

PAPER

Destiny rides again: the reappearance of silicone gel-filled breast implant toxicity

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Background: Twenty-five years ago attorneys representing ailing women in class action litigation against silicone breast implant manufacturers made the procedural error of defining silicone-induced toxicity in the courtroom before it was properly studied in the exam room. This aberrant methodology perverted the proper research process, rendered verification of any real disease elusive, and cemented the groundwork for a repeat public health crisis potentially affecting two million women in the USA who possess new silicone gel devices inserted over the past 10 years. **Patients and methods:** Six women, previously well, aged 27 to 53 (mean 42), were recipients of the new generations of cohesive silicone gel-filled breast implants approved for general use by the Food and Drug Administration (FDA) since December of 2006. They averaged seven years of total implantation time, and none experienced implant rupture. **Results:** All six became ill on average 3.5 years from the time of implantation. By seven years the women manifested multiple types of skin rashes, polyarthritis, fatigue, protracted AM stiffness, myalgias, headaches, photosensitivity, hair loss, paresthesias, tinnitus, lymphadenopathy, chest pain, cognitive dysfunction, dry eyes, skin pigment changes, itching, muscle twitching, dizziness, nausea, easy bruising, and odor and smell sensitivity. Three of the four who were explanted noted improvement and/or resolution of at least 50% of their total disease manifestations. **Conclusions:** These six women are representative of over 70,000 other breast implant recipients who, over the past three years, have had their new silicone devices permanently removed because of alleged gel-induced toxicity. The recurrence of this public health crisis has been fueled by manufacturers' research fraud, FDA ineptness, faulty informed consent, patient abandonment, proprietary manufacturing secrecy, misleading advertising, physician indifference, aberrant research methodology, and lax Congressional oversight. *Lupus* (2017) 0, 1–4.

Key words: Silicone; breast implants

Introduction

In 2012 an editorial analyzed the controversy from 25 years ago that surrounded assertions of systemic toxicity caused by silicone gel-filled breast implants manufactured in the 1970s and 1980s.¹ This analysis detailed multiple critical investigative errors, but in particular also scrutinized the methodology of attorneys forging the class action litigation against implant manufacturers who defined the disorder in the courtroom before it was properly studied in the exam room. Their expectation that

silicone toxicity would translate into classical connective tissue diseases was based on faulty and premature assumptions, which was then compounded when the legal definition became adopted as the medical definition. This aberrant methodology was seized upon by independent investigators² and multiple erudite scientific panels³ whose conclusions led to the erroneous perception that silicone-induced disease had been permanently laid to rest. In the end the attorneys were monetarily successful in rewarding their ailing clients, but for most clinicians the identification and verification of any legitimate illness linked to breast implants remained elusive. The groundwork was now cemented for an inevitable recurrence of this previous public health debacle.

In December of 2006, after a moratorium lasting 14 and a half years, the Food and Drug

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Administration (FDA) gave approval to Allergan and Mentor to market their new cohesive silicone gel-filled breast implants for general use. Subsequently, beginning in 2007 (i.e., after the fact), the FDA mandated that these manufacturers perform 10-year prospective studies on 80,000 women to determine the safety of these devices. Over 1000 plastic surgery centers were utilized for this process, without the scrutiny of internists. During the informed consent process, proprietary manufacturing details encompassing the synthesis of silicone gel (utilizing chemicals known to be neurotoxins and carcinogens) were not disclosed to implant recipients.⁴ At the halfway mark of these prospective studies, via the Freedom of Information Act, it is now known that the FDA had received data indicating that between 50% and 75% of implanted women in these study groups were complaining of systemic ailments.⁵ Virtually all of these women have subsequently been lost to follow-up, and recent patient information pamphlets distributed by manufacturers to prospective recipients are devoid of these facts.⁴

Patients and methods

Six women, aged 27 to 53 (mean 42), who were recipients of these new cohesive silicone gel-filled breast implants, were examined by this author. They averaged seven years of total implantation time, and each one complained of numerous systemic ailments at the time of presentation. Three had bilateral breast reconstruction after bilateral mastectomies for ductal carcinoma in situ. Two had unilateral reconstruction after a mastectomy for cancer. One was cosmetically enhanced bilaterally. None of the six had any symptoms of systemic illness prior to implantation, and none experienced implant rupture. The ethical committee at Monmouth Medical Center did not require prior approval for this study.

Results

The interval from the time of implantation to the onset of systemic complaints was an average of 3.5 years. By seven years the women manifested an average of 14 symptoms and signs. These encompassed multiple types of skin rashes, polyarthritides, fatigue, protracted morning stiffness, myalgias, headaches, photosensitivity, hair loss, tinnitus, paresthesias, chest pain, lymphadenopathy,

cognitive dysfunction, dry eyes (documented by a positive Schirmer test), skin pigment changes, itching, muscle twitching, dizziness, nausea, easy bruisability, and odor and smell sensitivity. Exhaustive immunologic, neurologic, endocrinologic, hematologic, and cardiac evaluations failed to reveal a recognizable textbook explanation for these phenomena. Four of the women have been completely explanted after an average seven years device insertion, with 2.5 years of subsequent follow-up. Improvement and/or resolution of at least 50% of their total disease manifestations has occurred in three of the four. During the entire observation period there has been no evidence for any recurrent or new anaplastic process in any of the women.

Discussion

In the past three years several new websites in North America have begun providing interactive complaint forums for the two million women in the USA who have had the new generations of cohesive silicone gel-filled breast implants inserted into their bodies within the past 10 years.⁶ Online allegations of repetitive silicone-induced ailments have been escalating ever since, all of which are eerily similar not only to phenomena exhibited by these six women but also to phenomena reported in publications from the 1990s and more recently.⁷⁻¹¹ The diversity of symptoms and signs in these six women is a reflection of the multiple biochemical and toxicological mechanisms of silicone-induced disease causation, which have little or nothing to do with autoimmunity.⁸ The novelty and validity of their silicone-induced illness relies on a variety of fundamental observations, including (but not limited to): (a) fulfillment of the Bradford Hill criteria for causation;¹² (b) the unique and reproducible disease development curve, which evolves in a pattern simulating a dose response curve and has intrinsic validity unto itself;⁷ (c) none of the women's ailments preceded implantation; (d) none of the women's ailments could be attributed to any other well-defined medical entity; (e) there was no evidence for any recurrent or new anaplastic process; and (f) the documented improvement in three of the four women who underwent explantation. This improvement and/or resolution of at least 50% of their total disease manifestations is similar to a prior report examining improvement of systemic phenomena following removal of gel-filled devices (whereby longer durations of implantation

time were related to less clinical improvement).¹⁰ Other investigators have also reported on incomplete resolution of systemic ailments following explantation.¹¹

Despite manufacturing claims of tight gel cohesiveness and complete inertness of their new products, a recent publication described dramatic changes of gel properties in new breast implant devices over time.¹³ Thus, over time, these new generations of breast implants can become slow delivery systems indistinguishable from the gel bleed of devices manufactured in the 1970s and 1980s.¹⁴ It has previously been asserted that the onset of silicone-induced disease is related to this microdispersion and occurs prior to any overt device rupture.⁷ This report is consistent with the findings of that earlier publication. Although extensive inflammatory and immunologic responses to gel bleed have been identified in the peri-prosthetic tissues surrounding breast implants,¹⁵ the expectation that these responses would solely initiate the systemic manifestations observed in implant recipients has not been realized. The recently proposed ASIA criteria (Schoenfeld's syndrome)¹⁶ does not change any of this, nor does it add to the identification and verification of silicone-induced illness, as it represents a gross oversimplification of what is clearly a much more complicated process⁸ and merely resurrects the prior ill-fated autoimmune theories.

In May of 2007 Congresswoman Rosa DeLauro of Connecticut introduced legislation (HR2503, The Scientific Fairness for Women Act), which, in part, stated that if the FDA could not determine with reasonable assurance the safety of a breast implant device that had already been approved for general use, it would be mandatory for the FDA to remove that device from the marketplace. This bill was not enacted and has not since been reintroduced, despite the fact that the FDA has never conclusively determined with reasonable assurance that any type of silicone gel-filled breast implant is safe. A judicial decision in late 2015 by the US Court of Appeals for the Ninth Circuit would appear to agree with this analysis, as the court rejected a preemption motion for dismissal in a lawsuit brought against a breast implant manufacturer.¹⁷ More recent litigation has shed additional light on this issue by providing evidence that manufacturers deliberately did not design proper studies where women could easily report comprehensive adverse experiences with their silicone breast implants.⁴ The resulting sparseness of data collection encompassing women's ailments allowed the manufacturers to minimize harmful

effects related to these devices. This, in turn, perpetuated the failure of implant manufacturers to properly warn future recipients and the FDA of the dangers of their products.⁴ In 2014, 2015, and 2016 over 70,000 women in the United States had their new cohesive gel devices permanently removed because of grievous complications. The recurrence of this public health crisis is not surprising, for it has been fueled by manufacturers' research fraud, FDA ineptness, faulty informed consent, patient abandonment, proprietary manufacturing secrecy, misleading advertising, physician indifference, aberrant research methodology, and lax Congressional oversight. The chaos of the 1990s is starting to repeat itself. How will the medical community deal with this public health debacle the second time around?

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