CME

The Silicone Gel–Filled Breast Implant Controversy: An Update

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Learning Objectives: After studying this article, the participant should: 1. Be familiar with the medical uses of silicone. 2. Have a working knowledge of the most important epidemiologic studies regarding silicone gel–filled breast implants. 3. Be aware of the issues about which patients desiring breast augmentation or reconstruction with implants must be counseled.

In January of 1992, the Food and Drug Administration implemented a voluntary but strongly urged moratorium on the sale and use of silicone breast implants pending a review of additional information. By April of that year, the Food and Drug Administration had converted this moratorium to what was essentially a ban. Since then, silicone gel-filled breast implants have been alleged to be associated with numerous health problems ranging from cancer to autoimmune disease. Plastic surgeons should be aware of the issues surrounding silicone gel-filled breast implants, be familiar with the medical uses for silicone, and have a working knowledge of the most important epidemiologic studies in this area. This knowledge will better enable plastic surgeons to counsel their patients regarding the risks and benefits of breast implant surgery. (Plast. Reconstr. Surg. 109: 742, 2001.)

In January of 1992, the Food and Drug Administration (FDA) implemented a voluntary but strongly urged moratorium on the sale and use of silicone breast implants pending a review of additional information.1 By April of 1992, the FDA had converted this moratorium to what was essentially a ban. The continued use of the implants in postmastectomy reconstruction was allowed, as was their use in a small number of breast augmentation patients who were willing to enroll in long-term studies. Since 1992, many reports have appeared that refute the alleged association of silicone gel implants with a number of health problems ranging from cancer to autoimmune diseases. In 1993, the Council of Scientific Affairs of the American Medical Association issued a report urging the association to “support the position that women have the right to choose silicone gel-filled or saline-filled breast implants for both augmentation and reconstruction after being fully informed about the risks and benefits.”2 The American College of Rheumatology also issued a statement, saying that “there is no convincing evidence that these implants cause any generalized disease.”3 Most recently, on June 21, 1999, the Institute of Medicine (IOM) of the National Academy of Sciences reported the conclusions of a 2-year investigation on the possible role of silicone gel implants in systemic diseases. This report was funded by the National Institute of Arthritis and Musculoskeletal and Skin Diseases and was created by a panel of 13 scientists under the auspices of the IOM, which is a private, non-profit organization that provides governmental health policy advice. This investigation discovered no association between silicone gel implants and cancer, immunologic disease, or other systemic diseases; moreover, they reported that implants pose no risk for breast feeding or to unborn infants.4–6 Nevertheless, the FDA’s ban remains in effect.

Plastic surgeons should be aware of the issues surrounding silicone gel breast implants and, in particular, should be familiar with the scientific evidence addressing the various health concerns that have been associated with these implants in the media and the medicole-
This knowledge will better enable the surgeon to counsel his/her patients about the risks and benefits of breast implant surgery.

**Silicone: A Brief Review**

Silicon is an element that appears throughout nature. Silicone is the generic name for a family of silicon-carbon–based polymers. Depending on the length and complexity of the polymer, silicone may exist as a liquid (short, simple polymer chains), gel, foam, resin, or rubbery material (elastomer; long, complex polymer chains).

One of the first uses of silicone in a medical implant was in ventricular shunts used to treat hydrocephalus. Since the introduction of these shunts in the 1950s, silicone in various forms has become an important part of many implants. Silicone is used in endotracheal tubes, in prosthetic ocular lenses, in artificial heart valves, and in facial implants for congenital deformities or postablative defects. Moreover, silicone is also found in medical devices such as syringes and intravenous tubing, which are used daily. Today, more than two million patients have implanted medical devices made partially or wholly of silicone. Over time, silicone in medical devices has demonstrated a proven record of safety.

Many studies in the early medical literature affirmed the safety of silicone in human patients. The use of silicone to correct deformities successfully was reported as early as 1950. Before the advent of silicone gel breast implants, Edgerton’s text on prosthetic surgery had identified silicone as an important implant material with diverse applications. In the 1960s, the satisfactory response of animals to implanted silicone, including exposures in rats and dogs for up to 3 years, was documented. Seven additional animal studies were published between 1965 and 1968, and all found no evidence of significant adverse reactions to silicone.

Animal and clinical research on the safety and efficacy of silicone and implantable silicone devices continued throughout the 1960s, 1970s, and 1980s, reaching its peak with a flood of epidemiological studies on human populations in the 1990s. In a 1991 application to the FDA seeking approval for the continued sale of its own brand of silicone gel breast implant, one manufacturer submitted more than 250 studies attesting to the safety of the device. Altogether, more than 2000 studies on silicone and silicone implantable devices have been reported in the past half century.

**Silicone Gel Breast Implants and Public Health Concerns**

A number of forces have participated in the generation of the controversy over silicone gel breast implants. Among these forces have been the media, trial lawyers, various social activists, and the FDA as it responds to pressure from these groups. Out of this controversy have arisen issues regarding the safety of silicone gel breast implants; specifically, silicone gel breast implants have been alleged to cause autoimmune diseases, breast cancer, and possible harm to nursing infants of mothers with implants. Numerous epidemiologic studies have conclusively and consistently refuted each of these alleged disease associations. The American Medical Association has urged that "physicians be informed of the current scientific data available to recognize and address the considerable public anxiety concerning the safety of breast implants, an anxiety not warranted based on current scientific evidence."

**Antisilicone Antibodies**

The detection of antisilicone antibodies in women with implants has been regarded by some as an indicator that implant leak is a cause of illness. However, antibodies develop in response to nonpathogenic foreign bodies as well. Moreover, the British Department of Health stated in its 1994 overview of the clinical studies of breast cancer health risks, “The fact that antisilicone antibodies have been detected both in silicone implant recipients and, at a lower titer, in people who had not received medical silicones, raises doubts about their significance.”

Antisilicone antibodies may be generated in response to the daily exposure of individuals to silicone in foods, beverages, cosmetics, and mundane medical equipment. In a two-phase study, Weinzeig et al. sought to determine whether there was any correlation between tissue silicone levels and connective tissue disease in women with implants. Women with both silicone gel and saline implants were studied, and silicone levels in both the capsular tissue immediately surrounding the implants and the breast tissue itself were determined. No statistically significant differences in tissue silicone levels could be found in relation to the presence or absence of autoimmune or connective-
tissue diseases in the patients with silicone gel implants. These conclusions further strengthened the case against any association of silicone breast implants with autoimmune disease.28

**Autoimmune Diseases**

The possibility that silicone implants might be linked to autoimmune disease was first reported in the Japanese medical literature; however, these were anecdotal reports of women who had received direct injections of liquid silicone (not gel) mixed with other oils or paraffin.29 Autoimmune or connective tissue disease can take many forms, including rheumatoid arthritis, scleroderma, systemic lupus erythematosus, Sjögren’s syndrome, fibromyalgia, and Raynaud’s disease.

In 1988, in response to a report of scleroderma occurring in a patient with implants,30 the American medical community at large began considering the possibility that silicone exposure might cause disease in some patients. A number of anecdotal reports of similar associations spurred the FDA to require further information on the safety and efficacy of silicone breast implants.31 During the late 1980s the FDA did not believe that there was cause for alarm about the safety of silicone breast implants. Nevertheless, in 1990, the FDA outlined the data manufacturers should submit on silicone gel–filled breast implants. They were especially seeking information on certain diseases, including autoimmune disease, and the effect implanted silicone might have on unborn children.32 Thereafter, the FDA began setting deadlines for compliance with its requests.33

A large number of animal and human studies have sought to identify a link between silicone exposure and connective-tissue or autoimmune disease. The British Department of Health reviewed approximately 270 papers and concluded that the animal studies “provide no immunological reason for concern over the use of silicone gels in implants. Even under forcing conditions . . . responses to the silicones have been minimal and of questionable significance.”27

One of the largest studies of connective-tissue disease to date was conducted by the Mayo Clinic and published in 1994. Twelve types of connective-tissue disease were evaluated, along with three other illnesses, including cancer other than breast cancer. No association was discovered between silicone gel breast implants and the diseases that were studied.34

The Universities of Maryland, Pittsburgh, and California and Johns Hopkins University examined the association between breast implants and scleroderma. A total of 869 scleroderma patients from rheumatology clinics at three universities were compared with 2061 women without the disease. Twelve patients (1.4 percent) had received breast implants before being diagnosed with scleroderma, compared with 23 patients (1.1 percent) with breast implants among the control group. No statistically significant difference was detected between the groups. It was concluded that “these data extend previously published preliminary results and fail to demonstrate a significant causal association between augmentation mammoplasty and the development of systemic sclerosis (scleroderma).”35

In 1995, a study of 41 types of connective-tissue disease among 87,501 nurses, of whom 1183 had implants, appeared in the New England Journal of Medicine. Again, this extensive investigation found no association between silicone gel implants and autoimmune or connective-tissue diseases or “signs or symptoms of these diseases.” Interestingly, women with silicone implants were less likely to report symptoms of these diseases or to complain of symptoms or signs of illnesses resembling connective-tissue disease.36

In its 1995 overview, the British Department of Health stated that no study had demonstrated a causal link between silicone gel breast implants and connective tissue diseases.27 Furthermore, the report stated, “It is unfortunate that this is not reflected in the public perception of these devices which, despite the scientific evidence, has been unduly influenced by media coverage of the FDA restrictions on the use of silicone gel–filled breast implants and the outcome of legal actions.”27

Also in 1995, the American College of Rheumatology stated that recent epidemiological studies “provide compelling evidence that silicone implants expose patients to no demonstrable additional risk for connective tissue or rheumatic disease.” The College urged that “anecdotal evidence should no longer be used to support this relationship in the courts or by the FDA.”37

Although the evidence against an association between silicone breast implants and autoim-
immune diseases was quite powerful by 1995, even more compelling evidence has been amassed since then. The IOM study released on June 21, 1999, found no evidence that silicone implants are responsible for any major diseases. Moreover, this study found no plausible evidence of a "novel autoimmune disease" caused by silicone gel implants.\(^6,38\)

In March of 2000, Janowsky et al.\(^39\) published the results of their meta-analysis of the relation between silicone breast implants and the risk of connective tissue diseases in the *New England Journal of Medicine*. These authors analyzed the results of 20 major studies on this subject. They found "no evidence of an association between breast implants in general, or silicone-gel-filled breast implants specifically, and any of the individual connective tissue diseases, all definite connective tissue diseases combined, or other autoimmune or rheumatic conditions."\(^39\)

**Breast Cancer**

The possible risk of cancer from implanted silicone medical devices was, for a long time, the only serious risk considered by physicians and health regulators. However, early studies in patients with many types of medical implants made of silicone and other materials demonstrated no such risk.\(^40–42\) More recently, larger epidemiological studies of women with breast implants have strengthened earlier conclusions that implants are not a cause of cancer.

The IOM report released in 1999 found no causal relationship between silicone implants and systemic diseases. No increase in primary or recurrent breast cancer incidence in women with breast implants was identified; moreover, some of the studies reviewed by the IOM suggested lower rates of breast cancer in women with implants.\(^6,38\)

Epidemiologic studies have never found higher-than-normal rates of breast cancer in women with silicone implants. One of these studies has been ongoing since 1986 and was most recently updated in 1995. The breast cancer incidence in 3112 women in Los Angeles County who received silicone breast implants for cosmetic purposes between 1959 and 1981 was compared with overall county breast cancer rates. Twenty-one breast cancers were found in the implant group compared with an expected incidence of 31.7. No increase in breast cancer incidence after augmentation mammoplasty was found; indeed, the incidence of breast cancer in augmented patients was lower than expected.\(^43\)

In the largest study to date, a group of almost 11,000 women from Alberta, Canada, was followed, and the incidence of breast cancer in women who had implants was compared with that in women without implants. The study concluded, "the incidence of breast cancer among the women who had breast augmentation could not be said to be either significantly higher or lower than that among the general population. . . ."\(^44\)

It has also been alleged that silicone gel breast implants can delay cancer diagnosis by blocking x-ray beams during mammography. Although some reports suggest this may be true, the American College of Radiology has determined that adequate examination is possible with commonly available techniques.\(^45\) In fact, it has been proposed that the risk of failing to diagnose a breast tumor is decreased in women with implants because they are more compliant with breast cancer screening guidelines.\(^2\) The consultant radiologist evaluating this issue for the FDA concluded that with specialized techniques (Eklund), "the effectiveness of mammography to screen women with breast implants for cancer is generally similar to that of women without implants."\(^46\)

Nevertheless, implants do complicate mammography in that the implant is radio-opaque. In addition, some patients will develop thin layers of calcium in the peri-implant capsular tissue. This phenomenon is typically observed 10 or more years after implantation. However, these calcifications do not generally obscure small lesions or mimic true cancers and do not contribute to either false-negative or false-positive readings. The calcium deposits may affect the ability of mammography to detect lesions close to the capsule.\(^47\) Patients should be referred to a mammographer experienced with breast implants. Additional mammographic views of the augmented breast are required. The Eklund technique, in which breast tissue is pulled forward as the implant is pushed back, thus maximizing visualization of the breast parenchyma, should be employed.\(^48\) There is strong evidence that subpectoral placement of breast implants improves mammography.\(^6\) In summary, patients with breast implants are not at an increased risk of developing breast cancer.\(^6\)
Breast Feeding

In one highly publicized report in the Journal of the American Medical Association, it was suggested that women with silicone gel implants who breastfeed may transmit autoimmune disorders to their children. However, this report has been widely criticized for its methodology and was later discredited, because one of the authors was linked to a class-action lawsuit against implant manufacturers.

A study by Dow Corning did find silicone in breast milk. However, essentially the same amount of silicone was found in breast milk, regardless of whether the mother had implants or not, thus providing further evidence of the ubiquity of silicone in our everyday environment.

In its 1994 overview of the clinical studies of breast health risks, the British Department of Health failed to discover any risks to nursing infants related to their mothers’ breast implants. It was concluded that “there is no evidence whatsoever to support the view that breast-feeding should be avoided by women with breast implants, and mothers should be given every reassurance that the advantages of breast-feeding strongly outweigh any improbable and unquantifiable risk attributed to silicone gel breast implants.”

Most recently, the IOM study clearly demonstrated that there is no danger in breast-feeding after breast augmentation. Cow’s milk and infant formulas contain a far higher level of silicon than does mother’s milk. The IOM recommends that mothers with breast implants for augmentation should try to breast-feed their babies.

CONCLUSIONS

Although it has taken more than 8 years for scientific validation and vindication in the struggle to evaluate the status and safety of silicone gel breast implants, certainly the scientific validation that has finally come has been worthwhile and serves as a lesson and model for future implantable technology. Nothing manmade that is implanted in the human body lasts forever. All types of implants have a characteristic cycle of aging, and they eventually break down and rupture. Inherent in the process of implant aging is a range of complications that must be clearly delineated to patients in a manner based soundly on scientific evidence.

It is incumbent on plastic surgeons to be aware of the various issues related to the breast implant controversy. Moreover, we must be familiar with the key epidemiologic and basic science studies that deal with these issues. Only then can we adequately educate and counsel our patients and help them make an informed decision about their breast surgery. It is hoped that the lessons learned from the breast implant saga will enable plastic surgeons, and the medical community at large, to deal better with the issues of new technology and medical devices. Ultimately, it must be our patients who reap the benefits.

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REFERENCES

1. SILICONE IS FOUND IN MANY MEDICAL DEVICES.
   A) True
   B) False

2. SILICONE BLEED HAS BEEN DEMONSTRATED TO CAUSE WHICH OF THE FOLLOWING:
   A) Scleroderma
   B) Systemic lupus erythematosus
   C) Breast cancer
   D) Rheumatoid arthritis
   E) None of the above

3. THE INSTITUTE OF MEDICINE REPORT RELEASED IN 1999 FOUND AN ASSOCIATION BETWEEN SILICONE
   BREAST IMPLANTS AND HEALTH PROBLEMS IN NURSING INFANTS OF MOTHERS WITH IMPLANTS.
   A) True
   B) False

4. SOME STUDIES HAVE DEMONSTRATED A LOWER INCIDENCE OF BREAST CANCER IN WOMEN WITH
   IMPLANTS THAN IN THOSE WITHOUT IMPLANTS.
   A) True
   B) False

5. REGARDING MAMMOGRAPHY, WHICH OF THE FOLLOWING IS FALSE?
   A) Mammography in women with breast implants requires additional views for complete assessment.
   B) Mammography in women with breast implants requires special implant displacement techniques for complete assessment.
   C) Because the implant is radio-opaque, some breast cancers may be obscured, increasing the risk of cancer in women with implants.
   D) Women with implants should follow the standard breast cancer screening guidelines.

To complete the examination for CME credit, turn to page 838 for instructions and the response form.