Intraoperative Comparison of Anatomical versus Round Implants in Breast Augmentation: A Randomized Controlled Trial

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Background: The purpose of this randomized controlled trial was to determine whether anatomical implants are aesthetically superior to round implants in breast augmentation.
Methods: Seventy-five patients undergoing primary breast augmentation had a round silicone implant of optimal volume, projection, and diameter placed in one breast and an anatomical silicone device of similar volume and optimal shape placed in the other. After intraoperative photographs were taken, the anatomical device was replaced by a round implant to complete the procedure. A survey designed to measure breast aesthetics was administered to 10 plastic surgeon and 10 lay reviewers for blind evaluation of the 75 cases.
Results: No observable difference in breast aesthetics between anatomical and round implants was reported by plastic surgeons in 43.6 percent or by lay individuals in 29.2 percent of cases. When a difference was perceived, neither plastic surgeons nor lay individuals preferred the anatomical side more often than the round side. Plastic surgeons judged the anatomical side superior in 51.1 percent of cases and the round side superior in 48.9 percent of cases ($p = 0.496$). Lay individuals judged the anatomical side superior in 46.7 percent of cases and the round side superior in 53.3 percent ($p = 0.140$). Plastic surgeons identified implant shape correctly in only 26.5 percent of cases.
Conclusions: This study provides high-level evidence supporting no aesthetic superiority of anatomical over round implants. Given that anatomical implants have important and unique disadvantages, a lack of proven aesthetic superiority argues against their continued use in breast augmentation. (*Plast. Reconstr. Surg.* 139: 587, 2017.)
CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, I.

Anatomical implants were approved by the U.S. Food and Drug Administration in 2012, but their role in breast augmentation remains controversial.[1] Although commonly used abroad,[2,3] use in the United States has been hampered by concerns over increased cost, malrotation potential, and lack of proven aesthetic superiority.[4] The recent association between anaplastic large-cell lymphoma (ALCL) and implant surface texturization has further heightened concerns.[5–7] As a result, round implant use continues to predominate in breast augmentation,[8] the most commonly performed aesthetic surgical procedure in the United States.[9]

Anatomical implant advocates claim that the characteristic teardrop shape yields a "more natural" result than that produced by round implants.[2,10–14] However, such claims are based largely on expert opinion and lack high-level evidence. The few observational studies published to

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date have found that surgeons and lay individuals not only appraise anatomical and round implants to be aesthetically similar but also are often unable to distinguish between implant shape in vivo.[3,15–17]

This randomized controlled trial was designed to investigate whether anatomical implants produce clear aesthetic superiority to offset their notable disadvantages. The hypothesis that anatomical implants are not aesthetically superior to round implants in breast augmentation was tested by comparing the two different devices in the *same* patient.

PATIENTS AND METHODS

Study Participants

This randomized controlled trial was approved by the Western Institutional Review Board. Patients seeking subpectoral breast augmentation with silicone implants placed through an inframammary incision were eligible for study enrollment. Strict exclusion criteria were observed because each patient served as her own control. Patients with a breast volume differential estimated greater than 25 g, a vertical nipple position differential over 1 cm, an areolar diameter differential over 0.5 cm, significant shape abnormalities or asymmetry, scoliosis, or chest wall deformities were excluded. Patients having had previous breast surgery and those requiring a simultaneous mastopexy were excluded.

Seventy-five of 207 patients presenting for breast augmentation between December of 2013 and November of 2015 met eligibility criteria and consented to study participation. Ten plastic surgeons and 10 lay individuals with equal gender representation in both groups served as reviewers to assess breast aesthetics based on intraoperative photographs.

Surgical Procedure and Devices

All procedures were performed by one surgeon (D.A.H.), and the cost of all devices was covered by the senior author's practice. Western Institutional Review Board–approved informed consent included the option of using anatomical implants as the final choice on both sides if warranted. Chest dimensions were graded by relative length and width, and these factors were considered while selecting similar volume anatomical and round implants with the optimal implant dimensions.

Through an inframammary incision, a subpectoral plane was developed by dividing the inferior origin of the pectoralis major muscle medially almost as far as the sternal attachments. Muscle release from the overlying breast tissue to optimize breast aesthetics was infrequently performed, very limited when done, and released to the same extent on both sides.

Once the final implant volume was determined, a round silicone implant was placed in one breast and either an anatomical silicone sizer [Mentor (Irvine, Calif.) or Allergan (Dublin, Ireland)] or actual anatomical implant [Sientra (Santa Barbara, Calif.)] of similar volume was placed in the other breast. The experimental side was determined by computer-generated random assignment. All implants were placed in the subpectoral plane. Standardized photographs were then taken in the completely upright position (Fig. 1). Finally, the anatomical device was replaced by a second round implant to complete the procedure.

There were 25 cases each using Natrelle Style 410 (Allergan), MemoryShape (Mentor), and Sientra HSC (Sientra). There are four Allergan, one Mentor, and five Sientra models within these styles that are currently U.S. Food and Drug Administration–approved for clinical use. The model selected was that which the surgeon judged optimized breast aesthetics for each patient's individual anatomy. Round implants used were from a single manufacturer (Mentor) in Moderate Classic and Moderate Plus profiles.

Anatomical silicone sizers from Allergan and Mentor were indistinguishable from their implant counterparts except for lacking a textured surface (Fig. 2). Sizers could be reused several times, thereby providing cost-effectiveness without compromising simulation accuracy. It was also easier to insert smooth sizers through a standard length incision. Sientra does not offer sizers; thus, actual implants were purchased for each patient in this subgroup. Sientra implants were placed with the aid of an insertion funnel.

Instrument Design and Pretesting

A survey was created to measure breast aesthetics with validity by applying rigorous instrument design principles,[18] and administered using Qualtrics software (Qualtrics, Provo, Utah). Patient cases were presented for assessment in random order, and reviewers were able to save incomplete surveys for completion at a later time. The preliminary survey was pretested to optimize content validity, face validity, and utility by means of a pilot study of two plastic surgeon and two lay reviewers. The questions were the same for both groups except that the plastic surgeons were also queried as to how the breast is better when one side was preferred and which implant shape they believe was placed on that side. After this pilot study, reviewers completed a 10-question content

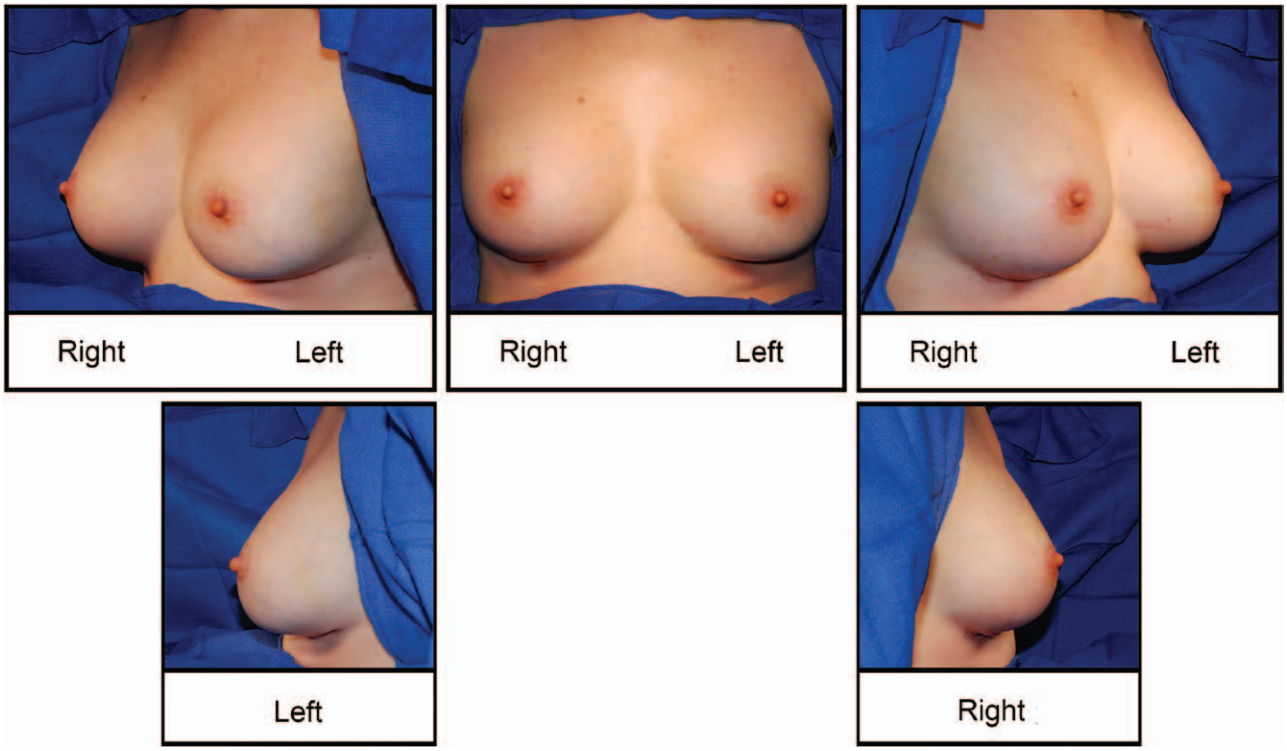

Fig. 1. Representative patient intraoperative photograph series. The right breast contains a round implant (Mentor) and the left breast contains an anatomical implant (Sientra).

validation survey, and the preliminary survey was revised into final form (Fig. 3).

Sample Size

Based on pilot study results, 312 patient assessments were required in each reviewer group to attain 80 percent power to detect a minimal clinically important difference of 5 percent in reviewers preferring the anatomical side more often than the round side. Ten plastic surgeons and 10 lay individuals were selected to review all 75 patients, yielding 750 patient assessments per group (1500 total).

Statistical Analysis

The data were summarized as counts, percentages, and means ± SD. Preoperative breast characteristics and device volumes between breasts were compared using two-sample t tests after confirming satisfaction of the parametric assumptions. Linear mixed modeling with crossed random effects of reviewers and patients was performed to account for the potential of correlation among measurements in this multilevel study design.

To determine whether reviewers preferred the anatomical side more often than the round side when they perceived an aesthetic difference between breasts, one-proportion z tests with a null hypothesis value of 50 percent was used. Linear mixed modeling was performed to determine whether reviewers' aesthetic preference depended on sizer/implant manufacturer and whether surgeons' correct implant identification rate depended on the implant shape producing the perceived aesthetic superiority. Likert scale data quantifying perceived aesthetic superiority were categorized into "less than moderately better" (<3) and "moderately better or greater" (≥3) groups to facilitate clinical interpretation, and linear mixed modeling was performed to determine whether the degree of perceived aesthetic superiority depended on implant shape. Two-proportion z tests with Bonferroni correction to control family-wise error rate were used to compare the breast characteristics accounting for surgeons' perceived aesthetic superiority. Cohen's kappa (κ) was calculated to determine interrater reliability among all reviewers and between reviewers within each group.[19]

The level of statistical significance for hypothesis testing was set at $\alpha = 0.05$. Statistical analyses were performed using SAS version 9.4 (SAS Institute, Inc., Cary, N.C.).

RESULTS

Patient age averaged 39.2 years and body mass index averaged 20.3 kg/m^2. Preoperative breast volume, base diameter, nipple position, and average

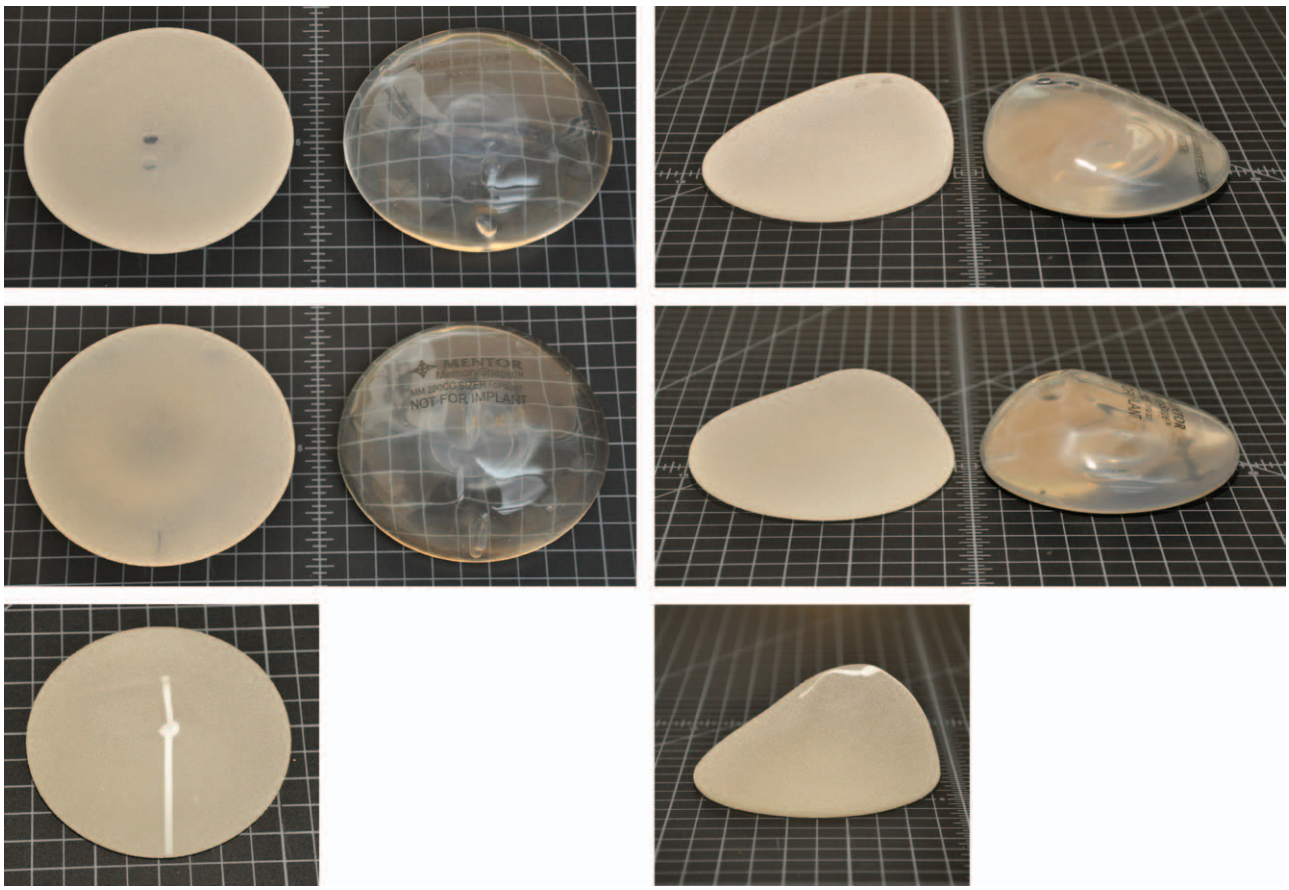

Fig. 2. Breast implants and sizers. (*Above*) Allergan Natrelle style 410 MM 280-cc anatomical silicone implant and sizer. (*Center*) Mentor Memory Shape 280-cc MM anatomical silicone implant and sizer. (*Below*) Sientra HSC round-base, high-projection 270-cc implant.

breast sizer/implant volume were not significantly different between sides (Table 1). The average anatomical device volume (278.1 cc; range, 170 to 385 cc) was also not significantly different from that of round implants (277.6 cc; range, 170 to 375 cc) ($p = 0.941$). The 25 devices from each manufacturer were tabulated by model used (Table 2).

Reviewer response rate was 100 percent. Plastic surgeons averaged 18.8 years of experience in either private (70 percent) or academic (30 percent) practice. Lay individuals averaged 54.7 years of age and represented various nonmedical vocations. The interrater reliability of the study survey was $\kappa = 0.133$ for reviewers overall, $\kappa = 0.152$ among plastic surgeons, and $\kappa = 0.141$ among lay individuals, corresponding each to a slight[20] but significant agreement ($p < 0.001$).

No observable difference in breast aesthetics between anatomical and round implants was reported in 36.4 percent of cases: 43.6 percent by plastic surgeons and 29.2 percent by lay individuals (Table 3).

In the remaining 63.6 percent of cases, reviewers perceived an aesthetic difference between breasts. However, on analysis, neither reviewer group preferred the anatomical side significantly more often than the round side. Surgeons judged the anatomical side superior in 51.1 percent of cases and the round side in 48.9 percent of cases ($p = 0.496$). Lay individuals judged the anatomical side superior in 46.7 percent of cases and the round side in 53.3 percent of cases ($p = 0.140$). Moreover, aesthetic preferences were not dependent on manufacturer, among either plastic surgeons ($p = 0.860$) or lay individuals ($p = 0.604$) (Table 4).

Both reviewer groups rated the side they judged aesthetically superior to be no more than "moderately" more pleasing than the contralateral side on average, whether an anatomical or round implant was present on the preferred side. Plastic surgeons rated the anatomical side superior on average 1.9 and the round side superior on average 1.9 ($p = 0.793$). Lay individuals rated the anatomical side superior on average 2.2 and the round side superior on average 2.2 ($p = 0.528$). This finding of no difference in aesthetic superiority rating between implant shapes

Plastic surgeon reviewer survey.

Which breast is more aesthetically pleasing?

- ☐ Patient's left breast
- ☐ Patient's right breast
- ☐ No observable difference

If one breast is more aesthetically pleasing, by how much?

A little		Moderately		A lot
1	2	3	4	5
☐	☐	☐	☐	☐

If one breast is more aesthetically pleasing, how is it better? (select all that apply)

- ☐ Better projection
- ☐ Better nipple position
- ☐ Better upper pole contour
- ☐ Better lower pole contour
- ☐ Other (please specify):

If one breast is more aesthetically pleasing, which implant shape do you believe was placed in that breast?

- ☐ Round
- ☐ Anatomical
- ☐ I don't know

Fig. 3. Plastic surgeon reviewer survey. Lay individual survey excluded the last two questions.

was confirmed using linear mixed modeling, among plastic surgeons ($p = 0.321$) and lay individuals ($p = 0.939$) (Table 5).

Regarding breast characteristics accounting for perceived aesthetic superiority, plastic surgeons did not choose "better upper pole contour," "better lower pole contour," and "better nipple position" more frequently when the preferred side had an anatomical rather than a round device (Table 5). Although "better projection" initially appeared to be selected more frequently by surgeons who preferred the anatomical side (20.8 percent) than by those who preferred the round side (11.6 percent) ($p = 0.010$), this difference was not statistically significant after the Bonferroni correction was applied.

Lastly, plastic surgeons reported not knowing which implant shape was producing the aesthetic superiority they perceived in 35.0 percent of cases.

Table 1. Comparison by Side of Breast Characteristics and Device Volumes Used

	Right Breast	Left Breast	*p*
Mean breast characteristic ± SD			
Volume, cc	144.9 ± 41.0	145.7 ± 39.0	0.903
Base diameter, cm	9.8 ± 0.7	9.9 ± 0.7	0.383
Nipple to clavicle, cm	19.7 ± 1.9	19.9 ± 1.9	0.520
Mean sizer/implant ± SD			
Volume, cc	277.5 ± 39.7	275.2 ± 41.9	0.731

In the remaining cases, surgeons believed they knew the implant shape, but were able to identify it correctly only 26.5 percent of the time. Furthermore, the identification rate was found not to depend on whether the preferred side contained an anatomical (24.5 percent) or round (28.5 percent) implant ($p = 0.143$).

The operating surgeon involved in all 75 cases did not perceive an aesthetic superiority of either implant type in any patient. As a result, the patient-approved option of using anatomical implants as the final selection instead of round implants was not applied.

DISCUSSION

Anatomical implants have been gaining popularity in the United States since U.S. Food and Drug Administration approval in 2012, with a market share estimated at 3 to 26 percent.[21] Half of American Society of Plastic Surgeons members report using them at least some of the time.[22] However, these devices have not been fully embraced because of notable disadvantages not shared by round implants.

Anatomical implants were conceived to attain a more natural result compared with round implants. Device development began in the 1980s with Surgitek's Replicon silicone devices,[23] and

Table 2. Round and Anatomical Sizer/Implant Models Used

Manufacturer	Height	Projection	No. (%)
Anatomical			
Allergan Natrelle 410	Medium	Medium	23 (30.7)
	Medium	Full	1 (1.3)
	Full	Medium	1 (1.3)
Mentor Memory Shape	Medium	Medium	25 (33.3)
Sientra HSC	Round-base	High	22 (29.3)
	Oval-base	Moderate	2 (2.7)
	Oval-base	High	1 (1.3)
Round			
Mentor		Moderate Classic	40 (53.3)
		Moderate Plus	35 (46.6)

followed with saline anatomical implants. The first highly cohesive gel anatomical implant was not introduced until 1993.[24] However, largely because of the U.S. Food and Drug Administration's silicone implant moratorium from 1992 to 2006, anatomical silicone implants did not become available in the United States until 2012, with device development before that occurring abroad.[25] Since then, several U.S. studies have been published showing that breast augmentation with anatomical implants is safe and effective, and produces patient satisfaction rates exceeding 90 percent.[13,26–29]

There are only a few clinical studies comparing the two different shapes. One evaluated radiographic images of anatomical and round saline implants in vivo and found that both had similar "teardrop" shapes when standing but that round implants appeared more natural supine.[15] Three subsequent studies compared postoperative photographs of patients who received either anatomical or round silicone implants and concluded that there was no significant aesthetic difference between them.[3,16,17] Reviewers actually scored breast naturalness significantly higher in patients with round implants in one of these studies.[17] These findings have led experts to theorize that the breast and wound healing shape the implant rather than the opposite.[30]

Although these studies indicate that surgeons and lay individuals appraise breast aesthetics using anatomical and round implants similarly, they are observational in design involving patient selection and surgeon biases. Considering that as many as 50 factors influencing results have been identified, a randomized trial offers the best option to control for confounding variables.[31] A recent cadaver study compared anatomical and round implants in the same breast, but breast aesthetics were not specifically evaluated.[32] This current study is the first randomized trial comparing breast aesthetics between anatomical and round implants within the same patient, therein controlling for important patient selection and surgeon biases.

Reviewers perceived no difference in breast aesthetics between anatomical and round implants in over one-third of cases. When a difference was perceived, neither reviewer group preferred the anatomical side significantly more often than the round side. Moreover, plastic surgeons reported not knowing which implant shape was producing the aesthetic superiority they perceived in 35.0

Table 3. Side Preference and Sizer/Implant Identification

	Plastic Surgeons		Lay Individuals	
	No. (%)	*p*	No. (%)	*p*
"Which breast is more aesthetically pleasing?"				
Round side	207 (48.9)	0.496	283 (53.3)	0.140
Anatomical side	216 (51.1)		248 (46.7)	
"No observable difference"	327 (43.6)	—	219 (29.2)	—
"Which implant shape do you believe was placed in that breast?"				
Round identified correctly	59 (28.5)	0.143		
Anatomical identified correctly	53 (24.5)			
"I don't know"	148 (35.0)	—		

Table 4. Reviewers' Sizer/Implant Preference by Manufacturer

	Plastic Surgeons			Lay Individuals		
Manufacturer	Round Side Preferred (%)	Anatomical Side Preferred (%)	*p*	Round Side Preferred (%)	Anatomical Side Preferred (%)	*p*
Allergan	15.1	16.1		18.1	14.7	
Mentor	13.5	15.4	0.860	14.9	16.0	0.604
Sientra	20.3	19.6		20.3	16.0	

Table 5. Degree and Quality of Perceived Aesthetic Superiority of Preferred Side

	Plastic Surgeons			Lay Individuals		
	Round Side Preferred (%)	Anatomical Side Preferred (%)	*p*	Round Side Preferred (%)	Anatomical Side Preferred (%)	*p*
"By how much?"						
Less than moderately better	163 (78.7)	162 (75.0)	0.321	182 (64.3)	163 (65.7)	0.939
Moderately better or greater	44 (21.3)	54 (25.0)		101 (35.7)	85 (34.3)	
"How is it better?"						
Better projection	24 (11.6)	45 (20.8)	0.010*			
Better nipple position	49 (23.7)	56 (25.9)	0.601			
Better upper pole contour	135 (65.2)	131 (60.6)	0.328			
Better lower pole contour	53 (25.6)	43 (19.9)	0.162			
Other	15 (7.2)	12 (5.6)	0.673			

*Not statistically significant after Bonferroni correction applied.

percent of cases. In the remaining 65.0 percent of cases, surgeons guessed correctly only 26.5 percent of the time, even lower than previous findings of 55.0 to 55.9 percent,[3,17] and correct identification was found not to depend on whether the preferred side contained an anatomical or round implant. These results provide compelling evidence that there is no aesthetic superiority of anatomical over round implants in breast augmentation.

Plastic surgeon reviewers were queried on the characteristics accounting for perceived aesthetic superiority. Possible responses were based on four key features previously reported to define aesthetically pleasing shape: upper pole–to–lower pole ratio of 45:55; upward nipple angulation of approximately 20 degrees; linear or slightly concave upper pole contour; and a tight, convex lower pole.[33,34] Taking into account that surgeons and patients can prefer different breast shapes,[35] response choices also integrated feedback provided by the content validation survey completed during instrument pretesting. However, none of the breast characteristics linked to aesthetic superiority was chosen more frequently for either implant type (Table 5). This further supports the thesis that implant shape per se has little effect on breast aesthetics.[36,37]

Proponents claim that anatomical implant shape creates a more natural result, and that round implants are contraindicated in patients desiring a natural appearance.[2,10–14] They have also asserted that anatomical implants are the best choice for patients with a very thin body habitus or who have less than the 1.5- to 3-cm thickness of upper pole breast parenchyma needed to hide the edge of a round implant.[2,17,38] Other purported advantages of anatomical implants include greater correction of breast ptosis and more flexibility in selecting the ideal implant by considering three dimensions (height, width, and projection) instead of only two (diameter and projection) with round implants.[38] However, considering the evidence to date including this study, such claims are based on expert opinion alone.

Anatomical implants have disadvantages not shared by round implants (Table 6). They feel more firm to the touch because of the highly cohesive filler consistency designed to resist deformational changes in vivo.[23,39,40] In addition, the asymmetric implant design creates a potential for rotation within its pocket, referred to as "malrotation" when breast shape is clinically altered. This is estimated to occur in 1.1 to 2.6 percent of patients,[13,27,41,42] although ultrasound screening of asymmetric patients suggests a rate as high as 25 percent.[43] Predisposing factors include pocket overdissection, unstable implant orientation before capsule maturation, excessive intracapsular fluid, and double-capsule formation.[14,44,45] Treatment for malrotation requires external manipulation and taping of the breasts for weeks at the least, but more commonly necessitates corrective surgery.[14,46] Besides needing another procedure, the patient now has to embrace using round implants, an option originally passed over.

Anatomical implants have a more aggressively textured surface compared with textured round

Table 6. Advantages and Disadvantages of Anatomical Implants Compared with Round Implants

Advantages
Better in ptotic patients?
Less lateralization supine
Disadvantages
More firm
Malrotation potential
Mandatory texturization
Greater cost
Limited incision choices
Longer incision or funnel needed
More complex operative technique
Can appear odd in the supine position
Limited applicability in secondary cases

implants. Whereas the intent in the latter example is to reduce the risk of capsular contracture, the primary purpose of aggressive texturization in anatomical implants is to securely hold them in the proper orientation by means of a hook-and-loop fastener–like bond.[14,47] Currently, there is a growing body of evidence linking implant texturization to late seromas, double capsules, and ALCL.[5–7] Although presumed rare, 7.1 percent of 1067 American Society of Plastic Surgeons members recently surveyed reported having witnessed a case in their practice.[4] Considering that many studies have not supported a lower rate of capsular contracture with textured implants, especially when placed in the subpectoral plane,[10] it appears prudent to avoid using textured implants of all types until the precise mechanism of ALCL pathogenesis is elucidated.

There are other disadvantages too. Incision choice is largely restricted to the inframammary approach because greater length is often needed to accommodate the stiffer gel and surface texturization of anatomical implants. Moreover, this approach also facilitates precise pocket sizing, another anatomical implant requirement. Shorter incisions are possible, but then a funnel is needed to ease insertion and prevent gel fracture. Anatomical implants are significantly more expensive than round implants with all three manufacturers, ranging to as high as twice the cost.[21] In addition, anatomical implants have limited applicability in secondary cases because either a capsulectomy or a neopocket is mandatory to minimize the potential for malrotation.[2]

Some assert that anatomical implants have a more demonstrable shape advantage in the subglandular plane because subpectoral placement compresses the implant, thereby neutralizing shape differences.[48] However, this point may be moot given that subpectoral placement favors improved breast imaging.[49,50] Furthermore, the subpectoral plane has a clear advantage in terms of minimizing the development of capsular contracture.[50–53] Subpectoral placement is therefore generally preferred, outweighing the small risk of significant animation deformity.

Regarding study limitations, it could be argued that resolution of surgical edema is necessary to demonstrate the aesthetic advantage of anatomical implants. However, significant edema did not develop within the first hour of the procedure during which time the experimental component of this study was performed. Although anatomical implants are thought to not "drop" as much over time as round implants, this and other issues related to long-term implant settling are beyond the scope of this study.[27]

Although silicone sizers were used instead of actual anatomical implants for two of the manufacturers, the sizers are identical to the implants except for lacking surface texturization (Fig. 2). Moreover, the actual implants used in the Sientra subgroup yielded findings no different than those with the sizers. Among all devices used, however, the maximum size was 385 cc. Subsequently, the conclusions of this study may not apply to larger implant sizes.

It might be argued that the optimal anatomical model was not selected for each patient. However, torso length and width were taken into consideration as important factors to include in the selection process. Variation in chest dimensions can influence preferred anatomical implant height and base shape (round or oval). Although five of the 10 U.S. Food and Drug Administration–approved styles were used, one style from each manufacturer predominated. These three styles were quite different from one another, yet there was no superiority of any manufacturer demonstrated. It could be extrapolated from this that differences in models within a manufacturer's styles would not have a significant impact in breast aesthetics either.

Lastly, although the reviewer survey was created using rigorous instrument design principles, it remains subject to measurement error. However, this was minimized by pretesting to optimize content validity, face validity, utility, and adequately powering the study. As a result, interrater reliability was higher in this study than for those designed for similar purposes in the literature.[54]

CONCLUSIONS

In this randomized controlled trial of anatomical versus round implants, reviewers commonly reported perceiving no difference in breast aesthetics between implant shapes. When a difference was noted, neither the anatomical nor the round side was preferred more often. Moreover, plastic surgeons identified implant shape correctly in only a minority of cases and often reported not knowing which implant shape was responsible for perceived superior aesthetics.

Considered together, the results of this study provide Level I evidence showing no aesthetic superiority of anatomical over round implants. Given the significant disadvantages enumerated, these findings argue against the continued

routine use of anatomical implants in breast augmentation.

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