

Silicone Particle Migration: A Misleading Report

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Research Consortium

Aesthetic Surgery Journal
2022, Vol 42(4) NP261–NP262

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Editorial Decision date: October 19, 2021; online publish-ahead-of-print October 25, 2021.

In a case series by Dijkman et al published recently in *JAMA Network Open*, investigators analyzed the presence of silicone particles in and around capsular tissue and lymph nodes of explanted silicone breast implants (SBIs).¹ They compared tissues of patients with implants containing liquid silicone (n = 343) with tissues of patients with modern cohesive gel implants (n = 46). In the overwhelming majority of cases (98.7%), silicone particles were present. In their report, the authors allude to a number of health issues that have been linked to SBIs since the early 1960s. With the exception of the extremely rare breast implant-associated anaplastic large cell lymphoma, none of these associations have been substantiated in thorough epidemiologic investigations.^{2,3} Nevertheless, the authors conclude their report with a call for an immediate ban on the utilization of all SBIs. We believe this appeal to result from a non sequitur. On behalf of the Dutch BIA-ALCL Research-Consortium, we would like to touch briefly on 3 concerns.

Firstly, the procedure to identify the cases has most likely resulted in a significant bias. As described by Dijkman et al, cases were retrieved from their institutional pathology database, which is part of the Pathological Anatomical National Automated Archive, in which all pathology reports in the Netherlands are coded and archived, with national coverage since 1990.⁴ Pathological Anatomical National Automated Archive allows for structured and complete searches and retrievals, both based on coded and textual information from pathology reports as submitted by the primary pathologists. In the present search, “breast” and “silicone” were included as search parameters. Thereby,

all cases were retrieved in which the original pathologist observed and reported silicone particles in breast tissue, whereas those without clearly visible or reported silicone material were excluded from the selection. This readily explains the very high rate of over 98% of cases with silicone particles and causes circular argumentation. Moreover, it is remarkable that data are based largely on original, non-protocolized pathology reports. The majority of these are from a different era of practice and far from meeting modern quality standards. Inevitably, this large variety of quality and reported detail precludes conclusions on the extent of silicone deposition, fibrosis, and composition and extent of inflammatory and macrophage infiltrates as suggested in the present publication.

The call by Dijkman et al to stop the utilization of silicone implants rests on the argument that both liquid and cohesive gel implants “bleed,” a conclusion that we refute on the arguments above. Moreover, a second essential

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weakness of the study is the lack of clinical data, especially concerning the indication for implant removal. Employing the same search strategy, 343 capsules related to implants with non-cohesive silicone were retrieved over a period of approximately 10 years (1986-1995/1999), whereas only 46 cohesive silicone implant-related capsules were retrieved in a subsequent 20-year period (1999-2020). This suggests a significant bias with a relation between risk of capsulectomy and type of implant. The fact that the study sample is likely not representative of the average woman with breast implants has already been appreciated by Löfgren et al.⁵ Women who opt for explantation most likely belong to a select population of individuals experiencing significant SBI-related complications or complaints.

Lastly, in reference to the discussion by Dijkman et al, we would like to remark that the mere presence of silicone particles in no way supports an association with complaints. Moreover, observational studies including appropriate comparison groups do not show a difference in prevalence of non-specific complaints between women with and without SBIs.^{6,7} Meticulous studies in large, unselected groups of women need to either confirm or refute the existence of the controversial syndrome that breast implant illness is. In the Netherlands, several hospitals are currently collaborating to provide more insight into these important questions.

Many women experience serious adverse effects in terms of psychological, emotional, and sexual well-being after breast cancer surgery and for those reasons choose for breast implants. Indeed, the literature provides ample evidence of improved quality-of-life outcomes in a large majority of these women as well as in the many women who chose breast implants for cosmetic reasons.^{8,9} Therefore, any potential adverse effect of SBIs must always be carefully weighed against the benefits of SBI-based reconstructions. Unsubstantiated potential ill effects should not be included in such considerations.

Acknowledgments

The Dutch Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL) Research Consortium includes Marc A.M. Mureau, MD, PhD, professor of oncologic reconstructive surgery, Erasmus University Medical Center, Rotterdam; René R.W.J. van der Hulst, MD, PhD, professor of plastic and reconstructive surgery, Maastricht University Medical Center, Maastricht; Hinne Rakhorst, MD, PhD, Department of Plastic and Reconstructive Surgery, Medisch Spectrum Twente, Enschede; Mintsje de Boer, MD, Department of Plastic and Reconstructive Surgery, Maastricht University Medical

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Disclosures

The authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

Funding

The authors received no financial support for the research, authorship, and publication of this article.

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