

Study confirms link between breast implants and rare form of cancer

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Breast implants appear to be associated with a rare form of lymphoma, but there is not yet evidence to show that the cancer is caused by implants or to suggest an underlying mechanism for how the disease might develop, according to a study by researchers from the RAND Corporation.

The study, published online by the journal *Plastic and Reconstructive Surgery*, also finds that the disease takes a slow course and can be controlled by surgical removal of the implant and surrounding capsule.

The conclusions are based on an exhaustive review of the medical literature regarding breast implants and anaplastic large cell lymphoma or ALCL, a type of [immune system cancer](#) that was first linked to breast implants more than a decade ago, and input from a multidisciplinary expert panel.

Concerns about an association between ALCL and breast implants were first raised in 1996 when doctors published a report describing a woman with implants who had developed the cancer in tissue located next to one of her implants. Since that time, similar reports have been published, estimating that about one to three cases would be diagnosed annually per 1 million women with implants.

Because of rising concerns, the Plastic Surgery Foundation and the Aesthetic Surgery Education and Research Foundation commissioned RAND to conduct an exhaustive review of the medical literature and organize a panel of medical experts to evaluate the evidence for a potential link and its implications.

"Much more research is still needed to explore the link between breast implants and ALCL and the clinical significance of this rare disease, but our findings provide useful information for both patients and physicians in the near term," said Dr. Soeren

Mattke, the study's senior author and a senior scientist at RAND, a nonprofit research organization.

Mattke and his colleagues identified 36 published cases of non-Hodgkin's lymphoma among women with breast implants, 29 of which were diagnosed as anaplastic large cell lymphoma. At least 12 of the 29 women had a prior history of a different type of cancer, including eight who had undergone mastectomy for breast cancer and two who had a previous history of ALCL. There was no evidence that patient risk factors or particular types of implants would increase the risk of the disease.

While some patients received chemotherapy and/or radiation, the treatment in most instances consisted of surgically removing the affected implant and surrounding tissue, which appeared to successfully control the disease. No deaths were reported among the 16 women for whom follow-up information was available.

RAND researchers shared the review findings with a panel of medical experts and asked them to weigh in on a series of questions related to the causes, diagnosis, and management of anaplastic large cell lymphoma associated with breast implants, based on their reading of the review and their own knowledge. The panel included experts from many disciplines, including epidemiology, oncology, immunology, pathology and material science.

The panel concluded that the evidence suggests an association between breast implants and anaplastic large cell lymphoma, but cannot definitely prove that implants cause the disease nor explain how the implants might trigger ALCL.

The experts recommended that the appearance of a fluid-filled sac near a breast implant six or more months after surgery should lead to a thorough diagnostic evaluation for anaplastic large cell

lymphoma. They also concluded that the diagnosis of anaplastic large cell lymphoma should result in a complete evaluation to rule out spread of the disease outside of the breast capsule (the lining that forms around the implant), followed by removal of the implant and capsule.

Experts did not believe that disease confined to the implant capsule warrants radiation treatment or chemotherapy after surgery and expressed the belief that the risk of recurrence or development of systemic disease following surgical removal was low, but that close clinical follow-up was necessary.

The U.S. Food and Drug Administration and the American Society of Plastic Surgeons recently announced an effort to create a registry that will collect information on women with breast implants who have been diagnosed with anaplastic large cell [lymphoma](#) in order to gather information that will help increase understanding of the disease.

Provided by RAND Corporation

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