

Recent controversy surrounding the breast implant has implications that reach far beyond the safety of this particular biomedical device. In question is whether science or anecdote will guide our medical decision-making. Where knowledge of the scientific method is scant, a sly and compelling form of "junk science" has insinuated itself, threatening to return us to reliance upon conjecture, hearsay, or wish, rather than upon our objective observations of the world as it is.

Because we know that all treatments, medicines and devices carry some risk, we must decide by consensus within the general medical community, and between doctor and patient, what constitute reasonable risks for each. In order to do this intelligently, we need to weigh those risks against the benefit likely to accrue to the patient if typical results are obtained.

The Foundation
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*Information
for women...*

Breast Implants
What Does
Science Say?



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Implants are all made from a Silastic" (silicone rubber) envelope which contains one or more filling materials. The filler may be saline (salt water), or a silicone "gel," (made up of silicone molecules of lower molecular weight than the rubber shell), or both. Among the myths recently propagated about silicone is that it was a largely untested substance used in an "experimental" way on unsuspecting patients. In fact, it was chosen as the basis for breast implants in 1960-62 because of its many-year history of successful performance in other implantable devices. Substantial laboratory and clinical evidence already existed at that time to show that the material was very well tolerated in most circumstances. In fact, silicone was then, (and is now), the standard by which the inertness of other polymer biomaterials is judged.

Do Breast Implants Cause Cancer?

The recent interest in breast implants and their possible relationship to cancer is based upon a rediscovery of old, poorly understood laboratory findings from the 1940's and 50's.

Nearly a quarter of lab rats will develop the rare cancer, fibrosarcoma at the site of silicone implantation. However, this reaction (the so-called Oppenheimer effect) is not limited to silicone, but will follow the implantation of any smooth surface, including that of other plastics or of glass. This reaction is peculiar to rats, and has never been observed in humans. Large studies have also been carried out in Los Angeles and in Canada to look at the incidence of standard breast cancer in women with implants. Both of these studies clearly show that there is no increase in breast cancer among women with implants.



Do Breast Implants Cause Immune-related Disease?

Concerns about a possible relationship between breast augmentation and auto-immune disease date back to the 1960's in Japan. Dr. Myoshi described two women (prostitutes) who developed polyarthritis many years after undergoing breast enlargement by illicit paraffin injections of the breast. He wondered if the wax had served as an "adjuvant," or agent acting to heighten a predictable immune response.

Western literature review of this and other cases from Japan did not occur until 1984. After this, anecdotes appeared describing women who complained of various chronic, non-specific symptoms (e. g. fatigue, muscle and joint pain) at varying times after breast augmentation with implants. These reports in no way established a causal relationship between the women's symptoms and their previous breast surgery, and early epidemiologic studies of this question failed to show any difference between women with prostheses and those without. However, the notariety of this issue and the growth of litigation made the FDA step in and ban the use of gel implants beginning in 1992.

Some studies reported since then suggest that some silicones may act as adjuvants, heightening normal immune reactions to other things. There have not been any works which show silicone itself to generate a specific antibody response, however. Other research suggests that combinations of silicone and protein may lead to antibody generation, but these antibodies can also be found in people who have no implanted devices. Also, the mere presence of antibodies in no way indicates a disease state.

Large epidemiological studies performed at the Mayo Clinic and Harvard have more recently provided strong evidence that breast implants are not related to auto-immune disease or rheumatologic symptoms. As a result, the American College of Rheumatology recommended to FDA that gel implants be returned to the market. Notwithstanding this fact, only saline implants are currently available for surgery in the United States,

(European and South American physicians and hospitals have continued to use gel devices during the American ban).

Do Breast Implants Hide Disease?

We now know that early detection of breast cancer can have an impact upon patient survival. Because nearly 1 in 9 American women will develop breast cancer, surgical changes in the breast which might make tumor surveillance more difficult should be carefully considered. Since breast implants do not transmit xrays well, they can render standard screening mammography less effective. Also, tissues which are compressed by implants appear more dense and difficult to read on xray. Finally, the fine calcifications which occur in some women around breast implants may at first confuse the diagnostic picture.

With all these concerns acknowledged, we must still be careful not to unsupportedly conclude that cancer diagnosis is delayed in women with implants. There are, in fact, conflicting data on this issue. Clearly, women considering breast augmentation must be made aware of the need for special follow-up and imaging studies in the future, and should be motivated to be even more fastidious about breast health than others. Those with strong family history of breast cancer should pursue breast augmentation only after an exhaustive consideration of these issues. Studies now show, however, that with proper examination and radiographic techniques, radiologists experienced in the imaging of the implanted breast can find tumors as small as those found in women without prostheses. Women should seek counsel from their plastic or general cancer surgeon regarding referral to a breast imaging center with the proper expertise. Mammography in these centers will always involve additional views and will usually employ special maneuvers to draw the breast off the implant. Ultrasound or scan can also be used in those situations where standard techniques are insufficient.