Breast Implant Complication Review: Double Capsules and Late Seromas

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Background: The problem of double capsules and late seromas is a relatively new phenomenon in breast augmentation surgery.
Methods: The author's experience with double capsules in 14 patients is outlined. The author reviewed all primary bilateral breast augmentations and primary bilateral mastopexy-augmentations after the moratorium in 1992. There were 209 patients with saline implants, 160 patients with CML and CMH Microcell textured surface implants, 105 patients with Biocell textured surface silicone gel breast implants, and 152 patients with smooth round silicone gel breast implants. Complications and revisions were reviewed to see if any patterns emerged.
Results: Fourteen patients were found to have double capsules. Double capsules were only seen with the Biocell textured surface implant. Three patients developed late seromas (more than a year after their original surgery), with two patients requiring urgent drainage of an expanding seroma/hematoma. Seven patients were found to have double capsules as an incidental finding for procedures, such as asymmetry and bottoming out, and five patients were found to have double capsules when surgery was performed for capsular contracture. The review of complications and revisions showed that the silicone gel implants were far better than saline implants. Highly cohesive Microcell textured CMH and CML implants had by far the best capsular contracture profile. Biocell texturing increased the capsular contracture rate.
Conclusions: Double capsules and late seromas are a relatively new problem in breast augmentation surgery. The problem was not seen in smooth saline or smooth silicone gel breast implants but only in aggressively textured implants. (*Plast. Reconstr. Surg.* 127: 56, 2011.)

Surgeons are documenting and discussing the complication of late seromas in breast augmentation surgery.[1–5] One theory is that the problem is an unusual late infection, but often the cultures have been negative. Some surgeons suggest that the problem is a mycobacterium that is difficult to culture.[6,7] The occurrence of a biofilm on implants has also been documented and implicated.[8]

In this review, only Biocell textured implants developed either a late seroma and/or a double capsule (Table 1). A more plausible theory may be that the initial adherence of the capsule to the textured implant becomes separated, with minor trauma resulting in two rough surfaces that create a seroma because of the shear forces involved.

In the author's experience, the polyurethane implants did result in true tissue ingrowth of the capsule into the implant. The capsule was almost impossible to separate from the implant, even with sharp dissection. The capsule on the Biocell textured implants adheres much like Velcro, and it can usually be separated with finger dissection. Although the author has not seen adherence with the Siltex textured implants, there is often a small associated seroma that is not seen with smooth-walled implants.

PATIENTS AND METHODS

A review of a single-surgeon practice over 27 years has revealed that the occurrence of double capsules and late seromas is a relatively new phe-

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Table 1. Double Capsules in Biocell Textured Implants

Case	Surgery	Right Implant	Left Implant	Pocket	Problem	Time after Original Operation	Findings
1	BBA	410FX-460 g	410FX-460 g	Subglandular	Seroma	19 mo	Left double capsule
2	BBA	410FX-360 g	CML-230	Subglandular	Shape	6 mo	Right double capsule
3	Mastopexy-augmentation	115–700 cc	115–700 cc	Subpectoral	Size	8 yr	Bilateral double capsules
4	Mastopexy-augmentation	115–213 cc	115–213 cc	Subglandular	Ptosis	9 mo	Left double capsule
5	BBA	115–354 cc	115–378 cc	Subglandular	Asymmetry	9 mo	Right double capsule
6	Mastopexy-augmentation	115–322 cc	115–322 cc	Subglandular	Left capsule	11 mo	Left double capsule
7	BBA	115–272 cc	115–222 cc	Subpectoral	Left capsule	15 mo	Left double capsule
8	BBA	115–322 cc	115–290 cc	Subpectoral	Distortion	7 mo	Left double capsule
9	BBA, previous BBR	115–290 cc	115–290 cc	Subglandular	Bottoming	16 mo	Bilateral double capsules
10	BBA, previous BBR	115–354 cc	115–354 cc	Subglandular	Bottoming	16 mo	Left double capsule
11	BBA	115–322 cc	115–354 cc	Subglandular	Left capsule	17 mo	Bilateral double capsules
12	Mastopexy-augmentation	115–378 cc	115–378 cc	Subglandular	Seroma	16 mo	Left double capsule
13	BBA	168–210 cc	168–210 cc	Subglandular	Left capsule	3.5 yr	Left double capsule
14	BBA	115–322 cc	115–322 cc	Subfascial	Seroma	2 yr	Bilateral double capsules

BBA, bilateral breast augmentation; BBR, bilateral breast reduction.

nomenon. This practice initially used smooth-walled Dow Corning silicone gel implants, a few Surgitek bilumen implants, and some polyurethane implants. Saline implants were used during the moratorium between 1992 and 2002. Because of special access conditions in Canada, the author used highly cohesive CML and CMH implants (CUI, Carpinteria, Calif.) from 2002 until 2006 when these implants became unavailable. After 2006, one-third of the patients were given Biocell textured responsive silicone gel implants (Allergan 115, 120; Allergan, Irvine, Calif.), one-third were given smooth-walled responsive gel implants (Allergan 15, 20), and one-third were given smooth-walled silicone gel cohesive I implants (Mentor, Santa Barbara, Calif.). These were relatively randomly assigned, but the subpectoral location was used for patients with relatively little padding. This review is clearly only a level 5 study.

No late seromas or double capsules were seen between 1983 and 2006 (23 years). A detailed review of complications has been performed on all patients with primary bilateral breast augmentation and primary bilateral mastopexy-augmentation since the start of the moratorium on silicone gel implants in 1992 until February of 2009—a full 17 years.

There were 209 patients with saline implants, 160 patients with CML and CMH Microcell textured surface implants, 105 patients with Biocell textured surface silicone gel breast implants, and 152 patients with smooth round silicone gel breast implants. Siltex textured implants were used in only four patients. Complications and revisions were reviewed to see if any patterns emerged.

Primary Bilateral Breast Augmentation Patients

The surgery was performed under general anesthesia in all but one patient. All patients were given perioperative antibiotics (usually cephalosporins) with 1 g of cefazolin given at induction of anesthesia and a week of oral cephalexin (500 mg four times per day) given postoperatively. Implants were soaked in Betadine solution before insertion, and the pocket was irrigated with a Marcaine/Betadine mixture. Skin preparation was done with Betadine or chlorhexidine solution. Gloves were not changed during surgery. Drains were not used.

Inframammary incisions were used in most patients. Of the 191 saline implant patients, 14 had periareolar incisions and 23 had transaxillary incisions. All the remainder had inframam-

mary incisions. Of the silicone gel implant patients, only nine patients had a periareolar incision. One patient (the only patient with an infection in the whole series) had a transaxillary incision. All the remaining patients had an inframammary incision.

Of the 191 saline implant patients, 152 had the implants placed in a subglandular location, and 39 patients had the implants placed in a subpectoral location. Of the 128 CML/CMH patients, 53 were subglandular, 53 were subfascial, and 22 were subpectoral. Of the 50 Biocell textured implants (only five other patients had Style 410 implants), 27 were subglandular, five were subfascial, and 13 were subpectoral. Of the smooth-walled silicone gel implants, 60 were subglandular, 11 were subfascial, and 27 were subpectoral.

Primary Bilateral Mastopexy-Augmentation Patients

The surgical preparation, antibiotics, and implant preparation were the same in the primary bilateral mastopexy-augmentation patients as they were with the primary bilateral augmentation patients. All patients had surgery under a full general anesthetic. Drains were not used.

Almost all patients had a vertical mastopexy using either a superior or medial pedicle for the nipple-areola complex. Eighteen patients had saline implants (14 subglandular, four subpectoral); 32 patients had CML/CMH implants (13

Table 3. Capsular Contracture Profile in Primary Breast Mastopexy-Augmentation*

Implant	Patients	Baker II (%)	Baker III (%)	Total (%)
Saline	18	2 (11)	4 (22)	6 (33)
CML/CMH	32	1 (3.1)	1 (3.1)	2 (6.3)
115/120	24	0 (0)	3 (12)	3 (12)
15/20	11	0 (0)	0 (0)	0 (0)
MPP	4	0 (0)	0 (0)	0 (0)

MPP, Moderate Profile Plus.
*Saline (1992 to 2004): smooth-walled McGhan and Mentor saline implants; CML/CMH (2002–2007): Microcell textured highly cohesive implants made by CUI (CML = low profile, CMH = high profile); 115/120 (2007 to 2009): Allergan Biocell textured responsive gel implants (115 = moderate profile, 120 = high profile); 15/20 (2007 to 2009): Allergan smooth-walled responsive gel implants (15 = moderate profile, 20 = high profile); MPP (Moderate Profile Plus; 2007 to 2009): Mentor smooth-walled cohesive I gel-filled implants.

Table 2. Capsular Contracture Profile in Primary Breast Augmentation*

Implant	Pocket	No. of Patients	Capsule: Baker II	Capsule: Baker III	Total Capsular Contracture
Saline					
Total		191	18 (9%)	29 (15%)	47 (25%)
	Subglandular	152	12 (8%)	26 (75%)	38 (25%)
	Subfascial	0	0	0	0
	Subpectoral	39	6 (15%)	3 (8%)	9 (23%)
CML/CMH					
Total		128	2 (2%)	1 (1%)	3 (2%)
	Subglandular	53	1 (2%)	0	1 (2%)
	Subfascial	53	1 (2%)	0	1 (2%)
	Subpectoral	22	0	1 (5%)	1 (5%)
115/120					
Total		45	2 (4%)	3 (7%)	5 (11%)
	Subglandular	27	1 (4%)	0	1 (4%)
	Subfascial	5	1 (20%)	0	1 (20%)
	Subpectoral	13	0	3 (23%)	3 (23%)
15/20					
Total		48	2 (4%)	2 (4%)	4 (8%)
	Subglandular	30	2 (7%)	2 (7%)	4 (13%)
	Subfascial	5	0	0	0
	Subpectoral	13	0	0	0
MPP					
Total		50	2 (4%)	5 (10%)	7 (14%)
	Subglandular	30	1 (3%)	4 (13%)	5 (17%)
	Subfascial	6	0	0	0
	Subpectoral	14	1 (7%)	1 (7%)	2 (14%)

MPP, Moderate Profile Plus.
*Saline (1992 to 2004): smooth-walled McGhan and Mentor saline implants; CML/CMH (2002 to 2007): Microcell textured highly cohesive implants made by CUI (CML = low profile, CMH = high profile); 115/120 (2007 to 2009): Allergan Biocell textured responsive gel implants (115 = moderate profile, 120 = high profile); 15/20 (2007 to 2009): Allergan smooth-walled responsive gel implants (15 = moderate profile, 20 = high profile); MPP (Moderate Profile Plus; 2007 to 2009): Mentor smooth-walled cohesive I gel-filled implants.

subglandular, 16 subfascial, three subpectoral); 24 patients had Biocell textured implants (12 subglandular, 10 subfascial, two subpectoral); and 15 patients had smooth-walled silicone gel implants (11 subglandular, two subfascial, two subpectoral).

RESULTS

Fourteen patients were found to have double capsules (Table 1). Double capsules were only seen with the Biocell textured surface implant. Three patients developed late seromas, with two

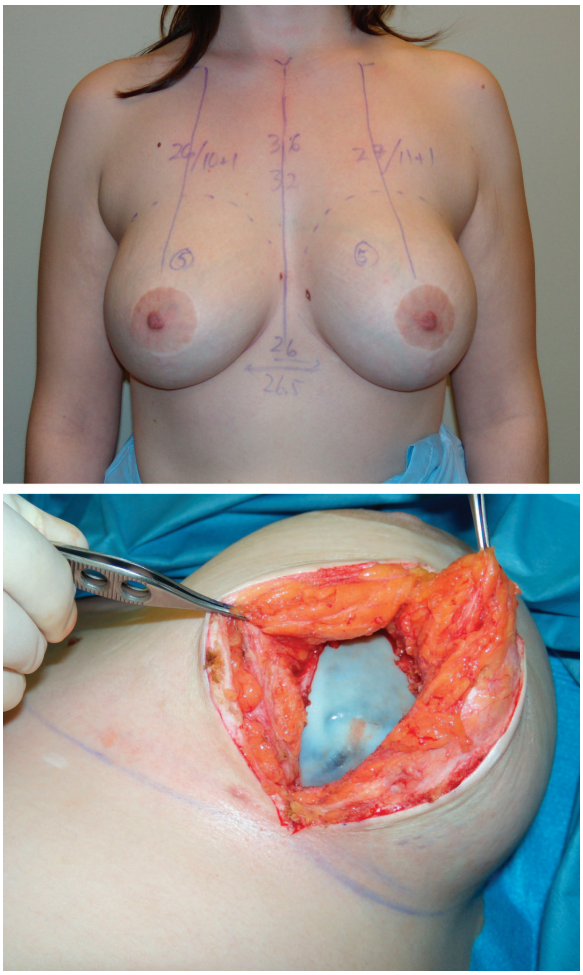

Fig. 1. Case 14. (*Above*) Frontal view 6 months after the patient developed swelling on her left breast. Although this was treated as a possible infection, it did not seem to respond to antibiotics and was probably a seroma that settled. There was no history of any trauma or aggressive sexual activity. The swelling settled, but she developed capsular contracture. Her original surgery was a mastopexy-augmentation with subfascial Biocell textured Style 115 implants (322 cc each) performed 2 years earlier. (*Below*) Appearance of the double capsule surrounding the implant after the normal capsule was opened.

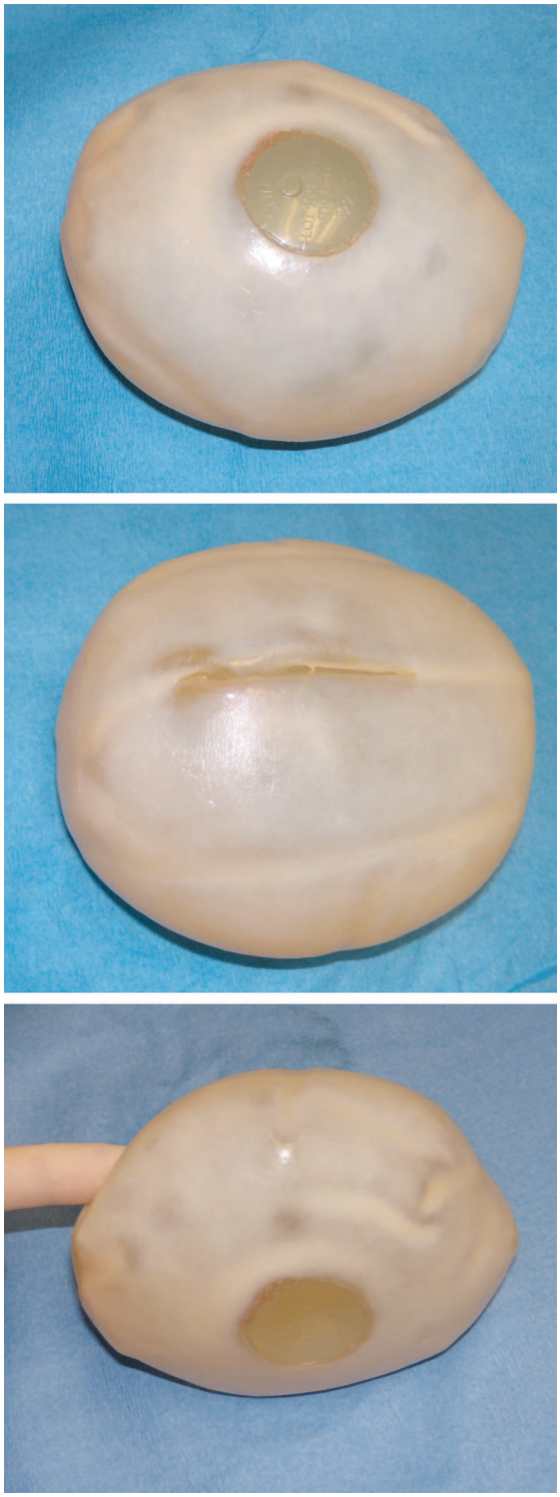

Fig. 2. Case 14. (*Above*) The implant was surrounded by a fairly thick double capsule except over the smooth patch on the back. (*Center*) The anterior surface of the implant is seen with the thick double capsule distorting the implant into an oblong shape and causing folding of the implant itself. (*Below*) A side view of the implant shows how the inner double capsule caused contracture.

patients requiring urgent drainage of an expanding seroma/hematoma. All of these patients had been symptom free for over a year following surgery. Seven patients were found to have double capsules as an incidental finding for procedures such as asymmetry and bottoming out, and five patients were found to have double capsules when surgery was performed for capsular contracture. Three patients had the implants in a subpectoral location, one was subfascial, and 10 were subglandular. One patient had saline implants.

Capsular contractures were evaluated by the author using the Baker classification.[9] No patient had a Baker IV capsule in this series. In the primary bilateral breast augmentation group (Table 2), the total capsular contracture rate was 25 percent in all saline implants (25 percent in the subglandular implants, 23 percent in the subpectoral implants). The total capsular contracture rate was 2 percent in the CML/CMH group, with no real difference among the subglandular, subfascial, and subpectoral pockets. The capsular contracture rate in the Biocell textured implants was 11 percent, with the implants in the subglandular pocket (4 percent) performing better than the implants in either the subfascial (20 percent) or the subpectoral location (23 percent). Capsular contracture rate was somewhat lower in the smooth-walled Allergan implants (8 percent) and slightly higher (14 percent) in the smooth-walled Mentor implants. The numbers are too small to reveal trends in the mastopexy-augmentation group (Table 3).

Of the other complications, only one patient had an infection (transaxillary CMH implant) in the primary bilateral breast augmentation group. Only one patient had a hematoma (smooth-walled gel subpectoral). Two saline (subglandular) implants leaked. Four patients had a revision because they wanted smaller implants, and seven patients had a revision because they wanted larger implants. Only one patient had the implants removed (saline, subglandular). Six patients developed bottoming out (all saline, five subglandular and one subpectoral).

Statistical analysis was not performed because the numbers are low and there are too many variables to make statistical analysis meaningful. On the other hand, some definite trends can be seen.

Representative cases are illustrated in Figures 1 through 9.

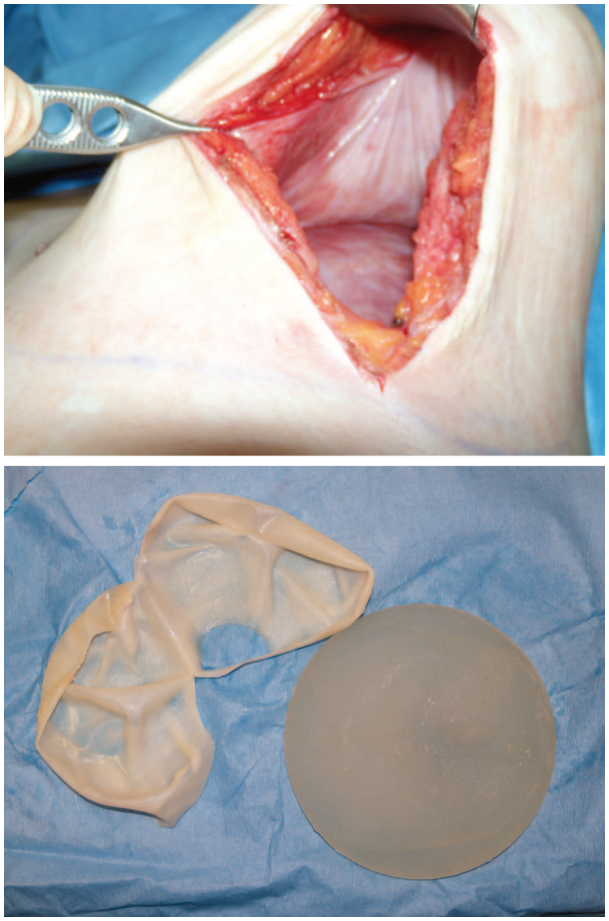

Fig. 3. Case 14. (*Above*) The outer (normal) capsule is seen in situ. It is thin and not contracted. (*Below*) The double capsule was adherent to the implant and needed to be peeled off the implant, much like separating Velcro.

DISCUSSION

The review of complications and revisions shows that the silicone gel implants in this study fared far better than saline implants for both capsular contracture rates and revision rates. Although this could be attributed to timing (longer follow-up period for the saline implants that were used from 1992 to 2002), it was interesting that the Microcell textured CMH and CML implants (used from 2002 to 2006) performed far better than either the smooth or textured silicone gel implants (used from 2006 to 2009).

The moratorium was instituted in Canada at the same time as the United States (1992), but silicone gel implants were allowed under special access in Canada starting in 2002. The CML and CMH implants were highly cohesive round implants with a Microcell textured surface. The texturing is more aggressive than the Siltex textured surface used by Mentor but less aggressive than the Biocell textured surface used by Allergan (Style 110, 115, and 120 and the shaped

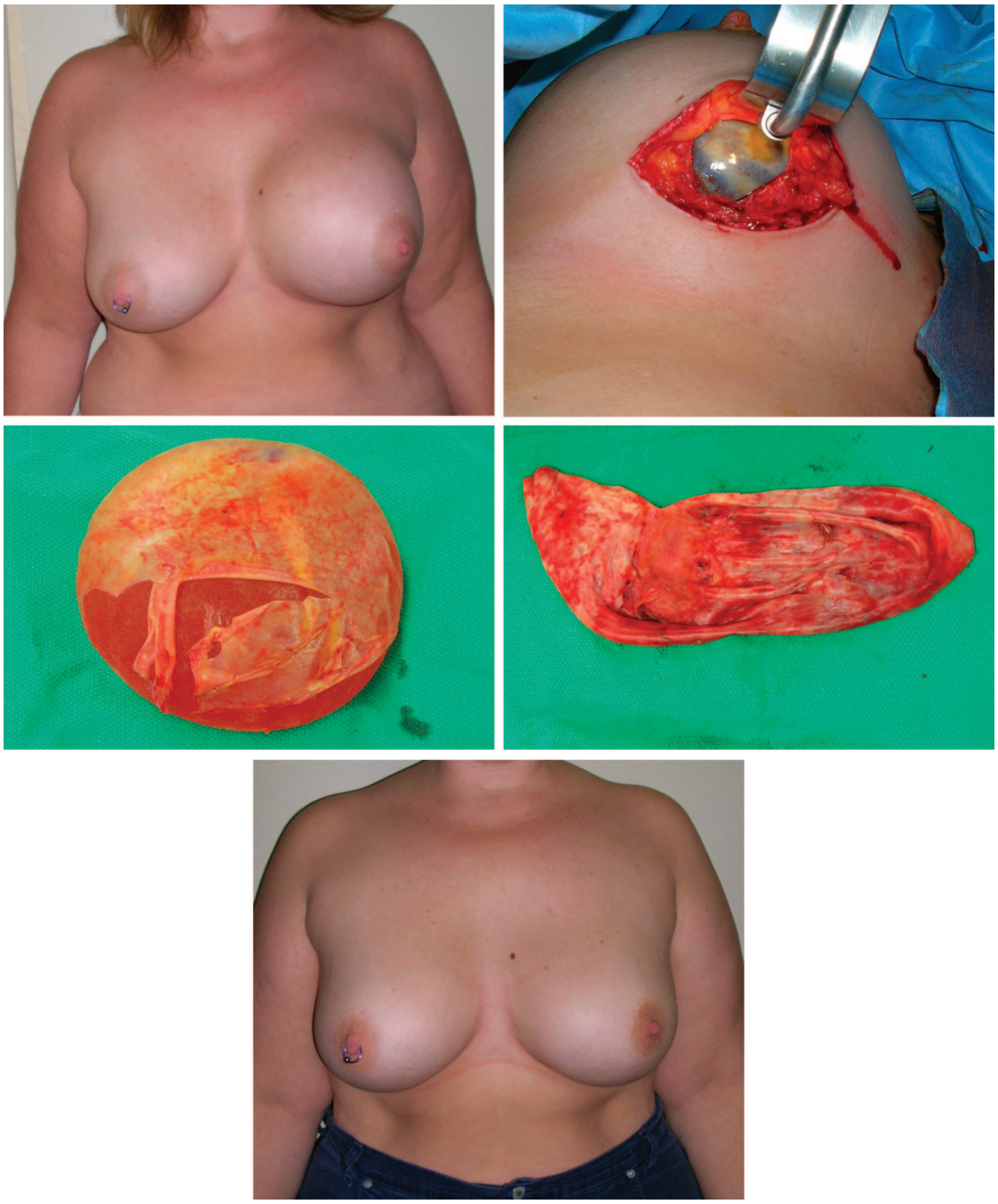

Fig. 4. Case 1. (*Above, left*) The patient is shown 2 months after onset of left breast swelling. Her original surgery was 19 months earlier with bilateral shaped Style 410 Biocell textured implants (460 g each) placed in the subglandular position. (*Above, right*) Upon opening the outer (normal) capsule, a large amount of serosanguinous fluid was removed. There was no evidence of infection, but there was a double capsule around the implant. (*Center, left*) The double capsule can be seen around the blood-stained implant. (*Center, right*) The double capsule was peeled off the implant. (*Below*) The patient is shown 3 months after removal of the seroma and replacement of the original implants. She subsequently developed a right capsular contracture.

Style 410 implants). Very few Siltex textured implants were used in this series because of an unfavorable experience with the Siltex saline implants (more rippling) and because of the sticky seromas that were often encountered in secondary surgeries. The author has not seen capsular adherence with either the Siltex or the Microcell textured implants.

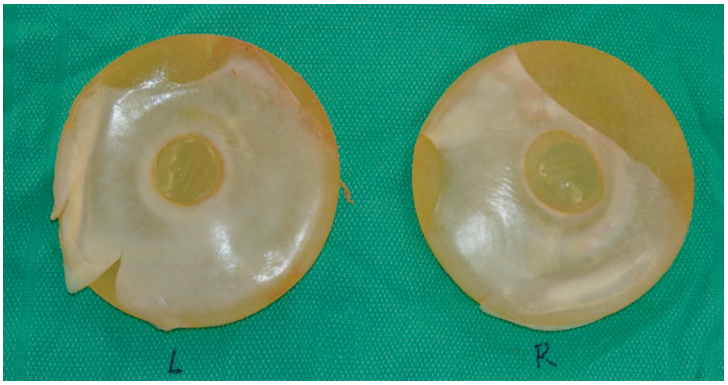

Fig. 5. Case 11. This patient had bilateral breast augmentation using Biocell textured Style 115 implants placed in the subglandular position. She developed a capsular contracture on the left breast, and both implants were replaced 17 months after the original surgery. She had developed double capsules around both implants. The capsule extended around the side of the implant, causing some folding in the implant itself.

The author saw some double capsule formation on some of the Biocell textured surface implants when revisions were being performed for various reasons (size change, capsular contracture) but did not take note until a patient with Style 410 implants presented with an expanding seroma 19 months after her original surgery (April of 2005). The left breast kept enlarging, and it was assumed that the problem might have been some form of infection, but extensive questioning did not reveal any potential infectious etiology. When the patient was taken back to surgery on an urgent basis (November of 2006), it was clear that there was a large amount of serosanguinous fluid and a double capsule (Fig. 4, case 1 in Table 1). The double capsule that was adherent to the implant was removed and the implant put back in place because there did not appear to be an infection (no new implant was available because the special access rules did not allow any consignment). The outer capsule was thin and not contracted, and it was therefore left undisturbed. Pathological examination of the inner capsule did not reveal any abnormalities, and both the usual anaerobic and aerobic cultures (along with specific requests for mycobacterial cultures) were all negative. The patient has now been doing well for 3.5 years after the implant was replaced (although she has now developed a mild Baker II capsular contracture on the opposite breast and is not sure that she wants another operation).

In another patient (Figs. 1 through 3, case 14 in Table 1), one breast enlarged and was treated with antibiotics; however, there was no evidence of an infection, and it did not respond as if it were an infection. This patient had had a mastopexy-augmentation one and a half years previously with Biocell textured implants placed in the subfascial location. The swelling eventually settled, but she developed a capsular contracture on that side. Six months later (2 years after the original surgery), she had the capsule released. A complete double capsule had formed around the implant, and the implant was firm and the envelope compressed into folds. In retrospect, this patient probably did not have an infection (her implants were replaced with smooth-walled gel implants, and she has since done well) but had a late seroma that settled on its own. Unfortunately, a double capsule had formed, causing capsular contracture. The other side had a partial double capsule and the question is hard to answer—was this an early double capsule that would progress to a full contracture, or was it an incidental finding (Figs. 5 through 9)?

The theory that this new phenomenon of late seromas and double capsules is infectious is seductive. Recently, a double capsule was sent to pathology from the author's practice, and scanning electron microscopy did show a biofilm of what appeared to be a *Staphylococcus epidermidis*. The fact that biofilms have been noted on other implants without double capsule formation[8] makes one wonder why the late seromas and double capsules have all—in this series—been confined to the Biocell textured implants.

The author purposely used several different varieties of implants to evaluate capsular contracture rates (by a single observer with minimal other variability) and therefore carefully used the same operative technique, preparatory solutions, and

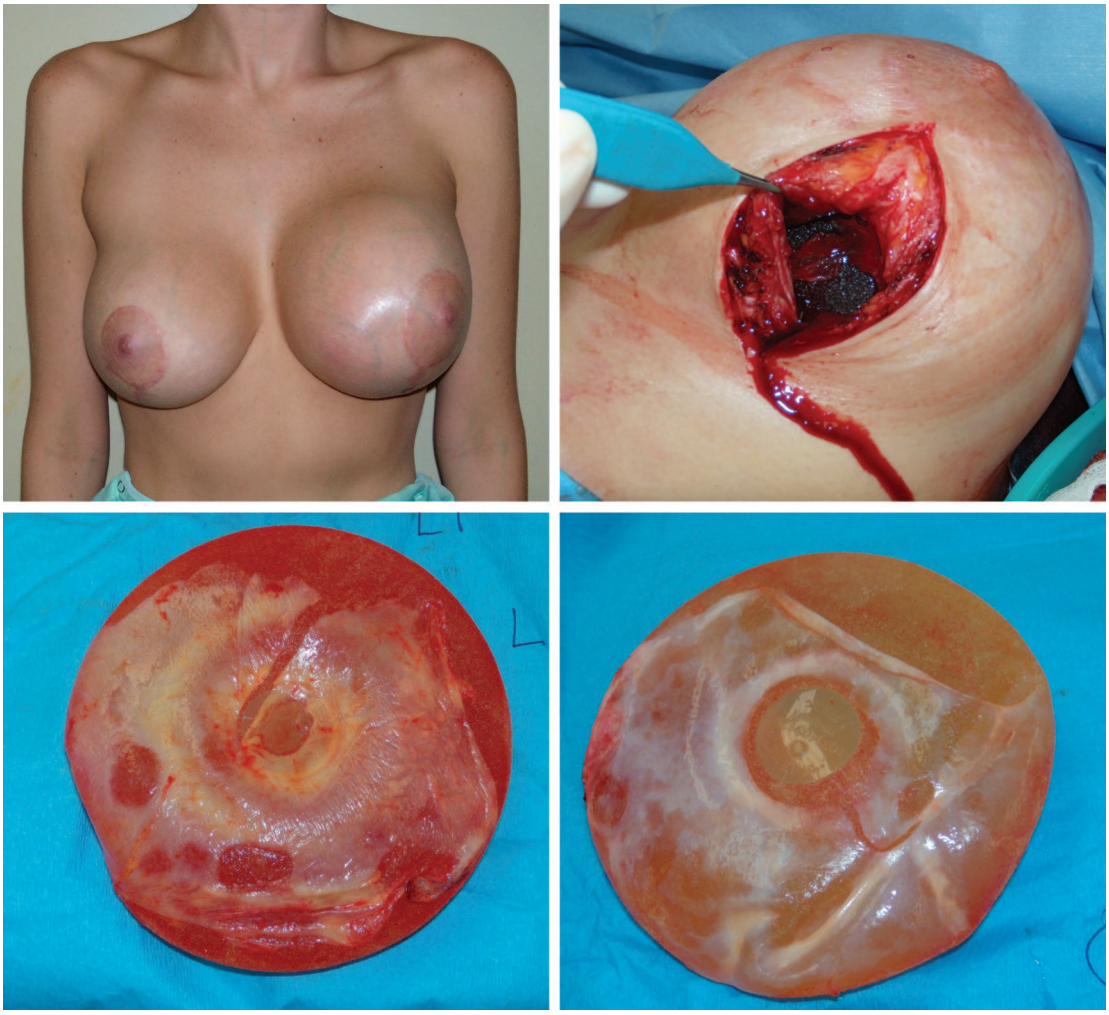

Fig. 6. Case 12. (*Above, left*) Frontal view of the swelling that developed 16 months after a mastopexy-augmentation. The patient's original surgery was performed with Biocell textured Style 115 implants (378 cc each) placed in the subglandular position. The only history of trauma was her toddler inadvertently kicking her in the chest while they were in bed. (*Above, right*) Serosanguinous fluid was encountered upon opening the outer (normal) capsule. The capsule was adherent to the implant but was also attached superiorly and medially to the outer capsule. (*Below, left*) The double capsule can be seen around the left implant. (*Below, right*) Both implants were removed and replaced with smooth-walled silicone gel implants, and it became evident that both implants had developed double capsules.

handling of the implants. The patient population and the practice parameters have not changed. The author has used several different varieties of implants: smooth saline, Microcell textured CML and CMH cohesive gel implants, smooth responsive gel implants, Biocell textured responsive gel implants (and a few Biocell textured cohesive shaped 410 implants), and smooth memory gel implants: The author has used all three pocket locations (subglandular, subfascial, and subpectoral). Most of the incisions in the primary bilateral augmentation patients were inframammary, and most of the incisions in the primary bilateral mastopexy-augmentation patients were vertical with either a superior or medial pedicle.

The only real differences noted among all the implants in this series were the low capsular contracture rate in the CML and CMH implants and the high capsular contracture rate in the saline implants. The author did not find that the textured implants had a lower capsular contracture rate—in fact, it is believed to be higher in the Biocell textured group because of the double capsules.

It is unlikely that the infection or biofilm theory would be the cause of double capsules and late

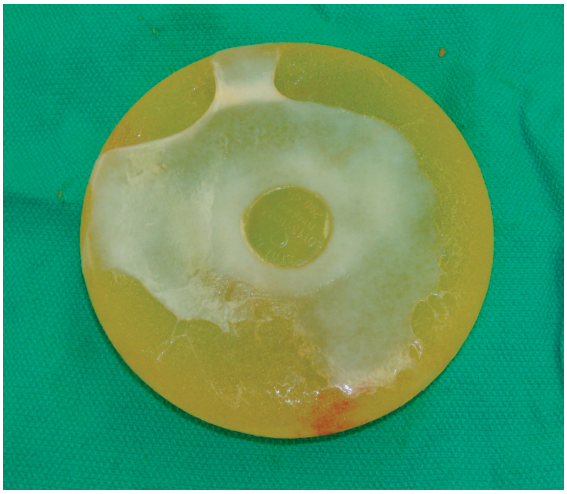

Fig. 7. Case 9. This patient underwent subglandular breast augmentation after a previous inverted-T breast reduction. She lost weight (and upper pole fullness). This loss exaggerated her already high nipples. Unfortunately, she developed bottoming out, which only exaggerated the problem. She underwent a revision 16 months after the augmentation, and it became evident that she had partial double capsules on both sides. The implants were Biocell textured Style 115 implants (290 cc each). The implant was not completely surrounded by a double capsule, but it can be seen extending around the edge of the implant and causing some folding in the implant itself.

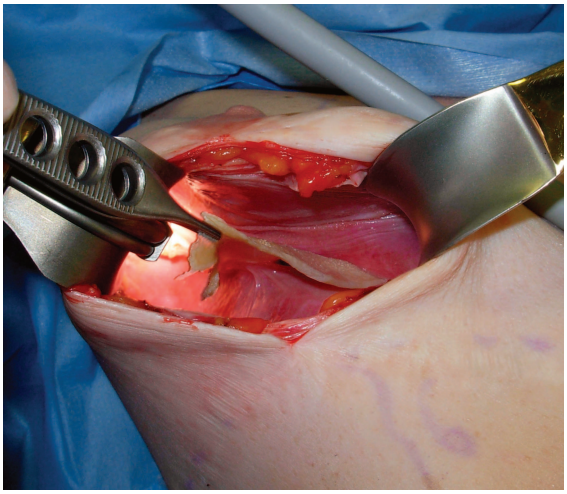

Fig. 8. Case 3. This patient had multiple procedures elsewhere with both silicone gel and saline implants. She kept getting larger and larger implants and finally decided to have them completely removed (along with a mastopexy). The implants were Biocell textured Style 115 implants placed in the subpectoral position. They were 700 cc each. The implants were separated from the double capsule during removal because the double capsule was partially adherent to the outer normal capsule. It is clear that the double capsule has a pebbled surface, and this was separated from the implant much like separating Velcro.

seromas if the problem is confined to one type of implant. Perhaps the bacteria can form a biofilm more easily around the aggressive texturing, but it is interesting that the problem did not occur in a fairly large number of Microcell textured implants. Perhaps the biofilm allows the adherence to separate more easily. Biofilms form around smooth implants as well. It is difficult to understand how a biofilm would cause a problem several years after the original surgery. Why would the problem not have occurred in the early years of breast augmentation, and why has it appeared as a relatively new phenomenon?

The best explanation at this time seems to be a mechanical one—with or without the biofilm having an additional role. The capsule sometimes (but not always) adheres to the Biocell textured implants. Capsules rarely (if ever) adhere to any of the other implants. Capsules always adhered to the polyurethane implants, but late seromas and double capsules have not been reported and were not seen with the polyurethane implants used in the late 1980s in the author's practice. The capsules in the Biocell textured implants adhere much like Velcro and can be relatively easily separated with finger dissection. They can probably be also relatively easily separated with minor trauma or from an aggressive partner. The Velcro can be "de-Velcroed." Once forced apart, the capsule has a rough surface, and the implant has a rough surface. It is surmised that the two rough surfaces create shear forces that are irritating and create a seroma.

Theoretically, double capsules could form without adherence but with seroma formation. Seroma fluid contains cells that can "seed" onto another surface. Perhaps the Microcell and Siltex textured surfaces are not conducive to seeding, and for that reason, we have not seen double capsules with those implants. On the other hand, we have seen seromas with both these implants but only very rarely in the smooth implants. These lightly textured implant surfaces may cause enough shearing to create a small seroma, but the texturing is not aggressive enough for double capsule formation. The author has seen partial double capsule formation and complete double capsule formation where the implant is fully encased in an inner contracted capsule.

The author believes that the problem is a mechanical one. The mildly textured surfaces can cause some irritation and a mild seroma, but the more aggressive textured surfaces can actually

Fig. 9. Case 8. This patient developed some bruising and swelling on her left breast after her primary subpectoral breast augmentation. It appeared that she may have had a small hematoma that did not need treatment. Her implants were Biocell textured Style 115 (right, 322 cc; left, 290 cc), and she underwent revision 7 months later because both implants were riding too high. The left implant is shown with some "early" evidence of double capsule formation. It is unknown whether this double capsule progresses to encapsulate the whole implant or whether it stops at some point.

cause some adherence of the capsule to the implant. This capsule can be forcefully separated from the implant, causing an expanding seroma and/or a double capsule. The problem does not happen in the polyurethane implants because there was true tissue ingrowth that could not be separated from the implant. The problem does not happen in the less aggressively textured implants because there is no true adherence to allow subsequent separation.

CONCLUSIONS

A review of the author's breast implant practice (primary bilateral breast augmentation and primary bilateral mastopexy-augmentation) has revealed a new complication of late seromas and double capsules. This complication was not seen in the early years of the author's practice starting in 1983, and it was only noted as a complication in 2006. The phenomenon of late seromas and double capsules has only been seen by the author in the Biocell textured surface implants—both the round and shaped implants and in all three (subglandular, subfascial, and subpectoral) pocket locations.

The infectious or biofilm etiology does not explain why the problem has only been seen by the author in these aggressively textured implants. A mechanical theory makes more sense in which shear forces cause irritation, seroma formation, and seeding of the implant surface. When the adherence of the capsule to the implant is traumatically separated, an expanding seroma can occur, which may not settle and which may require urgent surgery.

The occurrence of a double capsule is not likely an incidental finding. Many surgeons believe that there are fewer capsular contractures with textured implants,[10–15] but this review shows that this is not the case with the Biocell textured implants in the author's practice. There was definitely a low complication rate with the Microcell textured highly cohesive implant, and it might be the cohesiveness of the gel that made this implant perform well. Further studies are clearly needed, but this review should serve as a caution and draw attention to late seromas and double capsule formation.

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