American Association of Plastic Surgeons Consensus on Breast Implant–Associated Anaplastic Large-Cell Lymphoma

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Background: In the absence of high-quality evidence, there is a need for guidelines and multidisciplinary consensus recommendations on breast implant–associated anaplastic large-cell lymphoma (BIA-ALCL). The purpose of this expert consensus conference was to evaluate the existing evidence regarding the diagnosis and management of BIA-ALCL caused by textured implants. This article aims to provide evidence-based recommendations regarding the management and prevention of BIA-ALCL.

Methods: A comprehensive search was conducted in the MEDLINE, Cochrane Library, and Embase databases, and supplemented by manual searches of relevant English-language articles and "related articles" sections. Studies focusing on breast surgery and lymphoma associated with breast implants were included for analysis. Meta-analyses were performed and reviewed by experts selected by the American Association of Plastic Surgeons using a Delphi consensus method.

Results: A total of 840 articles published between January of 2011 and January of 2023 were initially identified and screened. The full text of 188 articles was assessed. An additional 43 articles were excluded for focus, and 145 articles were included in the synthesis of results, with 105 of them being case reports or case series. The analysis encompassed a comprehensive examination of the selected articles to determine the incidence, risk factors, clinical presentation, diagnostic approaches, and treatment modalities related to BIA-ALCL.

Conclusions: Plastic surgeons should be aware of the elevated risks by implant surface type, implement appropriate patient surveillance, and follow the recommendations outlined in this statement to ensure patient safety and optimize outcomes. Ongoing research on the pathogenesis, genetic drivers, and preventative and prophylactic measures for BIA-ALCL is crucial for improving patient care. *(Plast. Reconstr. Surg.* 154: 473, 2024.)

CLINICAL QUESTION/LEVEL OF EVIDENCE: Risk, V.

Breast implant–associated anaplastic large-cell lymphoma (BIA-ALCL) is an uncommon but concerning complication caused by textured surface breast implants. The relatively rare occurrence of the disease and its prolonged latency contribute to an absence of high-quality

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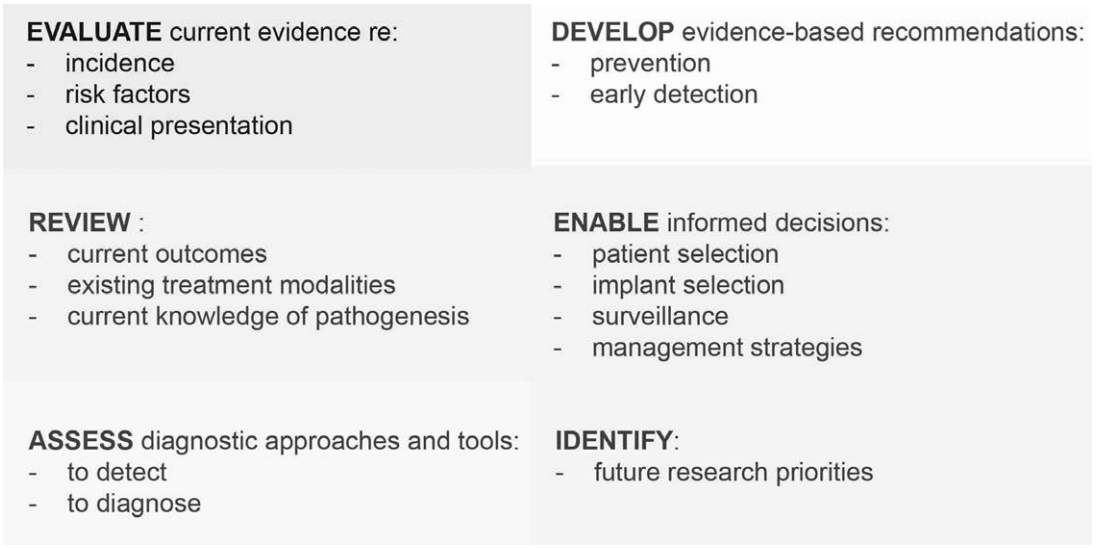

Fig. 1. Predetermined aims of the multidisciplinary BIA-ALCL expert panel.

evidence to inform our understanding of the pathogenesis, risk, and treatment outcomes of BIA-ALCL. In 2016, the National Comprehensive Cancer Network developed evidence-based, consensus-driven guidelines and followed up with annual updates to guide management for the majority of patients with BIA-ALCL.[1,2] Cases of advanced disease, refractory malignancies, and advanced disease with uncommon presentations require a more robust assessment.

Existing knowledge on BIA-ALCL and its incidence, risk factors, and advanced treatment modalities is evolving. In light of these gaps in knowledge and the potential impact on patient care, the American Association of Plastic Surgeons (AAPS) convened an expert consensus conference similar to those for previous consensus recommendations from the society.[3] The consensus conference led to this document, which seeks to address the current knowledge gaps and provide evidence-based guidance on BIA-ALCL (Fig. 1). Our intention is to promote patient safety and improve outcomes in breast implant procedures while ensuring that plastic surgeons are equipped with the necessary tools and knowledge to effectively address this uncommon complication.

Disclosure statements are at the end of this article, following the correspondence information.

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METHODS AND MATERIALS

The methodology for evidence identification, retrieval, synthesis, and interpretation for this consensus statement was similar to that of previous published consensus conferences in the field of surgery from the American Society of Plastic Surgeons and the AAPS.[4–6] A literature review was conducted to retrieve a comprehensive and all-inclusive set of publications on the topic of breast implants and BIA-ALCL. PubMed was used to identify relevant articles. (**See Document, Supplemental Digital Content 1**, which shows the PubMed search terms used to identify relevant articles, ***http://links.lww.com/PRS/G907***.) The search was limited to English-language articles published during the time period from January of 2011 to January of 2023.

Treatment recommendations on BIA-ALCL were assessed based on the available evidence. The widely adopted Grading of Recommendations, Assessment, Development, and Evaluation, or GRADE, framework was utilized to evaluate the level of evidence and assign a class of recommendation, either based on available evidence or by consensus when evidence was limited.

After systematic review and synthesis of the pertinent literature for the aims of this consensus document, the expert panel developed a series of

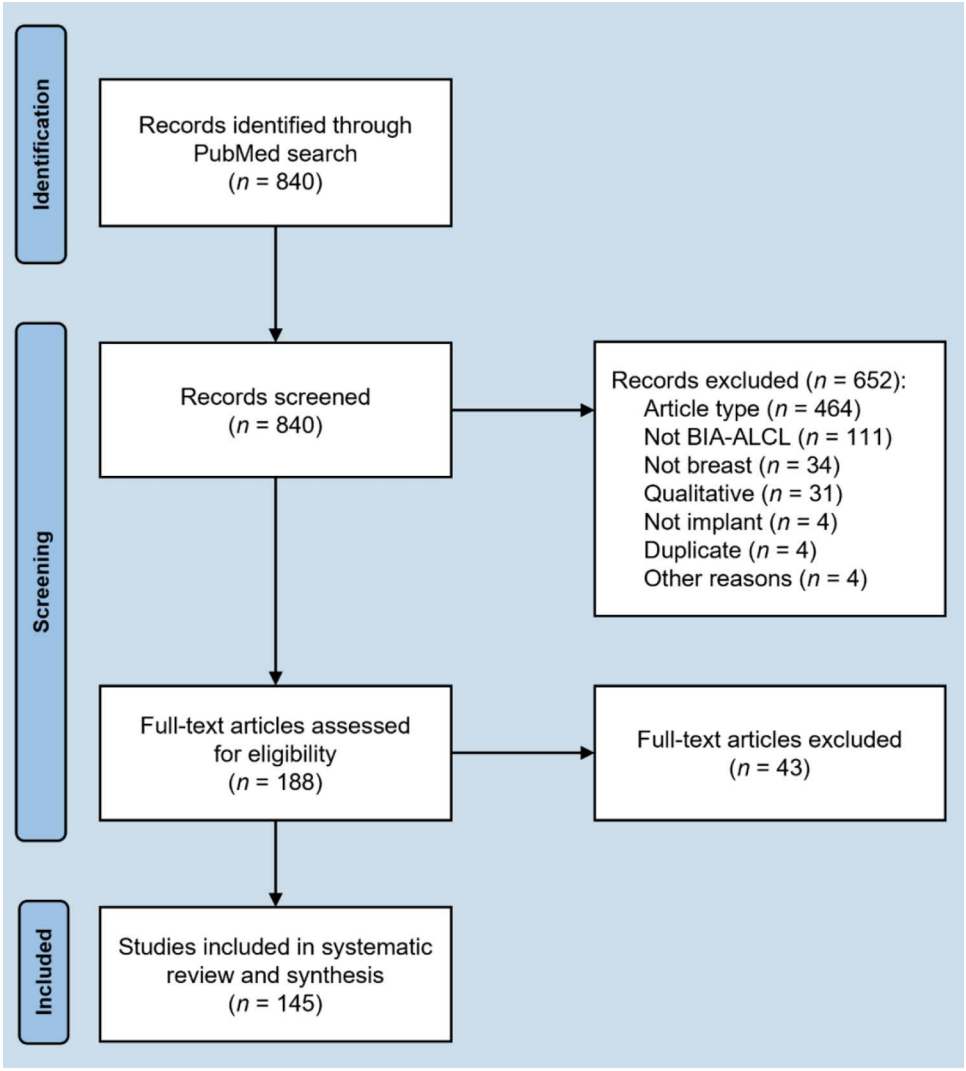

Fig. 2. Preferred Reporting Items for Systematic Reviews and Meta-Analyses flow diagram.

recommendations regarding BIA-ALCL and breast implants, with a particular focus on textured-surface breast implants. The American College of Cardiology/American Heart Association classification scheme for class of recommendation and level of evidence[7] and the GRADE class of evidence and strength of evidence[8] were used to categorize each recommendation. Given that BIA-ALCL is classified as an uncommon and emerging disease, the literature is limited by the types of studies that can be undertaken and randomized trials are not feasible, which does not allow for level A evidence or the highest strength of evidence classifications. However, the consistency of the literature did allow for other levels of evidence in the class of recommendation, as defined by the American College of Cardiology/American Heart Association.

RESULTS

We identified and screened 840 articles (Fig. 2). After 652 articles were excluded, the full text of 188 articles was assessed. Another 43 articles were excluded if no pertinent results for the aims of this project were included or if cohort studies found no incidence of BIA-ALCL. A total of 145 articles were included in the synthesis of results, including 105 case reports or case series (Fig. 2). Based on this search (**see Document, Supplemental Digital Content 1**, ***http://links.lww.com/PRS/G907***), descriptive statistics of cases (Table 1), research aims, and future research priorities (Table 2) were developed for the AAPS consensus conference, as described below. (**See Table, Supplemental Digital Content 2**, which shows demographic characteristics of patients with BIA-ALCL described in case reports, ***http://links.lww.com/PRS/G908***.)

Table 1. Descriptive Characteristics of Patients with BIA-ALCL in the Case Report Literature

Characteristic	No. of Patients	Value
Mean age, yr	147	53.2
Median postimplant time, yr	155	9
Saline fill, %	130	23
Silicone fill, %	130	77
Textured implants or textured tissue expanders, %	165	69
Smooth-only history, %	165	0
Unreported surface, %	165	33
Staging (available for 65 patients), %		
Stage I	43	66
Stage II	15	23
Stage III	4	6
Stage IV	3	5
Median follow-up time, mo	98	18
Event-free patients, %	98	93
Event-free patients without reported follow-up time, %	12	92

Aim 1: Epidemiology and Causation for BIA-ALCL

Research Question 1A: What is the known epidemiology of BIA-ALCL worldwide?

Data from the American Society of Plastic Surgeons BIA-ALCL Global Network shows that there are currently 1687 known cases of BIA-ALCL and 59 deaths across 51 countries worldwide as of April 1, 2024. The last published report from the U.S. Food and Drug Administration before these data were presented, aggregated from health regulator reports in 19 countries, found 1264 BIA-ALCL cases and 63 deaths worldwide as of June of 2023.[9] A survey of European countries identified a significant increase in BIA-ALCL cases reported from April of 2019 to November of 2020.[10–12] Descriptive characteristics of patients with BIA-ALCL found in the case report literature are presented in **Table, Supplemental Digital Content 2**, ***http://links.lww.com/PRS/G908***.

Table 2. Aim 4: Future Research Prioritization and Phased Approach

Research Question	Studies Needed	Phased Approach Prioritization
What further studies are warranted to understand how textured breast implants cause BIA-ALCL?	• Research into geographic variation of BIA-ALCL incidence	Midterm
	• Determine reporting differences and population-specific risk factors	Midterm
	• Establish registry of all implants (smooth and textured) for proper outcome tracking	Immediate
What studies are needed to determine effective treatment for BIA-ALCL, particularly by stage of disease?	• Study the effectiveness of systemic treatment before surgical explantation (neoadjuvant) in the presence of mass lesions and/or lymph node involvement	Immediate
	• Develop screening methods for asymptomatic high-risk populations considering prophylactic textured implant explantation	Mid-term
	• Investigate the use of germline mutation screening to guide breast implant selection, identify at-risk populations, determine prognosis, and assist in appropriate therapy for BIA-ALCL	Long term
	• Explore shared decision-making approaches to determine the need for prophylactic explantation	Long term
What studies are needed to establish genetic or other etiological pathways?	• Study the cell of origin and epigenome using single-cell sequencing to determine actionable targets for BIA-ALCL treatment	Long term
	• Pool sequencing and genomic data from lymphoma trials to further study BIA-ALCL	Midterm
	• Investigate the induction of immunogenesis by smooth or textured implants in mouse models	Long term
	• Determine the impact of *TP53* mutation in mouse models with implants	Midterm
	• Utilize rat models with different implant surfaces to elucidate the mechanism of host foreign body reaction inducing chronic inflammation	Long term
	• Study the metabolomics of seromas in BIA-ALCL cases	Long term
	• Investigate the association between BIA-ALCL and atopic dermatitis and related processes	Midterm
	• Explore the role of CD30 beyond a marker in the pathogenesis of BIA-ALCL	Long term
	• Develop a commercially available blood marker for screening BIA-ALCL	Midterm
	• Establish a collaborative database to study the pathogenesis of bilateral BIA-ALCL cases and determine whether they represent metastatic or synchronous disease	Long term
	• Investigate the release of cytokines by lymphoma cells and their potential role in spreading the lymphoma to other areas (eg, cutaneous)	Midterm

Research Question 1B: Is there an association between textured breast implants and incidence of BIA-ALCL?

Recommendation 1. Use of macrotextured breast implants should be discontinued, and surveillance of patients who received breast implants, whether smooth or textured surface, should be implemented.

Recommendation 2. Implant manufacturers should disclose publicly, or for independent academic analysis, their internal surveillance data, detailing both the number of BIA-ALCL cases reported to them and their country-specific and global sales and implantation figures for their respective breast implants.

Recommendation 3. No change in the use of smooth-surface breast implants is warranted at this time, based on BIA-ALCL data.

Reasoning. Initial findings from the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology, or PROFILE, for the period from 2012 to 2018 found 186 BIA-ALCL cases in the United States, with detailed information available in about half of cases (n = 89), all of which had a history of a textured breast implant.[13] In a nationwide Dutch registry, 28 of 32 patients with breast implants and ALCL in the breast had textured implants, while the other 4 patients had an unknown implant surface.[14]

A single-center study identified patients who underwent implant-based reconstruction during a 26-year study period.[15] Eleven of the patients were diagnosed as having BIA-ALCL, and all had a history of textured implants (incidence of 1.79 per 1000 patients). In another series of 52 patients diagnosed as having BIA-ALCL, 100% of the cohort had textured breast implants.[16]

A national registry study in Australia found that breast implants with greater surface area (OR, 1.20) and surface roughness (OR, 1.07) were associated with a greater risk for incidence of BIA-ALCL.[17] The study also found that macrotextured breast implants (ie, Allergan Biocell implants, Silimed polyurethane implants, and Nagor implants) were associated with greater risk for BIA-ALCL compared with a microtextured breast implant (Mentor Siltex implants; OR, 4.12 to 12.46).

Therefore, use of macrotextured breast implants, defined as larger than 50 μm by the International Organization for Standardization's 2018 classification,[18] should be discontinued due to a disproportionately higher risk of BIA-ALCL. The organization's finalized draft guidance for 2024 (ISO 14607:2024) is in the final approval phase.[19] (**See Table, Supplemental Digital Content 3**, which shows classification of textured breast implants, ***http://links.lww.com/PRS/G909***.) Because of limited data, consensus was not achieved as to whether to extend the recommendation to all textured implants. There is no association between BIA-ALCL and smooth-surface breast implants; therefore, risk of disease with a smooth-surface implant is essentially the same as the risk of ALCL within the general population (ie, 1 in 4 million).

Research Question 1C: Does the association between textured breast implants and incidence of BIA-ALCL meet the criteria for causation?

Recommendation 4. Currently available evidence is sufficient to determine that the association of textured breast implants and BIA-ALCL does meet the definition of *causation* based on the Bradford Hill criteria.

Reasoning. The strength of the association between textured breast implants and BIA-ALCL has been demonstrated by the evidence presented for aim 1, particularly given that there have been no published cases of BIA-ALCL in patients with a confirmed smooth-only device history. (**See Document, Supplemental Digital Content 4**, which shows expanded reasoning for aim 1, epidemiology and causation for BIA-ALCL, ***http://links.lww.com/PRS/G910***.)

Aim 2: Treatment Effectiveness

Research Question 2A: Is surgery effective for treating BIA-ALCL?

Recommendation 5. An en bloc capsulectomy with explantation, resection of associated masses, and excision of involved lymph nodes is recommended for patients with BIA-ALCL, when deemed appropriate as part of a multidisciplinary evaluation.

Reasoning. As described for the other treatment options, one study found no death or recurrence in 52 patients treated with surgery only,[16] and another study found a 6% event incidence (2 of 33) with surgery only.[14] Complete surgical excision with full capsulectomy demonstrated better survival (P = 0.022) and event-free survival (P = 0.014) than partial capsulectomy, systemic chemotherapy, or radiation therapy.[20] Another study found that none of the patients with BIA-ALCL who died had definitive surgery, defined as implant removal, total capsulectomy, and complete ablation of any masses.[21] In addition, early-stage BIA-ALCL was associated with greater

implementation of definitive surgery compared with advanced stages (88% versus 59%, $P = 0.001$).

In the case report literature, surgery alone had a 4% incidence of death or recurrence (2 of 56) at a median follow-up of 16.5 months. All cases with surgical explantation, regardless of adjuvant treatment, had a 7% incidence of death or recurrence (8 of 110) at a median follow-up of 18 months. Staging information was reported in 51 cases with surgical explantation; 1 patient with an event had stage I disease, and 3 patients with events had stage II disease.

Research Question 2B: Is chemotherapy/immunotherapy effective for treating BIA-ALCL?

Recommendation 6. The addition of chemotherapy/immunotherapy to surgical explantation of textured breast implants may be considered in patients with stage IIA disease if disease is unresectable (invasive to critical structures), and it is recommended for patients with stage IIB or higher-stage BIA-ALCL, when deemed appropriate as part of a multidisciplinary evaluation. Neoadjuvant immunotherapy may be considered for borderline resectable or locally advanced unresectable disease at diagnosis if it achieves enough downstaging to permit a curative-intent surgery.

Reasoning. It is challenging to evaluate the effectiveness of adjuvant therapy with BIA-ALCL, given that these treatment options are generally pursued because the patient has advanced disease or additional factors necessitating adjuvant therapy. However, a few studies have described the outcome of adjuvant chemotherapy/immunotherapy compared with surgery only. In one study, death/recurrence occurred in 10% of patients (1 of 10) with adjuvant systemic treatment versus 6% of patients (2 of 33) with explantation and total capsulectomy alone; all patients with events had stage I disease.[22] In another study, death or recurrence occurred in 29% of patients (4 of 14) with adjuvant systemic treatment versus 0 of 50 patients with surgery only; half of patients with events had stage II disease and half had stage IV.[23]

In the case report literature, death or recurrence occurred in 13% of patients (6 of 47) with adjuvant systemic treatment after a median follow-up of 22 months. Staging information, using tumor-node-metastasis staging proposed by the MD Anderson Cancer Center and adopted by the National Comprehensive Cancer Network,[24] was reported in only 17 cases with adjuvant systemic treatment, of which 3 patients with events had stage II disease. In particular, case reports on frontline or neoadjuvant use of brentuximab found complete remission in these patients.[25–27]

Research Question 2C: Is radiation therapy effective for treating BIA-ALCL?

Recommendation 7. The addition of radiation therapy (25 to 30 Gy) to surgical excision and explantation is recommended for patients with unresectable BIA-ALCL, when deemed appropriate as part of a multidisciplinary evaluation.

Reasoning. The indications for adjuvant radiation therapy differ from those for surgery alone, including staging of disease and presence of a mass, which can introduce selection bias. However, one study did find that 25% of patients (1 of 4) with adjuvant radiation had a follow-up event (patient had stage II disease) compared with 6% of the surgery-only patients (2 of 33).[20] The case report literature found that 15% of patients (4 of 26) with adjuvant radiation therapy had death or recurrence at a median follow-up of 24 months. General dosage guidelines are 24 to 36 Gy, according to National Comprehensive Cancer Network recommendations. The impact of prior radiation therapy, such as in breast cancer patients, was not available for review and is an area for further investigation. Staging information was reported in only 11 cases with adjuvant radiation, of which 2 patients with events had stage II disease.

Research Question 2D: Is prophylactic explantation surgery associated with BIA-ALCL risk reduction?

Recommendation 8. Based on the potential for risk reduction, prophylactic explantation of macrotextured surface implants can be deemed *reasonable*. Furthermore, after implementing a risk stratification and surveillance plan, coupled with an informed discussion about the benefits of surgery, it may also be considered reasonable for explantation of any type of textured implant. It is important to differentiate between a procedure being *reasonable*—referring to the potential to mitigate risk—and it being *advisable*. While we acknowledge the reasonableness of these procedures, the determination of their advisability rests solely with the discretion of the surgeon in consultation with the patient. Before the release of this consensus statement, government authorities and national surgical societies had not acknowledged the potential for risk reduction through prophylactic explantation. Consequently, they either have not recommended such procedures or simply have no existing recommendation on the matter.

Reasoning. As textured implants are implicated as a causative factor in the development of BIA-ALCL, and because it has been demonstrated that the duration of exposure affects the

risk of disease, it has been hypothesized that the removal of textured devices may result in a reduction of risk.[28] A systematic review of 248 published cases of BIA-ALCL reported that 14% (n = 35) of the total cohort had a history of textured implant removal and/or replacement and 11% (n = 27) had a history of two textured implant removal/replacement procedures. Using the Kaplan-Meier method, it was then suggested that the rate of disease was 108 cases per 1000 patients per year in patients who had a history of textured implants without a history of implant removal/replacement, and that the rate of disease went to 75 new cases per 1000 patients per year in those who underwent textured implant removal or replacement to smooth implants, and to 48 cases per 1000 patients per year in patients who underwent two exchange operations.[29,30] The exact indication for removal/replacement surgery and the role of capsulectomies performed at the time of exchange were not well documented in these cases.

A single-center study contacted all patients whose breast implant procedures were performed between 1979 and 2017, including 264 patients with textured implants.[31] Of the 16 patients with textured implants who responded, 9 chose to undergo prophylactic explantation. An additional 2 patients with textured implants underwent further evaluation but had benign findings on ultrasound and did not require surgical intervention. BIA-ALCL is reported following partial, nearly total, and total capsulectomy with explantation of breast implants; therefore, the additive effect on risk reduction remains unclear.[32,33]

The use of breast implants imparts an improved quality of life for many women. For some, however, the knowledge that their implants carry a risk of cancer may have a significant, negative impact on their quality of life, and these women may desire explantation. Surgical interventions inherently come with their own set of risks, and any theoretical benefit derived from prophylactic explantation of textured breast implants should be weighed against the risk of perioperative morbidity and the patient's expectations for a cosmetic and functional result. The morbidity incidence found in non–BIA-ALCL revisional surgery may serve as a representative baseline of risk.[34] Questions remain as to whether a specific type or extent of capsule resection is required for risk reduction of existing macrotextured implants, as limited case reports exist of disease manifestation years after capsulectomy, and there is no standardized approach to capsulectomy that is recognized internationally. Note that a total capsulectomy may not always be surgically feasible or warranted. Preservation of overlying skin vascularity, ensuring nipple perfusion, and avoidance of pneumothorax are some examples that take precedence over excising an otherwise normal-appearing capsule.

Our recommendation is that in some patients with macrotextured implants, there may be a relative indication for explantation. In a planned prophylactic explantation, histological examination with CD30 immunohistochemical analysis can be appropriate as a screening tool. It is important to note that this is based on a consensus recommendation, as evidence remains limited on risk reduction. Different textured implants carry very different risks for BIA-ALCL, and patients differ in their comorbidities and risk tolerance. The final decision for explantation with or without capsulectomy should be shared between patient and surgeon following an evaluation of the patient's goals balanced against the perceived benefits of the surgery and an individual surgical risk assessment.

Recommendation 9. Prophylactic explantation of the contralateral textured breast implant is recommended in patients with a confirmed BIA-ALCL diagnosis due to the risk of unrecognized or occult bilateral disease.

Reasoning. For patients with unilateral BIA-ALCL, all experts on the panel agree with implant removal of the contralateral textured breast implant, and total capsulectomy is recommended as these patients have already shown susceptibility or vulnerability to developing BIA-ALCL in response to textured breast implants. Prophylactic contralateral explantation should reduce the risk of incidental bilateral disease (1% to 3%) and prevent future BIA-ALCL development in the contralateral breast by removing the causal textured implant.[24]

Recommendation 10. Preemptive notification of the risk of developing BIA-ALCL is recommended for all patients with textured breast implants. Occult fluid collections or masses may be recognized earlier in patients with textured silicone implants undergoing routine surveillance for gel leak.

Reasoning. Complete surgical treatment provides a better prognosis and very minimal recurrence for early-stage BIA-ALCL. Therefore, surveillance of patients with textured breast implants (per U.S. Food and Drug Administration guidance) will increase the probability that any development of initial disease or recurrence is detected early and can be definitively treated. All

patients with breast implants should be informed that any changes in their breast appearance or changes in breast symptoms warrant an evaluation by their care provider. For all patients with silicone breast implants, surveillance should strictly adhere to the 2021 U.S. Food and Drug Administration recommendations made for silicone breast implants to screen for implant rupture. This involves conducting an ultrasound or magnetic resonance imaging (MRI) scan after the first 5 years and then continuing with ultrasound or MRI every 2 to 3 years thereafter.[35] Notably, the MRI performed in this setting screens specifically for implant rupture in patients with silicone implants and is not specific to textured implants. It is also important to note that there is no recommended radiographic screening test specifically for BIA-ALCL in asymptomatic patients, and that adherence to MRI-based surveillance remains notably low among breast implant patients and U.S. surgeons.[36] Given this shortfall in practice, it may be prudent to consider additional measures, particularly for patients with textured surface implants. Several strategies may be used to bolster patient adherence and safety, including (1) proactive annual communication, which can serve as a vital reminder about upcoming surveillance; (2) leveraging electronic reminder systems, such as automated emails or text messages, to ensure consistent communication; and (3) offering flexible scheduling options or telehealth visits to address convenience concerns and further encourage regular check-ins. In symptomatic patients with textured breast implants, the differential diagnosis of new breast signs and/or symptoms should include BIA-ALCL, and focused imaging with ultrasound or MRI is warranted. In patients with a history of BIA-ALCL, positron emission tomography–computed tomography or computed tomography scans every 6 months for 2 years are recommended, followed by Food and Drug Administration–recommended surveillance thereafter.

Aim 3: Etiology

Research Question 3A: Is BIA-ALCL associated with a consistent genetic etiology?

Recommendation 11. Genetic markers may have prognostic value and may implicate future therapeutic targets. Broad genetic testing of patients with BIA-ALCL beyond clinical trials is not recommended at this time; however, the further identification of markers may provide future indications for genetic testing.

Reasoning. This is a consensus recommendation, as evidence remains limited on the prognostic value of genetic testing in BIA-ALCL. Genomics has shown that patients with BIA-ALCL, in general, demonstrate an above-average accumulation of chromosomal and genetic abnormalities. Therefore, physicians should be aware of associations with concomitant neoplasia, as in the case of patients with Li Fraumeni syndrome (germline *TP53* mutations)[37–39] and patients who are *BRCA1/2* carriers.[40] Santanelli di Pompeo et al. recently demonstrated that the *BRCA1/2* and *p53* mutations are significantly associated with a shorter event-free time—115 and 36 months, respectively, compared with 148 months in patients without these mutations. Therefore, predisposing genetic factors, such as *BRCA* and *p53*, may be additional contraindications to the use of textured implants. Further clinical research is required for risk stratification and outcomes before broad genetic testing of BIA-ALCL patients can be recommended. (**See Document, Supplemental Digital Content 5**, for expanded reasoning for aim 3A, genetic etiology, ***http://links.lww.com/PRS/G911***.)

Research Question 3B: Are there nongenetic etiological pathways associated with BIA-ALCL?

Recommendation 12. Evidence of pathways involving chronic inflammation and the acquisition of driving oncogenic events may be considered as increasing the risk for developing BIA-ALCL in patients with textured breast implants.

Reasoning. BIA-ALCL is a cancer that represents a localized, microenvironmental, lymphoproliferative event. Oishi et al.[41] found dramatic upregulation and expression levels of hypoxia-associated biomarker CA9. Chronic inflammation is certainly involved in this process, particularly as a sequelae of textured breast implants.[42] Systematic review of the literature found 10 articles describing evidence for nongenetic etiologies of BIA-ALCL, synthesized below. At this time, unverified hypotheses have been presented, including allergic inflammation, digestion of silicone particulate, an ischemic[41] and immunocompromised microenvironment, lipopolysaccharide as a genetic ligand,[43] oncogenic virus, and silicone leachables, such as aryl hydrocarbons. A comprehensive review of available data shows that there is insufficient substantiated evidence to support a link between bacteria and the pathogenesis of BIA-ALCL. (**See Document, Supplemental Digital Content 6**, for expanded reasoning for aim 3B, nongenetic etiology, ***http://links.lww.com/PRS/G912***.)

CONCLUSIONS

This AAPS expert consensus on BIA-ALCL provides evidence-based recommendations for the management and prevention of BIA-ALCL caused by textured surface implants. Through a comprehensive analysis of the available literature, including case reports and case series, we report important insights on the incidence, risk factors, clinical presentation, diagnostic approaches, and treatment modalities associated with BIA-ALCL. Plastic surgeons must be vigilant about the elevated risks associated with different breast implant surfaces and should implement appropriate patient surveillance protocols. By following the recommendations outlined in this statement, plastic surgeons can contribute to ensuring patient safety and optimizing outcomes in cases of BIA-ALCL. Surgeon engagement in prospective registries, such as the American Society of Plastic Surgeons' National Breast Implant Registry and PROFILE BIA-ALCL registry (www.thepsf.org/PROFILE), is instrumental in equipping us with actionable insights into these evolving diseases. Ongoing research focused on the pathogenesis of BIA-ALCL and genetic and nongenetic drivers of the disease may inform patient care improvements and enhance our ability to effectively manage and prevent this condition.

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DISCLOSURE

Dr. Clemens is on the faculty of MD Anderson Cancer Center, which participates in clinical trials for Motiva US Safety Trial (Establishment Labs) and Mentor Corporation. Dr. Myckatyn receives unrestricted research funds and product development royalties from RTI and has received a research gift from Sientra. Dr. Feldman received research funding from Seattle Genetics, is an inventor of technology for which Mayo Clinic holds unlicensed patents, and is an inventor of intellectual property licensed to Zeno Pharmaceuticals. Dr. Haymaker is on the faculty of MD Anderson Cancer Center, which participates in clinical trials for Motiva US Safety Trial (Establishment Labs) and Mentor Corporation; receives speaker's fees from the Society for Immunotherapy of Cancer (Milwaukee, WI); serves as an advisory board member for Briacell (West Vancouver, CA) and the Mesothelioma Applied Research Foundation (Washington, DC); has received personal fees from Nanobiotix (Paris, France); and receives funding to the MD Anderson Cancer Center from Iovance (San Carlos, CA) Sanofi (Paris, France), Dragonfly Therapeutics (Waltham, MA), and BTG (São Paulo, Brazil) outside the submitted work. Dr. Horwitz has consulted for, received honorarium from, or participated in advisory boards for Acrotech Biopharma, C4 Therapeutics, Janssen, Kura Oncology, Kyowa Hakko Kirin, Myeloid Therapeutics, ONO Pharmaceuticals, Seagen Inc., Takeda, Trillium Therapeutics, and Vividion Therapeutics, and has received research support for clinical trials from ADC Therapeutics, Affimed, Aileron, Celgene, Daiichi Sankyo, Forty Seven Inc., Kyowa Hakko Kirin, Millennium/Takeda, Portola Pharmaceuticals, Seagen Inc., Trillium Therapeutics, and Verastem.

Dr. Hunt is on the faculty of MD Anderson Cancer Center, which participates in clinical trials for Motiva US Safety Trial (Establishment Labs) and Mentor Corporation. Dr. Kadin has received honoraria from Allergan, Inc., for serving on an advisory board for BIA-ALCL, and receives financial support for research on BIA-ALCL from the Aesthetic Surgery Education and Research Foundation. Dr. Miranda is on the faculty of MD Anderson Cancer Center, which participates in clinical trials for Motiva US Safety Trial (Establishment Labs) and Mentor Corporation. Dr. Prince is a consultant for and has held advisory board roles for BMS, Janssen, Amgen, and Sanofi, and receives funding from BMS. Dr. Santanelli di Pompeo is affiliated with the Neurosciences, Mental Health and Sense Organs Department, which received research funds from Motiva (Houston, TX), Establishment Labs (Alajuela, Costa Rica; in 2017), and GC Aesthetics (Dublin, Ireland; in 2018 and 2020). The department also received mini-implants from Establishment Labs, GC Aesthetics, and Sebbin (Boissy l'Aillerie, France) for research purposes. Dr. Santanelli di Pompeo is also a paid consultant for BellaSeno GmbH (Leipzig, Germany); received reimbursements for travel and lodging expenses from ICEAG (Bilthoven, Utrecht, the Netherlands; in 2015) and SCHEER-WG (Luxembourg City, Luxembourg; in 2019, 2020, and 2021); and is a member of Notified Body 0373, which is part of the Superior Institute of Health and which carried out CE Mark certification activities for the Italian Ministry of Health for the year 2021; he has no ownerships or investments to declare. The remaining authors (Drs. Di Napoli, Elaine S. Jaffe,

Colleen M. McCarthy, Sari D. Holmes, and Linda G. Phillips) have no financial interests to declare.

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