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The Emerging Crisis of Stakeholders in Implant-based Augmentation Mammoplasty in Korea

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Address for Correspondence:

Heung Kyu Park, MD, PhD

Department of Surgery, Breast Cancer Center,
Gachon University Gil Medical Center, 21
Namdong-daero, 774-beon-gil, Namdong-gu,
Incheon 21565, Republic of Korea.
E-mail: hgjh@gilhospital.com

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ORCID iDs

Jae Hong Kim
<https://orcid.org/0000-0002-7162-9944>
Nam-Sun Paik
<https://orcid.org/0000-0002-2733-2828>
Sang Yu Nam
<https://orcid.org/0000-0003-3078-7206>
Younghye Cho
<https://orcid.org/0000-0001-7208-1899>
Heung Kyu Park
<https://orcid.org/0000-0002-8284-9221>

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Data curation: Kim JH. Formal analysis: Kim
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Kim JH, Cho Y. Project administration: Paik

Jae Hong Kim ¹, **Nam-Sun Paik** ², **Sang Yu Nam** ³, **Younghye Cho** ⁴ and
Heung Kyu Park ⁵

¹The W Clinic, Seoul, Korea

²Department of Surgery, Breast and Thyroid Cancer Center, Ewha Womans University School of Medicine,
Seoul, Korea

³Department of Radiology, Gachon University Gil Medical Center, Incheon, Korea

⁴Department of Pathology, Jangwon Medical Foundation, Seoul, Korea

⁵Department of Surgery, Breast Cancer Center, Gachon University Gil Medical Center, Incheon, Korea

ABSTRACT

Background: Korea is no longer safe from the risk of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL); the first reported case was a Korean woman in her 40s who had a 7-year-history of receiving an implant-based augmentation mammoplasty using a textured implant. We conducted this study to discuss the emerging crisis of stakeholders in implant-based augmentation mammoplasty and to propose a multi-disciplinary approach to early detection of its complications.

Methods: We analyzed medical examination data that was collected from patients who visited us between August 12 and September 27, 2019. We evaluated a total of 114 women (n = 114) in the current study. They were evaluated for whether they were in healthy condition. Moreover, their baseline characteristics were also examined; these included age, gender, height (cm), weight (kg), duration since surgery (years), possession of a breast implant card, the site of surgical incision, side of symptoms and reasons for outpatient visit. Furthermore, the patients were also evaluated for their subjective awareness of the manufacturer, surface and shape of the breast implant. Potential complications include malrotation, folding, seroma, capsule thickening, upside-down rotation, rupture, capsule mass and breast mass.

Results: A majority of the patients had a past history of receiving textured implants. The corresponding percentage was 78.95% (90/114) and 85.09% (97/114) based on their subjective awareness of a breast implant and sonographic findings, respectively. That is, it was slightly increased with the use of a breast ultrasound.

Conclusion: Here, we propose the following approaches. First, patient data should be prospectively collected. By tracking outcomes and complications of an implant-based augmentation mammoplasty, both high-quality care and patient safety can be ensured. Second, stakeholders in implant-based augmentation mammoplasty should collaborate with customers and regulatory authorities. Third, surgeons should consider applying imaging modalities for early detection of postoperative complications.

Keywords: Breast; Breast Implants; Breast Implantation; Mammoplasty; Safety

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INTRODUCTION

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is an extremely rare, non-Hodgkin's lymphoma whose characteristics include abnormal growth of T lymphocytes and over-expression of protein cytokine receptor CD30. It annually occurs at an estimated incidence of approximately 3/100 million women in the United States.¹ Possible relationship between vulnerability to BIA-ALCL and placement of a textured breast implant was recently suggested. Cordeiro et al.² prospectively enrolled a cohort of 3,546 women receiving 6,023 textured implants between 1993 and 2017, all of whom were surgically treated at a median age of 48 (range, 18–89) years old by the same single surgeon and then followed up during a median period of 7 years (range, 3 days to 24.7 years). According to these authors, a total of 8 women developed BIA-ALCL after receiving textured implants during a median period of 11.2 (range, 8.3–15.8) years. The reported incidence corresponds to 1/433 women. According to these authors, 96.7% of textured implants were the BioCell® (Allergan Inc., Irvine, CA, USA); it has been recalled in some countries for safety reasons.²

In March 2017, the US Food and Drug Administration (FDA) released a report of 359 cases and 9 deaths of BIA-ALCL. This was also highlighted by the New York Times article titled “Nine Deaths are Linked to Rare Cancer From Breast Implants.”³

According to the US FDA plan for review of the safety of breast implants dated March 25 and 26, 2019, BIA-ALCL and other systemic symptoms were discussed in relation to implant-based augmentation mammoplasty.⁴ This was preceded by a compulsory recall request from the Agence Nationale de Sécurité du Médicament, prohibiting the clinical use of the BioCell® (Allergan Inc.).⁵ Moreover, recall of textured implants in association with BIA-ALCL was also discussed; controversial opinions existed regarding a ban on textured implants.⁶⁻¹²

A series of patients diagnosed with BIA-ALCL were reported between 2011 and 2017, which influenced viewpoints of the US FDA on it. In 2008, de Jong et al.¹³ analyzed a population of 8 million people during a 17-year period from 1990 to 2006 and then reported that 389 of them were diagnosed with breast lymphoma, 11 (2.83%) and 5 (1.29%) had a histopathologically-proven diagnosis of ALCL and association with a breast implant, respectively. Then, a total of 173 histopathologically-proven cases of BIA-ALCL were seen in women with a past history of receiving a textured implant.¹⁴ Thus, Srinivasa et al.¹⁴ performed an analysis of the published incidences of BIA-ALCL and then identified 363 reported cases, including 258 entries in the US Manufacturer and User Facility Device Experience (MAUDE) database, only 130 of which were histopathologically-proven cases of BIA-ALCL. This was followed by published studies about 72 cases in Australia, 41 cases in the UK, 22 cases in Italy, 43 in the Netherlands, 19 in France, 7 cases in Germany and 149 cases in the US.¹⁵⁻²¹

Korea is no longer safe from a risk of BIA-ALCL. Recently, it also occurred in Korea; the first reported case was a Korean woman in her 40s who had a 7-year-history of receiving an implant-based augmentation mammoplasty using the BioCell® (Allergan Inc.).²² It is allegedly reported that 222,470 textured breast implants have been circulated in Korea between 2007 and 2018. Of these, 114,365 breast implants were the Allergan products and only 4,560 were manufactured from a Korean company.²³

Given the above background, we conducted this study to discuss the emerging crisis of stakeholders in implant-based augmentation mammoplasty and to propose a multi-disciplinary approach to an early detection of its complications.

METHODS

Study patients and setting

The current single-center study analyzed medical examination data that was collected from patients who visited us for further evaluation and treatment between August 12 and September 27, 2019 since the report of the first Korean case of a woman diagnosed with BIA-ALCL.²²

Inclusion criteria for the current study are as follows:

- 1) Women aged 18 years or older
- 2) Women with a past history of receiving an implant-based augmentation mammoplasty at other hospitals before visiting us.

Exclusion criteria for the current study are as follows:

- 1) Women lost to follow-up
- 2) Women who were deemed to be ineligible for the current analysis according to our judgment.

We therefore evaluated a total of 114 women ($n = 114$) in the current study; it was conducted in compliance with the relevant ethics guidelines; all procedures performed in it were in accordance with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Patient evaluation and criteria

On history taking and physical examination, the patients were evaluated for whether they were in healthy condition. Moreover, their baseline characteristics were also examined; these included age, gender, height (cm), weight (kg), duration since surgery (years), possession of a breast implant card, the site of surgical incision, side of symptoms and reasons for outpatient visit. Furthermore, the patients were also evaluated for their subjective awareness of the manufacturer, surface and shape of a breast implant.

The patients underwent breast ultrasound, as previously described.²⁴ We used the Aplio i600 (Canon Medical System, Otawara, Tochigi, Japan) system with a 7–18-MHz linear transducer. Thus, they were further evaluated for the manufacturer, types and shape of the breast implant, any notable signs associated with an implant-based augmentation mammoplasty in the pocket or breast parenchyma and presence of nodules on the breast imaging-reporting and data system category. Potential complications include malrotation, folding, seroma, capsule thickening, upside-down rotation, rupture, capsule mass and breast mass (BM).

Analysis of the patient data

All data was expressed as mean \pm standard deviation or the number of patients with percentage, where appropriate.

Ethics statement

The current study was approved by the Internal Institutional Review Board (IRB) of the Korea National Institute of Bioethics Policy (IRB No. 2017-0324-001). Informed consent was waived due to its retrospective nature.

RESULTS

Baseline characteristics of the patients

A total of 114 patients ($n = 114$) were evaluated, all of whom were women with a mean age of 36.60 ± 8.20 years old and had a mean duration of 4.93 ± 2.95 years since surgery. Their baseline characteristics are represented in **Table 1**. Moreover, distribution of years since surgery is shown in **Fig. 1**.

The patients' subjective awareness of the breast implant

As shown in **Table 2**, the most prevalent manufacturer, surface and shape of a breast implant were 'Allergan Inc. (53.50%, 61/114)', 'Textured (78.95%, 90/114)' and 'Anatomical (50.88%, 58/114)', respectively. Moreover, distribution of the patients' subjective awareness of the surface of the breast implant is shown in **Fig. 2**.

Table 1. Baseline characteristics of the patients ($n = 114$)

Variables	Values
Age, yr	36.60 \pm 8.20
20–29	25 (21.93)
30–39	48 (42.11)
40–49	31 (27.19)
50–59	9 (7.89)
> 60	1 (0.88)
Gender	
Men	0 (0.00)
Women	114 (100.00)
Height, cm	162.88 \pm 4.25
Weight, kg	52.59 \pm 6.82
Duration since surgery, yr	4.93 \pm 2.95
1–5	70 (61.40)
6–9	33 (28.95)
10–15	11 (9.65)
Possession of a breast implant card	
Yes	52 (45.61)
No	61 (53.51)
Unknown	1 (0.88)
Site of surgical incision	
Axilla	68 (59.65)
Peri-areolar region	10 (8.77)
Inframammary fold	36 (31.58)
Presence of symptoms	0 (0.00)
Reasons for outpatient visit ^a	
Deformation or dissatisfaction with shape	4 (3.51)
Dissatisfaction with softness	10 (8.77)
Pain	29 (25.44)
Routine check-up	94 (82.46)

Values are presented as mean \pm standard deviation or the number (%).

^aMultiple responses allowed.

Table 2. Distribution of the patients' subjective awareness of a breast implant

Variables	Values
Manufacturer	
Groupe Sebbin SAS (Boissy-l'Aillier, France)	5 (4.39)
HansBiomed Co. Ltd. (Seoul, Korea)	4 (3.51)
Establishment Labs Holdings Inc. (Alajuela, Costa Rica)	3 (2.63)
GC Aesthetics PLC (Apt Cedex, France)	0 (0.00)
Allergan Inc. (Irvine, CA, USA)	61 (53.50)
Mentor Worldwide LLC (Santa Barbara, CA, USA)	10 (8.77)
Polytech Health & Aesthetics (Dieburg, Germany)	10 (8.77)
Sientra, Inc. (Santa Barbara, CA, USA)	2 (1.75)
Unknown	19 (10.67)
Surface	
Textured	90 (78.95)
Microtextured	4 (3.51)
Smooth	3 (2.63)
Non-applicable (saline breast implant)	17 (14.91)
Shape	
Anatomical	58 (50.88)
Round	46 (40.35)
Unknown	10 (8.77)

Values are presented as number (%).

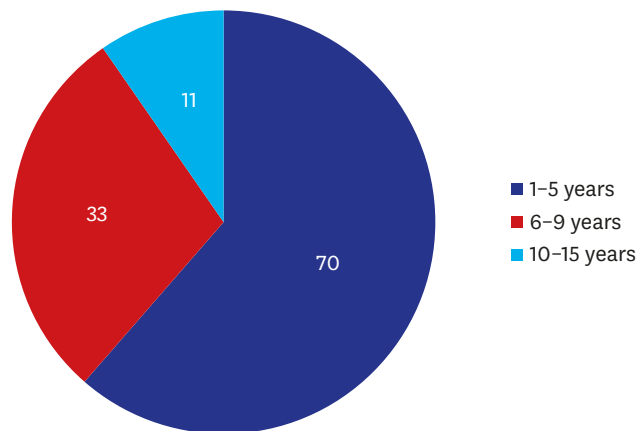


Fig. 1. Years since surgery. Of the total patients, 38.60% (44/114) had a duration since surgery of 6-15 years during which breast implant-associated anaplastic large cell lymphoma may occur.

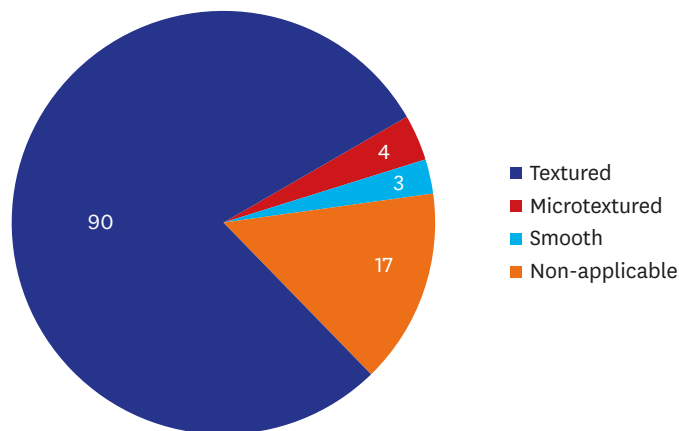


Fig. 2. Distribution of the patients' subjective awareness of the surface of a breast implant.

Table 3. Distribution of sonographic findings of a breast implant

Variables	Values
Manufacturer	
Groupe Sebbin SAS (Boissy-l'Aillierie, France)	4 (3.51)
HansBiomed Co. Ltd. (Seoul, Korea)	3 (2.63)
Establishment Labs Holdings Inc. (Alajuela, Costa Rica)	2 (1.75)
GC Aesthetics PLC (Apt Cedex, France)	0 (0.00)
Allergan Inc. (Irvine, CA, USA)	35 (30.70)
Mentor Worldwide LLC (Santa Barbara, CA, USA)	4 (3.51)
Polytech Health & Aesthetics (Dieburg, Germany)	15 (13.16)
Sientra, Inc. (Santa Barbara, CA, USA)	1 (0.88)
Unknown	50 (43.86)
Surface	
Textured	97 (85.09)
Microtextured	7 (6.14)
Smooth	10 (8.77)
Non-applicable (saline breast implant)	0 (0.00)
Shape	
Anatomical	55 (48.25)
Round	59 (51.75)
Unknown	0 (0.00)
Location of pocket	
Subpectoral pocket	108 (94.74)
Subglandular pocket	6 (5.26)

Values are presented as number (%).

Sonographic findings of a breast implant

As shown in **Table 3**, the most prevalent manufacturer, surface and shape of a breast implant were ‘Allergan Inc. (30.70%, 35/114),’ ‘Textured (85.09%, 97/114)’ and ‘Round (51.75%, 59/114),’ respectively. Moreover, distribution of sonographic findings of the surface of a breast implant is shown in **Fig. 3**. Furthermore, there was an increase in the proportion of the patients receiving textured implants on sonographic findings as compared with their subjective awareness of it (78.95% vs. 85.09%). Sonographic findings of a textured implant are illustrated in **Fig. 4**.

Sonographic findings of complications of an implant-based augmentation mammoplasty

In our series, there were six cases of malrotation, 27 cases of folding, eight cases of seroma, 15 cases of capsule thickening, three cases of upside-down rotation, seven cases of rupture, one case of capsule mass and 76 cases of BM (**Table 4**).

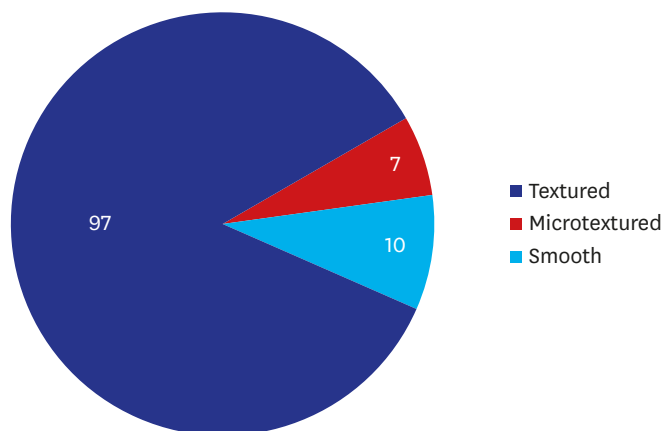


Fig. 3. Distribution of sonographic findings of the surface of a breast implant.

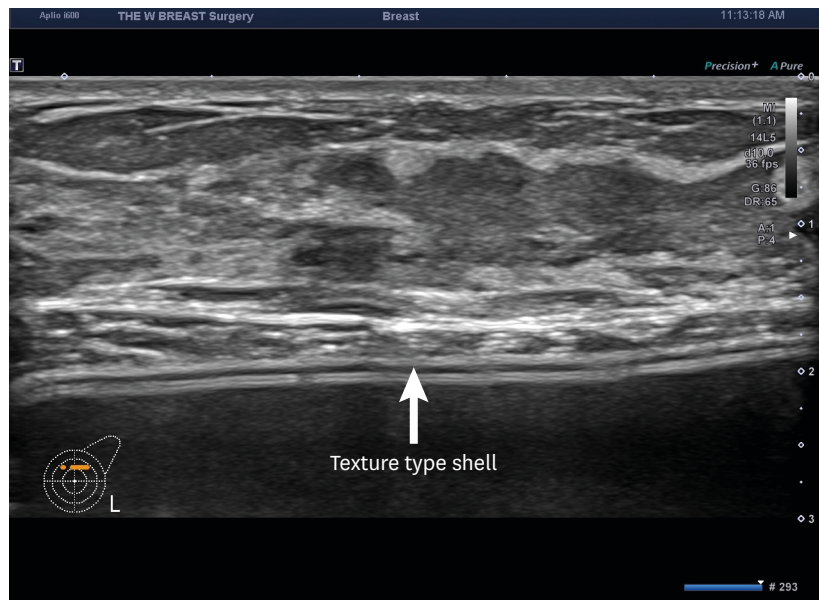


Fig. 4. Sonographic findings of a textured implant. Textured implants are visualized as hypoechoic images on breast ultrasound.

Table 4. Postoperative complications on breast ultrasound

Variables	Values
Malrotation	6 (5.26)
Folding	
Right side	7 (6.14)
Left side	8 (7.02)
Both sides	12 (10.53)
Seroma	
Right side	1 (0.88)
Left side	5 (4.39)
Both sides	2 (1.75)
Capsule thickening	
Right side	7 (6.14)
Left side	5 (4.39)
Both sides	3 (2.63)
Upside-down rotation	
Right side	1 (0.88)
Left side	1 (0.88)
Both sides	1 (0.88)
Rupture	
Right side	5 (4.39)
Left side	2 (1.75)
Both sides	0 (0.00)
Capsule mass	
Right side	1 (0.88)
Left side	0 (0.00)
Both sides	0 (0.00)
Breast mass	
Right side	16 (14.04)
Left side	14 (12.28)
Both sides	46 (40.35)

Values are presented as number (%).

DISCUSSION

The recent Allergan breast implant scandal reflects a chronic problem that may inevitably occur as a result of the interaction between the stakeholders in implant-based augmentation mammoplasty. In June of 2016, the Korean Ministry of Food and Drug Safety (KMFDS) approved the clinical use of the Motiva Ergonomix™ (Establishment Labs Holdings Inc., Alajuela, Costa Rica) whose safety has not been yet confirmed in Korean women. This was considered serious because medical devices would not be used for humans unless their safety is confirmed by the FDA in the US. The FDA approval process is well known for its rigorousness. The KMFDS routinely checks if a medical device is approved for its safety by the US FDA during the regulatory approval process. It is also no doubt that the FDA approval is not mandatory for the KMFDS one. But a sufficient level of safety should be ensured for the KMFDS approval of clinical use of a medical device in Korea.²⁵ Lack of safety studies also remains a serious problem in the US. As of March, 2019, the US FDA warned two manufacturers of a silicone gel-filled breast implant, the Mentor Worldwide LLC (Irvine, CA, USA) and the Sientra (Santa Barbara, CA, USA), of not conducting long-term safety studies although they were requirements for the regulatory approval by the US FDA.²⁶ This indicates that there would be a long way for both plastic surgeons and manufactures of breast implants to go if its safety is ensured for patients. On the other hand, the only Korean manufacturer of a silicone gel-filled breast implant, HansBiomed Co. Ltd. (Seoul, Korea), deserves special attention in that they dedicate themselves to assessing the safety of their products, the BellaGel®, in Korean women.^{27,28}

So-called “something-for-something relationship” between plastic surgeons and manufacturers of a breast implant could be found in the US. Shaped, textured breast implants belong to one of the best examples in this case.⁹ Disadvantages of shaped breast implants include a high rate of malrotation (42%), palpable margins, the possibility of causing double capsule and seroma and high cost as compared with their smooth round counterparts.^{29,30} Moreover, a high degree of vulnerability to BIA-ALCL and a lack of aesthetic advantage have also been reported to be problems due to the use of textured breast implants.³¹⁻³⁴ Over decades, however, textured, shaped implants have been reported to be better as compared with their lower-cost counterparts. This is in agreement with a previous published study showing that some plastic surgeons form a favorable relationship with manufacturers of a textured, shaped breast implant and are misled by them.³⁵

According to Swanson and Brown, the relationship with manufacturers of a breast implant could also be found in an industry-sponsored peer-reviewed article.¹² The authors of that article reported that complications (only one case of hematoma but no cases of malposition, pain, rippling, rupture, erythema and capsular contracture) occurred at an overall incidence of 0.3% and a reoperation rate of < 1% following the use of nano-textured, micro-textured implant in 4,103 cases of augmentation mammoplasty.³⁶ Although the authors of that article declared no conflict of interest relationship with the manufacturer, the corresponding author was designated as a medical advisor immediately after submission to a journal.¹²

In our series, a majority of the patients had a past history of receiving textured implants. The corresponding percentage was 78.95% (90/114) and 85.09% (97/114) based on their subjective awareness of a breast implant and sonographic findings. That is, it was slightly increased with the use of a breast ultrasound. This is of significance in that 38.60% (44/114) of the patients had a duration since surgery of 6–15 years during which BIA-ALCL may occur. Therefore, such

patients should be further evaluated for a risk of BIA-ALCL through our multi-disciplinary algorithm-based approach to an early detection of complications of an implant-based augmentation mammoplasty.

Currently, manufacturers of a breast implant face a crisis from the emergence of BIA-ALCL; they have been subject to myriads of external forces. To overcome this crisis, possible impacts of BIA-ALCL should be rigorously analyzed and appropriate measures should be taken as promptly as possible. We therefore propose the following approaches:

- 1) Patient data should be prospectively collected. By tracking outcomes and complications of an implant-based augmentation mammoplasty, both high-quality care and patient safety can be ensured.
- 2) Stakeholders in implant-based augmentation mammoplasty should collaborate with customers and regulatory authorities.
- 3) Surgeons should consider applying imaging modalities for early detection of complications of an implant-based mammoplasty. From this context, our multi-disciplinary, algorithm-based approach deserves special attention. In compliance with the National Comprehensive Cancer Network (NCCN) guidelines, we recommend that patients with an enlarged breast undergo ultrasound at an initial work-up. Thus, we evaluate them for whether they have fluid collection, a BM or enlarged regional lymph nodes (axillary, supraclavicular and internal mammary). Moreover, we consider the possibility of BIA-ALCL in patients with seroma of non-infectious or non-traumatic origin with a duration of > 1 year after an implant-based augmentation mammoplasty. In such patients, an ultrasound-guided fine-needle aspiration biopsy of seroma or surgical biopsy of capsule and seroma should be performed and then evaluated using immunohistochemistry for the purposes of establishing a diagnosis of BIA-ALCL. This should be followed by a positron emission tomography-computed tomography for the prevention of regional or systemic spread. According to the NCCN, both capsulectomy and implant removal should be considered as first line of treatment for the appropriate management of the affected capsule and a resectable mass. Moreover, chemotherapy should also be performed for patients with an advanced stage of BIA-ALCL involving local lymph or organ metastasis.

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