Natrelle Style 410 Form-Stable Silicone Breast Implants: Core Study Results at 6 Years

G. Patrick Maxwell, MD; Bruce W. Van Natta, MD; Diane K. Murphy, MBA; Araceli Slicton, BA; and Bradley P. Bengtson, MD

Abstract

Background: The Natrelle Style 410 shaped, form-stable silicone gel implant (Allergan, Inc; Irvine, California) has been the subject of a pivotal study that supports potential US Food and Drug Administration approval of the device. The 3-year results of this study were reported previously.

Objectives: The authors update the safety and effectiveness findings for the Natrelle Style 410 implants through 6 years of study.

Methods: This prospective, nonrandomized, multicenter study included 941 patients (492 primary augmentations, 156 revision-augmentations, 225 primary reconstructions, and 68 revision-reconstructions). Since the original 3-year report, follow-up visits have been conducted annually. Kaplan–Meier risk rates were calculated for local complications, reoperations, and explantations. One-third of the subjects were enrolled in the magnetic resonance imaging (MRI) cohort and underwent biannual MRI rupture screening. Effectiveness was measured by subject satisfaction on a 5-point scale.

Results: As expected after breast implantation, capsular contracture (CC) was one of the most common complications, with 6-year risk rates of 4.6% for augmentation, 6.9% for revision-augmentation, 10.7% for reconstruction, and 18.3% for revision-reconstruction. The rates for CC among augmentations and revision-augmentations were significantly lower with the Natrelle 410 implants than with other standard gel implants. The rupture rate (confirmed plus suspected) across all cohorts was 6.4% by subject and 3.8% by implant. The most common reasons for reoperation were style or size change (augmentation), implant malposition (revision-augmentation), scarring (reconstruction), and CC (revision-reconstruction). The satisfaction rate exceeded 80% in all cohorts.

Conclusions: These fifth-generation, form-stable implants represent another option to achieve desired aesthetic outcomes with minimal complications.

Level of Evidence: 2

Keywords
breast implants, silicone gel, patient satisfaction, reoperation, cohesive gel implants

Accepted for publication January 26, 2012.

The Style 410 shaped, form-stable silicone gel implant was introduced in Europe in 1993. Its “form stability” relates to increased cohesivity or stiffness of the gel filler, allowing the implant to maintain its shape in the upright position and avoiding upper pole fold-over and shell collapse. Since the original design of the form-stable implant, many shapes and sizes have been created; these are referred to collectively as Style 410 implants. These devices have gained widespread use throughout the world and have been assessed prospectively in the United States, since February 2001, in an Investigational Device Exemption study. The initial 3-year data from this study were published previously. The present report updates the clinical outcomes through 6 years of study.

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This ongoing, prospective, 10-year, multicenter study was designed to examine the safety and effectiveness of Natrelle Style 410 form-stable, silicone-filled breast implants (Allergan, Inc; Irvine, California) for augmentation, reconstruction, and revision procedures. Approval was obtained from the appropriate Institutional Review Board for each of the 48 investigational sites. All subjects provided informed consent prior to enrollment. The study was registered at www.clinicaltrials.gov (NCT00690339).

The study population comprised 941 women (representing 492 primary augmentations, 156 revision-augmentations, 225 primary reconstructions, and 68 revision-reconstructions). One-third of the subjects were enrolled in the serial magnetic resonance imaging (MRI) cohort. The study design, methodology, inclusion/exclusion criteria, subject demographics, baseline characteristics, and early safety and effectiveness results were previously published.1,2 The present report focuses on the 6-year results.

Follow-up visits occurred at 0-4 weeks, 6 months, and annually thereafter for safety and effectiveness evaluations. Subject satisfaction, rated on a 5-point scale from 1 (definitely dissatisfied) to 5 (definitely satisfied), was the primary measure of effectiveness at 6 years. Safety analyses included Kaplan–Meier risk rates for local complications, reoperations, and implant replacement or removal. Subjects in the serial MRI cohort underwent an MRI following the 1-, 3-, and 5-year follow-up visits to determine rupture risk rates. MRI results were read separately by a radiologist from the local MRI facility and an independent radiologist who reviewed every MRI in the study. The worse-case rupture status by either reviewer was used in

Table 1. Kaplan–Meier Key Risk Rates and 95% Confidence Intervals for the 6-Year Study

<table>
<thead>
<tr>
<th>Complication</th>
<th>Augmentation (n = 492)</th>
<th>Revision-Augmentation (n = 156)</th>
<th>Reconstruction (n = 225)</th>
<th>Revision-Reconstruction (n = 68)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Key risk rates</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Reoperation</td>
<td>19.4 (16.1-23.4)</td>
<td>35.1 (27.9-43.6)</td>
<td>43.1 (36.7-50.0)</td>
<td>33.7 (23.6-46.6)</td>
</tr>
<tr>
<td>Implant removal with replacement</td>
<td>9.6 (7.2-12.8)</td>
<td>20.2 (14.4-28.0)</td>
<td>23.7 (18.3-30.2)</td>
<td>20.1 (12.2-32.1)</td>
</tr>
<tr>
<td>Implant removal without replacement</td>
<td>0.7 (0.2-2.1)</td>
<td>3.6 (1.5-8.5)</td>
<td>4.6 (2.4-8.7)</td>
<td>1.9 (0.3-12.6)</td>
</tr>
<tr>
<td>Implant rupture</td>
<td>5.0 (2.4-10.2)</td>
<td>5.0 (1.3-18.4)</td>
<td>7.5 (3.2-17.2)</td>
<td>14.3 (4.8-38.0)</td>
</tr>
<tr>
<td>Capsular contracture III/IV</td>
<td>4.6 (3.0-7.1)</td>
<td>6.9 (3.8-12.5)</td>
<td>10.7 (7.1-16.0)</td>
<td>18.3 (10.5-30.8)</td>
</tr>
<tr>
<td><strong>Additional risk rates that occurred in ≥ 2.0% of patients</strong></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Implant malposition</td>
<td>2.3 (1.3-4.2)</td>
<td>6.1 (3.2-11.3)</td>
<td>2.9 (1.3-6.3)</td>
<td>4.9 (1.8-14.4)</td>
</tr>
<tr>
<td>Swelling</td>
<td>2.7 (1.5-4.7)</td>
<td>2.8 (1.0-7.2)</td>
<td>3.8 (1.9-7.5)</td>
<td>3.2 (0.8-12.4)</td>
</tr>
<tr>
<td>Breast pain</td>
<td>2.7 (1.5-4.7)</td>
<td>2.1 (0.7-6.3)</td>
<td>4.2 (2.1-8.2)</td>
<td>4.8 (1.6-14.3)</td>
</tr>
<tr>
<td>Infection</td>
<td>1.7 (0.9-3.4)</td>
<td>2.1 (0.7-6.3)</td>
<td>4.8 (2.6-8.7)</td>
<td>4.5 (1.5-13.3)</td>
</tr>
<tr>
<td>Seroma/fluid accumulation</td>
<td>1.4 (0.6-3.0)</td>
<td>2.4 (0.8-7.5)</td>
<td>1.4 (0.5-4.3)</td>
<td>6.2 (2.4-15.8)</td>
</tr>
<tr>
<td>Hypertrophic/abnormal scarring</td>
<td>1.1 (0.5-2.7)</td>
<td>2.7 (1.0-7.1)</td>
<td>4.8 (2.6-8.7)</td>
<td>3.2 (0.8-12.3)</td>
</tr>
<tr>
<td>Hematoma</td>
<td>1.1 (0.4-2.5)</td>
<td>2.0 (0.8-6.0)</td>
<td>1.0 (0.3-4.0)</td>
<td>0</td>
</tr>
<tr>
<td>Delayed wound healing</td>
<td>1.1 (0.4-2.6)</td>
<td>1.3 (0.3-5.1)</td>
<td>0.5 (0.1-3.3)</td>
<td>2.9 (0.7-11.3)</td>
</tr>
<tr>
<td>Asymmetry</td>
<td>0.8 (0.3-2.2)</td>
<td>5.7 (2.9-11.2)</td>
<td>9.1 (5.9-13.8)</td>
<td>15.1 (8.1-27.2)</td>
</tr>
<tr>
<td>Wrinkling/rippling</td>
<td>0.7 (0.2-2.0)</td>
<td>2.7 (1.0-7.1)</td>
<td>3.1 (1.4-6.9)</td>
<td>7.7 (3.3-17.4)</td>
</tr>
<tr>
<td>Redness</td>
<td>0.7 (0.2-2.0)</td>
<td>0</td>
<td>0.9 (0.2-3.7)</td>
<td>5.1 (1.6-15.3)</td>
</tr>
<tr>
<td>Upper pole fullness</td>
<td>0</td>
<td>1.4 (0.4-5.6)</td>
<td>4.2 (2.2-7.8)</td>
<td>1.5 (0.2-10.1)</td>
</tr>
</tbody>
</table>

All values are percentages.
the analyses, and all suspected ruptures were included in the rupture rate, whether or not they were confirmed via surgery.

**RESULTS**

At the start of the study, the median age range across cohorts was 36 to 52 years, and the overall age range was 18 to 80 years. Subjects were predominantly Caucasian (90.5%, 94.9%, 90.7%, and 94.1% for augmentation, revision-augmentation, reconstruction, and revision-reconstruction, respectively) and married (59.8%, 69.2%, 71.6%, and 73.5%, respectively).

Of the 4 device styles included in the study (full or moderate height and projection), the full-height moderate-projection (FM) implant was used most often for augmentation (49.3%), and the full-height full-projection (FF) implant was the most common for the other procedures (37.1%, 40.2%, and 62.5%, respectively). For all cohorts, partial submuscular placement was most common: 80.5% for augmentation, 65.8% for revision-augmentation, 59.7% for reconstruction, and 59.8% for revision-reconstruction.

Follow-up rates at 6 years were 72.9% for augmentation subjects, 75.5% for revision-augmentation, 81.9% for reconstruction, and 81.0% for revision-reconstruction. Among the MRI subgroup, compliance rates for the 5-year MRI (the third in the series) were 82.6% for augmentation, 81.6% for revision-augmentation, 87.5% for reconstruction, and 90.5% for revision-reconstruction.
Safety

Key complication Kaplan–Meier risk rates are provided in Table 1. As expected after breast implantation, capsular contracture (CC) was one of the most common complications. The 6-year cumulative risk rates were 4.6%, 6.9%, 10.7%, and 18.3% for augmentation, revision-augmentation, reconstruction, and revision-reconstruction, respectively. The overall rupture rate across all cohorts (suspected as well as confirmed ruptures) was 6.4% by subject and 3.8% by implant. Among the augmentation cohort, the rates for complications aside from CC and rupture were below 3%. In the revision-augmentation cohort, the only other complications that occurred in more than 3% of patients were implant malposition (6.1%) and asymmetry (5.7%). The only other complication in reconstruction patients that exceeded 5% was asymmetry (9.1%). For revision-reconstruction procedures, the most common additional complications were asymmetry (15.1%) and wrinkling/rippling (7.7%).

Reoperation rates were 19.4%, 35.1%, 43.1%, and 33.7% for augmentation, revision-augmentation, reconstruction, and revision-reconstruction, respectively. The primary reasons for reoperation and explantation are provided in Table 2. The most common reasons for reoperation and explantation were subject request for a style or size change (augmentation), implant malposition (revision-augmentation), scarring (reconstruction), and CC (revision-reconstruction). Among all cohorts, the most common reason for explantation was subject request for a style or size change. Most subjects who underwent explantation (89%) had their implants replaced after removal, usually with a larger 410 implant.

Figure 1. (A, C) This 34-year-old woman presented for breast augmentation. (B, D) Six years after augmentation with Natrelle 410 FM, 350-g implants (Allergan, Inc.; Irvine, California).
Satisfaction
At 6 years, the percentages of subjects who were satisfied or definitely satisfied with their implants were 95.1% for augmentation, 88.8% for revision-augmentation, 94.7% for primary reconstruction, and 80.5% for revision-reconstruction. These high satisfaction rates reflect the continuity of the aesthetic results achieved with the form-stable Style 410 implants.

Clinical results are shown in Figures 1-3.

DISCUSSION

Style 410 represents a 12-cell matrix array of form-stable, shaped, silicone gel implants, comprising a total of 205 subtypes. The implants are named by the x-axis (height) as the first letter and the y-axis (projection) as the second letter (eg, FM denotes full height and moderate projection; Figure 4). Implants from 4 of the 12 cells were utilized in this study (MM, FM, MF, and FF). The shells of all Style 410 implants have a Biocell (Allergan, Inc; Irvine, California) surface, an “aggressive open-pore texturization” with an irregular distribution of depression, and a pore diameter of 100 to 600 μm (average, 300 μm).3 These shaped, form-stable implants are referred to as fifth-generation silicone gel breast implants. They differ from the currently FDA-approved fourth-generation silicone breast implants, which are round and composed of a less stiff, non-form-stable silicone gel.4,5

The large number of available implant configurations in the Style 410 matrix and their design characteristics provide more options for surgeons and their patients. However,
the favorable characteristics of these new implants require surgeons to utilize more specific patient evaluation, implant selection criteria, surgical planning, operating technique, and postoperative care. When doing so, experienced surgeons may achieve unprecedented clinical outcomes with Style 410 implants.6-8 Although the present study offers just the initial clinical experience of US surgeons with this implant, its outcomes to date are superior to those of 6-year FDA clinical trials of fourth-generation implants in several important areas.9,10

The most important outcome in the Style 410 pivotal study is the relatively low rate of CC, particularly in comparison to other published 6-year data from core studies in augmentation and revision-augmentation patients. In the present study, the 6-year risk rate for CC was 4.6% (95% CI: 3.0%-7.1%) in augmentation subjects, compared with 9.8% (95% CI: 7.6%-12.7%) for Mentor gel implants (Santa Barbara, CA) and 14.8% (95% CI: 11.7%-18.5%) for Allergan standard gel implants.9,10 Among revision-augmentation patients, the 6-year CC rate for Natrelle Style 410 implants was 6.9% (95% CI: 3.8%-12.5%) versus 22.4% (95% CI: 16.3%-30.4%) for Mentor and 20.5% (95% CI: 14.5%-28.6%) for Allergan standard gel implants. The lower rate of CC may relate to the Biocell texture being pushed by the “stiffer” gel into the precise and atraumatically prepared pocket to facilitate “tissue adherence,” “immobility with softness,” and a “hand-in-glove” fit.11,12

The snug fit of the implant in the precisely dissected pocket, along with friction from the textured surface, also may contribute to the low rate of implant malposition (2.3% of augmentation patients). Our low incidence of CC and malposition with the Style 410 implants supports the findings of earlier reports on these devices from Canada and Europe.13-15

In non-form-stable silicone implants, visible or palpable wrinkling can be more apparent in the absence of CC. However, the present study shows the opposite: low rates
of wrinkling despite low rates of CC. Again, this is likely attributable to the stiffer, form-stable silicone gel of the Style 410 implant. The finding of low rippling and wrinkling with Style 410 in comparison to less-stiff competitive products corroborates the experience of others (Style 410 vs Mentor CPG). 16

One of the most favorable attributes of the Style 410 implant is that, in the absence of CC, the shape of the

![Figure 4](https://example.com/image4.png)

*Figure 4.* The Natrelle Style 410 matrix offers 205 implant options among 12 categories (cells), including 3 options for implant height and 4 for implant projection. Implants from 4 of these cells were used in the present study (MM, FM, MF, FF). Reprinted with permission from Bengtson BP, Van Natta BW, Murphy DK, Slicton A, Maxwell GP. Style 410 highly cohesive silicone breast implant core study results at 3 years. *Plast Reconstr Surg.* 2007;120(S1):40S-48S.

![Figure 5](https://example.com/image5.png)

*Figure 5.* (Left) The form-stable Style 410 silicone gel implant maintains its shape in the upright position. (Right) In the same position, the non-form-stable gel implant collapses to some degree because gel distribution is not maintained within the upper pole. Reprinted with permission from Bengtson BP, Van Natta BW, Murphy DK, Slicton A, Maxwell GP. Style 410 highly cohesive silicone breast implant core study results at 3 years. *Plast Reconstr Surg.* 2007;120(S1):40S-48S.

![Figure 6](https://example.com/image6.png)

*Figure 6.* MRI image of a form-stable Style 410 silicone gel implant shows that the device maintains its shape in vivo when the subject is in the prone position.
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breast is influenced by the shape of the implant because of the form-stable nature of the device (Figures 5 and 6). This breast shape-enhancing attribute, along with the vast array of matrix-cell options, enables the surgeon to more favorably individualize patient outcomes when all other aspects of the breast augmentation process are appropriately managed (Figures 1-3). The same is not necessarily true for non-form-stable implants, in which the breast defines the implant shape more so than the implant defines the breast shape.

The firmness of the silicone gel is determined by the extent of cross-linking of silicone polymers during the manufacturing process. When filler cross-linking occurs to the degree that the silicone gel implant will maintain its dimensions and form (ie, gel distribution within the shell) both in vivo and ex vivo, the cohesive gel implant is considered to be form stable (Figures 5 and 6).

Technology exists to measure the cohesivity (or stiffness) of the silicone gel within the implant shell. When the stiffness of the gel of commercially available devices from the 2 leading US manufacturers are represented graphically (Figure 7), clear and distinct differences are observed in cohesivity between form-stable and non-form-stable devices. Moreover, the measurements among form-stable gel devices vary greatly, with Style 410 (Natrelle TruForm 3; last bar of Figure 7) being the stiffest. These differences obviously will affect clinical outcomes.

The maintenance of gel distribution within the shell, especially in the upright position, helps to preserve the implant shape and is the most important attribute of form stability. However, the term is not absolute. In several cases, form change or shell rippling has been detected by MRI when the subject is in the prone position. The changes in form generally are not clinically significant and do not minimize the importance of this device-distinguishing attribute.

CONCLUSIONS

These next-generation, form-stable Style 410 implants offer surgeons and patients more options for attaining desired aesthetic outcomes. This prospective, nonrandomized, multicenter study of 941 subjects over 6 years of follow-up confirms that the devices are associated with low complication rates and a high level of subject satisfaction.

Disclosures

Dr Maxwell is a paid consultant, royalty recipient, and stockholder with Allergan, Inc, the manufacturer of the products discussed in this study. Drs Bengtson and Van Natta are paid consultants for Allergan and received research support for this study. Ms Murphy and Ms Slicton are Allergan employees and stockholders.

Funding

Allergan designed and funded the study, and performed statistical analysis of the data.

REFERENCES

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