Aesth Plast Surg (2019) 43:1429–1436
https://doi.org/10.1007/s00266-019-01465-8

ORIGINAL ARTICLE BREAST SURGERY

Is There a Breast Augmentation Outcome Difference Between Subfascial and Subglandular Implant Placement? A Prospective Randomized Double-Blinded Study

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Received: 15 March 2019 / Accepted: 18 July 2019 / Published online: 30 July 2019

Abstract

Introduction Subfascial breast augmentation is gaining popularity because of no distortion when the pectoral muscle is contracted and minimizing visualization of the edges of the implant. Although some studies have reported a satisfactory outcome with subfascial technique, it still is controversial the influence of the pectoral fascia and outcome compared to the subglandular technique. Therefore, this prospective randomized study aimed to investigate whether there are clinical/radiological differences between subfascial and subglandular pockets following primary breast augmentation.

Methods Twenty patient candidates for primary breast augmentation were recruited. Each patient was selected for subfascial or subglandular pockets in a randomized fashion. Both patient and surgeon were blinded. Clinical and radiological differences were evaluated through five independent surgeons and MRI (capsule, folds, fluids, base and projection). Median follow-up was 12 months.

Results Breast consistency ($p = 0.24$), implant pocket ($p = 0.52$), symmetry ($p = 1$), contour, and shape ($p = 0.09$) demonstrated no statistically significant difference after the surgeons' assessments at 3 and 12 months after surgery. MRIs demonstrated a larger implant base in the subfascial group ($p = 0.024$). No differences were observed in capsule thickness ($p = 0.42$), folds ($p = 0.51$), fluids ($p = 0.28$), or projection (0.20).

Conclusion The choice between subfascial and subglandular planes shows no clinical differences and can be selected according to individual professional experience, not evidencing any advantages of one over the other.

Level of Evidence II This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Breast augmentation · Subfascial technique · Subglandular technique · Outcome · Complication · Prospective study · Magnetic resonance imaging

Introduction

Breast augmentation has become one of the most frequently performed aesthetic surgical procedures [1]. Recently, improvements in surgical procedures and implant technologies have led to improvements in esthetic results [2–4].

Introduced in the 1990s, the subfascial approach is especially attractive for plastic surgeons who have been searching for alternative implant pockets [5]. The pectoral fascia is a unique layer that can be recognized, and has adequate strength that becomes evident during surgical

Ivan Maluf Junior, Ruth Maria Graf and Renato da Silva Freitas were equally important to carry out this study.

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manipulation [5–8]. According to some authors, when the subglandular dissection is performed, the fibers connecting the deep layer of the superficial fascia and the superficial layer of the deep pectoralis muscle fascia are divided [7–9]. Otherwise, when the subfascial dissection is performed, these fiber attachments are preserved and could maintain better implant positioning [8–12]. Additionally, it is referred that pectorals fascia favors the creation of a support structure for the upper pole of the implant and avoiding upper displacement of the implant and makes the upper pole more natural [13, 14]. Compared to other techniques, the advantages of the subfascial pocket could be supplementary soft tissue coverage and avoiding the limitations of the submuscular position without breast animation when the pectoral muscle is contracted [5–15].

Despite the lack of unanimity concerning the surgical pocket, the decision is usually defined by the surgeon's preference and experience, and the anatomy of the breast. Although the subglandular pocket is reliable, placing the silicone implant next to the glandular tissue may result in an unsatisfactory result in terms of implant visibility and palpability. This is especially noticeable in thin patients with smaller breasts and poor soft tissue coverage, where a sharp transition can be seen in the limits of the implant [13, 14].

Although the pectoral fascia is an anatomically recognized layer, there is no scientific evidence that it may provide adequate mechanical support for silicone implants. In addition, there are no previous clinical studies comparing subfascial and subglandular pockets in terms of aesthetic results and objective radiological analysis. Thus, this prospective study aims to compare subglandular and subfascial planes by clinical and radiological analysis in young patients submitted to breast augmentation with silicone implants.

Method

This study consisted of a prospective, randomized, controlled, double-blinded clinical trial. It was carried out by the Plastic Surgery Service, approved by the Research Ethics Board of this institution under number 53,899. The research was approved by the ethics board of this institution.

The project lasted 18 months. The inclusion criteria were as follows: female patients who wished to undergo the surgery for breast augmentation, normal weight or overweight (BMI between 18 and 30), minimum age of 18 years and anesthesiologist's authorization for the procedure. The exclusion criteria were as follows: patients who had previously undergone any kind of breast surgery, who evidenced any abnormalities in the preoperative imaging scanning (ultrasound scan or mammography), or congenital deformities in the thoracic wall. Patients who featured postoperative hematomas, infection or prosthesis extrusion, would also be excluded.

Twenty (20) patients, who wished to undergo aesthetic breast implants, with no previous history of breast surgeries, were selected. They were randomly divided, after the patient was marked and lying on the stretcher, a lottery was held. There were 40 tickets in a box, 20 tickets with SF writings, and 20 written SG. Each breast was drawn separately. The surgeon did not know which patient was operating, only one of the researchers had this information.

The patients were operated on over three consecutive weekends to be in the same evolution period at the moment of the assessment. They were guided on the proposed treatment and signed the Free Informed Consent Form. Procedures were carried out under general anesthesia. In that moment, after the surgical marks, the subfascial or subglandular procedure was chosen to be performed in the right breast, followed by the selection of the procedure in the left breast. Two main research surgeons were responsible for performing the surgeries. One of them was in charge of placing the implants in the subglandular plane (RSF), while the other was responsible for placing the implants in the subfascial plane (RMG). In both cases, access was performed through the inframammary fold.

A single patient could have a subglandular (SG) implant in one breast and a subfascial implant in the other breast, or could have both implants placed in the same plane (SG or SF). Information on the kind of implant placement and on the anatomical plane used was not passed on to patients, surgeons and evaluators during the study in order to avoid biases. Only one of the researchers (IMJ) knew about the implant placement plane. One of the researchers carried out the photographic recording and the pre- and postoperative guidance.

Patients' Evaluation

All patients were examined by five guest surgeons, non-research participants, in the 1st, 3rd, 6th, and 12th months to assess any differences between the breasts. The analyzed criteria were: breast shape, contour, consistency, and asymmetries.

Breast shape and contour were assessed to compare the difference between SG and SF planes. Breast consistency was assessed to observe the degree of capsular contracture (Baker classification), and to verify whether there was a higher contracture rate for either plane. Breast asymmetries aimed to assess whether the implant insertion by means of different planes in the same patient was perceptible.

MRI Assessment

Imaging assessment was held by means of MRI in the 3rd and 12th months after surgery aiming at observing the capsule, capsule thickness, seroma and the implant positioning. The imaging assessment was carried out at DAPI (Advanced Imaging Diagnostic Center). The MRI examination was performed by means of a Siemens Magneton Avanto 1.5T MRI Scanner (Avanto®, Siemens), in the prone position, using a dedicated 16-channel coil. The examination protocol included T2-weighted axial sequences with fat suppression, sagittal STIR with silicone saturation, sagittal STIR with water saturation followed by a dynamic T1-weighted 3D axial and sagittal sequence with fat saturation.

Subsequently, all examinations were sent to a workstation (Carestrean Health), where two breast radiologists classified the examinations under the following criteria:

- Location: described as (a) SF or (b) SG;
- Presence of periprosthetic fluid: rated as (a) absent; (b) minimal; (c) moderate and (d) high;
- Number of folds around the implants: rated as (a) absent; (b) between 1–3-fold; (c) between 4–6-fold; (d) over sixfold;
- Thickness of the reactive capsule around the implants: measured in mm, the thickest portion of the capsule, observed in the T2-weighted axial sequence (magnified 600%).
- Measurement of the implant base: measured in mm, designing two lines between the patch and the farthest portion of the implant base, observed in the T2-weighted axial image sequence (amplified 600%).
- Measurement of the implant projection: measured in mm, anterior–posterior direction, central portion of the implant (between the shell and the areola), observed in the T2-weighted sagittal image sequence.

Table 1 Kappa test to assess the agreement among the evaluators

Kappa (k)	Interpretation
≤ 0	No agreement
0.0 –| 0.2	Poor agreement
0.2 –| 0.4	Fair agreement
0.4 –| 0.6	Moderate agreement
0.6 –| 0.8	Substantial agreement
> 0.8	Almost perfect agreement

Statistical Tests

Friedman's tests with post hoc Dunn's test or Chi-square test (ZAR, 2009) were used to assess whether there was difference in the scores for breast symmetry, consistency, insertion plane, contour and shape among the evaluators. This analysis aimed to review whether any of the evaluators consistently featured different scores from the others. A second analysis was performed to measure the agreement among the results from the different evaluators, thus Kappa analysis was used (FLEISS & COHEN, 1973), where results can be interpreted according to Table 1. In case of differences among the evaluators, the different ones were discarded and a new analysis was carried out.

Mann–Whitney tests or Fisher's exact test (ZAR, 2009) were applied in order to analyze whether or not the evaluator was able to differentiate features of breast consistency, insertion planes, contour and shape in SG and SF planes.

Statistical analyses were performed by means of the GRAPHPAD PRISMA software. A significance level of 5% ($\alpha = 0.05$) was considered for all the analyses. After all, we analyzed the mean surgical time to compare both techniques.

Results

Breast Consistency—Analysis According to the Type of Implant—SG × SF

In Table 2, the score frequencies between both studied groups are shown. No evaluators scored a group higher than the other.

Insertion Plane

Table 3 shows the assessment result on the type of insertion plane used. The assumed probability of hits was 50%. No evaluators scored frequencies of hits/errors significantly different for the two groups.

Table 2 Breast consistency

SG (20)	SF (20)	*P*		
Baker I and II (%)	Baker III (%)	Baker I and II (%)	Baker III (%)	
3 months				
70.3	29.7	71	29	$p = 1$
12 months				
72.9	27.10	89.7	10.3	$p = 0.24$

Table 3 Assessment of the type of prosthesis insertion plane (SG – SF)

SG (HIT) (%)	SG (ERROR) (%)	SF (HIT) (%)	SF (ERROR) (%)	*P*
3 months				
56.1	43.8	56	43.9	$p = 1$
12 months				
64.3	35.7	49.1	50.9	$p = 0.52$

Table 4 Quality assessment of the breast contour

	SG (%)	SF (%)	*P*
3 months			
Poor	0.9	0	
Fair	8.9	5.7	
Good	44.2	43.8	
Excellent	46	50.5	$p = 1$
12 months			
Poor	0	0	
Fair	4	3.6	
Good	48	50.9	
Excellent	48	45.5	$p = 1$

Table 5 Assessment of the breast shape

	SG (%)	SF (%)
3 months		
Fair	10.1	5.6
Good	37.8	44.4
Excellent	52.1	50
12 months		
Poor	10	1.8
Good	41.5	47.2
Excellent	48.5	51

$p < 0.05$

Breast Contour

Table 4 shows the score frequencies for both studied groups. No evaluators scored a group consistently higher than the other.

Breast Shape

In Table 5, score frequencies for both studied groups. Only evaluator I and evaluator III, at the 1-month postoperative analysis, reported that the left breast featured significant differences in the scores for the SG and SF groups. For both evaluators, the SF group scored better than SG group. Postoperative assessments for 3 months were not shown as they are similar to the ones for 1 month after surgery.

Table 6 Means (standard deviation) or Medians (minimum–maximum) of the five studied variables in both implant groups for 20 patients at 3 months

Variable	SF	SG	*p*
Fluid (1–4)	2 (1–4)*	2 (1–3)	0.666
Folds (1–4)	1 (1–2)*	1 (1–2)	0.482
Capsule (mm)	1.6 (0.17)**	1.7 (0.14)	0.327
Base (mm)	95.7 (6.90)**	90.0 (8.70)	0.024***
Projection (mm)	50.8 (5.11)**	52.5 (4.45)	0.253

P values associated with Student's *t* test or Mann–Whitney's test

*Median; **Mean; ***$p < 0.05$

Table 7 Means (standard deviation) or Medians (minimum – maximum) of the five studied variables for both implant groups with 20 patients in the 12th month

Variable	SF	SG	*p*
Fluid (1–4)	2 (1–3)*	2 (1–3)	0.265
Folds (1–4)	1 (1–3)*	1 (1–3)	0.516
Capsule (mm)	1.7 (0.22)**	1.8 (0.23)	0.42
Base (mm)	94.9 (7.07)**	87.0 (8.34)	0.005***
Projection (mm)	52.0 (5.24)**	54.4 (5.64)	0.204

P values associated with Student's *t* test or Man–Whitney test

*Median; **Mean; ***$p < 0.05$

Table 8 Mean surgical time between subglandular and subfascial technique

	SG	SF
Mean surgical time	18.2 min (10–40 min)	30.7 min (14–45 min)

$P < 0.01$

Results of the radiological assessment

In the analysis of the correct implant positioning by means of MRI scanning, assessment error was evidenced in four patients, two in the subfascial and two in the subglandular group (Tables 6, 7). Statistical analysis did not evidence any different ratios of hits/errors between the groups either in the first examination ($p = 1.000$) or in the second examination ($p = 0.998$) (Table 8) (Figs. 1, 2, 3, 4 and 5).

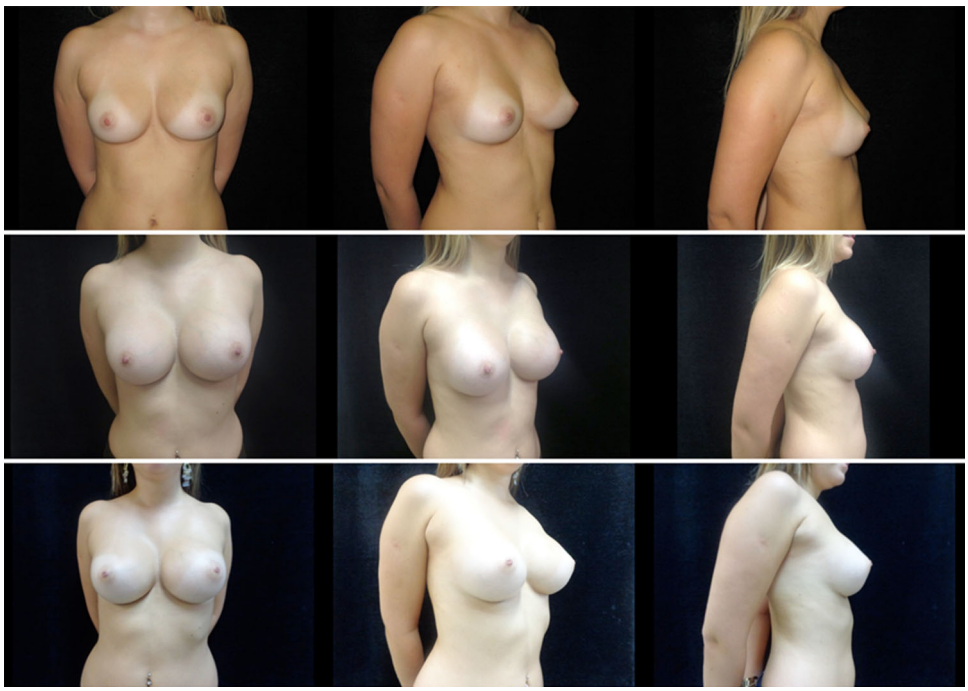

Fig. 1 Case of a bilateral subfascial breast implant. Line above is the postoperative pictures of 12 months, and line below the preoperative

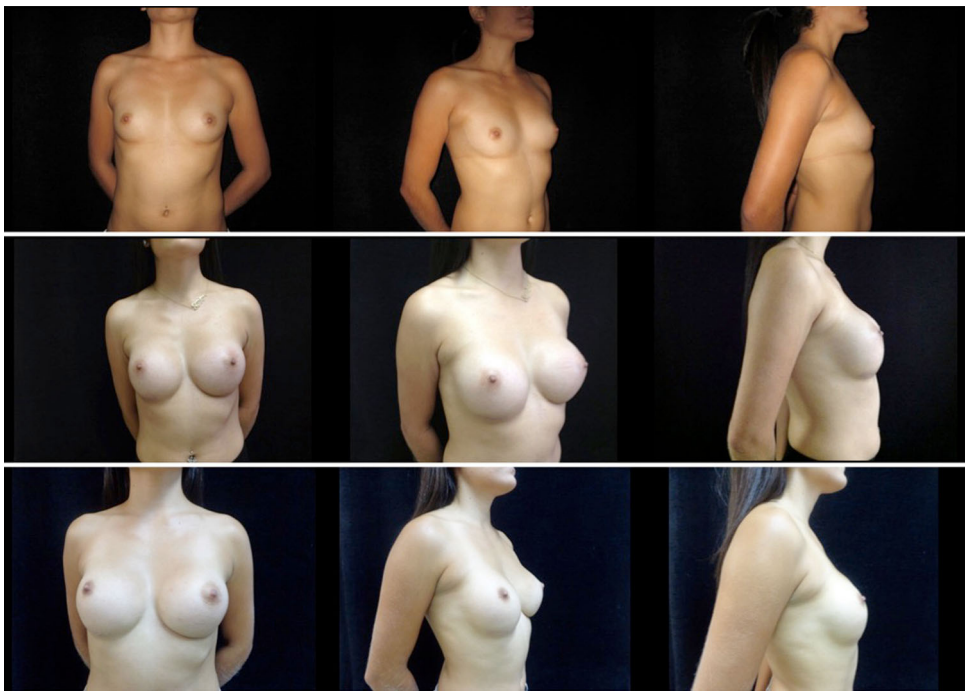

Fig. 2 Case of a subfascial breast implant on the right and a subglandular breast implant on the left breast. Line above is the postoperative pictures of 12 months, and line below the preoperative

There were no postoperative complications in either group. There were no cases of hematoma, infections, or prosthesis extrusion.

Discussion

The subfascial breast augmentation technique has been performed in recent years [5–17]. Its positive aspects are related to a painless recovery compared to the submuscular

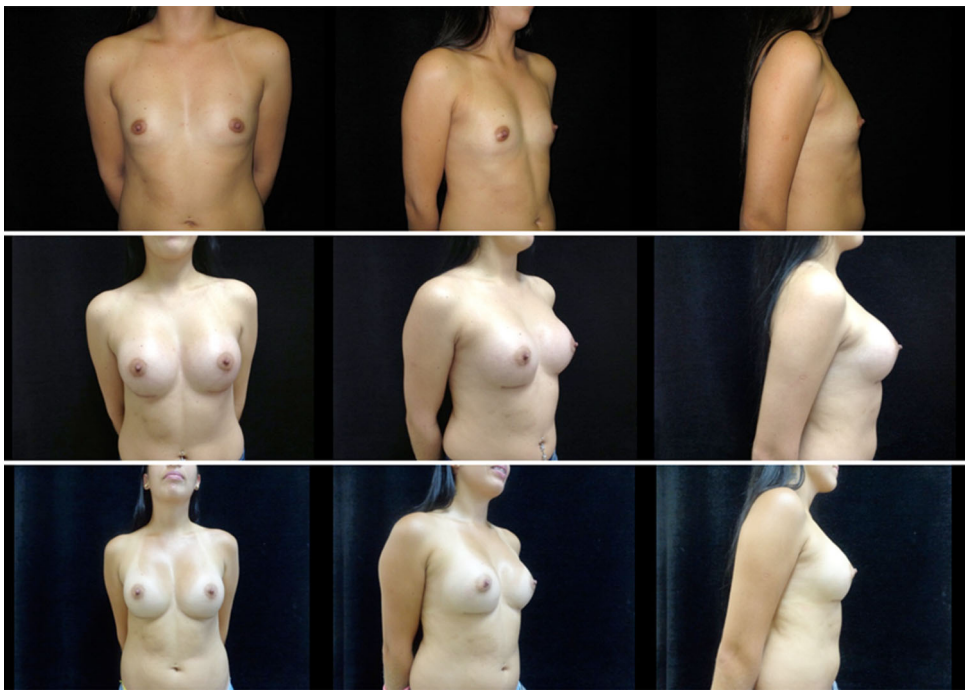

Fig. 3 Case of a subfascial breast implant on the left and a subglandular breast implant on the right breast. Line above is the postoperative pictures of 12 months, and line below the preoperative

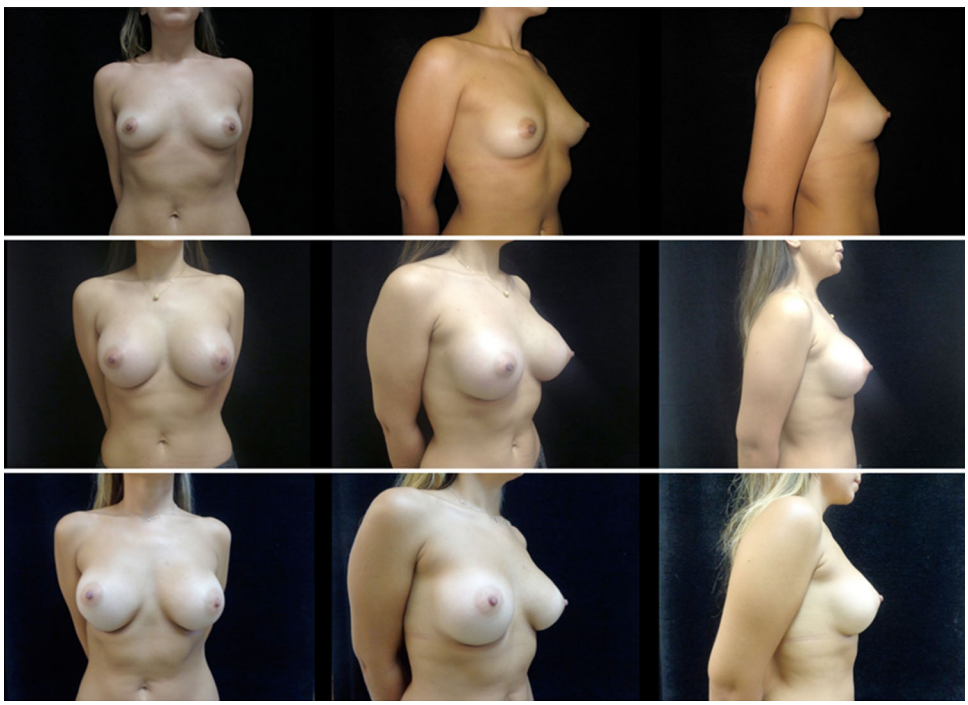

Fig. 4 Case of a bilateral subglandular breast implant. Line above is the postoperative pictures of 12 months, and line below the preoperative

position and provision of the implant with an extra tissue coverage. However, the preservation of the pectoral fascia and the influence on the aesthetic outcome and complications remains controversial. In spite of the absence of consensus concerning the suboptimal soft tissue coverage provided by the pectoral fascia and the limitation involved with its thickness, some studies have demonstrated a satisfactory outcome in selected patients [5–17]. However, many published articles include retrospective data collection or opinions based on their authors' experiences, and results are more objectively observed in relation to the complication rates than aesthetic results.

Pereira & Sterodimas in a prospective study compared postoperative results of transaxillary breast augmentations

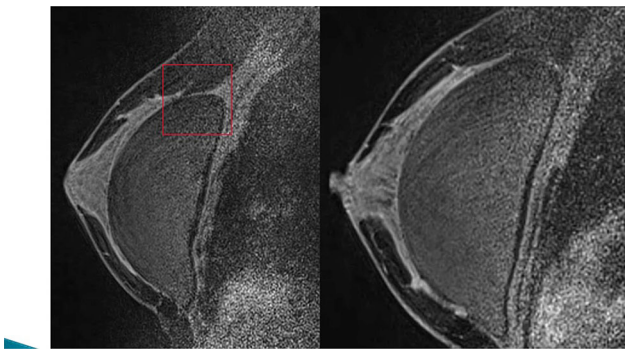

Fig. 5 Magnetic resonance imaging of a patient with breast implants in different planes. The left implant placed in the subfascial plane (image enhancing the fascia covering the top of the implant). The right implant located in the subglandular plane (noticeable absence of fascia coverage at the top of the implant)

in the subglandular, subfascial, and submuscular pockets. Except for three patients, who had mild implant distortion during major pectoralis muscle contracture, patients presented similar rates of satisfaction [16]. Brown et al. in a retrospective, non-randomized comparative study between subfascial and subglandular techniques with a follow-up of 51 months, observed no statistical differences, either in complication rates or in patient satisfaction [17].

In our study, a randomized, double-blinded prospective study was performed and enabled to have a more precise evaluation to compare both techniques, with similar tissues and features. The risks taken were asymmetries and higher rate of abnormalities from one technique in relation to the other. In the assessment of breast consistency, no differences were observed between the groups according to Baker classification. In addition, data from the 3rd month and after 12th month did not evidence the superiority of either technique. In addition, satisfactory rates (Baker I and II) were evidenced in around 70% of the cases.

Concerning the clinical differences related to the type of pocket, no evaluators scored frequencies of hits/errors significantly different between the SF and SG groups in terms of clinical examination (visual assessment/breast palpation). Assuming that the chance of hits and errors was 50%, it was concluded that the clinical findings for both techniques were similar in the studied population. Additionally, reviewing the evaluations of the five evaluators in the 3rd and 12th months, no differences between subglandular and subfascial insertion planes were observed. Similar results were observed in terms of aesthetic evaluation on breast shape and contour, where no statistical differences were noted between the two groups. When we compared the evaluation at the 3rd month and at the 20th month, good and excellent rates above 90% of the sample were observed for both groups.

As no clinical differences were found between the SF and SG, a radiological evaluation through MRI at the 1st and 12th postoperative months was performed. In order to avoid evaluation biases, two breast radiologists were selected for that task. The characteristics of the implant pocket and the identification of the fascia as a real anatomical structure on MRI was carried out, with the correct anatomical plane identification in 90% of the examinations. For this purpose, the identification of the subfascial pocket was possible due to the clarity of the fascial contour in the upper breast pole.

The presence of periprosthesis fluid, implant folds, capsule thickness, base and projection of the breast implant were the assessed items. No differences concerning the presence of fluid, number of folds in the implant or capsular thickness were observed between the groups, which corroborates the clinical data. The implant base in the SG group presented a smaller dimension, featuring a statistical difference when comparing the third and twelfth months. Until the current moment, no reoperation to treat any asymmetries or complications were necessary; however, patients are intended to be re-evaluated in the future.

The current study had some important strengths and limitations. The data reported here represent a unique view of real-world clinical practice approaches to breast augmentation using SG and SF techniques based on the experiences of a selected group of surgeons. The present study was designed to capture capsular contracture and, in the future, may be to assess rare complications such as double capsule, rotation, or late seroma. However, the subjective classification of contracture may produce bias. An additional limitation of the study is that it represents a highly selective group of patients with round, texturized implants from a unique manufacturer. Thus, these data cannot be used to draw conclusions about other implant types and brands because the study methodology addressed differ from other samples. In summary, the results of this prospective study have certain limitations; however, the analysis is unique in the objective to define the consequences of pocket decision.

Conclusion

Refinements in surgical procedures associated with new generations of silicone implants will possibly decrease the risks, complications, and reoperation rates associated with breast augmentation in the future. Integration of personal experience and scientific data is essential for the success of any surgeries, mainly in the aesthetic field, which often relies on personal opinions. The outcomes reported in this study provide a clinical perspective to the subfascial pocket, and highlight the need for longer follow-up and accounting for different factors when assessing outcomes among breast augmentation cohorts.

In conclusion, the choice between subfascial and subglandular planes does not feature any clinical differences, and priority for either technique may occur according to personal experience, as one technique is not superior to the other.

Compliance with Ethical Standards

Conflict of interest Breast implants were donated by Silimed. MRIs were freely held at DAPI (Diagnóstico Avançado por Imagem—Center of Advanced Imaging Diagnosis). None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this manuscript. The authors declare that they have no conflicts of interest to disclose.

Ethical Approval This article does not contain any studies with human participants or animals performed by any of the authors.

Informed Consent For this type of study, all the patients had signed the informed consent.

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