

From Breast Implant to Rough Implant Associated–Anaplastic Large Cell Lymphoma (RIA-ALCL)

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The FDA (Silver Spring, MD, USA) announcement in 2011 heralded the starting point of global alertness regarding the possible connection of breast implants with a rare form of a non-Hodgkin lymphoma: anaplastic large cell lymphoma (ALCL). Sporadic case reports, preliminary case review studies, and manuscripts proposing diagnostic, staging and treatment protocols, or etiopathogenesis theories filled the scientific literature. In 2016, this new pathology was added as a distinct entity in the update to the World Health Organization (Geneva, Switzerland) classification of lymphoid neoplasms and now includes over 420 cases in Europe¹ and 1148 cases worldwide according to BIA-ALCL Global Network and EURAPS Scientific Committee on Device Safety and Development. The interest of scientific research towards this pathology increased year by year and was further boosted by a recent increase in media attention; therefore, various names or abbreviations have been given to it. The first attempt to give it a name was made by Story et al. in 2013, who referred to it as implant-associated ALCL, or iALCL.² This was replaced the same year by Thompson et al. with the most widely accepted way of referring to it: breast implant–associated ALCL (BIA-ALCL).³

During the last 10 years, since the first FDA announcement, BIA-ALCL has been at the forefront of numerous discussions in conferences around the world and hearings by regulatory authorities such as the FDA, the French National Security Agency of Medicines and Health Products (Issy-les-Moulineaux, France), the Therapeutic Goods Administration (Woden, Australia), and so on. In the past decade, as awareness increased toward implants and their connection with ALCL, numerous case reports were presented in which ALCL arose in sites other than the breast. This includes the gluteal

region from textured gluteal implants, pacemakers, orthopedic implants for tibial and shoulder repair, dental implants, chest ports, and even bariatric surgery devices.⁴ Some patients have developed a misplaced fear of all breast implants, but to date no BIA-ALCL case has been published or officially registered with a clear history of only smooth implants; therefore it can be considered as a pathology connected to textured implant surfaces only. Additionally, the Scientific Committee on Health, Environmental and Emerging Risks (Brussels, Belgium) recently expressed their final opinion on the safety of breast implants in relation to ALCL and concluded the existence of a causal relationship between textured breast implants and BIA-ALCL, indicating the texturization as the risk factor.⁵ We believe the current definition of “breast implant associated” is misleading because it suggests a direct connection to breast or breast implant, whereas the same ALCL can occur, although occasionally, in regions other than the breast and with implantable medical devices different from breast implants, all connected to each other by the rough surface of devices. We therefore believe that a more specific term such as Rough Implant Associated–Anaplastic Large Cell Lymphoma (RIA-ALCL) is needed to better define this pathology.

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We believe that the term “textured” includes various categories of surfaces but is a commercial and generic description that refers only to breast implants, whereas “rough” is the term used in physics to characterize any surface and is directly connected to the pathogenetic mechanism of chronic inflammation leading to the implant-associated ALCL.⁵ Therefore, we suggest using RIA-ALCL because it better describes a unique type of ALCL that may occur in association to any implant with a rough surface.

Disclosures

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