

# Prospective Study of Saline versus Silicone Gel Implants for Subpectoral Breast Augmentation

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**Background:** Silicone gel implants are regarded as esthetically superior to saline implants, offering a more natural consistency. They are also considered less susceptible to rippling. However, objective measurements and patient-reported outcome studies are lacking. Similarly, minimal data are available quantitating animation deformity.

**Methods:** A 3-year prospective study was undertaken among 223 women undergoing primary subpectoral breast augmentation using either saline (n = 145) or silicone gel (n = 78) implants. Photographs obtained included frontal views with the patient flexing the pectoral muscles. Images were matched, and vertical differences in nipple position were measured. Breast implants were evaluated using high-resolution ultrasound to detect any ripples or folds at least 3 months after surgery. Outcome surveys were administered. Statistical analysis included the  $\chi^2$ test, point-biserial correlations, and a power analysis.

**Results:** Respondents reported visible rippling in 18% of women and palpable rippling in 32% of patients, with no significant difference between women treated with saline and silicone gel implants. Ripples were detected on ultrasound scans in 24% of women with saline implants and in 27% of women with silicone gel implants (difference not significant). Ripples were more common in women with lower body mass indices. Fifty percent of patients demonstrated nipple displacement <1 cm on animation. Nipple displacement occurred either up or down with equal frequency and a mean overall nipple displacement of zero.

**Conclusions:** Saline and silicone breast implants produce similar degrees of rippling, as determined on outcome surveys and ultrasound examination. Animation deformities tend to be minor and well-tolerated. (*Plast Reconstr Surg Glob Open 2020;8:e2882; doi: 10.1097/GOX.000000000002882; Published online 4 June 2020.*)

# **INTRODUCTION**

Both saline and silicone gel implants are widely used by plastic surgeons today in the United States, although silicone gel implants are favored.<sup>1</sup> In discussing the pros and cons of each implant style, plastic surgeons, including the author, have routinely advised patients that silicone gel implants feel more natural and are less prone to rippling. However, this claim has little scientific foundation. Few objective studies examine differences between saline and silicone implants.<sup>2</sup> Similarly, there is a paucity of patient-reported data comparing outcomes.

High-resolution ultrasound is quickly becoming a popular tool in plastic surgery offices.<sup>3</sup> This technology

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Received for publication January 24, 2020; accepted April 8, 2020. Copyright © 2020 The Author. Published by Wolters Kluwer Health, Inc. on behalf of The American Society of Plastic Surgeons. This is an open-access article distributed under the terms of the Creative Commons Attribution-Non Commercial-No Derivatives License 4.0 (CCBY-NC-ND), where it is permissible to download and share the work provided it is properly cited. The work cannot be changed in any way or used commercially without permission from the journal. DOI: 10.1097/GOX.00000000002882 allows point-of-care evaluation of breast implants and is accurate in detecting ripples, folds, and other abnormalities. Animation deformity is a well-known complication of subpectoral implants.<sup>4,5</sup> This problem was also evaluated using measurements of nipple displacement on matched photographs.

This study was undertaken to obtain objective data comparing saline and silicone gel implants. This information may be used by surgeons and patients when selecting an implant.

#### PATIENTS AND METHODS

This prospective study began in December 2016 and ended in December 2019. Institutional review board approval was obtained from Chesapeake IRB, now Advarra IRB (Columbia, Md.) before initiation of the study.

**Disclosure:** *Dr. Swanson receives royalties from Springer Nature (Cham, Switzerland).* 

Related Digital Media are available in the full-text version of the article on www.PRSGlobalOpen.com.

# Patients

All women undergoing primary cosmetic breast augmentation were asked to take part in the study. Unilateral procedures, mastopexies, breast reconstruction patients, and transgender patients were excluded.

# Surgery

All procedures were performed by the author at the Surgery Center of Leawood, Kansas. Total intravenous anesthesia was administered, using a propofol infusion and a laryngeal mask airway. As part of deep venous thrombosis prophylaxis, patients were scanned with Doppler ultrasound before surgery, the day after surgery, and approximately 1 week after surgery.<sup>3,6</sup>

All implants were placed subpectorally, with preservation of the inframammary ligaments. All implants were manufactured by Mentor (Mentor Corp., Irvine, Calif.). A supra-inframammary incision (<1 cm above the existing inframammary crease) was used in most patients, although occasionally the incision was located more inferiorly (eg, in patients with constricted breasts).<sup>7</sup> The pectoralis muscle was released inferiorly and along the inferior sternal border.<sup>7,8</sup> Saline implants were inflated to their labeled maximum fill volume.

# **Clinical and Photographic Evaluation**

Clinical, photographic, and ultrasound evaluations were performed on the same day, at least 3 months after surgery. Any visible rippling was noted (Fig. 1). A ruler was included in one of the photographs for calibration. To detect animation deformity, a second frontal photograph was taken, with the patient holding her hands together and flexing her pectoral muscles (Fig. 2). Photographic matching was facilitated by the Canfield 7.4.1 Mirror Imaging software (Canfield Scientific, Fairfield, N.J.).

#### Surveys

Surveys were administered by the office staff, usually the sonographer, at least 3 months after surgery. (See survey, Supplemental Digital Content 1, which displays the breast implant survey, http://links.lww.com/PRSGO/ B406.) All surveys were administered in person.

## **Ultrasound Scans**

Ultrasound scans were all performed by the same licensed sonographer using a Terason t3200 Ultrasound System Vascular series (Terason Ultrasound, Burlington, Mass.) (Fig. 3).

#### **Statistical Analysis**

Statistical analyses were performed using SPSS for Mac version 26.0 (SPSS, Inc., Chicago, Ill.). The  $\chi^2$  test of independence was used to compare dichotomous variables. Point-biserial correlations were computed between dichotomous and continuous variables. An independent *t* test was used to compare means. A *P* value <0.05 was considered significant. An a priori power analysis was performed. To achieve 80% power, with an  $\alpha$  level of 0.05, sufficient to detect a medium-sized treatment difference ( $\phi = 0.30$ ),<sup>9</sup> 88 subjects would be needed.<sup>10</sup>

#### **RESULTS**

Over the 3-year study period, 223 women underwent primary cosmetic breast augmentation. The mean patient age was 31 years (range, 18–62 years), and the mean follow-up time was 4.6 months (range, 1 day to 3 years). The mean implant volume was 426 ml (range, 250–800 ml). Saline



**Fig. 1.** This 41-year-old woman is shown before (A) and 3 months after (B) a subpectoral breast augmentation using Mentor 475 ml smooth, round Moderate Plus Profile MemoryGel implants. Rippling can be seen on the left lateral photograph (B). The patient was unaware of it.

implants were inserted in 65% of patients; silicone gel implants were used in 35% of patients. There were no significant differences in demographic data comparing patients treated with saline and silicone gel implants (Table 1).

## Complications

No systemic complications were encountered. No deep venous thromboses were detected. Five patients had visible rippling that could be seen on photographs (Fig. 1).



**Fig. 2.** This 29-year-old woman is shown 3 years after a subpectoral breast augmentation using Mentor smooth, round Moderate Plus Profile saline implants inflated to 390 ml per side. Resting (A) and exertional (B) photographs were matched for size and orientation using the Canfield Mirror 7.4.1 Imaging software (Canfield Scientific, Fairfield, N.J.). A horizontal plane was drawn at the level of the resting post-operative nipple position. Right and left postoperative nipple levels while flexing the pectoral muscles were compared using vertical measurements. On flexion of her pectoralis muscles, the nipples displace downward.



**Fig. 3.** This 22-year-old woman is undergoing an ultrasound scan of the breasts 6 months after a primary subpectoral breast augmentation using smooth, round Mentor Moderate Plus Profile saline implants inflated to 450 ml. A fold is visible in the left implant.

Ta	ble	1.	Pati	ient	Data
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Characteristic	Saline*	Silicone	Total, %
No. patients	145	78	223
Age, y			
Mean	31.1	31.9	31.4
Range	18.2 - 57.9	22.1 - 61.8	18.2 - 61.8
Follow-up time, mo			
Mean	4.5	4.6	4.6
Range	0.03 - 36.0	0.03 - 36.0	0.03 - 36.0
Smoking status			
Nonsmoker	111	62	173(77.6)
Smoker	34	16	50(22.4)
Body mass index, kg/m <sup>2</sup>			
Mean	22.7	22.1	22.5
Range	16.3 - 35.4	16.5 - 38.4	16.3 - 38.4
Right implant volume, ml			
Mean	424	430	426
Range	270-800	275 - 800	270-800
Left implant volume, ml			
Mean	424	430	426
Range	250-800	275 - 800	250-800
In combination with other	procedures		
No	130	68	198 (88.8)
Yes	15	10	25 (11.2)

\*Mentor Style 2000 smooth, round, Moderate Plus Profile saline implant. †Mentor Style 1000 Moderate Plus Profile Gel (n = 74); Mentor Style 4000 High Profile Gel (n = 4).

Four patients had animation deformities as determined by their surgeon. No patients were concerned about it or requested surgical correction. Three patients developed capsular contractures and were treated with open capsulotomies. One patient elected to have larger implants inserted simultaneously. There were no other reoperations for a size change. No significant differences were detected comparing complication and reoperation rates for the 2 patient groups (Table 2).

#### **Photometric Findings**

In 50% of the patients, pectoralis flexion produced <1 cm of nipple displacement bilaterally, with no significant

Table 2. Complications	and Reo	perations
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	Saline, %	Silicone, %	Total, %
Complications			
No	129 (89.0)	69(88.5)	198 (88.8)
Yes	16 (11.0)	9 (11.5)	25(11.2)
Rippling	3	2	5
Animation deformity	2	2	4
Hematoma	3	1	4
Capsular contracture	2	1	3
Asymmetry	1	2	3
Hypertrophic scar	2	1	3
Implant deflation	2	0	2
Cellulitis	1	0	1
Seroma	0	0	0
Symmastia	0	0	0
Delayed wound healing	0	0	0
Deep venous thrombosis	0	0	0
Total	16	9	25
Reoperations (total intravenous an	esthesia)		
Evacuation of hematoma	2 ′	2	4
Replacement of deflated implant	2	0	2
Open capsulotomy	1	1	2
Open capsulotomy and implant	1	0	1
replacement with larger size*			
Implant reposition for symmetry	0	1	1
Revisions (local anesthesia)			
Scar revision	2	1	3
Total	8	5	13(5.8)

\*One patient had both implants replaced at the time of a right open capsulotomy for capsular contracture.

difference observed between implant styles. In women who demonstrated nipple displacement >1 cm on animation, the nipple movement was equally divided between moving up (51%) and moving down (49%). The mean nipple displacement was zero (mean, down 0.02 cm; range, down 3.96 cm to up 3.40 cm). There were no cases of the nipple moving up on one side and down on the other.

#### **Survey Results**

One hundred seventy-one patients completed the surveys (inclusion rate, 76.7%). The proportion of surveyed women with saline (61%) and silicone gel (39%) implants was similar to the total patient population (Table 3). Overall, 18% of women reported visible rippling (wrinkling) and 32% of women reported palpable rippling. Patients who reported rippling had significantly lower body mass indices (P < 0.05) and lower implant volumes (P < 0.05), on average, than the respondents who did not report rippling.

Eighty-seven percent of respondents said that their firmness was "just right," 8% found their breasts too firm, and 5% found them too soft. Most women (73%) rated their postoperative size "just right." Twenty-five percent of patients would have preferred a larger size, and 2% of women would have preferred smaller breasts. There were no significant differences comparing saline and silicone gel devices.

#### **Ultrasound Evaluation**

One hundred forty-eight women underwent ultrasound scans (66.4%). Ripples were defined as a wrinkle in the anterior implant surface (Fig. 4). Ripples along the inferior margin, which were present in the majority of women, were not counted. A fold represented a deeper crease with shell-touching-shell (Fig. 5). Ripples were detected in 37 women, including 24% of patients with saline implants and 27% of women with silicone gel implants (Table 4). In 30 women, the ripples were found bilaterally (81%). Folds were detected in 10% of women with saline implants and 7% of women with silicone gel implants and were bilateral in 2 cases. There was no significant difference in the incidence of ripples or folds comparing saline and silicone gel devices. No implant leaks or ruptures were detected.

The mean body mass index for women who had rippling and folds was significantly lower (P < 0.05) on average (21.3 versus 22.8 kg/m<sup>2</sup>) than women without rippling/folds. There was no significant correlation between rippling and either follow-up time or patient age. Rippling and folds were significantly correlated (P < 0.05) with lower mean implant volumes (397 versus 435 ml for patients without ripples).

#### **DISCUSSION**

Among surveyed members of the American Society of Plastic Surgeons, 82% of respondents prefer silicone gel implants and 22% use silicone implants exclusively.<sup>1</sup> Silicone gel implants are believed to offer a more natural consistency and possibly less rippling than saline implants.<sup>2,11–14</sup> The author has counseled women for years

Tab	le	3.	Sur	vey	Data
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Characteristic	Saline, %	Silicone, %	Total, %
No. surveys	105 (61.4)	66 (38.6)	171
Age, y			
Mean	30.3	32.0	31.0
Range	18.2 - 35.9	22.1-60.8	18.2 - 60.8
Follow-up time, mo			
Mean	6.0	6.2	6.1
Range	3.0 - 36.0	3.0 - 36.0	3.0 - 36.0
Visible rippling			
No	82 (78.1)	58 (87.9)	140 (81.2)
Yes	23(21.9)	8 (12.1)	31 (18.1)
Palpable rippling			
Ňo	66(62.9)	50(75.8)	116(67.8)
Yes	39(37.1)	16(24.2)	55(32.2)
Does wrinkling bother you?			
No	19(18.1)	10(15.2)	29 (17.0)
Yes	11(10.5)	5(7.6)	16(9.4)
A little	11(10.5)	2(3.0)	13(7.6)
No wrinkling	64(60.9)	49(74.2)	113(66.0)
Breast firmness			
Just right	92 (87.6)	57(86.4)	149 (87.1)
Too firm	9 (8.6)	5(7.5)	14(8.2)
Too soft	4(3.8)	4(6.1)	8(4.7)
Look natural?			
No	2(1.9)	2(3.0)	4(2.3)
Yes	98(93.3)	60 (90.9)	158 (92.4)
No, but I wanted fake	5(4.8)	4(6.1)	9(5.3)
Size			
Just right	76(72.4)	49(74.2)	125(73.1)
Prefer larger	27(25.7)	16(24.2)	43 (25.1)
Prefer smaller	2(1.9)	1(1.5)	3(1.8)
Scars well hidden			
No	6(5.7)	7(10.6)	13(7.6)
Yes	99(94.3)	59(89.4)	158(92.4)
Implants at right level			
Yes	94(89.5)	56(84.8)	150 (87.7)
Too high	3(2.9)	7(10.6)	10(5.8)
Too low	8 (7.6)	3(4.5)	11(6.4)
Deflation or known leak			
No	105(100.0)	66(100.0)	171 (100.0)
Yes	0(0.0)	0(0.0)	0(0.0)
Would you do it again?			
No	1(1.0)	1(1.5)	2(1.2)
Yes	104 (99.0)	65(98.5)	169(98.8)
Choose same implants?			
No (silicone instead)	12(11.4)	0 (0.0)	12(7.0)
Yes	93 (88.6)	66(100.0)	159(93.0)
Result rating (1–10)*			
Mean	9.3	9.3	9.3
Median	10	10	10
Range	6-10	6-10	6-10

\*Patients were asked to rate their result on a scale of 1 (worst) to 10 (best).

that silicone gel implants offer these esthetic advantages and the likelihood of reoperation for rupture is lower because gel implants do not deflate. Of course, saline is completely absorbed in the event of a leak. These considerations are weighed against the disadvantages of silicone gel—greater cost and the fact that rupture is unlikely to be detected without imaging studies.

Handel et al<sup>13</sup> compared textured gel implants with textured saline implants, finding an advantage for textured gel implants. Textured saline implants are known to be susceptible to rippling.<sup>13–15</sup> Textured surfaces may affect the palpability of breast implant shells.<sup>16</sup> Tissue adherence to the implant may increase the rippling risk.<sup>17</sup> Handel et al<sup>13</sup> did not compare smooth gel and smooth saline implants. This comparison takes on new importance as most US surgeons now prefer smooth devices<sup>1</sup> because of

the link between texturing and breast implant–associated anaplastic large-cell lymphoma (BIA-ALCL).<sup>18</sup>

Although it is considered a complication, rippling results from normal deformation of a breast implant when it is positioned in the flat, upright, or lateral position.<sup>17</sup> Subpectoral implant placement is a well-known method to maximize soft tissue cover.<sup>17</sup> Suboptimal implant filling increases the risk of rippling.<sup>17</sup> Consequently, most plastic surgeons fill saline implants to the maximum recommended fill volume. "Gel fill" refers to the amount of silicone gel placed within a given shell size.<sup>16</sup> Allergan Natrelle Inspira implants (Allergan plc, Dublin, Ireland) have a high gel fill ratio.<sup>16</sup> However, clinical data substantiating any clinical advantages are lacking.<sup>16</sup>

Gel implants that feature greater cohesivity (ie, more silicone cross-linking)<sup>16</sup> are believed to cause less rippling, at the expense of greater implant firmness.<sup>16,17</sup> Surprisingly, rippling and folds occur even in the presence of the most cohesive "form stable" implant styles.<sup>17,19,20</sup>

More cohesive gel implants are designed to minimize gel bleed.<sup>17</sup> With increased cohesiveness to reduce gel bleed and (possibly) reduce rippling, the advantage of a more natural consistency using silicone gel may be lost.<sup>8,21</sup> A saline implant is softer and feels more natural than an overly firm silicone gel implant. Similar to the findings of an earlier outcome study,<sup>21</sup> survey results show that excessive firmness is more likely to be an issue for women (8.2%) than excessive softness (4.7%).

Rippling rates increase over time.<sup>22</sup> In a large retrospective study, Codner et al<sup>23</sup> reported a rippling rate of 7.1%, with no significant difference in rippling rates comparing saline (482 patients) and silicone gel (330 patients) implants. However, in a subgroup comparison of underweight patients (body mass index  $<18.5 \text{ kg/m}^2$ ) treated with subglandular implants, an association was found between rippling and saline implants (P = 0.045). Similar to the present study, the risk of rippling decreased with greater body mass indices. Saline implant deflation occurred in 2.7% of patients reported by Codner et al.<sup>23</sup> Only 2 saline implant deflations occurred in the present study (0.9%). However, the follow-up times were short, all <3 years. In a 10-year clinical study by the author,<sup>24</sup> with a large number of patients implanted with saline devices (490 patients), 4 patients returned with deflations (0.8%).

Walker et al<sup>25</sup> mailed questionnaires to patients with Allergan Natrelle saline implants. The authors reported wrinkling in 13.7% of patients and implant palpability/ visibility in 12.1% of patients. The authors compared these figures with data (1.2% and 1.6%, respectively) for women treated with Inamed (now Allergan) silicone gel implants,<sup>26</sup> finding an advantage for silicone implants in terms of "look and feel." However, 69.5% of the saline implants were textured versus 41.0% of the silicone gel implants. Moreover, the authors compared patientreported survey responses with surgeon-reported data from a separate study. To the author's knowledge, there is no published "apples to apples" comparison of rippling rates and patient-reported outcomes between women implanted with subpectoral smooth saline implants and smooth silicone gel devices.8



**Fig. 4.** This 31-year-old woman underwent primary subpectoral breast augmentation using 425 ml Mentor MemoryGel silicone gel implants. Her sonogram 3 months after surgery showed rippling of the left breast implant.



**Fig. 5.** This 52-year-old woman underwent primary subpectoral breast augmentation using Mentor smooth, round Moderate Plus Profile saline implants filled to their maximum capacity of 360 ml. Her sonogram, performed 3 months after surgery, shows a fold in the right breast implant.

Plastic surgeons are well aware that most women, when holding both implants in their hands in the office, prefer silicone gel. However, in vivo, especially in a subpectoral pocket, this difference may be more difficult to discern, particularly in a woman who has a moderate breast volume already.<sup>8</sup> Saline implants do have a number of advantages compared with silicone gel.<sup>27</sup> The incision is shorter.<sup>2</sup> A rupture is clinically obvious, and the leaked saline poses no health risk.<sup>23,27</sup> By contrast, detection of a silicone gel implant rupture often requires (expensive) magnetic resonance imaging or a high-resolution ultrasound examination.<sup>3,27</sup> Even these studies are not always reliable.<sup>2,28</sup> The absence of silicone gel makes silicone bleed a non-issue, whether or not such leakage is implicated in systemic

Characteristic	Saline, %	Silicone, %	Total, %
No. scans Rippling	88	60	148
No Yes	$ \begin{array}{c} 67 & (76.1) \\ 21 & (23.9) \end{array} $	44(73.3) 16(26.7)	$111 (75.0) \\ 37 (25.0)$
Folds No Yes	79 (89.8) 9 (10.2)	56 (93.3) 4 (6.7)	135 (91.2) 13 (8.8)

**Table 4. Ultrasound Findings** 

disease. There are few reliable data regarding capsular contracture rates,<sup>29,30</sup> although some authors report an advantage for saline implants.<sup>27</sup> Saline implants are also much less expensive than silicone gel.<sup>27</sup> A recent study found greater cost-effectiveness for saline implants used in breast reconstruction.<sup>31</sup>

The advantages of saline as a filler at the time of redo surgery are seldom discussed in the literature.<sup>8,27,32</sup> This is a highly relevant issue, as 10-year core studies find that between 29.7% and 36.5% of women return for redo surgery.<sup>27,33,34</sup> A capsular contracture is more easily treated in the presence of a saline implant, by open capsulotomy.<sup>32</sup> There is usually no need for a capsulectomy, site change, or implant exchange (or acellular dermal matrix), making the revision surgery much less expensive and easier for patients.<sup>32</sup> A thin capsule around a saline implant is gradually absorbed after explantation.<sup>35,36</sup> By contrast, capsules around silicone gel implants are exposed to silicone bleed, which can increase inflammation within the capsule<sup>36</sup> and increase the risk of capsular contracture.32,37,38 Silicone granulomas may develop.<sup>39,40</sup> Capsules can become thickened and calcified<sup>39-41</sup> and are unlikely to be absorbed.<sup>41,42</sup> A capsulectomy may be indicated,<sup>39</sup> with its attendant morbidity<sup>39</sup> and additional cost both for surgery and pathologic examination of the capsule. A more innocuous effect on the capsule around a saline implant is an underappreciated advantage of these devices.48

Both BIA-ALCL and Breast Implant Illness have heightened the awareness of possible immunologic effects of foreign bodies.<sup>43–46</sup> A particle theory for BIA-ALCL is gaining recognition.<sup>43,44</sup> Silicone shedding from the surface is eliminated by choosing smooth implants. Silicone bleed through the elastomer shell is eliminated with saline implants, making smooth saline implants a reasonable choice.

Patient satisfaction is the major determinant of success in cosmetic surgery.<sup>47</sup> Patient satisfaction rates are >86% for both saline and silicone gel implants.<sup>21,25,27,48-50</sup> The implants look the same in patients.<sup>11</sup> However, silicone gel implants are much more profitable for breast implant companies and are more heavily promoted.<sup>8</sup> Sientra Inc. (Santa Barbara, Calif.) does not even manufacture saline implants.<sup>8</sup>

Survey responses were notable for breast size assessments. Despite an average implant volume of 426 ml, 25% of women would have preferred a larger size. Only 2% of respondents would have preferred a smaller size. A preference for a larger size was also found in a previous outcome study,<sup>21</sup> challenging the conventional wisdom to be conservative in implant sizing. A significant correlation

between larger implant volumes and patient satisfaction has been documented.  $^{21,51}$ 

The surveys found a higher rate of rippling among women treated with saline implants, but the difference was not significant. One must consider that women with saline implants are already advised that they have a higher risk of rippling, so there may be a degree of bias in their assessments. This prejudice is less likely to affect ultrasound examinations. It makes sense that leaner women, with less subcutaneous fat, are more likely to have rippling, reflected in both survey responses and ultrasound findings.

Despite the similar findings regarding rippling, there may be less tangible advantages of silicone gel implants. Although the difference has not been quantitated, women who have had both types of implants frequently report a more natural consistency for silicone gel implants (in the absence of a capsular contracture or highly cohesive gel). In the event of a leak, there is likely to be no change in shape and size, and no unexpected and inconvenient return to the surgeon for implant replacement. Most women with some degree of silicone bleed are asymptomatic and unaware of it. The clinical importance of a small undetected intracapsular silicone bleed remains unknown.<sup>43</sup>

In performing the outcome study, an ad hoc survey was chosen.<sup>7</sup> Although more comprehensive surveys exist, they are of limited value when comparing specific surgical parameters of interest. Succinct questions contained on a single page (see survey, Supplemental Digital Content 1, which displays the breast implant survey, http://links.lww.com/PRSGO/B406) lend themselves to high patient compliance and ease of data interpretation and comparison with previous studies.<sup>7,21</sup> When surveys are done in person by an interviewer, patients are more likely to take greater interest and answer all of the questions.<sup>7,21</sup>

Most classifications of animation deformity are limited by subjectivity.52-54 Quantitating nipple movement requires exact matching of standardized images, facilitated by imaging software. Spear et al<sup>4</sup> reported that distortion of the breast during pectoralis muscle contraction is common (77.5% of women) after a subpectoral breast augmentation but is rarely severe. These surgeons released the inferior attachments of the pectoralis along the inframammary fold but left the sternal fibers intact.<sup>4</sup> Kim et al<sup>5</sup> recently evaluated nipple movement and area of skin contour irregularity in subpectoral tissue expander/ implant-based breast reconstructions. Animation deformity tends to be more common (100% in one study<sup>54</sup>) and more severe in breasts reconstructed with subpectoral implants because of the loss of the glandular tissue covering the implants and closer approximation of the pectoralis muscle to the skin.<sup>55</sup> In the present study, none of the patients complained about animation deformity, including fitness enthusiasts. The author prefers to release the muscle very cautiously (to avoid symmastia) from its origin along the lower sternal border, in addition to its inferior origin along the inframammary fold.<sup>7,8</sup> This maneuver allows the muscle to retract superiorly,<sup>4</sup> reducing muscle tension over the implant. A surprising finding was that nipple movement was not predominantly upward as expected, but equally as often downward. In patients with >1 cm of nipple displacement, there was no overall net movement in either direction. It is possible that the additional muscle release creates a more balanced effect on nipple level during pectoralis contraction.

### Limitations of the Study

This study is limited to smooth saline implants and minimally cohesive smooth silicone gel implants implanted subpectorally. The maximum follow-up time was 3 years. It is likely that some patients will go on to develop rippling in the future.<sup>22</sup> A minimum 3-month time period was chosen because breast swelling has largely resolved at this time.<sup>56</sup> Longer follow-up times are generally preferred but come at the cost of a reduced inclusion rate.<sup>56,57</sup> Higher inclusion rates (ie, fewer patients lost to follow-up) reduce sampling bias.<sup>4,58</sup>

#### Strengths of the Study

This comparative prospective level II study includes objective measurements on matched photographs, a reliable technology (ultrasound) for detection of implant ripples and folds, and inclusion of all-important patientreported outcomes. Because the author performed the operations using the same method in the same facility, over the same time period, confounders are avoided. The author has no financial conflicts with breast implant manufacturers.

# CONCLUSIONS

Outcome surveys and ultrasound scans show that rippling rates are similar when comparing saline and silicone gel implants. Animation deformities tend to be minor and well-tolerated.

Patients need to be properly informed of the pros and cons so that they can participate in the decision-making process. Plastic surgeons should be prepared to insert either device, in accordance with the patient's preference.

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# ACKNOWLEDGMENTS

The author thanks Christina Staab, RT, for data collection and sonograms and Jane Zagorski, PhD, for statistical analyses.

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