

ASSOCIATION BETWEEN BREAST IMPLANT-ASSOCIATED ANAPLASTIC LARGE CELL LYMPHOMA (BIA-ALCL) RISK AND POLYURETHANE BREAST IMPLANTS: CLINICAL EVIDENCE AND EUROPEAN PERSPECTIVE

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OBJECTIVE OF THE REVIEW

To present an overview on the use of polyurethane (PU) breast implants and the possible association with the risk of developing breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), with a special focus on the current situation in Europe.

DEFINITION

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL):

- is a rare type of non-Hodgkin's lymphoma.
- can occur in women after cosmetic or reconstructive surgery with breast implants.

Note: ALCL may occur also with other implants such as cardiac pacemakers, artificial hip joints and dental implants.

THEORIES OF CAUSATION

The real cause of BIA-ALCL remains unknown.

CURRENT HYPOTHESES BELOW REMAIN UNPROVEN AND HAVE NOT BEEN ABLE TO DEMONSTRATE STATISTICAL SIGNIFICANCE

- Genetic predisposition through gene mutation.
- An immune system response to chronic inflammation induced by silicone particulates or other factors.
- An infective cause and biofilm formation with a high bacterial load of Gram-negative & rod shaped bacteria.

THERE IS INSUFFICIENT EVIDENCE FROM PEER-REVIEWED LITERATURE TO ESTABLISH ANY SIGNIFICANT LINK BETWEEN THE DEVELOPMENT OF BIA-ALCL AND SURGICAL TECHNIQUE OR TYPE OF PATIENT.

WIDE GEOGRAPHIC VARIATION

- No scientific explanation can be found for the huge discrepancies in geographic distribution of BIA-ALCL.
- Australia reports a higher incidence than the United States, with no reported cases in Asia, and only a few in Latin America.
- Within Europe there are huge differences regarding the incidence of BIA-ALCL between countries, with Germany in particular having a very low incidence of BIA-ALCL, the only European country with a producer of PU implants, whose textured and PU breast implants have a large market share.

PROGNOSIS

It is probable that BIA-ALCL represents a spectrum of diseases ranging from seroma-only disease to a malignant cancer.

- The prognosis is favourable, especially those confined to the peri-implant seroma fluid and treated timeously with implant removal and total capsulectomy.
- However, some cases of solid infiltrating masses with an aggressive clinical course have been reported.

IMPACT OF THE IMPLANT SURFACE

It is widely assumed that the implant surface plays a crucial role.

- According to evidence-based medicine, the causal relation between the surface of breast implants and the increased risk of BIA-ALCL remains unclear.

SURFACE CLASSIFICATION OF BREAST IMPLANTS

New ISO guidelines provide precise definitions for the surfaces of mammary implants.

SURFACE DESCRIPTION BASED ON THE AVERAGE ROUGHNESS* MEASUREMENT ON THE FINISHED DEVICE

Type of surface	Roughness (µm)
Smooth	< 10
Micro-textured	10-50
Macro-textured	> 50

* The average roughness is measured as Ra or Sa

REGARDING BIA-ALCL CASES

- Most are associated with macro-textured implants (not supported by any clear clinical evidence).
- Cases have occurred with micro-textured implants, and in smooth implants, necessitating further investigation.
- Analysis of market data shows that far more textured implants (85 -90 %) are sold worldwide vs smooth implants (10-15 %), which could explain the predominance of BIA-ALCL cases with textured implants.

PU BREAST IMPLANTS CANNOT BE CLASSIFIED AS MACRO-TEXTURED IMPLANTS.

The PU foam that covers breast implants:

- Is a completely different surface with a 3D matrix that is incorporated into the shell & becomes an integral part of the capsule after a few months
- Mode of action related to tissue adhesion, as well as to fibrous capsule formation, differ substantially from those of smooth or textured implants

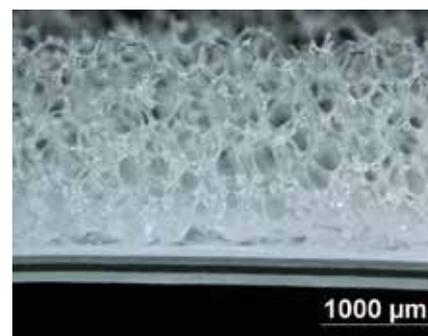
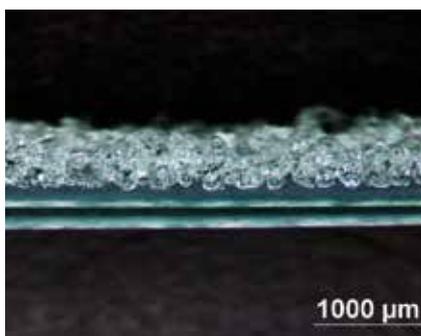


Figure 1: Lateral views taken with light microscopy demonstrating the difference between (A) a textured implant and (B) a polyurethane implant.

THERE ARE 2 TYPES OF PU BREAST IMPLANTS (FROM SILIMED & POLYTECH):

- They behave differently because of the use of different silicone materials and the methods used to embed the PU foam into the silicone shell of the implants.
- Early delamination has been reported with Silimed implants, however the impact on tissue ingrowth, biofilm formation is as yet unknown.

CONCLUSIONS

- According to the current clinical evidence **no conclusion can be drawn as to the real cause of BIA-ALCL** until a wide range of epidemiologic studies with statistically significant outcomes are published.
- **Implants covered with PU foam should not be classified as macro-textured implants.**
- **PU coated breast implants ensure a lower rate of CC and, according to current knowledge, a low rate of BIA-ALCL.**

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