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ORIGINAL ARTICLE BREAST

Back to the Future: A 15-Year Experience With Polyurethane Foam-Covered Breast Implants Using the Partial-Subfascial Technique

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Abstract
Background Implants with a polyurethane foam cover have been used by plastic surgeons since Ashley described them in 1970. Overwhelming evidence confirms the benefits of these implants, especially the extremely low incidence of capsular contracture (grades 3 and 4, Baker classification). On the other hand, except for a transient and self-limited rash, there is no evidence that polyurethane implants present more complications than texturized or smooth gel implants. Due to concerns of polyurethane-induced cancer, these implants were withdrawn in United States after approximately 110,000 American women had received them. This fact, together with the probability that these implants will be reintroduced in the United States, suggests that continued monitoring of their long-term safety and effectiveness is mandatory.
Methods A retrospective study analyzed the outcomes of 996 implants inserted during a period of 15 years. The incidence of early and late complications was analyzed as well as the aesthetic outcome.
Results The complications evaluated included hematoma (0.6%), infection (0.4%), seroma (0.8%), rash (4.3%), wound dehiscence (0%), capsular contracture (0.4%), implant malposition (0.8%), need for revisional surgery (1.2%), implant rupture (0.7%), rippling (1.8%), and polyurethane-related cancer (0%). Regarding the aesthetic outcome, 95% of the patients expressed satisfaction with their final result.
Conclusion The polyurethane foam-covered implants have been proven safe for use in breast surgery. They provide the lowest rate of capsular contracture (0.4% in the current study) and excellent aesthetic results.

Keywords Capsular contracture · Implant rupture · Partial-subfascial technique · Polyurethane implants · Polyurethane-induced cancer

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Implants with a polyurethane foam cover (1- to 2-mm-thick layer of polyurethane foam) have been used by plastic surgeons since 1970, when Ashley [1] used an implant that had a Y-shaped septum (natural-Y implant). After 2 years, he published his experience using this implant in 200 patients with very good results and minimal complications [2]. In 2007, Vasquez and Pellon [37, 39] modified the standard anatomically shaped implants, increasing the volume of silicone gel by 12.5%, making the point of maximum projection perpendicular to the ideal placement of the nipple–areola complex and improving the projection in the upper pole.

Many authors have described a low incidence of capsular contracture when using polyurethane-covered implants [3, 5–15, 17, 18, 20–28, 30, 31, 33–36] for breast augmentation, breast reconstruction, and breast-lift procedures. The average percentage of capsular contracture in the reported patients was approximately 2%. This percentage was maintained independently from the anatomic positioning of the implant, whether subglandular, submuscular, or subfascial. Pitanguy et al. [29] demonstrated this affirmation in their paper published in 1990 describing 73 patients who underwent breast augmentation using polyurethane-covered breast implants, with alternation of the anatomic planes. These authors found no difference in

capsular contracture incidence. In 1991, Handel [18] performed a comparative study of 250 patients with 439 smooth-surfaced silicone implants and 279 patients with polyurethane-covered breast implants, concluding that the incidence of capsular contracture is indeed higher among patients with smooth-surface implants.

The histology of the capsule that surrounds an implant once it is inserted into the body has been analyzed for an understanding of the physiologic process that occurs at the interface where the implant comes in contact with human tissues. This prompted our search for new ways to modify this response to prevent or lower the rate of formation of a problematic capsule.

In 1978, Zimman et al. [40] published his work using electron microscopy to evaluate the formation of collagen from fibroblasts in the presence of a smooth-surface implant. This work led to an understanding of the physiology of capsular formation.

The low incidence of capsular contracture when polyurethane-covered implants are used is due to the delayed growth of fibrotic tissue that extends from the polyurethane foam toward the periphery. This process is produced by free fragmented microcapsules that cause a chronic foreign body reaction, with the recruitment of macrophages and giant multinucleated cells. When these cells ingest the polyurethane fragments, they form microcapsules that avoid the formation of capsular contraction. The microcapsules prevent the organized alignment of myofibroblasts, interrupting the strength vectors needed for a capsular contracture to occur [6, 32].

In 1992, Barone et al. [3] published their research, concluding that the capsule produced in the body, when exposed to polyurethane-covered implants, is rigid and hard to the touch initially. However, after 4 weeks, most of the edema has subsided, causing the capsule to take on a softer consistency. At 8 months after the procedure, the breasts of the study group (with polyurethane-covered implants) were softer and less likely to form a capsular contracture than the implants in patients that had a texturized surface. On the other hand, except for a transient and self-limited rash, no evidence has shown that polyurethane implants present more complications than texturized or smooth gel implants [19].

In the late 1980s, there was concern that a relationship between the components derived from the degradation of polyurethane (especially 2,4 toluenediamine [TDA]) and breast cancer could exist [4]. This relation has since been disproved by many studies [18, 32] including reports from the Food and Drug Administration (FDA) [18, 32] stating the conclusion that the polyurethane foam is safe, that the concentration of TDA in the urine of patients with polyurethane-covered implants is minimal, and that no statistical difference in TDA concentration was found between patients with polyurethane-covered implants and a control group [16]. These affirmations were confirmed by Santerre [31], who stated that "2,4 TDA is not a toxic or a cancer-producing material."

The FDA concluded that the lifetime risk of polyurethane-induced cancer in women with a pair of foam-covered implants was about 1 in 1,000,000. Because the risk was so low, the FDA did not recommend explantation of these devices. Bristol-Meyers Squibb, the manufacturer of the polyurethane foam-covered implants used in the United States, voluntarily withdrew the product in 1991, by which time it had been implanted in 110,000 American women. Because so many American women have polyurethane implants and because they remain popular outside the United States, continued monitoring of their long-term safety and effectiveness is mandatory [19].

One of the major problems in breast augmentation surgery with the use of anatomically shaped implants in a subglandular plane is the lack of volume achieved in the superior pole and visualization of the implant in the upper pole. For this reason, the preferred plane for placement of the implant in our series was the subglandular plane in its majority, with elevation of the subfascial plane in the internal and superior [38] border of the dissected pocket. Thus, the implant was placed in a partial-subfascial plane, improving the contour of the implant edges, especially in the inner uppermost quadrant (Fig. 1).

Once this type of implant is inserted, small folds (not rippling but actual small folds) can be produced. After modification of these implants by an increase in the volume of silicon by 12.5%, we think the incidence of the small folds has decreased. Also, we always follow the recommendation to insert the implant in a partial-subfascial plane in an effort to provide better coverage for the implant and to minimize the risk of rippling or small folds. When the preoperative pinch test evaluation shows poor coverage,

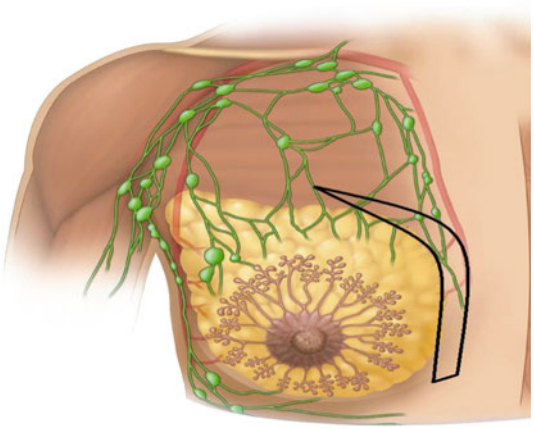

Fig. 1 Extent of the subfascial dissection for additional coverage of the implant (*black lines*)

with a thickness less than 2 cm, we prefer the insertion of implants in a submuscular pocket rather than in a partial-subfascial pocket. Another important aspect is to provide a pocket of appropriate size to avoid a tight implant and therefore the formation of small folds.

Materials and Methods

At the Institute for Plastic Surgery, we performed a retrospective study to analyze the outcomes for foam-covered polyurethane implants inserted from January 1995 through December 2010. All the surgeries were performed by the senior author, who is a board-certified plastic surgeon using our breast surgery protocol regarding the surgery itself as well as the pre- and postoperative management.

The inclusion criteria specified.

- Patients who underwent breast augmentation, mastopexy, or breast reconstruction with polyurethane implants during the study the period.
- Patients with previous breast surgery and capsular contracture who underwent explantation, capsulectomy, and reimplantation with polyurethane foam-covered implants.

The exclusion criteria ruled out.

- Patients with breast surgery but no polyurethane implants.
- Patients with incomplete follow-up evaluation because they were noncompliant with their visits or moved away or because of non–surgery-related death.

The variables studied were

- The aesthetic satisfaction rate
- The development of early complications (hematoma, infection, seroma, rash, wound dehiscence)
- The development of capsular contracture
- The development of implant malpositioning
- The need for secondary surgery
- Rupture of the implant
- The development of rippling
- The development of polyurethane-related cancer.

We have a breast surgery database at the Institute from which we were able to obtain data regarding demographics, type of surgery, volumes, plane of insertion, early complications (hematoma, wound dehiscence, infection, rash), development of capsular contracture, need for secondary surgery, and the like. Regarding aesthetic satisfaction, we used a questionnaire graded 1 (most dissatisfied) through 10 (most satisfied) completed by patients at every office visit, starting at the 3-month postoperative visit and then at every visit thereafter. For the patients who missed their visits, a phone call was made to secure the aforementioned data.

The most frequent surgical approach in our series was the periareolar incision because of its excellent scar quality and its ability to provide good visualization of the pocket. It must be clarified that choosing the incision for a breast augmentation depends on many factors including areolar diameter, implant size, patient preference, prior surgeries, presence of gland ptosis, body fat percentage, and associated procedures.

Once the approach was decided, the incision was made, dividing the skin and subcutaneous tissue. When the glandular tissue was reached, the dissection was performed in a tangential plane to the gland until the aponeurosis of the pectoralis major muscle was reached and a subglandular pocket was created. The subglandular plane was elevated until the internal and superior border of the previously marked reference points was reached. At this point in the procedure, the subfascial plane was elevated, especially in the upper pole of the inner quadrants.

Using a subfascial plane of dissection for placement of mammary implants has the advantages of affording a plane easy to create and giving additional coverage for the implant in the areas where an implant usually can turn visible. For cancer screening, we arrange an office visit once a year for every patient to undergo a full clinical assessment and review of their radiologic studies (ultrasonography or mammography).

The database was constructed and is maintained in Microsoft Excel for Mac (Cupertino, CA), and statistical analysis was performed using StatPlus for Mac.

Every implant was considered separately and tracked from insertion until the date of explantation or the most recent follow-up visit. The presence of early complications was evaluated by the senior author and recorded on the chart, where we recollected the data. Capsular contracture was graded using the Baker scale. Baker grades 1 and 2 capsules were defined as contracture free, and Baker grades 3 and 4 capsules were defined as having contracture.

For the final statistics, all numbers were calculated by implant except for patient satisfaction, which was calculated by patient. The study population was composed of 507 female patients ranging in age from 17 to 67 years (mean, 32 years). The mean follow-up period for this series was 6.8 years. A total of 996 polyurethane foam-covered implants were used (Table 1). All the patients received Silimed polyurethane foam-covered implants (Silimed, Rio de Janeiro, Brazil) the most popular volume size being 245 to 300 ml. All the implants had the following characteristics:

– The filling consisted of highly cohesive silicone gel.
– The polyurethane foam was adhered to the implant by a vulcanization process and no adhesives were present.

Table 1 Number of patients separated by procedure

	No. of cases
Breast augmentation	263
Breast augmentation with mastopexy	184
Re-augmentation with capsulectomy for capsular contracture	40
Unilateral breast reconstruction	18
Bilateral breast reconstruction	2
Total cases	507

– The transition zone between the dome and the base of the implant was placed in a more centric position than with traditional implants, thus lowering the possibility of the transition zone being viewed or felt once the implant was in place.

Results

During a 15-year period, 507 patients received polyurethane-covered breast implants. Of these 507 patients, 95% expressed satisfaction with their final result. Once the necessary period for achievement of the final softness and consistency had elapsed, 98% of the patients were satisfied with the aesthetic end result. Our final aesthetic index was of 9.8 based on the aforementioned 10-point scale.

Incidence of Early Complications

As shown in Table 2, the numbers were calculated by implant and not by patient. The early complications included hematoma with an incidence of 0.60% (6 implants), infection with an of 0.60% (6 implants), seroma with an incidence of 0.80% (8 implants), and local morbiliform rash with an incidence of 4.3% (43 implants). The hematoma cases were treated with surgical evacuation and reinsertion of the same implant. None of the hematoma cases involved delaminaton of the polyurethane-foam cover, so we were able to insert the same implant. The seroma cases were treated conservatively with rest and spirinolactone, and no case required evacuation. The infection cases required explantation of the infected side, which was unilateral in every case. The patients underwent reimplantation 3 months after resolution of the infection, and all had a good outcome. The morbiliform rash cases were treated with oral administration of difenhidramine, and every patient experienced resolution (Table 2).

Table 2 Early complications

Complication	No. of implants	%
Hematoma	6	0.6
Infection	4	0.4
Seroma	8	0.8
Rash	43	4.3
Wound dehiscence	0	0

Table 3 Late complications

Complication	No. of implants	%
Capsular contracture	4	0.4
Implant malposition	8	0.8
Need for revisional surgery	12	1.2
Implant rupture	7	0.7
Rippling	18	1.8
Polyurethane-related cancer	0	0

Incidence of Late Complications

Again, as shown by Table 3, the numbers were calculated by implant. The late complications included capsular contracture with an incidence of 0.40% (4 implants), implant malpositioning with an incidence of 0.80% (8 implants), a need for revisional surgery with an incidence of 1.2% (12 implants), rupture with an incidence of 0.7% (7 implants), rippling with an incidence of 1.8% (18 implants), and polyurethane-related cancer with an incidence of 0% (0 implants). The capsular contracture cases were treated by explantation, capsulectomy, and reimplantation in the same plane with the same implant type, all with good evolution and no capsular contracture recurrence to date. We needed to perform only one revisional surgery for implant malposition because the seven remaining cases were so subtle that patients decided not to undergo reinsertion. The rupture cases were treated by capsulectomy and reinsertion of the same implant type. No cases of cancer occurred (Table 3).The clinical outcomes obtainable with this type of implant are illustrated in the Figs. 2, 3, 4, 5, 6, 7, 8, and 9.

Discussion

In 1999, Vázquez [38] published a detailed analysis of the pathology, immunology, and biochemistry of the capsule surrounding polyurethane-covered breast implants. He described five layers in a concentric disposition from the implant to the periphery:

– Layer 1: a single-cell layer composed of macrophages, epithelial cells, and giant cells with foreign bodies inside

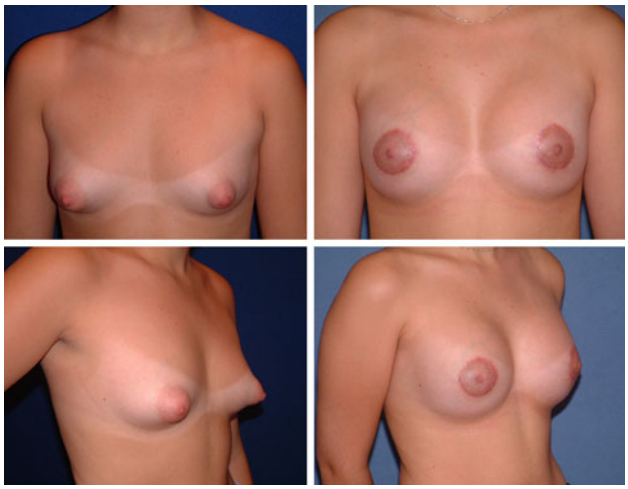

Fig. 2 A 19-year-old girl with tuberous breasts who requested breast augmentation. *Left row:* preoperative photos. *Right row:* postoperative photos. The girl underwent breast augmentation through a periareolar approach using anatomic 315-ml, gel-filled polyurethane foam-covered implants placed in the partial-subfascial plane. The postoperative photos were taken 3 months after the procedure

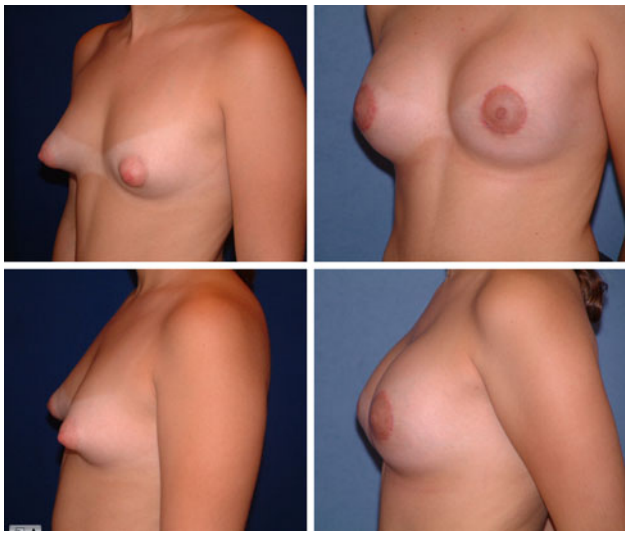

Fig. 3 Same patient as in Fig. 2. Oblique and lateral views. *Left row:* Preoperative photos. *Right row:* Postoperative photos. The postoperative photos were taken 3 months after the procedure

- Layer 2: tissue with microscopic evidence of subacute inflammation
- Layer 3: evidence of a plasmocytic infiltrate
- Layer 4: thick and fibrous connective tissue layer
- Layer 5: lax connective tissue in conjunction with the mammary parenchyma.

Later in 2007, Vasquez and Pellon [37] reported their experience with 1,257 surgically treated patients and concluded that the advances in the quality of implants (vulcanized instead of adhesive, more cohesive gel) contributed to even better outcomes with these implants. The benefits of polyurethane foam implants in reducing the risk of contracture have been reported previously [3, 5–15, 17, 18, 20–26, 30, 31, 33–36]. The current study confirmed these data, demonstrating an extremely low incidence of capsular contracture (0.40%), which was significantly lower than that reported in the literature for smooth implants (~6%) or texturized implants (~3%).

Regarding the other complications, we believe the advances in the technology of polyurethane implants also have significantly improved the outcomes to an even higher level than the previous experience in the United States. In our series, the complication rate for all the variables was below that previously reported, especially in relation to the development of the rash. This low incidence of rash, as reported by Vasquez and Pellon [37], can be explained because the newest implants (Silimed) have a thinner polyurethane foam than the first implants used in the United States. Also, the Silimed implants are vulcanized, eliminating the need for the adhesive. The rash likely was caused by a reaction to the adhesive rather than the foam itself.

The partial-subfascial plane provides advantages for either breast augmentation or mastopexy that have led us to considered it as the gold standard for alloplastic breast augmentation and mastopexy. These advantages are

- Adequate coverage for the implant, improving the upper poles, compared with use of the subglandular plane
- Intact preservation of the pectoralis major muscle, thus allowing a faster recovery with less pain.

The advantages of the partial over the total subfascial plane are

- Faster dissection
- Less intra- and postoperative bleeding
- All the advantages offered by the total subfascial plane
- No disadvantages of the total subfascial plane (longer procedure, more intraoperative bleeding, higher incidence of postoperative hemorrhagic complications).

In our series, the rate of rippling was far below that reported by other authors, and we think the partial-subfascial plane has helped us to achieve this low rippling incidence (Figs. 2, 3, 4, 5, 6, 7, 8, and 9).

The polyurethane foam-covered implants have been certified and proved to be safe for their use in breast surgery. They provide the lowest rate of capsular contracture (0.40% in the current study) and excellent aesthetic results (Figs. 2, 3, 4, 5, 6, 7, 8, and 9).

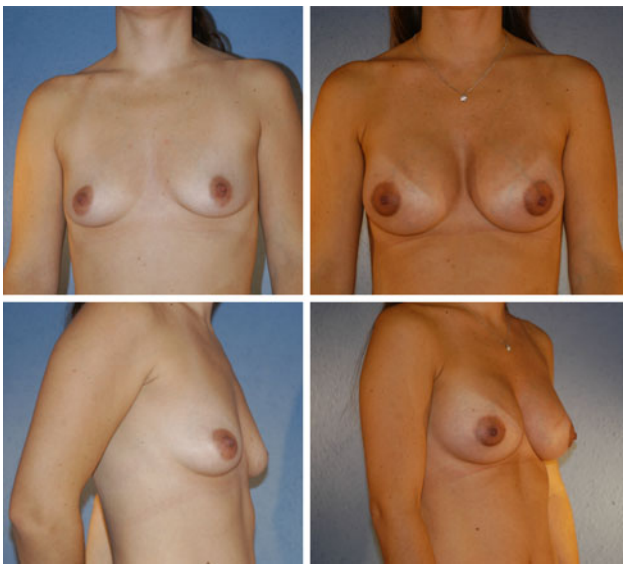

Fig. 4 A 28-year-old woman who requested breast enhancement. *Left row:* preoperative photos. *Right row:* postoperative photos. The woman underwent breast augmentation through a hemiperiareolar approach using anatomic 280-ml, gel-filled polyurethane foam-covered implants placed in the partial-subfascial plane. The postoperative photos were taken 1 year after the procedure

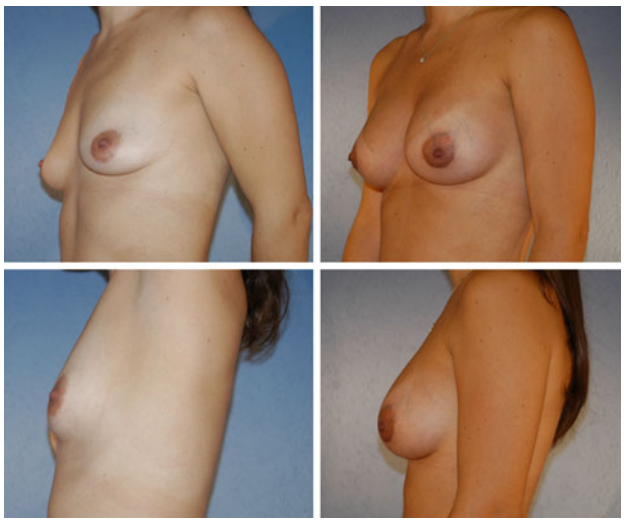

Fig. 5 Same patient as in Fig. 4. Oblique and lateral views. *Left row:* preoperative photos. *Right row:* postoperative photos. The postoperative photos were taken 1 year after the procedure

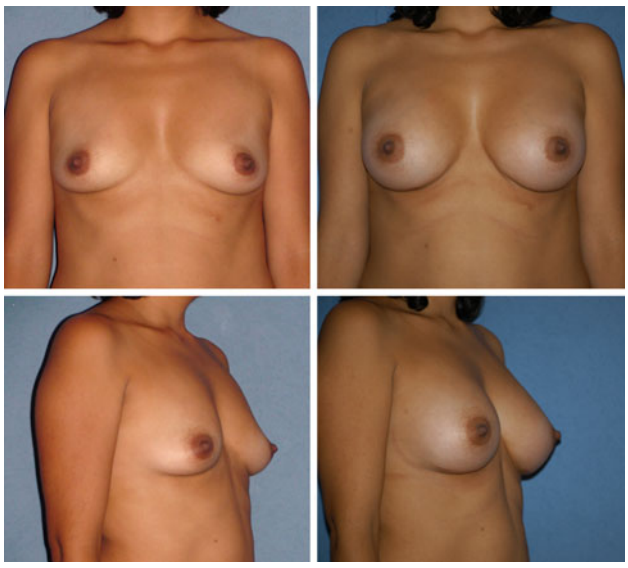

Fig. 6 A 34-year-old woman who requested breast augmentation. *Left row:* preoperative photos. *Right row:* postoperative photos. The woman underwent breast augmentation through an inframammary approach using anatomic 340-ml, gel-filled polyurethane foam-covered implants placed in the partial-subfascial plane. The postoperative photos were taken 4 years after the procedure. Note that despite poor coverage of the upper quadrants in the preoperative photos, the partial-subfascial technique provides adequate coverage that lasts during the long term

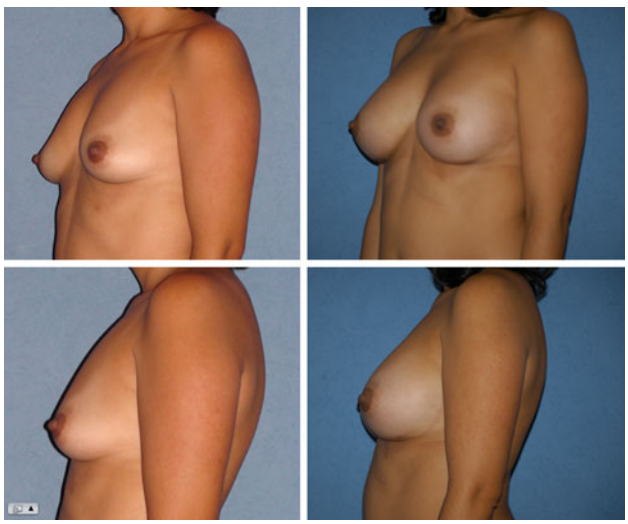

Fig. 7 Same patient as in Fig. 6. Oblique and lateral views. The postoperative photos were taken 4 years after the surgery

Conclusions

Overwhelming evidence points to the benefits of polyurethane foam-covered implants, especially those related to the extremely low incidence of capsular contracture [3, 5–15, 17, 18, 20–26, 30, 31, 33, 34, 36]. This low incidence of capsular contracture with the use of polyurethane-covered breast implants is due to the following:

- The capsule presents a totally different structure than the capsule that forms with a smooth or texturized implant.
- The friction between the implant and the surrounding tissue is decreased because the implant moves with the adjacent tissue.

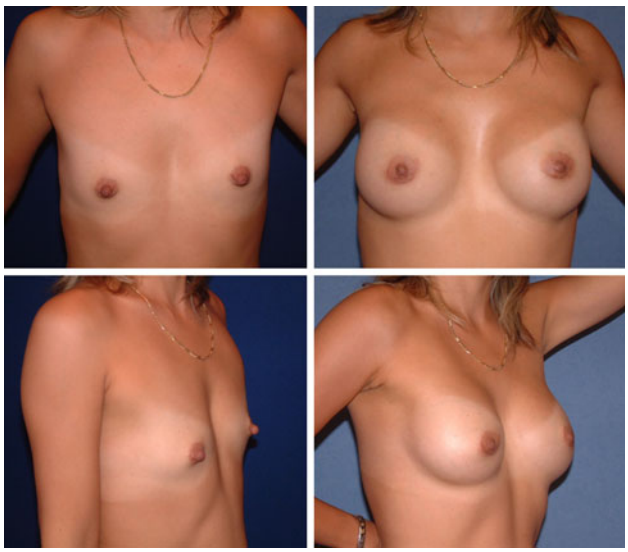

Fig. 8 A 38-year-old woman with breast hypoplasia who requested breast augmentation. *Left row:* preoperative photos. *Right row:* postoperative photos. The woman underwent breast augmentation through a hemiperiareolar approach using anatomic 380-ml, gel-filled polyurethane foam-covered implants placed in the partial-subfascial plane. The postoperative photos were taken 7 years after the surgery. Again, note the good coverage of the partial-subfascial plane 7 years after the surgery

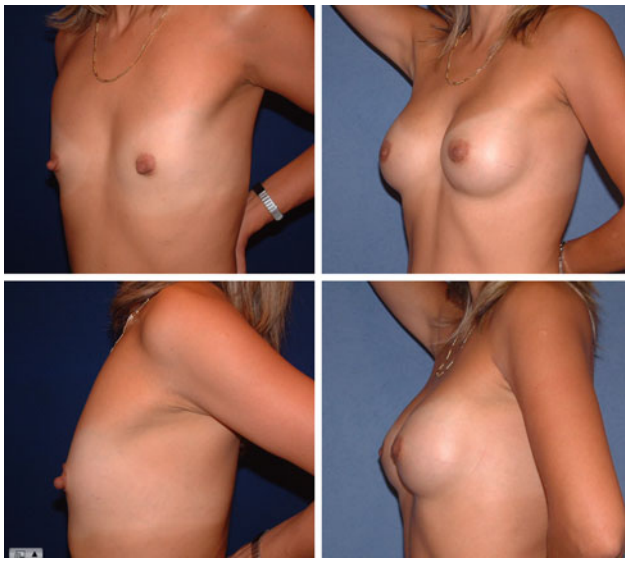

Fig. 9 Same patient as in Fig. 8. Oblique and lateral views. *Left row:* preoperative photos. *Right row:* postoperative photos. The postoperative photos were taken 7 years after the surgery

- Disorganization in the deposited collagen fibers interrupts the radial vectors of capsular contracture.

Findings have shown the polyurethane-covered implants to be the best option for breast augmentation, breast reconstruction, and secondary cases with previous capsular contracture, especially capsular contracture classified as Baker grade 3 or 4.

The scientific evidence regarding polyurethane foam-covered implants appears to be in their favor because they have all the advantages of texturized and smooth implants but with much lower incidences of capsular contracture and revisional surgery. Therefore, we add our experience to the worldwide medical literature regarding this topic. With more reports of this type in the future, we hope to obtain more evidence-based information and thus achieve better conclusions. Also, we think that our series, although not small (507 patients), is neither large nor long enough (median follow-up period, 6.8 years) to declare the absolute safety of these implants regarding cancer association. These results need to be confirmed with other studies. On the other hand, the partial-subfascial technique has allowed us to obtain the benefits of the subfascial technique in providing good coverage for the implant and thus lowering the rippling incidence and to avoid the disadvantages of the total subfascial technique (Figs. 2, 3, 4, 5, 6, 7, 8, and 9).

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