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Augmentation Mammaplasty After Breast Enhancement With Hyaluronic Acid

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Abstract

Background: Macrolane is a stabilized, hyaluronic acid–based gel that has been available since 2007 as a minimally invasive, nonpermanent option for breast enhancement. However, numerous controversies pertaining to its side effects have highlighted the need for studies involving larger groups of patients.

Objectives: The authors sought to determine complications of Macrolane injections for breast enhancement and performed surgical evacuation of cysts comprising collections of hyaluronic acid in patients who previously received Macrolane treatment and presented for augmentation mammaplasty.

Methods: The authors reviewed a case series of 20 patients who were treated elsewhere with intramammary injection of Macrolane for cosmetic purposes and who presented at the authors' medical studio with multiple intramammary and intramuscular cysts. All patients underwent surgical evacuation of the hyaluronic acid–based cysts in association with augmentation mammaplasty.

Results: Good aesthetic results were achieved in all patients. Three months after surgery, 15 of 20 (75%) patients rated themselves as very much improved; 4 patients (20%) rated themselves as moderately improved, and 1 patient (5%) rated herself as somewhat improved.

Conclusions: The authors suggest that Macrolane cannot be considered a valid alternative for breast augmentation at this time.

Level of Evidence: 4

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Macrolane (Q-Med, Uppsala, Sweden) is a nonanimal, stabilized, hyaluronic acid–based gel (ie, NASHA) that has increasingly been marketed as a minimally invasive, nonpermanent option for breast enhancement. Macrolane was first authorized in 2007 in France, and it received official European approval for breast augmentation in 2008. However, controversies concerning its side effects have led to its subsequent withdrawal from the worldwide breast augmentation market.[1-5] Studies involving larger groups of patients treated with Macrolane are needed. In this report, we describe a case series of 20 patients who presented to our office with complications of intramammary Macrolane injection.

METHODS

This case series included 20 consecutive women who were treated elsewhere with bilateral, intramammary injections of Macrolane for cosmetic purposes and presented to our medical studio from January 2012 to September 2013. All patients indicated that they had received Macrolane injections without ultrasonographic guidance during the preceding 12 months and had developed intramammary and

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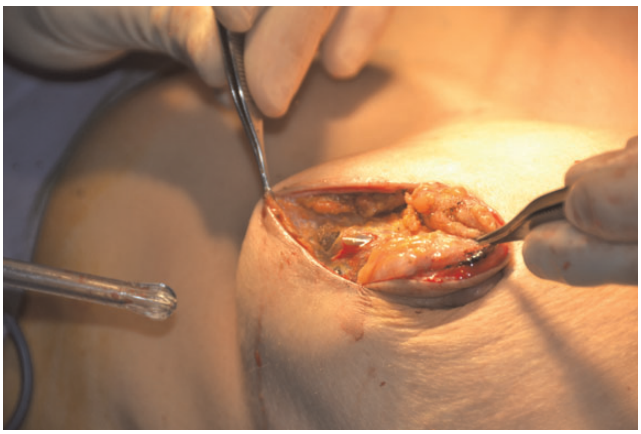

Figure 1. A Macrolane-based cyst with intraglandular localization in this 35-year-old woman who presented for surgical removal of Macrolane and breast augmentation.

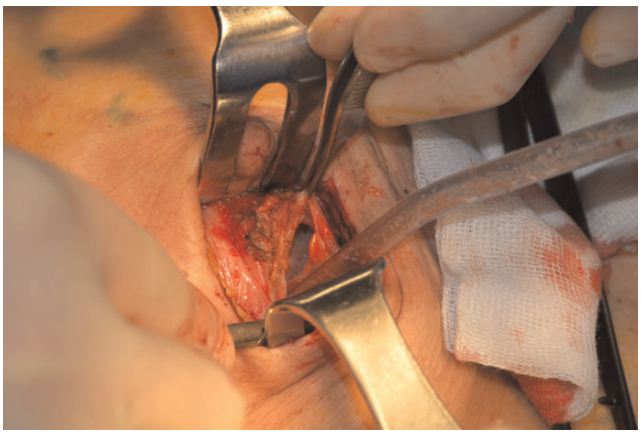

Figure 2. Tube suctioning of an intramuscular cyst containing Macrolane in this 47-year-old woman who presented for surgical removal of Macrolane and breast augmentation.

intramuscular cysts. Presenting concerns included breast lumpiness and rapid, asymmetric volume loss. Breast ultrasounds (US) were obtained for each patient during their first visit and before surgery. In women under 40, ultrasound is better at evaluating breast lumps compared to mammography. Ultrasound is excellent at imaging cysts and thus differentiating an area of fluid (cyst) from an area of normal breast tissue. Additionally, this method is less invasive and inexpensive.

All 20 patients were advised that the Macrolane should be surgically removed. Patients were not treated with hyaluronidase because of the large quantity of cysts. Injecting every lump would have been difficult and would have caused great discomfort to the patients. Because all patients still wished for an increase in breast volume, they were offered concurrent implant-based augmentation mammaplasty. Informed consent was obtained from all patients preoperatively. Patients were scheduled for surgery 3 to 6 months after the consultation to allow a 12-month lapse from the last Macrolane injection.

All patients received oral cefuroxime preoperatively. The cysts were not identified preoperatively by percutaneous needle placement because this procedure would have been arduous and uncomfortable for the patients. Instead, the cysts were readily identified intraoperatively. The whole breast was infiltrated with Klein solution, and inferior hemi-periareolar or inframammary incisions were made according to the localization of the cysts, the patient's preference, and the surgical technique. The breast parenchyma then was exposed to drain the cysts. Macrolane was obtained from multiple pockets within the breast parenchyma and the pectoralis major (Figure 1). To individually evacuate the breast lumps and avoid contamination of the pocket, the tissues were infused with saline, and the Macrolane was expelled by squeezing and removed by tube suctioning (Figure 2). The capsules were not excised to avoid reducing the breast volume and altering the breast parenchyma.[1]

For breast augmentation, the most appropriate implant pocket (subglandular, subpectoral, or dual plane) was selected after evaluating soft-tissue coverage and the degree of breast ptosis. The implant was placed in the subglandular plane if results of the pinch test indicated soft-tissue coverage > 3 cm and if the cysts had been completely evacuated. Breast augmentation subsequently was performed with textured, round, silicone-filled breast implants (Natrelle Inspira TRM, Allergan, Irvine, CA). Postoperative US were conducted to verify removal of the cysts 6 months after surgery. Patient satisfaction was assessed by the surgeon at follow-up by means of the 5-grade Global Aesthetic Improvement Scale at 6 months postoperatively. Patients were asked, "How would you describe the degree of improvement?" Possible responses were: (1) very much improved; (2) moderately improved; (3) somewhat improved; (4) no change; or (5) worse.

RESULTS

Patients ranged from 24 to 48 years of age (mean, 35.75 years; median, 36 years). All 20 patients presented with breast lumpiness and noted rapid, asymmetric losses in breast volume. Six of these patients were concerned about existing breast ptosis that had been worsening in association with the rapid resorption of hyaluronic acid. On initial examination, breast sizes ranged from 34B to 38C with first to second degree breast ptosis according to the Regnault classification. Irregular nodules that were occasionally associated with painful sensations on palpation were detected, primarily in the lower pole of the breasts. At

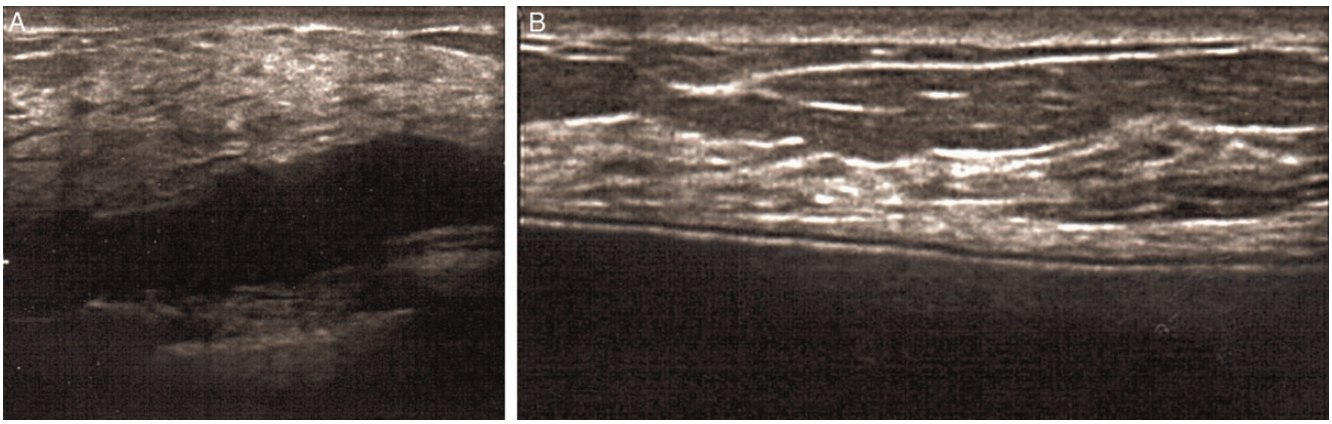

Figure 3. (A) Preoperative and (B) 6-month postoperative breast ultrasounds of this 35-year-old woman who underwent removal of Macrolane-containing cysts and breast augmentation. Note removal of cysts containing Macrolane in the postoperative sonogram.

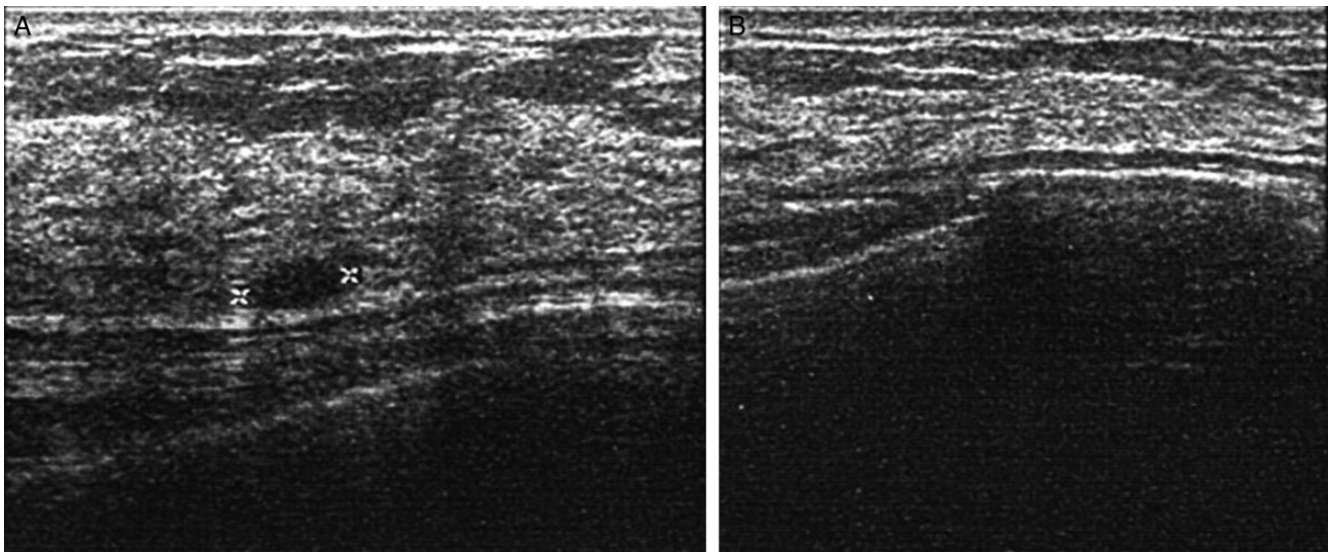

Figure 4. (A) Preoperative and (B) 6-month postoperative breast ultrasounds of this 47-year-old woman who underwent removal of Macrolane-containing cysts and breast augmentation. Note removal of cysts containing Macrolane in the postoperative sonogram.

time of surgery, the breast lumps had not been resorbed, and breast ptosis had worsened.

The results of breast imaging demonstrated the presence of intraglandular and intramuscular cysts preoperatively and the removal of the cysts 6 months postoperatively (Figures 3 and 4). Sequential preoperative US indicated that the cysts were not substantially modified and only decreased slightly in volume. All patients underwent surgical removal of at least 85% of the filler. Macrolane was expelled from an average of 10 lumps per breast (range, 5–12 lumps per breast); some of these lumps were found in the axillary cavity. The total amount of Macrolane removed ranged from 150 to 200 cc per breast (Figure 5).

Figure 5. Macrolane specimen.

Table 1. Patient Characteristics

Patient no	Age	Breast lumps (left/right)	Macrolane removed (cc)	Implant pocket	Implant size (cc)
1	35	11 L 10 R	160L 150R	Sub-pectoral	275
2	27	10L 12R	150L 170R	Sub-glandular	375
3	24	11L 9R	190L 180R	Sub-pectoral	345
4	40	10L 8R	170L 180R	Dual plane	310
5	33	7L 11R	200L 200R	Sub-glandular	375
6	31	10L 11R	180L 190R	Dual plane	345
7	29	12L 8R	170L 180R	Dual plane	275
8	42	8L 9R	180L 190R	Sub-pectoral	310
9	46	11L 10R	160L 150R	Sub-pectoral	345
10	28	6L 9R	200L 190R	Sub-glandular	275
11	48	10L 9R	180L 200R	Dual plane	375
12	31	12L 10R	170L 170R	Sub-pectoral	310
13	37	10L 8R	180L 180R	Dual plane	275
14	39	5L 7R	150L 160R	Sub-pectoral	345
15	41	12L 11R	200L 190R	Sub-glandular	275
16	38	9L 11R	160L 180R	Dual plane	310
17	25	10L 8R	180L 160R	Sub-glandular	345
18	44	10L 12R	170L 190R	Sub-pectoral	275
19	32	12L 10R	200L 190R	Dual plane	275
20	45	9L 9R	180L 180R	Sub-pectoral	310

Patients underwent augmentation mammaplasty by means of a subglandular pocket (5 patients), a subpectoral pocket (8 patients), or a dual-plane pocket (7 patients). The sizes of the textured, round implants ranged from 275 to 375 cc (Table 1). The length of hospital stay ranged from 1 to 3 days. After surgery, all patients received follow-up for 6 to 12 months (average, 8 months). The postoperative course was uneventful for 16 of 20 patients (80%). Complications included delayed wound healing (1 of 20 patients; 5%), hematoma (1 patient; 5%), and seroma (2 patients; 10%).

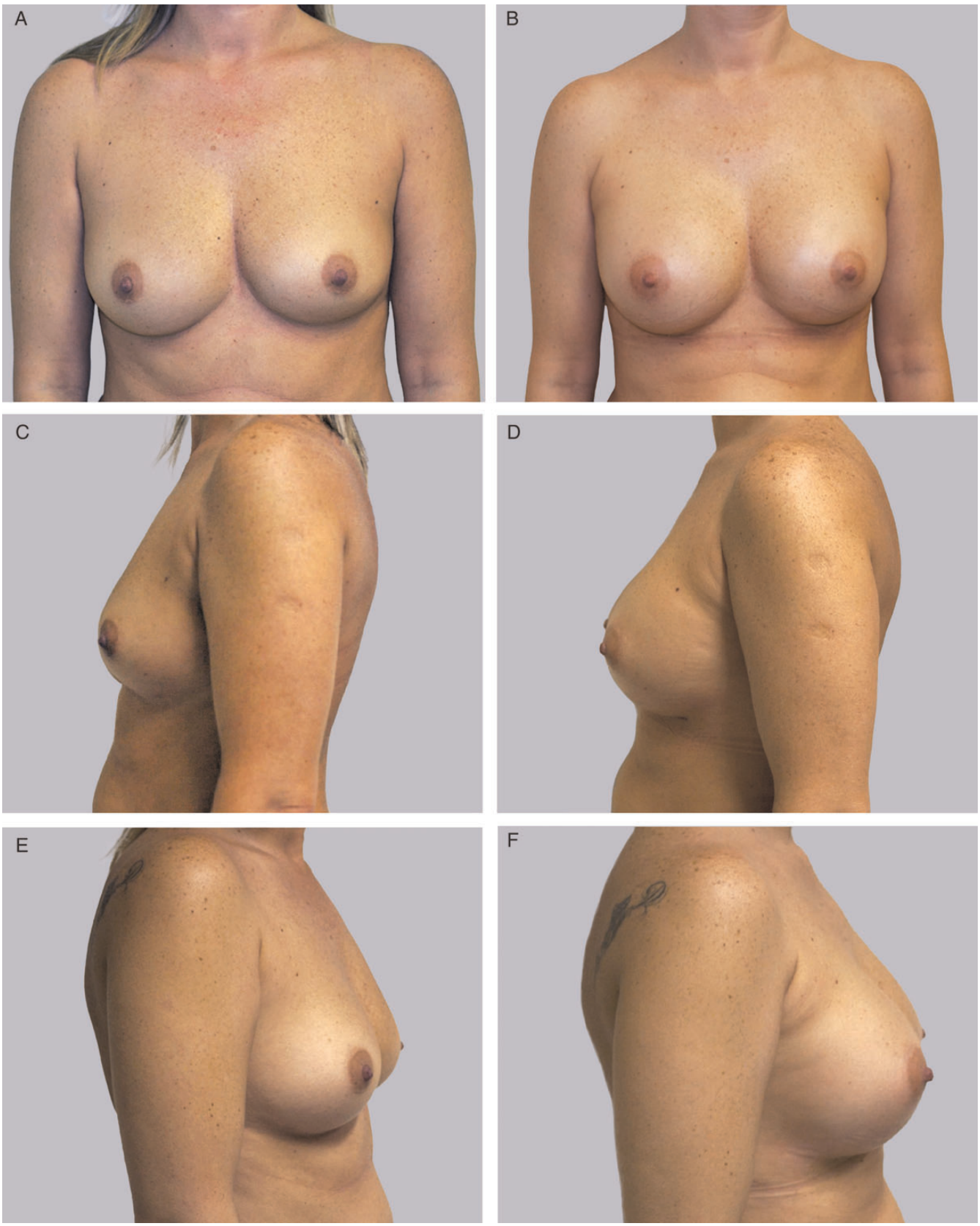

Figure 6. (A, C, E) Preoperative and (B, D, F) 6-month postoperative photographs of this 35-year-old woman who presented with moderately asymmetric breasts (larger right breast) with palpable lumps. She underwent surgical removal of cysts containing Macrolane and breast augmentation in the subglandular plane (275 cc, moderate projection, Natrelle Inspira TRM, Allergan). Note correction of breast lumpiness postoperatively. Patient satisfaction, according to the Global Aesthetic Improvement Scale, was very much improved.

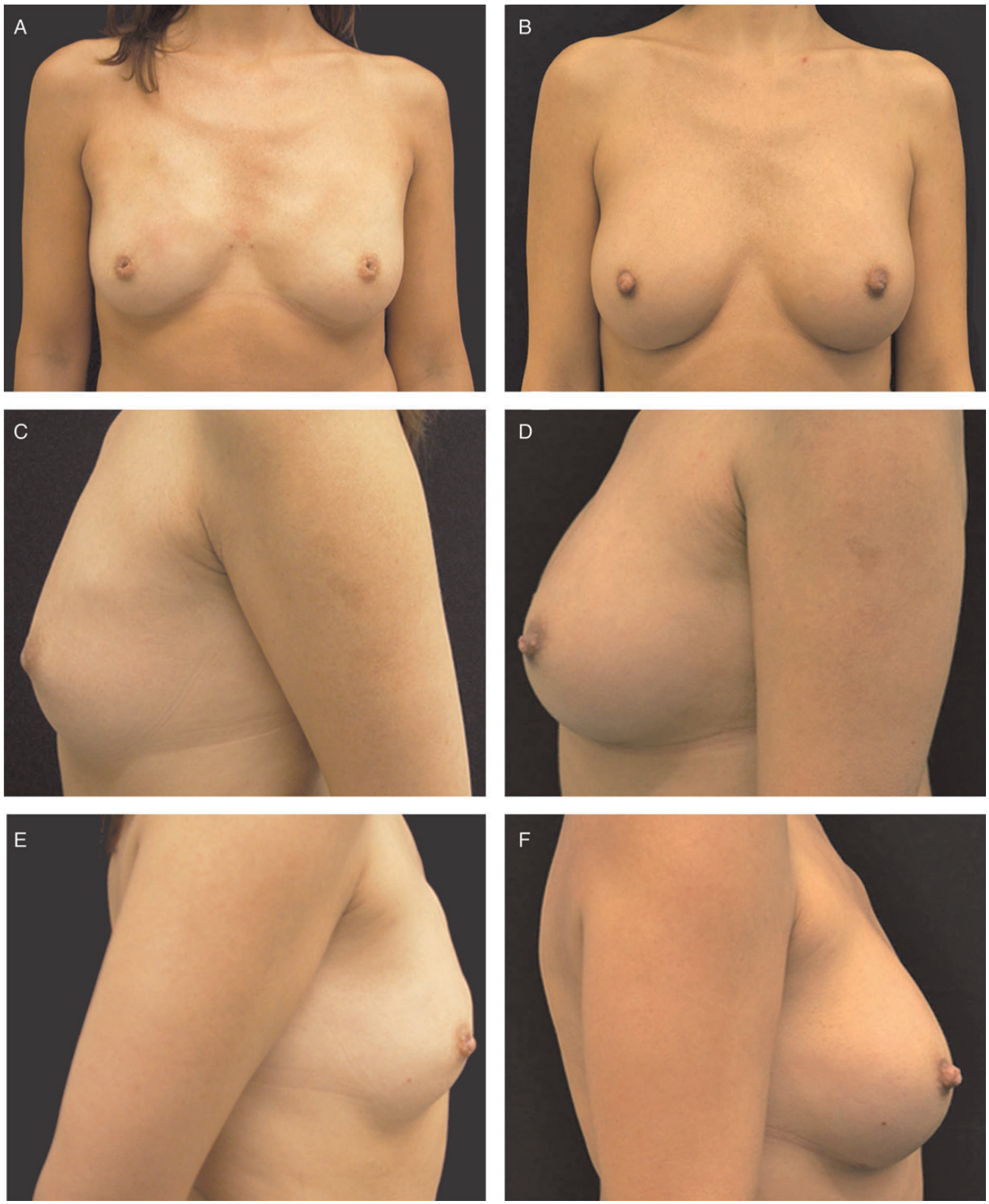

Figure 7. (A, C, E) Preoperative and (B, D, F) 12-month postoperative photographs of this 47-year-old woman who presented with mildly asymmetric breasts (larger left breast) with palpable lumps. She underwent surgical removal of cysts containing Macrolane and breast augmentation in the subpectoral plane (310 cc, moderate projection, Natrelle Inspira TRM, Allergan). Note correction of breast lumpiness postoperatively. Patient satisfaction, according to the Global Aesthetic Improvement Scale, was very much improved.

Table 2. Results of Patients' Satisfaction Assessment

Patients' GAIS	No of patients	% of patients
Very much improved	15	75
Moderately improved	4	20
Somewhat improved	1	5
No change	0	0
Worse	0	0

GAIS, Global Aesthetic Improvement Scale.

No major late complications occurred during follow-up. No capsular contracture was observed, and no implants were removed during follow-up. One patient complained of muscle twitching, which resolved after botulinum toxin injection in the pectoralis muscle.[6] Good aesthetic results were achieved in all patients (Figures 6 and 7). Three months after surgery, 15 of 20 (75%) patients rated themselves as very much improved; 4 patients (20%) rated themselves as moderately improved, and 1 patient (5%) rated herself as somewhat improved (Table 2).

DISCUSSION

Macrolane was temporarily withdrawn from the breast augmentation market in April 2012.[5] In this study, 20 patients who presented with cysts comprised of hyaluronic acid following bilateral breast injection with Macrolane underwent surgical evacuation of the cysts in conjunction with augmentation mammaplasty. To our knowledge, this study is the largest case series addressing complications of Macrolane for breast augmentation. Several authors have advocated for clinical trials addressing the injection of fillers into the breast.[7-12] Few reports address this topic, and the results of clinical series are limited by an insufficient level of evidence or conflicts of interest.[6,7,13-15] Data regarding the long-term effects of Macrolane are scarce, and concerns exist about imaging the Macrolane-injected breast. The implanted substance may alter anatomic structures of the breast and impede inspection of the whole breast tissue, thereby interfering with diagnostic screening.[8-10] The patient should be made aware of the potential impacts of Macrolane injection on the effectiveness of subsequent breast imaging and screening for breast cancer.[16,17]

We suggest waiting 9 to 12 months after the last injection of Macrolane into the breast before performing breast augmentation so that breast volume can be assessed adequately and the appropriate implant size can be selected.[18-21] Special care must be taken if a subglandular pocket is chosen for breast augmentation, because the kinetics of Macrolane resorption are poorly understood and decreased breast volume may lead to inadequate coverage of the prosthesis. All attempts must be made to place the implant in a Macrolane-free pocket.[11,22] If only a small amount of product remains and all cysts have been evacuated, the prosthesis may be placed in a subglandular pocket. However, the presence of cicatricial adhesions can hinder the creation of a subglandular pocket and make it necessary to place the implant retropectorally. The cysts of collected hyaluronic acid must be drained without removing the capsules, as described by McCleave et al,[11] and the material should be suctioned to avoid tissue contamination.

The only contraindication to inserting an implant at the time of Macrolane removal is the possibility that residual filler could be resorbed over time, reducing the volume of the breast. This possibility was discussed with the patients in our case series, but none wished to undergo 2 operations. The pocket was not contaminated during removal of the cysts; therefore, this procedure was not a contraindication to implant placement. Postoperatively, seroma formation occurred in 2 of 20 patients (10%) in our series. Seroma is a common complication in breast augmentation surgery, especially when drainage tubes are not placed. We were unable to determine whether the high seroma rate in our series was related to prior injection of Macrolane.

A potential limitation of our surgical approach is the possibility of leaving residual Macrolane in the breast. Nevertheless, our results suggest that good aesthetic outcomes can be achieved with up to 15% of the injected Macrolane remaining in the breast, and this residual product does not seem to increase the risk of postoperative complications or implant removal. A limitation of this study is its short follow-up duration. Additional investigations are needed to determine the stability of the aesthetic results.

CONCLUSIONS

Macrolane is marketed as a less-invasive alternative to breast augmentation with implants. The results of the present study suggest that Macrolane can be rapidly resorbed in the breasts and may collect in cysts, necessitating surgical removal. Therefore, we suggest that Macrolane is not a valid alternative for breast augmentation at this time.

Disclosures

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