

# The “Game of Implants”: A Perspective on the Crisis-Prone History of Breast Implants

Anand K. Deva, BSc (Med), MBBS (Hons), MS, FRACS;  
Amanda Cuss, BMedSci (Hons), MBBS (Hons); Mark Magnusson,  
MBBS, FRACS; and Rodney Cooter, MBBS, MD, FRACS

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## Abstract

Since their introduction into the market, breast implants have been the subject of many controversies. It is timely to examine the forces that have shaped the breast implant industry to make it what it is today. This review will concentrate more on the use of implants in aesthetic surgery rather than their use in breast reconstruction, but some of the factors have relevance to both indications.

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*“Are you afraid? Good. You’re in the great game now.  
And the great game is terrifying.”*

—Tyrion Lannister [to Daenerys Targaryen] *Game of Thrones* (Season 6, Episode 10)

The myriad forces that have shaped the breast implant industry are presented here as the “game of implants” (Figure 1). It is timely that we review the impact of each of these forces on the industry as it is today.

Cronin and Gerow engineered the first silicone implant with involvement of the Dow Corning Company inspired by the look and feel of a bag of blood.<sup>1</sup> This led to entry into the market of the Dow Corning implant in 1963. By 1992, the breast implant market generated annual revenues of approximately \$500 million, and around 80% of the revenue was generated by cosmetic augmentation.<sup>2</sup> Surgeons’ fees accounted for the bulk of the revenue. Although Dow Corning had a 35% market share, 4 other manufacturers also produced breast implants—Surgitek (subsidiary of Bristol-Myers Squibb), McGhan Medical Corporation (acquired by INAMED), Mentor Corporation, and Bioplasty.<sup>2</sup> The industry had already responded to early claims of silicone bleed and capsular contracture by modifying the outer shell of implants.

## The First Crisis: Dow Corning

The first report that silicone breast implants were potentially related to autoimmune disease surfaced in 1982 as a series of 3 case reports of patients who developed autoimmune connective tissue disease (Systemic Lupus Erythematosus, Mixed Connective Tissue Disease and Rheumatoid Arthritis) within 3 years of their cosmetic breast augmentation.<sup>3</sup> The authors cited risk of exposure to paraffin or processed petroleum from previous techniques of breast augmentation and postulated that the potential immunological activity of

Professor Deva is Head of Plastic and Reconstructive Surgery and Co-Director of the Surgical Infection Research Group, Macquarie University, Sydney, Australia. Dr Cuss is a Senior Medical Advisor, Devices Clinical Section, Medical Devices Branch, Medical Devices and Product Quality Division, The Therapeutic Goods Association, Canberra, Australia. Dr Magnusson is an Associate Professor, Griffith University, Southport, Queensland, Australia. Dr Cooter is an Adjunct Clinical Professor, Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, Victoria, Australia.

### Corresponding Author:

Prof Anand K. Deva, Suite 301, 2 Technology Place, Macquarie Park NSW 2109, Australia.

E-mail: [anand.deva@mq.edu.au](mailto:anand.deva@mq.edu.au); Twitter: [@saferimplants](https://twitter.com/saferimplants)



Figure 1. The game of implants.

silicone and its degradation “suggest the association may well be more than coincidental.”<sup>3</sup> The increasing reports of an association of silicone with adjuvant disease<sup>4,5</sup> led to the filing of multiple court actions against the leading implant manufacturer of the day, Dow Corning. The management of this crisis by Dow Corning has been a textbook example of how not to deal with a rising public and legal threat.<sup>6</sup> In short, the company failed to show sympathy and support for women who claimed to have been harmed, were slow to get the worst news out quickly, and, when faced with claims that were not strongly supported by scientific evidence, sought to obfuscate the truth rather than defend it by potentially misleading regulators, physicians, and consumers about the extent of uncertainty within the company about its own safety data.<sup>7</sup>

### Regulatory Response

When first introduced into the marketplace, breast implants were exempt from regulatory scrutiny as they

Table 1. Medical Device Classification of Risk<sup>9</sup>

Class	Description
I	Those devices for which “general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device” (eg, adhesive bandages, toothbrushes, eyeglasses, and thermometers).
II	Those devices for which “a performance standard exists to provide reasonable assurance of safety and effectiveness” (eg, cardiac monitors, anesthesia machines and defibrillators, and magnetic resonance imagers).
III	Those devices “purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury” (eg, silicone-gel breast prostheses [implants], IUDs, endolymphatic shunts, and osseous implants).

were considered a “medical device” as opposed to a drug. The United States began to regulate medical devices with amendments to legislation in 1976, but breast implants, which had been on the market for 10 years and mainly

for cosmetic indications, were “grandfathered” in and classified as Class II, moderate risk (Table 1).<sup>8</sup> The standard at the time was that breast implants had to be “substantially equivalent” to devices already on the market. In 1982, the US Food and Drug Administration (FDA) under pressure from increasing reports of adverse events including capsular contracture, gel bleed, and possible link to autoimmune disease, reclassified breast implants as class III devices, “subject to demonstration of safety and efficacy.” In 1991, following congressional hearings and popular opinion that implant companies were covering up evidence, the FDA issued a call for all manufacturers to submit safety and efficacy data (premarket approval [PMA]).<sup>9</sup> Around this time, the first textured implant, the Meme, was removed from the market in the United States. This was a polyurethane-coated implant that had been linked to the release of 2,4 toluene diamine, a carcinogen in animals.<sup>10</sup> It was later revealed that the implants were coated with polyurethane that was not sterile and not medical grade. Around 1 million of these implants had been already implanted into women without the proper scrutiny of both sterility and manufacturing standards. When the safety and efficacy data were finally received and reviewed by the FDA, the agency criticized all the studies as too small and too short term to prove safety. In January 1992, the FDA imposed a “voluntary moratorium” on breast implants.<sup>8</sup> This required the suspension of all sales and implantation of devices, pending receipt of new safety data. Implants could only be used for breast reconstruction or those receiving replacement for an existing implant and only in the context of ongoing prospective clinical studies. Many patients were enrolled, but because the goal was to simply satisfy entry into a trial, patients quickly dropped out of the studies, which negatively affected long-term follow-up data.

This decision opened the floodgates for litigation culminating in the filing of Chapter 11 bankruptcy by Dow Corning, the largest implant manufacturer at the time. They faced more than 20,000 individual lawsuits at the time, which then coalesced into a class action.<sup>2</sup> As part of a global settlement in 1994, a \$4.25 billion settlement was made with contribution by all manufacturers to provide affected women access to payments in spite of no proof of causation that their symptoms were related to their breast implants.

The FDA then required smaller, more detailed analyses over 2 to 3 years, which led to restricted approval of saline breast implants in 2000. In 2003, further limited approval was given for Allergan silicone gel-filled implants. This was followed by approval of Mentor and Allergan silicone gel-filled implants in 2006, but because of ongoing concerns, postmarket approval data were still required by the FDA and longitudinal core studies were planned to follow 100,000 women closely for 7 to 10 years.<sup>9</sup>

Not surprisingly, the European and Australian regulators began to follow the US lead in June 1993, restricting access to silicone gel breast implants as part of a broad push for better scrutiny by the European Commission.<sup>11</sup> They released a Medical Device Directive, which outlined the need for regulation around manufacturing, testing, and marketing of devices based on levels of risk. New devices were now also obligated to undergo a “conformity assessment” by an independent reviewer. The enforcement of the directive fell to individual member countries, the UK Medicines and Healthcare Product Regulatory Agency (MHRA) and the National Agency for the Safety of Drugs and Health Products (ANSM) being 2 such examples. It is not a uniform requirement for devices to undergo clinical trials and can be exempt if “it is duly justified to rely on existing clinical data.” Even if clinical trials were mandated, they were not required to be randomized or have a control arm, and they could have sample sizes as low as 100 patients. Once approved, they were given a “Conformite Europeene,” or CE mark, literally meaning “European conformity.”

### Some Early Failures

There has been faster passage of approval for breast implants in Europe, which has lowered the barrier of entry in some countries to a variety of implant manufacturers and implant types. In 1995, the Trilucent breast implant gained CE mark approval with preclinical safety data because it was claimed that the filler material, soybean oil, was safer than silicone and did not interfere with mammography. After 4 years of usage in patients, a clinical study from Belgium reported leakage of the soybean oil. This prompted further investigation by the MHRA, which found that the breakdown of the oil was linked to cancer and birth defects.<sup>12</sup> In 2000, Trilucent implants were removed from the market.

Two companies, PIP (Poly-Implant-Prothese) and NovaGold, released implants that were filled with hydrogel in the 1990s, which both gained CE mark approvals.<sup>13</sup> These devices were also found to have inadequate biological safety assessments by the MHRA and were voluntarily withdrawn from the market in December 2000.

By contrast, the FDA has been more stringent in limiting the entry of these implants into the US market.

### The Second Crisis: PIP

PIP also sold other types of breast implants and managed to gain approval for their saline-filled implants in the United States after FDA scrutiny in 1996. This was based on the evidence that their device was “substantially equivalent” to other implants approved by the FDA.<sup>9</sup> PIP saline

implants were then approved for sale in Europe in 1997. When the FDA called for PMA submission for all breast implants in 1999, they rejected the application by PIP and removed them from the US market. As part of their application, an inspection by the FDA identified 11 violations of good manufacturing practice.<sup>8</sup>

In 2001 to 2002, the first of several adverse event reports was noted by the MHRA.<sup>14</sup> Initially, it was thought that adverse events were a result of improvement in case reporting, but it became clear that the failure rate for PIP implants was double that of other types of breast implants. The manufacturer was notified and began to monitor the situation. In March 2010 and within days of each other, both the ANSM and MHRA announced the suspension of exportation, distribution, and sale of PIP silicone gel breast implants.<sup>15</sup> This followed an ANSM inspection of the manufacturing facility in La Seyne-sur-Mer, France. Ongoing investigations later revealed that implants made since January 2001 contained a cheap, nonapproved, industrial-grade silicone of the type used to make cleansers, adhesives, and cookware and that there was removal of the barrier layer contributing to fragility. The parallels with Meme implants should be noted. PIP implants were significantly cheaper than other implants and through this, they were able to capture sales. More than 300,000 women in 65 countries have received PIP silicone gel implants made with nonmedical-grade silicone.<sup>15</sup> The scandal was described by the UK health minister as “deliberate fraud” by a manufacturer that “actively covered up its deceit and showed a complete disregard for the welfare of its customers.”<sup>15</sup> This led to a global meeting of public health authorities, which led to some countries advising patients to have PIP implants removed and replaced with associated public funding to support the surgery.<sup>16</sup> In Australia, the crisis prompted a senate inquiry and independent evaluation by the Therapeutic Good Association in Australia, leading to the conclusion that there was no quantifiable risk to women but that implants should be monitored. Interestingly, these findings led to the establishment of an opt-out breast implant registry that has now reached a high penetrance with duplication through strong collaborations internationally.<sup>17,18</sup> The inevitable class actions followed and are still being pursued today.

## Silimed

Despite the withdrawal of polyurethane-covered implants in the United States, the MHRA were subsequently approached by a South American manufacturer, Silimed, to seek approval for sale of a new generation of polyurethane implants. In 2003, the MHRA concluded that the benefits did not outweigh the risks. However, when Silimed obtained CE mark approval from Germany, the MHRA

allowed entry to the UK market, provided patients have proper informed consent about risks and benefits. Silimed then went further to obtain approval for a new cohesive gel implant sale in the United States through a PMA in 2012, thus breaking the duopoly (Mentor and Allergan) of silicone gel implants there.<sup>11</sup> Interestingly, the application underwent no public advisory scrutiny, which was waived by the FDA in contrast to previous approvals. This was followed in 2013 by approval of both Allergan and Mentor cohesive gel implants.<sup>9</sup> All 3 approvals were predicated on the need for postmarket surveillance studies.

On September 23, 2015, the MHRA suspended all CE certification for Silimed medical devices after German inspectors found particle contamination in devices manufactured in Rio de Janeiro.<sup>19</sup> The Australian regulator, The Therapeutic Goods Association<sup>20</sup> and Brazil’s national health surveillance agency also followed by conducting an independent inspection. On October 9, Sientra, who had contracted Silimed to manufacture their proprietary implants, voluntarily suspended all implant sales in the United States as a precaution. Sientra is a US-based company that developed a nonpolyurethane texture manufactured utilizing ammonium carbonate vulcanization.<sup>21</sup> One month later, on October 23, 2015, a fire destroyed one of the Silimed manufacturing plants in Brazil. Sientra has now dissolved its manufacturing agreement with Silimed and established US manufacturing plants in Wisconsin to produce their implants. In 2018, after successfully submitting a PMA, Sientra obtained approval for its Opus range of implants from the FDA, which are now available for use in the United States (Figure 2).<sup>9</sup>

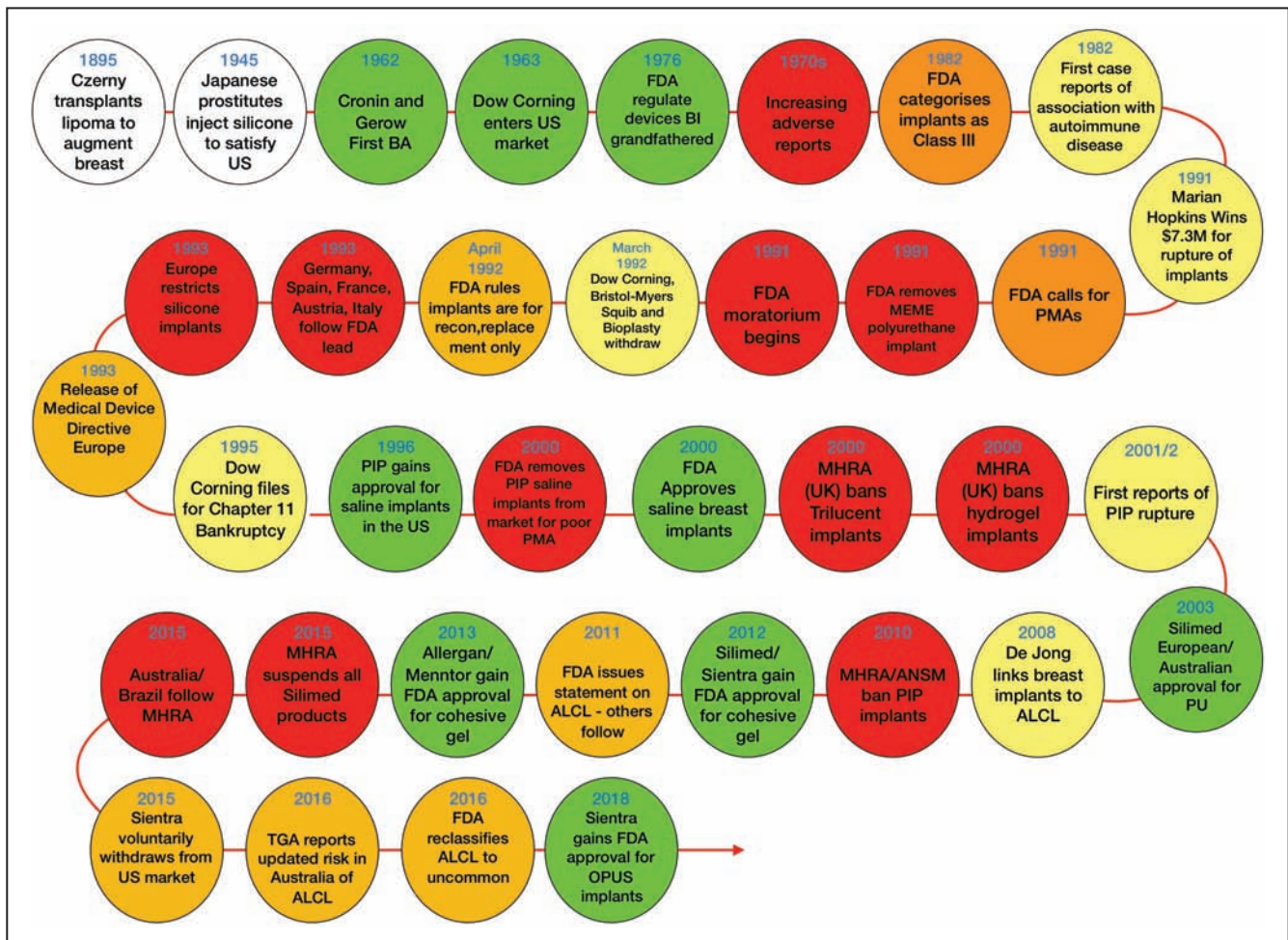
## Regulatory Perspective

From a public health perspective, it is perplexing that regulatory agencies have not pursued conclusive evidence of long-term safety for breast implants more rigorously. This is despite a higher level of scrutiny and clinical data required by all manufacturers prior to gaining market entry. The variable standard of these PMA and postmarket core studies may result from inconsistencies in operative techniques, postoperative follow-up, and lack of clear documentation and reporting of adverse events.<sup>22,23</sup> It is also inconsistent that regulators have focused their attention on breast implants but have not sought long-term clinical trials for orthopedic implants, surgical mesh, and some cardiac devices. The track record of variable standards for entry into the market and a failure to adequately perform postmarket surveillance is clearly illustrated by the PIP implant scandal.<sup>16</sup>

## Demand

Demand for breast augmentation continues to rise as it remains the most commonly performed aesthetic surgical





**Figure 2.** Historical timeline of breast implants.

procedure; more than 300,000 procedures were performed in 2017 in the United States alone, around 45% higher compared with estimates a decade ago.<sup>24</sup> Approximately 1% to 3% of adult women in Western countries have breast implants in situ for both cosmetic augmentation and reconstruction following mastectomy for cancer.<sup>25-28</sup> The current value of the breast implant market is estimated to be \$USD577 million in the United States and around \$USD1.2 billion globally and is projected to increase to \$USD2.0 billion by 2025.<sup>29</sup> There are many reasons for the recent increase including the prominence of media/social media attention, the rise of marketing in medicine, and the opening of lower price clinics, particularly associated with cosmetic tourism. With this demand comes commercial opportunity, which further fuels the growth of marketing and advertising—the perfect positive feedback cycle. The collapse of a recent large cosmetic chain into administration in Australia with subsequent class action from women who allege suffering and harm is a good example of how the boom/bust cycle predicated on low-cost, high-volume business models is not sustainable.<sup>30</sup> So too the

surgical risks associated with breast augmentation as part of medical tourism may significantly outweigh the fiscal benefits.<sup>31</sup>

## Conflicts of Interest

There is a growing recognition of the complex interplay between industry incentives, private practice, physician preference, and potential for conflicts of interest.<sup>32,33</sup> In breast implant surgery, the largest profit margins are for surgeons, and commercial arrangements to discount the price of implants can be a powerful incentive to use a particular brand or type of implant. The growth of PIP implant usage, for example, was predicated on their low price, which increased the profit margins of surgeons or alternatively allowed them to cut prices for a competitive advantage.<sup>14</sup>

Recognition of direct physician payments from industry led to the passing of the Physician Payments Sunshine Act in 2010 to collect, track, and report all financial transactions in the United States. Payments can be accessed at <https://>

**Table 2.** Proposed Conflict of Interest Template

1. Do you receive direct personal financial benefit through sales, royalties of implant, and/or any implant-related technologies?
2. Are you reliant on primary breast augmentation as your main source of income?
3. Do you receive any competitive advantage via commercial arrangements from suppliers/industry to support your practice via cost reduction, incentives, in kind contributions, and subsidies?
4. Have you received any personal industry payments for promotion or endorsement of any product related to breast implants or breast surgery?
5. Are your industry payments publicly available (eg, on <a href="http://openpayments.cms.gov">openpayments.cms.gov</a> )?
6. How many breast implant companies are you engaged with currently?
7. What is the nature of your engagement? a. Consulting b. Education c. Advisory boards d. Research 1. Contract research (funded through institution) 2. Collaborative research (funded through institution) 3. Peer review grant (matched with government/NFP) e. Marketing/sales f. Product endorsement
8. Are industry funds paid to you personally, to institution(s), or both?
9. Are you employed or engaged with the academic and/or not for profit sector?
10. Do you have a track record of publications in peer reviewed journals in this area of research?
11. Do you have track record of public competitive grants in this area of research?
12. Do you have any personal cases of BIA-ALCL arising from your personal practice? If so, how many?
13. Do you conduct a personal audit and follow-up of breast implant patients in your practice?

BIA-ALCL, breast implant-associated anaplastic large cell lymphoma.

[openpaymentsdata.cms.gov](http://openpaymentsdata.cms.gov).<sup>34</sup> Similar systems have now been established in other countries. Any presentation, endorsement, or research reporting on a device where the author(s) derive payments from shares or license/royalties are the most obvious conflicts.<sup>35</sup> Less apparent are cash discounts for products, subsidies for private practice costs, payments to promote or endorse a product (especially if this is linked to sales of the product), and discounts for volume of usage. These can provide direct benefits to profits from private practice and are a less apparent or discernable conflict. Figure 3 shows direct payments received from industry to speakers at a recent international meeting on a session on breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). These data show wide variation in monetary support and highlight the need for greater transparency and appreciation of the levels of conflict of interest (COI) in this space. As the impact of BIA-ALCL is now becoming felt, particularly with respect to the safety and efficacy of textured implants, the role of COI

in interpretation of data, publication of research/commentary, podium presentations, endorsements of one product over another, and claims of safety need to be carefully scrutinized. Evidence is mounting that reports by surgeons actively involved with industry partners to report on a product's performance almost routinely find in favor of the product from the company they represent.<sup>36</sup> Furthermore, the greater the financial reward, the more the level of conflict. Of all medical liaisons with industry, surgeons are the most highly reimbursed and at greater risk of introducing bias into their reporting, but enumerating the impact of this bias has remained elusive due to variable disclosure practices.<sup>37,38</sup> A recent study has shown significant discrepancies between declarations of COI to plastic surgery journals vs actual COI documented on open payments.<sup>39</sup>

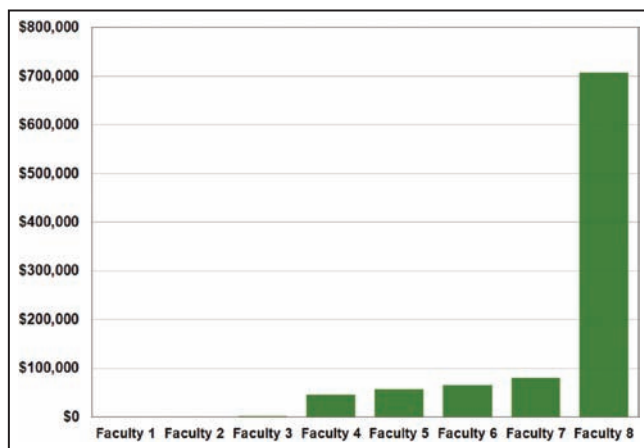
Table 2 summarizes a suggested template for COI disclosure around breast implant research.

## Health Risks and Evidence

Table 3 summarizes the known health risks of breast implants as reported in the literature and with frequency of occurrence from the Australia Breast Device Registry data.<sup>40</sup> The commonest reason for reoperation is capsular contracture, which now has been shown to be most commonly due to subclinical bacterial infection.<sup>41</sup> Many of these risks manifest years following the initial procedure, and a lack of systematic follow-up has hampered efforts to derive true rates of the adverse events and safety of these devices.

Systematic reviews of comparative clinical studies, including core FDA studies, have yielded conflicting results on the efficacy of particular implant surfaces and shapes.<sup>42</sup> In the 8 prospective RCTs of sufficient quality that have been published on outcomes following cosmetic breast augmentation, only 2 of these followed-up patients more than 12 months post initial procedure.<sup>42</sup> This significantly underestimates the true incidence of capsular contracture; longitudinal studies show a growing incidence from 2 to 5 years post initial placement. A new generic classification of implants has been recently proposed<sup>21</sup> and may provide a better framework for comparative study of outcomes for implant types.

The operative procedure has evolved significantly over the past 5 decades to one of precise pocket dissection, dual plane or subpectoral placement, preemptive hemostasis, and high levels of surgical antisepsis. The contribution of implant surface, for example, may not be as big a determinant to outcome as the surgeon's clinical assessment, implant choice, and skill in performing the procedure. Figure 4 plots the downward trend in rates of capsular contracture utilizing smooth implants only.<sup>42</sup> Further analysis of the impact of surgeon choice, skill, and technique are

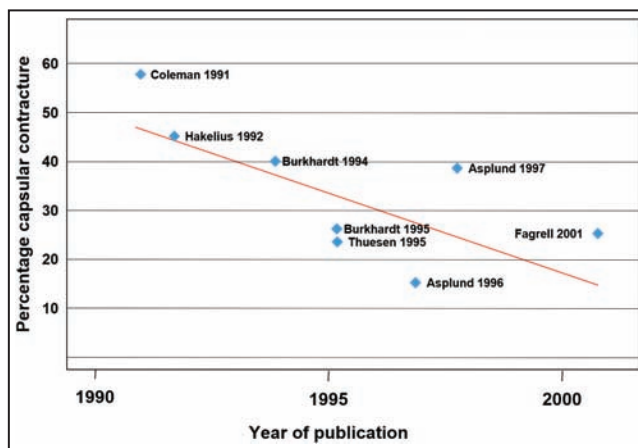


**Figure 3.** Open industry payments (\$USD) made from 2013 to 2016 to 8 faculty speakers on breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) at an international conference in 2018 (the authors considered a request by ASJ to name the conference but would prefer to keep the faculty names anonymous).

warranted and can be made possible through prospective data registries.

### Turf War: The Conundrum of Surgical Qualifications and Surgical Tourism

Plastic surgeons are only one craft group inserting breast implants. Nonspecialist plastic surgeons such as general surgeons are involved in breast and oncoplastic surgery, and doctors without specialist surgical training undertake cosmetic surgery. The latter are essentially a self-styled group of primary care physicians with varying degrees of training and standards who also perform breast implant procedures. More recently, the rise of cosmetic tourism with its inherent lack of accountability and reporting have further added to the difficulty in obtaining an accurate picture of implant use and efficacy.<sup>31</sup> The commoditization of cosmetic surgical tourism has served to reduce the patient’s perception of breast implants down to an “operation-only” concept rather than the responsible specialist surgical view of the operation being a part of a continuum of care for these high-risk devices that have a limited in vivo lifespan. Many of these business models also obfuscate the need for a minimum 7 day “cooling-off” period prior to surgery and do not provide the necessary period of aftercare to ensure primary wound healing free of infection. The reduced profitability and insurance-led dismantling of medical remuneration will push doctors to seek cosmetic practice to ensure a steady stream of income. Establishing a collaborative approach with data and outcome sharing is difficult when many disparate groups co-inhabit this space.



**Figure 4.** Downward trend in capsular contracture reported for smooth implants only from 1990 to 2000.<sup>42</sup>

**Table 3.** Adverse Events Following Insertion of Breast Implants with Relative Frequency as Reported by the Australian Breast Device Registry 2016 Annual Report<sup>40</sup>

Adverse event requiring revision	Frequency as percentage (N = 5290 breast implant revisions)
Capsular contracture	38.9%
Device malposition	22.0%
Device rupture	19.0%
Device deflation	9.3%
Skin scarring rippling	3.5%
Seroma/hematoma	2.5%
Deep wound infection	1.0%
Breast cancer	0.5%
BIA-ALCL	0.2%

BIA-ALCL, breast implant-associated anaplastic large cell lymphoma.

### Impact of Social Media and Consumer Advocates

The power of consumer advocacy and the media was an important driving force in both the Dow Corning and PIP crises. In both cases, “an angry public was demanding answers, but the data were just not available and yet a conclusion had to be reached.”<sup>14,15</sup> This is especially so with breast implants, because the long-term safety and efficacy data are simply not available. Additionally, there is an added challenge with the emergence, and growing power, of social media.<sup>43,44</sup> These platforms have been embraced in cosmetic surgery both as a source of information and also as a marketing tool.<sup>45-47</sup> Social media also functions to enable consumer and advocacy groups



to rapidly share ideas, information, and resources. While there are advantages to this, including patients being able to access support, it can also fuel misconceptions and fears of conspiracy.

## Are the Next Crises BIA-ALCL and Breast Implant Illness?

The first reports of an unusual anaplastic T cell lymphoma surrounding breast implants were initially dismissed as rare. It was unclear whether this disease was simply anecdotal and unrelated to breast implants. De Jong et al in 2008 were the first to publish a report identifying an increased risk of BIA-ALCL in association with breast implants (odds ratio = 18.2; 95% CI = 2.1 to 156.8).<sup>48</sup> Since then, several studies have shown that BIA-ALCL is related to textured implants and more specifically implant shells that have a high surface area.<sup>27,49</sup> As media and public attention increase, the calls for the banning of textured implants are starting to rise. To date, regulators have resisted this call and have been able to rely on good scientific evidence to guide them in their decision-making.

There is an emergence of a cohort of women pursuing an explanation for a range of symptoms including fatigue, chronic pain, rash, body odor, irregular heart rate, anxiety, neurologic abnormalities, hair loss, and endocrine dysfunction. These symptoms have coalesced to form “breast implant illness,” and online forums have reported resolution of symptoms after total capsulectomy and implant removal.<sup>50</sup> Recent publications have also reported the potential link to autoimmune/inflammatory syndrome induced by adjuvants.<sup>51</sup> It may well be that a proportion of these women have disease, but more research and evaluation of explanted devices and patients with symptoms are indicated.

The ever-present danger of over- or misinterpretation exists with both these emerging conditions, and so we, as doctors and scientists, need to ensure strict and rigorous scientific study is pursued. Without accurate data to dismiss radical claims about implant-related disease, there is significant risk of history repeating in a fashion similar to the Dow Corning crisis, where a lack of good scientific data made it impossible to refute the myriad claims.

## Legal Ramifications

The inevitable outcome of these cycles of crises is legal action and patient suffering. The lure of corporate coffers has created a generation of medical negligence firms that are quick to set the next target with “no win-no fee” incentives. Legal challenges have been launched in the United States, Europe, and Australia with regular frequency. The legal system, being adversarial and quick to apportion blame, should rely on unbiased evidence for prosecution

rather than impassioned, anecdotal, and speculative information. Our defense is for clinicians and researchers to take up the challenge by working to generate these data on high-risk devices through independent, high-volume datasets generated by clinical quality registries such as the Australia Breast Device Registry.<sup>52</sup> Because these issues are global, even stronger evidence will be required through the international collaboration of breast registry activities in organizations like the International Collaboration of Breast Registry Activities (ICOBRA), which aspires to harmonize data from several registries in an effort to generate answers more rapidly and arrive at better patient safety outcomes earlier than if all registries acted independently.<sup>52-54</sup>

## The Future

How do we avoid the next crisis? We could continue this game of implants and let increasing consumer and legal actions determine the future of breast implants. There are numerous challenges ahead if we are to avoid making the same mistakes again; history generally repeats and by doing nothing, it surely will.

Firstly, better means of prospective data collection are required. This has already begun in the wake of the PIP crisis with the establishment of breast device registries and the ICOBRA network.<sup>54</sup> The challenge here is to ensure that all craft groups utilizing implants contribute to data entry and that reporting of adverse events is captured through increasing cooperation and transparency and with an aim to include patient-reported outcomes. Should the role of government and regulator be expanded to mandate the use of registries? The answer to this question remains fraught with complex and varied rules, regulations, and philosophies. Prospective data collection will take years, perhaps even a decade, to fully mature and provide meaningful data. Validating the registry capture toward the true number of both implants deployed and revised will be difficult in light of the many women who are still undergoing breast augmentation hidden from means of proper data capture. Two Australian states (New South Wales and Victoria) have recently legislated that breast augmentation, among a few other cosmetic procedures, need to be performed in licensed surgical facilities.<sup>55</sup> This represents a means of ensuring that both quality and standards of care are maintained but also provides an opportunity to capture case data. The recent standardization of datasets across ICOBRA and the collection of patient-reported outcome measures is also a welcome move.<sup>56</sup> In the interim, the use of surrogate methods of risk assessment including the use of industry sales data<sup>49</sup> and radiographic surveillance<sup>27</sup> has been utilized and allowed a better understanding of the risk of BIA-ALCL.

Secondly, broader collaboration across clinicians, research groups, regulators, and patients is needed with



some urgency. When there is transparent sharing of outcomes and data without fear of reprisal, the system will benefit. This requires a bridge of trust to be built across many rival groups pushing for advantage and credibility within a very commercial space.

Thirdly, we need to rely on high-quality, peer-reviewed, and published scientific evidence. Many claims about breast implants are made around case reports or case series, often supported by industry funding. A sharing of data, laboratory evidence, and interpretation and debate of these findings will lead to a better rational understanding of etiology, pathogenesis, risk, and ultimately how best to prevent some of these implant-related complications. The clinical and scientific evidence supporting the mitigation of bacterial contamination, for example, is a good illustration of how translational research can guide better outcomes and provide comfort to patients and colleagues.

Finally, regarding implant complications, better communication in the public arena is required. The media are very attuned to reporting scandals and will sensationalize any findings to maximize click bait and increase viewership. It is vital that a consistent and clear communication of risk and clinical and scientific findings is made to avoid panic and misinterpretation. Fortunately, we have some good collaborative science around BIA-ALCL, which has provided clinicians and regulators with a platform for rational decision-making.

All these areas require clinical leadership, and plastic surgeons are well placed to guide the development and implementation of these strategies moving forward. Spear et al wrote in 2009, in the aftermath of the lifting of the moratorium: "To retain the confidence of the public, it will be critical to ensure that plastic surgeons are equipped with accurate information to counsel patients effectively, the resolve to practice ethically, the foresight to collect data, and the humility to critically assess our own results to continuously improve patient outcomes and safety."<sup>8</sup>

These words ring true more so today than ever before.

## Disclosures

Professor Deva is a consultant, educator, and research coordinator for Allergan, Mentor (Johnson & Johnson), Sientra, and Motiva (Establishment Labs). Associate Professor Magnusson is a consultant and educator for Allergan and Mentor. Professor Cooter and Dr Cuss declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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## REFERENCES

1. Champaneria MC, Wong WW, Hill ME, Gupta SC. The evolution of breast reconstruction: a historical perspective. *World J Surg.* 2012;36(4):730-742.
2. Lam ZSF, Hurry D. *Dow Corning and the Silicone Implant Controversy.* 1992:17. Historical Working Papers.
3. van Nunen SA, Gatenby PA, Basten A. Post-mammoplasty connective tissue disease. *Arthritis Rheum.* 1982;25(6):694-697.
4. Bridges AJ, Conley C, Wang G, Burns DE, Vasey FB. A clinical and immunologic evaluation of women with silicone breast implants and symptoms of rheumatic disease. *Ann Intern Med.* 1993;118(12):929-936.
5. Claman HN, Robertson AD. Antinuclear antibodies and breast implants. *West J Med.* 1994;160(3):225-228.
6. Feder BJ. Dow Corning's failure in public opinion test. *New York Times.* January 29 1992; Business:5.
7. Fisher JC. *Silicone on Trial: Breast Implants and the Politics of Risk.* New York: Sager Group LLC; 2015.
8. Spear SL, Parikh PM, Goldstein JA. History of breast implants and the food and drug administration. *Clin Plast Surg.* 2009;36(1):15-21, v.
9. FDA. *Regulatory History of Breast Implants in the US.* 2018. <https://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/breastimplants/ucm064461.htm>. Accessed August 30, 2018.
10. Benoit FM. Degradation of polyurethane foams used in the Mème breast implant. *J Biomed Mater Res.* 1993;27(10):1341-1348.
11. Zuckerman D, Booker N, Nagda S. Public health implications of differences in U.S. and European Union regulatory policies for breast implants. *Reprod Health Matters.* 2012;20(40):102-111.
12. Monstrey S, Christophe A, Delanghe J, et al. What exactly was wrong with the Trilucent breast implants? A unifying hypothesis. *Plast Reconstr Surg.* 2004;113(3):847-856.
13. Arion H. Carboxymethylcellulose hydrogel-filled breast implants. Our experience in 15 years. *Ann Chir Plast Esthet.* 2001;46(1):55-59.
14. Greco C. The poly implant prothèse breast prostheses scandal: embodied risk and social suffering. *Soc Sci Med.* 2015;147:150-157.
15. Spiegelhalter D, Knight S, Sant T. Breast implants the scandal the outcry and assessing the risks. *Significance - The Royal Statistical Society Journal.* 2012;17-21.
16. Donawa M, Gray R. The breast implant scandal and European medical device regulation. *GMP Journal.* 2012;11(1):2-4.
17. Hopper I, Best RL, McNeil JJ, et al. Pilot for the Australian breast device registry (ABDR): a national opt-out clinical quality registry for breast device surgery. *BMJ Open.* 2017;7(12):e017778.

18. Hopper I, Ahern S, Best RL, McNeil J, Cooter RD. Australian breast device registry: breast device safety transformed. *ANZ J Surg.* 2017;87(1-2):9-10.
19. MHRA. *Suspension of Devices Manufactured by Silimed.* <https://www.gov.uk/government/news/suspension-of-devices-manufactured-by-silimed>. Accessed November 8, 2018.
20. TGA. *Silimed Medical Devices (all - including breast implants).* 2017. <https://www.tga.gov.au/alert/silimed-medical-devices-all-including-breast-implants>. Accessed September 2, 2018.
21. Jones P, Mempin M, Hu H, et al. The functional influence of breast implant outer shell morphology on bacterial attachment and growth. *Plast Reconstr Surg.* 2018;142(4):837-849.
22. Spear SL, Murphy DK; Allergan Silicone Breast Implant U.S. Core Clinical Study Group. Natrelle round silicone breast implants: core study results at 10 years. *Plast Reconstr Surg.* 2014;133(6):1354-1361.
23. Cunningham B. The mentor study on contour profile gel silicone MemoryGel breast implants. *Plast Reconstr Surg.* 2007;120(7 Suppl 1):33S-39S.
24. Ballard TNS, Hill S, Nghiem BT, et al. Current trends in breast augmentation: analysis of 2011-2015 maintenance of certification (MOC) tracer data. *Aesthet Surg J.* 2018. doi: 10.1093/asj/sjy176.
25. Cook RR, Delongchamp RR, Woodbury M, Perkins LL, Harrison MC. The prevalence of women with breast implants in the United States-1989. *J Clin Epidemiol.* 1995;48(4):519-525.
26. Cook RR, Perkins LL. The prevalence of breast implants among women in the United States. *Curr Top Microbiol Immunol.* 1996;210:419-425.
27. de Boer M, van der Sluis WB, de Boer JP, et al. Breast implant-associated anaplastic large-cell lymphoma in a transgender woman. *Aesthet Surg J.* 2017;37(8):NP83-NP87.
28. Collett D, Rakhorst H, Lennox P, Cooter R, Deva AK. Current risk estimate of BIA-ALCL in textured breast implants. *Plast Reconstr Surg.* 2018; in press.
29. Grandview. *Breast Implants Market Size Worth \$2.0 Billion by 2025.* 2017. <https://www.grandviewresearch.com/press-release/global-breast-implants-market>. Accessed November 2, 2018.
30. Armitage R. *Women Bring Class Action Against Australia's Largest Cosmetic Surgery Provider.* 2017. <http://www.abc.net.au/news/2017-09-15/women-bring-class-action-against-the-cosmetic-institute/8948978>. Accessed September 2, 2018.
31. Brightman L, Ng S, Ahern S, Cooter R, Hopper I. Cosmetic tourism for breast augmentation: a systematic review. *ANZ J Surg.* 2018;88(9):842-847.
32. Deva AK. Response to "Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL): Why the Search for an Infectious Etiology May Be Irrelevant." *Aesthet Surg J.* 2017;37(9):NP122-NP128.
33. Fineberg HV. Conflict of interest: why does it matter? *JAMA.* 2017;317(17):1717-1718.
34. Ornstein C. Public disclosure of payments to physicians from industry. *JAMA.* 2017;317(17):1749-1750.
35. Lo B, Grady D. Payments to physicians: does the amount of money make a difference? *JAMA.* 2017;317(17):1719-1720.
36. Lopez J, Samaha G, Purvis TE, et al. The accuracy of conflict-of-interest disclosures reported by plastic surgeons and industry. *Plast Reconstr Surg.* 2018;141(6):1592-1599.
37. Lichter AS. Conflict of interest and the integrity of the medical profession. *JAMA.* 2017;317(17):1725-1726.
38. Dunn AG, Coiera E, Mandl KD, Bourgeois FT. Conflict of interest disclosure in biomedical research: a review of current practices, biases, and the role of public registries in improving transparency. *Res Integr Peer Rev.* 2016;1:pii: 1.
39. Boyll P, Neville M, Bernard R, Mahabir RC. Author disclosures in plastic surgery journals compared with information reported in the open payments database: how open are we? *Aesthet Surg J.* 2018. doi: 10.1093/asj/sjy218.
40. Hopper I, Parker E, Pellegrini B, et al. *The Australian Breast Device Registry 2016 Report.* Melbourne, Australia: Monash University, Department of Epidemiology and Preventive Medicine, Monash University; 2018.
41. Deva AK, Adams WP Jr, Vickery K. The role of bacterial biofilms in device-associated infection. *Plast Reconstr Surg.* 2013;132(5):1319-1328.
42. Tamblyn DJ, Parsons J, Salinger K, Ellery B, Merlin T. *The Comparative Safety and Effectiveness of Breast Implants with Different Surfaces.* Adelaide, South Australia: Adelaide Health Technology Assessment, University of Adelaide; 2017.
43. Chandawarkar AA, Gould DJ, Grant Stevens W. The top 100 social media influencers in plastic surgery on Twitter: who should you be following? *Aesthet Surg J.* 2018;38(8):913-917.
44. Rohrich RJ. So, do you want to be facebook friends? How social media have changed plastic surgery and medicine forever. *Plast Reconstr Surg.* 2017;139(4):1021-1026. [Epub ahead of print]. doi:10.1097/PRS.00000000000003785
45. Dorfman RG, Vaca EE, Fine NA, Schierle CF. The ethics of sharing plastic surgery videos on social media: systematic literature review, ethical analysis, and proposed guidelines. *Plast Reconstr Surg.* 2017;140(4):825-836.
46. Gould DJ, Leland HA, Ho AL, Patel KM. Emerging trends in social media and plastic surgery. *Ann Transl Med.* 2016;4(23):455.
47. Camp SM, Mills DC 2nd. The marriage of plastic surgery and social media: a relationship to last a lifetime. *Aesthet Surg J.* 2012;32(3):349-351.
48. de Jong D, Vasmel WL, de Boer JP, et al. Anaplastic large-cell lymphoma in women with breast implants. *JAMA.* 2008;300(17):2030-2035.
49. 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(4):645-654.
50. Tang SY, Israel JS, Afifi AM. Breast implant illness: symptoms, patient concerns, and the power of social media. *Plast Reconstr Surg.* 2017. [Epub ahead of print]. doi:10.1097/PRS.00000000000003785

51. Nunes E Silva D, Gründler C, Spengler MDGMT, et al. Autoimmune syndrome induced by adjuvants (ASIA) after silicone breast augmentation surgery. *Plast Reconstr Surg Glob Open*. 2017;5(9):e1487.
52. Cooter RD, Barker S, Carroll SM, et al. International importance of robust breast device registries. *Plast Reconstr Surg*. 2015;135(2):330-336.
53. Becherer BE, Spronk PER, Mureau MAM, et al. High risk device registries: global value, costs, and sustainable funding. *J Plast Reconstr Aesthet Surg*. 2018;71(9):1362-1380.
54. Cooter R, Barnett R, Deva A, et al. In defense of the international collaboration of breast registry activities (ICOBRA). *Aesthet Surg J*. 2016;36(7):NP225-NP227.
55. Health N. *Review of the Regulation of Cosmetic Surgery*. 2018. <https://www.health.nsw.gov.au/patients/cosmetic/pages/frequently-asked-questions.aspx>. Accessed September 2, 2018.
56. Hopper I, Ahern S, McNeil JJ, et al. Improving the safety of breast implants: implant-associated lymphoma. *Med J Aust*. 2017;207(5):185-186.