

# A Meta-Narrative Review of Textured Implants and Associated Lymphoma Risks

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## Introduction

- 4/ 2022, FDA has recorded a total of 1,130 US and global medical device reports (MDRs) of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).
- BIA-ALCL is a relatively rare disease that only accounts 1-2% of all non-Hodgkin's lymphoma but can be fatal. In most cases, BIA-ALCL develops in the scar tissue and fluid near the implant, while in some cases, it can spread throughout the body. It is found on average 8-10 years post implant surgery. (Health, 2021)
- There is a higher cancer risk with textured implants (Mehta-Shah, *et al*, 2018). Similarly, the FDA believes tissue expanders with a certain textured surface may be of concern.

## Research Question

How do different textures of breast implants affect BIA-ALCL (smooth and textured surface)?

## Source selection

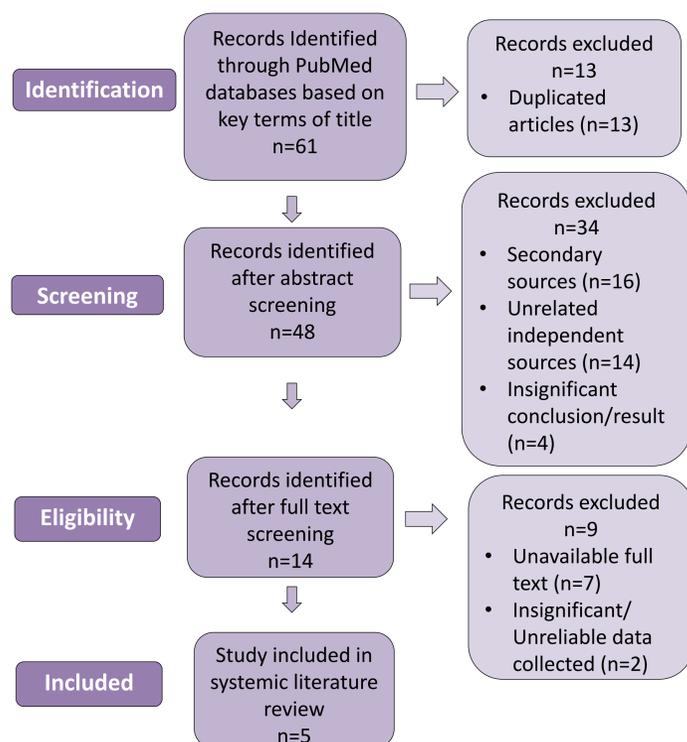


Figure 1. Articles selection process for meta narrative review of texture breast implants and BIA-CLCA

## Methodology

- Meta-narrative review (qualitative and mixed-method systematic review) is the selected approach to collect, contrast, and combine data.
- Highlight similarities and differences, making tables and diagrams; finding gaps and limitations among articles and investigating answers for new findings.

Authors/ year	Purposes	Findings
Atlan et al. 2018	To characterize the topography and surface area of 12 surface textures and evaluate how surface texture influences capsule formation and tissue adherence in rats.	Increasing complexity of the surface texture can markedly alter the pathophysiology of the foreign body response, leading to more tissue ingrowth, which disrupts capsule fiber organization and increases tissue adherence
Cordeiro et al. 2020	To determine the risk of BIA-ALCL with macro-textured breast implants and consistently followed long-term	Ten women, 1/354, developed ALCL after a median exposure of 11.5 years. The risk of macro-textured breast implants demonstrates the incidence rate of BIA-ALCL may be higher than previously reported.
Jones et al. 2018	To study the relationship between different textures of morphology and capacity for bacteria growth and attachment in vitro	The surface area/roughness associates with the growth of bacteria in vitro. The higher dimensional surface area ratio, the more bacteria grow.
Magnusson et al. 2019	To explain the risk of BIA-ALCL using parameters of different grading surface area/roughness	BIA-ALCL is essentially a disease associated with grade 3 and 4 based on surface area/ roughness level
Wixtrom et al. 2020	To quantitative information on Siltex textured breast implants, risk of BIA-ALCL and risk-reduction benefits compare with smooth implants.	Relative to smooth implants, Siltex devices reduce risks for reoperation inpatients who underwent primary augmentation (capsular contracture) or primary reconstruction (asymmetry).

Table 1. Summary of articles included in research and years published

## Main Findings

- Different classification systems of texture implant.
  - Smooth/nanotexture, micro-texture, macro-texture, and macro-plus texture (based on degree of texturing and depth increasing with each classification)
  - high, intermediate, low, and minimal for implant outer shells (based on the parameters of surface area, roughness, and bacteria growth)
- The bacteria's growth may play a role as a causing factor of BIA-ALCL. Textured implants support high rates of bacteria growth in vitro.

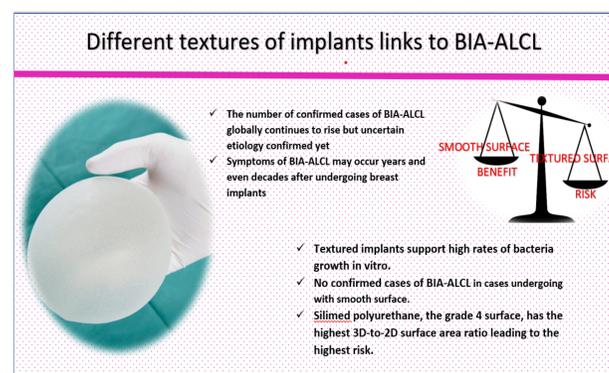


Figure 2. The key findings of BIA-ALCL relating to different textures of breast implants following the meta narrative process review

## Strengths and Limitations

The review is variability and validity because all the references are primary sources and within 5 years up to present. The analysis considers different textured breast implants, so its viability as a tool to help surgeons and patients to select the outstanding implants for breast reconstruction and augmentation. This disease takes a long time to develop and to be diagnosed. Therefore, it is time-consuming to do examinations, experiments, and follow-up with the disease. Furthermore, the main factor that links breast implants and BIA-ALCL has not been discovered yet. Almost all articles have a general conclusion that the textured breast implants are associated with BIA-ALCL.

## Conclusions / Implications

- The bacteria's growth may play a role as a causing factor of BIA-ALCL. The more complex surface enhances the probability of occurring the disease.
- There are various classification systems for implant surfaces with different context. The risk of BIA-ALCL differ depending on the texturing of the implant surface. Tissue ingrowth increased with increasing complexity of surface texture from smooth/nanotexture to macrotexture-plus. (Atlan et al., 2018).
- There have been no confirmed cases of BIA-ALCL in patients who have received smooth breast implants while evidence has reflected textured surface links to the risk of this cancer (Cordeiro et al., 2020).
- Intermediate and high textured surface are 10 times higher of being associated ALCL than low-surface-area texture (Siltex).
- Silimed polyurethane, measured as surface grade 4, carries the highest surface area and surface roughness and has been demonstrated higher rates of bacterial growth since being associated T-cell activation in both animal models and human series of capsular contracture (Magnusson et al., 2019).
- Without a uniform definition, using the same terms (eg, microtexture and macrotexture) in multiple contexts causes difficulties. There is no long-term clinical validation demonstrating that devices within a particular category have comparable risks for BIA-ALCL.

## References

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