

### Special Topic

# A Practical Guide to Managing Patients With Systemic Symptoms and Breast Implants

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### Abstract

Numerous studies have explored the possibility of an association between breast implants and systemic symptoms potentially linked to exposure to silicone. Some studies show no direct association whereas others provide insufficient scientific evidence to prove or disprove an association. Nonetheless, some patients with breast implants remain concerned about the possible role of their implants in systemic symptoms they may be experiencing. This paper provides a practical approach for plastic surgeons in managing patients with breast implants who present with systemic symptoms, including recommendations for patient counseling, clinical and laboratory assessment of symptoms, and/or referral. Integral components of patient counseling include listening attentively, providing unbiased information, and discussing the risks and benefits of options for evaluation and treatment. A thorough history and assessment of symptoms, including appropriate laboratory tests, may identify underlying conditions to expeditiously address patients' health issues through a specialist referral. Diagnosing and treating disorders that are causing a patient's symptoms, if unrelated to their implant, would avoid a potentially unnecessary surgery. Ultimately, better information is needed to reliably guide patients in an evidence-based fashion. Long-term follow-up of patients who are explanted to see what symptoms may or may not improve could be useful in educating patients. Control groups in studies prospectively following women with implants for development of systemic symptoms would also be useful because the symptoms reported are common in women without implants. Cases are presented to illustrate the recommendations for a practical approach toward management of women reporting systemic symptoms with breast implants.

### Level of Evidence: 4



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Women with breast implants may present with a variety of self-identified systemic symptoms that they suspect are directly connected to their implants. More than 50 patient-reported symptoms have been described in association with silicone breast implants (SBIs), and no specific diagnostic definition exists.<sup>1</sup> Symptoms include but are not limited to fatigue, chest pain, hair loss, headaches, chills, photosensitivity, chronic pain, muscle weakness, dry eyes, dry mouth, rash, body odor, “brain fog”/cognitive symptoms, sleep disturbance, anxiety, depression, neurologic issues, gastrointestinal symptoms, joint pain, and hormonal

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issues.<sup>2,3</sup> Although symptoms may present at any time, studies have reported a median duration from breast implantation to symptom onset of 4 to 10 years.<sup>4-7</sup> Concerns about the safety of SBIs originated with anecdotal reports in the 1980s and early 1990s of autoimmune disorders and nonspecific systemic symptoms in women with breast implants.<sup>8-11</sup> In response to these concerns, the United States FDA issued a voluntary moratorium on SBIs in 1992.<sup>12</sup> A review conducted by the Institute of Medicine in 1999 concluded that available epidemiological evidence from 11 cohort studies, 5 case control studies, and 1 cross-sectional study did not support a direct association between SBIs and systemic autoimmune diseases.<sup>13</sup> In 2006, the FDA permitted the sale of SBIs under the condition that the manufacturers implement ongoing 10-year breast implant safety studies.<sup>14</sup> A 2011 FDA update again concluded that there was no apparent association between silicone gel-filled breast implants and connective tissue diseases (CTDs).<sup>15</sup> In 2019, an FDA advisory panel on breast implant safety determined that there is currently insufficient evidence of a causal relationship between breast implants and the diagnosis of rheumatologic disease or CTDs but acknowledged that some women with implants who develop symptoms may notice improvement after implant removal.<sup>16</sup>

Numerous studies have explored the possibility of an association between breast implants and autoimmune CTDs, such as rheumatoid arthritis, systemic sclerosis, and systemic lupus erythematosus, and a number of epidemiological studies taken together are felt by many experts in the field to represent convincing evidence that there is no link between SBIs and auto-immune diseases.<sup>10,11,14,17-22</sup> Autoimmune/inflammatory syndrome induced by adjuvants (ASIA) is a term proposed by a group of Israeli researchers in 2011 to refer to symptoms they hypothesized were linked to previous exposure to immune adjuvants, including silicone and other implanted devices, as well as vaccines.<sup>23</sup> Key symptoms they proposed as being found in ASIA include joint pain, muscle pain, chronic fatigue, pyrexia, cognitive impairment, and neurological manifestations.<sup>3</sup> The data supporting an association between breast implants and CTDs or ASIA are largely anecdotal, comprising case reports, case series, and descriptive cohort studies with small sample sizes and no or inappropriate control groups.<sup>3-6,11,24-35</sup> A cross-sectional population-based analysis of women identified from a large health care database found a statistically significant association of having SBIs and a greater likelihood of being diagnosed with any autoimmune/rheumatic disorder.<sup>21</sup> Key study limitations were that a temporal relationship could not be established between breast implant insertion and CTD diagnosis, as well as the fact that publicity regarding a potential association could cause women with implants to seek health care and

make it more likely that they receive a diagnosis. The ASIA concept is considered largely hypothetical by most scientists given the lack of studies showing underlying mechanisms and scientific validity, the broad criteria for ASIA which may confound clinical applicability, and the wide time ranges between exposure to exogenous factors (eg, adjuvants) and onset of symptoms.<sup>36,37</sup> Although the focus has been on SBIs, there are also reports of systemic symptoms in women with saline implants,<sup>38,39</sup> making any specific illness due to the silicone shell less likely.

While further research into the link between breast implants and systemic symptoms is ongoing, patients with implants will continue to seek medical care for reported systemic symptoms. If patient concerns are not appropriately addressed, an underlying etiology of systemic symptoms not related to implants may be missed and/or women could be exposed to the surgical risks of so-called “specialized” explantations. At minimum, there is no definitively proven long-term benefit to explantation. Currently, there are no universally accepted best practices for diagnosing and treating these patients. Although plastic surgeons are not specialists in rheumatologic issues or medical evaluation of various systemic symptoms, patients with breast implants will often present to their surgeon for evaluation and guidance. This paper aims to provide a practical approach for plastic surgeons to facilitate discussion with prospective breast implant patients about systemic symptoms and help manage patients presenting with systemic symptoms based on the clinical experience of the authors, including recommendations for patient counseling, clinical and laboratory assessment of symptoms, and/or referral. Factors involved in decisions related to potential explantation surgery are also discussed.

## PATIENT COUNSELING

### Preoperative

A thorough discussion with the patient should occur as part of the informed consent process before surgical placement of a breast implant, including the risks of implants (eg, capsular contracture, implant rupture, implant malposition) and the fact that there are patients who develop systemic symptoms that they believe may be related to their implants. The goal is to have an informed patient who can be actively involved in decision-making. The preoperative education should review the information included in the breast implant labeling and acknowledge that (1) some patients receiving breast implants have reported a variety of systemic symptoms, (2) there is currently no scientific evidence to demonstrate causality by breast implants, (3) some of these patients have reported relief following implant removal, and (4) this topic is currently being

**Table 1.** Communication Points for Patients Presenting With Systemic Symptoms

Communication points
• Acknowledge that the symptoms the patient is experiencing are real
• Explain that there is no current scientific evidence of a direct link between breast implants and systemic symptoms
• However, there are some studies that suggest there is an association
• The medical community does not know for certain whether breast implants can cause systemic symptoms
• We do know that silicone is an inert substance
• Levels of heavy metals used in the manufacturing process of breast implants are extremely low
• Explain the reason for ordering general medical screening tests • Basic health screening can advise next steps in follow-up • Advanced testing by a specialist may be necessary to help understand whether an underlying condition is causing the symptoms so that the patient can be treated more effectively, and unnecessary breast removal surgery can be avoided
• Answer questions on capsulectomy and whether symptoms will improve with capsulectomy
• Although some patients experience improvement in systemic symptoms following implant removal, others do not or experience only transient relief
• There is no evidence that en bloc capsulectomy provides meaningful or durable relief of symptoms • The only scientifically proven indication for en bloc capsulectomy is to treat breast implant-associated anaplastic large cell lymphoma

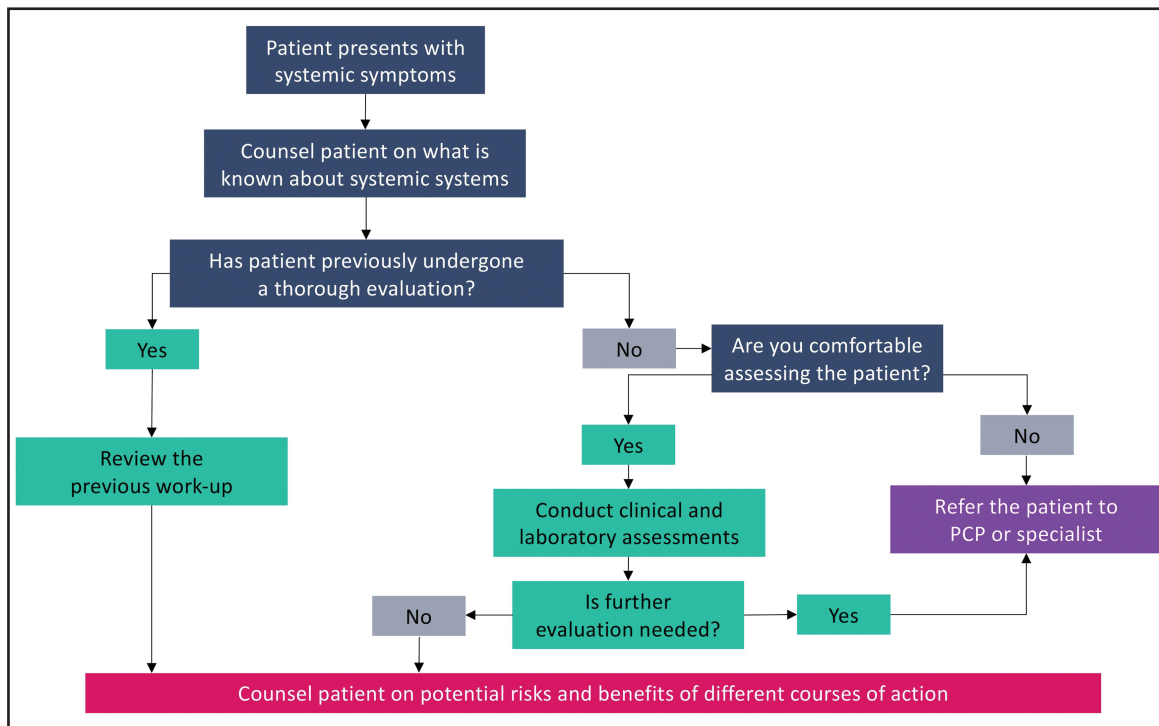
studied. Preoperative assessments based on medical history, physician exam, and testing could establish whether patients have an autoimmune disease or a compromised immune system. The safety and effectiveness of silicone implants have not been determined in these patient populations, which should be discussed with the patient before surgery.<sup>31,40,41</sup> Regular follow-up is critical after surgery to monitor patients for the development of symptoms and potential implant-related complications.

## Postimplant

Systemic symptoms are not unique in women with breast implants, and many are observed in other syndromes, including chronic overlapping pain conditions (eg, fibromyalgia) or chronic fatigue syndrome, seronegative or seropositive Lyme disease, Gulf War syndrome, and long coronavirus disease (COVID).<sup>42-47</sup> Patients with such conditions, often characterized by numerous nonspecific symptoms, may experience stigma and may feel abandoned by their physician and the health care system if they are told that their symptoms are imaginary or psychosomatic; the anguish and suffering experienced by these patients should not be trivialized or underestimated.<sup>45,46,48</sup> Accordingly, patients presenting with systemic symptoms postimplantation need to feel heard and supported regarding their health issues. An analysis of social media posts showed that patients expressed concern because they felt they had not been forewarned about the possibility of systemic symptoms and felt frustrated when plastic surgeons appeared dismissive of their symptoms.<sup>49</sup> Many patients are under tremendous stress, presenting after extensive workups and consultations with multiple physicians

and are distressed when no cause has been determined. Patients often come to believe these symptoms may be caused by their breast implants after doing their own research and finding internet and social media groups of women with similar concerns. Patients may also have been exposed online to questionable medical information or scams promoting phony tests and unproven treatments for their symptoms, such as chelation therapy and various detoxification programs.<sup>50,51</sup> Table 1 provides talking points for patients presenting with systemic symptoms.

Remaining open-minded and listening attentively to patient concerns is critical to open communication. An overview of the science should be presented in layman's terms that patients can understand.<sup>49,51</sup> Patients often request removal of their implants as a last resort, believing that explantation will resolve their symptoms. Given that currently available research has not established a clear relationship between breast implants and systemic symptoms, including autoimmune disease, there is no conclusive scientific evidence that removal of implants will result in symptom improvement.<sup>51</sup> It is important to emphasize that although there is currently no definitive evidence to link breast implants to systemic symptoms, plastic surgeons are continuing to research any possible long-term effects of breast implants and to better quantify the risks and benefits of explantation.<sup>51,52</sup> Any previous medical consultation and laboratory work should be reviewed to see if the most common potential causes have been ruled out. Counseling should also include discussion of options for further investigation of symptoms to evaluate for underlying causes, based on specific presentation of patient symptoms. Systemic symptoms attributable to breast implants is a diagnosis of exclusion because there are no



**Figure 1.** Algorithm for the management of systemic symptoms in patients with breast implants. PCP, primary care provider.

specific diagnostic tests or diagnostic criteria. Although patients may believe that their symptoms are caused by their breast implants, the importance of ruling out underlying and potentially treatable or reversible causes through appropriate workups cannot be overstated. Some authors have suggested that systemic symptoms in patients with breast implants represent a somatoform disorder because symptoms often cannot be fully explained by or are disproportionate to demonstrable tissue abnormalities,<sup>53,54</sup> but it is nonetheless essential that the patient receive a full medical evaluation.

## CLINICAL AND LABORATORY ASSESSMENT

Figure 1 shows approaches to the management of patients with breast implants presenting with systemic symptoms based on the authors' clinical experience. Establishing whether the patient has had a previous workup for her symptoms and, if so, whether the assessment was adequate is an essential initial step. Depending on the type and severity of the patient's symptoms, a plastic surgeon has to determine their comfort level for initiating a medical evaluation or whether to refer the patient to their primary care provider or specialist. Women who are likely perimenopausal who have not had a recent gynecological examination should be referred to a

gynecologist for assessment and hormone workup if indicated because many systemic symptoms (eg, brain fog/cognitive symptoms, mood symptoms, anxiety, sleep disturbance) may be associated with perimenopausal hormonal changes.<sup>55</sup>

Taking a holistic approach to patient care should be the goal, especially because many of the symptoms reported by patients are nonspecific and may potentially be due to, or influenced by, psychological or lifestyle factors, underlying health conditions, or current medications. In addition to undergoing a medical history and physical examination, patients should be asked about their personal history of allergies and autoimmune disease as well as about their family history of such conditions. Diet changes, such as a vegetarian, gluten free, or pescatarian, should be ascertained, especially if there has been a change within the time period when the symptoms began. General screening tests to evaluate overall health in patients with breast implants and systemic symptoms include complete blood count (CBC), C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), electrolytes, creatinine, thyroid and liver function tests, and vitamin D and calcium levels.<sup>1</sup> Imaging tests (eg, diagnostic ultrasound, 3-dimensional mammogram) should be performed if there is suspicion of a breast implant complication, such as capsular contraction or rupture or per the American Cancer Society's recommendation for screening depending on the patient's age or family history.<sup>56</sup> The next stages of follow-up (eg,

**Table 2.** Laboratory and Imaging Assessment of and Referral for Common Systemic Symptoms Reported by Patients With Breast Implants<sup>a</sup>

Symptom	Laboratory tests of overall health	Additional tests to consider	Appropriate specialist(s) for referral
Fatigue		EKG	Neurologist, psychiatrist, sleep disorders specialist
Brain fog		Neurological imaging if indicated (eg, TIA/stroke, cancer metastases suspected)	Gynecologist, neurologist, psychiatrist
Anxiety		None	Psychiatrist
Joint pain	CBC, CRP, ESR, iron, ferritin, urea, electrolytes, creatinine, thyroid tests, LFTs, vitamin D, calcium	Radiography and autoantibodies (eg, ANA, RF, anti-CCP) as indicated if high suspicion of autoimmune or rheumatic disease	Orthopedist, rheumatologist
Hair loss		None	Dermatologist
Gastrointestinal symptoms		Limited testing may be required to rule out specific gastrointestinal disorders	Gastroenterologist

<sup>a</sup>ANA, antinuclear antibody; CBC, complete blood count; CCP, anti-cyclic citrullinated peptide; CRP, C-reactive protein; EKG, electrocardiogram; ESR, erythrocyte sedimentation rate; LFTs, liver function tests; RF, rheumatoid factor; TIA, transient ischemic attack.

referral to a specialist and advanced testing) will be determined by the results of these evaluations. Overall, it is important to consider whether presenting symptoms are part of a larger clinical picture.

In the authors' experience, the most common complaints are fatigue, brain fog, anxiety, joint pain, hair loss, and gastrointestinal issues. The next sections will focus on potential causes for the most common symptoms and options for evaluation (Table 2).

## Fatigue

Fatigue has many possible causes, such as aging, motherhood, medication side effects, sleep disturbance, cardiopulmonary disease, anemia, infection, endocrine dysfunction (eg, diabetes, hypothyroidism), inflammatory/rheumatologic disease, psychiatric illness (eg, depression or anxiety), and lifestyle factors.<sup>57</sup> Among patients who undergo implant-based breast reconstruction following cancer surgery, it is important to perform a physical examination, including examining for lymphadenopathy, which could be a sign of recurrence or tumor spread. Type and dosages of prescription and over-the-counter medications should be reviewed. Laboratory tests that should be considered in most patients with at least a 2-week history of fatigue include an electrocardiogram or cardiac workup as dictated by symptoms, a CBC, ESR, vitamin D and calcium levels, chemistry panel, and thyroid, liver, and kidney function tests. Because nonorganic causes of fatigue are common, many plausible causes will likely remain once defined organic factors are ruled out for any given patient.

## Brain Fog

The term “brain fog” generally refers to cognitive symptoms such as an inability to think clearly and attentional or memory impairment. As described above, brain fog is a common symptom in the general population as well as potentially occurring in increased frequency in the context of perimenopausal hormonal changes.<sup>55</sup> Patients should be asked about menses as well as about possible causes of brain fog, such as transient ischemic attack symptoms and sleep problems or disorders. Thorough assessment should explore whether the patient is experiencing or has a history of other symptoms or medical conditions and whether the patient is taking medications, such as chemotherapy or anticholinergics, that may adversely impact their cognitive function. Assessment of medically unexplained neuropsychological symptoms such as brain fog should include psychological evaluation to determine whether a mood, anxiety, or psychotic disorder is present.<sup>58</sup> If dementia is suspected, an evaluation should be performed by a neurologist and/or psychologist. Neurological imaging may also be considered as appropriate (eg, if the patient has a recent history of transient ischemic attack/stroke symptoms or if cancer metastases are suspected). Accompanying neurological symptoms, such as tremors, nystagmus, abnormal reflexes, and gait abnormalities, require an examination by a neurologist.

## Anxiety

Anxiety symptoms may be due to an underlying anxiety or mood disorder but can also be associated with medical

conditions such as thyroid disease. In addition to taking a thorough patient history and inquiring about family history of psychiatric illness, clinicians should consider screening patients for depression and anxiety (eg, Hospital Anxiety and Depression Scale) and ensuring that the patient is receiving appropriate counseling and/or treatment.<sup>59</sup> Patients should be referred to their primary care physician or to a psychiatrist if a psychiatric disorder is suspected. Laboratory assessment should be performed as indicated by the patient's symptoms and examination. Patients with breast implants may also suffer from anxiety related to concerns about their implants. Social media has been shown to contribute to anxiety, and the recent publicity concerning breast implant–associated anaplastic large cell lymphoma (BIA-ALCL) could also contribute to women's anxiety about their implants.<sup>51,60</sup> It is important that plastic surgeons be able to address any patient concerns and put their particular risk into perspective based on the type of implant that they have.<sup>51,60</sup>

### Joint Pain

Joint pain can have many causes. Differential diagnosis includes trauma (eg, sprain, tendinitis), infection, crystal-induced arthropathy (eg, gout), degenerative joint disease (eg, osteoarthritis), malignancy, rheumatic disease (eg, rheumatoid arthritis, systemic lupus erythematosus [SLE]), and other conditions, such as Sjögren syndrome, scleroderma, and fibromyalgia. When assessing chronic joint pain, the physician should ask about the location(s), onset, and progression of the pain as well as the presence of systemic symptoms.<sup>61</sup> In addition to the patient's medical history, a family history of joint disease and rheumatic conditions should be reviewed. Physical examination involves inspection, palpation, range of motion, and other specialized tests. The occurrence of nocturnal or unremitting pain, systemic symptoms such as fever/chills or weight loss, or significant disability should prompt an immediate workup and referral. During physical examination, warm skin, erythema, and joint swelling indicate a need for a more urgent workup and are suggestive of conditions such as infection and/or autoimmune disease. Radiography is suggested if the patient displays swelling or tenderness, inability to bear weight, gross deformity, and older age. Laboratory tests do not often play a key role in the diagnosis of joint pain. Blood tests such as ESR and CRP can be helpful to rule out an autoimmune disorder, but other laboratory tests such as rheumatoid factor, anti-cyclic citrullinated peptide, ANA, and other auto-antibodies are often best ordered only when there is a strong clinical suspicion of an autoimmune disorder.<sup>6,29,61-63</sup> Elevated ESR and CRP are also often elevated in other conditions such as systemic infections or malignancy.<sup>64</sup>

### Hair Loss

Hair loss (alopecia) can be divided into cases in which the hair follicle is damaged and those in which the hair follicle is normal but hair growth cycle is abnormal.<sup>65</sup> A thorough medical history includes details on hair loss (duration and pattern), presence of breakage or shedding at the roots, and increased or decreased shedding or thinning.<sup>65</sup> Family history of alopecia, past and present medical conditions, diet, and current medications should also be reviewed. A thyroid function test should be performed, and patients should be referred to a dermatologist for further evaluation.

### Gastrointestinal Symptoms

Gastrointestinal complaints reported in association with breast implants are usually abdominal pain and changes in bowel movement patterns consistent with irritable bowel syndrome (IBS).<sup>3,6</sup> Notably, IBS with episodes of alternating diarrhea and constipation have been reported by patients with breast implants and other systemic symptoms. Evaluation should include a history of the location and duration of abdominal pain as well as a history of disordered bowel habits (ie, constipation, diarrhea, or both) and their temporal association with abdominal pain episodes.<sup>66</sup> Changes in diet or medications that affect gastrointestinal transit should also be assessed. Although the need for laboratory and other diagnostic testing is typically minimal for routine evaluation of IBS-like symptoms, limited testing may be required to accurately distinguish disorders such as inflammatory bowel disease, lactose and fructose intolerance, and celiac disease. Patients presenting with gastrointestinal complaints should be referred to a gastroenterologist for further evaluation and to determine the need for endoscopy and colonoscopy.

### EXPLANTATION CONSIDERATIONS

Some studies have reported an estimated 50% to 75% of patients report improvement of systemic symptoms after implant removal.<sup>3,6,67</sup> However, improvement may be partial and temporary.<sup>68,69</sup> Although it is not possible to predict with certainty which patients will improve, a stratification has been proposed based on diagnosis of preexisting disease and likely outcome based on observation of 100 women following explantation.<sup>68</sup> Women with no laboratory-confirmed disease were most likely to achieve symptom improvement following removal of their breast implants.<sup>68</sup> Those women who demonstrated abnormal markers consistent with rheumatic disease but had no clear-cut evidence of autoimmune disease tended to experience transient improvement, whereas women with proven autoimmune disease generally did not experience

symptom improvement or deteriorated further following explantation.<sup>68</sup> Patients with diagnosed autoimmune disease or with abnormal markers should understand that it is unlikely that their disease will improve with explantation. A retrospective analysis of clinical and survey data from 750 women who underwent explantation found that 11 surveyed systemic symptoms all improved significantly following surgery, with improvements sustained beyond 30 days postexplantation.<sup>39</sup> Patients with a BMI >30 and those with clinically detectable contracture demonstrated significantly greater symptom improvement, suggesting that these clinical features may be predictive of improvement following explantation. This study has several limitations that prohibit making broad conclusions, including the retrospective design, lack of a control arm, and short follow-up times; specifically, only 2.9% of patients in the study had follow-up after 1 year following explantation.

Explantation options include implant removal with or without capsulectomy. The discussion should also include whether a total precise capsulectomy can be performed or if “en bloc” capsulectomy is indicated.<sup>2</sup> The term total precise capsulectomy (included in the data collection menu on the Aesthetic One app) is defined as removal of the implant and the entire capsule, either with the implant in the capsule or the implant removed during the capsulectomy, to facilitate precise, bloodless remaining capsulectomy under direct vision. Patients may believe that the capsule is a potential site of inflammatory mediators or toxins and therefore request removing the entire capsule in addition to the implant.<sup>51</sup> This is usually possible, but the procedure can become more complicated if the posterior capsule is adhering to the chest wall, which may increase risk of pleural damage and pneumothorax.<sup>11,70</sup> Those patients who request or are considering en bloc resection should be educated on the anatomy of capsulectomy and on the potential risks of en bloc resection compared with a total precise capsulectomy or partial capsulectomy.<sup>51</sup> Patients should be counseled that en bloc capsulectomy is not always possible. It is sometimes necessary to leave behind part of the capsule to avoid damaging the muscle, rib, lung, or axillary blood vessels. Furthermore, the benefits of en bloc capsulectomy in providing meaningful or durable relief of symptoms have not been scientifically demonstrated,<sup>71</sup> although en bloc capsulectomy is an effective and recommended treatment for BIA-ALCL.<sup>72,73</sup> Although it is important to respect patients’ wishes regarding removal of implants, patients need to understand that during surgery, decisions sometimes have to be made depending on their anatomy and tissues; as a result, no guarantees can be made. If a surgeon feels that he or she cannot in good conscience perform the procedure that the patient requests because of potentially unreasonable expectations or an inability to obtain appropriate informed consent, the surgeon should suggest the patient consider another surgical opinion.<sup>49,51</sup>

## CASE STUDIES

The following cases from the authors’ clinical practice are representative of women with systemic symptoms and breast implants who were considering, or actually underwent, explantation. All patients provided written informed consent.

### Case #1

A 38-year-old woman had received implants approximately 10 years previously for breast augmentation. After experiencing joint-related pain during the first postoperative year, the patient underwent extensive medical evaluation, including a rheumatoid panel, and ultimately was diagnosed with seronegative rheumatoid arthritis, which was treated symptomatically with medications for rheumatoid arthritis. Approximately 10 years after the original surgery, the patient felt that her symptoms were worsening, and she requested removal of her implants. After counseling on the current state of evidence regarding breast implants and rheumatic disease and the inability to predict who will benefit from explanation, the patient elected to have her implants removed with a total precise capsulectomy. The patient was followed-up after implant removal. Early in the postoperative period, she did not experience any change in her symptoms. At 1 year postoperative, the patient reported that her systemic symptoms and overall health had not changed since the explanation and requested to have implant surgery again due to aesthetic concerns with her breasts.

This case illustrates the importance of patient choice once benefits and risks have been explained as well as the importance of explaining to patients the uncertainty regarding who will benefit from explantation and who will not (ie, the possibility that systemic symptoms of undetermined cause will continue even after explantation).

### Case #2

A 61-year-old woman presented 12 months after primary breast augmentation concerned about symptoms she had been experiencing for the previous 9 months. The patient stated that during this time she had bronchitis as well as “slight flu-like symptoms.” For the last 7 months, she had a fever >101.7° once a month, usually in the evenings. She had not seen her primary care physician since the fevers started, but 1 month prior to that she did see a physician assistant who told her that her “immune system was depleted.” The patient was unsure what that meant but improved her diet and started taking vitamins without improvement in her symptoms. She heard about breast implant illness (BII) in the news, and, although she was not sure that was the cause of her symptoms, she returned to

my office to discuss it. The patient was happy with the appearance of her breasts and, if anything, would prefer her breasts to be larger if the implants were not the source of her symptoms. Physical examination showed grade 1 capsules without mass, fluid, or asymmetry. No lymphadenopathy or abnormality in skin or incisions was noted.

Signs and symptoms of BIA-ALCL were discussed, of which she had none, as well as typical complaints associated with BII. The patient was counseled that typical BII symptoms are subjective and do not typically include a fever and was educated about the difficulty in diagnosing BII based on no single symptom, laboratory test, or clinical finding specific to diagnosis. The fever was not suspected to be due to periprosthetic infection because the breast exam was normal, and the patient was referred back to her primary care physician for further work-up of fever. She was told that the surgeon would be happy to re-discuss whether she wanted to remove the implants, exchange them for larger implants, or do nothing at all after a full medical work-up for fever. A screening mammogram was ordered because the patient was due and was normal.

Work-up by the patient's primary care physician revealed elevated liver function tests. The patient then underwent a liver ultrasound followed by a CT scan, which revealed a 10-cm × 9-cm × 9-cm enhancing mass of the right lobe of the liver involving the middle and left hepatic veins. Biopsy of the liver mass showed liver carcinoma. The mass was inoperable, and the patient was referred for radiation therapy and was subsequently lost to follow-up.

### Case #3

A 45-year-old woman had smooth saline implants placed 6 years prior to presentation requesting implant removal. Two years after her implants were placed she developed fatigue, difficulty sleeping, weight gain, headaches, low libido, joint pain, occasional rashes, muscle pain, memory issues, brain fog, and dry eyes. She was evaluated by her primary care physician, and blood work was performed looking at hormone levels, thyroid function, metabolic panel, and CBC. All of the laboratory workup was normal. She saw a rheumatologist, endocrinologist, and gynecologist, with no cause determined for her worsening symptoms. A friend suggested she look at a social media group on BII. After seeing the stories from many women with a similar story, she saw her plastic surgeon to request implant removal with "en bloc" capsulectomy. Her surgeon felt her implants were fine and discouraged her from having surgery. She sought another opinion and after discussion with another plastic surgeon, underwent implant removal with a total precise capsulectomy. The day after her surgery, she felt much better with significant improvement of her symptoms. Six months later, her headaches,

low libido, and joint pain had returned, but her remaining symptoms were improved.

## CONCLUSIONS

A causal relationship between breast implants and systemic symptoms cannot be conclusively established based on current scientific evidence. Nonetheless, there are patients who attribute such symptoms to their implants and request implant removal in hopes of achieving symptom relief. There is a need for common-sense, practical approaches to address the concerns of patients with breast implants experiencing systemic symptoms and have an honest discussion with the patient as to the potential outcome of explantation surgery, including the potential that they may not receive complete symptom relief and that there are potential risks with surgery. Ultimately, better information, including long-term follow-up in women who undergo explantation, is required to reliably guide patients and surgeons in an evidence-based fashion. Because the symptoms reported are also common in women without explants, control groups in studies prospectively following women with implants for development of systemic symptoms would also be informative. Until there are more data, clinicians need to look holistically at patients, considering their underlying medical conditions, family histories, and common factors or conditions that may explain their symptoms. Listening to patient concerns and counseling patients on what is known about systemic symptoms and breast implants and on the risks and benefits of different treatment options is the first step in helping patients navigate their health issues.

## Disclosures

Dr McGuire is a Consultant with Allergan (Irvine, CA), Galatea Surgical (Lexington, MA), Establishment Labs (Alajuela, Costa Rica); clinical investigator for Motiva US (Santa Barbara, CA), FDA clinical trials; and an Aesthetic Surgery Education and Research Foundation grant recipient. Dr Clauw attended an advisory board meeting for Allergan and is involved in breast implant litigation on behalf of Allergan. Dr Hammer is an employee of AbbVie (Irvine, CA) and may own stock or stock options. Dr Haws is an advisory board member for Sientra Strategic (Santa Barbara, CA) and RealSelf Business (Seattle, WA); an investor in Strathspey Crown (Newport Beach, CA). Dr Adams declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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## Safety and Performance of POLYTECH Mesmo Breast Implants: A 5-Year Post-Market Surveillance Study on 919 Patients

### Objectives

Provide an update on safety and performance outcomes at 5 years for Mesmo breast implants.



### Methods

Breast augmentation patients completed questionnaires to assess complications and satisfaction.



### Conclusions

With low complication rate, Mesmo implants are a safe choice for both surgeons and patients.



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