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# A 1-Point Plan to Eliminate Breast Implant–Associated Anaplastic Large-Cell Lymphoma

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Adams et al[1] report no cases of breast implant–associated anaplastic large-cell lymphoma (BIA-ALCL) among 21,650 patients treated with Biocell (Allergan plc, Dublin, Ireland) textured breast implants. Eight plastic surgeons contributed their "prospective" experience, with an average follow-up time of 11.7 years (range, 1–14 years). These surgeons were reportedly all routinely using at least 13 points of the authors' 14-point plan (2 surgeons did not prescribe antibiotics for subsequent procedures).[1] This claim is remarkable because the 14-point plan (since modified[1]) was published in 2013[2] and because it would be unlikely to find one surgeon who diligently followed this 14-point plan and did so without modification for up to 14 years. In truth, Mallucci,[3] a coauthor, was not using nipple shields or an introduction sleeve, but was using drains (violating points 3, 9, and 12) in 2013. Jewell, another contributor, was also using drains according to an article published in 2010.[4] Both surgeons prefer a prepectoral placement in some patients (violating point 7). Augmentation mastopexy, performed in 9.9% of patients, includes a dissection into the breast parenchyma (violating point 6). Atraumatic dissection (point 4) in these patients is an oxymoron.

The 2.2% capsular contracture rate[1] mirrors the 2.3% rate after breast augmentation recently reported by McGuire et al[5] for a large series of women treated with Allergan Natrelle 410 implants by surgeons who did not follow the 14-point plan.

The authors believe that their 14-point plan "will likely reduce the risk of implant-associated ALCL."[1] Retrospective studies such as this one invite the cherry-picking of patients that conform to the investigators' preferred outcome. Obviously, one could group together cases from other surgeons who do not use the 14-point plan and have encountered no cases of BIA-ALCL.

The mean follow-up time was extraordinarily long, 11.7 years, compared with 4.1 years for the large study by McGuire et al.[5] The inclusion rate is unreported. Usually average follow-up times are much shorter, reflecting the large number of patients who are lost to follow-up early on and the relatively few who return for follow-up 10 years or more after surgery.

An infectious etiology is by no means certain. Hu et al[6] found no more bacteria (in fact, less) in capsules from BIA-ALCL specimens than from capsular contracture specimens. Notably, in 3 women, Hu et al[6] reported the bacterial count from the control side but not the affected side. A sample size of 3 patients is insufficient to make any reliable conclusion, especially without normally distributed data.

Lista[7] has abandoned textured devices out of concern for BIA-ALCL risk. Hall-Findlay,[8] Hidalgo and Weinstein,[9] and I believe that macrotextured implants should no longer be offered to our patients. What is the commonality that links the opposition? Unlike the authors, 6 of whom are Allergan consultants,[1] none of us is burdened by a financial conflict of interest.[7–9] Plastic surgeons who have extolled the advantages of shaped, textured implants for decades find it difficult to accept that they were misled by the industry and allowed themselves to be misled. The fact that Allergan recently introduced a smooth round gummy alternative speaks for itself.

The authors' conclusion that the "technique is a critical factor"[1] remains unsupported. Ironically, the 14-step plan omits the only factor that is known to be associated with an increased risk of BIA-ALCL, a textured device. It is time for plastic surgeons to adopt a 1-point strategy to eliminate BIA-ALCL.

## REFERENCES

1. Adams WP Jr., Culbertson EJ, Deva AK, et al. Macrotextured breast implants with defined steps to minimize bacterial contamination around the device: experience in 42,000 implants. *Plast Reconstr Surg*. 2017;140:427–431.
2. Deva AK, Adams WP Jr, Vickery K. The role of bacterial biofilms in device-associated infection. *Plast Reconstr Surg*. 2013;132: 1319–1328.
3. Mallucci P. Inframammary fold aesthetics and placement. Paper presented at the Meeting of the American Society of Plastic Surgeons; October 11–15, 2013; San Diego, California.

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4. Jewell ML, Jewell JL. A comparison of outcomes involving highly cohesive, form-stable breast implants from two manufacturers in patients undergoing primary breast augmentation. *Aesthet Surg J*. 2010;30:51–65.
5. McGuire P, Reisman NR, Murphy DK. Risk factor analysis for capsular contracture, malposition, and late seroma in subjects receiving Natrelle 410 form-stable silicone breast implants. *Plast Reconstr Surg*. 2017;139:1–9.
6. Hu H, Johani K, Almatroudi A, et al. Bacterial biofilm infection detected in breast implant–associated anaplastic large cell lymphoma. *Plast Reconstr Surg*. 2016;137:1659–1669.
7. Lista F. Panel: Proactively managing complications before they manage you. Paper presented at the Meeting of the American Society for Aesthetic Plastic Surgery; April 27–May 2, 2017; San Diego, California.
8. Hall-Findlay E. Textured vs. smooth implants in breast augmentation. Paper presented at the American Society of Plastic Surgeons Breast and Body Contouring Symposium; August 10–12, 2017; San Diego, California.
9. Hidalgo D, Weinstein A. Reply: discussion on "Intraoperative Comparison of Anatomical Versus Round Implants in Breast Augmentation: A Randomized Trial". *Plast Reconstr Surg*. 2017;140:828e.