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SHORT COMMUNICATION

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The evolution of breast prostheses

Valeriano Vinci MD[1] | Costanzo Domenico MD[2] | Maione Luca MD[1] | Giannasi Silvia MD[3] | Veronesi Alessandra MD[4] | Catania Barbara MD[3] | Bandi Valeria MD[3] | Battistini Andrea MD[5] | Siliprandi Mattia MD[3] | Barbera Federico MD[5] | Lisa Andrea Vittorio Emauele MD[1] | Klinger Marco MD[1]

[1]Department of Medical Biotechnology and Translational Medicine BIOMETRA – Plastic Surgery Unit, Reconstructive and Aesthetic Plastic Surgery School, Humanitas Clinical and Research Hospital, University of Milan, Milan, Italy

[2]Humanitas University (Hunimed), Milan, Italy

[3]Plastic Surgery Unit, Department of Medical Biotechnology and Translational Medicine BIOMETRA, Humanitas Clinical and Research Center, Rozzano [Milan], Italy

[4]IRCCS Humanitas Research Hospital, Rozzano [Milan], Italy

[5]Plastic Surgery Unit, Department of Medical Biotechnology and Translational Medicine BIOMETRA IT, Plastic Surgery, Humanitas Clinical and Research Center, Rozzano [Milan], Italy

Correspondence
Dr Domenico Costanzo, Humanitas University (Hunimed), Milan, Italy.
Email: domenico.costanzo@mail.com

Abstract

Every year approximately 1.5 million prostheses are implanted worldwide for breast augmentation and reconstructive indications. The modern breast implant as we know was released to the open market in 1963. It has gone through intense phases of development which have improved the initially primitive and limited devices to current-day devices, which exhibit a tremendous range of surface textures, sizes, gel consistencies, and anatomical shapes. This article explores the evolution of breast implants providing historical facts and technical details.

KEYWORDS

breast implant-associated anaplastic large cell lymphoma, breast prosthesis, implant, surface texture

1 | INTRODUCTION

Every year approximately 1.5 million prostheses are implanted worldwide for breast augmentation and reconstructive indications.[1]

The history of implant-based breast reconstruction spans three centuries with the first report of successful breast augmentation in 1895, in which Czerny[2] described transplanting a lipoma from the trunk to the breast in a patient deformed by a partial mastectomy. In 1889, Gersuny attempted breast reconstruction with paraffin injections although with disastrous results.[3]

In the first half of the 20th century, surgeons employed other materials and prostheses as breast fillers and implants, respectively, such as ivory, glass balls, ground rubber, ox cartilage, Terylene wool, gutta-percha [...].[4]

During the 1950s and 1960s, breast augmentation with solid alloplastic materials was performed using polyurethane, polytetrafluoroethylene (Teflon), and expanded polyvinyl alcohol formaldehyde (Ivalon sponge).[5] However, the use of these materials was discontinued after patients developed local tissue reactions, firmness, distortion of the breast, and significant discomfort.[6]

In 1961, Uchida reported the injection of liquid silicone (polydimethylsiloxane [PDMS]) for breast augmentation.[6] Various other solid and semisolid materials have been injected directly into the breast parenchyma for augmentation, including epoxy resin, shellac, beeswax, paraffin, and petroleum jelly.[7] These techniques resulted in frequent complications, including recurrent infections, chronic inflammation, drainage, granuloma formation, and even necrosis.[8] Breast augmentation by injection of free liquid silicone and

The principles outlined in the Declaration of Helsinki have been followed in this study.

the various other solid and semisolid materials was abandoned in light of these complications.[9]

The evolution of the modern breast implant began with 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.[10] Both silicone gel- and saline-filled implants have undergone several technical alterations and improvements.[11,12]

2 | TYPES OF IMPLANTS

Modern implants were classically distinguished into saline- and silicone gel-filled implants. Both types have a silicone outer shell but vary in size, shell thickness, surface texture, and shape (contour). However, with the introduction of structured breast implants, classifying them on the basis of their filler material fails to identify differences in shell support that affect implant performance. A more informative classification is proposed nowadays: "unsupported shell" (saline) implants or "supported shell" (silicone gel and structured) implants.

3 | SALINE BREAST IMPLANTS

The use of inflatable saline-filled breast implants was first reported in 1965 by Arion in France.[12] These devices are inserted empty through a relatively small incision and are filled with saline at surgery. Each size has a recommended fill range provided by the manufacturer: overfilling produces a firm device; under-filling risks early rupture from a process called "fold flaw," which results in increased rubbing of the membrane at that point. Any breach of the shell results in instant deflation and harmless absorption of the saline over the next day or two.[13]

Saline implants do not have a natural feel because movement of the saline filler is rapidly displaced with motion. Because the implant shell is unsupported, the upper pole collapses when upright and the shell tends to wrinkle.[14]

4 | SILICONE IMPLANTS

The modern silicone breast implant as we know was released to the open market in 1963. It has gone through intense phases of development concerning surface texture, size, gel consistency, and anatomical shape.

Common to all implants is the outer shell made of silicone elastomer reinforced with silica. The shell can be single- or double-layered, smooth or textured, barrier coated and/or covered with polyurethane foam.[13]

The silicone gel implant has a natural feel because the viscosity of the silicone gel filler mimics the breast tissue. The cross-linked silicone gel supports the implant shell, so there is less upper pole collapse when upright and less wrinkling compared with the saline implant.[14]

The disadvantage of the silicone gel implant is that ruptures are silent and occur at a relatively high rate.[13,15,16]

4.1 | First generation (1960s)

The original silicone gel implant was developed by Cronin and Gerow and was named the "Silastic 0." These implants had envelopes of thick smooth walled silicone elastomer made in two sections and filled with viscous silicone gel material. The shell halves were then glued together. By the end of the 1960s, the shell was cast as a single unit and sealed with a small patch. Fixation patches were introduced in the early part of this period because it was felt that scar and tissue ingrowth were necessary to fix the implant and prevent migration. These fixation patches were made of Dacron mesh, perforated silicone, or polyurethane foam. Not only were the patches found to be generally unnecessary, they also increased the rupture rate by creating stress points in the envelope.[13]

4.2 | Second generation (1970s)

A new generation of thinner shells and less-viscous gels were released in the mid-1970s as attempts to reduce capsular contractures. Unfortunately, not only were capsular contracture rates unchanged, these fragile devices were more prone to rupture.[13]

4.3 | Third generation (1980s)

This period saw significant advances in silicone technology, and the implants produced during this era form the backbone of our current devices. Stronger shells reduced the amount of silicone oil "bleed" into adjacent tissues. The gel content was made more viscous and cohesive. Expandable implants with subcutaneous ports were also developed. In 1989, textured-surface envelopes became available. These were felt to reduce capsular contracture rates. Polyurethane coating of implants was first introduced in the 1960s but did not gain popularity until the 1980s. The reduction in capsular contracture seen with polyurethane-coated devices was attributed to its open cell structure which allowed tissue ingrowth and prevented a regular circumferential deposition of collagen.

In the early 1990s, the modern silicone implant was affected by a substantial negative media publicity campaign over the apparent danger of breast implants, resulting in a marked drop in the use of silicone implants for all indications. Safety issues centered around silicone oil leakage locally and systemically and the use of polyurethane coating that had become popular toward the end of 1980s.

Polyurethane was shown to undergo a degradation process in vivo that produced toluenediamine, a known carcinogen in rats. At that time, the risk to humans was unknown but has been since shown to be extremely low. Further, the polyurethane coating was found to completely delaminate from the underlying silicone shell after several years in vivo. This resulted in loss of implant form. The devices were voluntarily removed from the market in the early 1990s.[13]

4.4 | Fourth- and fifth-generation implants

The adverse publicity seen in the 1990s resulted in stricter manufacturing standards. Current implants of the fourth and fifth generations are essentially refined third-generation devices. These prostheses include cohesive gel products with increased cross-linkage. The resulting gel is much stiffer and maintains its shape even when cut, therefore capable of controlling the spread of gel contents in case of shell rupture. Larger breast incisions are, however, required to accommodate these less-flexible implants. In an effort to reduce gel bleed from silicone-filled devices, phenyl or trifluoropropyl groups are bonded to the shell to decrease the shell permeability to PDMS oil. These low-bleed implant shells with barrier coating are characteristic of current third-, fourth-, and fifth-generation implants.[13]

5 | STRUCTURED (IDEAL) IMPLANT

The structured IDEAL IMPLANT® is a round, smooth-surface, saline-filled implant with an internal structure. It has two lumens within two nested shells that are attached at the patch on the back. The inner lumen within the inner shell is filled through a valve in the patch with approximately two-thirds of the saline. The outer lumen within the outer shell and surrounding the inner shell is filled through a valve on the front with approximately one-third of the saline. Unattached and floating within the outer lumen is a baffle structure designed to restrict movement of the saline in the outer lumen. This internal structure is composed of one to three nested baffle shells that are perforated with slits, so the saline is free to move through the slits and around and between the shells. The number of baffle shells in an implant is proportionate to the size. The shape of this round implant was designed with the edge low, to contour to the convexity of the chest wall, and tapering from the dome to the edge so that the side of the implant does not bulge outward toward the arm.

The structured implant was designed to combine the peace of mind of the saline implant and the natural feel of the silicone gel implant, without the drawbacks that concern women most (ie, unnatural feel of the saline implant and silent rupture of the silicone gel implant).

It is named a "structured" implant because of its internal structure, which supports the shell, so there is less upper pole collapse when upright and less wrinkling compared to round saline and certain round silicone gel implants. Increasing the fill volume in the outer lumen of the structured implant increases support for the shell, so there is even less upper pole collapse when upright. As its unique design and technology are different from saline and silicone gel implants, the structured implant is a third type of breast implant.[14]

5.1 | Textured vs smooth surfacing

As described above, the evolution of textured implants began with polyurethane-coated implants reportedly having lower capsular contracture rates. These foam-coated implants were eventually removed from the US market because of concern caused by difficulty in complete removal and theoretic concern of carcinogenic conversion of the coating.

In the 1980s, manufacturers shifted their focus from foam-covered shells to textured silicone shells.

There are several commercially manufactured varieties of textured silicone elastomer shells with different pore sizes.

Mentor have developed the Siltex pattern, which results as a negative contact imprint of a texturing foam. This process produces many fine nodules on the surface of the shell in a regular distribution. Allergan's Biocell surface is produced through a lost salt technique. The implant shell is coated with finely graded salt under light pressure. The salt crystals are subsequently lost through the manufacturing process, leaving many fine depressions on the surface of the shell. True tissue ingrowth with textured surfaces only occurs reliably when the implant is placed in a snug pocket or in the tissue expansion environment. These textured surfaces may reduce the rate of capsular contracture, but this effect has only been seen in silicone implants and not in saline-filled devices. Texturing to provide adhesion of the implant to the surrounding tissue is an important consideration with shaped devices to prevent rotation but may impact negatively on implant scalloping of the overlying skin.[17] Further, textured (esp. macrotextured) surfaces have been shown to be associated with the development of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL); hence, companies have elected to recall their textured breast implants and tissue expanders in many countries.[18]

5.2 | Expandable implants

Permanent expandable implants combine an outer chamber of factory prefilled silicone with an inner chamber that allows postoperative filling with saline. These implants permit gradual and temporary overinflation to create an ample pocket and then can be left in as a permanent implant after the size has been adjusted satisfactorily.[13]

5.3 | Shaped versus round implants

We distinguish shaped and round implants. Shaped implants can also be referred to as tear-dropped, contoured, or anatomical. They

have greater fullness in the lower half and less fullness in the upper half. Some surgeons feel that these implants provide a more natural breast shape particularly in women with extremely little or no breast tissue as these women would appear too full in the upper pole if a round implant was inserted. Others feel that the shaped implant makes no difference to the final result and compensate for upper pole fullness in small breasted women by lowering the position of the implant. Further, because the silicone gel or saline component of the round implant gravitates to the lower pole of the implant when a woman stands, the lower pole naturally becomes fuller, and some argue that this negates the need for a shaped implant. The disadvantage of shaped implants is that postsurgery rotation would result in an obvious sideways appearance to the breast requiring revisional surgery, a problem that does not arise with round implants. Texturization of shaped implants reduces this risk.

Anatomical prostheses are generally more expensive than rounded implants.[13]

5.4 | DISCUSSION AND CONCLUSION

Breast prostheses are increasingly used in breast augmentation and reconstruction.[1] The evolution of these devices has spanned several decades. Manufacturers have been coming up with many types of implants differing in terms of surface shape, size, texture, and consistency. Still, these remain important areas of research. Clinicians should seek to provide ongoing data and push science to continue to improve the outcomes.

6 | LEVEL OF EVIDENCE

Level IV: Evidence obtained from multiple time series with or without the intervention, such as case studies.

CONFLICT OF INTEREST

The author declares that he has no conflict of interest.

ORCID

Costanzo Domenico https://orcid.org/0000-0002-5867-4409
Battistini Andrea https://orcid.org/0000-0002-8837-268X
Klinger Marco https://orcid.org/0000-0001-8417-0186

REFERENCES

1. National Plastic Surgery Statistics. 2018. American Society of Plastic Surgeons.
2. Czerny V. Plastic replacement of the breast with a lipoma. *Chir Kong Verhandl*. 1895;2:216.
3. Gersuny R.Uber eine subcutaneProsthese. Z. Heilk. 1900;1:199. GENERAL.
4. Institute of Medicine (US) Committee on the Safety of Silicone Breast Implants; Bondurant S, Ernster V, Herdman R. Committee on the Safety of Silicone Breast Implants (eds.). *Safety of Silicone Breast Implants*. Institute of Medicine; 1999:21. https://doi.org/10.17226/9602
5. Edgerton MT, McClary AR. Augmentation mammaplasty; 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.
6. Maxwell GP, Gabriel A. Possible future development of implants and breast augmentation. *Clin Plast Surg*. 2009;36:167-172, viii.
7. Clarkson P. Local mastectomy and augmentation mammaplasty for bilateral paraffinoma of breasts. *Nurs Mirror Midwives J*. 1965;121:13-16.
8. Regnault P, Baker Thomas J, Gleason Matthew C, et al. Clinical trial and evaluation of a proposed new inflatable mammary prosthesis. *Plast Reconstr Surg*. 1972;50:220-226.
9. Maxwell GP, Gabriel A. The evolution of breast implants. *Clin Plast Surg*. 2009;36:1-13, v.
10. Cronin TD, Brauer RO. Augmentation mammaplasty. *Surg Clin North Am*. 1971;51:441-452.
11. Tanne JH. FDA approves silicone breast implants 14 years after their withdrawal. *BMJ*. 2006;333:1139.
12. Maxwell GP, Gabriel A. The evolution of breast implants. *Plast Reconstruct Surg*. 2014;134(1 Suppl):12S-17S.
13. Tang SSK, Gui GPH. Implant and implant assisted breast reconstructions. In: Salgarello M, ed. *Breast Reconstruction - Current Techniques*. London, UK: IntechOpen; 2012.
14. Nichter LS, Hardesty RA, Anigian GM. IDEAL IMPLANT structured breast implants: Core study results at 6 years. *Plast Reconstruct Surg*. 2018;142(1):66-75.
15. Allergan, Inc. Directions for use: Natrelle Silicone-Filled breast implants and NatrelleInspira breast implants. Available at: https://allergan-web-cdn-prod.azureedge.net/actavis/actavis/media/allergan-pdf-documents/labeling/natrelleus/siliconeimplants/1034rev11.pdf. Accessed August 15, 2017.
16. Government of Canada. Summary basis of decision: Mentor MemoryGel Silicone Gel-Filled breast implants: Health Canada. Available at: https://hpr-rps.hres.ca/reg-content/summary-basis-decision-medical-devicedetailone.php?lang=en&linkid=sbd00412. Accessed August 15, 2017.
17. Neumann C. The expansion of an area of skin by progressive distention of a subcutaneous balloon; use of the method for securing skin for subtotal reconstruction of the ear. *Plast Reconstr Surg (1946)* 1957;19(2):124-130
18. Loch-Wilkinson A, Beath KJ, Knight RJW, et al. Breast implant-associated anaplastic large cell lymphoma in Australia and New Zealand: high-surface-area textured implants are associated with increased risk. *Plast Reconstr Surg*. 2017;140:645-654.

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