

Comparing Round and Anatomically Shaped Implants in Augmentation Mammoplasty: The Experts' Ability to Differentiate the Type of Implant

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Background: The purpose of this study was to determine whether the aesthetic results of subpectoral augmentation mammoplasty using anatomically shaped versus round prostheses are differentiable.

Methods: Thirty observers (i.e., plastic surgeons and nurses) assessed preoperative and postoperative photographs (frontal and oblique views) of 30 patients who had undergone subpectoral augmentation mammoplasty with cohesive silicone gel implants, with an average implant volume of 295 cc (range, 220 to 340 cc). The observers classified each case as round or shaped on two different occasions with a 12-week time interval. A statistical concordance analysis was performed, calculating the overall concordance rate, the interobserver, the intraobserver, and the overall intraobserver kappa indexes, to evaluate the expert observers' capacity to differentiate the implant type.

Results: Among the total of 1800 observations (30 observers assessed 30 cases on two occasions), the overall concordance rate was 50.33 percent (95 percent CI, 47.99 to 52.67). The interobserver kappa value was 0.010 (95 percent CI, 0.0025 to 0.04). The overall intraobserver kappa value was 0.0602 (95 percent CI, 0.0025 to 0.123). The observers were unable to recognize the type of implant used, nor was interobserver concordance noted. An agreement was not reached before the different observers, nor was an intraobserver concordance seen between the first and second classifications of the same cases by each observer.

Conclusion: The results obtained from subpectoral augmentation mammoplasty using anatomically shaped and round prostheses with a volume of 340 cc or less are indistinguishable, not justifying the systematic use of anatomically shaped implants in this patient. (*Plast. Reconstr. Surg.* 139: 60, 2017.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, III.

Numerous studies have been published since the commercialization of anatomically shaped implants describing the experience of surgeons with these prostheses and their advantages,¹⁻⁵ but few studies exist that compare the aesthetic results of round implants versus anatomically shaped implants.⁶⁻⁸ Mammary prostheses have evolved to improve their quality, safety, durability, and naturalness.^{9,10} The majority of implants used in Europe are silicone, which are considered to have greater longevity and a better feel than saline-filled implants.¹¹ With this as a starting

point, one of the most controversial issues is choosing the implant shape. Many surgeons tend to use either only round or only anatomically shaped implants, on the basis of their distinct advantages and disadvantages.² A widespread idea is that the anatomically shaped implants give more natural results than the round implants. The anatomically shaped implants have a straight trajectory in the upper segment, compared with the convex form of the round prostheses, although some surgeons argue that this convex form acquires an anatomical

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shape because of gravity and the pressure on the upper pole by the pectoral muscle. Many surgeons consider that obtaining the most natural result is dependent not on the use of one or the other form of prosthesis, but rather on choosing the correct implant according to the breast and chest characteristics of the patient's anatomy.^{12,13} The most important geometric difference between the anatomically shaped and the round prosthesis is the point of maximum projection, which is lower on the anatomically shaped prosthesis. The point of maximum projection in the round prostheses is the union at the center of the prosthesis, whereas in the anatomically shaped implant, it is the union of the lower third with the middle third. This difference becomes more noticeable as the volume of the prosthesis increases. As regards the surgical technique, the height of the maximum projection of the implant should coincide with the natural point of maximum projection of the breast (i.e., the nipple). If the point of maximum projection exceeds the nipple, the result will be an overfilled upper pole, obtaining a less natural result, which moves away from the ideal breast.¹⁴

A drawback of the anatomically shaped prosthesis is the possibility of rotation, with an estimated risk between 5.2 and 14 percent.¹¹ It leaves a clear deformity, especially in a prosthesis placement in the subglandular plane, giving the breast an abnormal appearance, which may require patient reoperation. Another difference between the two prostheses is the lower cost of the round prosthesis. No analytical study was found that investigated the possibility of visually differentiating the aesthetic results of anatomically shaped implants versus round implants, when the choice of implant had been individualized, following anatomical criteria.

Our hypothesis is that patients who are to undergo augmentation mammoplasty in the submuscular plane with a prosthesis not greater than 340 cc and with a distance greater than or equal to 4 cm from nipple to inframammary fold may use either round or anatomically shaped prostheses, because the aesthetic result is indistinguishable. The study objective was to determine whether there are differences that are visually identifiable by experts regarding the aesthetic results of augmentation mammoplasty with anatomical versus round prostheses in this population.

PATIENTS AND METHODS

The study included 30 patients who had undergone augmentation mammoplasty in the period between 2010 and 2013. All the patients included in this study chose the type of implant. Patients who accepted the implant proposed by the surgeon were excluded from the study. The inclusion of patients in the study followed a stratified randomization of the photographs of patients included in the mammary augmentation database belonging to one of the authors. Fifteen women received round implants (Fig. 1) and 15 women received anatomically shaped implants. Consent was given by these patients for the use of the photographs for teaching and scientific purposes.

The study inclusion criteria for patients who had undergone augmentation mammoplasty were as follows: prosthesis with a volume of 340 cc or less, in the subpectoral plane, with a distance greater than or equal to 4 cm from nipple to inframammary fold, and at least 1 year of evolution since the intervention. The study included round and anatomically shaped, moderate-plus profile cohesive silicone gel implants. The average size was 295 cc (range, 220 to 340 cc). All included patients were operated on by the same surgeon.

The cases included in the study were evaluated by 30 observers, 15 plastic surgeons (10 men and five women) and 15 plastic surgery nurses (four men and 11 women), who classified each case as "round" or "shaped" according to whether they considered a round or anatomically shaped implant had been used. Each observer was presented with the 30 cases consecutively, on two occasions, with an interval of 12 weeks. A PowerPoint (Microsoft Corp., Redmond, Wash.) presentation with the preoperative and postoperative photographs in frontal and oblique views was used to show the photographs of the cases. None of the observers knew what the study objective was, nor that they would be asked for an assessment on a second occasion, to avoid observer bias and recall bias. Neither the principal investigator, nor the case assessors, nor the data analyst knew or were involved in treating any of the cases included in the study.

The results of the questionnaires were coded in Excel 2012 (Microsoft). The concordance rate for round and shaped implants, the overall concordance rate for plastic surgeons and nurses, and a comparison of correct classifications between round and anatomically shaped

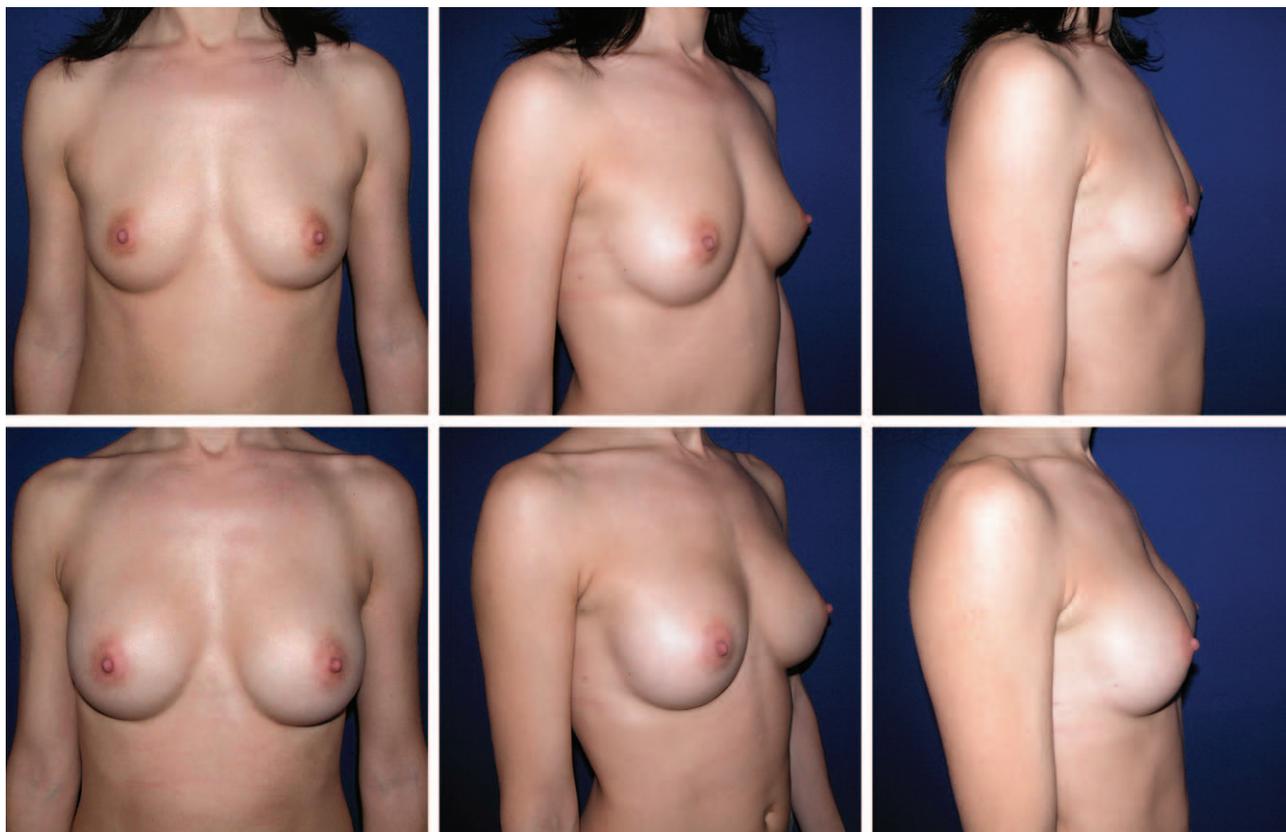


Fig. 1. A 32-year old woman with upper pole mammary deficit, who in this case chose a 300-cc round prosthesis. She obtained a full upper pole without producing an unnatural curve.

implants and among surgeons and nurses (using the chi-square test) were also calculated. Sample size calculation¹⁵ was based on an expected kappa coefficient of 0.9, with an absolute classification of observers of 90 percent, based on a previous study in which plastic surgeons had been questioned about their expected capacity to differentiate between anatomically shaped and round implants. A sample size of 24 was obtained, and entered in EPIDATA 3.1 (EpiData Association, Odense, Denmark). A ratio of correct classifications expected by the observers of 90 percent and an expected kappa coefficient of 90 percent with a precision of 0.3, was used for the calculation. The interobserver concordance was studied to measure the agreement rate between them and calculated using the Cohen kappa index with a 95 percent confidence interval.¹⁶ The intraobserver concordance was studied and calculated using the Cohen kappa index for each observer with a 95 percent confidence interval, comparing the responses of each observer in the first versus the second assessment of the cases. The overall intraobserver kappa value was calculated comparing the 30 kappa values with a 95 percent

confidence interval. All these kappa values were calculated using EPIDATA 3.1.

RESULTS

Observed Concordance or Agreement Indexes

Among the total of 1800 observations (30 observers assessed 30 cases on two occasions), an overall concordance rate of 50.33 percent (906 of 1800) (95 percent CI, 47.99 to 52.67) was observed. The observed concordance index for round prostheses was 48.3 percent (435 of 900) (95 percent CI, 45.03 to 51.65); whereas for anatomically shaped prostheses, it was 52.3 percent (471 of 900) (95 percent CI, 49.01 to 55.65). The difference of proportion of correct classifications between round and anatomically shaped prostheses is 4 percent (95 percent CI, -0.087 to 0.07) (Fig. 2).

The overall concordance index for plastic surgeons was 54.1 percent (487 of 900) (95 percent CI, 50.8 to 57.42); for nurses, it was 46.5 percent (419 of 900) (95 percent CI, 43.24 to 49.87). The difference of the percentage of correct classifications between surgeons and nurses was 7.6 percent (95 percent CI, 0.028 to 12.3).

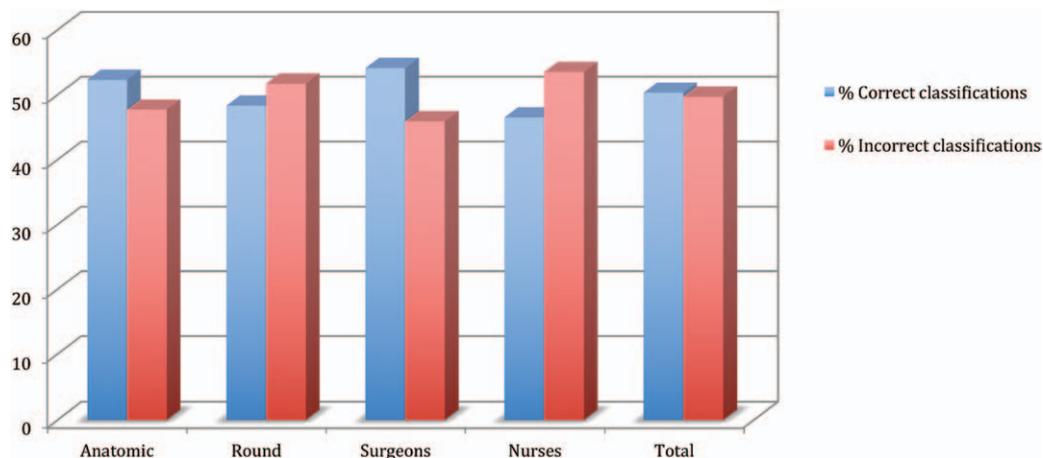


Fig. 2. Percentage of correct (blue) and incorrect (red) classifications for anatomically shaped prostheses (52.3 percent versus 47.7 percent), round prostheses (48.3 versus 51.7), plastic surgeons (54.1 versus 45.9), nurses (46.5 percent and 53.5 percent), and the total number of prostheses evaluated in the study (50.3 percent versus 49.7 percent).

Interobserver Kappa Concordance Index

The interobserver concordance analysis showed a kappa value of 0.010 (95 percent CI, 0.0025 to 0.04).

Intraobserver Kappa Concordance Index

Table 1 shows the intraobserver kappa index values gathered for each of the 30 observers who evaluated each case.

Overall Intraobserver Kappa Index

The overall intraobserver kappa value when comparing the 30 kappa values was 0.0602 (95 percent CI, 0.0025 to 0.123).

DISCUSSION

The results of this study show low concordance indexes; only 50.3 percent of the evaluated cases were correctly classified as round or anatomically shaped, and the a priori probability of correct classification was 50 percent. Although a higher percentage of the anatomically shaped prostheses were correctly classified compared with the round prostheses (48.3 percent versus 52.3 percent), these differences were not statistically significant. It was observed that the plastic surgeons correctly classified 54.1 percent of the prostheses, compared with 46.5 percent from the nurses, and these differences were statistically significant. This small difference could be attributable to the ability of the surgeons to deduce which type of prosthesis would probably be used from seeing the preoperative photographs.

The interobserver kappa index showed an insignificant agreement (kappa < 0.2), indicating

that the observers were not able to agree when classifying the type of implant used as round or anatomically shaped. The overall kappa value when comparing all the intraobserver kappa indexes also showed an insignificant agreement (kappa < 0.2). These results show the inability of observers to agree with themselves when they evaluate the same cases at two different times.

Regarding intraobserver kappa values, the lack of statistical significance can be appreciated. This may be because the sample size was calculated for the interobserver kappa index. Despite this, a tendency toward insignificant kappa values was seen (kappa < 0.2), except in four cases, where moderate intraobserver agreement (kappa = 0.4 to 0.6) was seen. This could be because of the predictive ability of any of the participants regarding the type of prosthesis that would be indicated in each case, from having seen the preoperative photographs rather than from the actual appearance as seen on the postoperative photographs.

Previous studies showed the inability of surgeons to identify the type of implant used.⁷ Our study is the first study having an analytical design with a rigorous statistical analysis to study whether it is possible to differentiate the aesthetic results obtained with anatomically shaped and round implants. A study was recently published in which no differences were found in the aesthetic results or in patient satisfaction between anatomically shaped and round implants in bilateral mammary reconstruction. Those results support the ones obtained in our study.⁸

Our results are based on patients in whom prostheses were used with a volume of 340 cc or less, in the subpectoral plane, with a distance greater than

Table 1. Agreement Expected by Chance, Observed Agreement, and Intraobserver Kappa Values with Confidence Intervals at 95 Percent for Each of the 30 Observers Who Rated Each Case

Observer	Agreement Observed	Agreement Expected	Kappa Value	95% CI
1	0.6000	0.5022	0.1793	-0.1549-0.5474
2	0.6000	0.5200	0.1820	-0.1900-0.5233
3	0.8000	0.5067	0.5946	0.3075-0.8817
4	0.6000	0.4933	0.2105	-0.1255-0.5465
5	0.5333	0.5067	0.0541	-0.3005-0.4086
6	0.6000	0.4933	0.2105	-0.1255-0.5465
7	0.6000	0.5022	0.1964	-0.1549-0.5478
8	0.5333	0.4889	0.0870	-0.2398-0.4137
9	0.7333	0.5111	0.4545	0.1443-0.7648
10	0.6000	0.5200	0.1667	-0.1900-0.5233
11	0.4667	0.5022	-0.0714	-0.4281-0.2852
12	0.3333	0.5022	-0.1823	-0.6741-0.0045
13	0.4667	0.5200	-0.1111	-0.4628-0.2406
14	0.4000	0.5067	-0.2162	-0.5595-0.1270
15	0.4667	0.5467	-0.1765	-0.4949-0.1420
16	0.4286	0.5408	-0.2444	-0.5796-0.907
17	0.4667	0.4933	-0.0526	-0.3979-0.2927
18	0.4667	0.5200	-0.1111	-0.4628-0.2406
19	0.4667	0.4933	-0.5026	-0.3979-0.2927
20	0.5333	0.5067	0.0541	-0.3043-0.2336
21	0.6000	0.5022	0.1964	-0.1549-0.5478
22	0.5333	0.4889	0.0870	-0.2398-0.4137
23	0.4667	0.5022	-0.0714	-0.4281-0.2852
24	0.6000	0.5022	0.1964	-0.1549-0.5478
25	0.4000	0.4889	-0.1739	-0.5020-0.1542
26	0.4667	0.5556	-0.2000	-0.5256-0.1256
27	0.4333	0.5222	-0.1860	-0.5214-0.1421
28	0.4000	0.4889	-0.1739	-0.5020-0.1542
29	0.5333	0.5067	0.0541	-0.3005-0.4086
30	0.3333	0.49333	-0.3158	-0.6483-0.0167

or equal to 4 cm from nipple to inframammary fold. According to our results in this population, the use of anatomically shaped implants is not justified because, besides having a higher cost, there is a risk of malrotation with no benefit over round prostheses. Future studies should evaluate the results obtained in the subglandular and subfascial planes and with prostheses with greater volume.

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