

Capsular Contracture after Breast Silicone Implants: A Comparative Study between Subglandular and Submuscular Implant Placement

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ABSTRACT

Background: One of the post-surgical complications is capsular contracture resulting from the body's immune response to foreign material. It frequently necessitates the replacement of implants and/or corrective surgery.

Objective: This study aimed to compare the incidence of capsular contracture following breast silicone implantation, focusing on the two placements: Subglandular (SG) and submuscular (SM).

Patients and methods: This randomized clinical open-label study involved 40 women, between the ages of 18 and 65, who underwent primary breast augmentation. Patients were chosen at random and divided equally among the groups: Patients in group I received SG implants. Group II: SM implants were performed on patients. A detailed history of weight loss, the preoperative and the presenting body mass index (BMI), complete nutritional evaluation, and medical comorbidities, was taken.

Results: The overall incidence of contracture rate was 9 (45%) patients in group I and 2 (10%) patients in group II with RR (95%CI) of 4.5(1.11:18.27). The overall incidence of contracture rate substantially decreased in group II compared to group I. (P=0.031). The grade of group II was substantially lower than that of group I, as per the Baker classification (P=0.046).

Conclusions: The SM group exhibited considerably lower rates of capsular contracture than the SG group, as evidenced by the study's findings, with no significant postoperative complications.

Keywords: Capsular contracture, Breast silicone implants, Breast augmentation, Subglandular implant, Submuscular implant.

INTRODUCTION

Plastic surgery has advanced substantially in recent decades as a result of the creation of novel surgical methods and materials that can replace organs and tissues ⁽¹⁾. One of the most common types of cosmetic surgeries is breast augmentation ⁽²⁾. This often entails the insertion of an implant into the breast to modify its size and shape ⁽³⁾. Many different types of implants exist, each with its own unique surface texture, filling material (saline or silicone), and overall shape (rounded or anatomically contoured). There are many different kinds of implants ⁽⁴⁾.

Currently, silicone breast implants are the most prevalent and widely acknowledged material for breast augmentation ⁽⁵⁾. There are two types of these: Silicone outer shells with silicone gel fillings and silicone outer shells with other fillings, such as saline ⁽⁶⁾. Nonetheless, the general consensus is that silicone implants behave mechanically more like genuine breast tissue after surgery than saline substitutes ⁽⁷⁾.

Subglandular (SG) breast implants are placed in the retromammary space, which is above the pectoralis major muscle and below the mammary gland. The delicate areolar tissue that separates the breasts from the pectoral muscles is a defining feature of this area ⁽⁸⁾.

Submuscular (SM) breast implants are most commonly placed using the "SM placement" method, which entails putting the implants above the pectoralis minor and below the pectoralis major muscles. An alternative to this is subpectoral placement, which involves sliding the implant's top half under the pectoral muscle. On the other hand, the bottom part stays in an SG position. A potential drawback of this placement is

that some people may find it unnatural because the lower part of the prosthesis moves a lot more than the upper part ⁽⁹⁾.

Capsular contracture is a post-surgical complication induced by the body's immune response to foreign material. Collagen capsules form and compress the implant and adjacent tissue, frequently resulting in pain, discomfort, and distortion ⁽¹⁰⁾. Capsular contracture frequently necessitates corrective surgery and/or the replacement of implants. Since type I indicates a completely normal-looking and feeling breast and type II indicates a little contracted breast that allows the surgeon to know surgery has taken place but no symptoms are present, neither type is clinically significant. The Baker method of classification uses this as one of its four categories. Class III denotes considerable contracture, with the patient reporting some firmness. Class IV is clinically substantial and symptomatic. Additionally, class IV denotes a patient's significant contracture, which is assessed as symptomatic based on observation ⁽¹¹⁾.

This investigation aimed to compare that of capsular contracture incidence associated with breast silicone implantation, with a particular emphasis on the two placements: SG and SM.

PATIENTS AND METHODS

Fourty women between the ages of 22 and 45 who were having primary breast augmentation at Tanta University Hospitals participated in this randomised, open-label trial. The purpose of the research was explained to them, and each patient was assigned a secret code number. Each patient's secret codes and private files ensured the

confidentiality of all patient data. The data was solely utilized for current medical research. The participants and the ethical committee will be promptly informed of any unforeseen hazards that may have arisen during the research.

Inclusion criteria: Forty women, aged between 22 and 45, undergoing primary breast augmentation.

Exclusion criteria: Prior breast surgery, history of breast cancer, contraindications for surgery, history of breast infections or autoimmune disorders, pregnancy or breastfeeding and severe comorbidities, such as uncontrolled diabetes or smoking.

Randomization and blindness: Computer-generated randomization numbers were used by using an online program for randomization (<http://www.randomizer.org>) to produce a random list, and the code of each patient was stored in a sealed envelope that was opaque. In parallel, patients were

randomly allocated to two groups with a 1:1 allocation ratio: Group I: Patients underwent SG implant. Group II: Patients underwent SM implant. The patient's medical history, current and previous weight reduction, preoperative and postoperative body mass indices (BMIs), nutritional status, and any comorbidities were all carefully documented. The operations were carried out under the influence of general anaesthesia. The patient was positioned on their back. Within the inframammary fold, a small incision was made.

Subglandular pocket creation: The dissection was begun by creating an SG pocket (above the pectoral muscle) beneath the breast gland. This pocket was created by gently separating the glandular tissue from the underlying chest wall. The integrity of the skin and glandular tissue was preserved to avoid damage. The pocket was dissected to provide sufficient space for the implant, ensuring that the implant can rest comfortably without excess compression (Figure 1).

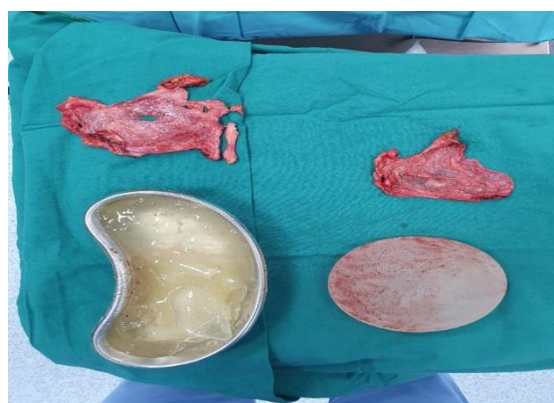


Figure (1): Female case presented with capsular contracture after subglandular technique.

Submuscular: During SM implantation, the implant's uppermost section was positioned beneath the pectoralis muscle. This involves elevating the muscle and creating a pocket for upper portion of the implant, while leaving lower portion of the implant above the muscle, within the SG space (Figure 2).



Figure (2): Female case presented with capsular contracture after submuscular technique.

Implant insertion: Once the pocket was prepared, the breast implant (a micro-textured implant from the same manufacturer) was implanted through the inframammary fold incision. The implant was positioned carefully within the created pocket.

In the SG technique, the implant was placed above the muscle. The upper part of the implant is placed in the SM compartment under the pectoralis muscle, while the lower part remains in the SG compartment. Follow-up was conducted with patients up to 42 months postoperatively. Capsular contracture was evaluated clinically and graded according to the Baker classification. Magnetic resonance imaging (MRI) was performed to detect capsular calcification.

Sample size calculation: The sample size was calculated using G*Power 3.1.9.2 (Universität Kiel, Germany). The subsequent considerations were made into account when determining the sample size: The incidence of overall contracture rate in the SM group was a 45% reduction compared to the SG group., as evidenced by a previous study ⁽¹²⁾ with a 0.05 α error and 80% power. To mitigate dropout rates, each group was supplemented with three cases. Consequently, each group was allocated 20 patients.

Ethical approval:

The study was approved by the Ethics Board of Tanta University and an informed written consent

was taken from each participant or their parents in the study. This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

Statistical analysis

This study used SPSS version 27, which was developed by IBM and is based in Armonk, NY, USA, for stats. The normality of the data distribution was checked using histograms and the Shapiro-Wilk test. The unpaired student t-test was used to assess the quantitative parametric data, which was then presented as mean \pm standard deviation (SD). We used the Chi-square test or Fisher's exact test to analyse the data, and we displayed the qualitative variables as percentages and frequencies. For statistical significance, a two-tailed P value of ≤ 0.05 was required.

RESULTS

Eligibility assessments were performed for 43 participants in this study. Four peoples chose not to take part, while nine were found to be ineligible. Two groups, each including twenty patients, were then randomly assigned to the remaining patients. All assigned patients were followed up and analysed statistically (Figure 3).

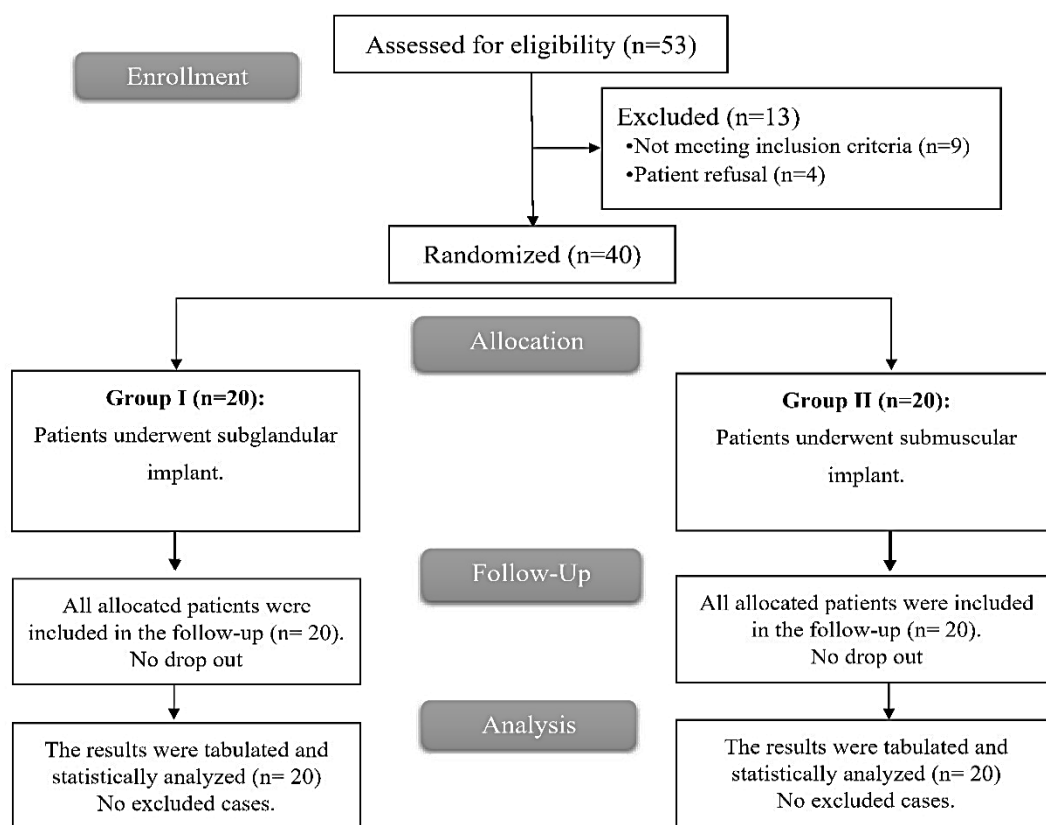


Figure (3): CONSORT flowchart of the enrolled patients.

There was no substantial difference between the two groups in terms of demographic data and comorbidities (Table 1).

Table (1): Demographic data and comorbidities of the studied groups

	Group I (n=20)	Group II (n=20)	P value
Age (years)	31.75 ± 6.32	33.45 ± 5.53	0.371
Weight before implantation (kg)	72.05 ± 13.16	73.35 ± 9.55	0.723
Height (cm)	166.95 ± 4.99	166.05 ± 5.63	0.596
BMI before implantation (kg/m ²)	25.92 ± 4.96	26.67 ± 3.78	0.594
Weight after implantation (kg)	72.82 ± 13.16	74.13 ± 9.54	0.720
BMI after implantation (kg/m ²)	26.21 ± 4.96	26.96 ± 3.78	0.591
Comorbidities	Hypertension	6 (30%)	4 (20%)
	DM	4 (20%)	3 (15%)
	Cardiovascular disease	1 (5%)	0 (0%)

Data are presented as mean ± SD or frequency (%). BMI: Body mass index, DM: Diabetes mellitus.

The overall incidence of contracture rate was 9 (45%) patients in group I and 2 (10%) patients in group II with RR (95% CI) of 4.5 (1.11:18.27). Compared to group I, the aggregate incidence of contracture rate substantially decreased in group II (P=0.031). The grade of group II was substantially lower than that of group I, as per the Baker classification (P=0.046) (Table 2).

Table (2): Overall incidence of contracture rate and grade according to Baker classification of the studied groups

	Group I (n=20)	Group II (n=20)	P value
Overall contracture rate	9 (45%)	2 (10%)	0.031 *
Grade	Grade I	0 (0%)	1 (5%)
	Grade II	3 (15%)	1 (5%)
	Grade III	5 (25%)	0 (0%)
	Grade IV	1 (5%)	0 (0%)

The frequency (percent) of the data is displayed. *: Significant when the P value is less than 0.05.

Postoperative complications (partial necrosis, seroma, and stretch marks) differed significantly between both groups (Table 3).

Table (3): Postoperative complications of the studied groups

	Group I (n=20)	Group II (n=20)	P value
Partial necrosis	0 (0%)	1 (5%)	1
Seroma	6 (30%)	3 (15%)	0.450
Stretch marks	1 (5%)	2 (10%)	1

Data are presented as a frequency (%).

DISCUSSION

The classical SG, subpectoral (SP), or SM and Subfascial planes are commonly used for implant augmentations ⁽¹³⁾. Additionally, surgical complications are typically diminished, surgery and recovery times are

usually shortened, and only local anaesthetic can be used for the surgery. SG placement does not necessitate the same level of deep tissue penetration as SM implant placement ⁽¹⁴⁾.

Despite its advantages, the SG placement of breast implants has become less common due to the potential for a variety of complications and unwanted adverse effects. Additionally, the prevalence of capsular contracture is greater than that of SM placement ⁽¹⁵⁾.

According to our trial's findings, group II had a significantly lower incidence of contracture rate compared to group I. Group II demonstrated a significantly lower grade compared to group I according to the Baker classification.

These results are consistent with **Puckett et al.** ⁽¹²⁾ who demonstrated a substantially lower SP group compared to the SG group, with a total contracture rate of 22% vs. 58% in the SG group. There were 48 contractures in the SG group and 14 in the SP group, with the latter showing more severe forms (Baker grades III and IV). Moreover, **Hendricks et al.** ⁽¹⁶⁾ showed an extremely low rate of Baker II capsular fibrosis, and no revisions of Baker III or IV capsular contractures were observed in the SM plane.

The pectoralis major muscle coated the implant with a more well-vascularized tissue layer. Increased blood flow improves the body's ability to fight bacteria, reducing low-grade infections (biofilm formation), a known contributor to capsular contracture ⁽¹⁷⁾. SG placement is closer to the breast ducts, a potential source of bacteria. Subpectoral placement moves the implant away from these ducts, reducing the risk of bacterial contamination and subsequent chronic inflammation that can lead to capsular contracture ⁽¹⁸⁾. The natural movement of the pectoral muscle provides a "massaging" effect over the implant. This prevents the capsule from becoming overly tight or forming in a rigid shape, reducing contracture risk ⁽¹⁹⁾.

Our analysis revealed that postoperative complications (partial necrosis, seroma, and stretch marks) differed significantly between both groups,

which is in the same line with **Daher *et al.*** ⁽²⁰⁾ who found that during outpatient follow-up, there were 19 cases of seroma, stretch marks were observed on the breasts of two patients, and one case of partial necrosis.

LIMITATIONS

Our trial has limitations, including a relatively limited sample size and being conducted at a single center. The complication, particularly the hematoma, implant displacement, and animation deformity, should be addressed in detail. In the interim, it is imperative to conduct further univariate investigations comparing the SM, Dual, subfascial, and SG planes to substantiate this claim.

CONCLUSION

According to the study's findings, the SM group exhibited substantially lower rates of capsular contracture than the SG group. Consequently, SM is a viable alternative to SG. Partial necrosis, seroma, and stretch marks exhibited no discernible variation.

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