Breast Cancer and Silicone Implants: Psychological Consequences for Women

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One of every nine women in the United States is expected to develop breast cancer at some point in her lifetime. An estimated 180,000 women are diagnosed with breast cancer each year (1-3). For many of these women, excision of the tumor, resulting in surgical modification of the breast, is the primary component of the treatment response. The U.S. Food and Drug Administration (FDA) (4) estimates that approximately 20% of these women elect breast implant surgery following mastectomy. The use of breast implants, particularly silicone implants, has generated considerable discussion in scientific forums, clinical treatment settings, lay consumer groups, legislatures, and regulatory agencies.

Surgical insertion of breast implants dates back to the initial use of polyvinyl alcohol sponges (5). However, relatively few implant procedures were performed until the introduction of implants constructed of silicone in 1963 (6). Silicone breast implants contain silicone materials in three forms: 1) silicone fluid (polydimethylsiloxane), which is the fluid component of the silicone gel; 2) silicone gel, which is the actual gelatin form that fills the implant envelope; and 3) silicone elastomer, which comprises the envelope that contains the fluid and the gel (7). In the original silicone implant device, the gel and fluid were enclosed in a thick, smooth-surfaced silicone envelope, which was subsequently altered over time (6).

From a scientific and clinical standpoint, silicone breast implants have been a topic of considerable discussion. One concern involved capsular contraction, a known side effect of breast implantation, and the subsequent use of polyurethane foam implant coverings in an effort to reduce capsular contraction rates. Capsular contraction results from the formation of a capsule-like layer of scar tissue in the surgical pocket created for the implant. Such scar tissue then squeezes the implant to varying degrees of firmness (6). When polyurethane-covered implants were observed to have a lowered capsular contraction rate, their use became frequent (8). This lowered rate was believed to be due to the peripheral breakup of fragments of the polyurethane foam and the subsequent phagocytosis of the fragments (9). Although the polyurethane itself has not been shown to be a carcinogen in either animals or humans (10), in vivo hydrolysis of the foam produces an end product known to be an animal carcinogen (2,4-toluenediamine [TDA]). If substantial amounts of TDA were produced by the chemical breakup of the polyurethane covering of the breast implant and then released into the blood during or after phagocytosis, the result might be an increased risk of cancer for women with implants. Subsequent tests of this possibility have not provided support for such an increased risk for malignancy due to TDA release (11,12). However, after April 1991, these polyurethane-covered implants were no longer marketed.

It has been demonstrated, however, that, when silicone elastomer is used as the breast implant envelope, the silicone gel does bleed through the breast implant elastomer and can migrate away from the implant site through a lymphatic or hematogenous pathway (13). No teratogenic effects have been noted with silicone fluid migration or bleeding through the elastomer (6), but concern has been expressed about the effect of silicones on the immune system. Over the last 14 years, a limited, but continuing, series of reports on clinical studies of breast reconstruction and augmentation have noted immune system reactions associated with the following procedures: silicone injection (14,15), combined silicone and paraffin injections (16), silicone gel implants (17), or saline-filled implants (15,18). Scleroderma has been cited as the most frequent clinical diagnosis, but approximately half of the patients' symptoms are suggestive but not diagnostic of a known clinical diagnosis. These symptoms often receive the general diagnosis of "human adjuvant disease," a term first applied in 1964 in two case reports (19) describing breast cancer patients who developed rheumatoid arthritis-like symptoms subsequent to paraffin injections for breast augmentation after mastectomy (20,21). Yet, studies of the immune system in animals have not provided evidence to support the hypothesis that silicone produces negative effects on the immune system (22-24). While some clinical reports have indicated a reduction in immune system symptoms following breast implant removal (19,25-30), the silicone particles that have already passed through the silicone elastomer of the implant should logically still be present in the body. In summary, the events that may involve the interaction of silicone with the human immune system remain unclear and continue to be the subject of substantial scientific and clinical discussion.

More recently, women have reported physical symptoms and problems associated with silicone breast implants. Acting as consumers, they have sought to focus attention on this issue through the media, litigation, support/advocacy groups, and legislation and by seeking increased control by regulatory agencies. Popular media reports of women with serious autoimmune disease symptoms have evoked commentaries from both physicians and attorneys stating alternative views as to whether such symptoms were causally related to silicone breast implants. Civil litigation against implant manufacturers has also been pursued, resulting in two nationally visible judgments against manufacturers (the Mariann Hopkins case in San Francisco, Calif., for $7.3

*See "Notes" section following "References."
From a statutory standpoint, state and Federal legislators have also responded to the silicone breast implant issue. At the state level, Maryland in 1987 and New York in 1991 both passed measures requiring physicians to provide printed risk information to all women considering breast augmentation or reconstruction (31). At the Federal level, involvement of regulatory agencies in regulation of silicone breast implants began with the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act. The responsibility for classifying medical devices as to safety and effectiveness was then assigned to the FDA Center for Devices and Radiological Health. Silicone breast implants were designated as class III (devices requiring proof of safety and effectiveness). After an extended period of review, the FDA General and Plastic Surgical Devices Advisory Panel recommended against assigning implant devices to a less regulated class, so implants continued to be categorized as a class III device.

However, Congressional concern with medical devices, including implants, continued to grow. This concern resulted in the 1990 Safe Devices Act, which mandates that health care providers report serious complications or fatalities involving medical devices to the Department of Health and Human Services and to the device manufacturer who, in turn, must notify the FDA. Most significantly, on April 16, 1992, the FDA issued a regulation limiting further use of silicone implants to experimental studies and to individual urgent-need exemptions. In January 1993, the FDA placed new benefit/risk assessment requirements on manufacturers of saline breast implants as well.

The FDA Breast Implant Information Line was established in February 1992 to provide current information on silicone gel breast implants following announcement of the FDA's advisory panel that met February 18-20. Additional information was provided as it developed including the conditions of these women's experiences were revealed: 1) Women did not receive adequate information prior to surgery, 2) women were not taken seriously by their physicians when they complained of pain or other symptoms, 3) women had difficulty maintaining their normal activities, and 4) women had concerns about the future and about not being able to get information (32). The qualitative analysis reviewed all letters (271) received in the FDA Office of the Commissioner during the period of January 1992–July 1992 from a group of women who described health problems they believed to be associated with their silicone implants. The most commonly cited complaints were breast pain (40%), rupture (31%), capsular contracture (29%), joint pain (39%), and fatigue (35%). The diagnoses most commonly described were arthritis (19%), autoimmune disease (7%), Raynaud's disease (5%), and connective tissue disorder (4%). The physical complaints from the descriptive analysis were then used as keywords for a computerized search of two FDA systems for reporting problems with silicone gel breast implants (the mandatory Medical Device Reporting [MDR] and the voluntary Product and Reporting Program [PRP] systems) in order to identify any similarities among the three. The search yielded a consistency in physical complaints and problems from these three sources (33).

From January 1, 1992, until July 1, 1992, the FDA received 7191 MDR unfavorable reports from manufacturers and 1136 PRP reports from users of silicone breast implants representing a significant increase in reporting as compared with similar reports from 1988 through 1992. Media attention of the silicone breast implant controversy and product liability court verdicts may have contributed to this increased reporting. Also, possible variations in manufacturer implant problem reporting criteria may account for the lower reporting prior to 1992. The authors of the FDA descriptive analysis suggest that information from the letters received by
the silicone implant controversy, being satisfied with the implant reconstruction, and currently being in good physical health. This finding is consistent with other limited existing sources of self-report or clinical data (e.g., FDA Breast Implant Information Line, anecdotal accounts by plastic surgeons, and a number of clinical literature reports of women with implant problems or potential problems related to implants) (13-18,20,21). These sources indicate that it is a minority of the 2 million women with implants (reconstruction and cosmetic combined) who have reported to their physicians physical symptoms possibly related to the implants. This limited rate of symptoms reported to physicians could be accounted for by one (or a combination) of five explanations: 1) Some women may be asymptomatic at this point in time. 2) Some women are unaware that certain physical symptoms may be associated with implants. 3) Some women have symptoms and have not sought health care. 4) There is a latency before implant-associated symptoms appear. 5) Such symptoms appear in a subsample of women who have a particular physical, immune system, and psychological profile.

Second, while women participants had a high level of awareness about the silicone implant controversy, over half had vague or inaccurate recollections about the types of problems that had been attributed to silicone implants, including the type of implant filler.

Third, almost half of the women did not contact their physicians, and only a few woman contacted a hotline or the FDA for information. These two findings may indicate a need to re-evaluate health education outreach efforts for women in these circumstances.

Fourth, while over half of the women worried about their implants, only slightly more than one fifth had even considered implant removal.

Fifth, more than one fifth of the women were willing to accept a one in four risk for implant leakage and the potential health problems attributed to such leakage.

These final two findings by Winer et al. indicate a multidimensional interaction in the health care decision-making process, involving emotion, risk assessment, and risk taking. For a significant number of the women participants in the Winer et al. study, this multidimensional interaction process was characterized by an absence of accurate information and individualized medical consultation.

While Winer et al. are appropriately conservative about the limitations in an initial study of this new area, their results are thought provoking for scientists, clinicians, and health policy makers alike. Women with breast cancer and silicone breast implants are faced with difficult decisions but have both limited information and limited individualized medical consultation. Enhanced understanding and assistance in the health care decision-making process for women with silicone implants are likely to involve interactions among three separate, but related, disciplines of study: 1) cognitive beliefs and health care decision models (both perceived health consequences, such as probability/severity of negative health effects, and perceived psychosocial effects, such as body image and interpersonal relationships) (48,49); 2) coping styles and affective responses (50-53); and 3)
physical health status (including immune system status) (54-59). Winer et al. have provided initial support for the position that the physical health care decisions faced by women with breast cancer and silicone implants involve important psychological variables as well. Their study highlights the current need for focused, cross-disciplinary research to determine patient risk and/or benefit with silicone implants, to achieve more effective health education, and to increase patient-physician individualized consultation.

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