Conical Polyurethane Implants: An Uplifting Augmentation

Garrick A. Georgeu, MB ChB, MSC, FRCS (PLAS); James D. Frame Jr.; and James D. Frame, FRCS, FRCS (PLAS)

Abstract

**Background:** Polyurethane-coated conical implants were introduced by Silimed (US distributor: Sientra, Santa Barbara, California) in 2008 and offer an alternative to round or anatomically shaped implants. By their design and volume distribution, they naturally create central volume and give a reasonable fullness to the upper pole while lifting some ptotic breasts, thus avoiding the need for classical mastopexy.

**Objectives:** The authors discuss the advantages of conical implants as an alternative to conventional silicone implants for women with breast ptosis.

**Methods:** In the 2-year period between December 2010 and December 2012, a consecutive series of 302 women underwent implant-based breast surgery procedures (236 primary augmentations, 59 revisions, and 7 mastopexy-augmentations) with conical polyurethane devices. Implant volumes ranged from 225 to 560 cc, with low- to medium-profile devices predominating. No extra–high-profile implants were used. Only 1 patient had a drain inserted on completion of a revision augmentation.

**Results:** There were no infections (0%) and no wound dehiscence (0%). Four cases required reoperation (1.3%). Patient satisfaction scores were universally high (average, 9.94/10). There have been no capsular contractures to date, but follow-up is short.

**Conclusion:** The modern conical, polyurethane implant has many advantages over the conventional round or anatomically shaped implants and offers patients an ideal compromise between volume, natural upper pole fullness, and a lift without mastopexy scars.

**Level of Evidence:** 4

**Keywords**

breast augmentation, conical implants, mastopexy, polyurethane implants

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very low CC rate (<1%) and very low reoperation rate (<2%) over 15 years. Despite the conflicting views by experts on the safety of polyurethane implants, there has never been scientifically accepted evidence to contradict their safe and continued use in humans.

Polyurethane implants were developed in response to the need for the prevention of implant displacement and to reduce the high incidence of CC, particularly during the 1980s. In 1992, at the time of the moratorium on the use of silicone implants in the United States, there was a suspension in the production of polyurethane implants. This was due to the concerns over silicone, not issues over the safe use of polyurethane. That generation of implants demonstrated premature separation of the polyurethane foam from the silicone implant. More modern polyurethane implants have a vulcanized coating, making premature separation prior to degradation extremely unlikely. There have also been changes to the sterilizing process and the introduction of a silicone sleeve as a means of reducing biofilm at insertion. More recently, cone-shaped polyurethane-covered implants have become available in the United Kingdom with a full CE mark. Evidence for low CC rates should encourage surgeons to confidently insert these implants in the subfascial rather than submuscular plane, thus reducing the significant morbidity associated with disruption of the musculoskeletal chest wall.

The aging female breast changes shape in response to normal physiological conditions, including postpartum effects. The various classifications of ptosis are essentially based on the position of the nipple in relation to the inframammary fold when the patient is in the erect posture. Complex breast ptosis is extremely difficult to treat and is notable in women who have very short subareolar to inframammary fold distances, tubular breasts, or with developmental abnormalities such as Poland syndrome. Women who request breast augmentation must be made aware of expected outcomes with each shape of implant currently available based on individual musculoskeletal variables. Round implants, particularly high-profile prostheses, can improve marginal ptosis at the expense of developing a higher and rounder, somewhat abnormal appearance. Submuscular placement of implants in larger breasted women often leaves the breast ptotic over an artificially high implant, and sliding ptosis often develops in later years anyway. Anatomical implants retain the low position of the nipple in a ptotic breast and leave the upper pole deficient of breast tissue. They can yield a good result in women with a positive upper thoracic vector and a negative lower thoracic vector if that is the shape the patient requests, provided the patient is not particularly seeking breast enlargement.

While compromise and alternatives—such as autologous fat grafting or mastopexy—are possible, the introduction of cone-shaped implants has provided an opportunity for improved results with primary, secondary, and reconstructive breast surgery. Mastopexy is clearly an option for patients with advanced ptosis and may be necessary even with polyurethane implants, but the avoidance of scars is obviously to the patient’s benefit. Conical polyurethane implants are available with different base widths and 4 different height projections. With judicious implant selection, it is less likely that there will be lateral fullness or abnormally superior breast bulging, and it is more likely that the result will be a centrally projecting breast with subsequent elevation of the nipple over the central mound. Polyurethane implants are better placed in the submammary, subfascial plane, and the cone-shaped implants, if situated correctly, do not ripple or show the complications associated with conventional implants.

This study investigates the use of conical-shaped silicone implants in a consecutive series of breast augmentation patients.

METHODS

A consecutive series of 302 consented women were retrospectively reviewed. Surgeries were carried out over a 2-year period between December 2010 and December 2012 (24 months). Polyurethane implants were placed mainly in primary augmentation but were also used for secondary implant surgery, augmentation-mastopexy, and postmastectomy reconstruction. In total, 604 implants were placed. The size of implant ranged from 225 to 560 cc, with profiles from low to high, with low predominating. No extra-high implants were used.

Our standard breast augmentation consultation included a general medical history, and a concerted effort was made to understand how the patient felt about the then-current status of her breasts and what expectations she had with respect to her ideal size (cup size) and/or shape. Many patients attended the consultation with pictures printed from the Internet, showing their preferences of appearance. Unfortunately, many of these images showed unrealistic expectations.

Objective measurements of breast width and distances from the nipple to the sternal notch, inferior mammary fold, and midline were recorded. Chest wall projection and sternal irregularities were noted. A “pinch test” was performed on the lower lateral breast using calipers. A skin roll test at the same site was performed and was recorded as either as good, where the attachment of the skin was unable to be rolled easily off the breast, or poor, where there was considerable “give” or laxity of the skin on the breast.

Patients were then shown a selection of implants with a range of shapes, volumes, and profiles. These were placed underneath a tight-fitting top and patients observed themselves in a full-length mirror. This was a simple but effective way to provide patients an indication of the “look” each implant was likely to give. Every patient was offered a second consultation to discuss any concerns prior to surgery and had the option of a resizing. The
patient decided which implant she wanted and signed a consent form for the size and shape preoperatively.

Since most women undergoing breast augmentation were young and fit for anesthetic, no routine preoperative blood tests were performed. Methicillin-resistant *Staphylococcus aureus* (MRSA) protocols between the 3 hospitals where the surgery was performed varied among (a) no screening, (b) swabbing on admission the day of surgery, or (c) swabbing in a more traditional nurse-led preassessment clinic 1 week prior to surgery. No patient in this series was reported as MRSA positive during this study period. The continuation of this screening system is being reviewed in a separate study.

All surgery was performed under a full general anesthetic, with an intravenous dose of antibiotics on induction. The patient’s arms were placed alongside the body for primary and revision surgery and laterally for mastopexy/augmentation cases. Preoperative skin cleansing was performed with a first preparation of povidone iodine 10%, superiorly from the clavicle to umbilicus inferiorly and to the maxillary line laterally. A second skin preparation was performed with chlorhexidine gluconate 20%, which was allowed to air dry.

Most implants were inserted via submammary incisions into subfascial pockets. The submammary incisions were approximately 6 cm in length but were longer if required. A spatulated Teflon-coated diathermy (Edge; Covidien, Mansfield, Massachusetts) was used for the dissection and hemostasis was meticulous. The implant pocket was deliberately made larger than the base width of the proposed prosthesis without the implant touching the skin surface. This theoretically reduces the risk of a biofilm. The technique requires experience for an atraumatic insertion.

Positioning of the implant is critical, since the polyurethane implant does not drop; therefore, accurate preoperative markings cannot be overemphasized. During the repositioning, the “Velcro effect” of the implant may often distort the shape of the breast; so to correct this, the breast tissue needs to be gently lifted off the implant circumferentially and redraped over the implant. A suction catheter may also be placed to ensure a correctly fitted implant without any folds. This was done atraumatically by passing the blunt end of the suction cannula over the top of the implant with the suction off. It is important that this is a “feeling” device only; it must not be used as a dissecting tool. Maintenance of hemostasis by dissection under direct vision only is vital in preventing hematoma formation. The next critical point is to make sure the position of the point of maximal projection of the implant (green dot) is situated at the lower border of the areola.

Once the implant was inserted and repositioned accurately, patients were placed in a sitting position to help decide on the need for a further skin-tightening procedure, which in some cases was discussed preoperatively.

Closure was completed with 3-0 PDS (Ethicon, Inc, Somerville, New Jersey) for fascia and 4-0 and 5-0 Vicryl Plus (Ethicon, Inc) for deep dermal and subcuticular layers, and finally Dermabond (Ethicon, Inc) was applied to the skin. All patients were put into an Anita (Anita International Corporation, Ft Lauderdale, Florida) bra for 6 weeks, in addition to a stabilizer and abdominal binder for extra support for the first 48 hours. No postoperative drains were placed for primary augmentation cases. Drains were placed only in secondary augmentation if necessary—that is, following bloody capsulectomy, which was particularly evident when implants had been inserted in submuscular pockets. Inflammatory tissue was highly evident in cases of ruptured Poly Implant Prothése (PIP).

### Table 1. Number of Women Undergoing Conical Implant Breast Augmentation From December 2010 to December 2012

<table>
<thead>
<tr>
<th>Type of Augmentation</th>
<th>Total No. of Patients</th>
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<tbody>
<tr>
<td>Primary augmentation</td>
<td>236</td>
</tr>
<tr>
<td>Revision augmentation</td>
<td>59</td>
</tr>
<tr>
<td>Mastopexy-augmentation</td>
<td>7</td>
</tr>
<tr>
<td>Total</td>
<td>302</td>
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</table>

Cone-shaped implants were inserted using the silicone sleeve method. This plastic sleeve, provided with every polyurethane breast implant, acts as a conduit to insert the prosthesis without the implant touching the skin surface. This theoretically reduces the risk of a biofilm. The technique requires experience for an atraumatic insertion.

Radial fasciotomies to the lower half of the breast were used in ptotic and cone-shaped breasts, particularly in patients with short subareolar to inframammary distances, to allow for expansion and elevation of the nipple. The technique first required placing the tissue under tension by inverting the breast. Then, under direct vision via the inferior mammary incision, the lower half of the breast tissue was scored with a spatulated, Teflon-coated diathermy in a radial, discontinuous pattern apexed at the central nipple level. A “give” was often felt as fibrous bands were sequentially released, allowing the lower pole of the breast to expand. The staggered pattern of scoring was used to limit the theoretical risk of decreased vascularity to a strip/segment of breast tissue.

The surgical space was internally measured with a ruler, ideally aiming for a pocket 1 to 1.5 cm larger than the chosen implant base. Each breast pocket was then irrigated with 30 mL of Videne (Ecolab, Swindon, United Kingdom) diluted with 30 mL of normal saline.

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implant exchange. Virtually all patients were discharged on the day of surgery.

RESULTS

Table 1 shows the case details and demographics of the consecutive series of 302 women in this series. Average follow-up was 15 months (range, 3-24 months). Patient ages ranged from 19 to 56 years (average, 31 years). Complications are shown in Table 2. In summary, there were no infections (0%). There were 4 cases of revision surgery (2 emergency, 2 nonemergency), for a reoperation rate of 1.3% at 2 years. These patients underwent augmentation in the earlier part of the series. The 2 patients who underwent emergency surgery both developed hematomas, which were attributed to excessive premature activity (ie, failure to follow postoperative advice), for a reoperation rate of 0.67%. The 2 nonemergency cases were elective revision surgery. The first patient required a minor adjustment of a medial edge of an inferior mammary fold (too low). The second case was a malpositioned implant due in part to a large pocket caused by previous surgery in a delayed breast cancer reconstruction re-revision patient. There were no cases of CC within our short follow-up period.

All patients in our practices are routinely seen at 4 months postoperatively and asked to complete a postoperative patient satisfaction survey (Table 3). The patient satisfaction scores in this series were universally favorable, with an average score of 9.94 out of 10. This was measured prospectively in a consecutive series of 50 patients. We realize the limitations of the simple scoring system used in the survey and are aware of more rigorous methods to assess postoperative patient outcomes (such as the Breast-Q), but we still believe our results show high patient satisfaction with these implants.
Clinical results are shown in Figures 1 through 7.

**DISCUSSION**

Many women presenting for breast surgery have preconceived ideals of size and shape. These ideals can be influenced by such factors as age and cultural, social, and professional backgrounds. For 40 years, despite significant differences between and within patients’ anatomy (eg, in chest wall vectors and asymmetry of rib and sternum), not to mention the size and shape variations in the breast itself, clinicians have been limited to the use of 2 implant shapes—namely, round or anatomical. In 2008, Silimed introduced the conical-shaped, polyurethane-covered silicone implant. We are among the first surgeons in the United Kingdom to recognize the benefits of the current generation of polyurethane implants and, in particular, conical-shaped implants for breast augmentation.

A surgeon’s choice and access to breast implants is not uniform throughout the world. In the United States and Canada, for example, polyurethane implants are not available, despite the abundance of evidence in many publications from South America and the rest of the world that demonstrates their efficacy in reducing CC and reoperation rates. This is because the FDA strictly regulates new implant usage within the United States, and FDA approval studies have not yet been completed for polyurethane.

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*Figure 1.* This 25-year-old woman with a 260-cc low-profile conical implant. (A, C) Preoperative frontal and lateral views; postoperative frontal and lateral views at 4 months (B, D).
Figure 2. This 31-year-old woman with a 295-cc low-profile conical implant. (A, C, E) Preoperative frontal, oblique, and lateral views; postoperative frontal oblique, and lateral views at 4 months (B, D, F).
implants. US surgeons therefore are limited in their choice of implant. Only recently (2012) have round and anatomically shaped Silimed implants (distributed by Sientra) been available.

Capsular contracture is the most common complication that occurs after breast augmentation, and we believe that evidence showing a 17% reduction of CC in clinical practice by the use of polyurethane implants should be discussed with all patients prior to surgery. Polyurethane implants also reduce the risk of CC associated with secondary surgery. In most countries that offer polyurethane implants—particularly Brazil and the South Americas, Australia, United Kingdom, Belgium, and New Zealand—there is a wealth of clinical experience indicating their efficacy in clinical practice. For good medical practice, the surgeon must review the clinical and scientific evidence, as well as discuss all options with the patient. Informed consent clearly should indicate that polyurethane implants have major advantages over silicone prostheses.

The ideal patient with ptotic breasts who would benefit from a polyurethane cone-shaped implant is a woman who does not want her result to have a “false” appearance and only wants to restore her breasts back to a shape with upper pole fullness and a degree of nipple projection. It is clear from the clinical photographs that cone-shaped implants do not necessarily result in a cone-shaped breast, but projection at the nipple level is the key to correcting ptosis. Physiological changes in breast shape with aging and pregnancy/breastfeeding are represented in a simple diagrammatic form in Figure 8. Loss of volume, shaded in pink, is more or less replaced by the dropped breasts’ increase in volume in the red shaded area. To restore the ptotic breast back to a more youthful shape and lift the

Figure 3. This 27-year-old woman with a 325-cc medium-profile conical implant. (A, C) Preoperative frontal and lateral views; postoperative frontal and lateral views at 4 months (B, D).
Figure 4. This 32-year-old woman with a 350-cc low-profile conical implant. (A, C, E) Preoperative frontal, oblique, and lateral views; postoperative frontal oblique, and lateral views at 4 months (B, D, F).
nipple up and outward, as in the Tebbetts stretch test, we create a conical-shaped defect behind the shaded red and pink areas.\textsuperscript{15}

If you compare round, anatomically shaped, and cone-shaped implants of similar volume and profile side by side, the conical implant, by its design, concentrates the volume centrally, providing a better lift and enhanced upper pole fullness (Figure 9A-E). The subareola to inframammary fold distance appears longer and the nipple appears higher on the breast, in a more correct anatomical position. In choosing the correct projection for the cone-shaped implant, due consideration must be given to the expected “take up” of the subareolar to inframammary fold. This means that a low- to medium-profile cone-shaped implant is often all that is needed, and this results in a softer, less stretched, and more natural appearance to the breast.

There are clearly limitations to the lift that can be obtained using just a conical implant—for example, a combination of significant ptosis (grade 3) and poor-quality breast tissue and skin (poor skin roll test) will affect the final result. In these situations, the patient should be given the option of augmentation, with bigger volume than she would ideally like, or a smaller implant with or without the mastopexy and its resulting additional scars on the breast. Mastopexy-augmentation operations are notoriously difficult, but inserting a small cone implant into the correct subfascial position and then closing the incision allows a superior pedicle mastopexy to be performed without connecting the 2 surgical wounds and results in a superior shape and nipple projection (Figure 6).

In the wake of the PIP scandal, a significant number of patients presented for removal and replacement of implants. Most had procedures performed 2 to 10 years previously, and these patients desired removal and replacement as quickly as possible. Over this period, most of

\textbf{Figure 5.} This 23-year-old woman with a 435-cc medium-profile conical implant. (A, C) Preoperative frontal and lateral views; postoperative frontal and lateral views at 4 months (B, D).
these breasts had become ptotic, with thinning of breast tissue and often asymmetry caused by incorrect placement of the implant in the submuscular plane. Revision of PIP implant surgery included removal of implants, partial or complete capsulectomy, radial and circumferential capsulotomy, and insertion of conical-shaped implants. Due to prior thinning of breast tissues, especially in the cleavage area, the majority of these patients were given low- to medium-profile implants to help soften the edges of the breast with good effect (Figure 7).

Adherence of surrounding tissues to the implant is crucial for long-term maintenance of the shape and form of the breasts. As stated, we routinely perform a “skin rolling test” to gauge subjectively the dermal-to-breast tissue attachments. In our anecdotal experience, a good skin roll usually indicates a potentially good postoperative result, whereas a poor skin roll may correlate with a poor aesthetic result, but this is not necessarily reported as such by the patient.

CONCLUSIONS

Polyurethane breast implants offer many advantages over the conventional silicone gel implants that are currently available. This consecutive series clearly demonstrates that conical implants have an important role in improving the appearance of women with physiologically ptotic breasts. These devices do not eradicate the need for mastopexy, but if used in combination, they can be a very useful adjunct to help surgeons obtain the best result, without “bottoming out” at a later stage in patients with more advanced breast ptosis.

Disclosures

The authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.
Figure 7. This 33-year-old woman who previously had a submuscular augmentation with 320XH implants. Revision procedure included removing the anterior portion of the capsule, reattaching the pectoralis major muscle to the original position, creating a fresh tissue plane above the muscle, and then inserting a 435-cc medium-profile conical implant. (A, C) Preoperative frontal and lateral views; postoperative frontal and lateral views at 4 months (B, D).

Figure 8. Diagrammatic representation of (1) a youthful breast, (2) physiological changes over time, (3) area of volume changes (loss seen as pink, “increase” in red), and (4) restoration of volume with a conical shape.
Figure 9. (A) Different shapes of a medium-profile implant on profile view: round 260-cc (left implant), conical 245-cc (middle implant), and anatomical 245-cc (right implant) implants; (B) low-profile conical implant; (C) medium-profile conical implant; (D) high-profile conical implant; and (E) extra high-profile conical implant. Figure 9B-E reprinted with permission from Silimed.
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**REFERENCES**


