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Review Article

History of breast implants: Back to the future

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ABSTRACT

Modern breast implants are a staple of plastic surgery, finding uses in esthetic and reconstructive procedures. Their history began in the 1960s, with the first generation of smooth devices with thick silicone elastomer, thick silicone gel, and Dacron patches on the back. They presented hard consistency, high capsular contracture rates and the patches increased the risk of rupture. In the same decade, polyurethane coating of implants was implemented. A second generation was introduced in the 1970s with a thinner shell, less viscous gel filler and no patches, but increased silicone bleed-through and rupture rates. The third generation, in the early 1980s, featured implants with a thicker multilayered elastomer shell reinforced with silica to reduce rupture risk and prevent silicone bleed-through. A fourth generation from the late 1980s combined thick outer elastomer shells, more cohesive gel filler, and implemented for the first-time outer shell texturing. In the early 1990s, the fifth generation of devices pioneered an anatomical shape with highly cohesive form-stable gel filler and a rough outer shell surface. Surface texturing was hampered by the discovery of Breast Implant Associated-Anaplastic Large Cell Lymphoma and its link with textured devices. From the 2010s, we have the era of the sixth generation of implants, featuring innovations regarding the surface, with biomimetic surfaces, more resistant shells and variations in

Abbreviations: BI, Breast Implant; BIA-ALCL, Breast Implant Associated Anaplastic Large Cell Lymphoma.

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gel consistency. The road to innovation comprises setbacks such as the FDA moratorium in 1992, the PIP scandal, the Silimed CE mark temporary suspension and the FDA-requested voluntary recall of the Allergan BIOCELL implants.

Introduction

The term "breast implant" (BI) refers to any implantable prosthesis used to modify or replace a person's breast contour, shape and size. Despite the great variability, they can be grouped according to three characteristics: fill, shell surface and three-dimensional shape.

In the European and American markets, they are most frequently filled with silicone gels of varying levels of cohesiveness, resulting in different viscosity and firmness. The second most commonly used filler material is saline solution. Less commonly used fillers include methylcellulose, soybean oil and others. All shells are made of silicone and fabricated by adding different layers (3–5) on top of each other to increase their strength against rupture or become impermeable to silicone, hindering bleed-through.

The external surface of the shell can have different aspect with different degrees of roughness, ranging from a non-perceptible one by touch (smooth), to a shallow or deep texturing, or it may also be coated with polyurethane (PU).[1]

Based on the above, several classifications mainly based on physical properties have been proposed. Barr et al. divided BIs according to surface roughness in Nano(<5 μm), Meso(<15 μm), Micro(10–75 μm), and Macro (>75 μm).[2] Although Atlan et al. used measurements of surface area to classify implants into Smooth (80–100 mm^2), Micro (80–100 mm^2), Macro (200–300 mm^2), and +Macro (>300 mm^2).[3] Jones et al. instead, first introduced the integration of a biologic property as the bacterial attachment to surface with the physical measurements of roughness, to classify implants into Minimal (<25 μm), Low (25–75 μm), Intermediate (75–100 μm), and High (>150 μm).[4]

Today the most widely accepted classification remains the ISO 14607:2018, which divides surfaces based on their average roughness into Smooth (<10 μm), Micro (10–50 μm), and Macro (>50 μm).[1] Nevertheless, there is still need for a more comprehensive classification of implants integrating physical properties to their host interaction connected with most of BI complications (capsular contracture, BIA-ALCL).

Shape can either be *round*, a lenticular shape, with a symmetrical curved anterior side (dome) and a flat round posterior base; or *anatomical,* a teardrop shape, with the upper half having a lower projection compared to the enhanced projection of the lower half. They have an asymmetric curved anterior side and a flat, more often round or elliptic posterior base. These implants are filled with a highly cohesive gel to maintain their anatomical shape and are rough to prevent their rotation.

BIs undoubtedly represent a staple of plastic surgery, finding indications for both esthetic and reconstructive purposes. Their manufacturing has evolved significantly to overcome health concerns all the while accommodating the needs of patients, which is why they have gone through several iterations of changes.[5,6] The aim of this paper was to present a recollection of the main BIs and relative events that paved the way to the development of modern BIs used today in the European and American markets, as well as the defining moments that will guide devices of the future.

"Prehistory" – the dawn of breast implants

The first modern BI was introduced by Thomas Cronin and Frank Gerow in 1962, and the first generation of these devices was commercially produced using silicone by the Dow Corning Corporation,

reaching US markets in 1964. They were manufactured with a smooth outer surface, a thick silicone elastomer (~0.75 mm) shell filled with thick viscous polydimethylsiloxane (PDMS) silicone gel (composed of a mix of 50% low molecular weight chain [LMWC] components which are more fluid, and 50% high molecular weight chain [HMWC] components which are more viscous) and Dacron fixation patches on the posterior aspect to maintain their position.[7] Later the Dacron patches were deemed dangerous as they created a stress point at which the outer shell could tear,[8] and the devices were performing too firm with an unnatural feel and a high capsular contracture rate. Soon after, in 1964, saline inflatable implants were developed by Laboratoires Arion,[9] and because of their softer consistency gained a first wave of popularity in the 1970s as an alternative to Dow Corning BIs. However, they presented many cosmetic disadvantages and a much higher risk of deflation and implant failure, thus their market remained limited to the USA.[10,11] Natural-Y Surgical Specialties Inc. developed in 1964 and made available in 1968, the first type of silicone BI with an irregular sponge-like surface, coated by a 1 to 2 mm-thick layer of PU foam. This feature was intended to enhance tissue integration[12] and counteract capsular contracture which plagued the previous generation of BIs.[13] Their internal baffle was divided in the shape of a "Y" into 3 compartments, to minimize bulging of one compartment when another was compressed.[14] In 1970s, silicone gel-filled Dow Corning implants were improved upon with a second generation having a thinner shell (~0.13 mm), no Dacron patches and less viscous, low cohesion silicone gel (containing a mix of 80% LMWC and 20% HMWC).[15] Although these BIs provided a more natural feel, their shell appeared to be permeable to silicone gel and they were subsequently plagued by microscopic bleeding and spreading of silicone droplets mainly to surrounding tissues and locoregional lymphonodes. In addition, they were less durable than their predecessors and ruptured frequently.[16,17]

Importantly, these concerns and drawbacks, on one hand caused silicone BI regulations to shift in 1976, with the Food and Drug Administration (FDA) subjecting BIs to controls and performance standards with the enactment of the Medical Device Amendments,[18] whereas forced companies for further innovations.

In 1976 Heyer-Schulte, in the attempt to overcome the silicone gel bleeding first introduced the "double lumen" BI, consisting of a silicone-filled core enclosed by a saline-filled outer shell.[19] This has paved the way for the introduction of a third generation of BIs in the 1980s, which implemented a thicker multilayered elastomer shell (0.28–0.3 mm) reinforced with silica to reduce implant rupture, prevent gel migration and stop silicone bleed-through. In 1984 Mentor manufactured a "reverse double lumen" implant also known as the Becker permanent expander, opposite to the previous produced by Heyer-Schulte.[20] It consisted of a saline implant connected to a filling tube and a valve encased within a silicone implant, in an attempt to combine the esthetic benefits of silicone gel in the outer lumen with a postoperatively adjustable volume from the inner lumen, particularly advantageous in reconstructive and asymmetry cases.

In spite of all the improvements, several reports of adverse events in patient with previous BIs began to appear in the medical literature" in the 1980s, and the FDA decided to designate BIs as class III medical devices with the Federal Register of June 24, 1988 (53 FR 23856): this implied that manufacturers needed rigorous approval from the FDA proving that their devices were medically safe before they could be sold and marketed.[21] Unfortunately the regulations arrived a little too late, as patients began suing manufacturing companies, arguing that the implants caused a variety of complications of which they had not been informed prior to surgery, including diseases of the immune system and breast cancer.

In the late 1980s, reports emerged also regarding the *in vitro* degradation of PU, which could lead to formation of 2,4-toluenediamine (2,4-TDA), known to be carcinogenic in animals, and raising concerns about its potential carcinogenicity in humans.[22,23] The FDA, after performing a risk analysis, concluded that the lifetime risk of PU-induced cancer in women with a single pair of PU-coated BIs was about 1 in 1,000,000. This, according to the WHO definition of "acceptable cancer risk",[24] led the FDA to recommend that women with PU BIs should not have their devices removed based solely on concerns about cancer from 2,4-TDA.[25] Although in 1991 the main PU-BI manufacturers Surgitek (subsequently Bristol-Myers Squibb) voluntarily withdrew its devices manufactured in the USA, which had been implanted in 110,000 American women by that time,[26,27] foreign producers continued to man-

ufacture PU-coated BIs outside the USA, and these devices have been widely used throughout Europe and other parts of the world in the following years.

From late 1980s onwards, the fourth generations of BIs were developed with manufacturing criteria and quality control more stringent and rigorous than ever, due to the legislative FDA changes of 1988. The BIs included thick outer elastomer shells (~0.5 mm), in some cases similar to that of previous generations of BIs, and a cohesive gel filler (manufacturer-specific) which was thought to be less likely to rupture and leak silicone.[28] They were most commonly round and with moderate cohesivity gel filler, and began implementing texturing of outer shells with different processes, including "*salt-loss*" and "*imprint stamping*" techniques to allow for more integration by tissue ingrowth into the irregular spaces of the shell.

In 1990 Mentor licensed barrier technology to McGhan (subsequently Inamed and then Allergan from 2006) which began producing their own line of "double-lumen" devices similar to Heyer-Schult. However, the complex structure of these devices caused higher failure rates than previous BIs, and despite Mentor Becker expanders still being in distribution, double lumen implants began falling out of favor at the turn of the century.[29]

By the early 1990s, Dow Corning was entangled in a litigation counting over 12,000 women who partook in a class-action lawsuit.[30] Pressured by media frenzy over BI litigation, the FDA evaluated that evidence supporting the safety and effectiveness of BIs was insufficient, and thus placed a temporary moratorium in January 1992, banning the use of silicone BIs in the USA.[31] In April of the same year, the ban was revoked, but access to silicone BIs was limited to breast reconstruction, correction of congenital deformities and revisional cases. During the moratorium, saline inflatable BIs received some newfound popularity because they became the only option for esthetic breast augmentations in the USA, but never gained much popularity in the rest of the market where moratorium and limitation were not imposed.[32,33] Meanwhile, Dow Corning which was the world's largest implant manufacturer of its time, controlling 35% of the market, agreed to pay $3.2 billion as settlement with the claimants in 1994, but then later filed for bankruptcy in 1995 due to the number of lawsuits it was still facing. This effectively caused the corporate giant to withdraw from the implant market.[34] Nevertheless, overwhelming research disproved the claims that BIs were linked with breast cancer and connective tissue diseases.[35],[36,37] Although the link with autoimmune and rheumatic diseases is up for debate, scientific evidence at the time failed to show that BIs caused disease, and after in-depth evaluation the FDA lifted the moratorium for good on November 2006, allowing the use of silicone BIs for women over the age of 22.[38,39] After lifting the moratorium, the FDA assessed results of core studies and approved in the USA only BIs produced by Allergan[40] and Mentor.[41]

"Middle ages" – the darkest hour of breast implants

A fifth generation of devices was introduced in 1993 with an anatomical teardrop or "gummy bear" shape and highly cohesive form-stable gel filler to maintain it,[42] combined with a rough outer surface of the shell (texturing) allowing for ingrowth and adherence with host tissues, necessary to stabilize implants in the correct position in the periprosthetic pocket.[43]

Some brands as Allergan (BIOCELL surface), Eurosilicone, GC Aesthetics, Silimed and others, began producing the "*salt-loss*" texturization either by spraying, by dipping or sprinkling fine salt crystals onto the silicone shell before curing, and supposedly removed afterwards by rinsing with water without brushing.[44,45] This texturization was coarse and somehow different from the one created by other manufacturers as Mentor's (Siltex surface), generating a finer homogeneous outer texture by a pressure imprint-stamping technique.[46,47]

In this period, fear over health concerns linked to silicone, favored the development of filler alternatives as the LipoMatrix's Trilucent BIs, marketed and sold in Europe from 1995 only with pre-clinical safety data. They differed from previous generations of BIs for being filled with soybean oil, thought to be safer compared to PDMS.[48] Later evidence suggested an high early implant rupture rate,[49] caused by extreme fragility of the implant's shell which deteriorated causing bleeding of the triglyceride filler, the latter linked to the formation of toxic oxidation products that caused pronounced inflammatory reaction.[50] The UK's Medicines and Healthcare products Regulatory Agency (MHRA) additionally found that the degradation of the oil was linked to cancer and birth defects. After adverse reports Trilucent

BIs were voluntarily withdrawn in March 1999[51] and in June 2000 were recommended to be removed due to the risk of local tissue exposure to toxic compounds.[52]

The Poly Implant Prothèse (PIP), French manufacturer, launched in 1991 and began producing in 1997 silicone-filled BIs which became popular for their competitive marketing strategy. After the FDA refusing to approve PIP BIs in 2000 because of deviations from good manufacturing practices, the company came under scrutiny from European regulators in March 2010 when the French Agency for the Safety of Health Products (formerly AFSSAPS, now ANSM) performed an inspection of the company's headquarters following numerous reports of early implant rupture. They found evidence of unapproved low-quality industrial-grade silicone gel used during the manufacturing process instead of medical-grade PDMS.[53] Consequently, they ordered to suspend the sale of all PIP BIs and their withdrawal from the market,[54] affecting approximately 400,000 women in 65 countries[55] from health risks of locoregional[56] and systemic silicone spread.[57,58] It ultimately led to PIP filing for bankruptcy and to the arrest of the company's Chief Executive Officer. Germany's Technical Inspection Association (TÜV Rheinland) was among the bodies that certified PIP implants, and was found liable by French judges according to whom TÜV could not have been oblivious to the fraud.[59] Because of the seriousness of the situation and the high risk of premature rupture, in December 2011 the ANSM recommended all women with PIP BIs to preemptively remove them,[60] applying the precautionary principle from the *Treaty on the functioning of the European Union*, Art. 191, which should be applied "when a product may have a dangerous effect, identified by a scientific and objective evaluation, if this evaluation does not allow the risk to be determined with sufficient certainty".[61,62]

Silimed, born in Rio de Janeiro in 1978, started production of BIs in 1981 including PU-coated BIs from 1989, and received the CE mark 1998. On September 2015, the German Federal Institute for Drugs and Medical Devices (BfArM) conducted an inspection of the Brazilian company's manufacturing plant, finding evidence that surfaces of textured and PU-coated implants were contaminated with man-made mineral fibers (MMMFs), potentially carcinogenic to humans. As a result of this discovery, the MHRA, jointly with European healthcare product regulators of member states, again followed the precautionary principle and ordered the suspension of CE certificate for all Silimed medical devices.[59,65] In the same year, health authorities in the Netherlands appointed the Independent Clinical Expert Advisory Group (ICEAG) to investigate whether MMMFs found on Silimed BIs could elevate cancer risk to a level higher than the "acceptable" one.[66] The authors of the risk analysis warned about important uncertainties and limitations to their estimate, like the intraperitoneal introduction of fibers in the rat model used for the study, or the larger size of the fibers (median length of $\sim$180 µm and diameter of 9 µm) found on Silimed implants, which may lead to a lower toxicity if encapsulated or conversely to a higher toxicity due to frustrated phagocytosis and increased biopersistence. In fact, macrophages fail to incorporate and remove foreign bodies larger than $>$30 µm, leading to cytokines storm and chronic persistent inflammation.[67] Based on that analysis, the cancer risk could range from lower (0.442:1000000) to higher (9:1000000) than 1 in 1000000, and it was considered "acceptable" by EU regulatory agencies, similar to previously done by the FDA when studying PU carcinogenicity. The ICEAG concluded that being the risk "very small and around the acceptability limit", that decisions about risk management in patients with potentially contaminated BIs should be made jointly by patients and their treating physicians. These MMMFs were not found on their smooth devices, and should not be found on any BI surface in general.[63,64]

The Australian Therapeutic Goods Administration (TGA) followed suit and canceled all Silimed devices from their register on November 2016,[68] and later Loch-Wilkinson et al.,[69] Collet et al.[70] and Magnusson et al.[71] showed a carcinogenicity risk for Silimed PU BIs as high as 1 in 2,832 implants. Sientra, which is a US-based company that hired Silimed for manufacturing their BIs, voluntarily placed a temporary hold on the sale in the US of all Sientra devices manufactured by Silimed, advising surgeons to discontinue implanting them.[72] Sientra has now severed ties with Silimed and manufactures its own BIs on American soil. Meanwhile, Silimed has addressed the health concerns and has recovered the CE mark, but Silimed products have not been sold in the EU since 2015.[73]

From 2010 onward, companies have attempted to introduce filler innovations such as the Diagon/Gel 4 (POLYTECH Health & Aesthetics GmbH) which combines 2 different types of silicone gel, softer on the back while firmer in the front, in a textured anatomical implant.[74]

Recently, all textured 4th and 5th generations of BIs become potentially afflicted by another crisis, related to the onset of a hematological cancer named Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). First reported in 1997 by Keech and Creech,[75] it was highlighted later by the FDA alert in 2011,[76] and finally recognized as a separate nosological entity by the World Health Organization in 2016.[77] In 2017, the European Commission on Health (DG SANTE) requested the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) to provide a scientific opinion on the safety of BIs, which concluded that there were "insufficient scientific information available to establish a methodologic robust risk assessment regarding a possible association between BI and ALCL development" and recommended the scientific community to conduct a more in-depth evaluation.[78]

On December 14th, 2018, French notified body GMED denied the renewal of the CE mark for Allergan BIOCELL textured BIs and tissue expanders.[79] This hindered the sale of Allergan BIs across Europe, and was followed soon after by the ANSM's ban on the sale and use of macrotextured and polyurethane-coated BIs in France on April 4th, 2019, affecting several brands.[80] FDA followed suit on July 24, 2019, ordering a class I voluntary recall of all Allergan textured devices from the market due to BIA-ALCL risk.[81]

In 2019, the European Commission on Health (DG SANTE) requested again the SCHEER to provide a scientific opinion on the safety of BIs.[82] Two years after the previous request it was concluded that there is a causal relationship between all textured BIs and BIA-ALCL, that not all devices give rise to the disease, and that the incidence is higher in patients with macrotextured devices according to ISO-14607:2018, being disproportionately higher with specific types or brands (Allergan Biocell, Silimed Polyurethane).[67,68] In addition, there is evidence to suggest that this type of ALCL is not only linked to BIs, but to implantable textured devices in general.[83]

The scientific evidence for causal relationship was weighted as "*moderate*", as there are sufficient scientific data from a primary line of evidence, based on a majority of epidemiological studies, that being retrospective case-control studies have limited ability for causal inference. Thus the claim for a causal relationship needs to be strengthened by a secondary etiopathogenetic line of evidence. While accounting for a possible genetic predisposition, the pathogenic mechanism of chronic inflammation leading to lymphomagenesis could be triggered by multiple, possibly combined, etiologic hypotheses such as bacterial contamination, shell shedding of particulates, shell surface characteristics leading to friction, or by implant-associated reactive compounds.[84] Nevertheless, because of the etiology gaps in the secondary line, reaching a *strong* weight of evidence would require randomized controlled trials on humans, which are obviously unethical and unachievable as high-risk devices have been withdrawn.[85] As most authorities are not giving precise guidance, some surgeons continue using macrotextured devices that are still available on the market.[86,87] Others have abandoned textured BIs altogether, implementing the use of smooth devices in their practice instead,[88] or even evaluating the pre-emptive explantation and replacement from textured to smooth devices.[89,90] Regardless of personal beliefs, BI markets have responded to the health crisis related to texturing by progressively shifting to smooth implants in some parts of the world.[91] In USA, the use of textured BIs for all placements which started at 3.4% in 2007, increased significantly and peaked at 22.89% in 2016, and then dropped again to 3.61% in 2019.[92] But with the exception of France, the same cannot be said for other European countries, where textured BIs still represent the majority of used devices until 2018.[93] There is no doubt that previous banning, cultural and market differences have created a population of surgeons that are more comfortable using smooth implants in the USA,[94] compared to their European counterpart, for whom a transition from textured shaped to round smooth devices might jeopardize esthetic outcomes,[84] and might require a learning curve before achieving similar results.[85]

"Modern times" – out with the old, in with the new

Necessity is the mother of invention. Today's most feared macrotextured implant-related complications have been linked to the potential effects of chronic inflammation.[95] Studies on animal models confirm this by reporting highest amounts of inflammation and foreign body response in devices with roughness >80 µm.[96]

This has pushed for the creation of safer BIs with a new sixth generation, which was introduced in the early 2010s and implements evidence-based modifications that help mitigate foreign body re-

Table 1
Silicone breast implant characteristics. Adapted from Barr et al.'s Table "Implant characteristics" (Barr S, Bayat A. Breast implant surface development: perspectives on development and manufacture. Aesthet Surg J. 2011;31(1):56–67. doi:10.1177/1,090,820 × 10,390,921).

Type of BI	Period of Use	Outer Surface	Core	Shell
First Generation	1963–1973	- Smooth (< 1 μm) - Dacron patches posteriorly	- Thick silicone - 50% LMWC - 50% HMWC	- ~0.75 mm
Second Generation	1972–1982	- Smooth (< 1 μm)	- Thin silicone - 80% LMWC - 20% HMWC	- ~ 0.13 mm - High bleed-through rate
Third Generation	1982 onward	- Smooth (< 1 μm)	- Thick silicone	- Early shell: 0.28–0.3 mm - Later shells: dependent on manufacturer - Reinforced with silica
Fourth Generation	1987 onward	- Textured (> 80 μm) - with salt-loss or imprint molding technique	- Manufacturer-specific - Generally moderate cohesivity silicone	- ~ 0.5 mm
Fifth Generation	1993 onward	- Textured - Anatomically-shaped - Implant stabilization	- Highly cross-linked, cohesive silicone - Form-stable	- Manufacturer-specific - Low bleed-through rate
Polyurethane	1968 onward	- Internal Y-shaped baffle (Natural-Y) - PU foam - Micro-PU foam (Microthane)	- Manufacturer-specific	- ~ 1.5 mm
Double Lumen	1976 onward	- Textured/smooth	- Silicone inner, saline outer - (vice-versa for Mentor Becker)	- Unknown
Trilucent	1995–1999	- Open-cell textured	- Soybean oil triglycerides	- Unknown
Poly Implant Prothèse	1997–2010	- Textured/smooth	- Low-quality industrial-grade silicone gel	- Unknown - Significant variation within sample and between samples
Diagon/Gel 4Two	2010 onward	- Textured - Micro-PU foam (Microthane)	- Softer gel on the posterior aspect - Firmer gel on the anterior aspect	- Unknown
Sixth Generation	2010 onward	- Smooth (~ 4 μm)	- Manufacturer-specific - Ergonomic and rheological filler (Motiva)	- Manufacturer-specific - ~ 0.5 mm (Motiva) - Advanced multilayered elastomer shell (GC Aesthetics)
B-Lite	2015 onward	- Textured/smooth	- Inert hollow borosilicate beads	- Unknown

BI, Breast implant; LMWC, Low molecular weight chain; HMWC, High molecular weight chain; PU, Polyurethane.

action.[97] These BIs include Motiva Silk Smooth, Sebbin Integrity and Sublimity, and Nagor Perle lines. Despite a smooth outer surface according to ISO-14607:2018,[98] they present peculiar biomimetic topography, different from previous smooth implants,[99,100] which aims at reducing bacterial growth and inflammatory response compared to macrotextured devices, all the while minimizing host response.[101,102] Other innovative features of new generation devices include the ergonomic and rheological filler gels which change shape and projection according to the position,[103] or advanced multilayered elastomer shells to minimize silicone diffusion.[104]

Another filler innovation was introduced in 2015 as a lightweight alternative to traditional silicone, implant named B-Lite, manufactured by the Israeli company G&G Biotechnology Ltd. and owned by POLYTECH Health & Aesthetics GmbH since 2018. They are silicone-filled BIs, with smooth or textured surface, that use innovative microsphere technology to disperse inert hollow borosilicate beads throughout its filler silicone, resulting in a lighter implant for a given volume.[105] On February 2021, B-Lite received a temporary CE mark suspension due to the concern for the presence of filler gel with beads, larger than 30 µm, on the outer shell of the devices. It is unclear whether was the filler bleeding through the implant shell or touching the outer surface during manufacturing. Nevertheless, the suspension was meant to last 3 months, and eventually the CE mark was reinstated,[106] but so far B-Lite are not yet available on the market and still have not received the FDA approval (Table 1).

As of today in absence of proper obligatory or opt-out breast implants registries, it can only be approximately estimated that millions of BIs are sold and implanted, assisting plastic surgeons in their pursuit to offer solutions in difficult clinical reconstructive and esthetic cases. Most women are pleased with their implants, and those on the marked today are considered safe by regulatory authorities. Nevertheless, history teaches us that only vigorous manufacturing processes, investment in innovation, and attentive vigilance can help us maintain these devices safe and available.

On the basis of previous failures and innovations, the latest frontier for implant is 3D bioprinting technology, which uses cells and growth factors as the “ink” to create structures that resemble natural tissues such as fat and blood vessels.[107,108] The promise of these technologies has the ultimate goal of producing de novo organs for transplantation.[109] The near future might also bring us the use of scaffolds that can act as standalone devices, functioning as temporary carriers for autologous tissues, where adipocytes introduced through fat transfers replace the scaffold over time.[110] Polycaprolactone has been recently found on a preclinical level as a successful biomaterial for breast tissue engineering.[111,112]

In conclusion, it is only by understanding the past of BIs that we can expect to move forward with innovative designs and refinements which will ultimately benefit patients’ health and satisfy their esthetic expectations.

Ethical approval

Not required.

Declaration of Competing Interest

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