

ASPS Statement on Breast Implant Specimens and Pathology

Background

Since 2010, approximately 1,400,000 breast augmentation procedures, 475,000 breast reconstruction procedures, and over 195,000 combined augmentation and reconstructive breast implant removals were performed by ASPS member surgeons.ⁱ Since the introduction of saline and silicone-gel filled breast implants in the 1960's, decades of research related to safety and efficacy have contributed to several generations of improved breast implant devices.^{ii,iii,iv,v,vi} Scientific literature continues to research the risks and possible associations of breast implants and clinical complications.

BIA-ALCL

Breast implant-associated Anaplastic Large Cell Lymphoma (BIA-ALCL) is a rare lesion presenting as a late seroma, a palpable mass, or less commonly, tumor positive lymphadenopathy.^{vii} In 2011, the U.S. Food and Drug Administration (FDA) released a safety communication that women with breast implants “may have a very small but increased risk of developing this disease in the scar capsule adjacent to the implant.”^{viii} An update in 2016 reported that 258 BIA-ALCL adverse event reports have been received to the FDA, and emphasized that physicians should report all confirmed cases to both the FDA and the PROFILE registry. Over 118 distinct case reports of BIA-ALCL have been published, and MD Anderson Cancer Center recognizes 160 pathologically confirmed BIA-ALCL cases worldwide from fifteen countries and the University of California has accumulated approximately 200 BIA-ALCL cases.⁹ Currently, all cases with adequate records for confirmation have involved a textured device. Associational research has shown no preference for aesthetic versus reconstructive surgeries or saline versus silicone gel devices.^{ix,x} The Plastic Surgery Foundation, the American Society of Plastic Surgeons and the FDA have created the PROFILE Registry (Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma etiology and Epidemiology). This Registry will increase the scientific data on BIA-ALCL, support research characterizing BIA-ALCL, and elucidate the role of breast implants in the etiology of the disease. Treating physicians are encouraged to report confirmed cases to the PROFILE Registry at www.thepsf.org/PROFILE.

Recommendation

In suspicious or confirmed cases of BIA-ALCL, The American Society of Plastic Surgeons recommends and encourages member surgeons to always submit breast implants, capsule, and effusion to pathology for examination. This is consistent with recommendations from the College of American Pathologists.^{xi} Surgeons should request that pathology laboratory perform CD30 immunohistochemistry of effusions and scar capsules in cases suspicious of an ALCL malignancy, such as spontaneous late seromas occurring after implantation.^{xii}

ⁱ American Society of Plastic Surgeons. (2014). 2014 Plastic surgery statistics report. Retrieved from <http://www.plasticsurgery.org/Documents/news-resources/statistics/2014-statistics/plastic-surgery-statistics-full-report.pdf>

ⁱⁱ Stevens, W.G., Harrington, J., Alizadeh, K., Broadway, D., Zeidler, K., & Godinez, T.B. (2015). Eight-year follow-up data from the U.S. clinical trial for Sientra's FDA-approved round and shaped implants with high-strength cohesive silicone gel. *Aesthetic Surgery Journal*, 35 Suppl 1:S3-10.

ⁱⁱⁱ Caplin, D.A. (2014). Indications for the use of MemoryShape breast implants in aesthetic and reconstructive breast surgery: Long-term clinical outcomes of shaped versus round silicone breast implants. *Plastic and Reconstructive Surgery*, 134 (3 Suppl): 27S-37S.

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- ^v Spear, S.L., Murphy, D.K. (2014). Natrelle round silicone breast implants: Core study results at 10 years. *Plastic and Reconstructive Surgery*, 133(6), 1354-61.
- ^{vi} Kinney, B.M., Jeffers, L.L., Ratliff, G.E., & Carlisle, D.A. (2014). Silicone breast implants: Science and testing. *Plastic and Reconstructive Surgery*, 134(Suppl): 47S-56S.
- ^{vii} Clemens MW, Medeiros LJ, Butler CE, et al. (2016) Complete Surgical Excision Is Essential for the Management of Patients With Breast Implant-Associated Anaplastic Large-Cell Lymphoma. *J Clin Oncol.* 10;34(2):160-8.
- ^{viii} United States Food and Drug Administration. (2011). Anaplastic large cell lymphoma (ALCL) in women with breast implants: Preliminary FDA findings and analyses. Retrieved from <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239996.htm>
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- ^x Thompson, P.A., & Prince, H.M. (2013). Breast implant-associated anaplastic large cell lymphoma: A systematic review of the literature and mini-meta analysis. *Current Hematologic Malignancy Reports*, 8(3), 196-210.
- ^{xi} College of American Pathologists. (2007). Surgical specimens to be submitted to pathology for examination. Retrieved from http://www.cap.org/apps/docs/laboratory_accreditation/build/pdf/surgical_specimens.pdf
- ^{xii} Miranda, R.N., Aladily, T.N., Prince, H.M., Kanagal-Shamanna, R., de Jong, D., Fayad, Le., et al. (2014). Breast implant-associated anaplastic large-cell lymphoma: Long-term follow-up of 60 patients. *Journal of Clinical Oncology*, 32(2), 114-120.