





"BEST PRACTICES" BREAST IMPLANT ASSOCIATED ALCL

The incidence of Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) remains rare and current research is directed at fully clarifying the underlying etiology as well as disease treatment and prevention. Current research points toward the formation of biofilm on the surface of implants as a contributing etiology and thus far BIA-ALCL has been more commonly observed with textured implants. There is evidence that BIA-ALCL may have a genetic predisposition in different parts of the world and/or that it could be a lymphoproliferative disease, but because it is so rare and there are so few diagnosed patients, research into the etiology is difficult. Thus, there are a number of details in consensus that collectively may improve patient outcomes. The recommendations elaborated below are not intended to become a standard of care, but rather thoughtful considerations to be taken under advisement throughout the planning and performance of breast implant surgery. The recommendations are grouped into pre-operative planning, operative technique, post procedure care and follow-up.

PRE-OPERATIVE: A thorough informed consent is essential. This should include a complete medical and surgical history. A family history of malignancy including breast cancer should be ascertained along with medication history and allergies. The Informed Consent process should include discussion of BIA-ALCL with any implant surgery, allowing ample time to allow for patient questions and answers. Dimensional planning is critical in determining implant selection. It is important to set realistic goals and expectations. Financial considerations should be discussed in terms of the potential cost of follow-up, lab testing and imaging, as well as a discussion that breast implants are not lifetime devices. A revision policy should be reviewed and well documented, including possibly a ten year warranty for implant rupture. Surgery scheduling should be a team effort ensuring implant ordering, facility, recovery time, and patient instructions, and appointments.

PROCEDURE: Techniques that can minimize the introduction of bacteria onto the surface of the implant or into the surgical pocket should be employed. Limit unnecessary personnel in the Operating Room. Consider using intravenous antibiotic prophylaxis at the time of anesthetic induction. Perform a careful atraumatic dissection to help minimize devascularized tissue. Use nipple shields to prevent seepage of bacteria into the surgical field. Avoid dissection into the breast parenchyma in order to minimize the number of ducts transected and the potential for bacterial spillage. Perform thorough pocket irrigation and irrigate implants with an appropriate antimicrobial solution. Use skin barriers such as drapes, shields and introducer sleeves. Minimize the implant open time and the replacement of implant or sizers. Be sure to keep the breast implant packaging sealed as long as possible. Change surgical gloves prior to handling breast implants using a minimal touch precaution, and change instruments when reentering the pocket.

POST-OPERATIVE: Incision care and shape assessment is essential. A discussion should be held with the patient to reinforce the need for regular follow-ups and to stress the signs and symptoms such as erythema, swelling and breast size change that would warrant more immediate follow-up evaluation. The use of antibiotic prophylaxis to cover any subsequent procedures that breach skin or mucosa including dental prophylaxis should be considered.

Self-breast exam instructions and identification of tenderness between muscle, glandular breast tissue and capsule is helpful.

FOLLOW-UP: Any signs of unilateral swelling or mass should lead to a thorough evaluation. Always consider the possibility of BIA-ALCL when you evaluate a patient with late onset, peri-implant seroma. Ultrasound imaging followed by fine needle aspiration of seroma fluid should be obtained. Collected fresh seroma fluid should be sent to a qualified lab for immunohistochemistry testing for cluster of differentiation (CD30) testing. Anaplastic Lymphocyte Kinase (ALK) testing of the seroma fluid can help differentiate BIA-ALCL from systemic forms of lymphoma that may appear in the breast. Most patients with BIA-ALCL are cured by removal of the implant and capsule surrounding the implant, however a small number act more aggressively and may require additional treatments. At the time of surgery capsule tissue should be sent for pathological evaluation. Always consider a second opinion. Develop an individualized treatment plan in coordination with a patient's multidisciplinary care team. Any confirmed cases of BIA-ALCL should be reported to the <u>PROFILE registry</u>, the <u>FDA MAUDE database</u> and implant manufacturer.

- Biomarkers Provide Clues to Early Events in the Pathogenesis of Breast Implant Associated Anaplastic Large Cell Lymphoma, M. Kadin, A. Deva, et.al., Aesthetic Surgery Journal 2016, Vol 36(7) 773-781.
- Breast Implant–Associated Anaplastic Large Cell Lymphoma: Report of 2 Cases and Review of the Literature, A. Hart, et.al., Aesthetic Surgery Journal 2014, Vol. 34(6) 884 –894© 2014.
- Lymphomas Associated with Breast Implants: A Review of the Literature, A. Rupani, et.al., Aesthetic Surgery Journal 2015, Vol 35(5) 533–544.
- Anaplastic large cell lymphoma occurring in women with breast implants: Analysis of 173 cases. Brody GS, et.al. Plast Reconstr Surg. 2015;135:695–705.

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