EVIDENCE BASED PERSPECTIVE:

Breast Implant-Associated Anaplastic Large Cell Lymphoma

What do we know about BIA-ALCL?

- BIA-ALCL is not breast cancer—it is a type of non-Hodgkin's lymphoma (cancer of the immune system), that affects lymphocytes (immune cells), typically taking between 8-10 years to develop.[1]
- Individuals who have been implanted with textured breast implants at some point during their clinical history have a risk of developing BIA-ALCL.
- In most cases (>85%), BIA-ALCL is found in the implant effusion (fluid surrounding the implant), which current data suggest may be cured by removal of the implant and capsule.[2]
- In some cases (10-15%), BIA-ALCL can present as a mass attached to the breast implant capsule. In these cases, the cancer may spread to the lymph nodes and can metastasize.[2]

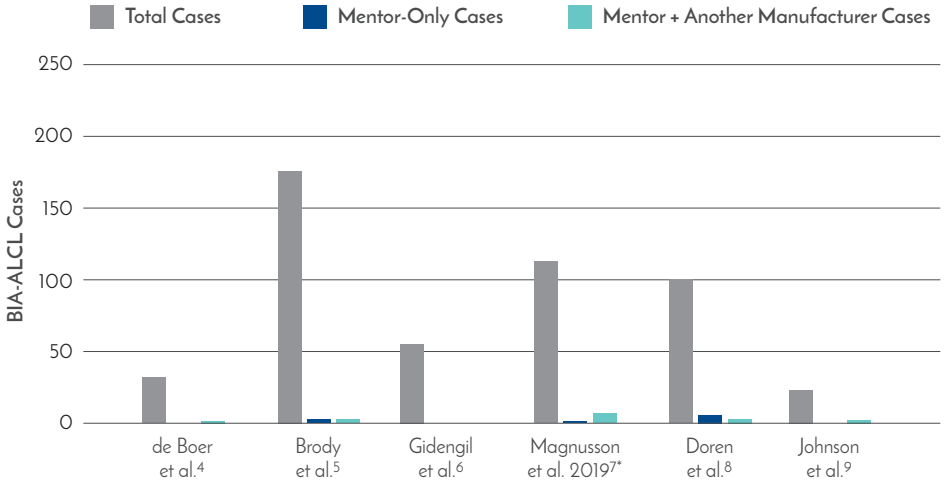
Current hypotheses regarding possible causes of BIA-ALCL include:

- Chronic Irritation over Time
- Bacterial Contamination
- Particulate Matter in the Breast Implant Capsule
- Genetic Predisposition
- Surface Texturing

How common is BIA-ALCL?[3]

As of **February 8, 2019** → **688** Confirmed cases of BIA-ALCL worldwide → **17** Deaths attributed to metastases or complications from cancer therapy

Multiple studies have shown a consistently low number of BIA-ALCL cases associated with MENTOR® breast implants as compared to those of other manufacturers.



*The Mentor + Another Manufacturer Cases includes 3 cases with Mentor smooth implant in patients who also had other textured implant of another manufacturer (there are currently no confirmed cases of BIA-ALCL in patients whose implant history included only smooth implants).

Does surface texture make a difference?

Recent literature suggests that the risk of developing BIA-ALCL differs between different textured devices. Current estimate, from a significant study conducted in Australia and New Zealand, put the risk at:[10]

1 IN 2,832
Polyurethane Implants

1 IN 3,345
Allergan Biocell® Implants

1 IN 86,029
MENTOR® SILTEX® Implants

What can I do to reduce the likelihood of BIA-ALCL for my patients?

- To date, there have been no cases of BIA-ALCL diagnosed in patients in which only smooth implants were used in their clinical history.
- Recent data suggests that preventing bacterial contamination may reduce the risk of developing BIA-ALCL. **For more information, visit www.saferbreastimplants.org**
- While textured breast implants have established clinical benefits, leading researchers recommend that clinicians should consider the relative risk of developing BIA -ALCL when selecting a textured implant for their patient; clinical need should be adequately justified when selecting higher surface area implants like Biocell and Polyurethane.

Where do I find resources on BIA-ALCL, diagnosis, and treatment?

Source	Website	Focus
National Comprehensive Cancer Network (NCCN) Guidelines	https://www.nccn.org/patients/guidelines/cancers.aspx	Diagnosis & Treatment
Patient Registry and Outcomes for Breast Implants and anaplastic large cell Lymphoma (ALCL) etiology and Epidemiology (PROFILE)	https://www.thepsf.org/research/registries/profile	Registry for reporting and tracking cases of BIA-ALCL
FDA	https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm	Report on FDA's findings and recommendations on BIA-ALCL
Therapeutic Goods Administration (TGA)	https://www.tga.gov.au/alert/breast-implants-and-anaplastic-large-cell-lymphoma	Report on TGA's findings and recommendations on BIA-ALCL
Medicines and Healthcare Products Regulatory Agency	https://www.gov.uk/guidance/breast-implants-and-anaplastic-large-cell-lymphoma-alcl	Report on MHRA's findings and recommendations on BIA-ALCL
Health Canada	https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/safety-reviews/breast-implants-assessing-potential-risk-cancer.html	Report on Health Canada's findings and recommendations on BIA-ALCL
American Society of Plastic Surgeons (ASPS)	www.plasticsurgery.org/alcl	BIA-ALCL Physician Resources
American Society for Aesthetic Plastic Surgeons (ASAPS)	www.surgery.org/professionals	BIA-ALCL Physician Resources
Association of Breast Surgery	https://associationofbreastsurgery.org.uk/clinical/bia-alcl/	BIA-ALCL Physician Resources
Mentor	http://www.mentorwwllc.com/global-us/SafetyInformation.aspx	Information for women considering breast implants

What resources does Mentor provide for me and my patients?

In March 2018, Mentor began contributing to an industry-funded BIA-ALCL Patient Assistance Fund for uninsured patients diagnosed with BIA-ALCL.

All Mentor Breast Implants come with a free, limited warranty program that offers lifetime product replacement and limited financial assistance if needed. More information on Mentor's warranty program can be found at: **https://www.breastimplantsbymentor.com/breast-implants/warranties**

1. Clemens, M.W., et al., How to Diagnose and Treat Breast Implant–Associated Anaplastic Large Cell Lymphoma. Plastic and Reconstructive Surgery, 2018. 141(4): p. 586e-599e. **2.** Deva, A.K. Breast Implant Associated Large Cell Lymphoma (BIA-ALCL) – Key Update. Plastic Surgery Hub. https://www.plasticsurgeryhub.com.au/breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl-key-update/. June 8, 2018, accessed Aug 7, 2018. **3.** ASPS. BIA-ALCL Physician Resources. February 8, 2019. Available at: https://www.plasticsurgery.org/for-medical-professionals/health-policy/bia-alcl-physician-resources. **4.** de Boer, M., et al., Breast implants and the risk of anaplastic large-cell lymphoma in the breast. JAMA Oncology, 2018. 4(3): p. 335-341 **5.** Brody, G.S., et al., Anaplastic Large Cell Lymphoma Occurring in Women with Breast Implants: Analysis of 173 Cases. Plastic and Reconstructive Surgery, 2015. 135(3): p. 695-705. **6.** Gidengil, C.A., et al., Breast Implant–Associated Anaplastic Large Cell Lymphoma: A Systematic Review. Plastic and Reconstructive Surgery, 2015. 135(3): p. 713-720. **7.** Magnusson M, Beath K, Cooter R, Locke M, Prince HM, Elder E, Deva AK. Special Update: The epidemiology of Breast Implant Associated Large Cell Lymphoma in Australia and New Zealand confirms the highest risk for grade 4 surface breast implants. Plast Reconstr Surg. 2019 Feb 13. doi: 10.1097/PRS.0000000000005500; with further details provided in Loch-Wilkinson et al., Plast Reconstr Surg. 2017;140(4):645-654. **8.** Doren, E.L., et al., U.S. Epidemiology of Breast Implant–Associated Anaplastic Large Cell Lymphoma. Plastic and Reconstructive Surgery, 2017. 139(5): p. 1042-1050. **9.** Johnson, L., et al., Breast implant associated anaplastic large cell lymphoma: The UK experience. Recommendations on its management and implications for informed consent. Eur J Surg Oncol, 2017. 43(8): p. 1393-1401. **10.** Deva, A.K. "BIA-ALCL: Translating Science Into Practice." The Aesthetic Meeting of ASAPS, April 29, 2018, Javits Center, New York, NY. Lecture in Panel: Hot Topics in Breast Surgery—ALCL, Texture, Biofilms.

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