

Breast Implant Illness: How Can We Help?

Patricia A. McGuire, MD; Melinda J. Haws, MD; and Foad Nahai, MD, FACS

Aesthetic Surgery Journal
2019, Vol 39(11) 1260–1263
© 2019 The American Society
for Aesthetic Plastic Surgery, Inc.
Reprints and permission: journals.
permissions@oup.com
DOI: 10.1093/asj/sjz227
www.aestheticsurgeryjournal.com

OXFORD
UNIVERSITY PRESS

Editorial Decision date: August 13, 2019; online publish-ahead-of-print August 20, 2019.

It is impossible to adequately discuss breast implant illness without first discussing the recent history of breast implants. In January 1992, responding to concerns over the possibility of a link between breast implants and a variety of autoimmune diseases, the US Food and Drug Administration (FDA) called for a voluntary moratorium on the use of silicone breast implants.¹ Later that year, restrictions were lifted for saline implants, but new regulations governing silicone gel-filled implants were imposed. These regulations limited the utilization of gel-filled devices to women seeking breast reconstruction or replacement of an existing implant. Additionally, implant manufacturers were required to collect expanded safety data and monitor the health of thousands of implant patients for a minimum of 10 years.² In 1999, an Institute of Medicine 400-page report, “The Safety of Silicone,” concluded there was no demonstrable link between silicone implants and diagnosed autoimmune disease. It was not until 2006, however, that restrictions on silicone gel-filled implants finally were lifted. At that time, the director of the FDA’s Center for Devices and Radiological Health called silicone breast implants “one of the most extensively studied medical devices.”³ Yet now, nearly 30 years after the moratorium, it appears many of the same questions that instigated the “breast implant crisis” of the ’90s have resurfaced. Why? And how can we, as plastic surgeons, responsibly address the current situation while helping to restore the well-being of patients who feel frightened and vulnerable?

Those of us who were in practice during the 1990s and early 2000s and lived through the uncertainty of those times do not want to see our patients go through the same or similar anxieties. Surgeons newer to practice may be less aware of historical details but nevertheless should

understand that there were patients during that era who felt “abandoned” or “misled” by their physicians. Such feelings most often were engendered not by actual indifference on the part of doctors but by a frustrating lack of definitive answers to highly complex scientific questions. It is always difficult to prove a negative (no association), and from an epidemiologic standpoint the numbers necessary for conclusive proof simply were not there. The absence of a verifiable alternative explanation for diverse yet seemingly related symptoms, coupled with a general climate of distrust, resulted in the perfect storm.

Today, in many ways, we find ourselves in a similar situation as the 1990s, though possibly a more complicated one due to compelling new factors. One of these factors is the emergence of reports describing breast implant-associated anaplastic large cell lymphoma in some women with textured-surface breast implants.⁴ The number of cases remains small in relation to the number of women who currently have breast implants, and the precise causative factors are yet undetermined. However, we can no longer state with scientific certainty, as researchers and government agencies have done for many years, that there is absolutely no association between breast implants and cancer.

Dr McGuire is a plastic surgeon in private practice in St. Louis, MO. Dr Haws is a Clinical Assistant Professor of Plastic Surgery, Vanderbilt University, Nashville, TN. Dr Nahai is a Professor of Plastic Surgery, Department of Surgery, Emory University School of Medicine, Atlanta GA; and is Editor-in-Chief of *Aesthetic Surgery Journal*.

Corresponding Author:

Dr Patricia A. McGuire, 845 N. New Ballas Court, Suite 300, St. Louis, MO 63141, USA.

E-mail: patricia.mcguiremd@gmail.com; Twitter: [@PatMcGuireMD](https://twitter.com/PatMcGuireMD)

Adding to the current dilemma was the missed opportunity for long-term data from the post-approval follow-up studies. As noted earlier, the FDA required US breast implant manufacturers to conduct scientific studies and commit to a minimum 10-year patient follow-up as part of the pre-market approval process for their devices. Thousands of women were enrolled in studies that, if extended beyond the 10-year requirement, would have led to additional data for analysis with respect to the long-term safety of implants. The implant companies, presumably because of the expense involved, made the decision to terminate this research. With closure of the studies, all participants and data were deidentified, which significantly limits the ability for further follow-up. It is not helpful when we must explain to our patients that, although 10-year data show no apparent association between silicone gel-filled breast implants and connective tissue disease,⁵ the hope of continued follow-up has not been realized.

The power of the internet is another factor working to exacerbate patient anxiety even beyond the levels experienced previously. The breast implant crisis of the '90s was, in large part, launched by a single sensational story on the alleged association between breast implants and autoimmune diseases, aired on CBS by television journalist Connie Chung.⁶ Other media were quick to follow Chung's lead, often interviewing "experts" with nonexistent credentials and citing "studies" that had no scientific basis. Today, in 2019, the reach and influence of television is dwarfed by that of the internet and especially social media where discussion groups centered on various medical problems are increasingly popular. Although some medical forums may in fact be helpful, others can promote the sharing of misinformation by individuals who are either unqualified to advise others or have a personal or profit-motivated agenda.

The largest social media group focusing on concerns about breast implant safety currently has over 80,000 members.⁷ Online discussion often centers around various theories about toxins leaking from the shells of breast implants and making women ill. Although manufacturers' proprietary formulary information is not readily available to the public—which undoubtedly contributes to the perception of industry's lack of transparency⁸⁻¹⁰—the FDA website includes a list of "ingredients" used by various implant manufacturers, and this list has been widely circulated.¹¹ (It should be noted that any "toxic" ingredients present in breast implants are either at undetectable levels or levels less than those found in drinking water.^{12,13}) Another common perception among participants in this social media group is that saline implants, which have been deemed safe by the FDA for years, were never studied to the same degree as silicone gel-filled implants. Some women with saline implants are worried by anecdotal reports of mold discovered in explanted devices and believe that such contamination could be responsible for their symptoms.

These types of concerns and speculations are virtually identical to those voiced by symptomatic women in the 1990s. At that time, unfortunately, doctors too often brushed aside such concerns without a serious attempt to provide explanations. It is important that our response, both as a specialty and individually, offers real assistance to those in need of guidance and care. Some patients experiencing symptoms will elect to have their implants removed and may also seek other remedies. Where they turn for help is critical to the opportunity for an outcome that improves rather than worsens their situation.

Although our first impulse may sometimes be to discourage a patient from implant removal, we must remember that women have as much right to have their implants removed as they did to have the prostheses placed into their body. Implant removal, like any plastic surgery, must be approached with appropriate informed consent based on the latest and best scientific evidence and with a full understanding of both risks and benefits. Our professional societies have generally recommended that a patient experiencing any type of difficulty possibly related to her implants should first return to her implanting surgeon. We believe this is still the best advice, assuming the original surgeon is prepared, first, to be a compassionate listener and then to help each patient reach an informed decision appropriate to her individual needs. This is how a plastic surgeon provides responsible patient care, even when surgeon and patient may start out with different beliefs about the problem and its best solution.

At the opposite end of the spectrum are physicians who see patient concerns as financial opportunities to be exploited. Some of these doctors tout themselves as "explant experts," as if they possess special surgical skills beyond those of the "average" highly trained plastic surgeon. One of the popular claims being made by such practitioners is that en bloc capsule removal has been established as the standard of care, even when there is no demonstrable capsule pathology. Many patients who insist on en bloc resection have been led to believe, usually through anecdotal reports on social media sites or direct solicitations by medical practitioners, that implant toxins may be left behind if this technique is not employed. Although en bloc resection is necessary in the event of malignancy, there is no science establishing a need or benefit when removing a benign capsule. In fact, when a capsule is thin and in a submuscular position, en bloc resection presents increased risks of significant bleeding or development of pneumothorax.¹⁴

The fear of implant toxicity may drive patients who have previously had their implants removed by capsulectomy to seek additional surgery, just in case there might be any microscopic fragments of the capsule remaining in their body. In our opinion, this is quite a different matter than performance of a primary capsulectomy upon request. Yet

there are practitioners willing to perform these secondary capsulectomies with no scientific, medical, or surgical indications for doing so. Again, it is essential to listen to patient concerns and take the time to explain the potential risks and benefits of various options. In the end, if a surgeon cannot in good conscience perform a requested procedure and the patient cannot be dissuaded, referral to another reputable doctor may be the best service one can provide.

Another challenge to patient care and safety is the proliferation of medical “scams” promoting phony tests and cures. Patients may be encouraged to seek out various detoxification programs, such as expensive chelation therapy, that are not scientifically proven to offer any benefit. They are told that breast implant illness can be specifically diagnosed with genetic or blood tests to determine if someone has a predisposition for breast implant illness when no such tests exist. In an aggressive attempt to attract business, a few physicians have created special websites with URLs that contain buzzwords reflecting the concerns of breast implant patients. Sadly, this kind of opportunism is not unusual in situations where patients are desperately searching for answers, but such “come-ons” are not worthy of medical professionals.

Breast implant patients are understandably frightened by the specter of lymphoma. It is not difficult to imagine how some make the leap from concern about breast implant-associated anaplastic large cell lymphoma, which remains only a remote risk, to fear that implants might provoke a variety of other more common disease processes. We must always keep in mind that these women are under tremendous stress, experiencing disturbing symptoms with causes that so far have eluded them and their doctors. Plastic surgeons need to remain openminded, listen to patient concerns, and discuss the scientific evidence in terms that are readily understandable. Currently available research does not directly link implants with autoimmune illness, so there is no guarantee that symptoms will improve with implant removal. On the other hand, studies have shown symptom improvement in some patients without laboratory evidence of autoimmune disease.¹⁵ We need to emphasize that medical science is always evolving, and there are many diseases and conditions that remain poorly understood despite years of research. We have not stopped looking for answers to the many legitimate questions that have been raised, nor will we stop until answers are found. For the present, however, we need to help our patients understand their current options and the potential risks and benefits of each course of action, including the possibility of doing nothing.

As surgeons, we are both scientists and caregivers. We must rely on scientific evidence to determine the best treatment for our patients with implants, but we also must communicate with patients in a way that establishes a human

connection. This is not “hand-holding.” It is a holistic approach to patient care that considers not only physical symptoms but the impact of those symptoms on the entire person. At the same time, plastic surgeons must not allow the tail to wag the dog. Patients frequently come into our offices requesting treatments that are not appropriate for them and that will not achieve their goals. Normally, we do not hesitate to say so. However, with respect to breast implants—perhaps because we want so very much to give these patients some peace of mind—we may be tempted to comply with ill-advised requests. In our opinion, performing en bloc resection simply because someone asks for it, without proper medical indications for employing this riskier technique, is not in a patient’s best interests. Instead, we should educate patients on the anatomy of capsulectomy, pointing out the potential risks of en bloc vs a precise capsulectomy. We should not be afraid to raise the question of whether a capsulectomy is even necessary.

For patients who are worried about implant toxicity, it may be useful to discuss the chemical composition of implants and what we know, based on decades of scientific research, about how these chemicals react with the body. We should try to restore trust in science but acknowledge where our knowledge falls short and more research is needed. To that end, The Aesthetic Society is currently funding a variety of scientific studies through the Aesthetic Surgery Education and Research Foundation to dig deeper into potential causes of the various symptoms described by breast implant patients and ultimately determine the best treatment for them. Answers to these questions are important not only for symptomatic women with implants but for patients who do not have symptoms and women currently considering implants for cosmetic or reconstruction reasons. The way forward, as suggested in one recently published article, must include further evaluation of breast implant outcomes facilitated by a robust registry system and relentless analysis of a range of implant/patient and peri-implant parameters.¹⁵

As physicians, we take an oath with the basic premise “*primum non nocere*” (first, do no harm). We should keep that oath in mind with every surgical decision we make and especially as we navigate the sometimes-murky waters of breast implant patient care. Think of our relationship with these patients as a partnership with the shared goal of supporting patient health and well-being. We may not always be successful in achieving that goal, but let us make sure our patients know we will never stop trying.

Disclosures

Dr McGuire is a consultant to Allergan, Establishment Labs, and Hans Biomed; and a clinical investigator for the Motiva US FDA clinical trials. Dr Haws is a past consultant and investigator for Sientra, a member of the RealSelf Business Advisory Board, and an investor in Strathspey Crown. Dr

Nahai declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

Funding

The authors received no financial support for the research, authorship, and publication of this article.

REFERENCES

1. US Food & Drug Administration. Statement from Benita Ashar MD of the FDA's Center for Devices and Radiological Health on Agency's Commitment to Studying Breast Implant Safety. September 14, 2018. <https://www.fda.gov/news-events/press-announcements/statement-binita-ashar-md-fdas-center-devices-and-radiological-health-agencys-commitment-studying>. Accessed August 8, 2019.
2. Deva AK, Cuss A, Magnusson M, Cooter R. The "Game of Implants": a perspective on the crisis-prone history of breast implants. *Aesthet Surg J*. 2019;39(Supplement_1):S55-S65.
3. Perkes C. FDA lifts 14-year ban on silicone breast implants. *Orange County Register*. November 16, 2006. <https://www.ocregister.com/2006/11/18/fda-lifts-14-year-ban-on-silicone-breast-implants/>. Accessed August 7, 2019.
4. Clemens MW. Introduction to the "current controversies in breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)" supplement. *Aesthet Surg J*. 2019;39(Supplement_1):S1-S2.
5. US Food & Drug Administration. Update on the Safety of Silicone Gel-filled Implants (2011)—Executive Summary. <https://www.fda.gov/medical-devices/breast-implants/update-safety-silicone-gel-filled-breast-implants-2011-executive-summary>. Accessed August 8, 2019.
6. PBS. Breast Implants on Trial: Chronology of Silicone Breast Implants. <https://www.pbs.org/wgbh/pages/frontline/implants/cron.html>. Accessed August 9, 2019.
7. Breast Implant Illness - Symptoms, Explant, Surgeons and Detoxification. <https://healingbreastimplantillness.com>. Accessed August 12, 2019.
8. Hoyer M. Breast implants reveal problems in tracking device safety. <https://www.apnews.com/4e480ae1661c46199b098876b4179bc7>. Published 2018. Accessed August 12, 2019.
9. Laurent L. Europe Just Banned Allergan Breast Implants. Here's Why. <https://www.msn.com/en-us/health/health-news/europe-just-banned-allergan-breast-implants-here%27s-why/ar-BBRaG58?OCID=ansmsnnews11>. Published 2018. Accessed August 12, 2019.
10. Moore S. From BII to BIA-ALCL – More Transparency is Needed for Women With Breast Implants. <https://www.leighday.co.uk/Blog/July-2019/From-BII-to-BIA-ALCL-More-Transparency-is-Needed>. Published 2019. Accessed August 12, 2019.
11. Breast Implant Safety - Breast Implants Linked With Autoimmune Disease. <http://healingbreastimplantillness.com/breast-implant-safety>. Accessed August 12, 2019.
12. Wixtrom RN. Silicone breast implants and platinum. *Plast Reconstr Surg*. 2007;120(7 Suppl 1):118S-122S.
13. US Environmental Protection Agency. 2018 Edition of the Drinking Water Standards & Health Advisory Tables. <https://www.epa.gov/dwstandardsregulations/2018-drinking-water-standards-and-advisory-tables>. Published 2018. Accessed August 7, 2019.
14. Gascoigne AC, Malata CM. Pleural damage during capsulectomy and exchange of long-standing breast implants in Poland syndrome: a cautionary tale. *Ann Plast Surg*. 2012;69(2):148-151.
15. Magnusson MR, Cooter RD, Rakhorst H, McGuire PA, Adams WP Jr, Deva AK. Breast implant illness: a way forward. *Plast Reconstr Surg*. 2019;143(3S A Review of Breast Implant-Associated Anaplastic Large Cell Lymphoma):74S-81S.