Role of Macrotextured Shaped Extra Full Projection Cohesive Gel Implants in Primary Aesthetic Breast Augmentation

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Abstract

Background: Extra full projection implants are used in a select group of aesthetic breast surgery patients. Their use is selective enough that they have not been included in long term manufacturer studies and the indications for their use have attracted much debate. Only a handful of studies have reported the outcomes from implantation of these devices.

Objectives: We review our experience of using extra full projection anatomically shaped macrotextured silicone gel implants discussing our rationale, indications, and results.

Methods: All patients undergoing primary aesthetic breast surgery with extra full projection anatomical implants by the first author (P.M.) over a seven-year period (January 2009 to December 2015) were included.

Results: Three hundred and ten female patients had 620 macrotextured extra full projection anatomically shaped cohesive silicone gel breast implants of mean volume 338 cc (range, 195-615 cc) placed over the seven-year period. All of them had at least a 6-months follow up. There were 39 complications (12.6%) at an average follow up of 12.3 months, including implant malposition/rotation (5.4%), capsular contracture (2.6%), and bottoming out (1.6%). A total of 41 patients (13.2%) were reoperated, of which 30 (9.7%) were due to a complication and 11 (3.5%) because of patient choice. Most of the complications were in the initial part of the case series.

Conclusions: The outcomes following the use of extra full projection implants in a carefully selected group of patients are comparable in the short term to those reported for other shaped implants and complications appear to decrease with experience.

Level of Evidence: 4

Breast augmentation is one of the most common aesthetic surgery procedures.1,2 In order to achieve predictable and stable results, a detailed preoperative planning is required with an appropriate patient and implant choice. Although the commercially available breast implants have standard shapes and volumes, there is a marked variation in patient morphology (eg, asymmetry in size, shape, volume of the gland, as well as size and shape of the chest) that these implants need to address. Many patients attend preoperative consultation with specific requests (eg, fuller upper pole, large volume) that the surgeons need to consider in their preoperative planning. Many of these clinical scenarios can be addressed with commonly available implants.

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and known protocols. However, if the chest wall morphology and soft tissue characteristics fall outside a certain range, the “standard” set of implant choices may become inadequate.

The use of extra full projection implants has been a subject of debate due to empirical concerns about their effects on adjacent gland and soft tissue. Extra full projection implants have not been investigated in the manufacturers’ long term studies and only a few authors have described their use in literature.

We present our seven-year review of aesthetic breast augmentation procedures carried out by a single surgeon (P.M.) using macrotextured extra full projection shaped form stable cohesive silicone gel implants in selected cases. Our aim was to evaluate their use in primary breast augmentation and discuss potential indications, results, and postoperative complications.

METHODS

This is a single center, single surgeon retrospective review of all patients who underwent primary breast augmentation with extra full projection implants (Natrelle 410 shaped gel implants, Allergan Inc., Irvine, CA) at our facility between January 2009 and December 2015. All patients were counselled in accordance with the Declaration of Helsinki guidelines and written informed consent was obtained from them preoperatively.

Data were collected on patient demographics, indication for surgery, surgical technique, type of implant, length of follow up, number and type of complications, and incidence of reoperation. Patients who had an augmentation mastopexy procedure or those with a follow-up less than 6 months, were excluded.

Patient Selection

Patients were selected to receive extra full projection implants by consideration of soft tissue characteristics of the existing breast, chest wall anatomy, and desire towards a specific shape and volume.

Soft tissue characteristics included presence of lax skin and/or some degree of ptosis, constricted lower pole, and tuberous breast deformities. Considerations in chest wall anatomy included a petite frame with narrow chest (in patients who wanted as much volume as possible, as discussed later). Extra full projection implants were also chosen for patients who requested greater projection or a bigger breast volume and had a soft tissue envelope to support it. Relative contraindication for the use of extra full projection implants were patients with excessively tight skin envelope.

Surgical Technique

All procedures were performed by the first author (P.M.) through an inframammary fold (IMF) incision using a dual plane technique. The IMF incision location was chosen according to the method previously described from our institution. A subglandular dissection with electrocautery was performed, to an extent that was determined by the type of dual plane technique chosen. The costal attachments of pectoralis major along the IMF were then divided, followed by dissection in the submuscular plane. The pockets were irrigated with a solution made of 300 mL of clindamycin in 200 mL of normal saline and the implants were also soaked into it before insertion. The surgeon changed gloves before placement of each implant. No drains were used for the implant cavity and the wound was closed in 4 layers.

RESULTS

A total of 310 female patients had primary breast augmentation with 620 extra full projection anatomically shaped devices with the technique described above. All patients were operated on by the first author (P.M.) between January 2009 and December 2015.

The average age at surgery was 30.8 years (range, 18-56 years), the average body mass index (BMI) was 21.3 kg/m² (range, 15.9-30.1 kg/m²), and the patients had an average of 1.1 children at the time of surgery. Eighty-seven patients described themselves as having ‘A’ cup size, 191 as a ‘B’ cup size, and 32 patients as a ‘C’ cup size. Forty-three patients admitted to the use of tobacco (average, 8.9 cigarettes/day) and 24 patients had at least one medical comorbidity (most commonly asthma and hypothyroidism).

All implants used were extra full projection Allergan Style 410 (Natrelle 410 shaped gel implants, Allergan Inc., Irvine, CA). Of the 620 implants used 28 (4.5%) were full height, 512 (82.6%) were medium height, and 80 (12.9%) were low height. The mean implant volume was 338 cc (range, 195-615 cc), rounded to the nearest cc.

The patients had a mean follow-up of 12.6 months (range, 6-72 months). During the follow up period, 39 patients (12.6%) developed a postoperative complication (Table 1). In total, 41 patients (13.2%) were reoperated (Table 2) of which 30 were reoperated due to a complication, 10 patients were unsatisfied with the volume and one patient requested explantation. Of the 17 malrotated implants, 1 (5.9%) was full height, 12 (75%) were medium, and 4 (23.5%) were low height. At the time of reoperation, 17 patients underwent a change of implant (mean new volume, 446 mL; range, 315-525 mL). One secondary mastopexy was performed after an early capsular contracture developed with an FX 615 implant.
Table 1. Complications

<table>
<thead>
<tr>
<th>Complication</th>
<th>No. of patients (%)</th>
<th>Right</th>
<th>Left</th>
<th>Bilateral</th>
<th>Time to complication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rotation</td>
<td>17 (5.4%)</td>
<td>5</td>
<td>11</td>
<td>1</td>
<td>Range: 3-34 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Average: 9.6 months</td>
</tr>
<tr>
<td>Capsular contracture</td>
<td>8 (2.6%)</td>
<td>2</td>
<td>5</td>
<td>1</td>
<td>Range: 10-45 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Average: 20.8 months</td>
</tr>
<tr>
<td>Bottoming out</td>
<td>5 (1.6%)</td>
<td>3</td>
<td>2</td>
<td>0</td>
<td>Range: 6-39 months</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Average: 14.2 months</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Outcome: 4, resutured; 1, resuture and net</td>
</tr>
<tr>
<td>Double bubble</td>
<td>4 (1.3%)</td>
<td>1</td>
<td>1</td>
<td>2</td>
<td>Range: 1-34 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Average: 17 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Outcome: 3, not corrected; 1, resuture and fat graft</td>
</tr>
<tr>
<td>Hematoma</td>
<td>4 (1.3%)</td>
<td>1</td>
<td>3</td>
<td>0</td>
<td>Range: 0-28 days</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Average: 11.7 days</td>
</tr>
<tr>
<td>Seroma</td>
<td>1 (0.3%)</td>
<td>0</td>
<td>1</td>
<td>0</td>
<td>9 months</td>
</tr>
</tbody>
</table>

Table 2. Reasons for Reoperation/Intervention

<table>
<thead>
<tr>
<th>Reasons for reoperation</th>
<th>No. of patients (%)</th>
<th>Type of reintervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant malposition/rotation</td>
<td>17 (5.4%)</td>
<td>Neo-submuscular pocket and implant exchange</td>
</tr>
<tr>
<td>Patient choice</td>
<td>11 (3.5%)</td>
<td>Larger implants (9 cases)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Smaller implant (1 case)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Explantation (1 case)</td>
</tr>
<tr>
<td>Bottoming out</td>
<td>5 (1.6%)</td>
<td>Fixation of the IMF</td>
</tr>
<tr>
<td>Capsular contracture</td>
<td>4 (1.3%)</td>
<td>Neo-submuscular pocket and implant exchange</td>
</tr>
<tr>
<td>Hematoma</td>
<td>2 (0.6%)</td>
<td>Surgical drainage</td>
</tr>
<tr>
<td>Double bubble deformity</td>
<td>1 (0.3%)</td>
<td>Fat graft</td>
</tr>
<tr>
<td>Seroma</td>
<td>1 (0.3%)</td>
<td>US and aspiration only</td>
</tr>
</tbody>
</table>

IMF, inframammary fold; US, ultrasound.

**DISCUSSION**

In order to choose an implant that gives good and stable results the surgeon needs to take account of multiple factors. These include chest wall shape, existing footplate, parenchymal volume and distribution, skin quality and laxity, glandular ptosis, as well as patient’s wishes.

There is a considerable variation in the body habitus, existing breast shape and volume of patients presenting for aesthetic breast augmentation. The dimensions of an implant’s base need to be constrained by the physical measurements of the patient’s chest so as not to be palpable around the existing soft tissue. Anatomically shaped silicone cohesive gel implants permit consideration and customization of patient’s existing shape in all three dimensions. Implant placement in a sub-muscular pocket decreases the risk of rippling and capsular contracture.

However, determining an implant’s optimal projection is less obvious and is a matter of debate. Tebbetts has suggested anterior skin stretch at nipple to estimate skin laxity and glandular contribution to the stretched envelope.

**Rationale for Using Shaped Extra Full Projection Implants**

Extra full projection anatomical implants have been available for many years but their use appears to have been
limited as judged by the few studies reporting their outcomes and their exclusion from long term studies.\textsuperscript{12-16} The core study\textsuperscript{12-14} only included implants with medium and full height and projection. Of the 983 implants used in the core study for primary augmentation,\textsuperscript{12, 215} (21.9\%) were full height full projection and 68 (6.9\%) were moderate height full projection while the other 700 (71.2\%) were full or moderate height moderate projection. In our case series all implants (\(n = 620\)) were extra full projection, of which 28 (4.5\%) were full height, 512 (82.6\%) were medium height, and 80 (12.9\%) were low height. So even the core study data is not directly comparable to our series.

In contrast to their use in aesthetic practice, extra high profile implants have been used more frequently in reconstructive breast surgery. Much of the current evidence about extra full projection implants comes from their use in breast reconstruction.\textsuperscript{17-19} However, due to routine use of two stage procedures and/or acellular dermal matrix, these studies cannot provide a head to head comparison with aesthetic use.

Due to its high collagen content (75\% of fat free dry weight\textsuperscript{20}) the dermis has considerably more structural strength than subcutaneous fat.\textsuperscript{21} Therefore, the major variables affecting skin stretch at the lower pole are the implant’s weight (ie, volume) and the quality and thickness of dermis. It is reasonable to assume that a thin, poor quality dermis under a relatively heavy implant is at higher risk of stretch due to disturbed viscoelastic properties.

Tebbetts and Teitelbaum\textsuperscript{22} have argued that the weight and pressure of full and extra full projection implants contributed to stretching and thinning of breast envelope and parenchymal atrophy. Although the opinion of some very well respected surgeons, no data was provided to support that argument. In the discussion of the very same article, Hammond\textsuperscript{23} pointed out the frequent use of extra full projection implants in breast reconstruction without significant complications. He suggested that the extra full projection implants may be chosen provided soft tissue tolerances are not exceeded. Nahabedian\textsuperscript{24} thinks that projection is not the only variable and that the interplay between implant volume, soft tissue compliance, and parenchymal volume determines the eventual long-term result. He suggested that the ratio of implant and preoperative breast volumes may be a better indicator for planning breast augmentation procedures.

Largent et al\textsuperscript{25} compared the complications in high and extra high projection implants with those in low and medium projection implants. They pooled 6 years’ manufacturer data from the round highly cohesive silicone implant Core study\textsuperscript{26} and style 410 form stable silicone breast implants.\textsuperscript{12} They reported that the relative risk of capsular contracture and of secondary procedures (as a result of a complication) was significantly lower in high profile implants. They did not find a difference in rates of implant malposition between the two groups. Their Kaplan-Meier plot of time to capsular contracture appears to show a steady rate of adverse events in the low and moderate projection group, whereas the same curve for full and extra full projection implants is relatively flat followed by a cluster of events. This may be because it takes longer to form a capsule encircling a more projecting implant, or that more projecting implants were placed in patients with better tissue support.

The major criticisms in using extra full projection implants in aesthetic surgery\textsuperscript{16} appears to stem from the use of round implants. It is important to note that for a given breast width, round implants are correspondingly heavier than anatomical ones of the same projection (Figure 1). A heavier implant increases the mechanical loading of the lower pole, making it prone to stretch. Interestingly, for a given breast width, full projection round implants are heavier than even a full height, extra full projection implant (Figure 1). Therefore, we feel that as long as there is enough skin laxity to accommodate it, an extra

![Figure 1. Implant weights as a function of their shape and projection. Note that the smooth round implants (of a given diameter) are considerably heavier than the anatomical counterparts (of the same base width). For a 13 cm breast width, a full height extra full projection (6.1 cm, 450 gm) anatomical implant is 35 g lighter than a full projection (5.3 cm, 485 gm) smooth round implant. A medium height extra full projection (6.1 cm) implant is nearly the same weight as a medium projection (4.4 cm) round implant (410 g vs 405 g, respectively).](https://academic.oup.com/asj/article-abstract/37/4/408/2521013)
full projection anatomical implant will have similar tissue-implant dynamics. Moreover, a round implant also has a fuller upper pole; however, to our knowledge, there is no bio-mechanical model to say how this difference in shape affects mechanical loading anteriorly. Even among anatomical implants, there is considerable variation in shape and volume. Atlan et al. showed that for 11 cm wide full height (13.5-13.7 cm) full projection anatomical implants, there is up to 11 mm difference in the “upper pole” projection and up to 50 g difference in weight among implants from various manufacturers. These differences were less marked in medium height implants and their study did not compare extra full projection implants.

A factor that can contribute to pectoralis major atrophy (such as that noticed by Tebbetts after implantation of extra full projection devices) is disuse atrophy of pectoralis major. An overly full upper pole alters the muscle’s resting length and its direction of pull, effectively weakening it and potentially rendering it prone to atrophy. Although there is about 9 mm of difference in projection between the full and extra full implants, it is difficult to isolate and quantify this effect as the implant itself is deformed by the overlying muscle.

Weck-Roxo et al. compared a group of 48 patients for 12 months after subglandular or submuscular primary breast augmentation with round textured high projection implants. Their mean age was 24 years, mean BMI was 21 kg/m², and mean implant volume was 273 mL (subglandular group) and 290 mL (submuscular group). The patients had an magnetic resonance imaging at 6 and 12 months after surgery for a volumetric assessment of native tissues. In both groups the breast tissue lost a statistically significant volume at 6 months. The difference was still statistically significant at 12 months after surgery in the subglandular implant group. This would suggest that for an implant of a given shape and volume, the type of surrounding tissue (whether muscle or breast parenchyma), and presumably its quality, affects the tissue response. Unfortunately, there is not a similar study to compare round and anatomical implants.

Our Indications

Our indications for the use of extra full projection implants are based on the anatomical characteristics of the breast tissue as well as patient’s wishes.

In patients with a lot of empty-looking deflated breast (eg, after breast feeding or weight loss, Figure 2) the excess envelope either needs to be filled out (with an extra full projection implant) or reduced (with a mastopexy). If enough projection is not provided, a lift at the same time is likely needed (Figure 3). Riggio et al. described their experience of Style 510 extra full projection implants in 50 primary aesthetic breast augmentations (in a cohort of 75 patients) whose mean age was 33.2 years and a mean BMI of 20 kg/m². Most of the implants were full or medium height extra full projection implants with an average volume of 345 cc. At a mean follow up of 26 months, their total complications (from all operations) were 16.6% with 2.6% malrotation, 1.3% capsular contracture, and 0.6% bottoming out.

In patients with constricted lower pole or tuberous breast, extra full projection implants expand the gland to its fullest extent (Supplementary Figure 1). The typical tuberous breast requires volume replacement in the lower pole, elevation of the nipple–areola complex, and avoidance of excessive fullness in the upper pole. In combination with the standard glandular scoring manoeuvres, an anatomically shaped device with extra projection is an option for dealing with these issues. The extra volume of the implant concentrated in the lower pole guarantees a certain degree of nipple elevation, restoring a normal appearance of the breast in the lower pole and avoiding excessive upper pole fullness. Although lower pole scoring may potentially weaken the area, this manoeuvre does not affect the dermis, which provides most of the structural stability. Our technique additionally involves suturing the Scarpa’s fascia of the lower pole to the chest wall in an attempt to support the implant. This, alongside an intact dermis may be able to support the implant in these patients.

Another indication for the use of extra full projection implants is to meet the patient’s request in terms of volume when selection of a wider implant is not possible. It is a common situation in our practice to have a patient with a narrow chest who wants a fairly large volume (Figure 4). It is inappropriate to choose a wider implant to increase volume in this situation because of palpability at the edges and the unnatural look and feel of the resulting conus. Thus, an alternative is to provide more volume by choosing an implant with more projection. Assuming there is enough tissue laxity and adequate quality, an extra full projection implant gives an impression of a “bigger breast” without adding undue weight (Figure 5). For an 11 cm breast width, the extra full projection anatomical implant weighs less than similar round implant. Medium height extra full projection implants are 55 cc (17.7%) lighter and full height ones are 30 cc (9.7%) lighter than textured round implants of similar projection from the same manufacturer. Moreover, anatomical implants provide 1.3 cm of additional projection (between medium and extra full projection implants) with 40 cc (if medium height) or 45 cc (if full height) of additional weight. In contrast, the equivalent projecting round implants have a weight difference of 70 cc for a 1.5 cm difference in projection.

The need for expansion of lower pole must take into account the existing soft tissue characteristics, especially quality and thickness of dermis. This may be very little in tuberous breasts and the implant may be palpable. This
is where the softness of gel matters to give it a natural feel. Macrotextured implants come in different choices of firmness to customize the eventual result. Decreased deformability and increased resistance to compression of the form stable textured anatomical implants contribute to maintaining their shape.

Figure 2. (A, C, E) A 34-year-old woman with two previous pregnancies presented for breast augmentation. Lax skin and empty-looking deflated breasts with some degree of ptosis are common features in these category of patients. Extra full projection implants were used, Allergan Style 410 - MX 325 on each side, with a dual-plane technique via a submammary incision. (B, D, F) Appearance at 15 months postoperatively shows natural looking breasts with nice restoration of volume and good filling of the skin envelope.
There are no large scale studies of extra full projection anatomical implants in aesthetic surgery with a long term follow up that we can use to compare our data. The core 410 study, which is the most comprehensive to date, did not include extra full projection implants and therefore cannot be used for a direct “head to head” comparison and at best we can infer some trends. One limitation of our data is the short follow up which means that we can only confidently talk about relatively short term results and complications. Part of the reason may be a self-selection bias among aesthetic patients who are not part of a clinical trial, so the ones with a complication are more likely to be followed up for longer. Nonetheless, a longer follow up will allow for a better comparison with existing literature. Another limitation is the attrition in follow up. It can be difficult to avoid as our institution received patients from a large geographical area. If the patient is happy with the results, they may not want to travel a long distance for a “routine” follow up. On the flip side, patients with complications are more likely to return for follow up. Lastly, we did not collect data on the number of pregnancies in our patient cohort and effect of extra full projection implants on the ability to breast feed which could have been of interest.

The rate of implant rotation of our extra full projection series appears to be relatively high. Implant rotation was clinically apparent at a mean 9 months after surgery (median, 7 months; range, 3-34 months). Of the 17 malrotated implants, 1 (5.9%) was full height, 12 (75%) were medium, and 4 (23.5%) were low height. Although the numbers are small, the low height implants appear to have a higher tendency for malrotation. Eight (of the 17) mal-rotated implants were associated with double capsules that may have contributed to the complication. It is worth noting that 13 of the 17 implant rotations occurred in the first half of our case series (Figure 6), whereas in the later half of the series (155 cases over 33 months) there have only been 4 cases of implant rotation. Since the median time to implant rotation is 7 months, we think that this decrease in incidence of rotation in the later half is a true reflection of decrease in complication rate. It appears that, like any surgical technique, there is a learning curve to using the extra full projecting implants and that with regular use, the risk of implant rotation decreases over time. Although Bengtson and Eaves have reported using high resolution ultrasonography to assess implant rotation, we use clinical symptoms (ie, an apparent change in shape of the breast) to guide management as is the standard practice among most surgeons.

Adams reported on 172 patients who underwent primary breast augmentation with form stable shaped gel implants. One hundred and thirty-five patients received moderate projection Mentor CPG (Mentor Worldwide LLC, Irvine, CA) implants, 32 received moderate projection Allergan 410 and only 5 received full projection (full height) Allergan 410 implants. The mean implant volume was 276 cc (range, 180-395 cc). There were no full projection implants used. There were two complications in the Allergan 410 group (with zero percent reoperation rate at a mean 1.7 year of follow up) and 29 complications (22.5%) with a 3.7% reoperation rate (at a mean follow up of 2.5 years). He credited tissue based planning (as well as preoperative patient counseling, improved surgical technique and postoperative care) for his outcomes.
He thinks\textsuperscript{36} that high projection implants are usually not appropriate and if tissue based planning is followed, high projection implants are rarely needed.

Tebbetts\textsuperscript{37} described 468 patients who had dual plane breast augmentation over a 6 year period. Seventy-eight percent of patients had between 6 and 23 months of follow up. Ninety-one percent of patients had full height anatomic saline implants and 7.3% had round textured saline implants. Seventy-nine patients were suitable for type III dual planing and were encouraged to choose a high projection implant (either round or anatomical). Eighty-four percent of these had excellent or very good result and 16% had satisfactory or fair results (unblinded). In comparison, breasts suitable for type II dual planing had 73% excellent/very good and 27% satisfactory/fair results while those suitable for type I dual planing had 85% excellent/very good and 15% satisfactory/fair results.

Jewell and Jewell\textsuperscript{38} reviewed their 7-year data of using Allergan 410 (Allergan Inc.) and Mentor CPG (Mentor Worldwide LLC) shaped implants for primary breast augmentation. Figure 4. (A, C, E) This 26-year-old woman had a narrow chest and was 156 cm tall. Her desire was to have a moderate enhancement of her breasts with a fairly natural look. In this situation, it is inappropriate to choose a wider implant to increase volume because this would result in change of body proportions, unnatural look and palpability of the edges. A better alternative is to provide more volume by choosing an implant with more projection. Extra full projection implants were used, Allergan Style 410 - MX 255 on each side, with a dual-plane technique via a submammary incision. (B, D, F) Appearance at 13 months postoperatively shows natural looking breasts with conservation of the body proportions.
augmentation. Sixty percent of Allergan 410 and 40% of Mentor CPG implants were subglandular while the rest were biplanar. 87.4% of Allergan 410 were moderate and 12.6% were full projection implants, while 81.4% of Mentor CPG implants were moderate and 18.6% had “moderate plus” projection. There were no extra full projection (or equivalent) implants. The patients received a stipend from the manufacturers for the follow up and average follow up was 42.5 months (Allergan 410) and 51.8 months (Mentor CPG). They reported 1.7% rate of implant rotation in Allergan 410 group but zero in the Mentor CPG group. There was 2.4% (Allergan 410) and 0.8% (Mentor CPG) risk of Baker’s grade 3 capsular contracture.

The rate of capsular contracture in our series was 2.6% (8 patients, as compared to the 1.9% reported by Bengtson et al[12] after 3 years). In our patients it occurred at a mean 20.9 months postoperative (median, 13.5 months; range, 10-45 months). These patients had a mean implant size of 390 cc (median, 370 cc; range, 255-615 cc). Capsule contracture evolves over time and our follow up in this series is admittedly not long enough to allow a definitive comment on that. However, 7 of the 8 cases of capsule contracture occurred in the first 100 cases (ie, first 3 years). Since we know that the median time to develop contracture was 13.5 months. If that initial rate of complications had continued, the “expected” contracture cases in year 4 and 5 would have been 3.2 and up to 5.2 in year 5. In reality there has been only one case of capsular contracture since year 3 of the case series. This again suggests a relation between the learning curve and the complication rate. There is a similar trend with the other complications (Figure 6) as well. Thirty-two out of the 40 of complications in our series were noted within 15 months postoperatively. As the median time to develop these complications is shorter than the follow up, we think that the apparent reduction in complication rate in the later half of our series is at least partially due to an actual decrease in complications.

Some patients return soon after surgery to request a larger implant and unfortunately, this can happen even after detailed preoperative counseling regarding implant size. This being said, if these patients understand the risks, are willing to undergo a second operation and have

![Figure 5](https://example.com/figure5.png)

**Figure 5.** Rationale for using extra full projection implant to add volume in a narrow chest. In medium height implants for a given breast width (11 cm in this case) there is a 40 ml (18.6%) difference in volume because of different projection alone. This volume difference, due to projection alone, is more marked (21.2%) for full height implants.

![Figure 6](https://example.com/figure6.png)

**Figure 6.** Incidence of complications during the case series and the duration after surgery that the complication occurred. There is a strong trend of diminishing complications with increasing number of cases.
appropriate soft tissue support, they are offered surgery. Ten patients (3.2%) out of 310 had a reoperation only for a change of implant size in this series. These patients were reoperated at an average of 20.8 months after the index surgery (median, 16.5 months; range, 6-47 months) and received a new implant with mean size of 456 cc. One patient requested explantation due to psychological reasons, even though there was no complication or aesthetic compromise. Existing literature shows a wide variation in the proportion reoperated due to patient’s request for a change in size. Bengtson12 described 16.7% patients requesting implant size change at 3 years, as part of Allergan 410 premarket approval study. Hammond30 (1143 Mentor CPG implants) has reported 3.7% rate of patients requesting a change in size at 6 years, while Spear40 quoted 20.6% of primary breast augmentation patients (with Inamed round implants) requested size/style change at 6 years.

As with any operation, the indications and techniques evolve. Our follow up is shorter than the manufacturer’s study but our data comprises different implants as well, for which large case series are not available for comparison. We noticed in this series that once the patient selection and indications became established and the operative technique matured, the risk of complications steadily declined. With a longer follow up we will be better able to draw direct comparison with existing studies.

CONCLUSION

The use of extra full projection implants in primary breast augmentation allows fine customization of implant dimensions to address a variety of clinical conditions (eg, tuberous breast, moderate ptosis) and patients’ wishes. With experience, the risk of short term complications appears to decrease. However, longer follow up is needed to quantify some of the long term effects.

Supplementary Material

This article contains supplementary material located online at www.aestheticsurgeryjournal.com.

Disclosures

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