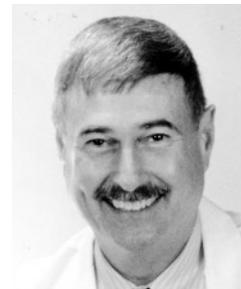


Where There's Smoke There's Fire: The Silicone Breast Implant Controversy Continues to Flicker: A New Disease That Needs To Be Defined



The bonfires of the silicone breast implant controversy in the 1990s have been reduced to coals in 2003. The burning medical and legal issues have been extinguished. The spark in North America occurred in 1979 when a woman in Pittsburgh developed an acute illness suggesting toxic shock immediately post implant placement. No organism could be cultured and she had to have her silicone breast implants removed 10 days after placement. She made a complete recovery¹.

Case reports and case series as well as press coverage of this formerly emotionally charged issue resulted in epidemiologic studies focusing on defined connective tissue diseases as well as undefined symptom complexes. Studies of defined diseases were either negative^{2,3} or showed only a small but statistically significant relative risk⁴. Studies of systemic lupus erythematosus (SLE) and systemic sclerosis did not show an association with silicone breast implants, but studies of symptoms did (Table 1)⁵⁻¹⁰. Because of a lack of consistency in methodology of symptom searches and in study findings some reviewers do not believe there is fire to be found¹¹. Since then, a Dow Corning-funded study (2496 reduction mammoplasty patients versus 1546 silicone breast implanted women, 1/6 of whom had saline-filled silicone envelope implants) has documented that all 28 symptoms were increased in silicone patients (16 of 28 were statistically increased)⁵. In a comparison study, there was a statistical correlation between local problems and systemic problems.

Also important, in the first full article detailing the benefits of silicone breast implant removal on symptom expression, the authors cautiously interpreted their data as showing a "temporary" improvement in that they had only 6 months of followup post-removal⁹. Our study with 21-month followup confirms and prolongs these observations¹². Prompt onset of local and systemic symptoms, delayed

removal after becoming symptomatic, and ruptures found at the time of removal all predict delayed improvement. Exercise-induced exacerbations of pain, fatigue, and bladder irritability help separate women with silicone-related symptoms from "personally driven" fibromyalgia, in which exercise helps.

In women with defined diseases, case reports and case series showed a suspiciously high improvement rate post implant removal^{13,14}. These observations suggested women could have a combination illness expressing both a naturally occurring defined rheumatic disease with co-expressing silicone component. Rheumatologists were urged to suggest the consideration of silicone breast implant removal in women with SLE or scleroderma. Insurance companies who deny benefits to very symptomatic women who only worsen while implant removal is delayed particularly frustrate all concerned. The women become disabled, lose their insurance, and have no way to fund removal.

The literature suggests that the vast majority of symptomatic women had a fibromyalgia/chronic fatigue-like illness, which has still not been defined. It is time for organized medicine to convene a group of clinicians who understand the disease (rheumatologists, plastic surgeons, and others) and epidemiologists who know how to define the disease in order to document the medical necessity of implant removal. Eosinophilia myalgia, with only 3500 sufferers, was defined within 4 years of the initial case reports. In Table 2, we propose criteria to be tested. Other authors have proposed and tested criteria, but they have not been published¹⁵.

Dow Corning recently quietly sent settlement packages to distribute 4.6 billion dollars to injured women. Other manufacturers including Bristol Myers Squibb, 3M, and Baxter have largely settled their cases as well.

In this issue of *The Journal*, Dutch investigators throw

See Rupture of silicone gel breast implants and symptoms of pain and fatigue, page 2263

Table 1. Symptoms/signs associated with rupture of silicone breast implant.

	OR	Statistics RR	95% CI	p
I. Body ache				
1. Arthralgia				
a. Painful joints for more than 3 mo ⁵		1.3	1.0–1.5	
b. Joint pain ⁶				< 0.005
2. Myalgia				
a. Muscle pain ⁷				< 0.001
b. Fibromyalgia ⁸	2.7		1.4–5.2	
3. Unspecified				
a. Body pain ⁹				0.001
b. Neck ache ⁵		1.5	1.3–1.9	
c. Shoulder ache ⁵		1.4	1.1–1.7	
d. Back ache ⁵		1.2	1.0–1.5	
e. Hand pain ⁷				< 0.001
II. Abnormal fatigue ⁵		1.4	1.1–1.7	
III. Impaired cognition				
1. Thought problems ⁷				< 0.001
2. Hard to find words ⁵		1.3	1.0–1.8	
IV. Depression ⁵		1.2	1.0–1.5	
V. Dry eyes				
1. Burning eyes ⁶				< 0.01
2. Recurrent sensation of sand or gravel in eyes ⁵		2.2	1.3–3.8	
VI. Dry mouth for more than 3 months ⁵		1.4	1.0–2.1	
VII. Skin abnormalities				
1. Redness on cheeks ⁵		1.8	1.2–2.8	
2. Unspecified ⁵		1.8	1.3–2.3	
a. Unspecified ⁶				< 0.005
VIII. Paresthesia				
1. Tingling and numbness ⁵		1.3	1.0–1.6	
2. Numbness in the extremities ⁷				< 0.001
IX. Swollen glands under arms ¹⁰				< 0.05
X. Tender glands under arms ¹⁰				< 0.01
XI. Unexplained fever ⁵		2.5	1.6–3.9	
XII. Hair loss ⁵		1.3	1.0–1.8	
XIII. Headache ⁷				< 0.001
XIV. Morning stiffness ²		1.81	1.11–2.95	

OR: odds ratio; RR: relative risk; CI: confidence interval.

Table 2. Proposed definition of silicone-related disorder.

Major criteria
Silicone breast implant with local problems including tenderness, capsule formation, change in shape or position, and/or rupture of the envelope
Chronic fatigue lasting 6 months
Myalgias with tender muscles
Minor criteria
Postexertional symptom exacerbation
Livedo reticularis
Bladder dysfunction including dysuria, frequency, nocturia, hematuria, and interstitial cystitis
Dry eyes and/or mouth
Impaired cognition—short term memory
Paresthesias/neuropathic pain
Unexplained fever intermittently over 3 months
Arthralgia
Lymphadenopathy
Unrefreshing sleep

fuel on the fire by further correlating the high rate of self-reported envelope rupture with statistically increased frequency and severity of symptoms including muscle pain, joint pain, memory loss, and post-exertional malaise, among others. The mechanism behind this phenomenon remains unproven; however, the loss of envelope integrity would allow a greater load of silicone/silica gel to escape into the surrounding tissues, regional lymph nodes, and possibly into the bloodstream (if the element silicon can be taken as a marker for silicone polymer). They also reported compelling data to demonstrate that the symptom complex of silicone breast implant recipients with chronic fatigue differed markedly from those patients with the “naturally occurring” chronic fatigue syndrome¹⁶.

It's time to end the burning disagreements over silicone breast implants. Happily, informed consent before silicone breast implant placement has gone from a few paragraphs to many pages. Nevertheless, we believe the significant problems of eventual undetected silicone envelope rupture and risk of systemic symptoms should dictate removal of silicone gel-filled breast implants from the market as too dangerous for human use as the physiologic equivalent of the injection of loose silicone gel into the human body.

An extensive informed consent does not deter women who are obtaining silicone breast implants at a higher rate than ever. They do not appear to understand that “saline implants” have a silicone envelope. Some of our patients with “saline implants” have the same symptom complex and local complications as patients with gel-filled implants, but they should be safer because there is less silicone load and any rupture releases saline.

Plastic surgeons as well as rheumatologists and clinical epidemiologists who are on the front lines in seeing these patients need to be involved in the definition process. A definition that surgeons and everyone else can use should improve insurance coverage and speed implant removal in women requiring it.

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