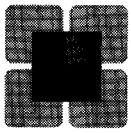

Current status of silicone breast implants

In this issue of the *Cleveland Clinic Journal of Medicine*, Dowden and Yetman[1] review in detail the technical aspects of immediate breast reconstruction following mastectomy. As the article points out, over the past 30 years breast reconstruction has been perfected to the point where it can be performed today by most breast surgeons with minimal risk of major local complications such as infection, obvious rupture or breakage of the implant, or significant local deformity.

■ *See Dowden and Yetman, p 499*

Presumably because of the documented success of the surgery, augmentation mammoplasty has become a widely accepted procedure both for reconstructive and cosmetic purposes. It is estimated that more than 2 million women, most for cosmetic reasons, have undergone mammoplasty in the United States.[2] Until now, the main problem associated with these implantable devices has been the development of capsular scar tissue, leading to tightening and contraction.

Recently, though, major questions and controversy have arisen about potentially more serious consequences of silicone gel implantation. The concern is felt to be of such a critical nature that in April, 1992 the Food and Drug Administration restricted the use of silicone breast implants to breast reconstruction surgery performed under carefully controlled trials. At issue are unanswered technical aspects of the implants; ie, how long do the devices last, and what percentage of them will silently rupture. It has previously been thought, on the basis of manufacturers' reports, that asymptomatic rupture has been low (about 1% or less). Findings presented at the FDA Advisory Panel's meeting suggested the incidence of asymptomatic ruputure may be as high as 4% to 6%.[3] Additionally, issues of concern about quality control and reproducibility of the implants by manufacturers were raised.[3]

However, the critical concern that appeared to be the driving force behind the current evaluation of silicone breast implants was the issue of the possible subsequent development of autoimmune disorders in women who have received them. Unfortunately, the issue of a causal relationship between silicone implants and autoimmune disorders became highly publicized and sensationalized. In such a climate, it can be difficult to sort through the morass of sensationalist reports and self-serving publications to arrive at objective medical conclusions. However, the following points appear to be clear:

1. There is a growing number of well-described case reports of immune/autoimmune dysfunctions associated with silicone gel breast implants.[4–16] Earlier reports described primarily scleroderma-like phenomena, occurring predominantly in Asian women (perhaps suggesting a genetic predisposition).[9,13,16] The most compelling of these cases show a marked and rapid improvement of the disease after removal of the silicone.[4–9,14] Ordinarily, such improvement would not be expected in naturally occurring scleroderma-like syndromes.

2. More recently, a variety of other autoimmune-like disorders have been noted, including systemic lupus erythematosus (SLE) and Sjögren's syndrome.[7,10,17] In most instances, though, the association with silicone implants and improvement after removal of the devices has been less clear-cut than as seen in scleroderma-like illness.

3. The association of silicone breast implants with fibromyalgia-like syndromes, as suggested in a number of recent reports[18] (many of which are yet unpublished in the medical literature) is highly questionable. Fibromyalgia is a very common rheumatic disorder, and one could therefore expect to see this condition in at least some patients who have undergone breast implantation.

4. The limited number of controlled, retrospective studies looking at this issue have failed to consistently show an association between silicone breast implants

and subsequent autoimmune disorders.[19]

5. To date, no well-designed epidemiologic studies have been performed that take a critical look at the association between silicone breast implants or other silicone-containing prosthetic devices and the subsequent development of autoimmune disease.

6. The population most likely to undergo breast reconstruction surgery—women ages 18 to 44—is also statistically most at risk for the onset of autoimmune disorders. Thus, it is expected that some women with breast implants (of any type) will develop an autoimmune disease. Only strictly controlled prospective studies will be able to determine if observed rates of autoimmune disorders in breast implant recipients are greater than expected.

Recently, there have been scattered (and predominantly unpublished) reports of other silicone-containing devices associated with autoimmune disorders. One report, which is of particular concern, describes a patient who developed an autoimmune-like illness after receiving saline-filled implants with silicone-containing envelopes (most saline-filled implants are in fact contained in such envelopes). The disorder resolved following removal of the implants.[20] If confirmed, this case suggests that even saline implants might put the patient at risk.

I have seen cases of fibromyalgia in patients with silicone joint prostheses, and a case of SLE-like syndrome occurring after implantation of one of the new subdermal contraceptive systems (which contains silicone). The list of autoimmune disorders associated with other silicone-containing prosthetic devices is small but growing. However, when one takes into consideration the widespread use of silicone-containing devices (eg, prosthetic joints, artificial heart valves, ventricular shunts, penile prostheses), the relatively small number of reports of associated autoimmune disease suggests that the incidence of silicone-induced immune dysfunction is low.

Nevertheless, there is reason to remain concerned about silicone-induced immune disease. Rodnan and associates[21] demonstrated an association between silicosis and progressive systemic sclerosis (PSS) many years ago. Silica is structurally similar to silicone, although the latter has been felt to be chemically inert. However, local inflammatory reactions surrounding silicone breast implants have been observed, and it is known that macrophage ingestion of silicone particles does occur. It has been postulated that such phagocytosis by macrophages and other inflammatory cells may lead to the breakdown and conversion of silicone to microscopic silica particles, which then elicit an immune response.[4–6]

Whatever the conclusive relationship between silicone prosthetic devices and autoimmune diseases, current data dictate prudence, but not hysteria, when deciding on the use of these implants. Numerous patients clearly have benefited for many years from these devices without developing autoimmune disorders. Yet, we know that case reports often are the first evidence of subsequent causative associations.

Therefore, use of silicone-containing devices should be based on medical need and consent by a patient who has been informed of the possible risks. I believe that the new FDA guidelines, in general, are in keeping with this principle. The controlled conditions by which the implants are now available involve three stages.[3] The first stage makes the implants available to women whose need for them is most urgent, including those who already have in place temporary breast tissue expanders or who are awaiting permanent reconstructive surgery. In the second stage, women who desire implants for breast reconstruction will be able to obtain them under the guidelines of extended availability protocols. In the third stage, implants will only be offered in carefully controlled clinical trials to women requiring them for the purposes of reconstruction. The use of these implants will no longer be available for routine cosmetic surgery.

In addition to the new guidelines outlined by the FDA, it may also be advisable to evaluate the patient's risk of autoimmune disease prior to implantation. Unless the medical need is critical, physicians should defer using any silicone-containing prosthetic device in women at risk (eg, those who have first-degree relatives with autoimmune disease, or those who have autoantibodies but are asymptomatic). In cases where patients with silicone breast implants have developed autoimmune disorders, routine removal currently is not recommended since this has not been shown to consistently result in resolution of the disease. However, if the condition is life threatening, removal is a rational therapeutic option.

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