Outcomes Utilizing Inspira Implants in Revisionary Reconstructive Surgery

Steven Sigalove, MD, FACS
G. Patrick Maxwell, MD, FACS
Allen Gabriel, MD, FACS

Winfield, Ill.; and Loma Linda, Calif.

Background: Inspira round implants have a higher fill ratio than standard round implants and the 3 available implant types have increasing gel cohesivity. Collectively, these features may help provide a fuller upper pole and help reduce the risk of rippling, visible implant edges, and palpability and may be particularly beneficial in patients undergoing prepectoral reconstruction. Patient outcomes after prepectoral revision reconstruction with these implants are reviewed in this study.

Methods: This retrospective study included consecutive patients who had previously undergone subpectoral (dual plane), implant-based, breast reconstruction and presented for revision reconstruction between June 2015 and January 2018. Reasons for revision included animation deformity, pain, asymmetry implant malposition, size change, capsular contracture, and rippling. Revision reconstruction involved implant removal, site change from subpectoral to prepectoral, and immediate implant replacement in all patients. Complications after revision reconstruction were obtained from patient records.

Results: A total of 64 patients (124 breasts) met the inclusion criteria. During a mean follow-up period of 18.9 months, complications occurred in 4 breasts (3.2%) and included implant loss (1.6%), seroma (1.6%), hematoma (0.8%), surgical site infection (0.8%), and skin necrosis (0.8%). There was no incidence of capsular contracture and presenting complaints were resolved in all cases.

Conclusions: Prepectoral reconstruction, in conjunction with Inspira round implants, appears to be a safe and effective approach in suitable patients presenting for revision surgery, at least in the short term. Implant features facilitate prepectoral implant placement, resulting in pleasing aesthetic outcomes. Whether these outcomes will withstand the test of time remains to be seen. (*Plast. Reconstr. Surg.* 144: 66S, 2019.)

The Inspira (Allergan, Madison, N.J.) series of round implants were recently approved by the US Food and Drug Administration (FDA) for patients undergoing breast augmentation and reconstruction. There are 3 implant types in this series—Responsive, SoftTouch, and Cohesive.[1] The Responsive implant contains the least cohesive silicone gel (Allergan TruForm 1) and is the standard silicone gel that is used in the Natrelle implants that was approved by the FDA in November 2006. The SoftTouch and Cohesive implants are considered to be form-stable implants and were approved by the FDA on January 2017 and September 2016, respectively. The Cohesive implant contains the highly cohesive TruForm 3 gel which is used in the Natrelle 410 anatomic implants. The SoftTouch contains TruForm 2 gel which is of intermediate cohesivity. All 3 implant types are available with smooth or textured surfaces.

A characteristic feature of these implants is the higher fill ratio than standard round implants. The higher fill ratio provides a fuller upper pole and is suitable for patients who lack upper pole subcutaneous tissue coverage. In addition, the

From DuPage Medical Group/DMG Aesthetics and the Department of Plastic Surgery, Central DuPage Hospital/Northwestern Medicine; and Department of Plastic Surgery, Loma Linda University Medical Center.
Received for publication January 20, 2019; accepted April 24, 2019.

DOI: 10.1097/PRS.0000000000005952

Disclosure: *Drs. Sigalove, Maxwell, and Gabriel are consultants for Allergan. Drs. Gabriel and Sigalove are also consultants for Acelity. No funds were received or utilized for the research reported in this article.*

higher fill ratio, together with the increasing gel cohesivity of the implants in this series, help reduce the risk of rippling, visible implant edges, and palpability.

Although recently marketed in the United States, the Inspira implants have an established safety and efficacy profile as they have been available in Canada and other countries for many years. The authors have used these implants in a variety of breast surgery patients and have found them to be particularly beneficial in patients undergoing prepectoral reconstruction. This study reports on their clinical experience of using the Inspira implants for prepectoral revision reconstruction.

PATIENTS AND METHODS

Consecutive patients who had previously undergone subpectoral, implant-based, breast reconstruction and presented for revision reconstruction between June 2015 and January 2018 in the author's practice (A.G.) were included in this retrospective study. Patients who had undergone autologous reconstruction, augmentation, or mastopexy were excluded from the study. Patient demographic data, reasons for revision, and complications after revision reconstruction were obtained from patient records. Information on the status of the presenting complaints following revision surgery was also obtained. The study was approved by PeaceHealth Southwest Medical Center Institutional Review Board (Vancouver, Wash.).

Revision reconstruction involved implant removal, site change from subpectoral (dual plane) to prepectoral, and immediate implant replacement in all patients. However, site change to the prepectoral plane was only considered after ascertaining that patients had no contraindications, including poor skin quality or perfusion, thin subcutaneous tissue, uncontrolled diabetes, and current smoking.[2] Skin perfusion was determined intraoperatively using a perfusion imaging system, when available, or clinically when the flap was tenuous.

Site change from dual plane to prepectoral was performed as described previously.[3,4] Essentially, this involved removing the previous implant and freeing the pectoralis major muscle from its attachments anteriorly and posteriorly. The implant was accessed and removed via the previous inframammary fold (IMF) incision or a new IMF incision if the previous incision was centrally located. As the majority of breast projection is in the central area, repeated access to the pocket via the central mastectomy scar was avoided to prevent additional thinning in this region. Thus, we advocate creating a new IMF incision in patients with a central mastectomy scar that is approximately 5–7 cm. The central incision was retained only if the breast was reconstructed with a latissimus dorsi (LAD) flap. Lower-pole acellular dermis, if present, was removed together with the underlying capsule. In patients who had a LAD flap placed at the lower pole during primary reconstruction, the pectoralis muscle was detached from the flap, which was retained at the lower pole. The anterior capsule was detached from the overlying pectoralis major muscle and removed, when possible. The pectoralis muscle was released from the overlying subcutaneous tissue. The freed muscle was then tacked down to the chest wall with 0-Vicryl sutures (Ethicon US LLC, Somerville, N.J.). A new implant was placed anterior to the tacked down pectoralis major muscle. A 16 cm × 20 cm, thick sheet of perforated or pie-crusted acellular dermal matrix (AlloDerm Tissue Matrix; Allergan Corporation, Branchburg, N.J.) was placed anterior to the implant and a bioabsorbable 10 cm × 2 cm mesh (GalaFLEX; Galatea Surgical Inc., Lexington, Mass.) posterior to the implant, both of which were secured to the chest wall tissues and to the IMF inferiorly. The implants were wrapped in acellular dermal matrix with or without bioabsorbable mesh (off-label) depending on the size of the implant. Implants greater than 350 cc required more pieces, and due to cost, bioabsorabable mesh was utilized. A drain was inserted laterally between the acellular matrix/mesh construct and mastectomy flap before skin closure. Incisional management device (Prevena; KCI, San Antonio, Tex.) was placed over the incision. Patients were subsequently fitted with a compression bra. Autologous fat grafting (processed using Revolve; Allergan Corporation) was performed as a secondary procedure, when needed. If tissues were thin at time of presentation, then a consideration for preoperative fat grafting was made for thickening of the flaps.

RESULTS

A total of 64 patients (124 breasts) who had previously undergone subpectoral, implant-based, breast reconstruction presented for revision reconstruction during the study period (Table 1). With a mean age of 50 years, half of the patients were obese and a quarter had controlled diabetes. The majority of mastectomies were bilateral; almost half were skin-sparing and

Table 1. Baseline Patient Characteristics

	Value
No. patients	64
No. breasts	124
Age, yr	
Mean (±SD)	49.8 (±10.5)
Range	31–69
BMI, kg/m^2	
Mean (±SD)	28.8 (±6.5)
Range	19–54
Comorbidities, no. patients (%)	
Obesity (BMI ≥ 30 kg/m^2)	33 (51.6)
Diabetes mellitus (controlled)	10 (15.6)

Table 2. Primary Reconstruction

	Value
Type of incision, no. breasts (%)	
Central	57 (46.0)
IMF	67 (54.0)
Type of mastectomy, no. breasts (%)	
Skin sparing	63 (50.8)
Nipple sparing	61 (49.2)
Laterality, no. patients (%)	
Unilateral	4 (6.3)
Bilateral	60 (93.8)
Type of reconstruction, no. breasts (%)	
One stage (DTI)	22 (17.7)
Two-stage (expander/implant)	98 (79.0)
Expander alone*	4 (3.2)
Size of implant, cc	
Mean (±SD)	606 (141.6)
Range	325–800
Radiation, no. breasts (%)	
Any	6 (4.8)
Before	0
After	6 (4.8)
Chemotherapy, no. patients (%)	
Any	31 (48.4)
Before	3 (4.7)
After	28 (43.8)

DTI, direct to implant.
*Two patients (4 breasts) underwent revision reconstruction at the expander stage (ie, after the first-stage reconstruction).

half were nipple-sparing mastectomies (Table 2). Fifty-four percent of the mastectomies were performed via an IMF incision and 46% via a central incision. Implants were placed in a dual plane and ranged in size from 325 to 800 cc, with a mean of 606 cc. Six of the reconstructed breasts were irradiated postmastectomy; none were irradiated premastectomy. About half of the patients had received chemotherapy, the majority postmastectomy.

All patients presented with multiple reasons for revision (Table 3). Animation deformity, pain, and asymmetry were the predominant reasons, with almost all patients reporting these complaints. Other reasons for revision included implant malposition in 69% of breasts, size change in 27%,

Table 3. Reasons for Revision

Presenting Complaint*	Breast (N = 124), n (%)
Capsular contracture	21 (16.9)
Animation deformity	123 (99.2)
Pain	123 (99.2)
Asymmetry	119 (96.0)
Size change	33 (26.6)
Increase	9 (7.3)
Decrease	24 (19.4)
Implant malposition	85 (68.5)
Rippling	2 (1.6)
Other	0

*All patients presented with >1 complaint.

Table 4. Revision Reconstruction

	Value
Incision type, no. breasts (%)	
IMF	119 (96.0)
Central	5 (4.0)
Implant size, cc	
Mean (±SD)	580.8 (152.1)
Range	275–800
Gel type*, no. breasts (%)	
Responsive	52 (41.9)
Cohesive	50 (40.3)
SoftTouch	22 (17.7)
Fat grafting, no. breasts (%)	58 (46.8)

*Inspira.

and capsular contracture in 17%. Rippling was a concern in less than 2% of breasts.

Revision reconstruction involved a site change from dual plane to prepectoral in all cases. The existing implant was accessed via an IMF incision in all but 5 cases (Table 4). In these 5 breasts, a LAD flap was part of the primary reconstruction and the implant was accessed through the previous central incision. Implants placed ranged in size from 275 to 800 cc; the mean implant size was 581 cc. All implants placed were Inspira round smooth implants, including Responsive gel implant in 42%, Cohesive implant in 40%, and SoftTouch implant in 18% of cases. Forty-seven percent of breasts required fat grafting to enhance breast volume and shape at a secondary surgery.

Patients were followed-up for a mean of 18.9 ± 11.0 (range: 6.1–41.6) months. Complications occurred in 4 breasts from 3 patients. The overall per breast complication rate was 3.2% (Table 5) and the per patient complication rate was 4.7%. Two implants were explanted for a failure rate of 1.6%. Other complications included 2 cases of seroma (1.6%) and 1 case each of hematoma, surgical site infection, and skin necrosis (0.8% each). Three breasts (2.4%) required treatment in the operating room: 2 for implant exposure/loss and 1 for seroma. There was no incidence of capsular

Table 5. Complications after Revision

Complication	Breast (N = 124), n (%)
Surgical site infection	
Any	1 (0.8)
Minor (requiring oral antibiotics)	1 (0.8)
Intermediate (requiring IV antibiotics)	0
Major (return to OR plus antibiotics)	0
Wound dehiscence	0
Skin necrosis*	
Minor	1 (0.8)
Intermediate (in-office debridement)	1 (0.8)
Major (return to OR plus antibiotics)	1 (0.8)
Seroma	2 (1.6)
Hematoma	1 (0.8)
Implant exposure and loss	2 (1.6)
Capsular contracture	0
Return to OR	3 (2.4)
Any	4 (3.2)

IV, intravenous; OR, operating room.
*The same breast progressed through all 3 stages of skin necrosis.

contracture and no recurrence of the presenting complaint.

DISCUSSION

Inspira round implants are the newest series of cohesive silicone gel implants to be approved for aesthetic and reconstructive surgery in the United States. The safety and efficacy of these implants following prepectoral revision reconstruction surgery were assessed in this study. Over an average 18-month follow-up period, 95% of patients experienced an uneventful postoperative course. Five percent of patients (3.2% breasts) had complications, which included a reoperation rate of 2.4% and a failure rate of 1.6% at the breast level. In this subgroup of patients, 6 breasts had prior postmastectomy radiation therapy. These cases were carefully evaluated and site change was only attempted if the skin were supple, mobile, and there were no associated capsular and/or soft tissue contracture. In addition, the patients were informed of the high risk of failure and the potential for a muscle only versus myocutaneous latissimus flap. In all patients, the presenting complaints for revision reconstruction were resolved and there were no recurrence of symptoms. These data suggest that prepectoral revision reconstruction with Inspira implants is a safe and effective procedure.

In the authors' opinion, the use of the Inspira implants also likely contributed to the pleasing aesthetic outcomes obtained in this cohort of patients (representative outcomes of patients shown in Figs. 1 and 2). The higher fill ratio of these implants is particularly suited for prepectoral placement. As reconstructive patients often lack sufficient soft tissue coverage at the upper pole, the Inspira implants provide a range of options for augmenting upper pole fullness. The

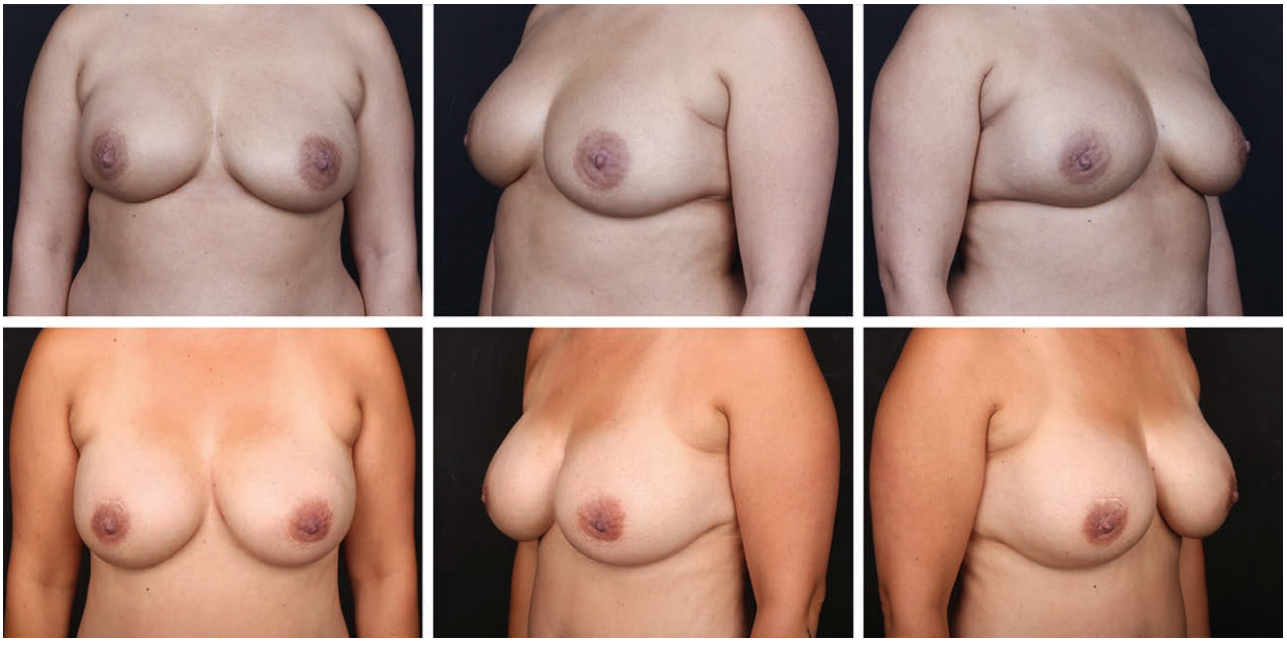

Fig. 1. Forty-year-old woman after bilateral mastectomy and 2-stage reconstruction (dual plane and acellular dermal matrix) with 650-cc Style 20 implants (*above*). Patient presented with concerns of pain and animation. Patient at 1 year following site change to prepectoral plane and reconstruction with acellular dermal matrix and smooth cohesive (TruForm 3) 650-cc implants (*below*).

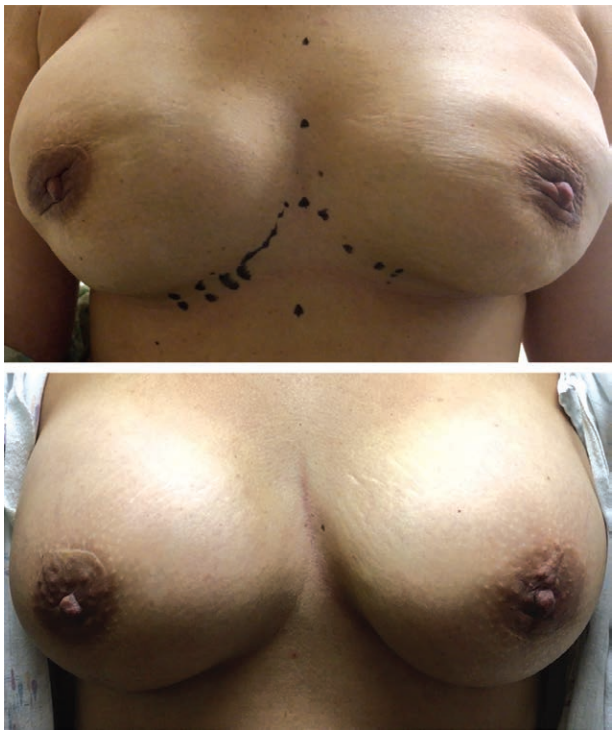

Fig. 2. Patient with animation deformity following 2-stage dual-plane reconstruction with Style 20, 650-cc implants (*above*). Patient at 6 months after site change to prepectoral plane with no animation deformity with smooth cohesive (TruForm 3) 650-cc implants (*below*).

authors typically use the Responsive or the Soft-Touch implant in patients with thicker upper pole soft tissue and the Cohesive implant for patients with thinner soft tissue. Body mass index (BMI) is not a reliable surrogate measure of soft tissue thickness, which is supported by the observation in the current study of almost identical mean BMI of patients who received each of the implant types (Table 6).

Historically, revision surgery for implant-related complaints, such as asymmetry, implant malposition, and capsular contracture, has typically involved implant removal, capsulectomy, creation of a neosubpectoral pocket, use of acellular dermal matrix or bioabsorbable mesh, and implant exchange (Fig. 4).[5] If the presenting complaint was animation and pain, neosubpectoral pocket is not the answer. The solution in this case includes eliminating the muscle from covering the implant by applying the site change principle of repositioning the implant from the subpectoral to the prepectoral space. In this study, the authors have showed that site change to the prepectoral plane can also be applied to the correction of implant-related complaints.

Table 6. BMI and Gel Type

Gel Type	BMI (Mean ± SD [Range]) Kg/m^2
Responsive	28.9 ± 7.8 (20–54)
Soft touch	28.0 ± 4.1 (23–34)
Cohesive	28.9 ± 5.9 (19–37)

It is noteworthy that almost all patients who presented for revision in this study had animation deformity and pain. Animation deformity, pain, pectoral muscle spasm, implant distortion, and chest tightness/discomfort are the well-recognized constellation of symptoms that are the direct consequence of elevating the pectoralis major muscle for implant placement in the subpectoral plane.[6–8] Until recently, the prevalence and the severity of animation deformity and its impact on patients' quality of life had received little attention. A study by Becker and Fregosi[7] found that all patients with subpectoral implant placement experience some degree of animation deformity. Moreover, 80% of patients who had animation deformity were bothered by it, half of whom were bothered to a significant degree by it. In addition, half of patients who had animation deformity felt that it interfered with their daily life.

Given the gravity of animation deformity, it is surprising that it has not emerged as a prominent reason for revision reconstruction in the published literature. Even in the Core Clinical Studies of implant manufacturers, animation deformity is not listed as a reason for revision surgery.[9–13] In these studies, the most common reasons were capsular contracture, implant malposition, asymmetry, device rupture, and size change. It is likely that animation deformity may not have been considered to be as "serious" as other complications, such as capsular contracture and implant malposition, to merit evaluation and correction. Moreover, there were no corrective measures apart from fat grafting, which did not completely resolve the problem. With the emergence of prepectoral reconstruction, there now appears to be a reliable means of correcting animation deformity. The authors predict that as patients become aware of the prepectoral option, there is likely to be a surge in requests for corrective surgery for animation deformity. In addition, with the recent advances in implant designs, surgical techniques, and fat grafting together with the use of acellular dermal matrix and bioabsorbable mesh in reconstructive surgery, there is less of a concern for the traditional reasons of revision. Consequently, there is likely to be a shift in focus to

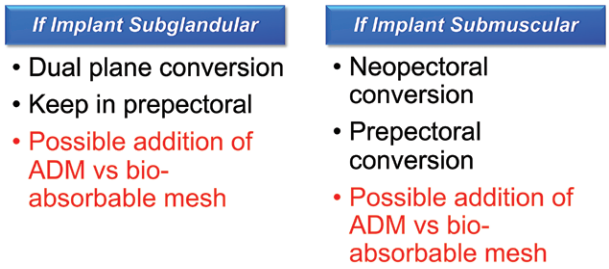

Fig. 3. Principles of site change in reconstructive and aesthetic revision surgery.

other potential reasons for revision surgery such as animation deformity.

In the author's practice, animation deformity and its impact on patients quality of life has been systematically evaluated in all patients. As a result, over the past 7 years, the authors have performed prepectoral revision reconstruction to treat animation deformity on a total of 226 breasts (121 patients), including 124 from the current study and 102 breasts from a previous study. In the latter study, prepectoral revision was performed in conjunction with the use of Natrelle 410 implants with excellent results.[3]

The principles of prepectoral revision surgery described in this study in reconstructive patients are generally transferable to aesthetic patients with subpectoral implants (Fig. 3). In the author's practice, aesthetic revision surgery typically involves implant removal, site change to the prepectoral or neosubpectoral plane, use of acellular dermal matrix or bioabsorbable mesh, and placement of an appropriate Inspira round implant since their availability. Before the availability of the Inspira implants, Natrelle 410 implants or classic gel implants were used with satisfactory long-term outcomes.[5] The results with Inspira implants have been satisfactory thus far and patients are being followed to evaluate long-term outcomes.

This study has several limitations. The retrospective study design and unblinded patient evaluations are associated with inherent bias. The study did not control for the revision approach with traditional subpectoral or neosubpectoral revision surgery or implant type with standard round silicone implants with a lower fill ratio to assess for the contribution of the prepectoral approach or the use of Inspira round implants to outcomes. The study period was relatively short, and long-term follow-up is needed to assess the effectiveness of the prepectoral approach. Last, rippling after revision surgery was not assessed as an outcome of revision surgery, which is the major limitation of this study. However, fat grafting in the majority of cases was due to rippling and patients requested fat grafting to mask rippling. Notwithstanding these limitations, the resolution of the presenting complaints in all cases, with a low failure rate, and pleasing aesthetic results suggest that the use of Inspira implants in the prepectoral position can be considered as an option in revision reconstruction. In addition, preoperative planning, precise surgical technique, and defined postoperative care are also important elements for successful outcomes and these should not be overlooked.

CONCLUSIONS

Prepectoral revision reconstruction with Inspira round implants successfully resolved presenting complaints of animation deformity/pain, capsular contracture, implant malposition, and asymmetry in this series of patients. High cohesivity and high fill ratio of the implants facilitate prepectoral implant placement and contribute to aesthetic outcomes. Long-term follow-up is needed to assess durability of outcomes.

Allen Gabriel, MD, FACS
Department of Plastic Surgery
505 NE, 87th Avenue, Suite 250
Vancouver, WA 98664
gabrielallen@yahoo.com
Instagram: @allengabrielmd
Twitter: @allengabrielmd
Facebook: Allen Gabriel MD

ACKNOWLEDGMENT

The authors thank Kalanethee Paul-Pletzer, PhD, for providing medical writing and Vadim A. Pletzer for data analyses support for this article.

REFERENCES

1. Jewell ML, Bengtson BP, Smither K, et al. Physical properties of silicone gel breast implants. *Aesthet Surg J.* 2019;39:264–275.
2. Sigalove S, Maxwell GP, Sigalove NM, et al. Prepectoral implant-based breast reconstruction: rationale, indications, and preliminary results. *Plast Reconstr Surg.* 2017;139:287–294.
3. Gabriel A, Sigalove S, Sigalove NM, et al. Prepectoral revision breast reconstruction for treatment of implant-associated animation deformity: a review of 102 reconstructions. *Aesthet Surg J.* 2018;38:519–526.
4. Lesavoy MA, Trussler AP, Dickinson BP. Difficulties with subpectoral augmentation mammaplasty and its correction: the role of subglandular site change in revision aesthetic breast surgery. *Plast Reconstr Surg.* 2010;125:363–371.
5. Maxwell GP, Gabriel A. Non-cross-linked porcine acellular dermal matrix in revision breast surgery: long-term outcomes and safety with neopectoral pockets. *Aesthet Surg J.* 2014;34:551–559.
6. Spear SL, Schwartz J, Dayan JH, et al. Outcome assessment of breast distortion following submuscular breast augmentation. *Aesthetic Plast Surg.* 2009;33:44–48.

7. Becker H, Fregosi N. The Impact of animation deformity on quality of life in post-mastectomy reconstruction patients. *Aesthet Surg J*. 2017;37:531–536.
8. Nigro LC, Blanchet NP. Animation deformity in postmastectomy implant-based reconstruction. *Plast Reconstr Surg Glob Open*. 2017;5:e1407.
9. Spear SL, Murphy DK; Allergan Silicone Breast Implant U.S. Core Clinical Study Group. Natrelle round silicone breast implants: core study results at 10 years. *Plast Reconstr Surg*. 2014;133:1354–1361.
10. Caplin DA. Indications for the use of MemoryShape breast implants in aesthetic and reconstructive breast surgery: long-term clinical outcomes of shaped versus round silicone breast implants. *Plast Reconstr Surg*. 2014;134(3 Suppl):27S–37S.
11. Maxwell GP, Van Natta BW, Bengtson BP, et al. Ten-year results from the Natrelle 410 anatomical form-stable silicone breast implant core study. *Aesthet Surg J*. 2015;35:145–155.
12. Hammond DC, Canady JW, Love TR, et al. Mentor contour profile gel implants: clinical outcomes at 10 years. *Plast Reconstr Surg*. 2017;140:1142–1150.
13. Stevens WG, Calobrace MB, Alizadeh K,et al. Ten-year core study data for Sientra's Food and Drug Administration-approved round and shaped breast implants with cohesive silicone gel. *Plast Reconstr Surg*. 2018;141(4S Sientra Shaped and Round Cohesive Gel Implants):7S–19S.