What Is Breast Implant Illness?

Breast implant illness (BII) is a term that some women and doctors use to refer to a wide range of symptoms that can develop after undergoing reconstruction or cosmetic augmentation with breast implants. It is also sometimes referred to as autoimmune/inflammatory syndrome induced by adjuvants (ASIA). BII can occur with any type of breast implant, including silicone gel-filled, saline-filled, smooth surface, textured surface, round, or teardrop-shaped.

BII impacts each individual in a unique way. Symptoms can include:

- joint and muscle pain
- chronic fatigue
- memory and concentration problems
- breathing problems
- sleep disturbance
- rashes and skin problems
- dry mouth and dry eyes
- anxiety
- depression
- headaches
- hair loss
- gastrointestinal problems

The symptoms can appear any time after implant surgery — some people develop symptoms immediately, while some develop them years later.

A lot of the symptoms of BII are associated with autoimmune and connective tissue disorders, such as lupus, rheumatoid arthritis, and scleroderma. Some people who have BII also get diagnosed with a specific autoimmune or connective tissue disorder, but many do not.

In many, but not all cases, surgery to remove the breast implants improves or completely resolves the BII symptoms.

BII is not currently recognized as an official medical diagnosis, and there is no diagnosis code for it. It is poorly understood and hasn't been studied much as a unique condition.

"BII is a cluster of symptoms that don't fit into any other classic disease diagnosis," says Diana Zuckerman, Ph.D., president of the National Center for Health Research and a researcher who studies breast implant safety issues. "We believe that it eventually will be recognized as a medical condition, but that process will take time."

Recently, the U.S. Food and Drug Administration (FDA), the major plastic surgery societies, and other health authorities have been devoting more attention to BII than they did in the past. In May 2019, the FDA released a statement noting that the agency's officials are "taking steps to better characterize [BII] and its risk factors, and are considering ways to help to ensure women have all of the information they need to make informed decisions about whether to obtain breast implants or to remove existing breast implants in an effort to reverse systemic symptoms." In October 2019, the agency published a draft of recommendations to implant manufacturers for new labeling for breast implants. The agency advised manufacturers to include information about the risk of systemic symptoms in a boxed warning and in a patient decision checklist that would be included in patient information booklets.

In addition, the American Society of Plastic Surgeons and the Aesthetic Surgery Education and Research Foundation are developing and funding new research on BII.

Number of cases of breast implant illness

To date, there haven't been any studies that looked at the number of women with breast implants who develop BII. More women have been reporting BII symptoms to doctors and to the FDA during the last few years, which may be because social media groups and media coverage helped to raise awareness of the condition. Thousands of women have joined online communities related to breast implant illness. For example, the Breast Implant Illness and Healing by Nicole Facebook group currently has more than 100,000 members.

Diagnosis of breast implant illness

Currently, there are no commonly used diagnostic tests or diagnostic criteria specifically for BII.

Plastic surgeons who have treated a lot of patients with BII say that it's common for those who seek treatment to have multiple symptoms that are interfering with their ability to function. Many have gone to a number of other doctors before realizing that their symptoms may be connected to their implants.

"Usually, my clients with BII find me after exhausting all other medical avenues and going through exhaustive medical testing," says Robert Whitfield, M.D., FACS, a plastic surgeon in Austin, TX, who treats patients with BII and the 2019 president of the Aesthetic Surgery Education and Research Foundation.

In general, a plastic surgeon should try to rule out other potential causes of the symptoms (that are unrelated to the breast implants). This may involve looking at the results of tests the patient has received (such as tests related to diagnosing arthritis or Lyme disease) and finding out if any symptoms improved when the patient received treatment for other conditions. In some cases, a patient may have both BII and a diagnosed autoimmune disease or other conditions.

Treatment of breast implant illness

Breast implant illness isn't well understood, and individual plastic surgeons take different approaches to treating it.

The plastic surgeons we spoke with who have a lot of experience treating BII said the treatment most likely to improve symptoms over the long term is removing the implants and the surrounding scar tissue capsules and not replacing the implants with new ones. They said that it's important to ask your surgeon to remove the scar tissue capsules because that is a key part of the treatment.

Some plastic surgeons recommend a procedure called an "en bloc capsulectomy" — removing the implant and capsule in one piece. This approach can theoretically help prevent silicone, biofilm (colonies of bacteria that stick to each other and the implant), or other substances that are within the capsule from escaping into the body. Fully removing the scar tissue

capsules also may lower the risk that fluid will collect in that area after the surgery (this is known as a seroma). Others may recommend a “total” (or “complete”) capsulectomy, which involves removing both the implant and the capsule, just not in one piece.

Some women who have had BII symptoms opt to replace their implants with new ones of a different type — for example, switching from a textured silicone gel-filled implant to a smooth saline-filled implant. This approach may improve BII symptoms but may carry a greater risk that symptoms will return again over time.

“I tell patients with BII symptoms that I don’t recommend getting implants again because they are probably predisposed to reacting to breast implants. And both the saline and silicone types are made from similar materials; both have shells made from silicone,” says Matthew G. Stanwix, MD, FACS, a plastic surgeon in private practice in Richmond, VA who treats patients with BII. “Ultimately, though, the decision is up to the patient.”

If you’re considering surgery to address BII symptoms, be sure to ask your plastic surgeon about the risks and benefits of the various surgical treatment approaches. It’s also important to remember that it’s not possible to predict whether the removal of your implants will improve or resolve your BII symptoms.

Outcomes after implant removal to treat breast implant illness

There isn’t much research on outcomes after implant removal surgery for BII. According to the American Society for Aesthetic Plastic Surgery, a small study of 100 patients with self-reported BII in one surgeon’s practice showed that 89% of patients who had implant removal and capsulectomy experienced improvement in some of their symptoms within 3 months of surgery.[1] Symptoms that improved included fatigue, cognitive problems, burning pain in the chest wall and breast, dry eyes, anxiety, and joint pain. Another study published by researchers in the Netherlands in 2013 looked at 80 women with silicone gel-filled implants and autoimmune symptoms.[2] They found that symptoms improved in 69% of the women after implant removal surgery.

The plastic surgeons we spoke with said that many — but not all — of their patients have experienced an improvement in BII symptoms after removal of their implants.

Some doctors say that it can be particularly helpful after implant removal surgery for BII to eat a healthy diet, get regular exercise, and decrease stress. These steps may promote healing and decrease the inflammation in the body that can be associated with BII.

Who may be at risk of developing breast implant illness?

Some doctors who have treated many patients with BII say they’ve found that it is more likely to occur in people who have a personal or family history of autoimmune conditions, allergies, and conditions such as irritable bowel syndrome, migraines, chronic fatigue, or fibromyalgia. But some women who develop BII don’t have any of these risk factors. There’s no evidence that a history of breast cancer or any other cancer makes you more likely to develop BII.

What causes breast implant illness?

Researchers don’t know why some women with breast implants develop BII. A leading theory, according to experts, is that some people are predisposed to having an immune reaction to the materials that are used to construct breast implants, creating inflammation that leads to symptoms such as joint and muscle pain, rashes, and gastrointestinal problems.

Studies have shown that substances from breast implants (such as very small amounts of silicone and platinum) can “bleed” through an intact shell and into the surrounding tissue. Substances from an implant can also spread within the

capsule of scar tissue surrounding the implant or to other parts of the body, often because an implant has ruptured. The longer a breast implant is in place, the more likely it is to rupture. Some, but not all, people with BII turn out to have a ruptured implant.

All women with breast implants are exposed to silicone to some degree, because all implants have a silicone shell.

“It may be that the immune system is reacting to the silicone polymers that have been dispersed from the implant into the body,” says Lu-Jean Feng, M.D., a plastic surgeon and the founder and medical director of the Lu-Jean Feng Clinic in Pepper Pike, Ohio, who has been treating patients with BII since the early 1990s. “Certain people may be genetically predisposed to be more reactive.”

Jan Willem Cohen Tervaert, M.D., Ph.D., director of the division of rheumatology at the University of Alberta in Canada and professor of medicine and immunology at Maastricht University in the Netherlands, has studied the possible links between breast implants and autoimmune illnesses since the early 1990s. At the FDA’s General and Plastic Surgery Devices Advisory Panel public meeting on breast implants in March 2019, he presented an overview of scientific evidence that the silicone in breast implants can activate the immune system, resulting in inflammation and autoimmune problems.

Currently, the idea that the silicone in medical devices can affect the immune system isn’t widely accepted in medicine. The FDA announced in March 2019 that it is undertaking new efforts to evaluate the safety of medical device materials, including silicone.

Emerging research on breast implant illness

For the most part, the existing scientific literature doesn’t show a definite link between breast implants and autoimmune or connective tissue diseases and doesn’t show that that breast implants cause these conditions. A couple of recent studies suggest that silicone gel-filled breast implants are associated with a slightly higher risk of developing an autoimmune or connective tissue disease. One of the reasons these studies are notable is that each included a larger number of women tracked over a longer period than most previous studies on safety outcomes for women with breast implants:

- In a study published online in the journal *Annals of Surgery* in September 2018[3], a team of researchers at the University of Texas MD Anderson Cancer Center (that included Dr. Clemens) looked at the medical records of 99,993 women who had implants and were enrolled in long-term safety studies required by the FDA. The researchers found that compared to women in the general population, women with silicone gel-filled implants were 8 times more likely to be diagnosed with Sjögren syndrome, an autoimmune disorder characterized by dry eyes and a dry mouth; 7 times more likely to be diagnosed with scleroderma, a group of autoimmune diseases that cause the skin and connective tissues to become hard and tighten; and nearly 6 times more likely to be diagnosed with rheumatoid arthritis. Some weaknesses of the study are that: some of the diseases were reported by patients and not necessarily diagnosed by a physician; outcomes were collected under more than one protocol, and a significant number of patients dropped out before the studies ended.
- In a study published online in the *International Journal of Epidemiology* in October 2018[4], a team of researchers (that included Dr. Cohen Tervaert) examined the electronic health records of 123,255 Israeli women (24,651 had silicone gel-filled breast implants and the rest did not have breast implants). The records contained up to 20 years of data. The researchers found that the women with silicone gel-filled breast implants were significantly more likely to be diagnosed with autoimmune or rheumatic disorders, such as Sjögren syndrome, systemic sclerosis, and sarcoidosis, compared with women without breast implants of a similar age and socioeconomic status.

What all this may mean for you

- If you're considering getting breast implants for the first time or replacing ones that you already have, talk with your plastic surgeon and your other doctors about whether you have any of the potential risk factors for BII — for example, a personal or family history of autoimmune conditions or allergies. If you do have any of the risk factors, it may make sense to consider alternatives to implants, such as autologous reconstruction.
- If you think you may have BII, you may want to seek out a board-certified plastic surgeon who has experience treating patients with the condition or at the very least one who takes your concerns seriously and isn't dismissive about the symptoms you are experiencing. Don't automatically assume that the surgeon who placed your implants is the one you should choose to remove them.
- In most cases, private health insurance plans cover surgery to remove breast implants in women who have had a mastectomy and breast reconstruction. Since there is no diagnosis code for BII, plastic surgeons typically list problems the patient is experiencing like pain, implant rupture, and shortness of breath to make the case to the insurance company that the surgery is medically necessary. Some women have opted to pay out-of-pocket for implant removal because the plastic surgeon they chose does not accept insurance or is out of network for their insurance.

Read more of this Breastcancer.org Special Report on breast implant illness and BIA-ALCL, and please take our brief survey to share your feedback.

References

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