WELLNESS | BODY

New Studies Shed Light on Breast Implants' Risk for Causing Cancer

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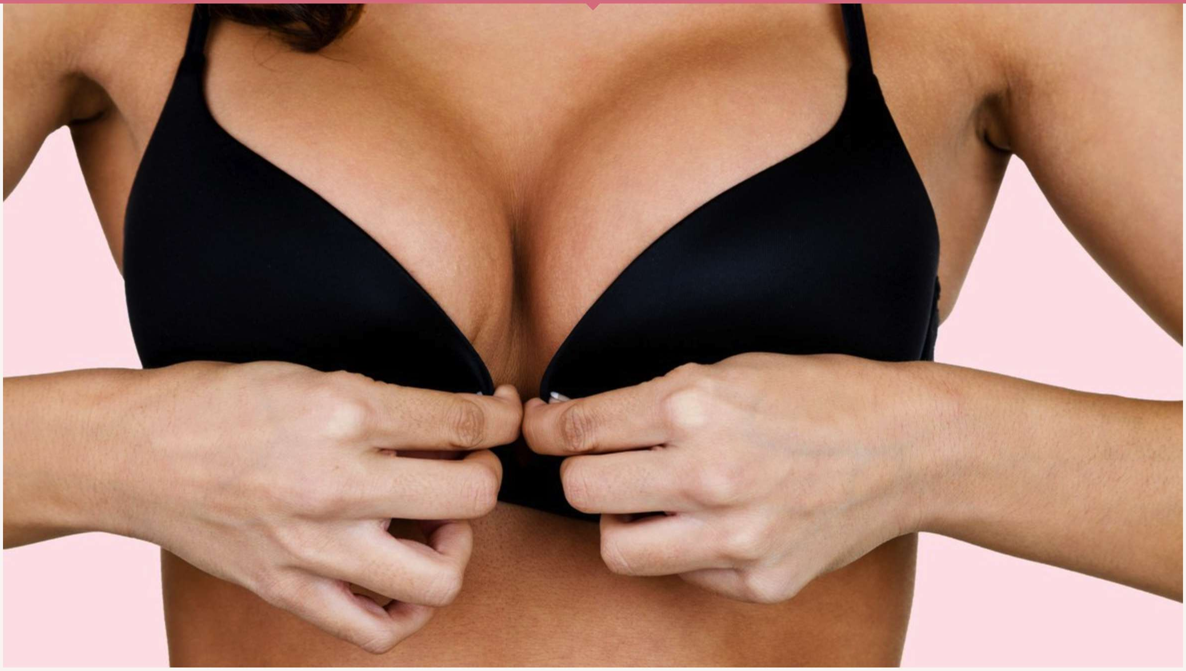

Getty Images

Last March, in the wake of an FDA update on breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) — and the ensuing media firestorm — we dissected the facts and figures surrounding the disease to contextualize the actual risk breast implants may pose.

To recap, BIA-ALCL is not breast cancer. It's an extremely rare type of non-Hodgkin's lymphoma — a cancer of the cells of the immune system — that can affect those possessing both a genetic predisposition and textured breast implants. (Unlike smooth-shelled implants, textured ones have an irregular surface that acts like Velcro, which helps keep them from changing position.) While researchers don't fully understand the link between implants and BIA-ALCL, "we believe the disease arises as a result of a long-term inflammatory reaction to probable bacterial contamination, particularly in the presence of textured implants, which present more interstices for bacterial adhesion," explains Adam Kolker, an associate clinical professor of surgery at the Icahn School of Medicine in New York City. Simply put: the nooks and crannies comprising textured shells can be ripe for germ colonization.

While doctors and patients in the U.S. overwhelmingly prefer the natural feel of smooth implants — they're used in 87 percent of surgeries — textured implants do offer distinct advantages for certain people. "The main reason many surgeons choose textured implants is because they are also shaped [rather than round]," says Lara Devgan, an attending plastic surgeon at Lenox Hill Hospital and Manhattan Eye, Ear & Throat Infirmary. With a teardrop appearance that mimics the silhouette of a natural breast, shaped implants only come with clingy textured shells, because "even a small degree of rotation can cause them to look askew," she adds. They can be preferable in breast-reconstruction surgeries following mastectomies, as they give form where there is none, and they're often used to "correct size and shape deformities," says Kolker. They're also beloved abroad, being used in 90 percent of augmentation cases in Europe and Australia.

That said, an American woman's risk of developing BIA-ALCL lies between 1 in 30,000 and 1 in 50,000. “BIA-ALCL can develop years — two to 20 or more — following breast-implant surgery, and can present as a new swelling of the breast, a lump, or fluid collection around the implant,” says Kolker. (The lymphoma cells are generally found in the fluid surrounding an implant, or in what’s called the capsule, a smooth, soft sheath of normal scar tissue that forms around an implant.) BIA-ALCL is not difficult to diagnose, notes Kolker, and with an accurate and timely diagnosis, cure rates are currently 100 percent.

According to data from the American Society of Plastic Surgeons (ASPS), the American Society for Aesthetic Plastic Surgery (ASAPS), and the International Society of Aesthetic Plastic Surgery (ISAPS), there are more than 30 million women with textured breast implants globally. And, to date, there have been 12 BIA-ALCL deaths worldwide — the majority “resulting from misdiagnoses, late diagnoses, or improper treatment,” says Rian Maercks, a plastic surgeon in Miami and New York City.

TWO NEW STUDIES REALITY-CHECK THE RISK

New research is now rekindling — and generously informing — the BIA-ALCL conversation. Aiming to undercut recent sensationalism, a study in the *Aesthetic Surgery Journal (ASJ)* calculates the precise risk of dying from BIA-ALCL using a micromort analysis. A micromort is a measure of relative risk. One micromort is equal to a one-in-one-million chance of death. The authors found that, for a woman with two textured breast implants, the risk of dying from BIA-ALCL is .4 micromorts. Which likely means very little to the average patient — until her doctor provides crucial context: The micromort risk from drinking two glasses of wine, or simply living two days in New York City, is two-and-a-half times higher than the micromort risk from having breast implants. Traveling eight hours by car carries a 40 times higher micromort risk. According to study co-author William P. Adams, Jr., an associate professor of plastic surgery at UT Southwestern Medical Center in Dallas, the micromort of BIA-ALCL is so comparatively low, scientists are pushing to have the disease reclassified as a lymphoproliferative disorder rather than an actual lymphoma, which bears a much higher micromort. “A lymphoproliferative disorder is a reactive condition with a spectrum of progression to cancer,” Adams says. “The majority are benign, but in the end stages, they can become true lymphomas.”

A second article, published online last month in the *ASJ*, presents a peer-reviewed analysis of five 10-year FDA studies conducted by three U.S. breast-implant manufacturers (Allergan, Mentor, and Sientra) on the long-term safety of both textured and smooth implants. Beyond elucidating the pros and cons, the report explores the various types of textured-shell surfaces produced by each company via its own specific manufacturing technique. The authors state, “The unique characteristics of the different implants mandate that we consider each textured device on its own merit, and avoid generalizing all textured implants as one in the same.” Mentor's implants have more of a "microtexture" — think fine-grit sandpaper as opposed to the coarser “macrotexture” of Allergan's (Sientra's implants are a mix of micro- and macrotextures). As Maercks explains, “We know that large texturing is one requirement [for ALCL] and theories exist that the friction caused by macrotexture, the increased surface area and potential for bacterial colonization, and the tendency to have silicone particulate shed may all contribute to inducing this disease.” In fact, the study notes that 70.3 percent of BIA-ALCL cases were associated with Allergan’s implants (both saline and silicone).

When asked to comment on this stat, Allergan shared that “while [their] efforts to enhance understanding and awareness [of BIA-ALCL] are ongoing, they continue to support the needs of customers and their patients [by] providing a wide variety of implants, [as] there are cases in which textured implants are the most appropriate option based on a variety of factors [such as] skin quality, breast asymmetry, existing breast tissue, and lifestyle.” Adds Maercks, “Even if these were the only implants I ever used, BIA-ALCL is so rare, I’d be very unlikely to ever see a case in my career. And Allergan texturing is still the choice of many women who understand the data.”

The point of the article, however, isn’t to villainize or celebrate any one implant, but “to emphasize the importance of choice for surgeons and our patients,” says lead author M. Bradley Calobrace, a plastic surgeon in Lexington and Louisville, Kentucky. “This information allows surgeons to look at all of the data concisely, review the risks and benefits, and have a better understanding of the current dialogue concerning smooth and textured implants. Thoughtful, measured consideration is so important right now, [as] over-exaggerated, non science-based claims may jeopardize our ability to take first-rate care of our patients."

BETTER BOOB JOBS: WHAT'S NEW...

By meticulously refining their surgical approach, doctors have been striving to do just that. "Breast augmentation has come a long way," says Devgan. "In my hands, it's a 30-minute operation with minimal downtime, negligible blood loss, and an easy recovery for most patients." By routinely using a three-day nerve block, she can eliminate the need for narcotics in over half her patients. To decrease odds of infection and other complications, she follows an exacting protocol, placing smooth implants through an inch-and-a-half incision below the breast (rather than through the nipple or armpit) using a no-touch technique: "The implants are bathed in antibiotic irrigation, poured into a sterile Keller Funnel, and propelled into the breast without ever coming into contact with human hands," she says — slashing the risk of contamination, and consequently, BIA-ALCL.

The latest implant designs also put safety first. Take the newish generation of cohesive silicone-gel implants: Semisolid like Jell-O, they don't leak when torn, boosting patients' peace of mind. (While silicone implants have been proven safe, tears can be hard to detect — the implant doesn't obviously deflate like saline styles — which is why the FDA recommends those with silicone implants get regular trouble-spotting MRIs.)

Despite the surveillance they demand, silicone implants have long trounced saline in popularity. While saline implants don't require MRIs to check for ruptures — leaks are readily absorbed by the body, and easy to diagnose — and typically come with smaller price tags and shorter scars, they have two big drawbacks: a decidedly less natural feel (basically bags of saltwater, they tend to slosh around), and shells that are prone to rippling. Recently, however, Kolker has seen a small, but definite, spike in the number of women choosing saline — thanks, in part, to the Ideal implant, which won FDA approval in 2014. "It's a structured saline implant with two internal chambers and a series of baffles that control the movement of the saline and support the edges of the implant [to prevent wrinkling and folding]," he explains. "With a smooth surface, saline fill, and a feel that's almost indistinguishable from that of a silicone-gel implant, the Ideal's aesthetic results and safety profile show tremendous promise." What's more, ruptures, should they occur, only involve one chamber, so the implant maintains some of its volume, making fix-it trips to the OR somewhat less urgent.

...AND WHAT'S NEXT

American implant manufacturers are making moves to arrest complications. In an email to *Allure*, Sientra highlights "the decades of safety and millions of satisfied patients with [its] current technologies," adding that Sientra's existing implants already have "the newest technology in high-strength cohesive gel-fill and a unique surface that produces optimal patient outcomes and low complications." However, they add, "We are always assessing new technologies that might offer further innovation while maintaining the highest safety standards."

Allergan states: "However small the risk, [we] take BIA-ALCL seriously, and remain committed to providing technologies and products to surgeons to help them improve the procedures for breast augmentation and reconstruction." A prime example: Allergan recently acquired the aforementioned Keller Funnel, a single-use, lubricated plastic cone that's integral to non-touch breast-implant procedures.

Mentor tells *Allure* they're "continually investigating new materials, processes, and designs…to reduce complications and provide long-lasting patient satisfaction." Currently in the works: larger size breast implants for women in need of post-mastectomy breast reconstruction surgery, who require more substantial implants to achieve the best aesthetic result. (Both smooth and textured surfaces are being used in the clinical trial.) The company is also enrolling over 2,500 patients in a 10-year post-approval study to collect data on the long-term performance of its silicone-gel implants — both textured and smooth, round and shaped — "to help assure [their] continued safety and effectiveness."

The bottom line: Breast implants are getting safer by the day, but continued vigilance is key. If you have implants, or plan on getting them, educate yourself on the risks, perform regular self-exams, and see your surgeon at the first sign of pain or swelling.

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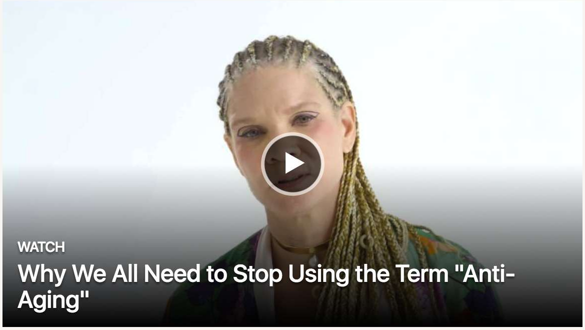
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