Breast Implant Illness - Frequently Asked Questions

Breast implant illness (BII) is a subject that is increasingly on the minds of many of our patients. Because of low incidence and variable presentation, it will be some time before we understand the etiopathogenesis and best treatment for this condition.

Patients with this condition require and deserve the best possible care and must not be preyed upon by an overly aggressive work-up or treatment. Symptoms are real and some patients are suffering. Even though there is no test for BII does not mean it is not an actual syndrome. We are here to listen if you are having problems.

1) There is currently no science to support genetic testing as a means of determining which patients may be susceptible to BII.

2) There is no evidence that capsulectomy is the treatment for BII. However, patients' wishes must be respected (if safe and reasonable). Further, there is no evidence that an *en bloc* capsulectomy is superior to precise capsulectomy or more limited forms of capsulectomy.

Q: What is Breast Implant Illness (BII)?

A: *Over 40 million women world-wide have breast implants. Most of these women seem satisfied with their implants and do not experience any local or systemic symptoms. However, there are presently women who are reporting various systemic symptoms thought to be related to their breast implants and this is referred to as Breast Implant Illness (BII).*

Reported symptoms include but are not limited to fatigue, chest pain, hair loss, headaches, arthralgias, allergies, easy bruising, heartburn, decreased sex drive, gastrointestinal upset, heart palpitations, hot flashes, infections, night sweats, heat/cold intolerance, migraines, anxiety, swelling, tinnitus, weight gain, chronic muscle/joint pain, rash, body odor, brain fog, sleep disturbance, depression, cognitive dysfunction, hormonal issues, dry eyes, and skin changes.

Q: Is there a link between silicone and any disease?

A: *Silicone is an element that exists in nature as crystalline silica, which has been shown to activate the immune system in conditions such as systemic sclerosis which has been seen in stone masons. Silicone used in breast implants is different as it does*

not exist is nature; it is created by hydroxylating silica to form polydimethylsiloxane. Medical grade silicone has had antioxidants, dyes, and plasticizers removed during processing and is used in many medical products, including but not limited to catheters, tubing, and implants that are inserted throughout the body.

Q: Are there any tests that would indicate a connection between implants and these symptoms?

A: *There is no diagnostic testing specifically for breast implant illness. This is one of the current areas of focus for the Aesthetic Surgery Education and Research Foundation (ASERF), the research arm of the American Society for Aesthetic Plastic Surgery (ASAPS). Tests for autoimmune diseases can be performed to evaluate for potential causes of a patient's symptoms. There are patients who have symptoms attributed to BII with positive immune testing and others with all laboratory tests which show no abnormalities.*

Patient evaluation by primary care physicians, rheumatologists, allergy and immunologists, and neurologists can be helpful. Recommended lab work should include a full blood count, an electrolyte panel including urea and creatinine levels, liver function tests, C-Reactive Protein levels, Erythrocyte Sedimentation Rate, Thyroid-Stimulating Hormone, Iron, Ferritin, Serum IgG and Ig, folic acid and homocysteine levels. Autoimmune disease markers include: ANA, Anti-neutrophil cytoplasmic antibody, Anti-double stand DNA. Anti-Sjogren's syndrome A, Anti-Sjogren's syndrome B, Rheumatoid Factor, Anti-ribonucleic acid protein, Anti scleroderma antibodies, anti-TGG. MTHFR genetic screening has also been recommended.

Q. Is there any scientific data showing association or causation between implants and these symptoms?

A: *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 demonstrated clear link between silicone implants and any systemic illness. To-date, there has been very little in the way of research into BII. There have been studies of many different sizes and design to look at the safety of breast implants themselves. These have looked at specific autoimmune disorders and diseases, but not specifically at BII. In aggregate, these studies show little to no links between breast implants and these diseases. Reliable, peer-reviewed, properly conducted scientific studies of patients who have symptoms that they have related to their breast implants have not shown consistent laboratory abnormalities to define a distinct syndrome at this time.*

Q: Does implant removal improve a patient's symptoms?

A: *Various studies show different degrees of improvement in patients after removal of their breast implants, some of which are temporary, and some showing permanent resolution of symptoms. There are no studies which specifically show which symptoms may or may not improve with implant removal with or without capsulectomy.*

There is no current definitive epidemiological evidence to support a direct link between breast implants and any specific disease process. However, this does not mean further research is not 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 and further study is required to determine the best way to potentially screen patients prior to breast implant surgery and to determine which of the multitude of reported symptoms might improve with implant and capsule removal.

A lack of a direct, proven scientific link does not mean that the symptoms experienced by patients with BII are not real. There are patients that have legitimate concerns about a potential link between breast implants and their symptoms. Further scientific research is needed to better determine what symptoms may improve with explanation of implants.

Because there are many women that identify as having BII, The American Society of Aesthetic Plastic Surgery (ASAPS) and The Aesthetic Surgery Education and Research Foundation (ASERF) are developing a new scientific study to examine this entity. They are also providing members with a questionnaire to use to collect a record of complaints from patients with implants, as well as one to utilize for post-explantation. We cannot yet define BII and therefore cannot say with any certainty that it exists, because we do not have any tests we can run to prove or disprove its existence. However, I believe that as a physician, it is my duty to listen to and partner with my patients to determine what is the best course of action for them

Q: What options are available to patients with symptoms of Breast Implant Illness?

A: *Options can include further medical work up, observation without medical work up, implant removal with total or en bloc capsulectomy. It is important that plastic surgeons enter their data in The National Breast Implant Registry (NBIR), which is set up as a platform to evaluate real world data on the safety and performance of breast implants. It is hoped that the NIBR will help identify risk factors for complications, such as a patient's own medical history, the specific type of operation, the type of implant used, and concomitant use of other medical devices.*

Additional options include further medical work up with or without the consultation of a rheumatologist, observation without medical work up, implant removal without capsulectomy, exchange 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 any specific know disease entity. This does not mean their symptoms are not real and they deserve a full evaluation. The various options need to be discussed and hopefully, with further research, we may be able to determine which patients may see symptom improvement or resolution with removal of their implants and which may not see any change.

Q: What is the risk of developing Breast Implant Illness?

A: *As there is no definitive link between the often subjective and divergent list of symptoms, and no means for testing, it is impossible currently to calculate a risk to each person. Some patients with breast implant illness report a prior history of numerous environmental, food, and drug allergies. This information is currently being researched as a possible mechanism for BII.*

Q: Is an en bloc capsulectomy mandatory?

A: *The answer to this is currently unknown as the exact cause of BII is not clear currently. It is suggested that total capsulectomy is necessary to remove all causative agents. En bloc capsulectomy pertains to the technique where the implant and capsule are removed as one piece. With the en bloc procedure, a very large incision is required and oftentimes, the procedure can be unsafe, as the posterior capsule in subpectoral implant placement is directly adherent to the rib cage. In these situations, it is safer to remove the implant to allow direct visualization of the capsule as it is peeled off the chest wall, rather than to risk a lung puncture. In rare cases, it may not be possible to remove all the capsule. Sometimes a portion of the capsule must be left behind or is disintegrated with the use of electrocautery to prevent significant damage to muscle, rib or lung.*

Q: Will my health insurance cover removal of my breast implants?

A: *Breast surgery in patients with a history of breast cancer is always covered by health insurance.*

Q: Can a breast lift and/or fat grafting be performed at the time of implant explantation?

Breast lift and fat grafting may be performed at the time of explantation in selected cases. Factors to consider include the health of the patient, amount of skin stretch the implants caused, the volume of breast tissue present to be reshaped into an aesthetic breast mound, and the tissue trauma caused by the capsule and implant removal. Of course, if a patient is so disabled from their illness, it is not wise to subject them to additional elective surgery until their bodies heal. In these patients, only explantation is performed in the hopes that they will improve, regain their health, and be able to tolerate another surgery.

In other patients, cosmetic reshaping of the breasts can be considered. After implant removal, skin will retract and tighten based on your skin quality and the size of the implants that caused the stretch. Many patients are happy to see their breasts return to

the more natural version of their pre-augmented breasts. It sometimes makes sense to let the body repair itself before undertaking more extensive surgery. A breast lift will reposition the nipples and tighten the skin of the breast; a lift without added volume may not give the breast enough projection so fat grafting would be suggested. Fat transplantation requires a healthy bed of tissue for it to re-establish its blood supply. Therefore, in some cases, it is safer to perform fat grafting as a second procedure later.

Each case should be considered on an individual basis, taking into consideration the desires of the patient and the safely of the proposed procedures. Breast lifts and fat grafting to the breast after explantation for BII have not been covered by health insurance companies in this office's experience. Hospital and anesthesia fees are based on time. En bloc explantation can take between 2-3 hours. Fat grafting can take between 2.5-5 hours depending on the number of donor sites needed for fat grafting.

A: *There are many medical inaccuracies perpetuated by the internet. BII patients tend to believe that a total capsulectomy is necessary to remove all causative agents and they prefer it en bloc. There are increased surgical risks associated with en bloc capsulectomy which requires a longer incision, complete dissection of all the tissues surrounding the breast implant and, that there is not enough collective data to guarantee any improvement in symptoms they have labelled Breast Implant Illness (BII).*