

# Breast implant design

G. Patrick Maxwell, Allen Gabriel

Department of Plastic Surgery, Loma Linda University Medical Center, Loma Linda, CA, USA

*Contributions:* (I) Conception and design: All authors; (II) Administrative support: All authors; (III) Provision of study materials or patients: All authors; (IV) Collection and assembly of data: All authors; (V) Data analysis and interpretation: All authors; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

*Correspondence to:* Allen Gabriel, MD, FACS. Clinical Associate Professor of Surgery, Department of Plastic Surgery, 505 NE, 87<sup>th</sup> Avenue, Suite 250, Vancouver, WA 98664, USA. Email: gabriellallen@yahoo.com.

**Abstract:** Breast Augmentation remains as one of the most common procedures performed in the United States. This article explores the evolution of breast implants with special emphasis on the advancement of the silicone implants.

**Keywords:** Anatomic implants; highly cohesive implants; round implants; silicone breast implants; textured implants

Submitted Aug 01, 2016. Accepted for publication Oct 31, 2016.

doi: 10.21037/gs.2016.11.09

View this article at: <http://dx.doi.org/10.21037/gs.2016.11.09>

## Introduction

There has been a steady increase in breast augmentation surgery with the evolving importance of body image, changes in societal expectations, and the increasing acceptance of aesthetic surgery in the United States. Augmentation mammoplasty, performed 286,694 times in 2014, ranks as the most frequently performed cosmetic surgical procedure in women in the United States (1).

The first report of successful breast augmentation appeared in 1895 in which Czerny described transplanting a lipoma from the trunk to the breast in a patient deformed by a partial mastectomy (2). In 1954, Longacre described a local dermal-fat flap for augmentation of the breast (3). Eventually, both adipose tissue and omentum were also used to augment the breast.

During the 1950s and 1960s, breast augmentation with solid alloplastic materials was carried out using polyurethane, polytetrafluoroethylene (Teflon), and expanded polyvinyl alcohol formaldehyde (Ivalon sponge) (4). Ultimately, the use of these materials was discontinued after patients developed local tissue reactions, firmness, distortion of the breast, and significant discomfort (5). Various other solid and semi-solid materials have been injected directly into the breast

parenchyma for augmentation including epoxy resin, shellac, beeswax, paraffin, petroleum jelly and liquid silicone (6). In 1961, Uchida reported the injection of liquid silicone (polydimethylsiloxane) into the breast for breast augmentation (5). This technique resulted in frequent complications including recurrent infections, chronic inflammation, drainage, granuloma formation and even necrosis (7). Breast augmentation by injection of free liquid silicone and the various other solid and semi-solid materials were abandoned in the United States in light of these complications (8).

The evolution of the modern breast implant began as a two-component prosthetic device manufactured with a less permeable silicone elastomer shell filled with a stable filling material, consisting of either saline solution or silicone gel. This shell and gel filler implant was originally developed by Cronin and Gerow in 1962 using silicone gel as the filling material contained within a thin, smooth silicone elastomer shell (9). Since that time, both silicone gel and saline-filled implants have undergone several technical alterations and improvements (10).

## Evolution of saline implants

The use of inflatable saline-filled breast implants was first

reported in 1965 by Arion in France (8). The saline-filled implant was developed in order to allow the non-inflated implant to be introduced through a relatively small incision, and then the implant was inflated *in situ* (7).

Although these implants allow slight overfilling, aggressive overfilling may lead to a more spherical shape and scalloping along the implant edge with knuckle-like palpability and unnatural firmness. A disadvantage of saline-filled implants is that the consistency on palpation is similar to that of water instead of the more viscous feel of natural breast tissue.

### Evolution of silicone implants

The first generation silicone gel-filled implant introduced in 1962 by Cronin and Gerow was manufactured by Dow Corning Corporation (9). The shell of the first generation implant was constructed using a thick, smooth silicone elastomer as a two-piece envelope with a seam along the periphery. The shell was filled with a moderately viscous silicone gel. The implant was anatomically shaped (teardrop) and had several Dacron fixation patches on the posterior aspect to help maintain the proper position of the implant. These early devices had a relatively high contracture rate, due to the quality of the shells and the lack of cohesivity of the gel, which then encouraged implant manufacturers to develop second-generation silicone gel-filled implants (11).

In the 1970s, the second-generation silicone implants were developed in an effort to reduce the incidence of capsular contracture with a thinner, seamless shell and without Dacron patches incorporated into the shell. These implants were round in shape and filled with a less viscous silicone gel to provide a more *natural feel*. However, the second-generation breast implants were plagued by diffusion or *bleed* of microscopic silicone molecules into the periprosthetic intra-capsular space due to their thin, permeable shell and low viscosity silicone gel filler. This diffused silicone produced an oily, sticky residue surrounding the implant within the periprosthetic capsule which was noticeable during explanation of older silicone-filled implants (12).

The development of the third-generation silicone gel-filled implants in the 1980s focused on improving the strength and permeability of the shell in order to reduce silicone gel *bleed* from intact implants, and to reduce implant rupture and subsequent gel migration. The manufacturers designed new implant shells that consisted of multi layered silicone elastomer. These third-generation

prostheses reduced gel bleed by introducing a barrier layer and a thicker shell which significantly lowered the device shell failure rate.

After the FDA required the temporary restriction of third-generation silicone gel implants from the American market in 1992 (13-18), the *fourth and fifth-generation* gel devices evolved. These silicone gel breast implants were designed under more stringent ASTM (American Society for Testing Methodology) (19) and FDA-influenced criteria for shell thickness and gel cohesiveness. Furthermore, they were manufactured with improved quality control (20), and with a wider variety of surface textures and implant shapes. They are currently available from all three breast implant manufactures in the United States (Sientra, Allergan, and Mentor) (21-25).

During the same time the concept of anatomically shaped implants were introduced with the *fifth-generation* silicone gel implants (26). In addition to having a textured surface, these anatomically-shaped implants are filled with a more cohesive gel. The FDA approved 5<sup>th</sup> generation implants from all of the U.S. manufacturers in the following order: Sientra [2012], Allergan and Mentor (both 2013). Each manufacturer was approved for a variety of shapes and styles with Sientra offering five styles of the HSC+ line, four 410 implant styles from Allergan, and one CPG implant from Mentor (22,27,28).

To further understand the evolution of silicone-filled implants, implant characteristics will be further reviewed, as the resultant breast form is not only dependent on the soft tissue envelope (in augmentation and reconstruction) and the breast parenchyma (in augmentation) but also on the following implant characteristics: Surface, Filler, Shell and Implant Shape.

### Surface

Surface characteristics have undergone changes and evolved with all three manufacturers working towards the common goal of utilizing texture to possibly minimize or even disrupt capsule formation (29,30). The evolution of textured implants began with polyurethane-coated implants reporting lower capsular contracture rates (31). These *foam*-coated implants were eventually removed voluntarily from the US market because of concern from difficulty in complete removal and theoretical concern of carcinogenic conversion of the coating. Polyurethane foams are thought to undergo partial chemical degradation under physiologic conditions releasing compounds that could

become carcinogens in animals but are not known human carcinogens (32).

In 1980s, manufacturers shifted their focus from foam covered shells to textured silicone shells with different pore sizes. None of the textured surfaces are created in the same manner and each manufacturer has a proprietary process in place. One of the critical issues during the evolution of the texture is to find a way to stabilize the implant in the breast pocket. Studies have demonstrated that the pore size is critical to allow for tissue adherence leading to the “adhesive effect” and implant stabilization (33). However, it was not clear if the pore size correlated with a reduction in capsular contracture, but did correlate with implant stabilization (33). Danino *et al.* compared the BioCell texture with pore diameter of 600–800  $\mu\text{m}$  with a depth of 150–200  $\mu\text{m}$  to Siltex pore diameter of 70–150  $\mu\text{m}$ . It was noted that Siltex pores lead to no “adhesive effect” (33).

The manufacturing process of textured surface implants can be complex while smooth surface implants are made by dipping a mandrel into *liquid* silicone creating multi layers, followed by allowing the surface to cure in a laminar flow oven. Additional steps beyond creating smooth surface implants are involved in the creation of textured implants (34). Sientra’s Silimed implant (Sientra, Inc. Santa Barbara, USA), named as TRUE Texture avoids the use of sodium chloride, sugar, soak/scrub, or pressure stamping (28,35,36). Small hollow pores are formed with minimal thin cell webbing that reduces particle formation. The BioCell (Allergan, Inc. Irvine, USA) texture is created using a “loss-salt” technique (34), which includes a layer of salt crystals with a thin overscoat of silicone followed by curing in a laminar flow oven (34). The Siltex surface (Mentor Corp., Santa Barbara, USA) on the other hand, is created by “imprint stamping” (34), which dips the chuck into uncured silicone, pushing it into polyurethane foam and finalizing the imprint with pressure (34).

## Filler

Silicone is a mixture of semi-inorganic polymeric molecules composed of varying length chains of polydimethylsiloxane [(CH<sub>3</sub>)<sub>2</sub>-SiO] monomers. The physical properties of silicones are quite variable depending on the average polymer chain length and the degree of cross-linking between the polymer chains (37). Liquid silicones are polymers with a relatively short average length and very little cross-linking. They have the consistency of an oily fluid and are frequently used as lubricants in pharmaceuticals and medical devices. Silicone *gels* can be

produced of varying viscosity by progressively increasing the length of the polymer chains or the degree of cross-linking.

When enough filler cross-linking is achieved to the degree that the silicone gel implant will maintain its dimensions and form (i.e., gel distribution within the shell), the cohesive gel implant is considered to be “form stable”, although this terminology has recently been questioned as no gel implant on the market is truly form-stable. Form stable may more appropriately refer to the ability of an implant to maintain shape. Technology exists to measure the cohesivity of the silicone gel of commercially available devices and was utilized to measure the stiffness of both Allergan and Mentor shaped and round implants. This study showed that the 410 implant (Allergan Inc.) had the stiffest gel representing the highest cohesivity vs. the CPG implant (Mentor) (27). In a separate study it was found that the Sientra form-stable implant is the least cohesive as compared to both CPG and 410 implants. It is important to note that cohesivity is only one implant characteristics and one must take in to account various implant features in order to evaluate the implant as a whole (27). In this same study it was demonstrated that Allergan’s round implants were the least cohesive as compared to Mentor’s round implants and Sientra’s implants were the most cohesive as compared to both Allergan’s and Mentor’s round implants.

In the past, the effect of the filler material has been shown to have an effect on capsular contracture rates (38–40). However, these studies compared the third generation silicone implants to saline implants and therefore the current implants may have other outcomes since 4<sup>th</sup> generation silicone breast implant safety and long-term outcomes have been described (22,23,25,27,28,41).

## Shell

Extensive chemical cross-linking of the silicone gel polymer will produce a solid form of silicone referred to as an *elastomer* with a flexible, rubber-like quality. Silicone elastomers are used for the manufacture of facial implants, tissue expanders, and the outer shell of all breast prostheses.

Introducing shell modifications such as; barrier layers and triple shell elastomer to protect the gel (year?), have led to safer implants (22,23,27,28,42). The elastomeric shell characteristics are also dependent on the relationship of the gel and shell. Shell characteristics also depend on the thickness of each shell and how the internal gel is bonded to the shell which leads to stability of the final shape.

## Implant shape

The maintenance of gel distribution within the shell helps to preserve the form stability (42). The more cohesive the gel, the higher the gel-shell fill ratio, and the more enhanced bonding of the gel to the shell, will lead to more improved shape maintenance. The gel-shell fill ratio varies among the manufacturers and can produce visual clinical differences may result in rippling and upper pole collapse if not used in the proper patient. It is important to note that all types of implants in the round portfolio of United States manufacturers vary in the gel-shell fill ratio within the different profiles (i.e., low, moderate, high). MRI study showed that shell rippling is still noted in a prone position in of one of the most cohesive form stable implants (43). Changes in shape/form in different positions are generally not clinically significant but can be a patient concern.

## Discussion

The *ideal* size and shape of the female breast is inherently subjective and relates to both personal preference and to cultural norms. However, most surgeons will agree that there are certain shared characteristics which represent the aesthetic ideal of the female breast form. These characteristics include a profile with a sloping or full upper pole and a gently curved lower pole with the nipple-areola complex at the point of maximal projection. The breast structure itself may be thought of as the breast parenchyma resting on the anterior chest wall surrounded by a soft tissue envelope made up of skin and subcutaneous adipose. Clearly, the resulting form of the breast after augmentation mammoplasty will be determined by the dynamic interaction of the breast implant, the parenchyma, and the soft tissue envelope (44).

Silicone implants have undergone an evolution with the availability of both 4<sup>th</sup> and 5<sup>th</sup> generation devices from the three leading manufacturers in the United States. Concerns regarding auto-immune reaction against silicone implants remain among a small group of the population, despite the numerous studies showing safety of the new implants (22,23,25,27,28,41). Several clinical studies have shown no difference in the incidence of autoimmune diseases in mastectomy patients receiving silicone gel implants compared to patients who had reconstruction with autogenous tissue (45-51). Even meta-analysis research combining data from over 87,000 women has revealed no association between silicone breast implants and connective

tissue diseases (52,53). Notably, virtually all industrialized nations in the world except the United States use silicone gel implants almost exclusively for breast augmentation.

There are important clinical differences in the use of the form-stable silicone implants compared with round devices. Careful dimensionally based patient analysis is crucial and implant selection should not exceed tissue characteristics and breast dimensions (27).

The future of implant design may include different types of surfaces and fills, which alter the weight and quality of the adherence of the implants. The coming years will be exciting as new products are introduced to the market.

## Conclusions

Implant characteristics on the bench differ from implant performance within the body. Shape, feel, safety and longevity of the implants remain an important area of research. The data provided by all three manufacturers demonstrate safety and efficacy of these medical devices. Clinicians should strive to provide ongoing data and sound science to continue to improve clinical outcomes in the future.

## Acknowledgements

None.

## Footnote

*Conflicts of Interest:* Drs. Maxwell and Gabriel are consultants for Allergan and Dr. Maxwell is a stockholder for Allergan and Mentor.

## References

1. Procedural statistics. Available online: <http://www.surgery.org/media/statistics>, 2014.
2. Czerny V. Plastic replacement of the breast with a lipoma. *Chir Kong Verhandl.* 1895;2:216.
3. Longacre JJ. Correction of the hypoplastic breast with special reference to reconstruction of the "nipple type breast" with local dermo-fat pedicle flaps. *Plast Reconstr Surg* (1946) 1954;14:431-41.
4. Edgerton MT, Mcclary AR. Augmentation mammoplasty; psychiatric implications and surgical indications; (with special reference to use of the polyvinyl alcohol sponge ivalon). *Plast Reconstr Surg Transplant Bull* 1958;21:279-305.

5. Maxwell GP, Gabriel A. Possible future development of implants and breast augmentation. *Clin Plast Surg* 2009;36:167-72, viii.
6. Clarkson P. Local mastectomy and augmentation mammoplasty for bilateral paraffinoma of breasts. *Nurs Mirror Midwives J* 1965;121:13-6.
7. Regnault P, Baker TJ, Gleason MC, et al. Clinical trial and evaluation of a proposed new inflatable mammary prosthesis. *Plast Reconstr Surg* 1972;50:220-6.
8. Maxwell GP, Gabriel A. The evolution of breast implants. *Clin Plast Surg* 2009;36:1-13, v.
9. Cronin TD, Brauer RO. Augmentation mammoplasty. *Surg Clin North Am* 1971;51:441-52.
10. Tanne JH. FDA approves silicone breast implants 14 years after their withdrawal. *BMJ* 2006;333:1139.
11. Cronin TD, Greenberg RL. Our experiences with the silastic gel breast prosthesis. *Plast Reconstr Surg* 1970;46:1-7.
12. Thomsen JL, Christensen L, Nielsen M, et al. Histologic changes and silicone concentrations in human breast tissue surrounding silicone breast prostheses. *Plast Reconstr Surg* 1990;85:38-41.
13. Cohen IK. Impact of the FDA ban on silicone breast implants. *J Surg Oncol* 1994;56:1.
14. Lundberg GD. The breast implant controversy. A clash of ethics and law. *JAMA* 1993;270:2608.
15. Kessler DA, Merkatz RB, Schapiro R. A call for higher standards for breast implants. *JAMA* 1993;270:2607-8.
16. Handel N, Wellisch D, Silverstein MJ, et al. Knowledge, concern, and satisfaction among augmentation mammoplasty patients. *Ann Plast Surg* 1993;30:13-20; discussion 20-2.
17. Stompler RE. Breast implants and the FDA: past, present, and future. *Plast Surg Nurs* 1993;13:185-7, 200.
18. Fisher JC. The silicone controversy--when will science prevail? *N Engl J Med* 1992;326:1696-8.
19. Guidoin R, Rolland C, Fleury D, et al. Physical characterization of unimplanted gel filled breast implants. Should old standards be revisited? *ASAIO J* 1994;40:943-58.
20. Sitbon E. Manufacturing of mammary implants: a manufacturing of high technology. *Ann Chir Plast Esthet* 2005;50:394-407.
21. Spear SL, Parikh PM, Goldstein JA. History of breast implants and the food and drug administration. *Clin Plast Surg* 2009;36:15-21, v.
22. Cunningham B. The Mentor Study on Contour Profile Gel Silicone MemoryGel Breast Implants. *Plast Reconstr Surg* 2007;120:33S-39S.
23. Cunningham B. The Mentor Core Study on Silicone MemoryGel Breast Implants. *Plast Reconstr Surg* 2007;120:19S-29S; discussion 30S-32S.
24. Cunningham B, McCue J. Safety and effectiveness of Mentor's MemoryGel implants at 6 years. *Aesthetic Plast Surg* 2009;33:440-4.
25. Spear SL, Hedén P. Allergan's silicone gel breast implants. *Expert Rev Med Devices* 2007;4:699-708.
26. Bengtson BP, Van Natta BW, Murphy DK, et al. Style 410 highly cohesive silicone breast implant core study results at 3 years. *Plast Reconstr Surg* 2007;120:40S-48S.
27. Maxwell GP, Van Natta BW, Murphy DK, et al. Natrelle style 410 form-stable silicone breast implants: core study results at 6 years. *Aesthet Surg J* 2012;32:709-17.
28. Stevens WG, Harrington J, Alizadeh K, et al. Five-year follow-up data from the U.S. clinical trial for Sientra's U.S. Food and Drug Administration-approved Silimed® brand round and shaped implants with high-strength silicone gel. *Plast Reconstr Surg* 2012;130:973-81.
29. Brohim RM, Foresman PA, Hildebrandt PK, et al. Early tissue reaction to textured breast implant surfaces. *Ann Plast Surg* 1992;28:354-62.
30. Abramo AC, De Oliveira VR, Ledo-Silva MC, et al. How texture-inducing contraction vectors affect the fibrous capsule shrinkage around breasts implants? *Aesthetic Plast Surg* 2010;34:555-60.
31. Handel N, Jensen JA, Black Q, et al. The fate of breast implants: a critical analysis of complications and outcomes. *Plast Reconstr Surg* 1995;96:1521-33.
32. Daka JN, Chawla AS. Release of chemicals from polyurethane foam in the Mème breast implant. *Biomater Artif Cells Immobilization Biotechnol* 1993;21:23-46.
33. Danino AM, Basmacioglu P, Saito S, et al. Comparison of the capsular response to the Biocell RTV and Mentor 1600 Siltex breast implant surface texturing: a scanning electron microscopic study. *Plast Reconstr Surg* 2001;108:2047-52.
34. Barr S, Hill E, Bayat A. Current implant surface technology: an examination of their nanostructure and their influence on fibroblast alignment and biocompatibility. *Eplasty* 2009;9:e22.
35. Stevens WG, Nahabedian MY, Calobrace MB, et al. Risk factor analysis for capsular contracture: a 5-year Sientra study analysis using round, smooth, and textured implants for breast augmentation. *Plast Reconstr Surg* 2013;132:1115-23.
36. Hammond DC, Perry LC, Maxwell GP, et al. Morphologic

- analysis of tissue-expander shape using a biomechanical model. *Plast Reconstr Surg* 1993;92:255-9.
37. Brody GS. Silicone technology for the plastic surgeon. *Clin Plast Surg* 1988;15:517-20.
  38. Asplund O. Capsular contracture in silicone gel and saline-filled breast implants after reconstruction. *Plast Reconstr Surg* 1984;73:270-5.
  39. Burkhardt BR, Dempsey PD, Schnur PL, et al. Capsular contracture: a prospective study of the effect of local antibacterial agents. *Plast Reconstr Surg* 1986;77:919-32.
  40. Gylbert L, Asplund O, Jurell G. Capsular contracture after breast reconstruction with silicone-gel and saline-filled implants: a 6-year follow-up. *Plast Reconstr Surg* 1990;85:373-7.
  41. Spear SL, Murphy DK, Slicton A, et al. Inamed silicone breast implant core study results at 6 years. *Plast Reconstr Surg* 2007;120:8S-16S; discussion 17S-18S.
  42. Brown MH, Shenker R, Silver SA. Cohesive silicone gel breast implants in aesthetic and reconstructive breast surgery. *Plast Reconstr Surg* 2005;116:768-79; discussion 780-1.
  43. Weum S, de Weerd L, Kristiansen B. Form stability of the Style 410 anatomically shaped cohesive silicone gel-filled breast implant in subglandular breast augmentation evaluated with magnetic resonance imaging. *Plast Reconstr Surg* 2011;127:409-13.
  44. Tebbetts JB. Dual plane breast augmentation: optimizing implant-soft-tissue relationships in a wide range of breast types. *Plast Reconstr Surg* 2001;107:1255-72.
  45. Schusterman MA, Kroll SS, Reece GP, et al. Incidence of autoimmune disease in patients after breast reconstruction with silicone gel implants versus autogenous tissue: a preliminary report. *Ann Plast Surg* 1993;31:1-6.
  46. Park AJ, Black RJ, Sarhadi NS, et al. Silicone gel-filled breast implants and connective tissue diseases. *Plast Reconstr Surg* 1998;101:261-8.
  47. Edworthy SM, Martin L, Barr SG, et al. A clinical study of the relationship between silicone breast implants and connective tissue disease. *J Rheumatol* 1998;25:254-60.
  48. Gabriel SE, O'Fallon WM, Kurland LT, et al. Risk of connective-tissue diseases and other disorders after breast implantation. *N Engl J Med* 1994;330:1697-702.
  49. Kaiser J. Panel discounts implant disease risk. *Science* 1999;284:2065-6.
  50. Nelson N. Institute of Medicine finds no link between breast implants and disease. *J Natl Cancer Inst* 1999;91:1191.
  51. Nyrén O, Yin L, Josefsson S, et al. Risk of connective tissue disease and related disorders among women with breast implants: a nation-wide retrospective cohort study in Sweden. *BMJ* 1998;316:417-22.
  52. Sánchez-Guerrero J, Colditz GA, Karlson EW, et al. Silicone breast implants and the risk of connective-tissue diseases and symptoms. *N Engl J Med* 1995;332:1666-70.
  53. Karlson EW, Hankinson SE, Liang MH, et al. Association of silicone breast implants with immunologic abnormalities: a prospective study. *Am J Med* 1999;106:11-9.

**Cite this article as:** Maxwell GP, Gabriel A. Breast implant design. *Gland Surg* 2017;6(2):148-153. doi: 10.21037/gs.2016.11.09