CANADIAN SOCIETY FOR AESTHETIC PLASTIC SURGERY
SOCIÉTÉ CANADIENNE DE CHIRURGIE PLASTIQUE ESTHÉTIQUE
70 Carson Avenue
Whitby, Ontario L1M 1J5
csapsoffice@gmail.com
Tel: (905) 655-9889; 1-800-263-4429
Fax: (905) 655-7319
www.csaps.ca

CANADIAN SOCIETY OF PLASTIC SURGEONS
SOCIÉTÉ CANADIENNE DES CHIRURGIENS PLASTICIENS
803 Laurier Avenue E. #2
Montréal, QC H2J 1G2
csps_sccp@bellnet.ca
Tel: (514) 843-5415; 1-800-665-5415
Fax: (514) 843-7005
www.plasticsurgery.ca

December 3, 2019

Dear CSPS and CSAPS Members:

Many members have written to us and asked for an update on BIA-ALCL. Below is a synthesis of the currently available data and literature on this issue, which supplements our previous advice. CSPS and CSAPS acknowledge that there may be geographical differences in available resources and specific expertise that may supersede the guidelines below and we continue to advise our members to remain current with the literature and interpret new scientific data using their own best judgment. Knowledge on BIA-ALCL is continuously expanding and, therefore, all information and guidelines including the below, are subject to change as additional data are emerging.

Much of the below information is derived from a webinar on November 4, 2019 that was organized by the Association of Specialists in Plastic and Aesthetic Surgery of Quebec with Dr. Mark Clemens as guest lecturer. We sent all members of CSAPS and CSPS an invitation to participate in this webinar. As most of you are aware, Dr. Clemens is a plastic surgeon who is affiliated with MD Anderson Cancer Centre in Texas and a world expert on BIA-ALCL. He provided the latest information about BIA-ALCL including the guidelines from NCCN (National Comprehensive Cancer Network) and the information from the First World Conference on BIA-ALCL that was held in Rome, Italy on October 6, 2019. Dr. Clemens was the co-chair of this conference.

Current known cases of BIA-ALCL (statistics as of August 2019):

There are 18 clusters around the world associated with BIA-ALCL. The cause of these clusters is not known.
USA 164 cases
Canada 31 cases
Remaining world 511 cases

BIA-ALCL cases causing death:

Canada 1 death
World 33 deaths

Incidence by implant texture type:

Macro textured implants (including Biocell) - all companies worldwide incidence is approximately 1:2200

Incidence by implant company in Canada:

Allergan Biocell incidence is approximately 1:3345
Mentor Siltex incidence is approximately 1:86,000

Ratio of incidence in Canada:
Biocell : Siltex is 25 : 1

To-date, there has never been a case of BIA-ALCL in a patient that has only ever had a pure smooth implant(s).
To-date, there is no association between BIA-ALCL and surgical technique at the time of implantation or an infectious cause.
To-date, there is no distinct microbiome associated with BIA-ALCL.
At present, no plastic surgery professional society in North America (CSPS / CSAPS / ASAPS) or ISAPS and no government agency (Health Canada / FDA) is suggesting or recommending the prophylactic removal of macro textured breast implants.

Presentation of BIA-ALCL:

BIA-ALCL may present as an effusion, mass, skin rash or ulcer in a patient who has had textured implants for greater than one year (peak incidence is 8 to 10 years). There is a bell curve distribution in the occurrence of BIA-ALCL ranging from 2 to 22 years post implantation with a peak at 8-10 years post-implantation.

It is normal in all breast implant patients to have 10 to 15 cc of fluid around all breast implants. In cases of BIA-ALCL there is usually 100 to 1000 ml of fluid around the implant.

Ultrasound seems an appropriate first test to evaluate the implant, the capsule, the chest wall and the adjacent lymph node basin. In addition, the contra-lateral breast implant should be assessed by ultrasound. If ultrasound detects any abnormality, MRI is the most appropriate follow-up investigation.

If fluid is present, a fine needle aspiration should be done under ultrasound control. The fluid should be sent for cytology, flow cytometry for T cell clones and, if available, IHC for CD30 and possible additional markers to differentiate further, if the aspirate is CD30 positive. When possible, aspirate 50 cc or more to increase the accuracy of the cytology. Availability of these tests may differ by regional differences in provinces and territories, as well as the presence of radiologic expertise.

If a mass is present, an incisional biopsy or core needle biopsy is indicated.

Possible diagnostic outcome scenarios of cytologic fluid aspirate:

Negative:
Cytology is negative for lymphoma, has normal cells and / or scant CD30 cells – benign.
No additional treatment required. Routine follow-up is recommended.
It is important to know that in 90 % of patients that present with a late seroma, it will be benign.

Inconclusive / Indeterminate:
If cytology is "inconclusive", it is advised to refer to a regional cancer centre for multidisciplinary assessment, consultation and further investigation.

Positive:
If cytology is positive for BIA-ALCL refer to regional cancer centre for multidisciplinary treatment.

Treatment:

Patients with biopsy proven BIA-ALCL require a multidisciplinary approach including an oncologist (lymphoma specialist), surgical oncologist, plastic surgeon and an oncologic haematologist.

Surgical treatment:
All cases require surgical intervention including en-bloc resection of the implant, capsule and surrounding tumour that extends beyond the capsule. Surgical treatment includes lymph node biopsy and / or removal.

In 85% of cases, the surgery will be definitive treatment.
It is currently acceptable to use a smooth implant at the time of reconstruction after treatment of BIA-ALCL.

Chemotherapy:
15% of patients will need adjunctive chemotherapy. Oncologists can consider either a standard approach for systemic ALCL (NCCN guidelines for first-line therapy of a peripheral T-cell lymphoma) such as combination anthracycline-based chemotherapy or, alternatively, a combination with brentuximab vedotin. Case reports have demonstrated favorable activity of brentuximab vedotin in BIA-ALCL, and the combination of anthracycline-based chemotherapy and brentuximab vedotin demonstrated an overall survival advantage compared with chemotherapy alone in the first-line treatment of CD30 expressing peripheral T-cell lymphomas in the ECHELON II trial 22-27. Based on the results of the ECHELON II trial, the addition of brentuximab is now considered "preferred" first line therapy for peripheral T-cell lymphomas. The determination of the most appropriate course of chemotherapy is generally outside the scope of plastic surgeons and should be initiated in conjunction with local oncologists.

Prophylactic removal of Biocell textured implants and the surrounding capsules:

There are currently no Plastic Surgery professional societies or government agencies (Health Canada / FDA) in North America that recommend the prophylactic removal of Biocell implants and the surrounding capsules.

At present, it is believed that an exchange of a patient's textured implants for smooth implants with or without partial or complete capsulectomy does **not** eliminate the risk of a patient developing BIA-ALCL. There have been two patients who underwent total capsulectomy and removal of their textured implants who developed BIA-ALCL at a later date (remote from the explantation and capsulectomy).

Prophylactic removal of textured implants for patient anxiety / fear / concern and not for established BIA-ALC has been associated with significant morbidity. Complications have included - but are not limited to - pneumothorax, exposure of the pericardium and damage to the subclavian vessels with significant intra-operative bleeding. The prophylactic removal of a submuscular grade I capsule is near impossible to do "en-bloc". When planning a prophylactic removal, we advise to discuss these risks with patients and, in particular, patients should be aware that a complete capsulectomy does not necessarily impart a "guarantee" that they will not develop BIA-ALCL at a later date.

After discussions with CMPA, it is recommended that all plastic surgeons document their complete discussion with patients seen in consultation for concerns about their textured implants and BIA-ALCL. This must include the current position of HC / FDA / CSAPS / CSPS / ASAPS / ASPS / ISAPS at the time of the consultation. It must also include full disclosure of the risks associated with surgery in general and those risks specific to the explantation with or without capsulectomy including those above. The consent document must also include information about the fact that the explantation of the implant (with or without replacement with a smooth implant) with or without a complete capsulectomy does not necessarily prevent someone from developing BIA-ALCL.

The reasons postulated for this development of BIA-ALCL after capsulectomy are:
The disease may be related to bacteria – possibly a gram-negative infection (unproven)
The disease may be related to particulate matter causing an exhaustive phagocytosis and the conversion of normal lymphocytes into lymphoma (unproven)
The disease may be related to a "toxin" aero hydrocarbon released from the implant that may bind to a receptor in susceptible individuals who possess this receptor (unproven)

All three of these potential causes can pass through an implant capsule, which is just a collagen sheath around the implant, and does not prevent the "seeding" of the adjacent tissue when the implant is in-situ.

Please refer to the following sources for additional information on BIA-ALCL:

March 2019 PRS

March 2019 ASJ

2019 NCCN Consensus Guidelines on the Diagnosis and Treatment of Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

Aesthetic Surgery Journal, Volume 39, Issue Supplement_1, March 2019, Pages S3–S13,
https://academic.oup.com/asj/article/39/Supplement_1/S3/5304919

Link to the First World Conference on BIA-ALCL October 6, 2019 in Rome, Italy

https://www.youtube.com/playlist?list=PLlPMloWRvwV-ZtmsU-hcO3x3M2gwMyflN&fbclid=IwAR31fJ2FqtbBi2Z_j33o-GB2vRkRG4Mzj6dZ3SBOu7X9h-30GTqbo4WQcQs

We hope that this letter provides a useful summary of the current state of knowledge around the diagnosis and treatment of BIA-ALCL. We encourage our members to continue to provide the best possible care for our patients.

Sincerely,

Bing Siang Gan MD, FRCSC
President
Canadian Society of Plastic Surgeons

Scott Barr, MD, FRCSC
President
Canadian Society for Aesthetic Plastic Surgery