

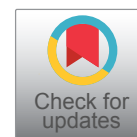


COMMENTARY

The Clever Deception by Silicone Gel-filled Breast Implant Manufacturers Regarding the Phenomenon of Gel Bleed

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Introduction

From April of 1992 through November of 2006 a moratorium existed in the USA prohibiting the use of silicone gel-filled breast implants for routine cosmetic enhancement. This mandate, implemented by the Food and Drug Administration (FDA), centered around escalating claims of device-related systemic illness affecting hundreds of thousands of recipients who had these devices placed in their bodies during the 1970's and the 1980's. Varied theories of disease causation were proposed by numerous researchers, all of whom relied on the routine occurrence of silicone gel microdispersion to distant anatomic areas as a result of gel bleed through an intact elastomer envelope. In essence, breast implant devices were slow delivery systems unrelated to rupture because their contents were soup mixtures of various sized polymer compounds, many of which were smaller than the pore size of the rubber shell that surrounded them. The subsequent challenge facing manufacturers (in concert with multiple other implant-related problems, such as rupture) was to devise a more stable product.

The Birth of Cohesive Gel and Problems with its Usefulness

The theoretical solution to the problem of gel bleed was to synthesize organosiloxane (organosilicone) polymers that were of sufficient uniform length and then cross link them together in a tight binding manner, thereby preventing microdispersion via excessive size. However, once this was achieved,

the physical chemists, chemical engineers and other scientists working on this project for Allergan and Mentor had to contend with rapidly emerging bio-system revelations in the late 1990's by researchers investigating the complexities of geomicrobiology, bioremediation, and biofilms. In the aggregate these revelations negated the prior sixty years of "conventional wisdom" that high molecular weight polymeric siloxanes were chemically and biologically inert. Specifically, with regard to geomicrobiology, it became apparent that bacteria routinely present in dirt and soil were capable of degrading any chemicals they had never previously encountered, including those that contained artificial silicon-carbon bonds (i.e., organosilicones) [1-5]. One such research article was authored by Dow Corning scientists, creating an ironic turn of events since Dow Corning was one of many defendants in the class action breast implant litigation of the early 1990's [3]. These observations then circuitously reinforced the field of bioremediation, because it now became obvious there was a novel method of remedying environmental contamination. Concurrently, by the late 1990's, publications authored by plastic surgeons and infectious disease specialists clearly demonstrated that bacterial containing biofilms, routinely present on all implantable medical devices, also formed externally and internally on silicone gel-filled breast implants [6-8]. Identifiable bacterial species colonizing breast implants were legion, often requiring special methods of identification beyond routine cultures. Linkage of breast

implant bacterial colonization to capsular contracture became routine and circuitously reinforced other studies implicating gel bleed as a cause of capsular contracture [6-9]. Stated more simply, degradation of the new cross-linked silicone gel was an inevitable occurrence caused by device colonizing bacteria, and this has been convincingly proven by sophisticated *in vivo* studies [10,11]. *In vivo* studies have also demonstrated that this degradation process is augmented by macrophage hydrolases, which simultaneously release amorphous silica from the shells [10,11]. Thus, *in vivo*, these new generations of breast implants essentially become slow delivery systems indistinguishable from the gel bleed of prior generations of devices manufactured in the 1970's and 1980's. Bacterial populations colonizing the implants could not be prevented nor eradicated by local and systemic antibiotics, changes in the textures of elastomer envelopes, special coatings on the inner and outer surfaces of the envelopes, nor by alterations of surgical techniques. All of these revelations outlined above then provided an adequate explanation for other published observations, including (but not limited to): (a) The demonstration of dramatic changes in gel properties over time in new cohesive breast implant devices that had subsequently been surgically removed from recipients [12]; (b) The demonstration that degradation remnants of original silicone gel polymers from these new devices were now easily detectable in multiple distant organs [13]; (c) The acknowledgement in March of 2019 by the FDA that 350,000 USA recipients over the prior ten years had notified the FDA of grievous systemic ailments directly attributable to their devices [14]; and (d) Peer-reviewed publications by multiple investigators that unreservedly supported the women's assertions and concluded that there was indeed a recurring public health debacle caused by the new generations of gel-filled breast implants [15-18].

Circumventing Reality and Blindsiding the FDA

How, then, could the scientists at Allergan and Mentor overcome the insurmountable and inevitable occurrence of gel bleed in order to satisfy a major FDA requirement that gel bleed be demonstrably minimized as a prerequisite for granting reapproval of unrestricted marketing of silicone gel-filled breast implants? The answer to that question were clever "smoke and mirror" experiments designed to avoid real life *in vivo* conditions. Cohesive gel devices were immersed and incubated in a bath of either porcine or bovine serum, followed by serial analyses over the next six months of the serum specimens for the presence of silicone polymers and smaller organosiloxane constituents (the latter mimicking the soup mixture ingredients known to exist in devices from thirty and forty years ago) [19,20]. Any high school biology student would know that serum represents

a sterile blood product devoid of cells, bacteria, coagulation factors and living tissue constituents, and that there was absolutely no validity for manufacturers' premarket applications to the FDA in November of 2006 asserting such incubations replicated *in vivo* conditions. Indeed, miniscule and insignificant determinations of gel bleed would be the expected results of such experiments before they were even performed. In essence, these attempts by breast implant manufacturers to prove the stability of their products were based on a premeditated foundation of false methodology. Deliberate deception of FDA regulators and the general public was the intended goal of implant manufacturers, and their strategy has subsequently adversely impacted numerous recent individual breast implant litigation filings where preemption dismissal of individual product liability lawsuits by uninformed judges is the norm. If this deception is allowed to continue unchallenged, the three-decade-old-truths verifying systemic silicone breast implant toxicity will be buried a second and final time.

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