a decreased number of muscle fibers and focal muscle fiber degeneration. Serra et al.<sup>40</sup> observed muscle atrophy in the gluteus maximus muscle following intramuscular gluteal augmentation.

Our results showed significant reduction in muscle volume in the submuscular group at the 6-month postoperative follow-up and the volume loss persisted at 12 months after surgery. Despite muscle disuse atrophy being a possible cause of muscle volume reduction,<sup>41</sup> volumetric analysis was performed after a long postoperative period and return to physical activity was allowed 60 days after the surgical procedure. Mascarinas et al.<sup>42</sup> reported a case of pectoral muscle atrophy due to pain and restriction of movement. In our study, there were no reports of prolonged pain that would lead to muscle atrophy due to movement restriction. Thus, the hypothesis of disuse atrophy was discarded and the reduction in muscle volume was attributed to extrinsic compression.

Some studies<sup>43–45</sup> have shown volumetric loss of free muscle flaps due to muscle atrophy. In these cases, muscle atrophy is related to denervation and not ischemia. Pectoralis major muscle is innervated by branches of the medial and lateral pectoral nerves. The lateral pectoral nerve has a constant position, parallel to the toracoacromial vessels, following an inferior-medial direction on the posterior surface of the pectoralis major muscle, underneath its fascia.46 The medial pectoral nerve has two variations, but anatomical studies<sup>47,48</sup> show that the branches of the lateral and medial pectoral nerves penetrate the pectoralis muscle at a considerable distance from the lateral edge of the sternum, bilaterally. Therefore, release of the pectoralis muscle from its lower and medial portions (abdominal and sternum origins), performed during breast augmentation, is a safe procedure with no risk of nerve injury. Thus, the hypothesis of muscle atrophy by denervation can be discarded.

Implant pressure, in the same fashion as any implant, affects the surrounding tissues, and so the breast implant causes muscle atrophy by local pressure. Also, release of part of the muscle origin may contribute to atrophy as well.

One of the limitations of this study is that it was not possible to determine a relationship between implant projection and tissue atrophy. Also, as there were no patients with capsular contracture, no correlation could be made between loss of volume and this complication. Further studies are needed to elucidate those questions.

Although most patients were satisfied with the outcome of breast augmentation, the surrounding tissue may lead to a decrease in volume. This should be considered in the preoperative planning of this type of operation. Therefore, choice of an implant according to the expected volume loss should be considered and discussed with the patient during the surgical planning.

#### CONCLUSIONS

Atrophy of the mammary gland occurs after subglandular breast augmentation, but not following breast augmentation in the submuscular plane. In submuscular breast augmentation, the pectoralis major muscle seems to protect the mammary gland from volume loss but undergoes marked atrophy.

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