

**Bones, groans, and silicone**

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## VIEWPOINT

# Bones, groans, and silicone

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Twenty years have elapsed since contentiousness and confusion began to dominate the issue of silicone gel-filled breast implants. In early 1992 the world literature on this topic could be summed up in one sentence: silicone gel-filled breast implants, when inserted into a live human being, had the capacity to make the recipient ill. The literature did not specifically state what the illness was, nor did it deduce with certainty that there even was such an illness. Subsequently there transpired a grievous and fundamental error in reasoning: silicone-induced disease was defined in the courtroom before it was adequately studied in the examination room. Stated more simply, plaintiff and defense lawyers went to the rheumatology textbook, listed the criteria for classical connective tissue diseases (lupus, etc.), and forged a global class action settlement stating that if anyone became ill with such a disorder they would be compensated. A few other categories were defined for the stragglers, namely 'atypical connective tissue disease' and 'atypical neurological disease', whose criteria were also based on a preconceived idea of how the women were supposed to become ill.

The stage was now set for chaos, which ensued shortly thereafter as a result of three events: (1) instead of 40,000 women showing up at the front door as expected, over 400,000 showed up; (2) there was a timetable to get all of the women examined (by August of 1994); and (3) the legal definition of silicone toxicity became adopted as the medical definition. Examinations of breast implant recipients were invariably geared toward gathering just enough information to place women on a legal compensable grid. Stated another way, the disorder was studied for what it was supposed to be rather than for what it was. By failing to consider multiple

potential mechanisms of disease causation, data bases were artificially truncated and only a fraction of the women's ailments were recorded. A further leap of faith transpired when it was assumed that the inflammation manifested in the local breast milieu would invariably precipitate and be responsible for the systemic phenomena. Sooner or later, along the way, the immunologists would bail everyone out by coming up with the proper diagnostic tests. This aberrant and contrived methodology permeated the thought processes of nearly all investigators, yielding the dubious distinction 4 years later of having over 200,000 women examined and very little useful data (with the exception of the escalating reports of device rupture).

Once the illness was defined by attorneys, it was a simple matter for implant manufacturers to fund studies to show that the fictitious illness did not exist. This proved very effective in the public arena via a simple slight-of-hand illusion: if a sick breast implant recipient does not have 'A' (something in the textbook), then she does not have 'B' (something new), i.e. she has nothing. This served to heighten the vociferous efforts of the breast implant recipients themselves, because now they felt victimized twice: once by a faulty product that made them ill, and second by clever manipulation of misleading data. Little did they realize that media coverage would come back to haunt them whereby women were blamed for inventing the illness after hearing about it. Sympathetic investigators were besieged by an army of company researchers who conducted critical and scathing reviews of the theories and premises of silicone-induced immune activation. The trashing of immunotoxic mechanisms paralleled the vacuum created by the lack of careful and meticulous bedside observations, rendering disease verification elusive. Plaintiff's lawyers began reeling from a succession of adverse jury verdicts and were left wondering why their 'science' was not yielding better results. Numerous erudite scientific panels also deduced that not enough data was present to reach any definite conclusion on causation.

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Many critics at the time debunked not only silicone toxicity but also Gulf War Syndrome (the latter was eventually proven to be a real and debilitating illness).

Other errors and omissions transpired during the 1990s that further hampered the processes of disease identification and epidemiological comparisons to textbook entities. These included the gross failure to consistently record detailed and accurate chronology of disease development, as well as the lack of photographic documentation of clinical features. The latter would have easily demonstrated what all proponents of silicone toxicity already knew, namely the monotonous, repetitive and redundant presentation of identical skin rashes and multiple other phenomena following implantation. In a similar vein, persistence and/or subsidence of these phenomena following explanation were poorly recorded. After all, how could one analyze data that was never taken down in the first place? Compounding all of this was the lack of appropriate long-term follow-up in large part because many implant recipients became partially or totally disabled, lost their health insurance, could not afford to revisit their doctor, or became separated or divorced.

The original silicone gel-filled breast implants were slow delivery systems due to the phenomenon of gel bleed through an intact envelope or shell. This microdispersion began on day one of implantation, but has also been readily demonstrated to occur from the new generation of cohesive gel devices produced in the USA by Mentor and Allergan. Implant rupture causes macrodispersion, which can make the recipient disfigured and gravely ill in a manner comparable to individuals who have received multiple silicone injections. During the 1990s the rupture rate was noted to be 5% per year. The shell, or envelope, holding the contents of silicone gel is solid silicone, and is manufactured by adding silica (coal miner's dust) to a viscous polymer of silicone gel to produce a rubber elastomer. Hydrolases released by macrophages can readily release the bound silica, which is one mechanism producing rupture. If the fibrocollagenous capsule that had formed around the implant was still intact, a patronizing reassurance was given to patients that they had 'rupture with containment'. Little thought was given to the fact that electron microscopy of capsular collagen fibrils clearly showed no impediment to continued silicone migration into the body.

The current crisis developing simultaneously in many countries over the issue of silicone gel-filled breast implants has three components, all apparently linked to devices manufactured by Poly

Implant Prothese (a company known as PIP): (1) an unusually high rate of rupture, (2) the substitution of substandard 'industrial-grade' silicone for conventional 'medical-grade' silicone and (3) the potential propensity to produce a rare form of cancer known as anaplastic large-cell lymphoma. With regard to rupture, it would not be surprising in the future to discover that devices from any manufacturer were readily failing at the rate of 5% per year. With regard to cancer, a discussion of that issue is beyond the scope of this editorial.

The distinction between industrial-grade silicone and medical-grade silicone is a clever illusion propagated by manufacturers to allay fears over the latter. Although industrial silicone is a soup mixture of diverse organo-silicon components, all silicone molecules are capable of promoting intense inflammation, and all are subject to degradation in the body and thus are not chemically inert. Silicones are also not biologically inert, yet is anyone asking these implant recipients if they are ill? Knowledge of the normal integration of the element silicon in higher organisms is essential to understanding its role in causing biochemical aberrations when present in excess. Researchers need new tools to study the mechanisms by which excess silicon causes interference with the molecular basis of life (and, hence, disease), which may in turn unearth abnormalities that immunologists are fond of studying. In the end I suspect that an insight gleaned from these endeavors will inadvertently redefine inflammatory and immune responses, and could have major implications regarding the pathogenesis of lupus and other classical connective tissue diseases.

What do plastic surgeons think of all of this? Not much. They have attributed problems with implants to poor operative technique, poor patient selection and lack of antibiotic use. Plastic surgeons have a great deal of data on local breast phenomena based on direct patient examinations. Unfortunately, their attitudes regarding silicone-induced systemic ailments have relied entirely on questionnaires and telephone interviews. We have known for decades that assessments of disease activity in lupus and other connective tissue diseases are reliable only when direct face-to-face contact is established. Why has there been a double standard with regard to silicone toxicity?

The moratorium on silicone gel-filled breast implants in the USA lasted from April of 1992 to December of 2006. During this interval cohesive gel devices were implanted in patients undergoing post-mastectomy reconstruction who consented to be part of a research study. The Food and Drug

Administration only required 3 years of observational data, with no post-marketing surveillance after that. I now have six patients from the cohesive gel era who have developed a systemic illness comparable to my original cohort of 500 recipients seen in the 1990s. The latency period to disease onset in these six patients averages 3 ½ years, which explains why their medical records are virtually devoid of problems. It is therefore no surprise to me that a new epidemic may be emerging in multiple other countries since the United States lags behind the stampede to enhance one's beauty by 10–15 years. And even if my prediction of a repeat debacle does indeed develop in the USA in the near future, will any medical association urge researchers to revisit this issue? In the latter half of the 1990s the American College of Rheumatology issued a position paper debunking silicone-induced disease.

Plaintiff's attorneys representing implant victims were not knights in shining armor either. They were not willing or able to remedy their mistakes because they needed to recoup their \$100 million

investment. The best way to do this, short of continuing to spend their way through 10 more years of proper research, was to use the rejection of untenable medical evidence to their benefit. This allowed them to bundle cases together dealing only with local breast phenomena (rupture, etc.), avoid costly court cases on systemic ailments, and avoid the perception of client abandonment. If you find yourself in a losing situation, go with the flow and use it to your advantage. The entire scenario also suited the judicial system well because it allowed gigantic and unmanageable court backlogs to be dispensed with.

So what really happened? The lawyers created the science. The science they created served their purpose very poorly. They therefore had to abandon the science, and the best way to do this was to have national science panels do it for them. Will history repeat itself as newer implant recipients voice their concerns? Hopefully not, but this will depend in large part on giving ear to the clamor and guiding investigators to utilize proper methodology.