Breast Implant Surface Development: Perspectives on Development and Manufacture

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Abstract
Capsular contracture poses a significant clinical and scientific research challenge for breast surgeons. Some researchers have pointed to the surface features of implant devices as being responsible for the potential tightening and hardening of the surrounding capsule. In this article, the authors review the history and development of breast implant design, specifically the data supporting improvements that have potential to mitigate the incidence of capsular contracture. The literature suggests that development of new implant surfaces designed to reduce a patient’s foreign body response will improve the safety profile of implant devices and increase patient satisfaction in the long-term.

Keywords
breast implant, history, manufacture, capsular contracture, surface

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The pursuit of evidence-based research and the application of critical appraisal techniques have become paramount for clinicians who are seeking to enhance the quality, safety, and efficacy of healthcare. Several of these investigations in aesthetic surgery have focused on clinical outcomes data for biological implants—more specifically, breast implants. Capsular contracture (CC) following breast implant placement poses a healthcare research challenge and will continue to do so as the demand for breast implants continues to increase.1 CC, the tightening and hardening of the capsule surrounding the device as a result of chronic tissue response or foreign body reactions, remains the most frequent complication following breast augmentation and is a major cause of patient dissatisfaction. Although the rate of incidence is clear, the true source of contracture remains elusive.2–4

Histologically, a capsule is made up of a central portion of fibroblasts, myofibroblasts,5 and histiocytes, with a thicker layer of collagen bundles arranged in parallel around this central portion.6 It has been theorized that structures on the surface of some textured implants promote “budding” of the collagen bundles around the implant, which thereby increases the friction between the implant and capsule. This process disrupts the regular alignment of the capsule, reduces synovial metaplasia,7 and promotes integration of the implant with breast tissue.8

Although textured implants are certainly available, CC remains a significant clinical problem. A detailed review of the safety of silicone prostheses recently inferred that...
silicone gel prostheses have now been afforded an almost clean “bill of health,” but the perfect implant surface—one capable of reducing contracture—has yet to be discovered. To evaluate potential improvements to the design of implant devices, we reviewed the existing literature on the history of implant manufacture, specifically focusing on the implant surfaces commonly available to the clinician today. We also outline the current mechanisms for manufacturing implants and discuss how further research could shape the development of future implants.

**LITERATURE REVIEW**

A Medline (www.pubmed.com) and Scopus (www.scopus.com) search was conducted to identify all relevant clinical studies that evaluated the history, manufacture, and potential future of breast implants. The search was limited to articles published in English and French. Keywords were entered in various combinations, including: “breast,” “implant,” “augment*,” “mammar*,” “history,” “evolution,” “texture,” “polyurethane,” “silicone,” “capsule*,” “contracture*,” “manufacture,” “product,” and “develop” (where * is a “wildcard” truncation). The reference sections of review articles were cross-checked as additional sources of primary papers, which were then added to the master list of compiled articles.

**THE HISTORY OF BREAST AUGMENTATION**

Breast augmentation has a history that dates back over a century. The first known breast augmentation was performed by Verneuil in 1887 with autologous tissue from the patient’s contralateral breast; Neuber began using adipose tissue for augmentation as early as 1893. These
techniques were eventually abandoned in favor of more modern methods, since the eventual loss of autologous tissue was dramatic.\textsuperscript{18}

Gersuny first injected paraffin into the breast in 1889, which showed good early results but very poor long-term results, often resulting in fistulas, granulomas, pulmonary emboli, and tissue necrosis.\textsuperscript{19} Subsequently, in the early 1900s, other materials were placed into the breast, including ivory, glass balls, ground rubber, polyvinyl alcohol-formaldehyde polymer sponges, and polyether foam sponges.\textsuperscript{20} These materials all proved extremely unsatisfactory for augmentation purposes and their research was abandoned.

Injectable materials continued to be popular in the 1950s and 60s. Silicone in liquid form, which was originally utilized during World War II,\textsuperscript{21} was administered often and was a major cause of complications.\textsuperscript{22} Many women experienced “siliconomas”—the granulation of tissues around this silicone liquid, a term coined by Sternberg et al—which often resulted in mastectomy.\textsuperscript{23}

Silicone implants as they exist today (a silicone shell filled with a liquid core of either saline or silicone) were derived in the 1950s from a urethral implant designed by De Nicola.\textsuperscript{24} This innovation, along with the consistently poor results from injectable materials, encouraged the development of a new form of breast implant in 1963. This new design, now known as the first-generation breast implant, was conceived by Cronin and Gerow and produced with Dow Corning Corporation (Midland, Michigan). Since this first implant, over 240 styles and 8300 models of implants have been manufactured.\textsuperscript{25}

After the release of the first prosthesis, further modifications were made at the request of the plastic surgeons who were placing them. The thickness of the implant shells was reduced\textsuperscript{26} and a less cohesive, thinner-consistency gel was placed to give a more natural feel to the implant.\textsuperscript{27} The Dacron patches (Unifi, Inc., Greensboro, North Carolina) were removed due to concerns that they were causing the implant to split or forming a focus for contracture.\textsuperscript{28} These alterations gave rise to the second generation implant (Table 1).\textsuperscript{29}

These new implants showed good early results, but the reduced shell thickness resulted in “gel bleed” (the gradual seep of silicone gel through the shell), generating a similar rate of contracture to what was seen with the direct injection of silicone into the breast years earlier.\textsuperscript{30} Subsequently, third-generation shells emerged in the early 1980s; these were thicker, more resilient, and contained a second layer of diphenyl- or fluorosilicone within their shells, modifications which all remain in today’s implants.\textsuperscript{16,31} Double-lumen implants were also designed. These have a silicone-filled core enclosed by a saline-filled outer shell, which presumably reduces the movement of silicone from the inner layer and can also act as a drug delivery device for steroids and antibiotics.\textsuperscript{32} The reverse double-lumen device, developed later, has an outer silicone and an inner saline compartment; this type of implant remains in distribution as the Mentor Becker device (Mentor Corporation, Santa Barbara, California).\textsuperscript{33,34}

Saline implants first appeared in the French literature in 1965.\textsuperscript{35} The concept behind these implants was to offer a prosthesis that could be filled after the empty shell had been placed in the breast pocket, thus allowing a far smaller incision. Early problems of deflation, saline valve failure, and wrinkling led to surgeons filling the implants with higher-than-recommended levels of saline, a technique still common today.\textsuperscript{27,36,37}

### Table 1. Implant Characteristics

<table>
<thead>
<tr>
<th>Period of Use</th>
<th>Outer Surface</th>
<th>Core</th>
<th>Shell</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Generation</td>
<td>1963 – 1973</td>
<td>-Smooth surface + -Dacron patches posteriorly</td>
<td>Thick silicone 50% LMWC 50% HMWC\textsuperscript{20}</td>
</tr>
<tr>
<td>Second Generation</td>
<td>1972 – 1982</td>
<td>Smooth</td>
<td>Thin silicone 80% LMWC 20% HMWC\textsuperscript{20}</td>
</tr>
<tr>
<td>Third Generation</td>
<td>1982 onward</td>
<td>Smooth</td>
<td>Thick silicone</td>
</tr>
<tr>
<td>Fourth Generation (Textured)</td>
<td>1967 onward</td>
<td>Textured with salt-loss technique or imprint moulding</td>
<td>Manufacturer-specific</td>
</tr>
<tr>
<td>Fifth Generation (Cohesive Gel)</td>
<td>1993 onward</td>
<td>-Textured/smooth surface -Anatomically-shaped -Low bleed</td>
<td>Highly cross-linked silicone</td>
</tr>
<tr>
<td>Polyurethane</td>
<td>1968 onward\textsuperscript{24}</td>
<td>Polyurethane foam</td>
<td>Manufacturer-specific</td>
</tr>
<tr>
<td>Double Lumen</td>
<td>1976 onward</td>
<td>Textured/smooth</td>
<td>Silicone inner, saline outer (vice-versa for Mentor Becker)</td>
</tr>
</tbody>
</table>

LMWC, Low molecular weight chain; HMWC, High molecular weight chain.
popularity. Simultaneously, the US Food and Drug Administration (FDA) began to develop guidelines governing the manufacture and placement of implants. In 1976, the Medical Device Amendment was ratified. In it, breast implants were specified as a Class II device (out of three broad classes), a designation which required manufacturers to provide assurances that their implants did not cause harm to their recipients, although no formal testing or protocols were specified.

In subsequent years, gel bleed and capsular contracture were reported in the literature. As a result, the FDA amended the ranking to a Class III, which meant that breast implants were deemed to present “...a potential unreasonable risk of illness or injury...” The FDA also published a notice of intent which required submission for premarket approval for saline- and silicone-filled implants by November 1991. On this deadline, a panel of experts concluded that more research was needed, but permitted the implants to continue being sold.

However, in 1992, the FDA commissioner called for a voluntary withdrawal of silicone gel-filled implants from the general market pending further investigation, saying that, although the implants were not necessarily unsafe, more data were needed before a final conclusion could be made regarding their safety. This reversal was perceived by the media as a ban and, after several lawsuits from patients, a class-settlement was issued for approximately $4 billion. This ruling essentially caused all but McGhan (subsequently known as Inamed and now owned by Allergan, Inc., Irvine, California) and Mentor to withdraw from the market due to financial pressures. With these withdrawals, several implant surface types were lost to history or were sidelined, including the Dow Corning Silastic Microstructured Implant (MSI; 750 mm high and 250 mm in diameter, with pillars 500 mm apart on its surface) and the Bioplasty Molecular Impact Surface Texture Implant (MISTI).

Trilucent breast implants from LipoMatrix, Inc. (Neuchatel, Switzerland), which contained soya oil and were designed to be radiotranslucent, were also voluntarily removed from the market in 1999 due to concerns about the lipid filler material generating genotoxins in the tissues surrounding the implant and also due to observed clinical problems with swelling and inflammation. Polyvinylpyrrolidone “bio-oncotic” gel implants containing polysaccharides were also withdrawn as a result of insufficient safety and efficacy data, as well as clinical evidence polysaccharide implants swelled over time.

**THE DEVELOPMENT OF TEXTURED IMPLANTS**

The first textured implant was produced in 1968 based on a design from plastic surgeon W. Pangman and was known as the “Natural Y” implant, so named because it consisted of three internal compartments which were meant to retain the shape of the upper aspect of the implant. It was essentially a regular, smooth-surfaced silicone implant with a polyurethane foam coating of 1.5–2 mm on its surface. Over 100,000 patients underwent augmentation with this implant. The device had an external texture that was strikingly similar to the prior iterations of the Ivalon implant, with an open-pore texture that promoted in-growth of tissue.

Results with the “Natural Y” were very promising, especially during the first few years of implantation, when the subglandular rate of contracture was 3.3%. The theory was that the foam inhibited fibroblasts and, therefore, also inhibited immune reactions to the implant. As the polyurethane constituent of the implant fragmented with time, it caused acute and chronic inflammation with slow fibrotic growth, thus disrupting collagen bundle formation and hindering fibrous capsular formation. However, over the long-term, the implant coating was eventually eroded in vivo, revealing the silicone shell beneath it. This caused some researchers to postulate that polyurethane implants only delayed the process of contracture, rather than preventing it entirely. Furthermore, in 1989, a study examining the safety of polyurethane in mice caused concern when evidence showed that the polyurethane-coated implants degraded under physiological conditions, producing metabolites such as 2,4-toluenediamine (TDA), which were thought to be carcinogenic to mice and therefore possibly to humans.

As a result, polyurethane implants were voluntarily removed from the US market in April 1991 by their adopted manufacturer Surgitek (now defunct). Later research by Bristol-Myers Squibb (New York, New York) concluded, however, that the levels of free TDA in the urine of patients who had polyurethane implants was extremely small and posed a lifetime cancer risk of one in 400 million, which was “the equivalent of developing cancer from having smoked one cigarette.” In short order, several new textured surfaces for implants were designed almost simultaneously—Biocell (Allergan), and Siltex (Mentor)—in an effort to emulate the success of the polyurethane implant.

These past events have clearly influenced the makeup of the implants currently on the market. Their development and design relies heavily on early trial-and-error with coating and texturizing techniques that existed before the onset of regulation from the FDA; the Medical Devices Amendment Act made it clear that all subsequent medical devices should either be tested through extensive premarket approval or should be wholly similar to medical devices already in use.

**MANUFACTURE OF CURRENTLY-AVAILABLE IMPLANT DEVICES**

The implant surfaces currently on the market are not dissimilar to those initially developed in the 1970s, although breast implant manufacture is now governed by a strict set of manufacturing standards regulating the shell, contents, biocompatibility, and even packaging. Nevertheless, there
is no enforced standardization for the surface texture of breast implants. The only published stipulation is that the texture "... may not alter the other characteristics of the device."\textsuperscript{62–64} Perhaps for this reason, there is a large range of options in terms of filler material, shell composition, and expansion accessory ports,\textsuperscript{65} but significantly fewer options for surface texture.

Today, there are two broad groups of implants available: smooth and textured. Smooth-surface implants, the "original," comprise the largest group. The textured category includes several different types, including the Biocell surface (Allergan), the Siltex surface (Mentor), the Cereform surface (Cereplas, Provile, France), and the polyurethane surface (Polytech Health and Aesthetics GmbH, Dieburg, Germany).

**Manufacturing Techniques**

All breast implants follow a similar manufacture routine, up to a point; the basic protocol is shown in Figure 2. Many companies still manufacture implants by hand, relying on implant-shaped templates (or mandrels) to form the scaffolds that sustain the implant. Implant mandrels are reusable, made of lightweight plastic or stainless steel, and follow the internal dimensions of the implant, with a handle or stem protruding from the posterior aspect of the mandrel surface. The mandrel is dipped into liquid silicone for several seconds to produce a homogeneous layer, then placed into a laminar flow cabinet to "set," or polymerize. Curing in a laminar flow oven ensures that heat is transferred to the silicone evenly, avoiding the introduction of any weaknesses in the implant shell.

![Figure 2](https://academic.oup.com/asj/article-abstract/31/1/56/273842)

**Figure 2.** The basic protocol for current implant manufacturing techniques, regardless of surface texture, is illustrated. The implant-shaped template (or mandrel) forms scaffolds that sustain the implant. The mandrel is dipped into liquid silicone for several seconds to produce a homogeneous layer, then placed into a laminar flow cabinet to "set," or polymerize. Curing in a laminar flow oven ensures that heat is transferred to the silicone evenly, avoiding the introduction of any weaknesses in the implant shell.

If the implant is destined to be smooth, it is steeped in a solvent to further even this outer surface. (Note that even when a surface is intended to be smooth, it is actually a regularly-ridged topography that results when the silicone creeps down the surface of the mandrel during curing [Figure 3].) For silicone gel-filled implants, a second layer of silicone is included in the mixture, with a phenyl group in place of the methyl group to prevent seepage of the silicone gel through the barrier of the implant.

In terms of textured surfaces, the Biocell surface results from a "salt-loss technique."\textsuperscript{12} After the mandrel is coated in silicone and before the implant surface is cured, an additional step is introduced into the standard protocol, during which the silicone-coated mandrel is pushed into granular salt before being allowed to cure in the laminar flow oven (Figure 4). Once the surface has cured, this salt is then removed by washing the surface of the implant in water, but the implant surface remains pitted with randomly-arranged, cubed indentations. The Cereform surface is also manufactured with a salt-loss technique, but the salt is brushed before curing to create the unusual surface topography (Figure 5). Mentor designed the Siltex surface to emulate the polyurethane coating of previous-generation implants. For these implants, the texturization is created with a negative-contact imprint from a polyurethane foam. Between the coating and curing stages, the implant is pushed into polyurethane foam. The features of this surface are shown in Figure 6.

Whether smooth or textured, once the implant has been cured, it is removed from the mandrel and is subjected to a control step, evaluating that it adheres to the specifications required for medical placement. Microscopic analysis is utilized to detect the presence of air bubbles within the implant surface. Measurement at the pole and equator of the implant then helps to establish that adequate silicone thickness has been achieved. Finally, to verify that the implant does not contain any surface holes, it is submerged in water and filled with air to see if any bubbles emerge from its surface.\textsuperscript{67}
Implant surface features have been shown to directly influence CC rates and dictate the ability of implants to integrate with body tissue, since they act as the direct interface between the device (a foreign body) and breast tissue. This aspect of breast implant manufacture is, therefore, critical to the long-term success of the operation; as such, the surfaces of future breast implants should be reliant upon scientific principles and well-conducted research.

Despite their documented significance, the features of current breast implant surfaces remain relatively basic. Breast implant surfaces are still manufactured with templates devised in the 1960s and 70s, from designs that sought to generate random features in the surfaces of silicone shells. The simple manufacturing techniques utilized now do not reflect production technology available to manufacturers at present.

This can, in part, be explained by the complex history of breast implant technology as described in this literature review. Designs were initially created and marketed, then brought in line with new legislation, which prevented the development of new surfaces that were better equipped for the task of biointegration. The design of an effective surface texture has been disrupted by the withdrawal of different implant surfaces from the market, contradictory data from animal models, and the alteration of popular scientific opinion as to what constitutes the ideal implant surface.

One obstacle in the development of a new implant surface will undoubtedly be the extensive and uncertain investment required to bring a new surface to market. With the litigious environment that has developed around breast implants, it is not surprising that manufacturers elect to simply continue with well-established product.
As patients become ever more health conscious and increasingly educated, though, we believe it is likely that the future of breast implant manufacturers will be dependent on willingness to improve the device options based on solid scientific principles.

We predict that the surfaces of future silicone implants will evolve from examples of adhesion already present within nature. Simple surfaces with 5-µm-square projections have been shown to reduce the planar arrangement of fibroblasts seen in contracture, nanoscale islands of 35 nm have been shown to increase optimum adhesion compared with smooth controls, and endocytic reactions have been promoted in fibroblasts through surface features. Could a surface that combined these nano- and microscale features of planar capsular disruption, with the addition of an outer adhesive protein coating such as ICAM-1, be a template for the future of silicone implants? Perhaps a multilayered implant composed of a permanent outer façade and a removable silicone implant, allowing these components of the implant to operate independently, would also provide a feasible alternative.

The ultimate goal in future implant development is a personally-tailored device, from both a physical and biological perspective. Tebetts and Adams outlined over 34 different parameters that come into play when selecting the perfect personal implant. Aligning product decisions with preimplantation laboratory testing to determine the
risk of CC would allow the surgeon and the patient to make a more informed decision, therefore providing a far more holistic surgical plan.

However, the “perfect” implant is not determined on surface features alone; CC remains a multifactorial challenge and we should continue to explore augmentation options that do not rely on implantable devices, such as tissue engineering constructs (ie, acellular dermal matrixes) that gradually reabsorb to leave autologous adipose tissue or local hormonal factors. Autologous adipose tissue grafting
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The published literature on breast implant manufacturing and marketing techniques indicates a complex history and evolution. Pertinent and well-structured research is needed to further evaluate the importance of and options for surface texturization, which has been shown to somewhat mitigate the results of untoward (and common) side effects such as capsular contracture. This research will help to produce an implant surface better suited to its role within the patient’s body, therefore, improving both its safety and efficacy profiles.

CONCLUSIONS

The published literature on breast implant manufacturing and marketing techniques indicates a complex history and evolution. Pertinent and well-structured research is needed to further evaluate the importance of and options for surface texturization, which has been shown to somewhat mitigate the results of untoward (and common) side effects such as capsular contracture. This research will help to produce an implant surface better suited to its role within the patient’s body, therefore, improving both its safety and efficacy profiles.

Figure 6. Still other manufacturers (Mentor, Inc.) emulate the polyurethane coating of previous-generation implants by using a negative-contact imprint from a polyurethane foam (A) to generate the surface texture (B). Between the coating and curing stages, the implant is pushed into polyurethane foam.
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