



## Invited Discussion: A Review of the Literature on the Management of Silicone Implant Incompatibility Syndrome

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Received: 13 June 2019/Revised: 13 June 2019/Accepted: 18 June 2019/Published online: 9 July 2019  
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The possibility that silicone gel breast implants could play a role in causing an adverse immunologic reaction in selected patients was first postulated in the early 1990s. This led to a moratorium on the use of these devices for many years, with only selected indications being deemed acceptable by the FDA while further study of the issue was undertaken. The ultimate findings of these comprehensive studies were that there was no convincing scientific evidence that silicone gel breast implants resulted in immunologic disease in humans. This resulted in the ultimate re-introduction of these devices which now are used across the world for both aesthetic and reconstructive breast surgery.

Recent findings have re-raised the issue of whether or not silicone gel implants cause immunologic disease. As a result, women are once again consulting with physicians requesting that their implants be removed in an attempt to treat a host of presenting symptoms. This paper reviews the available literature related to the results of treatment in these women, using both medical and surgical means. It is a timely review and merits further comment.

As was noted during the initial experience with this issue nearly 30 years ago, the presenting symptoms for

these patients remain vague and difficult to quantify. These symptoms, which are outlined in the paper, including myalgias, arthralgias, chronic fatigue, sleep disturbance and cognitive impairment, are largely subjective; therefore, accurate documentation as to severity and response to treatment becomes uncertain at best and impossible at worst. Therefore, any attempt to develop an effective treatment for these symptoms is based on such a level of uncertainty that any reporting of results has next to no scientific merit and basically becomes a reporting of subjective impressions. This environment is subject to a host of confounding variables including a vast variety of personality subtypes, the placebo effect and more social concerns including medico-legal confounding variables and interested parties that have various conflicts of interest. All of these factors make it difficult to provide accurate and effective counsel to patients who present with these symptoms and who also have silicone gel breast implants. This endeavor is only made more difficult by the rise of social media and great amount of misinformation and hearsay that is reported under the guise of sound medical advice or reporting.

What can be proposed when consulting with symptomatic women who are requesting that their implants be removed is nicely outlined in the paper. First, the presenting symptoms must be taken seriously and potential alternative diagnoses investigated as much as can be done using standard medical knowledge. It is here that a qualified internist, rheumatologist, immunologist or other health care professional can be of great assistance in outlining a diagnostic plan including blood work and imaging trying to identify well more recognized disease patterns such as rheumatoid arthritis or other connective tissue diseases. Building the framework of a proper workup will allow

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appropriate follow-up to assess the effectiveness of any given treatment. In the absence of any identifiable disease process, the issue of implant removal becomes problematic. As noted in the paper, the goal of this review was not to document an association between breast implants and symptomatic immunologic disease, but rather to assess the results of treatment. When one is uncertain whether the proposed disease even exists let alone how it might be associated with silicone gel breast implants, any recommendation for implant removal as a form of treatment amounts to an educated guess. As a result, and as noted in the paper, the results of implant removal often play little to no role in alleviating symptoms. This is further complicated by the fact that simple removal is generally considered to be incomplete treatment with full capsulectomy being required to completely remove any silicone penetration into the capsule. Full capsulectomy requires additional dissection that can result in bleeding, hematoma formation, infection, deformity and the need for a postoperative drain. This additional morbidity associated with full capsulectomy must be taken into account, and the decision to undergo this procedure cannot be taken lightly.

In summary, this paper highlights an important facet of caring for the modern breast implant patient. The issues surrounding the potential association of breast implants with immunologic disease are summarized well and the recommendations for treatment evenly presented. To avoid the misinformation and interruption in available treatment options for both aesthetic and reconstructive breast patients that occurred during the early 1990s, it is imperative that we as plastic surgeons now demand that further implant design modifications and recommendations for use be based on sound scientific data. Only then will we be able to adequately care for our patients.

#### **Compliance with Ethical Standards**

**Conflict of interest** Dr. Hammond has a consulting agreement with the Mentor Corporation, Establishment Labs, Pathay Medical, W.L. Gore, The Musculoskeletal Transplant Foundation.

#### **Statement of Human and Animal Rights or Ethical Approval**

This article does not contain any studies with human participants or animals performed by any of the authors.

**Informed Consent** For this type of study, informed consent is not required.