BIA-ALCL-Horizon Scanning

Patrick Mallucci\textsuperscript{a,∗}, Giovanni Bistoni\textsuperscript{b,c}

\textsuperscript{a} Director of Plastic Surgery at Mallucci London, 13 crescent Place, London, SW3 2EA, UK
\textsuperscript{b} Sapienza University of Rome, Policlinico Umberto I, Department of Surgery "P. Valdoni", Plastic and Reconstructive Surgery Unit, Piazzale Aldo Moro 5, 00185 Roma, Italy
\textsuperscript{c} Hospital General de Valencia, Plastic Surgery Unit, Avenida Tres cruces 2, Valencia, Spain

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\textbf{ABSTRACT}

BIA-ALCL is a subject that has dominated the world of breast implant surgery over the past 7 or 8 years. It is a controversial entity that has stoked much debate amongst the profession of plastic surgery and its associated scientific specialists. Whilst much has been learned about the disease, including its diagnosis, prognosis and treatment, there is still much debate related to aetiology and incidence. Experts remain divided on fundamental principles such as implant selection and appropriate advice to patients and expert bodies. The article is very much the authors’ viewpoint based on the current literature and available data as it stands today.

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\textbf{Introduction}

The advent of BIA-ALCL has put the world of breast augmentation through its sternest test since the 14-year moratorium on silicone breast implants which took place in the US between 1992 and 2006.\textsuperscript{1} Just as then, both industry and the medical profession have come together to try and understand the disease better in terms of incidence, causation and risk, and how to optimize safety for women requiring or desiring breast implantation. Since its identification as a specific pathological entity by the WHO in 2016,\textsuperscript{2} it has been the most discussed topic on the international stage. During
this period, it has perhaps been the most published topic in the aesthetic surgery literature (first case report was published in 1997).\(^3\) It has been a source of media fascination and hype which has penetrated public interest globally, and it represents perhaps the most serious ‘hiccup’ in the 60-year history of breast augmentation – the most popular aesthetic surgery procedure worldwide. Aesthetic breast surgery, however, is no stranger to scandals with major episodes such as the raluent implant (soya gel) scandal,\(^4\) hydrogel implants,\(^5\) the PIP scandal\(^6\) and now the breast implant illness\(^7\) and BIA-ALCL. Notwithstanding such difficulties, breast augmentation seems to find a way to navigate through troubled waters and has continued to grow despite the setbacks it has encountered in the past.

The disease has proven to be one of the greatest sources of controversy throughout the plastic surgery community with widely varying opinions regarding just about every one of its aspects. From aetiology, incidence, treatment, change in practice, as well as interaction, education and informing of patients. It is an emotive subject on which there is little consensus amongst ‘experts’. This makes it difficult to fully inform, educate or advise the public, the authorities or, indeed, the surgical community itself.

Perhaps the only observation that is universally agreed upon is that the disease appears to be more associated with textured-surface implants than with smooth-surfaced implants.\(^8\) However, the simplistic conclusion that elimination of textured implants is the solution to breast augmentation is open to challenge by many; after all, texture and shape were developed for good reason.\(^9\)

Aetiology

The aetiology of the disease remains largely unresolved with several theories abounding. The most popular hypothesis is linking the disease to the presence of a bacteria-derived microbiome around an implant. This acts as a chronic inflammatory stimulus triggering T cell activation and transformation to eventually give rise to BIA-ALCL.\(^10\) This theory links the greater association of textured-surface implants with the disease because of their ability to accommodate bacteria within their rugose exterior surface. A smooth-surfaced implant is unable to ‘house’ bacteria as readily and, hence, has less propensity to support a microbiome. The ‘infective’ theory is also possibly the best explanation regarding why there are marked geographical differences and pockets of the disease in certain parts of the world or even in certain countries.\(^11\) There are pockets of unexpectedly high number of cases of BIA-ALCL in some areas of Australia and New Zealand, for example, as there are also amongst a few select individuals elsewhere in the world.\(^12\) These are rather unique situations which perhaps warrant more in-depth investigation, with their vastly increased numbers perhaps able to shed some light on causation. Some bacterial subtypes such as *Ralstonia pickettii* have been identified in unexpectedly high numbers around the affected implant capsules and are known occupants of biofilms in general.\(^13,14\) However, there has been no real pattern to account for clustering, and, as such, absolute association with the microbiome hypothesis remains unproven. Other theories include speculation around fragmentation of particulate matter from the implant shell (also more likely with a textured device than a smooth shell), the presence of heavy metals in the manufacturing process and the interplay of genetic predisposition in all the above.\(^10,15-18\) It is likely to be a combination of many factors, including the passage of time, that eventually lead to disease development\(^10,19\).

The Surface Debate

Whilst there is no doubt that BIA-ALCL is almost exclusively associated with textured-surface implants, there is some ambiguity regarding whether any pure smooth cases have been identified, and it would be impossible to exclude this as a possibility.\(^20\) However, given the overwhelming preponderance of texture, many attempts have been made to try and understand this relationship better. In particular, attempts have been made to quantitate risk according to the degree of texturization. Deva et al\(^21\) have classified surfaces into four groups: smooth (group 1), microtexture (group 2), macrotexture (group 3) and polyurethane-coated implants (group 4). The ISO has produced a similar three-category classification.\(^22\) The proposition has been that BIA-ALCL is largely a disease of groups 3 and 4 (Deva) or groups 2 and 3 (ISO). The theory is that the more textured a surface, the higher the incidence of BIA-ALCL. However, in reality, this correlation is not linear, and the problem with these classifications
is that the observation relating the degree of texturization and incidence is not consistent, with a wide variation of incidence in each group. An example of this is Deva’s group 4 polyurethane – more than 90% of all polyurethane-derived cases are from Silimed. If Silimed is removed from the group, the incidence of cases from Polytech’s microthane or Surgitek is comparable with run rates in groups 1 and 2 – the microtextured group (Table 1). Whilst it might appear convenient to jump to the conclusion that the degree of texturization has a valid correlation with disease risk, the data do not support this.

In contrast, the most overriding observation of all is that the overwhelming majority of cases of BIA-ALCL are derived from the Biocell surface of Allergan implants. According to the latest FDA figures, 91.5% of all cases of BIA-ALCL are Biocell-derived (Clemens M., 3rd world consensus conference on BIA-ALCL, Rome October 2021). The other surface with a disproportionately high incidence of the disease was Slimed polyurethane but with much smaller numbers globally. Neither surface is in production or available for use anymore. It is worth noting for the UK market that the incidence is spread more evenly across different textured surfaces and is not so heavily weighted towards Biocell; however, the sample size is smaller than the FDA’s which supposedly collects global data. The reason Biocell is so closely associated with the disease is not understood but goes beyond a simplistic degree of texturization argument. It has been suggested that the method of manufacture of the Biocell surface could account for its association with BIA-ALCL. It was produced by a salt loss technique of the outer shell leaving large open pores to promote tissue ingrowth and adherence. However, this method of surface production has been emulated by other manufacturers such as Nagor and Sebbin but with only a miniscule number of cases than that of Allergan. The truth is that the association of the Biocell surface with BIA-ALCL remains a mystery as yet unsolved. However, its absence from the market has very great significance on any discussions pertaining to the risk and incidence for the future.

Incidence/Risk

The incidence of BIA-ALCL is controversial and has been difficult to quantify with wildly varying figures in the literature ranging from 1:300/400 cases to 1: 100 000/200 000 cases. Poor data on global sales figures and the lack of accurate registries have rendered the task of quantification extremely difficult. The problem with such differing figures on incidence is that they are open to manipulation and differing interpretation and allow surgeons to sway patients in whichever direction they want; those surgeons wanting to convince patients to stay away from texture can quote a very high incidence of 1:300, and those who want to use texture on their patients can use figures of 1:100 000 to perhaps persuade them that the risk is not so high. But who of the two is right? It is also

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Table 1
Frequency of Implant Types Associated with BIA-ALCL in This Cohort of Patients* with Comparison to Previous Report in 2016

| Manufacturer     | Texture Type | Surface Area | Mean Implant Duration (yr) | Surface Grade† | 2016§ (n = 75) | 2018 (n = 110) | Percentage |
|------------------|--------------|--------------|----------------------------|----------------|---------------|---------------|------------|
| Allergan/Inamed  | Biocell (salt loss) | Intermediate | 7.8 | 3 | 44 | 61 | 55.5 |
| Silimed          | Polyurethane | High         | 5.2 | 4 | 14 | 23 | 20.9 |
| Surgitek         | Polyurethane | High         | 25.0 | 4 | 1 | 1 | 0.9 |
| Polytech         | Polyurethane | High         | 4.5 | 4 | 0 | 1 | 0.9 |
| Nagor            | Nagotex (salt loss) | Low     | 6.4 | 2 | 5 | 7 | 6.4 |
| Mentor           | Siltex       | Low          | 4.0 | 2 | 5 | 7 | 6.4 |
| PIP              | PIP          | Low          | 2.5 | 2 | 4 | 4 | 3.6 |
| Mentor           | Smooth       | Minimal      | 15.5 | 1 | 2 | 3 | 2.7 |
| Unknown          | Smooth       | Minimal      | 15.5 | 1 | 2 | 2 | 1.8 |
| Unknown          | Textured     | ?            | 9.0 | 7 | 0 | 1 | 0.9 |

* = 110 implants in 81 patients because of reoperation.
†Grading system based on classification system published by Jones et al. (Jones P, Mempin M, Hu H, et al. The functional influence of breast implant outer shell morphology on bacterial attachment and growth. Plast Reconstr Surg. 2018;142:837-849).
§Mean implant duration of implant exposure before development of BIA-ALCL are included, but these differences were not significant.

P.I.P. Poly Implant Prosthesis.

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important to understand that personal experience, irrespective of literature values, has a large part to play in surgeon behaviour.

It is also the authors’ view that a common error when talking about the risk of BIA-ALCL as related to texture is to talk about a single figure of incidence. In other words, clumping all textured implants together – no surgeon uses all textured implants. Most surgeons will use one manufacturer, maybe two, and because much more is known about individual risk within manufacturers, it makes much more sense to talk about the risk pertaining to the particular manufacturer being used. In other words, for example, a mentor user who knows the risk of BIA-ALCL is about 1:87 000 cases for mentor implants should quote this as a risk to his or her patients when discussing implant selection, and it would not be appropriate for him or her to discuss an overall risk of all textured implants of, say, 1:300 or 1:400.

Furthermore, currently any discussion of BIA-ALCL risk must take into account two fundamental observations – firstly, the overwhelming association of the disease with the Allergan Biocell surface (91.5% of all cases), and secondly, the fact that Biocell is no longer in existence. Most published data on incidence are inclusive of the presence of Biocell. Therefore, although the overall rates of incidence vary from 1:300/1:400 or 1:100 000, these include Allergan’s Biocell surface as a major contributor to that incidence. Whilst these figures are important to understand what numbers might be presented in the future, they will be wildly inaccurate and greatly overestimate the incidence of the disease because Biocell is no longer in existence.

If 91.5% of all cases of BIA-ALCL are Biocell-derived, once it is removed, it follows that only 8.5% of the risk remains. Therefore, for the pessimistic observers who believe the current risk is around 1:300, the risk is more likely to be 1:300 × 8.5% which equates to 7/25 000 cases or a little more than 1:3000 cases. For those quoting risks of 1:30 000 the actual risk without Biocell would be 1:30 000 × 8.5% = 7/2500000 or a little over 1:300 000.

As with all risks, it needs to be put into perspective – what does a risk of 1:30 000 actually mean? A publication by Sieber and Adams28 examined a micromort analysis comparing these numbers with the risk of death from everyday life occurrences such as driving a car, drinking a glass of wine, taking an aeroplane journey or living in New York for a couple of days as a few examples. Driving a car 1 hour per day carries 5 times the lifetime risk of death than that of BIA-ALCL from a textured implant (including Biocell), living 2 days in New York carries a 2.5x greater risk of mortality, etc. It is a sobering perspective or a cold shower on what the numbers we quote patients actually mean to them in terms of the risk they are taking and is a useful way of communicating with them when it comes to discussions around implant selection. Finally, as a point of perspective, even if an incidence of 1:3000 cases was taken as accurate, if the average plastic surgeon carries out 50 breast augmentations per year (a comfortable overestimate) it would take 60 years, or two working lifetimes, before he or she saw just one case in his or her own patients. For those who believe the incidence is 1:30 000 or less, it would take 600 years or more before a case emerged.

No risk, no benefits

Given the hype that has surrounded BIA-ALCL, it would seem that the logical step would be to ban textured devices and only offer women round smooth alternatives.29 By banning texture, the possibility of using shaped or anatomical devices is eliminated and the benefits of texture are also removed. It follows, therefore, that banning texture would be justified if there were no advantages of using either shaped devices or if there were no added benefits of having textured surfaces. Herein lies the source of further heated debate within the expert community.

The round smooth lobby has been trying to convince others that there are no differences between round and anatomical devices and that we as surgeons are unable to tell the difference.30-32 This is a reflection of poor study design rather than reality, and perhaps stems from a culture of not being familiar with the use of textured anatomical devices and not wanting to become familiar with them. The 14-year moratorium on silicone breast implants in the US froze practice in time for many. By the time the moratorium was lifted, Europe and much of the rest of the world had developed and embraced the use of anatomical textured devices, leaving behind the shortcomings of round smooth devices.
It is the authors’ firm belief that there are very radical and fundamental differences between round and anatomical devices. This is not to say that there is no role for round implants; on the contrary, it is simply unnecessary to use a shaped device on many occasions. However, there are equally many occasions when a round device simply cannot achieve what an anatomical device can achieve by virtue of its differing volume distribution, its lower projection point, and the possibility of changing three dimensions independently of each other as opposed to only two in a round device. Consequently, women with challenging anatomy such as complex asymmetries, constricted lower poles, pseudoprosis, chest wall anomalies, tuberous breasts, complex revision surgery or those who simply want as natural a look as possible can benefit from these devices, achieving outcomes that would not have been possible or as good with a round smooth equivalent.\textsuperscript{9,33,34} Given the life-changing impact these interventions can have on women who have been burdened by poor body image or the lack of self-esteem as a result of their appearance, the importance of achieving the best possible outcome cannot be underestimated and sheds a different perspective on the concept of risk.

With regard to texturization, the main benefits pertain to tissue stability, reduction in rotation for anatomical implants, but also positional stability and historically lower capsular contracture rates (this last point is debatable today.\textsuperscript{35}) Round smooth devices have higher re-operation rates\textsuperscript{36} (even if the capsular contracture element is left out of the debate), because of malposition – bottoming out and lateralization through poor tissue stability and adherence. For those unwilling to use texture, the introduction of expensive meshes/ADMS to counter these problems has seen a surge in popularity – introducing potential further complications and cost without proven long-term data – perhaps an unnecessary step when there is a cheaper more reliable alternative – the textured implant.

In considering the overall risk picture, neither should the risk to the patient of re-operation be overlooked. Mortality rates from elective surgery vary from 1:50 000 to 1:100 000 in the literature.\textsuperscript{37} It might be surmised, therefore, that the overall risk to the patient of using a less stable round smooth device comfortably surpasses any mortality risk posed by BIA-ALCL from using a more predictable, stable, textured device with lower re-operation rates in the first instance.

In conclusion, the BIA-ALCL risk debate is complex and goes beyond the simple discussion of incidence in grouped texture devices, and neither can risk be considered without benefit.

**BIA-ALCL – horizon scanning**

There is no doubt that the onset of BIA-ALCL as an entity has influenced many surgeons’ behaviour in terms of implant selection and discussion with patients. Perhaps some have jumped too soon, particularly with Biocell no longer in existence, and are now encountering a host of problems they had not foreseen with round smooth devices they were unaccustomed to using. Politics, personal agendas, the threat of medicolegal action and economics undoubtedly muddy the waters of ‘truth’ and make it difficult for both surgeons and the public to navigate through complex issues. It may appear that the easy choice is to walk away from texture, but in doing so are surgeons really ‘protecting their patients’ or are they protecting themselves? It is the authors’ belief that women should be fully informed regarding all the elements of risk vs. benefit when it comes to shape/texture/no texture, including re-operation risk as laid out in this article, and that ultimately the choice should be theirs.

For the sake of balance, it is possible that incidence has been underestimated and cases have been missed through poor vigilance, lack of diagnosis and individual or collective ignorance about the disease. It, therefore, behooves us as a speciality along with industry to remain vigilant and focused on improving reporting systems and registries nationally and internationally to monitor and better understand its evolution. It is of interest, however, that there has been a decline in the number of reported cases in the last 2 years, whether this is a coronavirus disease-related effect or the start of a new era without Biocell is too soon to tell. For the first time, it is also no longer the most discussed topic on the international breast conference circuit, and there are also signs that interest in the topic has started to wane with the media and the public at large. This is not a cue for complacency, and a better understanding of aetiology, incidence and treatment must continue. However, perhaps as we observe the natural progression of the disease an adjustment in perspective is also required.
Declaration of Competing Interest

P Mallucci is a minor shareholder in B-lite implants. He is a key opinion leader for Polytech and Laboratoires Sebbin.

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References

1. Spear SL, Parikh PM, Goldstein JA. History of breast implants and the food and drug administration. Clin Plast Surg. 2009 Jan;36(1):15–21. PMID: 19055957. doi: 10.1016/j.cps.2008.07.007.

2. Swerdlow SH, Campo E, Pileri SA, Harris NL, Stein H, Siebert R, Advani R, Ghielmini M, Salles GA, Zelenetz AD, et al. The 2016 revision of the World Health Organization classification of lymphoid neoplasms. Blood. 2016;127:2375–2390 [PubMed].

3. Keech Jr JA, Creech B. Anaplastic T-cell lymphoma in proximity to a saline-filled breast implant. Plast. Reconstr. Surg. 1997;100:554–555 [PubMed].

4. Chatrath P, Oliver DW, Walker MS, Lamberty BG. Anti-soya antibodies and trilucent breast implants. Plast Reconstr Surg. 2003 Jan;111(1):98–101 discussion 102PMID: 12496569. doi: 10.1097/01.PRS.0000076876.69392.C7.

5. Hardwicke J, Gaze NR, Laitung JK. A retrospective audit of Novagold 'hydrogel' breast implants. J Plast Reconstr Aesthet Surg. 2007;60(12):1313–1316 Epub 2007 Jun 4. PMID: 17544350. doi: 10.1016/j.bjps.2007.04.009.

6. Greco C. The Poly Implant Prothèse breast prostheses scandal: Embodied risk and social suffering. Soc Sci Med. 2015 Dec;147:150–157 Epub 2015 Nov 2. PMID: 26584233. doi: 10.1016/j.socscimed.2015.10.068.

7. Kaplan J, Rohrich R. Breast implant illness: a topic in review. Gland Surg. 2021 Jan;10(1):430–443 PMID: 33634001; PMCID: PMC7882356. doi: 10.21037/gs-20-231.

8. Kroth A, Graf R. Breast Implant- Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) and the Textured Breast Implant Crisis. Aesthetic Plast Surg. 2020 Feb;44(1):1–12 Epub 2019 Oct 17. Erratum in: Aesthetic Plast Surg. 2020 Oct;44(5):1951. PMID: 31624894. doi: 10.1007/s00226-019-01521-3.

9. Mallucci P, Bistoni G. The Use of Anatomic Implants in Aesthetic Breast Surgery. Plast Reconstr Surg. 2021 Jan;48(1):141–156 Epub 2020 Nov 3. PMID: 33220901. doi: 10.1016/j.prs.2020.09.010.

10. Deva AK, Turner SD, Kadim ME, Magnusson MR, Prince HM, Miranda RN, Inghirami GG, Adams Jr WP. Etiology of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL): Current Directions in Research. Cancers (Basel). 2020 Dec 21;12(12):3861 PMID: 33371292; PMCID: PMC7765924. doi: 10.3390/cancers12123861.

11. Loch-Wilkinson A, Beath K, Knight RJW, Wessels WLF, Magnusson M, Papadopoulos T, Connell T, Lofis J, Locke M, Hopper I, et al. Breast implant-associated anaplastic large cell lymphoma in Australia and New Zealand: High surface area textured implants are associated with increased risk. Plast. Reconstr. Surg., 2017;140:645–654.

12. Cordeiro PG, Ghione P, Ni A, Hu Q, Ganesan N, Galasso N, Dogan A, Horwitz SM. Risk of breast implant associated anaplastic large cell lymphoma (BIA-ALCL) in a cohort of 3546 women prospectively followed long term after reconstruction with textured breast implants. J Plast Reconstr Aesthet Surg. 2020 May;73(5):841–846 Epub 2020 Jan 20. PMID: 32008941; PMCID: PMC7247545. doi: 10.1016/j.jsps.2019.11.064.

13. Moon DJ, Deva AK. Adverse Events Associated with Breast Implants: The Role of Bacterial Infection and Biofilm. Clin Plast Surg. 2021 Jan;48(1):101–108 Epub 2020 Nov 3. PMID: 3220897. doi: 10.1016/j.cps.2020.09.009.

14. Deva AK, Adams Jr WP, Vickery K. The role of bacterial biofilms in device-associated infection. Plast. Reconstr. Surg., 2013;132:1319–1328 [PubMed].

15. Lechner MG, Megiel C, Church CH, Angell TE, Russell SM, Sevell RB, Jang JK, Brody GS, Epstein AL. Survival signals and targets for therapy in breast implant-associated ALK—Anaplastic large cell lymphoma. Clin. Cancer Res., 2012;18:4549–4559 [PubMed].

16. Silicone-induced granuloma of breast implant capsule (SIGBIC): Similarities and differences with anaplastic large cell lymphoma (ALCL) and their differential diagnosis. Breast Cancer. 2017;9:133–140.

17. Webb LH, Aime VL, Do A, Mossman K, Mahabir RC. Textured breast implants: A closer look at the surface debris under the microscope. Plast Surg. 2017;25:179–183.

18. Oishi N, Miranda RN, Feldman AL. Genetics of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Aesthet Surg J. 2019 Jan 31 [Suppl 1]:S14–S20 PMID: 30715169. doi: 10.1093/ajss/ajy331.

19. Lajevardi SS, Rastogi P, Isacson D, Deva AK. What are the likely causes of breast implant associated anaplastic large cell lymphoma (BIA-ALCL)? JPRAS Open. 2022 Jan 16;32:34–42 PMID: 35242986; PMCID: PMC8867047. doi: 10.1016/j.jpra.2021.11.006.

20. Nelson JA, McCarthy C, Dabic S, Polanco T, Chilov M, Mehrara BJ, Disa JJ. BIA-ALCL and Textured Breast Implants: A Systematic Review of Evidence Supporting Surgical Risk Management Strategies. Plast Reconstr Surg. 2021 May 1;147(5S):7S–135 PMID: 33890875; PMCID: PMC9157223. doi: 10.1097/PRS.00000000000008040.

21. Magnusson M, Beath K, Cooter R, Locke M, Prince HM, Elder E, Deva AK. The Epidemiology of Breast Implant-Associated Anaplastic Large Cell Lymphoma in Australia and New Zealand Confirms the Highest Risk for Grade 4 Surface Breast Implants. Plast Reconstr Surg. 2019 May;143(5):1285–1292 PMID: 30789476. doi: 10.1097/PRS.0000000000005500.
22. Wixtrom RN, Garadi V, Leopold J, Canady JW. Device-Specific Findings of Imprinted-Texture Breast Implants: Characteristics, Risks, and Benefits. *Aesthet Surg J*. 2020 Jan;29(2):167–173 Erratum in: *Aesthet Surg J*. 2021 Jun 14;14(7):859. PMID: 31121016. doi: 10.1093/ajas/sjz155.

23. Santanelli di Pompeo F, Clemens MW, Atlan M, Botti G, Cordeiro PG, De Jong D, Di Napoli A, Hammond D, Haymaker CL, Horwitz SM, Hunt K, Lennox P, Mallucci P, Miranda RN, Munhoz AM, Swanson EC, Turner SD, Firmani G, Sorotos M. 2022 Practice Recommendation Updates from the World Consensus Conference on BIA-ALCL. *Aesthet Surg J*. 2022 May 26;ejstc133 Epub ahead of print. PMID: 35639805. doi: 10.1093/ajas/sjac133.

24. Atlan M, Biggerelle M, Larreta-garde V, Hindé M, Hedén P. Characterization of Breast Implant Surfaces, Shapes, and Biomechanics: A Comparison of High Cohesive Anatomically Shaped Textured Silicone, Breast Implants from Three Different Manufacturers. *Aesthetic Plast Surg*. 2016 Feb;40(1):89–97 Epub 2016 Jan 8. PMID:26746882. doi: 10.1007/s00266-015-0603-8.

25. Nelson JA, Dabac S, Mehrara BJ, Cordeiro PG, Disa JJ, Pusic AL, Matros E, Dayan JH, Allen Jr RJ, Condldi M, Polanco TO, Shamsunder MG, Wiser I, Morrow M, Dogan A, Cavalli MR, Encarnacion E, Lee ME. McCarthy CM. Breast Implant-associated Anaplastic Large Cell Lymphoma Incidence: Determining an Accurate Risk. *Ann Surg*. 2020 Sep 1;272(3):403–409 PMID: 32694446. PMCID: PMC833676. doi: 10.1097/SLA.0000000000004179.

26. Lynch EB, DeCoster RC, Vyys KS, Rinker BD, Yang M, Vasconez HC, Clemens MW. Current risk of breast implant-associated anaplastic large cell lymphoma: a systematic review of epidemiological studies. *Ann Breast Surg*. 2021;5:30 Epub 2021 Sep 30. PMID: 35415602; PMCID: PMC9000366. doi: 10.21037/abs-20-96.

27. Ionescu P, Vibert F, Amé S, Mathelin C. New Data on the Epidemiology of Breast Implant-Associated Anaplastic Large Cell Lymphoma. *Eur J Breast Health*. 2021 Oct 4;17(4):302–307 Erratum in: *Eur J Breast Health*. 2021 Dec 30;18(1):107. PMID: 34651107; PMCID: PMC8496114. doi: 10.4274/eqb.jfills.2021.2021-5-6.

28. Sieber DA, Jr Adams WP. What’s Your Micromort? A Patient-Oriented Analysis of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). *Aesthetic Surg J*. 2017 Sep 1;37(8):887–891 PMID: 29036945. doi: 10.1093/asj/sjx127.

29. ANSM. https://www.ansm.sante.fr/L-ANSM/Recours-a-l-expertise-externe/Appela-candidature-en-vue-d-une-audition-publique-sur-les-implants-mammaires-en-chirurgie-esthetique-et-reconstructrice/; 2018.

30. Rubi CG, Lozano JA, Pérez-Espadero A, Leache ME. Comparing Round and Anatomically Shaped Implants in Augmentation Mammoplasty: The Experts’ Ability to Differentiate the Type of Implant. *Plast Reconstr Surg*. 2017 Jan;139(1):60–64 PMID: 28027228. doi: 10.1097/PRS.0000000000002890.

31. Cheng F, Cen Y, Liu C, Liu R, Pan C, Dai S. Round versus Anatomical Implants in Primary Cosmetic Breast Augmentation: A Meta-Analysis and Systematic Review. *Plast Reconstr Surg*. 2019 Mar;143(3):711–721 PMID: 30601325. doi: 10.1097/PRS.0000000000005371.

32. Hidalgo DA, Weinstein AL. Intraoperative Comparison of Anatomical versus Round Implants in Breast Augmentation: A Randomized Controlled Trial. *Plast Reconstr Surg*. 2017 Mar;139(3):587–596 PMID: 28234826. doi: 10.1097/PRS.0000000000003114.

33. Adams Jr WP, Afrozon PN, Stuzin JM. Tissue-Based Planning and Technique for Breast Augmentation with Anatomical Implants. *Plast Reconstr Surg*. 2019 Jun;143(6):1634–1636 PMID: 31136478. doi: 10.1097/PRS.0000000000005663.

34. Montemurro P, Adams Jr WP, Mallucci P, De Vita R, Layt C, Calobrace MB, Brown MH, Nava MB, Teitelbaum S, Del Yerro JLM, Bengston B, Maxwell GP, Hedén P. Why Do We Need Anatomical Implants? the Science and Rationale for Maintaining Their Availability and Use in Breast Surgery. *Aesthetic Plast Surg*. 2020 Apr;44(2):253–263 Epub 2020 Jan 2. PMID: 31897627. doi: 10.1007/s00266-019-05195-z.

35. Filiciani S, Siemienczuk GF, Etcheverry MG. Smooth versus Textured Implants and Their Association with the Frequency of Capsular Contracture in Primary Breast Augmentation. *Plast Reconstr Surg*. 2022 Feb 1;149(2):373–382 PMID: 35077412. doi: 10.1097/PRS.0000000000008717.

36. Somogyi RB, Brown MH. Outcomes in primary breast augmentation: a single surgeon’s review of 1539 consecutive cases. *Plast Reconstr Surg*. 2015 Jan;135(1):87–97 PMID: 25539298. doi: 10.1097/PRS.0000000000000773.

37. Keyes GR, Singer R, Iverson RE, McGuire M, Yates J, Gold A, Reed L, Pollock H, Thompson D. Mortality in Outpatient Surgery. *Plast Reconstr Surg*. 2008 July;122(1):245–250. doi: 10.1097/0b013e31817747fd.