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The Textured Breast Implant Crisis

A Call for Action

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On March 25 and 26, 2019, the US Food and Drug Administration plans to review the safety of breast implants. First and second on the agenda are breast implant–associated anaplastic large cell lymphoma (BIA-ALCL) and systemic symptoms reported in patients receiving breast implants.[1] This meeting takes place in the wake of a compulsory recall request from the Agence Nationale de Sécurité du Médicament, banning Allergan's Biocell (Allergan plc, Dublin, Ireland) textured breast implants in Europe.[2] Simultaneously, 2 plastic surgery journals are publishing industry-sponsored supplemental issues devoted to this topic.[3,4] The views regarding BIA-ALCL reflect heavily the perspective of Dr Anand Deva, a coeditor,[3] who disagrees with a ban on textured implants.[5] The mainstream view, calling for additional study while textured implants remain available, has been met with a challenge from plastic surgeons who believe that it is time (indeed, well past time) to abandon textured devices.[6–8] This subject serves as a case study of the pervasive influence of commercial interest in plastic surgery through funding investigators, journal editors, and even our scientific publications.[9]

Deva laments a "never-ending cycle" of breast implant crises.[5] Critics of textured implants, he believes, are motivated by emotion and fear, not science.[5] Deva contends that those of us who are not informed by reason cannot be persuaded by reason,[10] and that focusing on texture is simplistic and wrong.[5,10] He cautions that the recent French regulatory action has caused a "crashing halt as we head down a path that leads to increasing uncertainty and fear."[5] Deva prefers to continue publishing articles on this topic and presenting at meetings.[5] However, we cannot allow women to be unnecessarily harmed while we collect data. Capsulectomies, positron emission tomography and computed tomography, the cost of medications (brentuximab is very expensive), and the emotional and financial impact of BIA-ALCL take a heavy toll on affected women, even if the disease is seldom fatal.[8]

Deva believes that funding for implant evaluation should come from industry, which "has a social responsibility to do the right thing."[5] Perhaps, but plastic surgeons share that responsibility and should not outsource it to regulators, implant companies, or the legal system. It is unwise to let the implant manufacturer decide the merits of its product. Allergan disagrees with the French action and defends the safety of its textured implants as not creating any "immediate" risk for women.[2] Of course, the concern is the long-term risk.

Deva insists that his research is funded by industry but "free from any commercial strings."[5] His microbiological studies seek an infectious etiology for BIA-ALCL.[11] Plastic surgeons are blamed for failing to observe adequate surgical sterility rather than finding fault with the device.[8] The 14-point plan is offered as a remedy by authors that include 6 Allergan consultants.[12] Ironically, none of the points call for avoiding textured implants—the only factor known to be associated with BIA-ALCL.[7,13] A 1-point plan is sufficient.[13] Deva believes that removing implants from the marketplace, after they have been approved already, does considerable harm to patients and limits their choice.[5] He notes that textured implants were introduced to "counter some of the significant complications and high reoperation rates that we saw with smooth implants." Deva erroneously references 2 studies published in 2006 to support a benefit in longevity and outcomes, and fewer revisions using textured devices.[14,15] These meta-analyses reported a significantly decreased capsular contracture rate for textured implants, but only when placed above the muscle.[14,15] Neither review found more favorable longevity, outcomes, or fewer revisions with textured implants.[14,15] On the contrary, Barnsley et al,[14] in their meta-analysis, found no significant difference in complications comparing textured and smooth devices. Wong et al[15] reported that women preferred smooth implants because they were less palpable and less visible.

Today, we know that textured implants have not fulfilled their early promise. Hall-Findlay[16] discovered late seromas and double capsules around Biocell implants. Van Slyke et al[17] recently revealed that Biocell implants had the shortest times to explantation and the greatest risk of performance failure, including malposition, malrotation, seroma, rippling, capsular contracture, rupture, pain, and double capsules. All 45 double capsules occurred around Biocell implants. The frequency of pain in women undergoing explantation was a new finding, reported by 21.1% of women with Biocell

Received February 27, 2019, and accepted for publication, after revision March 13, 2019.
Private Practice, Leawood, KS.
Conflict of interest and sources of funding: The author receives royalties from Springer Nature (Cham, Switzerland). The author received no financial support for the research, authorship, and publication of this article.
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ISSN: 0148-7043/19/8206–0593
DOI: 10.1097/SAP.0000000000001963

implants versus 1.4% for other implants. Sieber et al,[18] in an ultrasound study of textured, shaped Mentor (Irvine, California) CPG and Allergan 410 (Biocell) implants, reported a 42% rate of implant malrotation. These studies were not funded by industry, and the authors reported no conflict of interest.[16–18]

At a recent meeting, Deva showed a slide featuring Miss Piggy, the Muppets character, in the operating room, with the implication that plastic surgeons do not practice adequate sterile technique.[19] He seems unpersuaded that the breast is a clean-contaminated environment, populated by commensal bacteria, making anything more than standard operating room sterility extraneous.[7] Many of the 14 points[12] do not make much sense, such as "minimize implant open time" and "use a dual-plane pocket" to avoid contamination from breast tissue by placing it in a plane that is partly touching the muscle and partly touching breast tissue. Without a known break in sterility, where is the logic in replacing sterile instruments, gloves, and drapes with sterile instruments, gloves, and drapes? In truth, none of the 14 points have been shown to have any relationship to BIA-ALCL.[7,13,19]

Some surgeons are concerned that abandoning textured implants and mailing warning letters to patients might create a panic. Potochny et al[20] have demonstrated that this concern is unfounded. After mailing 264 letters to women with textured implants, 9 women chose to remove or replace their textured devices.[20] The panic, or rather outrage, is much more likely to occur when women discover that they are not being properly informed of the risk and alternative options (ie, smooth implants).

As if matters were not bad enough with BIA-ALCL to worry about, an article published in *Annals of Surgery* concludes that breast implants, and specifically Mentor breast implants, carry an increased risk of rheumatic arthritis, scleroderma, Sjogren syndrome, melanoma, overall cancer, and neurological disorders.[21] The findings are undermined by flawed methodology and an undisclosed conflict of interest.[22] Questions regarding implant safety were answered after the first breast implant crisis in 1992. Several large reputable studies found that breast implants do not cause systemic illnesses or cancer.[22]

Failure to act on a faulty device risks painting all breast implants with the same brush. The unfortunate publication by Coroneos et al[21] is likely to cause unnecessary alarm and may jeopardize the availability of any breast implant, smooth or textured. Such an outcome would certainly not be in anyone's best interest.

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