Silicone Implant Illness: Science versus Myth?

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Summary: The purpose of this Special Topic article is to present the current state of scientific evidence related to the safety of silicone breast implants. There is presently overwhelming evidence to support the safety of silicone breast implants. Ultimately, the decision to obtain, keep, or remove breast implants is the choice of the patient. If a patient chooses to have her breast implants removed, it is important to find a board-certified plastic surgeon with expertise in breast surgery. Ongoing studies are strongly encouraged in all areas, from cancer detection to autoimmune disease, as we strive for improved patient safety, patient awareness, and patient education. To the best of our body of scientific knowledge to date, there have not been any concrete or evidence-based studies or peer-reviewed data concerning the formation of a new syndrome: "silicone implant illness." Silicone breast implants are used in nearly 300,000 breast augmentation and 100,000 breast reconstruction operations annually in the United States.[1] Silicone gel–filled implants were first approved by the U.S. Food and Drug Administration in 1962. Since that time, few medical devices have been studied as closely for their safety and associated adverse outcomes. Despite multiple generations of implant shells and gel fillers, the basic components remain as originally designed.[2,3] (*Plast. Reconstr. Surg.* 144: 98, 2019.)

In the 1980s, as consumer concern regarding silicone breast implant safety grew, the U.S. Food and Drug Administration's new surveillance system began to identify local complications associated with silicone implants in addition to several published case reports that described an association between cancer and connective tissue disorders in patients with these devices.[4] For more than 60 years, there has been controversy as to the safety of these devices, with more than 400 reports on various health conditions in association with breast implants.[5]

Ultimately, in 1992, the U.S. Food and Drug Administration determined that silicone implant manufacturers had not provided enough data to adequately address consumer concerns, and silicone implants were removed from the market. On their return, the U.S. Food and Drug Administration required all major breast implant manufacturers to conduct core studies to assess overall implant safety profiles.[6–10] Seven years after the U.S. Food and Drug Administration moratorium on silicone implants, the Institute of Medicine released a detailed report of the current literature entitled *Safety of Silicone Breast Implants*, which ultimately concluded that local complications were of primary concern and that, to definitively comment on systemic disease such as cancer or autoimmune disorders, further studies were needed, as there was currently a paucity of significant, well-controlled studies.[4]

The Institute of Medicine report was the first step toward the return of silicone breast implants and was instrumental in clarifying the scientific

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evidence and identifying information gaps on the safety of these devices. Since their return, there has been ongoing extensive research concerning their safety, which is in part attributable to the U.S. Food and Drug Administration's stipulation that the two manufacturers of silicone breast implants at that time, Allergan plc (Dublin, Ireland) and Mentor Corp. (Minneapolis, Minn.),[11] conduct large postapproval studies to guarantee that these potential long-term risks did not go unmonitored.[12]

The extent of our knowledge on prior safety concerns has expanded since the U.S. Food and Drug Administration's decision to remove silicone breast implants from the market.[4,13] It is our responsibility as plastic surgeons to hold industry and one another accountable for the care of our patients by increasing awareness of evidence-based practices.[12,14,15] This Special Topic article reviews the current literature regarding the safety of silicone breast implants and the concerns that remain about these devices in light of recent consumer and social media about the possible existence of a "silicone implant illness" syndrome, an entity that currently has no clear definition but has been popularized by both health care providers and the media.

CANCER

The concern for potential carcinogenicity of silicone breast implants was initially sparked after the publication of a case series describing three women with breast implants diagnosed with cutaneous T-cell lymphoma in 1995.[16,17] To date, there have been a myriad of studies investigating the potential association between these devices and malignancy; most have adequate sample size and long-term follow-up (Table 1).[12,18–34]

To date, there are extensive data refuting any association between these devices and an increased incidence of breast cancer, as many studies have shown that these patients have a lower incidence of primary breast cancer.[12,19–23,25–39] Some articles claim a risk reduction of between 10 and 50 percent.[40] In 1999, the International Agency for Research on Cancer published a report stating there was evidence to support a lack of breast carcinogenicity in women with silicone breast implants,[36] and this was later backed by the Institute of Medicine Committee on the Safety of Silicone Breast Implants.[41] Recent publications examining the incidence of breast cancer in patients with silicone breast implants include a meta-analysis by Noels et al.[39] that analyzed results from 17 previously published articles. Ultimately, the authors found that breast implants are not associated with an increased incidence of breast cancer, and a 2016 review article by Balk and Raman[31] confirmed these findings.

Some reports describe an increased cancer risk among patients with cosmetic breast implants, including brain, cervical, vulvar, and lung, in addition to nonmelanoma skin cancer.[4,12,42] However, the data do not support breast implants as being responsible for these findings.[4,13,43] Between 1999 and 2005, multiple independent scientific review boards concluded that there is no excess risk of cancer of any type in women with silicone breast implants.[13,35–37,41] Since the release of these advisory reports,[35–37] numerous studies have been conducted to better quantify the risk of breast and other types of cancer in women with breast implants.[12,20,21,26–31,38,39] Many have definitively concluded that their cancer incidence closely matches that of the general population.[27–30] However, in 2018, the largest study of patient safety and implant-specific outcomes for breast implants found that patients with Mentor silicone implants were 1.54 times (95 percent CI, 1.42 to 1.68 times) more likely to develop a cancer diagnosis compared with the general population.[12] Brinton et al. reported a slight excess of cancer in patients with breast implants as a result of statistically significant increased risks for cervical, vulvar, brain cancer, and leukemia compared with the general public. It is important to recognize that the authors clearly state that this observed difference is likely attributable to both selection bias and lack of cancer diagnosis validation.[21] In addition, there are multiple epidemiologic studies in the literature that found that women with breast implants have different patient demographics and lifestyle and/or reproductive characteristics compared with the general population that may explain these findings.[44–47]

There is a breadth of literature concerning the risk of brain cancer in patients with breast implants, including a multitude of large-scale incidence studies[12,27–30,48] and five mortality studies.[38,49–51] All but one study consistently failed to show an increased incidence of brain cancer or mortality from brain cancer in patients with breast implants. Such findings were explained by evidence that metastatic disease from distant sites is often not reflected in the diagnostic accuracy of death certificates in patients who die as a result of brain cancer.[48]

Since the original article by McLaughlin et al. in 2007 that concluded that there is no credible evidence to support a causal relationship between

Table 1. Studies Investigating the Potential Association between Breast Implants and Malignancy

Study	Country	Article Classification	Sample Size	Follow-Up	Conclusion on Silicone Implants	Independent vs. Industry-Funded
Gabriel et al., 1994	United States	Retrospective cohort	749	Average, 7.8 yr	No association with CTD or other systemic disorders	Independent
Bryant et al., 1995	Canada	Retrospective cohort	Not stated	Not stated	Risk of breast cancer not higher or lower than the general population	Independent
Brinton et al., 1996	United States	Case control	2,174	Not stated	Are not associated with breast cancer and do not delay breast cancer detection	Independent
Deapen et al., 1997	United States	Retrospective cohort	3182	Average, 14.4 yr	Breast cancer risk at or below the expected rate	Industry-funded
Kern et al., 1997	United States	Retrospective cohort	680	Average, 4.6 yr	Not associated with increased risk of breast or nonbreast cancer	Industry-funded
McLaughlin et al., 1998	Sweden	Retrospective cohort	3473	Average, 10 yr	No increased risk of cancer	Independent
Brinton et al., 2000	United States	Retrospective cohort	13,488	Not stated	Do not alter risk of breast cancer	Independent
Mellemkjaer, 2000	Denmark	Retrospective cohort	1653	Not stated	Cancer risk not increased	Information not found
Brinton et al., 2001	United States	Retrospective cohort	13,488	Average, 12 yr	Increased risk of cancers of the stomach, cervix, vulva, brain, and leukemia	Independent
Pukkala et al., 2002	Finland	Retrospective cohort	2171	Maximum, 29 yr	Are not a cause of cancer and do not delay breast cancer detection	Information not found
Breiting et al., 2004	Denmark	Retrospective cohort	190	Average, 19 yr	Associated with local complications but no systemic illness	Industry-funded
Friis et al., 2006	Denmark	Retrospective cohort	2763	Maximum, 30 yr	Are not carcinogenic	Industry-funded
McLaughlin et al., 2007	Sweden	Retrospective cohort	3486	Average, 18.4 yr	No increased risk of any cancer type	Industry-funded
Brisson et al., 2006	Canada	Retrospective cohort	24,558	Not stated	No increased long-term risk of developing cancer	Independent
Balk and Raman, 2016	United States	Systematic review	32 studies	Not stated	Statistical associations for increased risk of lung cancer, rheumatoid arthritis, Sjögren syndrome, and Raynaud phenomenon compared with general population	Independent
Coroneos et al., 2018	United States	Prospective cohort	55,000 Allergan; 44,997 Mentor	7 yr	Both companies independently found an association with CTD	Independent

CTD, connective tissue disease.

breast implants and cancer, much of the literature on this topic has remained consistent. This is supported by a large multicenter observational study published in 2017 that looked at the long-term safety of women with Natrelle round silicone gel–filled breast implants. Their study population of 55,279 women, which represented an interim data set that was later fully reported on by Coroneos et al.,[12] showed no excess risk for any cancer diagnoses including brain, cervical/vulvar, lung, or breast cancer.[52] Newly published literature found an increased incidence of melanoma in patients with Mentor breast implants compared with the general population.[12] Despite some reports of an increased incidence of lung cancer in certain populations with breast implants, studies that examined characteristics of these patients found an elevated proportion of smokers in addition to various lifestyle characteristic differences as more likely culprits.

ANAPLASTIC LARGE CELL LYMPHOMA

Reports from the scientific community have suggested a possible link between anaplastic lymphoma kinase–negative anaplastic large cell lymphoma (ALCL) and breast implants.[4,17,53] The 2011 U.S. Food and Drug Administration report included 17 articles published between 1997 and 2010 that accounted for 34 patients with ALCL, a rare form of non-Hodgkin's lymphoma associated with strong expression of CD30.[4,54] In 1997, Keech and Creech published the sentinel case report of breast implant-associated (BIA) ALCL.[55] Since then, over 170 cases have been recorded,[56] and according to multiple recently published articles including a 2018 U.S. Food and Drug Administration update, 414 cases of BIA-ALCL have been reported by the U.S. Food and Drug Administration over the past 10 years, including nine deaths, over half of which were in patients that had undergone reconstruction following breast cancer treatment.[53,57,58] A recent 2017 article entitled, "U.S. Epidemiology of Breast Implant-Associated Anaplastic Large Cell Lymphoma," reported an incidence that varies between one in 3800 and one in 30,000 cases per 100,000 women with breast prostheses per year.[59] It is important to recognize that although an association between breast implants—specifically, textured devices—and ALCL exists, no causative relationship has been documented. All but two cases of BIA-ALCL have occurred in association with textured silicone implants,[17,53,58,59] and these outlying reports remain highly questionable, as these patients had either an unknown implant surface or a situation in which the implant in question was exchanged multiple times for various types of partially documented implants that included at least one textured implant.[60,61] In 2011, the U.S. Food and Drug Administration published a safety communication stating that "[w]omen with breast implants may have a very small but increased risk of developing ALCL in the scar capsule adjacent to an implant."[4] A more recent update by the U.S. Food and Drug Administration published in 2016 maintains its stance that all breast implants, smooth and textured, have a reasonable safety assurance and that ALCL is a very rare disease.[59] In response to Doren et al.'s recently published epidemiologic study covering BIA-ALCL in the United States, Dr. Anand Deva urges readers to recognize that textured silicone implants continue to be responsible for the overwhelming risk and thereby should provide a sense of direction for future research on this topic.[62]

CONNECTIVE TISSUE DISEASE

In the 1980s and early 1990s, anecdotal reports of connective tissue disorders in women with breast implants were first published. Through 2004, data from all but one study unanimously concluded that there is no association between breast implants and connective tissue disease (Table 2).[41,63–70]

Before recent reports, the only finding of a relationship between connective tissue disease and breast implants came from a large cohort study of female health professionals published in 1996.[71] Compared to women without breast implants, women with breast implants had a relative risk of 1.24 (95 percent CI, 1.08 to 1.41) for any self-reported combined connective tissue disease. For individual connective tissue disorders, including rheumatoid arthritis, polymyositis/dermatomyositis, scleroderma, and Sjögren syndrome, the relative risk of disease was slightly elevated but did not show statistical significance. Only 22.7 percent of cases of self-reported connective tissue disease were confirmed in patients' medical records.[72] Additional evidence of overreporting and diagnostic biases was also evident in a U.S. Cohort study that looked at connective tissue disease in 7234 women in the United States with breast implants.[73] After examination of the medical record by what were deemed expert rheumatologists, only a minority of self-reports of connective tissue disease were declared as "likely," and the relative risk among women with breast

Table 2. Studies Investigating the Potential Association between Breast Implants and Connective Tissue Disease

Study	Country	Article Classification	Sample Size	Follow-Up	Conclusion on Silicone Implants	Independent vs. Industry-Funded
Hennekens et al., 1996	United States	Retrospective cohort	10,830	N/A	Statistically significant increased risk of "other connective tissue disease" and borderline statistical significance for rheumatoid arthritis, Sjögren, dermatomyositis or polymyositis, or scleroderma	Independent
Tugwell et al., 2001	United States	Systematic review	N/A	N/A	No evidence to support association between silicone implants and CTD	Independent
Holmich et al., 2003	Denmark	Retrospective cohort	238	Not stated	No association between implant rupture and CTD	Information not found
Fryzek et al., 2007	Denmark	Retrospective cohort	2761	Not stated	Unrelated to the development of CTD	Independent
Holmich et al., 2007	Denmark	Literature review	N/A	N/A	No association between implant rupture and CTD	Authors were paid consultants to Allergan
Lipworth et al., 2011	United States	Editorial	N/A	N/A	Slightly elevated risk of self-reported combined CTD	Independent
Balk and Raman, 2016	United States	Systematic review	32 Studies	Not stated	Statistical associations for increased risk of lung cancer, rheumatoid arthritis, Sjögren syndrome, and Raynaud phenomenon compared to general population	Independent
Singh et al., 2017	United States	Retrospective cohort	55,279	5 yr	No increased risk of systemic disease	Industry-funded
Coroneos et al., 2018	United States	Prospective cohort	99,993	7 yr	Associated with increased risk of Sjögren syndrome, rheumatoid arthritis, scleroderma	Independent
Watad et al., 2018	Israel	Cross-sectional study	123,255	10 yr	Statistical association with any autoimmune/rheumatic disorders, Sjögren, systemic sclerosis, sarcoidosis	Independent

N/A, not applicable; CTD, connective tissue disease.

implants was not significant for rheumatoid arthritis, scleroderma, or Sjögren syndrome combined when compared to the general population.

Fryzek et al.[74] compared 2761 Danish women with breast implants to 8807 women who had undergone reduction mammaplasty. All outcomes were verified and based on thoroughly reviewed medical records. After a mean follow-up time of 13.4 years, the authors concluded that there was no significant increase in the incidence of any specific connective tissue disease or any of the connective tissue diseases combined for women with breast implants. In addition, this study confirmed no difference between the two cohorts pertaining to the incidence of fibromyalgia. Although self-reported, Brinton et al.[73] also found that women with breast implants were not at increased risk of developing fibromyalgia compared to those who underwent other types of plastic surgery procedures. This study did include a category of conditions termed "other disorders," for which they reported a risk ratio of 1.4 (95 percent CI, 0.8 to 2.6) before 1992 and 3.6 (95 percent CI, 1.9 to 7.0) for the period that followed, a period marked by widespread litigation in the United States thereby supporting the authors' claim that these results were largely attributable to reporting bias among subjects.

Implant rupture has traditionally been thought of as an important risk factor for the development of connective tissue disease in patients with breast implants. Two large-scale studies published before 2007 confirmed that implant rupture does not place patients at increased risk of developing connective tissue disease.[75,76] One earlier study showed an increase in self-reported Raynaud syndrome in patients with isolated extracapsular implant rupture (OR, 4.2; CI 95 percent, 1.1 to 16.0) and "other connective tissue disease" (OR, 2.7; 95 percent CI, 0.8 to 8.5). In this study, the authors did not discern whether or not onset of symptoms were before breast augmentation.[77]

It is important to recognize that, based on the evidence presented at the time, the 1999 Institute of Medicine[41] report found no "convincing evidence for atypical connective tissue or rheumatic disease or a novel constellation of signs and symptoms in women with silicone breast implants." The authors of this report acknowledged that the study was underpowered and therefore would not have found an association had one existed. Following this report, Tugwell et al.[69] completed a systematic review per the request of a U.S. Federal Court–appointed national science panel to assist in evaluating expert testimony that was being presented in lawsuits brought against various breast implant manufacturers. It too found no evidence of an association between breast implants and connective tissue disease, therefore discrediting the expert testimony that had been presented.

In May of 2011, Lipworth et al.[78] published an article entitled "Silicone Breast Implants and Connective Tissue Disease: No Association," with the intention of clarifying remaining claims regarding breast implants and connective tissue disease. Of note, the authors of this editorial were paid consultants of the implant manufacturers and concluded that these claims were a byproduct of "unprecedented large-scale product liability litigation" rather than sound scientific evidence. In it, they cite 18 large-scale cohort studies, 11 case-control studies, and 13 additional independent meta-analyses and critical reviews, all of which unequivocally refute an association between breast implants and connective tissue disease. It showed a small increased risk of self-reported connective tissue diseases in women with breast implants (relative risk, 1.24; 95 percent CI, 1.08 to 1.41). The relative risks for each individual connective tissue disease including rheumatoid arthritis, polymyositis/dermatomyositis, scleroderma, and Sjögren syndrome were all slightly elevated but not statistically significant, and a later study found that only a small fraction of diagnoses could be confirmed.[72]

Early reports of expert evidence reviews, including a National Science Panel Report published in 1998,[79] the 1999 Institute of Medicine report,[41] and a 2011 U.S. Food and Drug Administration review,[4] all supported that there was no evidence to link silicone breast implants with an increased incidence of connective tissue disease. They did recognize that there were limitations to the existing evidence and further investigation was warranted. A 2017 article discussed previously[52] reported that after looking at 55,279 women with breast implants, over a 5-year follow-up period, silicone gel–filled implants had no increased risk of any connective tissue disease compared with national norms or those with saline implants. It is important to highlight that the data presented in this study represent the interim analysis of prospectively collected data, the same data analyzed by Coroneos et al.,[12] and were published 4 months after the final data became publicly available. Furthermore, all reported instances of adverse events were confirmed with the diagnosing physician to prevent inaccurate diagnoses based solely on patient-reported symptoms.

Recently, the largest and most comprehensive epidemiologic study of patient safety and

implant-specific outcomes for breast implants in the literature was published by Coroneos et al.[12] In their prospective analysis of nearly 100,000 patients over a 7-year follow-up period, the authors found that there were multiple connective tissue disorders for which diagnoses exceeded double that of the general population, conclusions that were contradictory to the interim analysis discussed above. These included Mentor patients with Sjögren syndrome (standardized incidence ratio, 8.14; 95 percent CI, 6.24 to 10.44), scleroderma (standardized incidence ratio, 7.00; 95 percent CI, 5.12 to 9.34), and rheumatoid arthritis (standardized incidence ratio, 5.96; 95 percent CI, 5.35 to 6.62). In addition, it showed an increased risk of developing multiple sclerosis and myositis, although both at rates less than twice that of the general population. Data for Allergan implants had a 7-year follow-up period, were based on physician-confirmed diagnoses, and had an excellent follow-up rate. Patients that underwent revision of prior breast reconstruction with Allergan implants had incidence ratios greater than 2.0 for scleroderma, Sjögren syndrome, and both dermatomyositis and polymyositis at 7-year follow-up. Finally, Coroneos et al. reported 500 autoimmune events in the silicone implant cohort compared with five events in those with saline devices. The authors of this report highlight that although Mentor data were patient-reported, as opposed to Allergan data, which were confirmed by a physician, plastic surgeons must be aware that patients may report to the clinic with symptoms that must be referred for evaluation by a rheumatologist. These results are congruent with the largest meta-analysis to date written by Balk and Raman that pooled outcomes from 32 observational studies and a recent review article published in 2018 that found a statistically significant association between silicone breast implants and autoimmune/rheumatic disorders, Sjögren syndrome, systemic sclerosis, and sarcoidosis.[31,80]

In response to the media craze that ensued following publication of the article by Coroneos et al.,[12] the U.S. Food and Drug Administration released a statement to address the findings discussed above. In it, they urge both the public and health care providers to view their conclusions with caution, as the study has major shortcomings. Although the authors' analysis was sound, the process used for data collection was designed by the implant manufacturers, and not without inconsistency and bias, conclusions that were recognized by Coroneos et al. and in a recently published editorial by Colwell and Mehrara.[81] Binita Ashar, M.D., reminds readers that the current evidence "does not conclusively demonstrate an association" and that "more evaluation is required."[82] The aforementioned editorial by Colwell et al. also highlights that the authors analyze a much smaller group of patients (<34,000 versus 99,993) for 7 years despite previous data concerns of poor follow-up and issues with data acquisition.

MENTAL HEALTH

Plastic surgeons must consider how our work affects patients' psychiatric well-being. Breiting et al.[18] found that women with breast implants had a higher self-reported rate of psychotropic medication use that included both antidepressants and anxiolytics. Although not diagnostic, they concluded that, despite there being no association between breast implants and depression, increased use of these medications warrants further investigation as to how breast implantation affects psychopathology.[31]

Coroneos et al.[12] found no association between breast implants and the rate of suicide in the United States; this conclusion opposed that of previous literature.[49–51,83–85] These conclusions were highlighted in the 2017 publication by Singh et al.[52] stating that the suicide rate (10.6 events per 100,000 person-years) was not significantly higher than that of the national norm. Although literature before this supported an association, it remained unclear whether or not it represented a causal link or whether it was secondary to an increased prevalence of prior underlying psychopathology.[86] This relationship may reflect other important underlying factors, including socioeconomic status, self-esteem, psychological distress, and psychotherapy among individuals undergoing treatment with breast implants.[4,12,31] This is highlighted in the Danish breast implant mortality study,[50] which showed that women undergoing cosmetic breast implantation had a higher prevalence of previous hospitalization for psychiatric illness compared with those undergoing both reduction mammaplasty and other types of cosmetic surgery.

NEUROLOGIC DISEASE

In the early 1990s, multiple case reports and case series described patients with silicone breast implants who had subsequently developed various neurologic symptoms or disorders. These conditions included multiple sclerosis, "multiple sclerosis type syndrome," both motor and peripheral

neuropathies, and "atypical neurologic disease syndrome." In response to these reports, three large population-based cohort studies[87–89] examining the possible association between breast implants and neurologic conditions were conducted. The results of all failed to report an association between these devices and the aforementioned conditions.[13] Shortly thereafter, the American Academy of Neurology published a statement[90] explaining that claims made in prior case reports were insufficient to establish a causal relationship because of the methodologically unsound nature of these reports. To the best of our knowledge, no new epidemiologic evidence has emerged since McLaughlin et al. reached this conclusion in 2007.

OFFSPRING EFFECTS

Early case reports of isolated adverse health outcomes in children born to mothers with silicone breast implants were published in the mid 1990s. Such conditions included difficulty swallowing, irritability, nonspecific rashes, and fatigue, among other symptoms.[91–96] These studies lacked a control group; in addition, there was apparent selection bias, as many of these children were born to families with a history of scleroderma and esophageal dysmotility.

To date, four large-scale epidemiologic studies have analyzed health outcomes among children born to mothers with silicone breast implants, all of which concluded there is no evidence to suggest a causal relationship (Table 3). The first of these articles, written by Kjøller et al.,[97] compared 939 children born to women with silicone breast implants to 3906 children of mothers who had undergone breast reduction surgery between 1977 and 1992. After a mean follow-up of 5.5 years, they observed a higher than expected rate of esophageal disorders in children born to women with breast implants compared with the general population. However, this excess was also observed in those who had undergone breast reduction surgery and among children born before their mother's breast implant surgery. In a follow-up study,[98] they observed higher than expected rates of esophageal disorders for children born before (observed-to-expected ratio, 2.0; 95 percent CI, 1.3 to 2.8) but not after (observed-to-expected ratio, 1.3; 95 percent CI, 0.5 to 2.9) maternal breast implant surgery, with similar excess seen both before (observed-to-expected ratio, 2.1; 95 percent CI, 0.5 to 2.9) and after (observed-to-expected ratio, 1.6; 95 percent CI, 1.1 to 2.3) breast reduction surgery. No excess of rheumatic disease was seen. Ultimately, they concluded that any observed increased risk of adverse health outcomes appears to be unrelated to breast implants, as these findings are evident among children born both before and after breast implant surgery and in children born to control mothers who underwent breast reduction surgery. A large retrospective cohort study examining 5874 children born to Swedish women with breast implants supported the conclusions above.[99] The fourth and final study conducted in Finland by Hemminki et al.,[100] which sought to evaluate perinatal health outcomes in infants born to mothers with silicone breast implants, suffered from major methodologic flaws that included inadequate controls and confounding variables.

In addition, women with breast implants after augmentation worry about their ability to safely breast-feed their children following surgery. In a study that looked at 5736 live births following breast augmentation, 79.4 percent of women

Table 3. Studies Investigating the Potential Association between Health Outcomes in Offspring of Implant Recipients

Study	Country	Article Classification	Sample Size	Follow-Up	Conclusion on Silicone Implants	Independent vs. Industry-Funded
Kjøller et al., 1998	Denmark	Retrospective cohort	939 children	Not stated	No increased risk of esophageal disorders or other illness in offspring	Industry-funded
Kjøller et al., 2002	Denmark	Retrospective cohort	2854 children	Not stated	Risk of malformations not significantly higher for women with breast implants	Industry-funded
Signorello et al., 2001	Sweden	Retrospective cohort	5874 children	Not stated	Rates of adverse birth outcomes no different to children born before or after implant surgery	Industry-funded
Hemminki et al., 2004	Finland	Retrospective cohort	Not stated	Not stated	Pregnancy and infant health are considerations for mothers with implants; methodologically flawed study	Information not found

breast fed at least one child, with the most common complication being insufficient milk production in 20 percent of cases, a number that closely mirrors that of the general population.[101]

CONCLUSIONS

The purpose of this Special Topic article is to present the current state of scientific evidence related to the safety of silicone breast implants. It is the responsibility of all physicians, especially plastic surgeons, to always put patient safety first and to critically self-evaluate our practices and the industry partners who serve our patients. Physicians must be familiar with the exact language used by implant manufacturers in device package inserts that explain potential risks associated with these devices. Not doing so ensures an inadequate informed consent process.

Few medical devices have undergone the degree of scrutiny and speculation that silicone breast implants have. At the present state, there is overwhelming evidence to support the safety of silicone breast implants. Ultimately, the decision to obtain, keep, or remove breast implants is the choice of the patient. If a patient chooses to have her breast implants removed, it is important to find a board-certified plastic surgeon with expertise in breast surgery. If a patient chooses to have implants removed, she should consider having the entire capsule removed, unless the posterior capsule is adherent to the chest wall, which may increase the risk of pneumothorax. In cases of ALCL or ruptured implants with thick calcified capsule, a total capsulectomy is mandated.[102]

Ongoing studies are strongly encouraged in all of these areas, from cancer detection to autoimmune disease causes as we strive for improved patient safety, patient awareness, and patient education. To the best of our body of scientific knowledge to date, there have not been any concrete or evidence-based studies or peer-reviewed data concerning the formation of a new syndrome: silicone implant illness.

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