UDC 618.19-089.844-089.197.7 -77-007.41
DOI http://doi.org/10.30978/GS-2023-2-47

ISSN 2786-5584 print
ISSN 2786-5592 online

Quantitative assessment of the breast implant malposition after augmentation mammaplasty

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Slight displacement of breast implants from initial positioning is expected and inherent in submuscular augmentation mammoplasty (SAMP). However, due to various factors, displacement of implants can progress, causing discomfort, changes in the shape of the breast, and deterioration of aesthetics. The boundary between normality and pathology in the case of displacement of the mammary glands (MG) implants is currently unclear due to various reasons, including the lack of a quantitative measure of its assessment.

Objective — to develop a quantitative assessment of breast implant malposition (BIM) and to determine its one-year frequency within a year after SAMP.

Materials and methods. The study included 112 women who underwent SAMP for hypomastia in the period from 2020 to 2022 at the Bogomolets National Medical University. The average age was 34.1 ± 6.7 years, body mass index — 20.4 ± 1.8 kg/m^2; 78 (69.6 %) women had a history of pregnancy and childbirth, and 75 (67.0 %) were breastfeeding. Round prostheses with a smooth surface were implanted in all patients. The value of BIM was evaluated one year after SAMP according to the developed method as a percentage of the increase in the area of the non-ossified area in relation to the area of the prosthesis.

Results. In all women, there was a 7.94.5 % (from 1.5 % to 34.5 %) displacement of the implants from their initial location in all MG. Among the vectors of BIM, lower-lateral ones prevailed — 124 (55.4 %) MG compared to 53 (28.6 %) upper-lateral ones, p = 0.001. Lower 18 (8.0 %) and upper-lateral at 150° — 11 (4.9 %) BIM were the least common. Symmetrical matching of prosthesis movement vectors in both MGs was observed in 75 (67.0 %) women; in 37 (33.0 %), they were different. The same values of BIM in both MGs were observed in 54 (48.2 %) women. In other cases, the values of BIM were greater in the right MG — 40 (35.7 %) or in the left MG — 18 (16.1 %). Cluster analysis classified the displacement of implants into 4 degrees: the first — from 1.5 % to 6.4 %, the second — from 6.5 % to 10.4 %, the third — from 10.5 % to 20.0 %, and the fourth -> 20.0 %.

Conclusions. Using smooth-surfaced, round implants, the displacement of all implants from their initial site was shown to be 7.9 ± 4.5 % one year following SAMP.

Keywords
augmentation mammoplasty, malposition of implants, diagnosis, classification.

ARTICLE • Received 2023-07-25 • Received in revised form 2023-09-02

Augmentation mammaplasty (AMP) of the mammary glands (MG) remains the most common surgical procedure. According to ISAPS data, in 2021, AMP of the MG was performed in 1,685,471 women [9]. In 36 % of cases, there is a need for revision surgery after the initial AMP [2]. At the same time, the number of surgeries to remove implants is growing [9]. One of the reasons for removing or replacing an implant is its malposition [4, 8]. Under the breast implant malposition (BIM) the incorrect position of the prosthesis is understood, which can occur due to the incorrect position of the implant during AMP or due to the displacement of the implant in the prosthetic neopocket after surgery [3, 17]. There are lower, medial, lateral, upper and rotational malpositions [1, 3, 14], but the vector of displacement of implants can be any.

After primary AMP, the frequency of repeated surgeries associated with implant malposition is 4.7—5.2 % [7, 10], and after secondary AMP, it is about 10 % [11—13, 18]. This statistic applies only to the pronounced malposition of implants, in which

there are significant changes in the shape and contour of the breast and they get an ugly appearance. If all degrees of BIM are taken into account, its frequency can be significantly higher — up to 94 % of cases after 7 years [20]. At the same time, there is no quantitative assessment of the degree of BIM. The division of BIM into such categories as mild, moderate, severe and similar is based only on the subjective opinion of the doctor or patient, which does not allow us to unify the results of research on this problem.

Objective — to develop a quantitative assessment of the breast implant malposition and to determine its one-year frequency within a year after submuscular augmentation mammaplasty.

Materials and methods

The study included 112 women who underwent dual plane submuscular AMP (SAMP) to treat hypomastia in the period from 2020 to 2012 at Bogomolets National Medical University.

The average age of women was 34.1 ± 6.7 years old (from 19 to 51 years old; Fig. 1); average body mass index — 20.4 ± 1.8 kg/m^2 (from 17.4 to 25.3 kg/m^2; Fig. 2).

Pregnancy and childbirth were in the history of 78 (69.6 %) women, and 75 (67.0 %) women breastfed (Fig. 3).

All patients were implanted with round prostheses with a smooth surface.

The median area of the base of the prosthesis was 122.7 cm^2 (interquartile range (IQR): 108.4—132.7), median projection of the prosthesis — 4.3 cm (IQR: 4.0—5.0), median prosthesis volume — 400.0 cm^3 (IQR: 340.0—475.0).

The assessment of the malposition of the MG prosthesis was carried out according to the developed method.

Method of diagnosis of malposition of breast prostheses

BIM was understood as any movement of the MG prosthesis from its location created during the surgery.

All women had standardized prosthesis positioning. The main condition for implantation of the prosthesis was to place the center of the sphere of the prosthesis with a point crossed by the mid-clavicular line, the length of which was 22 cm in women over 175 cm tall, 21.5 cm in women 165—174 cm tall, and 21 cm in women below 165 cm with a line drawn from the jugular fossa of a similar length (Fig. 4). This point of intersection of the lines corresponded to the projection of the nipple on the chest in the patient's standing position with her arms lowered. The area of the base of the implants was supposed to provide an intramammary distance of 3 cm.

After 6 and 12 months, the implant location was evaluated in relation to the initial position in the patient's standing position with her arms lowered.

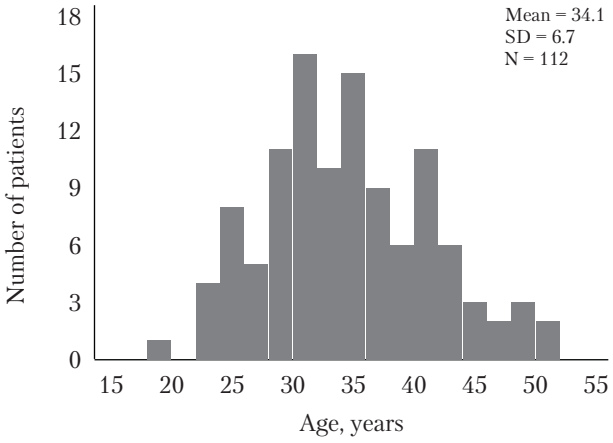

Figure 1. **Distribution of patients by age**

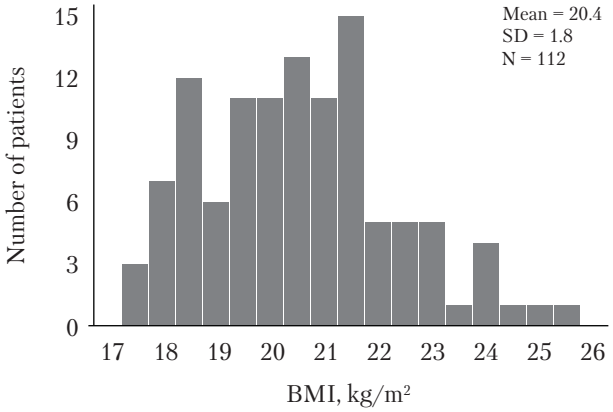

Figure 2. **Distribution of patients by body mass index**

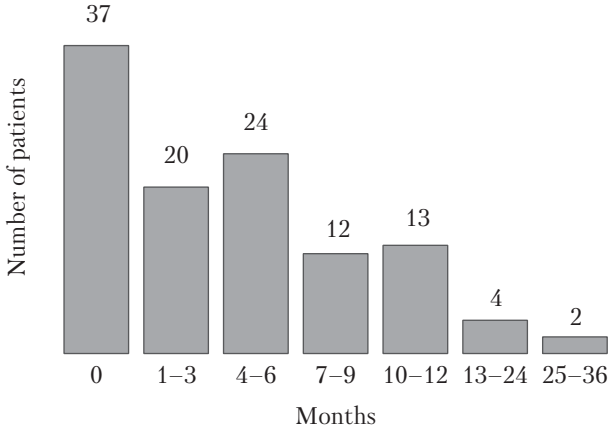

Figure 3. **Distribution of patients by lactation period**

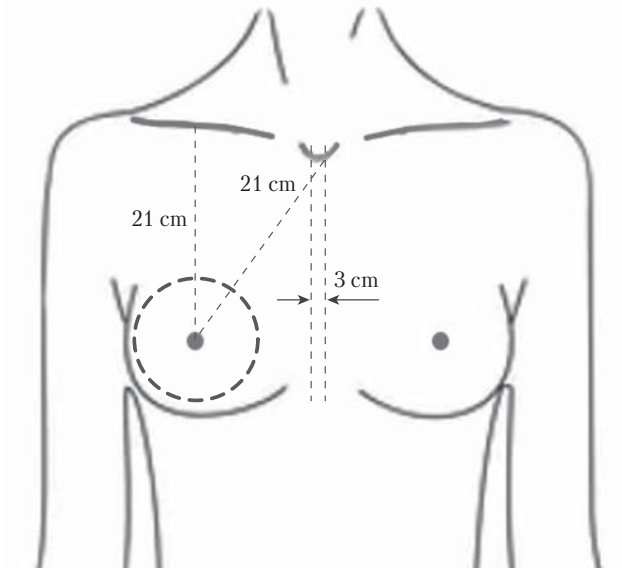

Figure 4. **Determining the location of the implant center. A dashed line marks the contour of the base of the prosthesis**

To do this, the primary boundaries of the prosthesis placement were outlined according to the standard marking. Then the boundaries of the prosthesis were marked by moving it clockwise (for the right breast) and counterclockwise (for the left breast), starting from the 6 o'clock mark for every + 30 degrees. The marked points were connected to each other by arc-shaped lines that corresponded in shape to the arc of the prosthesis sector at 30 degrees. As a result, the boundaries of the area within which the implant was located were obtained a year after surgery. This area corresponds to the area of the base of the neopocket prosthesis (hereinafter referred to as the neopocket area). The area of the neopocket had the shape of an ellipse and was calculated by the formula:

$$S = R_1 \cdot R_2 \cdot 3{,}14,$$

where R_1 and R_2 are the largest and smallest radii of the ellipse, respectively.

The percentage increase in the area of the neopocket relative to the area of the prosthesis is a quantitative measure of the movement of the implant (malposition) after surgery and was calculated by the formula:

$$\text{BIM, \%} = 100 \cdot (\text{neopocket area} - \text{implant area}) : \text{implant area}.$$

The degree measure of the angle between the long axis of the ellipse and the mid-clavicular line served as an estimate of the direction of the prosthesis malposition (Fig. 5).

Statistical processing of the obtained data was performed using the IBM SPPS Statistics 22 statistical package. They performed descriptive statistics. The normality of the data distribution was checked using the chi-square test. Quantitative data, depending on the nature of the distribution, are presented as the arithmetic mean (M) ± standard deviation (SD) or as the median (Me) and IQR. For data whose distribution does not differ from the normal one, the comparison was performed using the paired Student t-test for related samples and the Student t-test for unrelated samples. For data whose distribution differs from normal, variables were compared using the Wilcoxon sign rank criterion for related samples and the Wilcoxon-Mann-Whitney criterion for unrelated samples. An ANOVA analysis of variance was performed to determine statistical differences in mean values between three or more groups.

The relative values were compared using the Pearson chi-square test. A two-step cluster analysis was performed to identify groups of similar objects. The null hypothesis of equality of variables was rejected at $p < 0.05$.

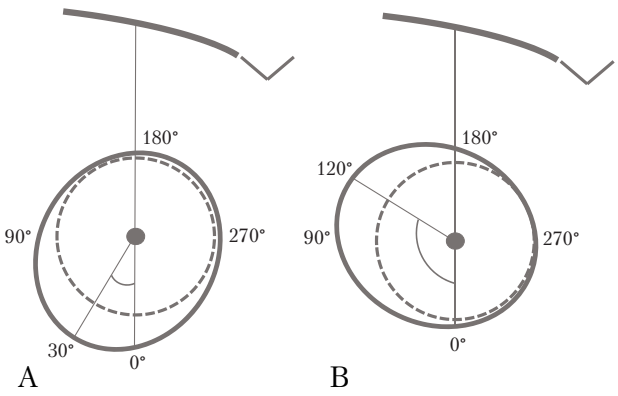

Figure 5. **Measurement of malposition angles: lower-lateral BIM at an angle of 30° (A) and upper-lateral breast implant malposition at an angle of 120° (B).** A dashed line indicates the contour of the base of the prosthesis; a solid line indicates the boundaries of the base of the neopocket prosthesis (the boundaries of the prosthesis displacement)

Results

A year after SAMP, there was a displacement of implants from their original location in all MGs. The implant was placed within the capsula, the base of which corresponded to the shape of an ellipse. The larger diameter of this ellipse increased compared to the implant diameter from 0.2 cm to 3.0 cm: Me — 0.6 cm (0.2—0.7); the smaller diameter of the ellipse increased from 0 cm to 0.9 cm: Me — 0.2 cm (0.2—0.3). The average percentage increase in the area of the neopocket of implants and, consequently, the quantitative value of implant movement (malposition) was 7.9 ± 4.5 % (from 1.5 % to 34.5 %) (Fig. 6).

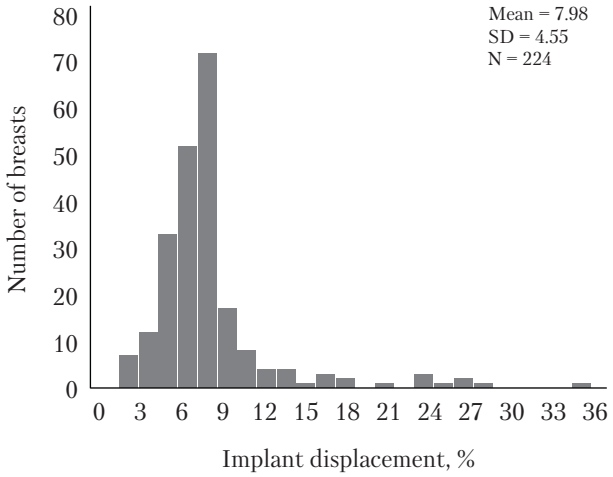

Figure 6. **Distribution of patients by percentage of breast implant malposition**

The average BIM value did not differ in the right and left MG: 8.01 ± 4.34 cm², and 7.94 ± 4.77 cm² accordingly (p = 0.891).

However, the same BIM values in both MGs were observed in 54 (48.2 %) women and averaged 6.9 ± 1.0 % (from 4.9 % to 9.4 %). In other cases, BIM was higher in the right MG — 40 (35.7 %), by an average of 3.2 ± 4.8 % (from 0.4 % to 20.2 %), or in the left MG — 18 (16.1 %), by an average of 6.1 ± 7.3 % (from 0.1 % to 26.4 %).

Cluster analysis of BIM percentage indicators revealed four clusters with a good degree of connectivity and separation. The silhouette measure of connectivity and cluster separation was 0.8.

The first cluster includes BIM indicators from 1.5 % to 6.4 %, the second cluster from 6.5 % to 10.4 %, the third cluster from 10.5 % to 20.0 %, and the fourth > 20.0 % (Table 1).

There were also no significant differences between MGs in the distribution of clusters that characterize the degree of implant displacement (p = 0.520) (Table 2).

According to the cluster size, 89 (79.5 %) women had the same malposition in both MGs, and 23 (20.5 %) women had different malposition values in MG (Table 3).

Consequently, 18 (16.1 %) women had BIM values in the third and fourth clusters in at least one of the MGs.

In our study, we observed six variants of BIM directions: down in the vertical direction at an angle of 0° ± 15°; in the lower-lateral directions along vectors of 30° ± 15° and 60° ± 15° from the vertical; in the lateral direction by 90° ± 15° from the vertical; and in the vertical-lateral directions by 120° ± 15° and 150° ± 15° from the vertical (Fig. 7).

Table 1. **Results of a two-step cluster analysis**

Cluster	BIM, % (Min—Max)	Number of MGs
First	1.5—6.4	79 (35.3 %)
Second	6.5—10.4	118 (52.7 %)
Third	10.5—20.0	18 (8.0 %)
Fourth	20.1—34.5	9 (4.0 %)

Table 2. **Distribution of clusters that characterize the degree of malposition of the implant in the right and left mammary gland**

Cluster	Right	Left	Total
First	40 (35.7 %)	39 (34.8 %)	79 (35.3 %)
Second	61 (54.5 %)	57 (50.9 %)	118 (52.7 %)
Third	6 (5.4 %)	12 (10.7 %)	18 (8.0 %)
Fourth	5 (4.5 %)	4 (3.6 %)	9 (4.0 %)
Total	112	112	224

Table 3. **Distribution of women by the ratio of malposition clusters in both mammary glands**

Ratio of BIM clusters	Quantity (n = 112)
First : First	34 (30.3 %)
Second : Second	50 (44.6 %)
Third : Third	5 (4.5 %)
First : Second	10 (8.9 %)
First : Fourth	1 (0.9 %)
Second : Third	4 (3.6 %)
Second : Fourth	4 (3.6 %)
Third : Fourth	4 (3.6 %)

Among the BIM vectors, lower-lateral — 124 (55.4 %) mammary glands prevailed compared to upper-lateral — 53 (28.6 %), p = 0.001. The least frequently noted was the lower 18 (8.0 %) and upper-lateral at 150° — 11 (4.9 %) BIM (Table 4).

There were no cases of medial displacement of prostheses or vertical displacement of prostheses by 180° ± 15°.

Symmetrical coincidence of prosthetic movement vectors in both MGs was observed in 75 (67.0 %) women, and 37 (33.0 %) women had different directions of BIM. At the same time, there

were no differences between the right and left MGs in terms of the time of implant movement directions (p = 0.279; see Table 4).

However, it should be noted that the upper-lateral directions of movement of MG implants on the left were more common than in the right MG (30.4 % against 17.0 %), but in the right MG, lower-lateral movement of implants was more common (78.2 % against 62.2 %, respectively) (p = 0.021).

In general, the direction of BIM did not affect the average value of malpositions, according to the ANOVA analysis of variance. At the same time, the average values of BIM in the lower-lateral direction by 60° were significantly higher than with the lower, lateral, and upper-lateral by 150° directions of implant displacement (p < 0.05 for all) (Fig. 8).

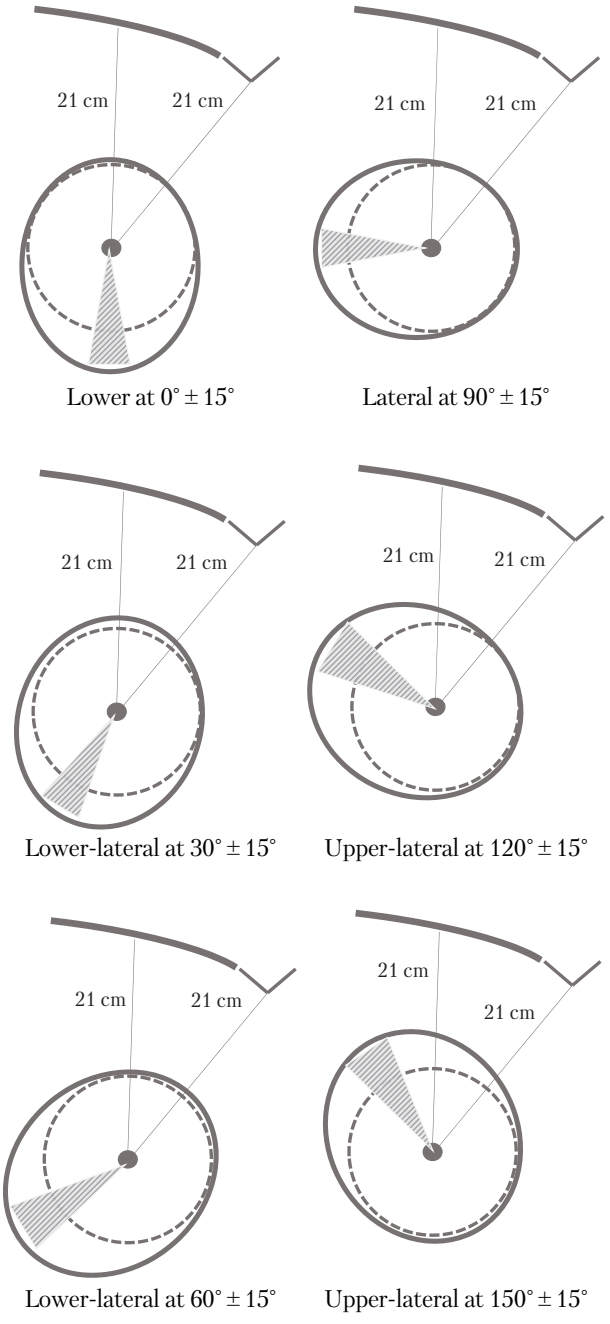

Figure 7. **Variants of the BIM vector in the example of the right MG one year after SAMP.** Dashed line indicates the contour of the base of the prosthesis; a solid line indicates the boundaries of the base of the neopocket prosthesis (the boundaries of the prosthesis displacement). Shaded sector indicates the angle of movement of the prosthesis

Discussion

Placing an implant in a specific area of the body for therapeutic or aesthetic purposes always requires reliable fixation in the selected area. The tendency of a foreign body to dislocate is a common medical problem. Breast implants are no exception, especially since their fixation cannot be recognized as absolute. You can always expect MG implants to mix at a certain distance in any direction from the placement site. This displacement can be subtle for the patient and others or cause aesthetic problems and require revision surgery [7, 10—13, 18]. If we recognize postoperative implant displacement as

Table 4. **Frequency of directions of breast implant malposition**

Direction of BIM	Right	Left	Total
Lower	9 (8.0 %)	9 (8.0 %)	18 (8.0 %)
Lower-lateral at 30°	24 (21.4 %)	21 (18.8 %)	45 (20.1 %)
Lower-lateral at 60°	44 (39.3 %)	35 (31.3 %)	79 (35.3 %)
Lateral	16 (14.3 %)	13 (11.6 %)	29 (12.9 %)
Upper-lateral at 120°	14 (12.5 %)	28 (25.0 %)	42 (18.8 %)
Upper-lateral at 150°	5 (4.5 %)	6 (5.4 %)	11 (4.9 %)
Total	112	112	224

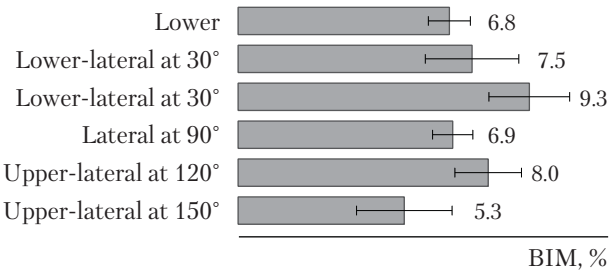

Figure 8. **Average values of the percentage of breast implant malposition depending on the direction of displacement of the prostheses**

an attribute of augmentation mammaplasty (94 % of cases 7 years after subpectoral augmentation mammaplasty [20]), then the question arises as to what is the minimum amount of malposition that is acceptable with the augmentation mammaplasty technique and a certain type of implant, and what is the amount that exceeds the predicted value. This is not only clinically and practically important, but also legally important, because it is almost impossible to avoid displacement of the MG implant after surgery, and the subjective attitude of patients toward even a slight displacement can be extremely negative. The solution to this problem is the need to create a tool or technique for quantitative measurement of the amount of implant displacement. Currently, the existing methods for determining the degree of BIM are based on a qualitative subjective assessment [5, 12, 15, 19]. The exception is quantitative methods for assessing the degree of malrotation of the anatomical prose of the MG [1, 6].

Absolute indicators, such as the amount of movement in any direction in relation to stable anatomical features, can determine the degree of malposition. However, the same absolute value of the prosthesis displacement will look different depending on the size of the implant. Therefore, a more correct assessment of malposition should take into account the ratio of the size of the implant to the size of the displacement of the prosthesis. Since the displacement of the prosthesis occurs within the prosthetic neopocket and is associated with an increase in the area of its base, the amount of malposition can be estimated as a relative value: the percentage by which the area of the prosthetic neopocket has increased relative to the implant area. Using this approach, we found that one year after SAMP using round prostheses with a smooth surface, 112 women showed a displacement of implants from the original location in all MGs by 7.9 ± 4.5 % (from 1.5 % to 34.5 %). The same BIM values in both MGs were observed in 54 (48.2 %) women. In other cases, BIM was higher in the right MG — 40 (35.7 %), or in the left MG — 18 (16.1 %).

Taking into account the significant range of BIM values, we performed a cluster analysis, which made it possible to classify the displacement of implants into four stages (clusters) with specific quantitative values. The first cluster includes BIM indicators from 1.5 % to 6.4 %, the second cluster from 6.5 % to 10.4 %, the third cluster from 10.5 % to 20.0 %, and the fourth > 20.0 %. These degrees of BIM can probably correspond to certain clinical manifestations and quantify categories such as subclinical, mild, moderate, and severe BIM. Nevertheless, this assumption requires a special study. The use of the quantitative assessment method made it possible to determine the frequency of various directions of BIM and their degree, which in the future can contribute to the development of methods of prevention and treatment.

Declaration of interests

The authors declare that they have no conflicts of interest.

Funding. No grants or funding were used in this study.

Ethics approval

The study was conducted in accordance with the Helsinki Declaration of Ethics. The study protocol was approved by the ethics committee of Bogomolets National Medical University (protocol N 139 signed November 24, 2020).

Authors contributions

Y. M. Susak: conceptualization, methodology, editing; A. B. I. Mohammad: investigation, statistical analysis, writing, and original draft.

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Кількісна оцінка мальпозиції імплантів молочної залози після аугментаційної мамопластики

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Незначне зміщення імплантатів молочної залози (МЗ) від первинного позиціювання є очікуваним і притаманним субмускулярній аугментаційній мамопластиці (САМП). З різних причин зміщення імплантатів може прогресувати, що спричиняє дискомфорт, зміну форми грудей, погіршення естетичного вигляду. Межу між нормою та патологією у разі зміщення імплантатів МЗ не визначено, зокрема через відсутність кількісної міри її оцінки.

Мета — розробити кількісну оцінку мальпозиції імплантатів молочної залози та визначити її частоту протягом року після субмускулярної аугментаційної мамопластики.

Матеріали та методи. У дослідження було залучено 112 жінок, яким виконано САМП з приводу гіпомастії в період з 2020 до 2022 р. на базі Національного медичного університету імені О. О. Богомольця. Середній вік пацієнток — (34,1 ± 6,7) року, індекс маси тіла — (20,4 ± 1,8) кг/м^2. Вагітність і роди в анамнезі були у 78 (69,6 %) жінок, годували грудьми 75 (67,0 %). Усім пацієнткам імплантували круглі протези з гладенькою поверхнею. Оцінку величини мальпозиції (відсоток збільшення площі неокишені щодо площі протеза) імплантатів молочної залози (МПІМЗ) проводили через рік після САМП за розробленою методикою.

Результати. У всіх жінок в обох МЗ виявлено зміщення імплантатів від початкового розташування від 1,5 до 34,5 % (у середньому — на (7,9 ± 4,5) %). Серед векторів МПІМЗ переважали нижньо-латеральний (124 (55,4 %) МЗ) порівняно з верхньо-латеральним (53 (28,6 %), p = 0,001). Найрідше реєстрували нижній (18 (8,0 %)) та верхньо-латеральний на 150° (11 (4,9 %)). Симетричний збіг векторів переміщення протезів в обох МЗ зафіксовано в 75 (67,0 %) жінок, у решти вектори були різні. Кластерний аналіз дав змогу класифікувати зміщення імплантатів на 4 ступені: перший — від 1,5 до 6,4 %, другий — від 6,5 до 10,4 %, третій — від 10,5 до 20,0 %, четвертий > 20 %.

Висновки. Через рік після САМП із використанням круглих імплантатів із гладенькою поверхнею зареєстровано зміщення всіх іплантатів щодо початкового розташування у середньому на (7,9 ± 4,5) %. Симетричне переміщення протезів в обох МЗ зареєстрували в 75 (67,0 %) жінок, у решти — несиметричне. Однакову величину мальпозиції імплантатів в обох МЗ відзначили у 54 (48,2 %) жінок. Величина мальпозиції була більшою в правій МЗ у 40 (35,7 %) випадків, у лівій МЗ — у 18 (16,1 %).

Ключові слова: аугментаційна мамопластика, мальпозиція імплантатів, діагностика, класифікація.

FOR CITATION

Susak YM, Mohammad IAB. Quantitative assessment of the breast implant malposition after augmentation mammaplasty. General Surgery (Ukraine). 2023;2;47-53. http://doi.org/10.30978/GS-2023-2-47.