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Original Article

Prospective Study Comparing Two Brands of Cohesive Gel Breast Implants with Anatomic Shape: 5-Year Follow-Up Evaluation

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Abstract.
Background: The new generation of breast implants has an anatomic shape. These implants are made with a textured shell and filled with a cohesive silicone gel. Available since 1993 except in the United States, these implants are gaining in popularity for breast enlargement and reconstruction. This prospective, randomized, controlled, and blinded study was designed to compare mid- and long-term results with the use of cohesive gel-filled implants from two different manufacturers: Style 410 of the McGhan brand (MG) made by Allergan and Vertex made by Eurosilicone (ES).
Methods: From May 1997 to May 1999, 80 women underwent breast augmentation: 40 with Style 410 implants (MG) and 40 with Vertex implants (ES). All surgeries were performed by the same surgeon (I.N.). Another physician (G.J.) interviewed and examined 64 of these women (80%) 4 to 6 years (median, 5 years) after implantation. In addition, 10 patients responded to the same questionnaire and were interviewed by phone, bringing the follow-up rate to 92.5%.
Results: Overall, satisfaction was high, with 98.6% of the patients evaluated after 4 to 6 years "very satisfied" or "satisfied" with the result in general. Approximately 20% of the patients who responded judged their breasts to be firmer than desirable. Breast augmentation classification (BAC) was used to grade the breast firmness of the 64 patients examined by G. J. At examination, 24% of patients had soft breasts, 53% had slightly firm breasts, and 23% had moderately firm breasts. That last category also was classified as capsular contracture. No patient was graded as having very hard breasts (BAC 4). Skin sensitivity of the breast adjacent to the incision was altered for 25% of the patients. The implant rotated in four patients (5%). Breast firmness, implant palpability, nipple sensitivity, and skin sensitivity were further analyzed by implant location (submuscular vs subglandular) and implant size (volume). Frequency of the breast asymmetries and the impact of augmentation on asymmetric breasts also was studied. All these analyses were performed with the entire pool of examined patients who answered the follow-up questionnaire. Data also were analyzed by distinguishing between results of the two each implant manufacturers. The results showed no difference between the Eurosilicone and McGhan implants except for the self-evaluation of "breast consistency" by the patient. A higher percentage of patients with the Vertex implants than with the McGhan implants reported that their breast was "firmer than desired."
Conclusions: Breast augmentation with anatomic, textured, cohesive silicone gel-filled implants is a reliable procedure with consistently good results. The results also show that candidates for breast enlargement should be informed that their implanted breast may feel firmer than their natural breasts. They also may experience reduced sensation of their nipple or breast skin.

Key words: Breast augmentation—Cohesive silicone gel—Follow-up—Mammary implants—Prospective study

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The newest generation of textured, anatomic, cohesive silicone gel-filled mammary implants was originally developed by McGhan Medical Corporation (currently Allergan, Santa Barbara, CA, USA.) with the help of Dr. John Tebbetts [22]. These implants were introduced worldwide in 1993, except in the United States, where their use is currently limited to clinical trials conducted under Food and Drug Administration (FDA)-approved protocol. Cohesive gel-filled breast implants have become available in Sweden and many other countries [3,9,10,13,15] since the mid-1990s.

Anatomic implants present a larger volume and a maximum projection at their lower pole. They also maintain their shape whatever the position of the woman's body. Cohesive silicone gel also has the advantage that in the case of shell rupture, the gel does not disperse throughout the body, but instead keeps its integrity (Fig. 1).

After positive early feedback from surgeons using the McGhan Style 410 gel-filled breast implant, other manufacturers developed and marketed their own cohesive silicone gel mammary prostheses. Among them were Nagor of Great Britain, Eurosilicone of France, Silimed of Germany, and Mentor of the United States. Each manufacturer provides data to support claims of unique advantages and benefits of their products. Currently, nearly all breast implant manufacturers offer several styles of cohesive gel-filled implants with different shapes and degrees of gel cohesivity.

A few published studies have investigated patients who have received McGhan Style 410 cohesive gel-filled implants. These studies are of limited value because they are retrospective patient chart reviews, and their data are based on only 2 years of follow-up evaluation. They were not designed as blind investigations, so their data are biased because the evaluating physician was the same as the implanting surgeon [3,9,10]. Data on the outcome of implantation with other brands of cohesive gel-filled breast implants are not available. Therefore the current prospective, randomized, controlled, and blinded study was initiated in 1997 to evaluate the quality of results a median of 5 years after implantation of anatomic cohesive gel-filled breast implants. The study also evaluated the impact of the implant size and the site of the implantation (i.e., submuscular or subglandular).

The study was performed by evaluating patients 4 to 6 years after implantation. It consisted of an examination by an independent physician and answers to questionnaires on breast firmness, breast skin sensitivity, nipple sensitivity, and other possible complications. The analysis also evaluated the dependence of the results on the brand of the product.

Breast and chest asymmetries were observed during a pilot study [13]. As recently suggested by Spear [18], it was interesting to determine the extent of preexisting breast asymmetries in our patient population, then to follow and evaluate whether their breasts looked better or worse after augmentation.

Materials

During 2 years, May 1997 to May 1999, a comparative trial using McGhan Style 410 mammary implants and Eurosilicone Vertex implants (Apt, France) was conducted at the Lidingö clinic in Stockholm. Both types of implants have very similar technical characteristics. They have a full height and moderate projection. Their envelope is manufactured from dispersed silicone of the same or similar formulation produced by NuSil Technology (Carpinteria, CA, USA) Both have a textured shell created by a "salting" method and irregular large pores in the range of 200 to 400 μm (Fig. 2).

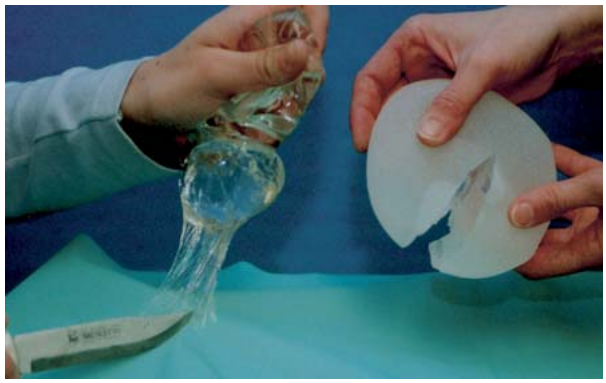

Fig. 1. The mammary implant filled with cohesive silicone gel maintains its integrity even if the shell is damaged. In contrast, on the left, liquid silicone runs out through the opening in the shell.

The same surgeon (I.N.) performed all 80 aesthetic breast augmentations using a standardized technique [15]. Of the 80 patients, 40 received a pair of Style 410 and 40 received a pair of Vertex prostheses. The brand of the implant was assigned randomly. Only the surgeon knew which type was implanted. Interesting observations could have resulted from a randomized trial between the right and left breasts using each brand of implant for a single patient, but this approach [7] was not feasible. We therefore elected to randomize the patients rather than the breasts. All the patients were healthy and had no known history of any systemic disease according to American Society of Anesthesiology status (ASA class 1).

Before surgery, 43 patients presented with postpartual atrophy of the breast gland. The goal of these patients was to restore the shape and volume of their breasts to their prenursing state and not to enlarge them. Approximately half of the remaining 37 patients desired breast enlargement because of micromastia, with the other half seeking enlargement for self-image. The volume of the implants used varied from 240 ml to 500 ml (median, 300 ml; average, 310 ml) (Fig. 3). The patients ranged in age from 17 to 51 years (median, 28 years).

Standard primary augmentation was performed for 67 of the patients (83%). The remaining 13 cases (17%) were difficult and nonroutine. Among these 13 patients, 8 had already undergone a breast augmentation, 3 had severe atrophy of the breast gland with ptosis, 1 presented with pectus excavatum and tubular breast deformity, and 1 had a deficiency of the lower medial quadrant and breast base constriction in the contralateral breast. Of the 13 difficult cases, 8 received implants from Eurosilicone (ES),

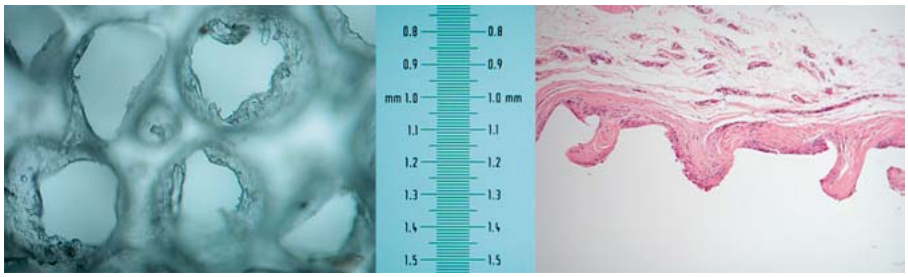

Fig. 2. (*Left*) Histomorphometric examination of the Style 410 implant shell sliced horizontally. The diameter of the pores is 0.2 to 0.4 mm. (*Right*) Connective tissue adjacent to the shell surface grows into the pores and shows no inflammation (hematoxylin & eosin stain).

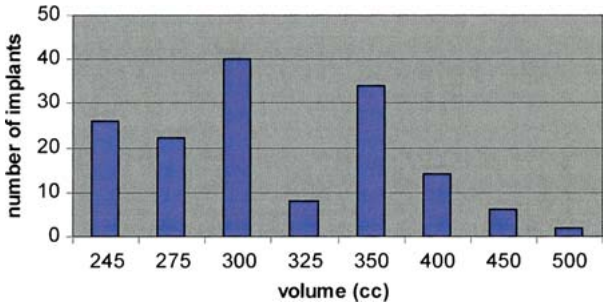

Fig. 3. Number and volume of breast implants with anatomic shape and filled with cohesive silicone gel, used from May 1997 to May 1999. The total number of implants is 160.

and 5 received McGhan (MG) implants. Seven pairs of implants in the difficult cases were placed subglandularly, and six were placed under the pectoralis major muscle.

Methods

Detailed descriptions of the preoperative evaluation and preparations, operative technique, and postoperative care have been published previously [15]. A video and DVD also are available [16]. Therefore, the methods will be described only briefly in this chapter.

Preoperative Evaluation

All the patients were assessed preoperatively with the help of Tebbett's Patient Evaluation and Operative Planning Sheet or Eurosilicone's planning chart. The size of the implants was chosen in collaboration with the patient. Evaluation included the desires and expectations of the patient as well as many other factors such as the patient's height; weight; width of hips, shoulders, and thoracic cage; breast appearance; degree of ptosis; presence of asymmetries; thickness of the subcutaneous tissue in the upper and lower poles of the future breast; professional occupation; past and future pregnancies; marital status; and age. The experience and recommendations of the surgeon also were taken into account.

When round implants are used, volume alone is the basis for the surgery of breast enlargement. When anatomic implants are used, the surgery is based on width and projection of the implant, the patient's dimensions, and the individual breast tissue characteristics rather than on the implant volume alone [22]. The parameters of the patient's original breast also must be considered, so that the outer edges of the implant do not exceed the width and height of the breast gland.

A personal method with preoperative drawings was used to plan for the breast augmentation using anatomic implants filled with cohesive gel (Fig. 4) [15,16]. Drawings were made while the patient was standing. Breast and thoracic cage asymmetries were detected, incorporated into the preoperative design, and eventually, whenever possible, corrected.

Photographs were taken during the initial consultation and later posted in the operating room during the procedure. The standard projections used were frontal and right three-quarter views. For patients who presented with asymmetric breasts, the left three-quarter view also was also taken. Photographs also were taken during the follow-up evaluation. Preoperative photos were done with a 35-mm single-lens reflex (SLR) camera. The follow-up photographs were made with a digital camera.

Operative Technique

The principles of rigorous sterility proposed by Mladick [11] were implemented. After the standard preparation in the operating room, the entire chest was covered with protective OpSite film (Smith & Nephew, Hull, UK). Talc-free gloves were used and changed immediately before the insertion of the implants. All operations were performed with the patient under general inhalatory anesthesia using a larynx mask. The breasts were injected using 25 ml of 1% Xylocaine with 5 μg of adrenaline/ml (AstraZeneca, London, UK) diluted with 50 ml of normal saline. Preoperative antibiotics generally were not given.

The original cohort was equally divided between subglandular and submuscular implant placement. Within each subgroup, the subglandular location was preferred for the correction and camouflage of mild breast ptosis. Submuscular placement was chosen for slimmer, petite patients with very small breasts, in

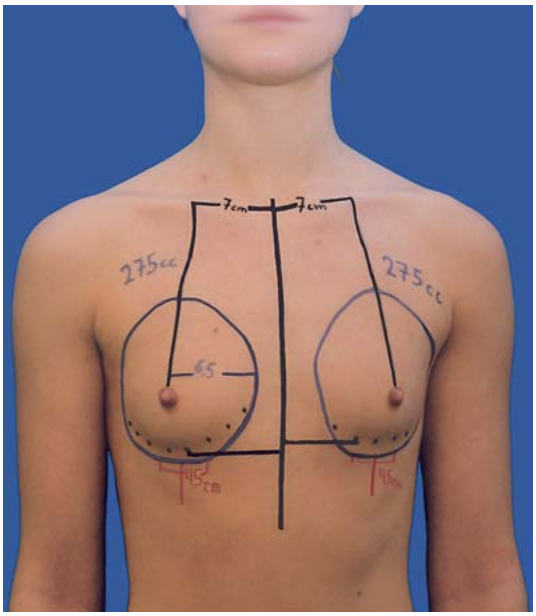

Fig. 4. Preoperative drawings for planning of breast augmentation with anatomically shaped implants filled with cohesive silicone gel. From I. Niechajev: Innovative augmentation. *Body Language Plast Cosm Surg* **11:**16, 2003. Published with the permission of the New Millenium Publishing, Ltd.

five secondary augmentations and for some athletes. The maximum implant size under the muscle was approximately 300 ml. It was feared at the time that larger implants placed under the muscle could have caused tenting of the pectoralis major muscle, possibly impairing the function of the arms. As a result, placement of the implants was subglandular for 58 patients (72%) and submuscular for 22 patients (28%).

The incision was submammary for 69 patients (86%). Its length was 45 to 55 mm, mostly 50 mm, and it was placed at the inframammary fold (IMF) level in ptotic breasts and 10 mm above the IMF in nonptotic breasts. For 10 patients (12.5%) who had areolas with circumferences larger than 10 cm, a periareolar incision was used for both the subglandular and submuscular placements. A transaxillary approach was used once (1.5%) for the submuscular insertion of smaller implants in an athlete who was very slim.

Dissection was performed using the electrocautery knife under direct vision, a Reynolds dissector (Padgett/Integra, Plainsboro, NJ, USA), and long Mayo scissors. A cold-light retractor was always available. Microvac drains (Maersk Medical A/S, Lynge, Denmark) were placed in the pocket. Sterile tissue lubricant was spread on the upper third of the implant to facilitate the insertion. Either Norm-gel, which is normal saline in gel form, or Xylocaine gel (AstraZeneca) was used for this purpose.

Wound closure was completed in layers using running 3.0 Vicryl for the fascia and subcutaneous fat because of its softness. Skin closure was performed with 3.0 unifilament resorbable Monocryl (Ethicon GmbH, Norderstedt, Germany) running suture, placed intracutaneously at the mid-dermis level [15,16].

Postoperative Care

The breasts were immobilized for 1 week by Microfoam tape (3M; St. Paul, MN, USA) from below and with Microfoam and elastic breast bands from above. The patients were given a special supportive, properly sized bra with the clasp in the front. All patients stayed in the clinic overnight under the care of a registered nurse. Drains were removed at the time of discharge from the clinic. After 1 week, the Microfoam tape was removed. The suture lines then were covered with fresh transparent adhesive film (OpSite) for another 2 weeks. This dressing allowed patients to shower. Taping of the incision lines and protection from the sun were recommended for 6 months after the operation.

Postoperative Controls

Postoperative control assessments were at 7 days, 14 days, and 1 year. Some patients also returned for an examination after 2 or 3 months. Controls were performed for all 80 patients by the operating surgeon (I.N.). In 1999, he published these preliminary results and referenced them as a pilot study [13]. He compared the outcomes for the different patients at the 1 year follow-up evaluation. To extend this pilot study, all the patients were asked to return 4 to 6 years after the date of their original surgery for a personal follow-up consultation in the clinic. This time, the new evaluation was performed by an independent surgeon (G.J.). This surgeon had joined the staff of the Lidingö clinic after all the original surgeries had taken place. The data regarding the implants including style, brand, and size were not given to him.

Both the examiner and the patients had to complete a separate assessment chart, which was followed by a physical examination and photographs.

The patients were asked whether the size of their implanted breasts met their expectations. Breast consistency was evaluated separately and independently by the patients and the examiner because there often is a great discrepancy between these two assessments of the results [6]. The women were asked to judge their breasts as "soft and natural," "firmer than desirable," "hard," or "too soft." The examining surgeon used the 4-point breast augmentation classification (BAC) scale to evaluate clinical breast density. Each grade in the BAC scale is made of two modalities determined by manual palpation and visual appraisal. This scale, intro-

duced by Gylbert et al. [6], is based on the Baker classification [19], but the self-assessment by the patient is excluded (Table 1).

The patients were questioned about sensation in their nipples and the skin of their breasts and about their assessment of the quality of the scars. The surgeon examined sensation by gentle finger touch on all four breast quadrants and the nipples. He noted the color, position, and width of the scars. The general appearance of the patients was evaluated in terms of their body weight. The examiner observed and palpated the thickness of the subcutaneous fat on the chest and abdomen and assessed abdominal muscles, comparing the patient's current figure with his or her body appearance in the preoperative photographs.

The surgeon evaluated how breast augmentation affected known (preoperative) breast asymmetries. In particular, variations in the projection vector of the nipple–areola complex and the breast mound was investigated in detail. Finally, the patients were interviewed concerning the overall impact of the breast enlargement or breast restoration on their lives. After the last examination of the last patient, details of all the data were given to the surgeon examiner. The data then were reviewed and analyzed by both surgeons (Tables 2–7). The results concerning firmness, palpability, nipple sensitivity, and skin sensitivity were analyzed by correlating them with the implant size (Table 8) and location (Table 9). Only 64 patients with personal follow-up data were included in the analysis. The first two authors have 25 years of clinical and academic experience with breast surgery.

Statistical Analysis

The percentages for the data are shown in Tables 2, 3, and 4. The analysis segregated data by the brand of the implant used. The ratio of explained variation to total variation was considered, and the magnitude of scaling used equals that used in studies of non-implant patients. For reliability, qualitative bivariate tabular analysis and quantitative standard statistical significance was used in Pearson chi-square tests of the data tables. No significant difference was found between the brands, as determined by p values of 0.05.

Results

The median patient follow-up time was 5 years (range, 4–6 years). Of the 64 patients (80% of the total cohort) examined by a surgeon, 32 (50% of the examined patients) had received Vertex implants and 32 (50% of the examined patients) had received Style 410 implants. All the examined patients and 10 additional patients who were not able to visit the surgeon answered a detailed questionnaire. Therefore, the questionnaire was answered by 74 patients (93% of the original cohort). Of the 10 patients who answered the questionnaire only by mail and phone, 5 had received Vertex implants and 5 had received Style 410 implants. The remaining six patients (7%) were not available for follow-up evaluation. Most of the patients in the follow-up evaluation (72 of 74, 97%) indicated that the first year after the surgery, considered the "healing phase," was uneventful. They reported that from a few weeks to a few months, the aesthetic results were "very good," or "good" and "lasting" (Figs. 9–13). Our analysis led us to the conclusion that the quality of the aesthetic results depended largely on the quality of breast gland and skin before the operation.

Table 1. Breast augmentation classification (BAC)[a]

acceptable	BAC 1	Soft No deformation
	BAC 2	Slightly thickened consistency None to slight deformation
non-acceptable	BAC 3	Firm to hard None to slight deformation
	BAC 4	Hard Severe deformation

[a]The BAC takes into account the examiner's opinion only and is based on his or her assessment of breast appearance and tissue density after augmentation.

Patient Satisfaction

Overall satisfaction was high for all but one interviewed women. Of the 74 patients interviewed at 5 years, 73 (98.6%) reported that they were "very satisfied" or "satisfied" with the result in general. The patients stated that breast enlargement or restoration gave them feelings of increased self-confidence and higher self-esteem. They reported that their clothes fit better, and they felt more attractive. They also reported improvement in quality of life. Among the 64 patients examined in the 5-year follow-up evaluation, 52 (81%) were satisfied with the size of their new breasts. Although, 10 patients (16%) found their breasts to be too small, they nevertheless were pleased with the increased breast volume. Two patients (3%) complained that their breasts were too large.

Of the 74 patients who answered the questionnaire, 22 (30%) found their scar to be "very good," 27 (36%) found it to be "good", 17 (23%) found it to be "acceptable," and 8 (11%) found it to be "bad." Of the latter 8 patients, 3 (4% of the follow-up cohort) required a revision of the scar because it had widened to more than 4 mm. The primary scar for 96% of the population examined after 4 to 6 years had an average width of 2 to 3 mm (Fig. 14). A total of 28 patients (38%) said their scars were located "too high" or "slightly too high," and 3 (4%) rated their

Table 2. Breast orientation vector in 80 consecutive patients, assessed before surgery, and the impact of augmentation on the breast asymmetry

Preoperative			Postoperative							
			Aesthetic outcome for the 35 patients with asymmetry							
Breast orientation	No. of patients	%	Improved	%	No change	%	Worse	%	Not available	%
Left nipple–areola complex and breast mound lateralized	27	34	11 (10 sg, 1 sm)	31	3 (2 sg, 1 sm)	9	7 (6 sg, 1 sm)	20	6	17
Right nipple–areola complex and breast mound lateralized	8	10	4 (1 sg, 3 sm)	11	3 (2 sg, 1 sm)	9	—		1	3
Forward oriented nipple–areola complex and breast mound	45	56								
Total	80	100								

sg, subglandular implant location; sm, submuscular implant location.

scars as "too low." The remaining 43 patients (58%) were satisfied with the location of their scars.

Breast Asymmetries

Analysis of the preoperative photographs showed that 45 patients (56% of the original 80 patients) presented with good symmetry of the breast nipples and orientation of the breast mounds. One breast was lateralized in 35 patients (44% of the original cohort). The left breast was laterally oriented for 27 patients (34%), and the right breast was laterally oriented for 8 patients (10%) (Table 2). Of the 35 patients with preoperative asymmetry, only 28 (80%) were evaluated at the 5-year follow-up assessment. Of those 28 patients, 7 (20% of the population with original asymmetries) presented with worse postoperative asymmetry (Fig. 10), 6 (18%) had an unchanged appearance, and 15 (42%) had visible improvement (Table 2).

Misplaced nipple–areola and lateralization of the breast mound may require a periareolar incision for satisfactory correction [8]. However, many patients find scars on the areola objectionable. Therefore, this surgical approach was not generally used.

The difference in the volume of breast mounds, requiring the use of implants with different volumes, was evident in four patients. If the volumes between the right and left breasts of a patient are significantly different, then implants with a volume difference of at least 50 ml and a larger projection should be used to obtain satisfactory equalization. Good equalization was observed for three of four patients. For the fourth patient, significant improvement was obtained (Fig. 11). Retrospectively, better results would have been achieved if a larger implant had been used in the right breast of that patient. One patient had a funnel chest deformity and tubular breasts. Another had a constricted breast base and a deficiency of the lower quadrant in the contralateral breast. Many asymmetries were improved and often completely corrected by the individual choice of the size and shape of implants and the type of dissection (Figs. 11–13).

Breast Consistency

As perceived by the patient, 26% of the breasts (19/74) that had received a Vertex implant and 16% (12/74) that had received a Style 410 implant were "firmer than desired" (Table 3, Fig. 5). The difference was found to be statistically significant.

The examiner also assessed breast consistency for the patients who returned for follow-up evaluation. The surgeons used the BAC scale. Accordingly, 24% of the breasts (31/128) were classified as "soft" (BAC 1), whereas 53% (68/128) were classified as "slightly firm" (BAC 2). The breasts classified as "firm" (BAC 3) (23%, 29/128) also were classified as having "cap-

Table 3. Patients' opinion on breast consistency 4 to 6 years after augmentation

	Vertex (37 patients, 74 breasts)			Style 410 (37 patients, 74 breasts)			
	Left *n* (%)	Right *n* (%)	%	Left *n* (%)	Right *n* (%)	%	Total *n* (%)
Soft	26 (70)	26 (70)	70	28 (76)	29 (78)	77	109 (74)
Firmer than desired[a]	9 (24)	10 (27)	26	7 (19)	7 (19)	19	33 (22)
Too soft	2 (5)	1 (3)	4	2 (5)	1 (3)	4	6 (4)
Total	37	37		37	37		148

[a]Vertex (19/74, 26%), Style 410 (14/74, 19%). This percentage calculation is based on the number of breasts, not the number of patients.

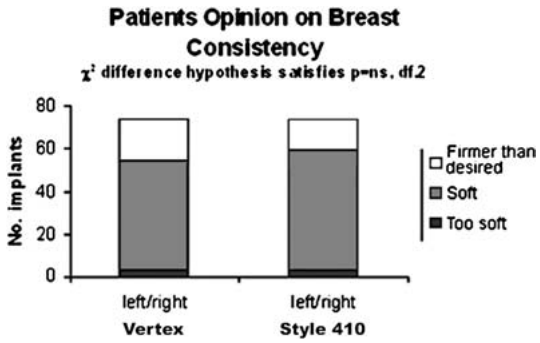

Fig. 5. Patients opinion on breast consistency. χ^2 (chi squared) difference hypothesis satisfies p = ns, df. 2.

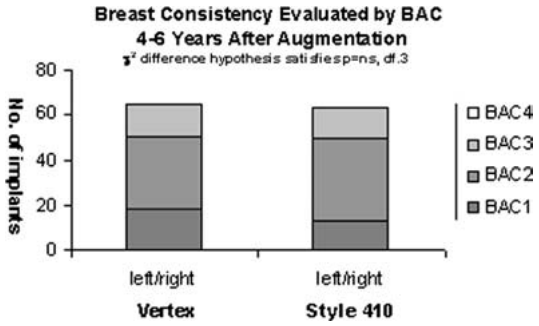

Fig. 6. Breast consistency evaluated by BAC 4-6 years after augmentation. χ^2 (chi squared) difference hypothesis satisfies p = ns, df. 3.

Table 4. Breast consistency evaluated by BAC 4 to 6 years after augmentation[a]

	Vertex (32 patients, 64 breasts)			Style 410 (32 patients, 64 breasts)			
	Left	Right	%	Left	Right	%	Total *n* (%)
BAC 1	9	9	28	7	6	20	31 (24)
BAC 2	15	16	48	19	18	58	68 (53)
BAC 3	8	7	23	7	7	22	29 (23)
BAC 4	0	0		0	0		

BAC 1 & 2, acceptable; BAC 3 & 4, capsular contracture.
[a]Adverse capsular contracture rate: Vertex 23% (15/64), Style 410 22% (14/64). This percentage calculation is based on the number of breasts, not the number of patients.

sular contracture.'' No patients were classified as having a ''hard breast'' and more significant capsular contracture (BAC 4). There was no statistical difference in the percentage among the categories of breast consistency based on the type of implant (Vertex or Style 410) used (Table 4, Fig. 6). Our results did not confirm the theory that larger implants increase the likelihood of firmer breasts (Table 8). Also, the data on firmness and palpability analyzed by implant position were inconclusive (Table 9).

Sensation

Sensitivity of the skin on the breasts decreased (''slight loss'' or ''severe loss'') for 26% (38/148) of the augmented breasts (Table 5, Fig. 7). The majority of the decrease reported (96%, 50/52) was a slight decline in sensation or the presence of paresthesia, limited to the triangular area above or below the incision (Fig. 14). Among these were five patients (i.e., every second patient) who underwent surgery through the periareolar approach. Normal, unaltered sensation in the breast nipples was present or reported for 119 (80%) of 148 investigated breasts. Two patients had loss of sensation in one breast nipple, whereas 10% of the breasts had an increased sensitivity in the nipples after augmentation (Table 6, Fig. 8). The implant volume and position showed no statistically significant relationship with the decrease in sensitivity of the breast skin and nipples. Among 17 breasts with increased nipple and skin sensitivity,

Table 5. Breast skin sensitivity 4 to 6 years after augmentation[a]

	Vertex Eurosilicone (37 patients, 74 breasts)			Style 410 (37 patients, 74 breasts)			
	Left *n* (%)	Right *n* (%)	%	Left *n* (%)	Right *n* (%)	%	Total *n* (%)
Normal	26 (70)	25 (68)	69	28 (76)	27 (73)	74	106 (72)
Increase	1 (3)	1 (3)	3	1 (3)	1 (3)	3	4 (3%)
Slight loss	9 (24)	10 (27)	26	8 (22)	9 (24)	23	36 (24)
Severe loss	1 (3)	1 (3)	3	0	0		2 (1)
No sensitivity	0	0		0	0		0
Total	37	37		37	37		148

[a]Breast skin sensitivity was affected (increase or loss) in 28% of the surgically treated breasts (42/148).

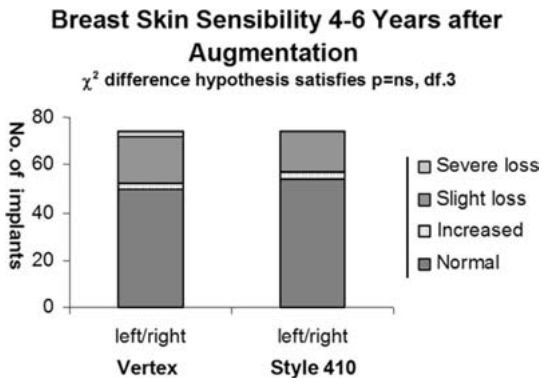

Fig. 7. Breast skin sensitivity 4-6 years after augmentation. χ^2 (chi squared) difference hypothesis satisfies p = ns, df. 3.

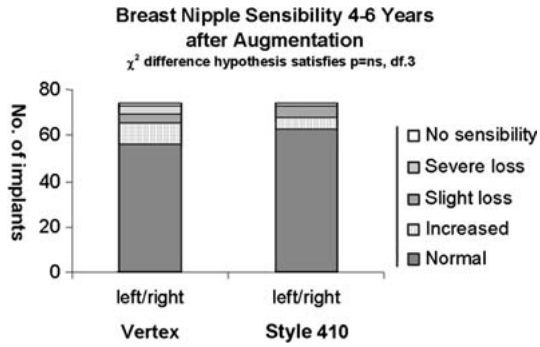

Fig. 8. Breast nipple sensitivity 4-6 years after augmentation. χ^2 (chi squared) difference hypothesis satisfies p = ns, df. 3.

Table 6. Breast nipple sensitivity 4 to 6 years after augmentation[a]

	Vertex Eurosilicone (37 patients, 74 breasts)			Style 410 (37 patients, 74 breasts)			
	Left *n* (%)	Right *n* (%)	%	Left *n* (%)	Right *n* (%)	%	Total *n* (%)
Normal	29 (78)	27 (73)	76	32 (86%)	31 (84%)	85	119 (80)
Increase	5 (13)	5 (13)	13	2 (5)	3 (8)	7	15 (10)
Slight loss	2 (5)	2 (5)	5	2 (5)	3 (8)	7	9 (6)
Severe loss	1 (3)	2 (5)	4	0	0	0	3 (2)
No sensitivity	0	1 (3)	1	1 (3)	0	1	2 (1)
Total	37	37		37	37		148

[a]Breast nipple sensitivity was adversely affected in 9% of the surgically treated breasts(14/148), present in 9 (12%) patients.

16 had implants in the subglandular pocket, and only 1 had submuscular implant placement (Table 9).

Complications

The overall complication rate per implant was 5% (8 of the 160 implants used, 10% of the patients) (Table 7). Among the 13 patients classified as difficult cases because of breast anomalies or because the augmentations were secondary, 3 had complications during the first few months after implantation (Table 7). Unilateral implant torsion occurred with two primary and two secondary augmentations. Rotation occurred more frequently for patients with ptotic breasts because their tissues were prone to distension and the implants were not firmly encapsulated. Two rotations were corrected by external manipulation and taping for 1 month and two by open surgery. Inflammation in one breast caused by an aseptic seroma developed 1 week after the operation for two patients who underwent surgery by the periareolar approach. Both had a history of breast feeding [2]. One patient had a

Table 7. Complications during the first year after surgery[a]

Complication breasts	A Primary augmentation (n = 134 breasts) (67 patients)	B Secondary augmentation (n = 26) (13 patients)
Postoperative bleeding		1(V, 300 ml, sm)
Infection	1 (S, 340 ml, sg)	
Aseptic seroma	2 (V, 500 ml, sg; S, 270 ml, sg)	
Implant rotation	2 (S, 300 ml, sg; V275 ml, sg)	2 (S400, sm; S270 sg)
Total	5	3

A, routine primary augmentation (n = 134); B, patients with anatomic breast anomalies and secondary augmentations due to previous unsatisfactory results (n = 26); S, Style 410; V, Vertex; sg, subglandular implant location; sm, submuscular implant location

[a]80 patients (160 implants) received Style 410 and Vertex implants. The results are displayed per breast. In all patients with complications, only one breast was affected.

Table 8. Results by implant volume calculated per number of breasts: 128 breasts, 64 examined patients (n = number of breasts)

	Implant volume in ml					
	240–275 (n = 44)	300–325 (n = 32)	340–350 (n = 24)	395–400 (n = 20)	440–500 (n = 8)	Total (n = 128)
Firmness						
BAC 1	14	6	6	4	1	31
BAC 2	17	21	15	8	7	68
BAC 3	13	5	3	8	—	29
BAC 4	—	—	—	—	—	0
Total	44	32	24	20	8	128
Palpability						
Soft	32	19	21	18	4	94
Firm	9	11	3	2	3	28
Too soft	3	2	—	—	1	6
Total						128
Nipple sensitivity						
Normal	36	24	22	13	6	101
Increased	1	6	2	2	2	13
Slight loss	2	2	—	5	—	9
Severe loss	3	—	—	—	—	3
No sensitivity left	2	—	—	—	—	2
Total						128
Skin sensitivity	35	26	16	10	4	91
Normal	—	—	—	2	2	4
Increased	7	6	8	8	2	31
Slight loss	2	—	—	—	—	2
Severe loss						128
Total						

hematoma drained on postoperative day 2, and another had an infected haematoma caused by her own negligence. Patients with seromas and hematomas were administered a preventive antibiotic (flucloxacillin [Heracillin, AstraZeneca] 750 mg twice daily for 3 weeks) active against penicillinase-producing staphylococci. At the follow-up evaluation, all patients with the initial complication had results equal to those for the rest of the group. There were no detected implant ruptures during the observation time.

Discussion

Anatomically shaped cohesive gel implants provide an aesthetically pleasing breast shape with desired moderate fullness of the upper quadrants, medial fullness of the breast mounts, a variable cleavage, and some lateral protrusion beyond the thoracic contour (Figs. 10 and 13). The cohesive filler allows for control of gel distribution inside the implant and consequently the distribution of fill in the breast. Other positive factors are a good correction effect on a slight or even

Table 9. Results by implant position, calculated per breast: 128 breasts, 64 examined patients (n = number of breasts)

–	Submuscular (n = 36)	Subglandular (n = 92)
Firmness		
BAC 1	5	26
BAC 2	21	47
BAC 3	10	19
BAC 4	—	—
Palpability		
Soft	26	68
Firm	10	18
Too soft	—	6
Nipple sensitivity		
Normal	30	71
Increased	1	12
Slight loss	3	6
Severe loss	2	1
No sensitivity	—	2
Skin sensitivity		
Normal	28	63
Increased	—	4
Slight loss	6	25
Severe loss	2	—

moderate ptosis without need for massaging. Therefore, the frequency of control visits can be reduced, making these implants suitable for patients living at an inconvenient distance from the surgeon.

The limitations of cohesive gel-filled breast implants are a long incision (5 cm) in the inframammary fold used for the majority of patients, a slightly firmer feel than with liquid silicone gel-filled implants, implant edge palpability, occasional lateral or inferior visibility in slim patients, and a higher cost. As compared with gel-filled round implants, anatomically shaped gel-filled breast implants may rotate. This often is used as an argument against anatomic cohesive gel-filled implants. However, the overall advantages outweigh the disadvantages.

High overall satisfaction, expressed by the 98.6% of the interviewed patients, confirmed the value of breast enlargement for women. Our patients gained better self-esteem and were more satisfied with their quality of life. The practice of placing the submammary incision 10 mm above the IMF in nonptotic breasts arose from the idea that when patients lie on the beach, the bra of their bikini slides upward and exposes the IMF. After receiving negative feedback from our patients, we later stopped using that approach and began placing the incision in the IMF.

The complications in this study occurred during the first postoperative year, and their frequency was similar to that reported by Heitmann et al. [10], who had complication rates of 10% after primary and 31% after secondary augmentations. In the current study, complications after primary augmentations occurred in 4% (5/134) of the surgically treated breasts (Table 7). When the patients were subjected to a secondary mammary augmentation or presented with breast anomalies, the rate of complications increased threefold to 12% (3/26). The complications were related to healing or rotation problems. Such increased risks are recognizable during the initial consultation, and patients should be duly informed about them.

Capsular contracture is a major complication of aesthetic and reconstructive mammary augmentation. It is unclear why the patients from this study with implants containing cohesive silicone gel did not experience severe capsular contracture (BAC 4, Baker IV). The most plausible explanation is that the increased filler cohesivity withstands the contractile forces of the newly formed tissues surrounding the implant. Recently, cohesive gel-filled breast implants became available with a less cohesive gel and less cross-linking [3]. More time is necessary to determine whether this new breast implant filler will result in permanently softer and shape-stable breasts.

Baeke [1] observed 14% rotations with saline anatomic implants. He used a periareolar approach with extremely wide and short implants (Mentor, Santa Barbara, CA, Style 2700 and 2900). This could have influenced the ingrowth process negatively (Fig. 2) [12]. We had 5% of rotations, all correctable, which also is unsatisfactory, but on the tolerable level. On the other hand, Tebbetts [21] reported no rotation among 609 patients with anatomic, saline-filled implants after 5 years. This study was not based on a review of the results by an independent examiner, and others were not able to reproduce it [1]. In our opinion, using the saline as a filler for anatomic implants does not make sense because of the pliability exhibited by implants filled with saline.

A decrease in sensation of the breast skin in an area adjacent to the incision occurred in 25% of the augmented breasts. This finding was not previously reported, but in our opinion not because it was absent. Surgeons evaluating augmented breasts tend to pay more attention to the shape, consistency, and sensation in the breast nipples than to skin sensation.

We investigated the position of the breast mound in the horizontal dimension and found that 43% (35/80) of our patients had one breast lateralized (Table 2). Our findings are in concordance with the recent study by Rohrich, Hartley, and Brown [17], who determined that 53% of women had asymmetrically placed nipple—areolas. Both studies thus show the remarkably high incidence of asymmetries, with consequences for the results of breast augmentation. Yet, to date, the aspect of breast asymmetries is frequently overlooked by surgeons.

Seven years have passed since we completed the last surgery. Since then, manufacturers have introduced new shapes and sizes of implants with varying gel cohesivity, different implant projection, and other dimensions. Most cohesive implants currently have no "memory."

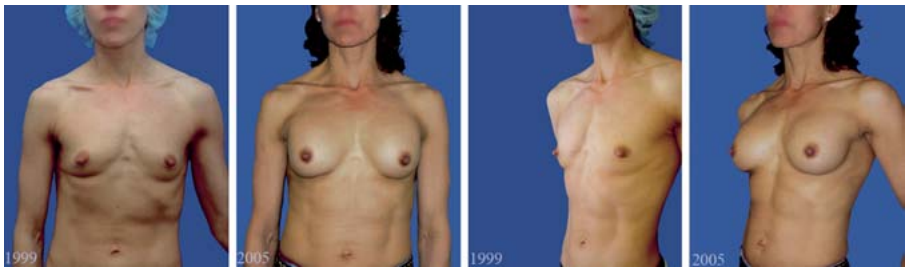

Fig. 9. Frontal and oblique views of a 38-year-old runner, mother of three children. (*Far left and right*) Before and (*left and far right*) 6 years after submuscular augmentation with 250-ml Style 410 implants. Noticeable positive weight gain after breast correction is seen.

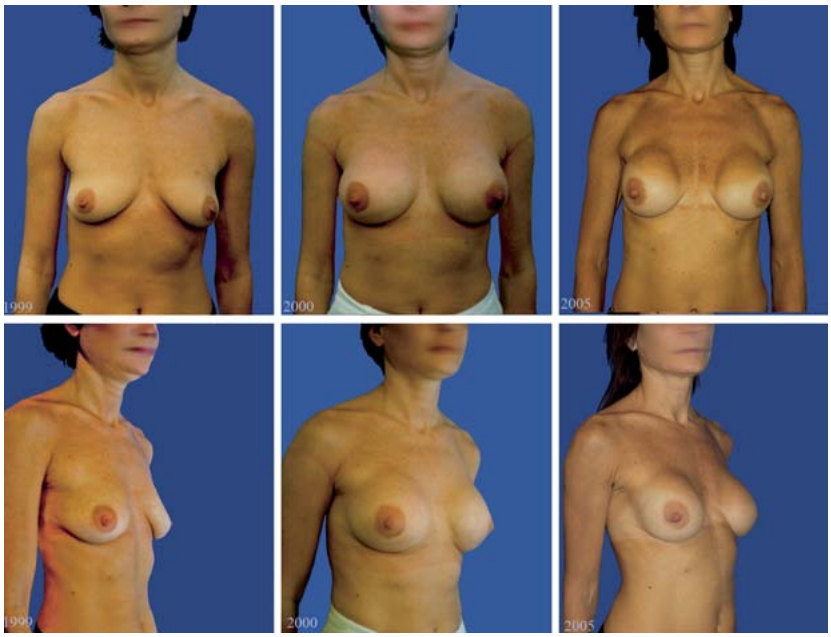

Fig. 10. A 37-year-old (*left*) before augmentation. (*Center*) One year after the periareolar, subglandular augmentation with 350-ml Vertex implants, her breasts have a natural appearance. (*Right*) The implant edges became noticeable 6 years after augmentation and 2 years after delivery of her first child. Lateralization of her left breast is more pronounced after breast enlargement.

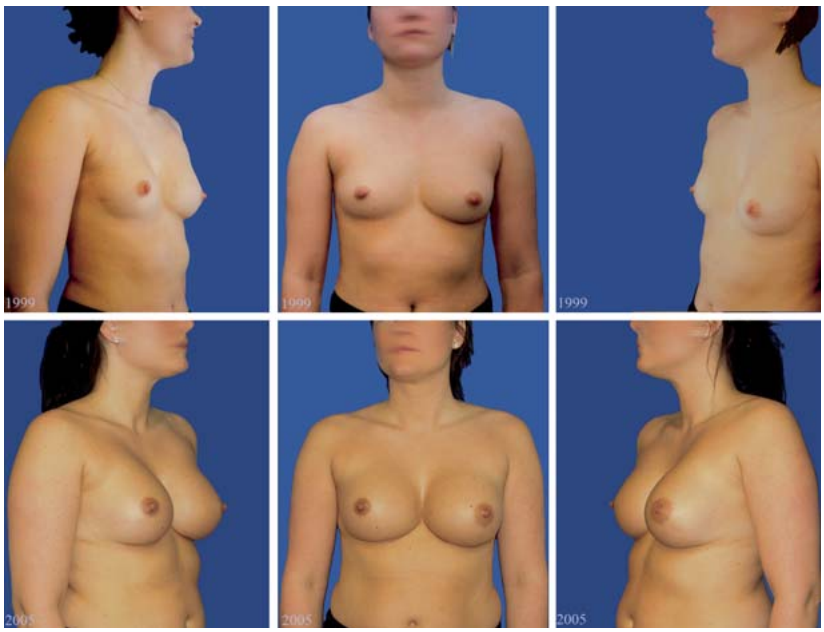

Fig. 11. (*Upper*) A 22-year-old nullipara woman with breast asymmetry. (*Lower*) View 6 years after correction with Vertex implants in the submuscular position: 325 ml in the right breast and 300 ml in the left breast. She still has 4 kg of residual weight gain 1 year after child delivery.

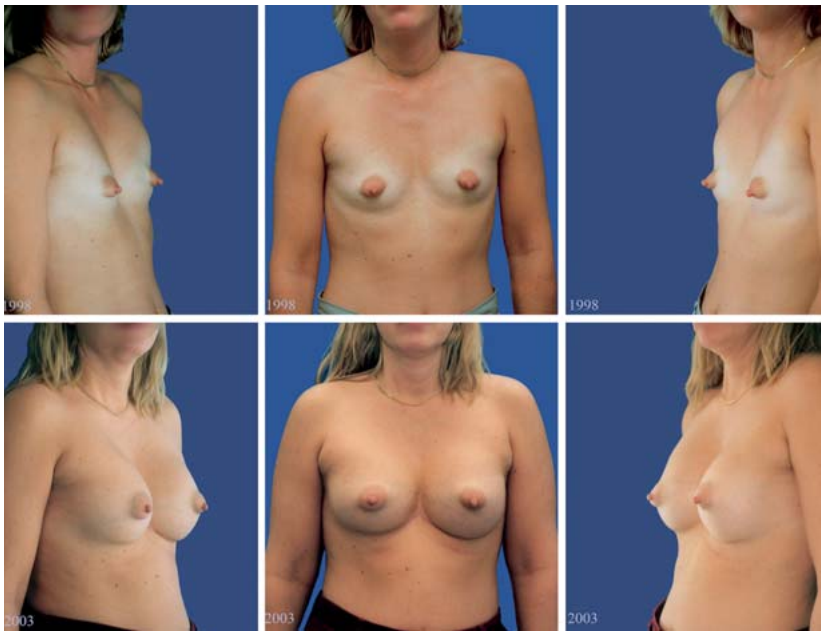

Fig. 12. A 35-year-old, 1-para, heavy smoker with pectus excavatum and tubular breasts. (*Above*) Preoperative views. (*Below*) 4.5 years after correction with 340-ml Style 410 implants placed subglandularly.

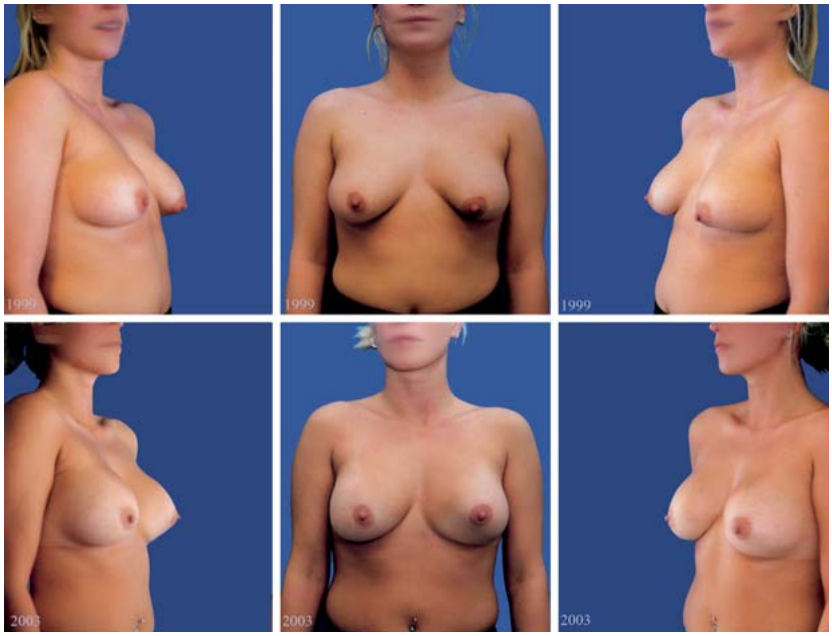

Fig. 13. (*Above*) Preoperative views of a 20-year-old nullipara woman with breast asymmetry. Her left breast was smaller and located higher on the chest, showing deficiency in the lower medial quadrant. The right breast had lower pole constriction. (*Below*) 4.5 years after correction with Vertex implants in the submammary location: 250 ml for the right breast and 325 ml for the left breast. The left implant was placed diagonally.

The operative and anesthetic techniques also have changed. For the past 2 years, we have been providing postoperative analgesia through an epidural catheter in the breast pocket and using intermittent flushing with the long-working local anesthetic solution Narop (AstraZeneca) [14].

In this study, 72% of the devices were implanted in the subglandular location. Following patients for several years, we observed that the implants were not visible within 1 to 2 years after the surgery. This is consistent with reports from other studies [3,4,7]. We also observed that after an event such as weight loss or motherhood, the edge of the implant could become noticeable (Fig. 10). This is one of the reasons why 90% of implants currently are placed submuscularly or partially submuscularly using dual-plane [20] or high pectoralis split techniques [14]. Round implants are offered when the patient desires a transaxillary approach and is selected for secondary augmentations. The current techniques also will certainly evolve over the next few years.

Most comparative studies of breast augmentation are retrospective. Prospective, controlled studies are scientifically more valuable but difficult to conduct.

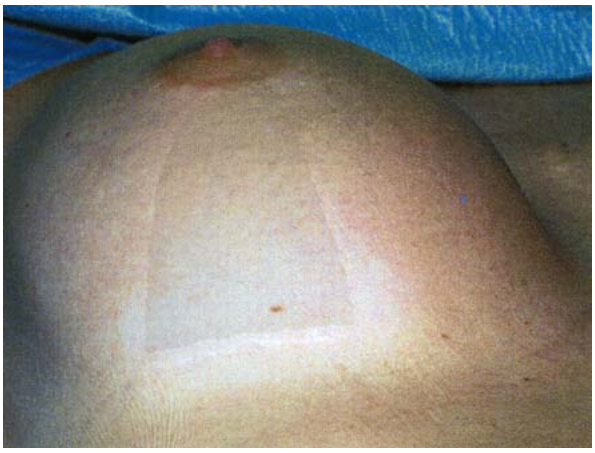

Fig. 14. The area of breast skin that may be affected by a decrease in sensitivity. The usual appearance of the inframammary scar after 1 year.

The patient population must be large enough for statistical calculations; the follow-up period must have a span of at least a few years; and the majority of patients must return for a controlled examination. Finally, by the time the study is concluded and published, the investigated implants are frequently modified by the manufacturer and may no longer be the primary choice. Available prospective studies on the safety and efficacy of breast implants have investigated patients implanted with first- or second-generation mammary implants filled either with physiologic saline solution or low-cohesivity silicone gel [4,5,7]. This report is the first investigation fullfilling basic scientific criteria for the study of mid- to long-term outcomes of breast augmentations with mammary implants of the teardrop shape (anatomic) and filled with cohesive silicone gel.

This study showed the mid- to long-term safety of the cohesive gel implants for aesthetic breast enlargement. Our Excel database patient registry now contains 1,248 patients who received cohesive gel-filled breast implants. Lower cost without compromised quality is a main objective of the health care system, and the cost is very important to private patients. Vertex implants cost about two-thirds the price of the Style 410 implant. With the exception of patients' opinions on breast consistency, no difference in clinical results or frequency of complications was found between the patients augmented with Style 410 and those who received Vertex implants.

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References

1. Baeke JL: Breast deformity caused by anatomical or teardrop implant rotation. *Plast Reconstr Surg* **109:**2555–2567, 2002
2. Boer HR, Arnido G, MacDonald N: Bacterial colonization of human milk. *South Med J* **74:**716–718, 1981
3. Brown MH, Shenker M, Silver SA: Cohesive silicone gel breast implants in aesthetic and reconstructive breast surgery. *Plast Reconstr Surg* **116:**768–779, 2005
4. Coleman DJ, Foo IT, Sharpe DT: Textured or smooth implants for breast augmentation? A prospective controlled trial. *Br J Plast Surg* **44:**444–448, 1991
5. Fagrell D, Berggren A, Tarpila E: Capsular contracture around saline-filled fine textured and smooth mammary implants: A prospective 7.5-year follow-up. *Plast Reconstr Surg* **108:**2108–2112, 2001
6. Gylbert L, Asplund O, Jurell G, Olenius M: Results of subglandular breast augmentation using a new classification method: 18-year follow-up. *Scand J Plast Reconstr Hand Surg* **23:**133–137, 1989
7. Hakelius L, Ohlsén L: A clinical comparison of the tendency to capsular contracture between smooth and textured gel-filled silicone mammary implants. *Plast Reconstr Surg* **90:**247–253, 1992
8. Hammond DC: Discussion of Rohrich RJ, Hartley W, and Brown S: Incidence of breast and chest wall asymmetry in breast augmentation: A retrospective analysis of 100 patients. *Plast Reconstr Surg* **111:**1520, 2003
9. Heden P, Jernbeck J, Hober M: Breast augmentation with anatomical cohesive gel implants: The world's largest current experience. *Clin Plast Surg* **28:**531–552, 2001
10. Heitmann C, Schreckenberger C, Olbrisch RR: A silicone implant filled with cohesive gel: advantages and disadvantages. *Eur J Plast Surg* **21:**329–332, 1998
11. Mladick RA: "No touch" submuscular saline breast augmentation technique. *Aesth Plast Surg* **17:**183–192, 1993
12. Niechajev I: Anatomical breast implants: Different experience (letter to the editor). *Plast Reconstr Surg* **112:**1186, 2003
13. Niechajev I: High-cohesive gel silicone implants: Advantages and disadvantages (in Swedish). *Hygea* **108:**102, 1999
14. Niechajev I: Innovative augmentation: Body language. *Plast Cosm Surg* **11:**16–18, 2003
15. Niechajev I: Mammary augmentation by cohesive silicone gel implants with anatomic shape: Technical considerations. *Aesth Plast Surg* **25:**397–403, 2001
16. Niechajev I, Jurell G: Cohesive anatomic shaped silicone gel implants for mammary augmentation. Edited instructional video 15' Eurosilicone, Apt, France, 2001
17. Rohrich RJ, Hartley W, Brown S: Incidence of breast and chest wall asymmetry in breast augmentation: A retrospective analysis of 100 patients. *Plast Reconstr Surg* **111:**1513–1519, 2003
18. Spear SL: Discussion of Rohrich RJ, Hartley W, Brown S: Incidence of breast and chest wall asymmetry in breast augmentation: A retrospective analysis of 100 patients. *Plast* Reconstr Surg 111:1521–523, 2003
19. Spear SL, Baker JL Jr: Classification of capsular contracture after prosthetic breast reconstruction. *Plast Reconstr Surg* **96:**1110–1123, 1995
20. Tebbetts JB: Dual-plane breast augmentation: Optimizing implant–soft–tissue relationships in a wide

range of breast types. *Plast Reconstr Surg* **107:**1255–1272, 2001
21. Tebbetts JB: Patients' acceptance of adequately filled breast implants. *Plast Reconstr Surg* **106:**139–147, 2000
22. Tebbetts JB: McGhan's biodimensional augmentation system cohesive gel mammary implants. Instructional video, 55', McGhan Medical Corporation, 1993