Late Seromas after Breast Implants: Theory and Practice

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Background: Late seromas surrounding breast implants are becoming an increasingly important issue in breast surgery. The authors report their experience with late seromas and describe their previous management options.
Methods: A multicenter retrospective review of patients who developed late seromas (clinically presenting seromas without evidence of overt or documented infection more than 1 year after implant operation) was performed. Management, surgical technique, outcomes, complications, culture findings, and cytology results were recorded.
Results: Between 2005 and 2010, 28 late seromas were identified in 25 patients. The average interval from the patient's last surgery to seroma onset was 4.7 years; 27 of 28 breasts (96 percent) had a Biocell textured device in place at the time of seroma development. The late seromas in the series were managed as follows: 15 (53.6 percent) by complete capsulectomy, seroma drainage, and new implant placement; three (10.7 percent) by seroma drainage and new implant placement but without capsulectomy; two (7.1 percent) by complete capsulectomy and seroma drainage but without implant replacement; five (17.9 percent) by only ultrasound-guided seroma drainage without the need for surgical intervention; and three (10.7 percent) by antibiotic therapy alone. All cultures and cytology studies were negative for malignancy or infection; 27 of 28 seromas (96 percent) were treated successfully by one of the described approaches.
Conclusions: Biocell textured implants were more likely to be associated with late seromas than were smooth shell implants. The overwhelming majority of late seromas appear to be idiopathic, without clear evidence of infection or malignancy. A graduated approach, including several different management strategies, was used to successfully manage these patients. (*Plast. Reconstr. Surg.* 130: 423, 2012.)
CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.

The occurrence of late seromas surrounding breast implants is arousing increased interest in both cosmetic and reconstructive breast surgery. Late seromas are often theorized to be related to some sort of trauma or low grade, subclinical infections (e.g., mycobacterium or biofilm).[1–3] The interest surrounding late periprosthetic breast seromas is now even greater given the recent reports of a possible rare connection between breast implants and anaplastic large cell lymphoma, as these tumors often present as late seromas.[4,5] This study is not a theoretical algorithm but rather is a look back at a large experience with late seromas and describes those findings. We define a late seroma as a clinically symptomatic seroma that develops at least 12 months after the most recent breast implant surgery. These cases all presented with clinically evident breast swelling. We do not specify the volume amount but rather require that the presentation of the patient be clinically evident swelling. We believe, in fact, that in many other cases fluid might be an incidental radiographic or ultrasound finding

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around many implants, but that would not fit our criteria.

Seroma following breast implant surgery is a rare occurrence, particularly in the late postoperative period, arbitrarily defined here as greater than 1 year. Descriptions of late seromas in the literature have been mainly individual or small case reports, generally followed by speculation as to etiology. The first description of seroma following breast implant surgery appears to have been in 1991,[6] and for the following two decades, only a few surgeons have added their isolated series.[7–14] Several themes have been prevalent. First, late seromas are remarkably rare. In those reports, the incidence of late seromas among their own primary augmentations was 1 percent or less.[11,14,15] Second, the vast majority of late seromas reported in these earlier reports were in patients who previously had Biocell (Allergan, Irvine, Calif.) textured implants, leading several authors to speculate that the Biocell textured surface might play a role in the pathophysiology of late seroma formation.[11,15] Third, pocket placement (subpectoral versus subglandular) and device content (saline versus silicone) did not appear to influence the incidence of late seromas. Fourth, despite nearly uniform submission of seroma samples for microbiologic and cytologic examination, the vast majority of seromas were negative for both sets of studies. Finally, although late seromas have been reported to be managed variously by surgery (seroma evacuation and implant exchange), ultrasound-guided aspiration, and conservatively (often with oral antibiotics alone), regardless of treatment the majority of seromas have resolved and recurrence was uncommon.

To further study the characteristics of late seromas, we retrospectively evaluated all clinically evident late seromas that presented to the practices of three established plastic surgeons with different clinical management styles. This review involved patients seen before the recent increased interest in biofilm and before the increased awareness of anaplastic large cell lymphoma and other possible lymphoproliferative disorders in women with breast implants. At the time these patients were managed, these surgeons had no preconceptions regarding the etiology of late seroma formation. These three practices functioned independently and managed these late seromas empirically without referring to any specific theoretical algorithm. With the study period occurring before the recent heightened concern over lymphoproliferative disorders, these patients were treated with a graduated practical approach with the underlying assumption that late seromas could be successfully treated with more than one approach, including antibiotics, percutaneous drainage, or more aggressively with surgery.

We were interested in determining whether the prevailing sentiment linking such seromas with textured implants was correct and how different seroma management techniques fared. Our study was not designed to specifically estimate the incidence or frequency of late seroma formation, as we studied patients who presented to one of the three clinical practices with a seroma, regardless of where or when their previous surgery was performed.

PATIENTS AND METHODS

An institutional review board–approved, multicenter retrospective review was carried out on patients who developed late seromas. The review took place on patients seen and treated over a 5-year period between December of 2005 through December of 2010 in the practices of Scott Spear, M.D., at Georgetown University Hospital, Washington, D.C.; Caroline Glicksman, M.D., in Sea Girt, N.J.; and Mitchell Brown, M.D., in Toronto, Canada (Figs. 1 through 4). All patients diagnosed with a late seroma were included in this study and could include patients who had their implant surgery initially performed by one of these three surgeons, as well as patients who were initially operated on elsewhere who presented later to one of these three surgeons with a seroma. Data collected included patient demographics, indications for initial surgery, subsequent revision surgeries, and time of seroma onset. Preoperative and postoperative photographs, management technique outcomes, complications, cultures, and cytology results were recorded. Biofilm studies, including polymerase chain reaction–based laboratory testing, were not done due to the timing of this study and the availability of those techniques. A late seroma was defined as a seroma that first presented clinically as symptomatic swelling of the breast 1 year or longer after the most recent breast surgery. Incidental seromas found during surgery or reported on imaging would not qualify unless they were first clinically symptomatic and the radiologic study was performed to make the diagnosis. Statistical analysis was performed with the chi-square test to evaluate for the probability of difference of sets of outcomes.

RESULTS

Over a 5-year period between December of 2005 and December of 2010, 28 late seromas were

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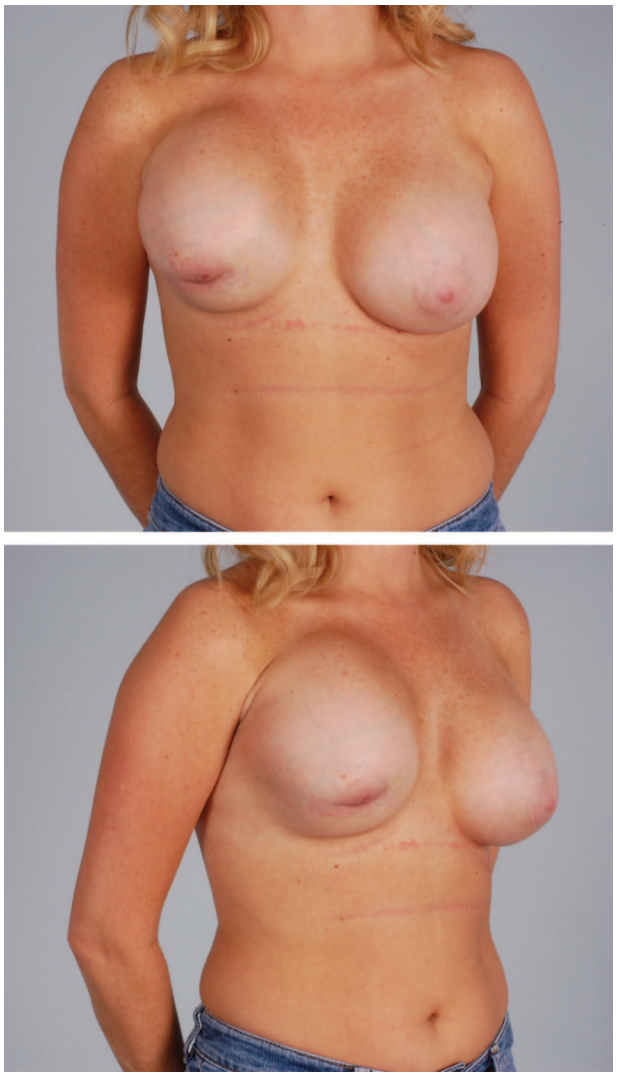

Fig. 1. A 38-year-old woman underwent bilateral subpectoral breast augmentation. She developed several right-sided capsular contractures, each treated with capsulectomy and implant exchange to Style 68 high-profile smooth saline implants (Allergan, Inc., Irvine, Calif.); 2.3 years (845 days) after the most recent capsulectomy, she developed a right-sided seroma and bilateral capsular contractures.

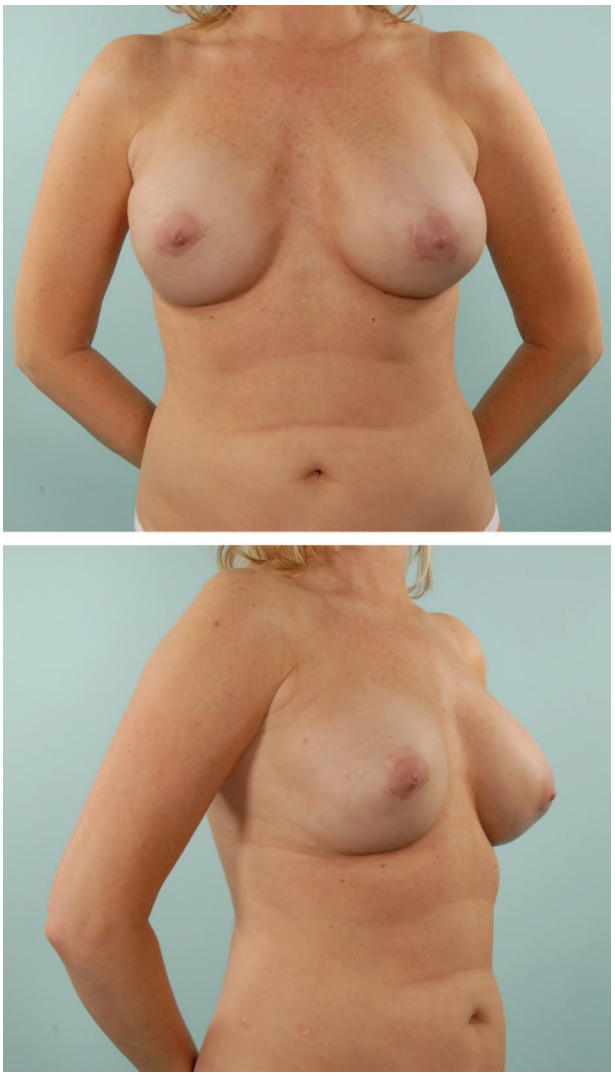

Fig. 2. The patient shown in Figure 1 subsequently underwent bilateral capsulectomies, seroma drainage, and implant replacement to Style 120 textured implants (Allergan, Inc., Irvine, Calif.). Results of intraoperative cultures and cytologic analyses were negative.

identified in 25 patients (Table 1). Three patients developed bilateral seromas simultaneously. The average age across all patients was 44.9 years (range, 26 to 68 years), and average body mass index was 24 kg/m^2 (range, 20 to 29 kg/m^2). In 19 breasts (68 percent), the preceding surgery was cosmetic breast augmentation, and in the remaining nine breasts (32 percent), it was breast reconstruction. Three of the nine reconstructed breasts (33 percent) were previously irradiated, and one (4 percent) patient was a former smoker's. The average time from the patient's last implant surgery to seroma onset was 4.7 years (Fig. 5). At the time of seroma development, 27 breasts (96 percent) had Biocell textured devices in place, and one breast (4 percent) had a smooth implant in place ($p < 0.0001$). Although this review included all patients seen and treated over the 5-year period in the three practices, all of the seromas reported here developed around implants placed by one of the three surgeons.

Some of the seromas in this series had associated findings that were conjectured possible etiologies. Five breasts (18 percent) in four patients presented with findings of possible infection, including redness, swelling, and/or fever. Of these five breasts, two

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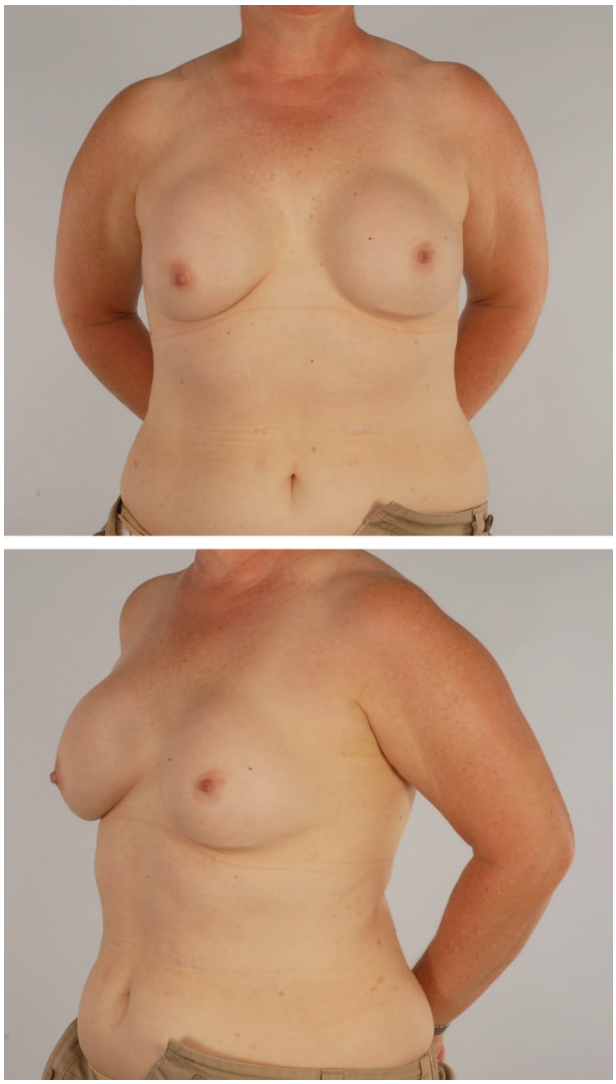

Fig. 3. A 60-year-old woman underwent bilateral subpectoral breast augmentation. She developed bilateral capsular contractures, each treated with capsulectomy and implant replacement to Style 120 textured devices (Allergan, Inc., Irvine, Calif.); 1.5 years (545 days) after the capsulotomy procedure, she developed a left-sided seroma.

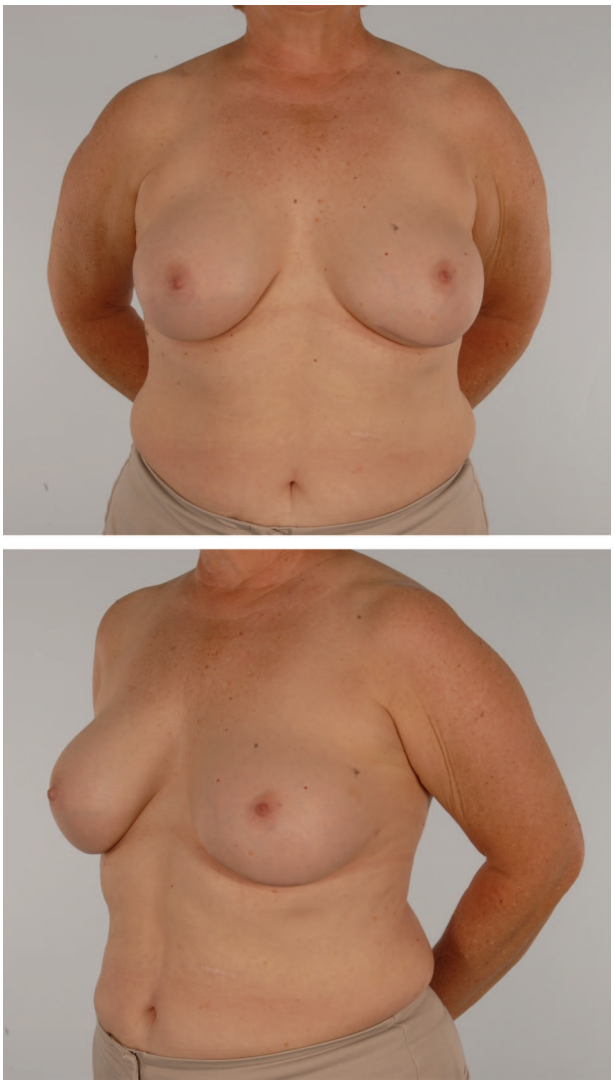

Fig. 4. The patient shown in Figure 3 subsequently underwent left seroma drainage, capsulectomy, and implant replacement with Style 20 smooth round implants (Allergan, Inc., Irvine, Calif.). Results of intraoperative cultures and cytology studies were negative.

resolved with ultrasound-guided drainage of the seroma and antibiotics. Two breasts (in the same patient) were successfully treated with capsulectomy, seroma drainage in the operating room, and implant replacement. One patient whose breast presented with erythema and swelling consistently refused recommended surgical intervention; she was treated on three occasions with oral antibiotics that each time resolved her symptoms; on her last visit, she had no symptom recurrence 4 months after the last episode of swelling and erythema. None of these patients had purulent fluid found on drainage (either ultrasound-guided or open surgical), and all of the cultures were sterile, suggesting either no infection, subclinical infection, or seroma fluid sterilized by antibiotic therapy.

Three of the seromas (11 percent) were associated with precedent overt trauma that on clinical examination did not appear to be hematomas. Two of these three seromas were managed with ultrasound-guided drainage that successfully resolved the seromas. The third seroma was treated with capsulectomy, open drainage, and implant exchange, which also successfully treated the seroma. Separately, two of the breasts (7 percent) had dark fluid that resembled a resolving hematoma. This finding was observed during capsulectomy and implant ex-

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Table 1. Patient Data

Patient No.	Surgeon*	Age (yr)	Previous Operations	Previous Implants	Etiology	Device at Time of Seroma	Time to Seroma (days)	Ultrasound-Guided Drainage?
1	S.L.S.	38	Cosmetic augmentation, revised twice	Mentor HP350	Idiopathic	Allergan Style 68HP (smooth, saline), subpectoral	845	Not attempted
2	S.L.S.	51	Cosmetic augmentation, revised once	300–340 double lumen	Idiopathic	Allergan Style 110 (textured, gel), subpectoral	2733	Not attempted
3	S.L.S.	51	Cosmetic augmentation, revised once	300–340 double lumen	Idiopathic	Allergan Style 110 (textured, gel), subpectoral	2733	Not attempted
4	S.L.S.	56	Staged breast reconstruction with expander then implant, no radiation	McGhan 131	Possible subclinical hematoma	Allergan Style 153 (textured, gel), subpectoral	4342	Not attempted
5	S.L.S.	60	Cosmetic augmentation, revised once	Silicone gel, subglandular	Capsular bleeding/ possible subclinical hematoma	Allergan Style 120 (textured, gel), subglandular	545	Collection deemed too small to drain percutaneously (based on MRI)
6	S.L.S.	68	Staged breast reconstruction with expander then implant + radiation	Tissue expander (McGhan)	Implant rupture	Allergan Style 153 (textured, gel), subpectoral	6689	Not attempted
7	S.L.S.	52	Staged breast reconstruction with expander and AlloDerm then implant; no radiation (expander stage complicated by early seroma)	Tissue expander (133MV) 15–575	Idiopathic	Allergan Style 410MF (textured, gel), subpectoral	1102	Ultrasound-guided aspiration performed; seroma recurred three weeks later and therefore patient was taken to surgery
8	S.L.S.	48	Staged breast reconstruction with expander and AlloDerm, then implant; no radiation; previous revision	Tissue expander (133) 363LF	Undocumented suspected infection	Allergan Style 410MF (textured, gel), subpectoral	509	Not attempted
9	S.L.S.	48	Staged breast reconstruction with expander and AlloDerm, then implant; no radiation; previous revision	Tissue expander (133) 363LF	Undocumented suspected infection	Allergan Style 410MF (textured, gel), subpectoral	649	Not attempted
10	S.L.S.	63	Staged breast reconstruction with expander then implant; no radiation	Tissue expander (133MV)	Implant rupture	Allergan Style 410MF (textured, gel), subpectoral	2716	Not attempted
11	S.L.S.	63	Staged breast reconstruction with expander then implant; no radiation	Tissue expander (133MV)	Implant rupture	Allergan Style 410MF (textured, gel), submuscular	2716	Not attempted
12	C.G.	44	Previous cosmetic subglandular augmentation, followed by staged breast reconstruction with expander (complicated by delayed wound healing) then implant, no radiation	Saline subglandular implant; tissue expander (133MV)	Idiopathic	Allergan Style 410FX (textured, gel), subpectoral	1295	Ultrasound-guided drainage performed and was successful

(*Continued*)

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Table 1. (*Continued*)

Patient No.	Surgeon*	Age (yr)	Previous Operations	Previous Implants	Etiology	Device at Time of Seroma	Time to Seroma (days)	Ultrasound-Guided Drainage?
13	C.G.	60	Staged breast reconstruction with expander then implant, revised twice, no radiation	Tissue expander (133); Mentor Siltex 153–450	Undocumented suspected infection	Allergan Style 410 FX (textured, gel), subpectoral	1034	Ultrasound-guided drainage performed and was successful
14	C.G.	44	Cosmetic augmentation, revised once	Mentor Siltex 354–2712	Trauma	Allergan Style 153 (textured, gel), subpectoral	1778	Not performed
15	C.G.	34	Cosmetic augmentation	None	Trauma	Allergan Style 115 (textured, gel) subpectoral	468	Ultrasound-guided drainage performed and was successful
16	C.G.	48	Cosmetic augmentation, revised once	Smooth round saline (submuscular)	Undocumented suspected infection	Allergan Style 153 (textured, gel) subpectoral	2526	Ultrasound-guided drainage performed and was successful
17	C.G.	28	Cosmetic augmentation	None	Undocumented suspected infection	Allergan Style 110 (textured, gel) subpectoral	1031	Not attempted
18	C.G.	39	Cosmetic augmentation	None	Idiopathic	Allergan Style 110 (textured, gel) subpectoral	2651	Collection deemed too small to drain percutaneously (based on MRI and ultrasound)
19	C.G.	36	Cosmetic augmentation	None	Exercise-induced trauma	Allergan Style 153 (textured, gel) subpectoral	1041	Ultrasound-guided drainage performed and was successful
20	M.H.B.	38	Cosmetic augmentation mastopexy	None	Idiopathic	Allergan Style 410MF (textured, gel) subglandular	865	Ultrasound-guided aspiration performed; seroma recurred and therefore patient was taken to surgery
21	M.H.B.	45	Cosmetic augmentation	None	Idiopathic	Allergan Style 115 (textured, gel) subglandular	635	Not attempted
22	M.H.B.	42	Cosmetic augmentation	None	Idiopathic	Allergan Style 410MF (textured, gel) 410 MF subpectoral	840	Not attempted
23	M.H.B.	32	Cosmetic augmentation	None	Idiopathic	Allergan Style 115 (textured, gel) subglandular	970	Ultrasound-guided aspiration performed; seroma recurred and therefore patient was taken to surgery
24	M.H.B.	39	Cosmetic augmentation	None	Idiopathic	Allergan Style 410FF (textured, gel) subpectoral	955	Ultrasound-guided drainage performed and was successful

(*Continued*)

Table 1. (*Continued*)

Patient No.	Surgeon*	Age (yr)	Previous Operations	Previous Implants	Etiology	Device at Time of Seroma	Time to Seroma (days)	Ultrasound-Guided Drainage?
25	M.H.B.	26	Cosmetic augmentation	None	Idiopathic	Allergan Style 410MM (textured, gel) subpectoral	1370	Not attempted
26	M.H.B.	31	Cosmetic augmentation	None	Idiopathic	Allergan Style 410FX (textured, gel) subpectoral	1395	Ultrasound-guided drainage performed and was successful
27	M.H.B.	36	Cosmetic augmentation	None	Idiopathic	Allergan Style 410MM (textured, gel) subpectoral	2720	Ultrasound-guided aspiration performed; seroma recurred and therefore patient was taken to surgery
28	M.H.B.	36	Cosmetic augmentation	None	Idiopathic	Allergan Style 410ML (textured, gel) subpectoral	765	Not attempted

MRI, magnetic resonance imaging.
*The surgeons were Scott L. Spear, M.D. (S.L.S.); Caroline Glicksman, M.D. (C.G.); and Mitchell H. Brown, M.D. (M.H.B.).

Fig. 5. Scatter graph of onset of late seroma formation. Note the two clusters of onset, the first between 600 and 1100 days, and the second between 2500 and 2700 days.

change, with successful resolution in both. Finally, four breasts (14 percent) were found to have ruptured implants or gel bleeding associated with the seromas; all four breasts were successfully managed with capsulectomy, open surgical drainage of the seromas, and implant exchange.

The late seromas in our series were managed in a variety of different ways (Table 2). Twenty of the 28 seromas (71 percent) ultimately underwent open surgical treatment, whereas eight (29 percent) did not. Fifteen of the 28 patients (54 percent) underwent a complete capsulectomy with simultaneous drainage of their seroma and placement of a new implant. Nine textured devices and six smooth devices were used to replace these 15 explanted implants. Three patients (11 percent) had their implants replaced with simultaneous drainage of their seroma, but without capsulectomy. Two of these new devices placed were smooth, and one was a Biocell textured implant. Two breasts (7 percent) underwent complete capsulectomy with seroma drainage but did not have implant replacement. Thus, 15 seromas (54 percent) were treated with capsulectomy with or without replacement, and 16 seromas (57 percent) underwent implant replacement with or without capsulectomy.

Four of the 20 patients ultimately treated surgically initially had percutaneous seroma drainage procedures without resolution of the seroma either because of recurrence or intentionally incomplete drainage. This led to open surgical drainage of the seroma, capsulectomy, and implant replacement. The average follow-up length was 401 days for those five seromas successfully treated only with ultrasound-guided drainage, 439 days for those treated with antibiotics alone (n = 3), and 364 days for those treated with surgery (n = 20). The average follow-up duration after seroma treatment for all patients was 12.8 months.

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Table 2. Management of Seromas

Patient No.	Management	Culture	Cytology	Follow-Up Duration (days)	Outcome/ Complications
1	Capsulectomy, seroma drainage, implant replaced with Style 120 implant (textured, silicone)	Neg	Neg	870	Seroma resolved
2	Capsulectomy, seroma drainage, implant removal	Neg	Neg	26	Seroma resolved; implant not replaced
3	Capsulectomy, seroma drainage, implant removal	Neg	Neg	26	Seroma resolved; implant not replaced
4	Capsulectomy, seroma drainage, implant replaced with Style 45 implant (smooth, silicone)	Neg	Neg	275	Seroma resolved
5	Capsulectomy, seroma drainage, implant replaced with Style 20 implant (smooth, silicone)	Neg	Neg	192	Seroma resolved
6	Capsulectomy, seroma drainage, implant replaced with Style 20 implant (smooth, silicone)	Neg	Neg	371	Seroma resolved
7	Capsulectomy, seroma drainage, implant replaced with Style 410MF implant (textured, silicone)	Neg	Neg	244	Seroma recurrence; eventual explant
8	Capsulectomy, seroma drainage, implant replaced with Style 410MF implant (textured, silicone)	Neg	Neg	441	Seroma resolved
9	Capsulectomy, seroma drainage, implant replaced with Style 410MF implant (textured, silicone)	Neg	Neg	441	Seroma resolved
10	Capsulectomy, seroma drainage, implant replaced with Style 410FX implant (textured, silicone)	Neg	Neg	489	Seroma resolved
11	Capsulectomy, seroma drainage, implant replaced with Style 410FX implant (textured, silicone)	Neg	Neg	489	Seroma resolved
12	Seroma resolved with ultrasound-guided drainage; patient later underwent capsulectomy and implant replaced with Style 410FX implant (textured, silicone)	Neg	Neg	179	Seroma resolved
13	Ultrasound-guided drainage, antibiotics	Neg	Neg	233	Seroma resolved
14	Capsulectomy. seroma drainage, implant replaced with Style 410FF implant (textured, silicone)	Neg	Neg	1189	Seroma resolved
15	Ultrasound-guided drainage	Neg	Neg	539	Seroma resolved
16	Seroma resolved with ultrasound-guided drainage; patient later underwent capsulectomy and implant replaced with Style 20 implant (smooth, silicone)	Neg	Neg	216	Seroma resolved
17	Antibiotics; seromas developed twice more and resolved with oral antibiotics	Not done	Not done	628	Seroma recurred two more times, and both times successfully treated with oral antibiotics (patient refused surgery)
18	Antibiotics	Not done	Not done	446	Seroma resolved
19	Ultrasound-guided drainage	Neg	Neg	692	Seroma resolved
20	Capsulectomy, seroma drainage, implant replaced with Style 15 implant (smooth, silicone)	Neg	Neg	99	Seroma resolved
21	Capsulectomy, seroma drainage, implant replaced with Style 115 implant (textured, silicone)	Neg	Neg	90	Seroma resolved
22	No capsulectomy, seroma drainage, implant replaced with Style 15 implant (smooth, silicone)	Neg	Neg	1175	Seroma resolved
23	No capsulectomy, seroma drainage, implant replaced with Style 15 implant (smooth, silicone)	Neg	Neg	285	Seroma resolved
24	Ultrasound-guided drainage	Neg	Neg	180	Seroma resolved
25	No capsulectomy, seroma drainage, implant replaced with Style 410MM implant (textured, silicone)	Neg	Neg	110	Seroma resolved
26	Ultrasound-guided drainage	Neg	Neg	360	Seroma resolved
27	Capsulectomy, seroma drainage, implant replaced with Style 15 implant (smooth, silicone)	Neg	Neg	80	Seroma resolved
28	Antibiotics	Not done	Not done	540	Seroma resolved

Neg, negative.

Of the 18 breasts of 28 (64 percent) that underwent implant exchange procedures, one (6 percent) had a smooth device exchanged for a Biocell textured device, eight (44 percent) had textured devices exchanged for smooth devices, and nine (50 percent) had textured devices replaced with a new Biocell textured device.

Of the eight patients successfully treated without surgical intervention, five (18 percent) resolved with only ultrasound-guided seroma drainage, and three (11 percent) seromas resolved with antibiotic therapy alone. Overall, ultrasound-guided drainage procedures successfully resolved the seromas in five of the nine patients (56 percent) in whom it was attempted.

All patients who had ultrasound-guided or surgical drainage had seroma fluid sent for culture as well as cytology. All tested specimens were negative for malignancy or infection. The three patients whose seromas resolved on antibiotic therapy alone did not have the seroma fluid evaluated with culture or cytology; 27 of 28 seromas (96 percent) were treated successfully by one of the five described approaches. There was one recurrent seroma (3.6 percent) in our series. This patient was initially treated with complete capsulectomy with drainage and placement of a new Biocell textured implant. Ten weeks postoperatively, she developed erythema and swelling consistent with a seroma or infection. This was successfully managed with surgery, including drainage of the seroma, device explantation, and oral antibiotics. All her cultures were negative.

As a frame of reference for the type of devices commonly used by the three lead investigators, all implants placed in these practices for a representative single year from 2005 to 2006 were reviewed. A total of 950 devices were placed in 509 patients; 482 (51 percent) were smooth, and 468 (49 percent) were Biocell textured devices. Of the 509 patients, 147 (29 percent) underwent breast reconstruction, whereas 362 (71 percent) had cosmetic breast surgery procedures.

At Georgetown University Hospital, our reference data on 142 patients operated on during that 1-year period showed a stronger preference for smooth devices (210 implants; 86 percent) versus Biocell textured implants (33 implants; 14 percent). Drs. Glicksman and Brown use a majority of Biocell textured devices. A total of 435 (62 percent) of the 707 devices they placed during that 1-year period were Biocell textured implants. All three surgeons use only the Biocell variety of textured implants. Based on this ratio of usage of textured versus smooth implants in this single year, and assuming that the usage ratio is relatively constant, textured Biocell implants were statistically more likely to be associated with late seroma ($p < 0.0001$) compared with smooth implants in this study. This series represents the retrospective evaluation of three independent plastic surgeons. Each of the surgeons had his or her own specific decision process for selecting the particular treatment plan for each patient. Although care is individualized to each patient, each plastic surgeon had his or her own individual thought process that drove treatment selection.

Dr. Spear's decision process centered on narrowing the diagnosis, followed by a definitive treatment. Specifically, if a late swelling developed in a patient with a breast implant, the patient was first brought for serial examinations over several weeks to determine whether the symptoms progressed or resolved spontaneously. If there was any erythema, warmth, or malaise, the patient was empirically started on antibiotics. Those patients whose swelling did not appear to be infectious (either no signs of infection or the swelling remained despite a course of antibiotics) were then deemed to have late seromas. The patient was sent for a diagnostic ultrasound; if the radiologist found that it could be easily and safely tapped, then it was drained and sent for studies; if the seroma did not recur following such drainage, then no further intervention was performed. If the seroma was not percutaneously drained, then the patient was taken to the operating room, where the seroma was drained and the periprosthetic space evaluated. Seroma fluid was sent for Gram stain, aerobic and anaerobic culture, and cytologic analysis. The implant was removed, and if the capsule was thickened or appeared abnormal in any way, a surgical capsulectomy or capsule curretage was performed. The cavity was irrigated copiously with Betadine (Purdue Products, Stamford, Conn.) irrigation followed by antibiotic-containing saline, and then a new smooth implant was placed in the same setting. Of the 11 breast seromas treated by Dr. Spear, all underwent capsulectomy (100 percent), nine (82 percent) underwent capsulectomy and implant exchange, and two (18 percent) had capsulectomy and implant removal without placement of new implants.

Dr. Glicksman's decision-making process centered around avoiding the loss of an implant due to an infection. If the patient presented with late swelling associated with any signs/symptoms of infection (erythema, warmth), then the patient was empirically prescribed oral antibiotics, while an attempt was made to schedule a diagnostic

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ultrasound with aspiration of periprosthetic fluid as soon as possible. Fluid collected was sent for aerobic and anaerobic cultures and Gram stain; cytologic analysis was requested on all reconstructive patients who presented with late seromas since 2009. Not all late seroma patients were compliant, and several refused ultrasound and drainage. If a patient underwent ultrasound-guided drainage and there was no recurrence of swelling within 6 months, then no further intervention was performed. In those patients with older generation round silicone gel or McGhan Style 153 implants, imaging studies were performed to evaluate for rupture. Patients with ruptured implants underwent explantation, capsulectomy, and replacement with either smooth or Biocell textured devices. Patients with evidence of infection underwent explantation without replacement.

If the ultrasound-guided drainage was followed by seroma recurrence with no evidence of infection, the patient was given the option of repeat ultrasound-guided drainage or implant removal with cultures, Gram stain, triple antibiotic irrigation, Betadine irrigation, complete capsulectomy, and replacement to a new implant. Of the eight breast seromas treated by Dr. Glicksman, three underwent capsulectomy and implant exchange, three had ultrasound-guided drainage alone, and two were treated with antibiotics alone.

Dr. Brown's approach was to initially assess for a history of trauma and to examine for any evidence of infection. If a fluid wave was clearly visible, he generally attempted ultrasound-guided drainage, sending fluid for culture and cytology. If the seroma resolved with aspiration, he then prescribed a course of anti-inflammatory medications and/or antibiotics. If the seroma recurred following ultrasound-guided drainage, then the patient was taken to the operating room for exploration. If the capsule was mature and thin, without evidence of infection, then the wound was irrigated and the implant replaced; capsulotomy was performed if necessary. If the capsule was thickened, then a capsulectomy was performed and the implant usually changed. Of the nine breast seromas treated by Dr. Brown, three underwent capsulectomy and implant exchange, three had implants exchanged without capsulectomy, two had ultrasound-guided drainage alone, and one was treated with antibiotics alone.

DISCUSSION

The etiology of late periprosthetic breast seromas has been the subject of speculation without any clear cut consensus regarding their frequency or likely usual cause. There have been only a handful of case and small series reports of late seromas.[6–14] Fewer than 20 cases of late seromas have been published to date. Suspected causes of late seroma have included clinical infection, subclinical infection (including biofilm), malignancy (including anaplastic large cell lymphoma), capsule tear, microtrauma, mechanical shearing, and idiopathic. In a 2004 article, Adams and colleagues published a comprehensive article on the management of a wide variety of breast implant–related issues in an effort to address the U.S. Food and Drug Administration's concern over reoperation rates, and to guide physicians and patients in the management of certain potentially challenging situations.[15] They made comprehensive diagnostic and therapeutic recommendations for the following six scenarios: request for implant size exchange, capsular contracture, stretch deformities, silent rupture, undefined systemic symptom complexes, and possible periprosthetic space infection or seroma. At that point in time, the emphasis was mostly on diagnosing and treating infection rather than on seroma. Once infection was ruled out clinically and by culture, options for seroma management included, in part, doing nothing, removal of one or both implants, and removing the affected implant and surrounding capsule with or without replacement. There did not appear at that time to have been any special or heightened concern regarding malignancy or a causative role for any one type of implant.

The relationship between implant type and the development of late seroma has been unclear. Hall-Findlay recently reported her observations that late seromas appeared more common with certain aggressively textured implants.[16] She reviewed 626 consecutive patients who underwent primary bilateral breast augmentation or primary bilateral mastopexy-augmentations after the moratorium in 1992. A total of 105 patients (17 percent) in her report had Biocell textured silicone implants placed. She found double capsules in 14 patients, all of whom had Biocell textured surface silicone implants. Of these 14 patients, three had seromas. She further reports that she had no late seromas or double capsules in her primary augmentations between 1983 and 2006, before she started using Biocell implants, and suggests that seromas and double capsules are therefore a complication unique to these aggressively textured Biocell implants.

In our current study, 27 of 28 (96 percent) of our reported late seromas were associated with Biocell textured implants, whereas our percentage of Biocell textured implants used in our three

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practices during that overlapping year ranged from 14 percent (S.L.S.) to 94 percent (C.G.), with an overall mean of 49 percent. Although our seroma data regarding texturing are dominated by the Biocell type of textured implant, this result could be in part due to selection bias because only the Biocell type of textured implant is used in our practices.

The subject of late seromas after breast implants has received renewed interest with the recent description of anaplastic large cell lymphoma occurring after the placement of breast implants. Part of the presentation of this lymphoma has been its frequent association with a late symptomatic swelling or seroma around a breast implant. In their systematic review of anaplastic large cell lymphoma, Kim and colleagues were able to identify 34 articles that included 36 cases of it and other non-Hodgkin's lymphomas involving the breast.[17] Twenty-nine of the 36 (81 percent) were anaplastic large cell lymphoma. Fourteen of the 29 cases (48 percent) were reported as presenting with a seroma, whereas another 14 of the 29 cases (48 percent) did not provide sufficient information to ascertain whether a seroma was the presenting complaint or not. Only one (3 percent) was specified as not presenting as a seroma.

Increasing concern about the management of such late seromas and the heightened awareness of the possibility of associated malignancy has led to various new recommendations or algorithms for late seroma management.[18] These algorithms include obtaining fluid for sophisticated cytology and culture.[19] There are also more recent specific recommendations for what sort of cytological and pathological examinations are appropriate depending on the fluid and capsule findings. Current routine culture techniques are not sufficiently sensitive or accurate for the detection of chronic biofilm infections. In addition, biofilm evaluation techniques are not available at every facility. Despite these valid recommendations, it is interesting to note that all 25 cultures performed in this report were negative, as were the 25 specimens sent for cytology. The potential benefit of such more sophisticated and important tests despite their theoretical significant value may be very low, based on our experience of successful management of such late seromas without this new information.

All but one of the patients in our series were ultimately successfully treated for their seromas, and none had any clear evidence of malignancy or documented subclinical infection. The successful outcomes of our reported cases support the notion that all or most of these late seromas were idiopathic in the sense that we were unable to document either a suspected infection or occult malignancy. Although the relationship between biofilm and capsular contracture has been documented,[20,21] the connection between biofilm and late seroma has not yet.[16] Biofilm does need to be at least considered as a possible etiology in the future. However, without specifically treating or looking for a biofilm source, 27 of our 28 cases of late seroma were successfully treated with the described methods. Among the 28 seromas described in this study, 13 (46 percent) had associated findings that suggest an etiology or at least an aggravating factor. These factors include suspected (but undocumented) infection (five breasts, 18 percent), implant rupture or bleed (four breasts, 14 percent), trauma (three breasts, 11 percent), and dark fluid resembling old hematoma (two breasts, 7 percent). Although all 13 of these breasts had a clinical diagnosis of seroma at the time of treatment, the associated findings raise the suspicion that these factors contributed to seroma formation. All the patients with findings suggestive of infection had fluid sent for culture, yet the results were uniformly negative. Although systemic antibiotics might have reduced many of the symptoms of infection, the inflammatory effects probably manifested as seroma. Similarly, hematoma, gel bleeding, and trauma could have promoted an inflammatory reaction that resulted in seroma in these cases.

There are a variety of recently described methods to manage late seromas.[18,19] The literature suggests early acquisition of the seroma fluid to rule out infection and malignancy with microbiology and cytology evaluation. The physician must decide whether to proceed with percutaneous versus open therapeutic drainage of the fluid collection. If the decision is made to surgically drain the seroma, the capsule needs to be inspected to determine whether local biopsy or total capsulectomy is necessary. Implant replacement also needs to be considered. In our series, the most common methods were implant replacement and seroma drainage (18 of 28, 64 percent), with capsulectomy in 15 of 28 (54 percent), or without capsulectomy in three of 28 (11 percent). Indications for capsulectomy include but are not limited to a thick, nonpliable capsule, evidence of infection or inflammation or an abnormal mass within the capsule, or failure of a prior drainage procedure. It should be noted that if biofilm is in fact part of the etiology of a late seroma, such implant replacement and total capsulectomy would most likely

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also be the most effective way of successfully treating the problem and reducing the risk of recurrence.

The fact that these late seromas were successfully managed by a variety of different approaches speaks to the possibility of trying less aggressive treatment plans first. So, depending on the clinical circumstances, ultrasound-guided therapeutic aspiration with culture and cytology may often be a rational first step. If this resolves the problem, nothing further need be done. On the other hand, the more definitive and reliable approach appears to be surgical intervention with drainage, device exchange, and possible capsulectomy. One surprising feature of this review was the equivalent and almost paradoxical success with implant exchange whether replacing with a new Biocell textured or smooth implant.

Although in an early case in our series we replaced a smooth implant with a Biocell textured device at the time of seroma drainage and capsulectomy, the fact that 27 of 28 of our late seromas occurred with Biocell textured implants certainly suggests that replacement of a textured implant with a smooth implant when possible should logically maximally reduce the likelihood of a recurrence, especially in the long run. With late seromas seen most often with Biocell textured implants, replacement with a smooth implant seems logical. Also, given the fact that seroma aspiration alone was successful 56 percent of the time, this might be an appropriate first step both diagnostically and therapeutically for many patients. Our experience supports the hypothesis that late seromas are most reliably treated with implant exchange with or without capsulectomy based on success with that approach in 19 of 20 breasts. Finally, it is important to remember that these cases represent seromas that developed late (at least 1 year) following implant placement. Our study is not geared to address whether the treatment would prevent future late seromas, and although some of our patients were followed for more than 1 year, we cannot speculate on whether these patients might develop a new longer-term late seroma.

CONCLUSIONS

Based on our experience in this series, including following routine microbiology and cytology studies, the majority of late seromas seen in our practices remain defined as idiopathic, without hard evidence of infection or malignancy. The overwhelming majority of such seromas in this report of 28 cases were found to involve a Biocell textured surface breast implant. A graduated hierarchy of different management strategies may be appropriate, with surgical intervention and device replacement being the most definitive. Virtually all implant-related late breast seromas in this series were successfully managed by the various described techniques. The recent increased interest in biofilm and anaplastic large cell lymphoma in association with breast implants will likely encourage more sophisticated testing and more aggressive treatment of late seromas and capsules, but in the meantime, this study suggests that these patients can be successfully treated with less sophisticated means.

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New Submission Guideline: Level of Evidence

Beginning with submissions made July 1, 2011, and going forward, all manuscripts amenable to Level of Evidence grading need to indicate the clinical question addressed by the article and the Level of Evidence. The **clinical question** will be one of three categories: Diagnostic, Therapeutic, or Risk. Please use the ASPS Levels of Evidence and Grading Recommendations: Evidence Rating Scales to grade the level of evidence in your manuscript.

In general, the following types of articles are not gradable for level of evidence:

- Animal studies
- Cadaver studies
- Basic science studies
- Review articles
- Instructional course lectures
- CME courses
- Editorials
- Correspondence

As far as what is or is not ratable, the standard is to exclude basic science, bench work, animal, and cadaveric studies because the information gained from these studies is not something that can be applied directly to patient treatment decisions.

See the article "The Level of Evidence Pyramid: Indicating Levels of Evidence in *Plastic and Reconstructive Surgery* Articles," in the July 2011 issue (Plast Reconstr Surg. 2011;128:311–314), for more information on determining the Level of Evidence of your manuscript.

NOTE: While we require authors to provide an initial Level of Evidence grade for their submissions, the final LOE grade for accepted papers will be determined and assigned by an independent panel of LOE experts, whose determination is final.

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