Breast Implant Illness:

Frequently Asked Questions & Talking Points

What is Breast Implant Illness (BII) ?

Breast Implant Illness (BII) is a term used by women with breast implants who describe a variety of symptoms including (but not limited to) fatigue, chest pain, hair loss, headaches, chills, photosensitivity, chronic pain, rash, body odor, anxiety, brain fog, sleep disturbance, depression, neurologic issues and hormonal issues that they believe are the result of their saline or silicone, textured or smooth breast implants. The onset of symptoms varies from immediately after implantation to years later.

BII is NOT BIA-ALCL. BII is a completely separate entity. While it is theoretically possible that a patient could develop both ALCL and BII, the two entities are distinct and not related to each other.

The recent increase in patients reporting Breast Implant Illness (BII) symptoms may be related to social media. As of August 2020, one Facebook group had more than 100,000 members, all of whom self-reported Breast Implant Illness (BII) symptoms. This is not to say that social media is the cause of Breast Implant Illness (BII), however, the communication on social media may account for the rapid increase in patient reporting.

BII is not an official medical diagnosis. It is a diagnosis of exclusion; patients need a thorough medical evaluate to rule out other potential causes of their symptoms. There is no diagnosis code at this time.

At this time there are patients with implants from all manufacturers with all surface textures (including smooth), and with both saline and silicone fill who have self-identified as having BII.

Is there a link between medical grade silicone implants and any disease?

To date, there is no proven scientific link between silicone and any defined autoimmune disease. The type of silicone used in breast implants does not exist in nature; it is created by chemical conversion of silica to polydimethylsiloxane.

Are there any tests that indicate a connection between breast implants and symptoms that are being labelled Breast Implant Illness (BII)?

There is no diagnostic test specifically for Breast Implant Illness (BII). This is one of the current areas of focus for the Aesthetic Surgery Education and Research Foundation (ASERF), the research arm of The Aesthetic Society. There are, however, tests for autoimmune diseases. Some patients who report having Breast Implant Illness (BII) have positive tests and others have negative tests for autoimmune diseases.

Is there any scientific data showing causation between implants and these symptoms?

Until recently, BII has not been studied as a specific entity. There are currently several ongoing studies by The Aesthetic Society. members looking at the effect of implant removal on symptoms. Many patients appear to have some improvement lasting at least 12 months, but response is variable. Some patients report no improvement.

In 1999, the Institute of Medicine Committee on the Safety of Silicone conducted an extensive review of the available literature and concluded there was no clear link between silicone implants and any systemic illness. Many studies have searched for a connection to specific autoimmune disorders and diseases. In aggregate, these studies show no definite link between breast implants and any specific disease. Patients who report that they have BII have not shown consistent laboratory abnormalities to define a distinct syndrome.

Does implant removal cure a patient who has a medically diagnosed disease entity like an autoimmune disease?

Various studies of patients with documented autoimmune conditions show varying degrees of improvement after removal of implants, including no improvement, temporary improvement and permanent resolution of symptoms.

There are no studies that indicate which symptoms may or may not improve after implant removal with or without capsulectomy. Studies have shown that symptoms may at least temporarily improve after implant removal, there is no scientific evidence that shows a diagnosed autoimmune disease will cured with implant removal.

The FDA recently released an update including their query of all Medical Device Reports (MDR) posted January 2008 through October 2019 which included one of over 80 symptoms OR one more of the following terms: BII, Breast implant illness, generalized/unexplained illness, or unexplained systemic symptoms. It should be noted while the MDR database is useful it has significant limitations (as described by the FDA) including but not limited to: incomplete, inaccurate, untimely, unverified, or biased data in the reports; potential for under reporting or duplicate reporting; and the fact that receipt of an MDR does not in and of itself establish or confirm the device caused or contributed to the adverse event or symptom reported. These reports are not medically validated.

Data points as follows:

- This query identified 3,577 MDRs 70% of which were recorded October 2018-October 2019.
- Average age of onset was 43 years old as determined from the available from data from 56% of these reports.
- 75% of the MDRs (2,675/3,577) had enough information to determine average time to onset from implantation was 4.9 years.
- Only 290 MDRs provided information related to the status of symptoms following explant. Of these, 279 noted improvement and 11 noted no improvement or worsening of symptoms.

*Medical Device Reports for Systemic Symptoms in Women with Breast Implants

There is no definitive epidemiological evidence to support a link between breast implants and any specific disease process. However, further research is clearly indicated. In rare and unusual disease processes it can take years to come to a scientific conclusion. There are many factors that can affect the interaction between a patient and her breast implants. Further study is required to determine the best method of screening patients prior to breast implant surgery to determine which patients, if they later developed BII, are likely to improve with implant removal.

The lack of a proven scientific link between implants and BII does not mean that the symptoms experienced by these patients are not real or that a link may not be discovered in the future. If a patient's symptoms resolve after implant removal, the presumptive diagnosis is BII.

What are The Aesthetic Society and ASERF doing to investigate this group of systemic symptoms being called Breast Implant Illness (BII)?

Because there are many women who self-identify as having Breast Implant Illness (BII), we are listening. The Aesthetic Society and ASERF are developing and funding new scientific studies to examine this entity. We are also providing our members with a questionnaire with which to collect a record of complaints attributed to implants, as well as one to utilize post-explantation. We cannot yet define BII and therefore cannot say with certainty that it exists.
However, we can now report the preliminary findings of The Aesthetic Society members who are tracking their patients after implant removal. A preliminary study of 100 patients with self-reported BII in one surgeon's practice revealed that 89 percent of patients undergoing implant removal and capsulectomy experienced improvement in some of their symptoms within 3 months of surgery.

Symptoms that improved included fatigue, cognitive dysfunction, burning pain of the chest wall and breast, dry eyes, anxiety, and joint pain. As mentioned above, these systemic symptoms have been reported in patients with all breast implants, by all manufacturers, with all different degrees of texture and types of fill.

Finally, the symptom relief seems to be equally likely after en bloc vs. precise capsulectomy. There are studies showing that early symptom improvement is common, but long-term symptom improvement has not be scientifically proven. There are studies that show recurrence of symptoms at 6 months to a year.

What should a physician do when a patient complains of Breast Implant Illness (BII) symptoms?

Do not ignore your patient's concerns. The FDA stated in March 2019, "We have heard from patients who are concerned that their implants may be connected to other health conditions that could be associated with their immune system's response to these devices, resulting in symptoms like chronic fatigue, cognitive issues and muscle pain. While the FDA doesn't have definitive evidence suggesting breast implants are associated with these conditions, we're looking to gain a fuller understanding of this issue to communicate risk, minimize harm and help in the treatment of affected patients." This can be read in full here: https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-systemic-symptoms-women-breast-implants/?utm_campaign=2020-08-20%20Breast%20Implants%3A%20FDA%20Provides%20Updates%20on%20Medical%20Device%20Reports&utm_medium=email&utm_source=Eloqua

If implant removal is a procedure you offer in your practice, there is no reason not to offer it to these patients. Depending on symptoms, the work-up may include ruling-out other causes. Options for work-up and treatment may include observation without medical work-up, medical evaluation with or without Rheumatology consultation, implant

removal without capsulectomy, exchange of implants with or without capsulectomy, removal with total capsulectomy, or removal with en bloc capsulectomy.

Patients who present with concerns of Breast Implant Illness (BII) have real symptoms that often cannot be categorized into a specific disease entity. This does not mean their symptoms are not real and therefore these patients deserve a full evaluation. The various options require discussion. With further research, we may be able to determine which patients will experience symptom improvement or resolution with removal of their implants and which patients will not.

What is the risk of developing Breast Implant Illness (BII)?

Because there is no definitive link between the symptoms and breast implants, and no diagnostic test, there is no known risk statistic that can be cited. Many of the symptoms described by breast implant patients are experienced by the general public on a regular basis. Because of a lack of centralized data, it is impossible at this time to extrapolate the incidence or risk of BII.

Patients must be informed of the risks associated with breast implants, including (but not limited to) BIA-ALCL, a rare lymphoma that develops in association with textured implants. Patients should know that BIA-ALCL is not a cancer of the breast tissue itself and that when caught early, it is usually readily curable. If the disease is advanced, chemotherapy or radiation may be required. 36 patients have died from BIA-ALCL as reported in "Medical Device Reports of Breast Implant-Associated Anaplastic Large Cell Lymphoma": https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma?utm_campaign=2020-08-20%20Breast%20Implants%3A%20FDA%20Provides%20Updates%20on%20Medical%20Device%20Reports&utm_medium=email&utm_source=Eloqua

A discussion of the FDA stance on BII, the typical symptoms reported by patients, and the current studies mentioned above may be included in your discussions with patients. The Aesthetic Society is working to help improve informed consent with breast implants. Part of this consent will include check lists Included in a Patient Decision Aid.

If after the discussion of risks and the possibility that there may be no improvement post-explantation, what should be done if the patient insists on "En bloc" or "total" capsulectomy?

There are many medical inaccuracies perpetuated by the internet. Most BII patients tend to believe that a total capsulectomy is necessary to remove all causative agents and they often request “en bloc” removal, often times without having a full understanding of what size incision is required for en bloc removal. In your consult, first discuss the reasons you would or would not perform a total capsulectomy. Not all plastic surgeons routinely perform a capsulectomy with explantation.

It is important to explain that it is not always possible to remove all of the capsule. Sometimes a portion of the capsule must be left behind to prevent significant damage to muscle, rib, axillary vessels or lung. If the patient had an axillary or periareolar approach for breast implant placement, she needs to understand that she cannot have the capsulectomy through the same incision. It is recommended to reinforce that there are increased surgical risks associated with en bloc capsulectomy which requires complete dissection of all the tissues surrounding the breast implant and that we do not have enough data to guarantee any improvement in symptoms. In one surgeon’s study of 69 patients undergoing en bloc capsulectomy and 31 patients undergoing total, or complete, capsulectomy, there was no difference in the percentage of patients who reported resolution of symptoms.

To reiterate, there is no scientific data that supports the need for en bloc capsulectomy in the absence of malignancy.