Silicone breast implantation: doubts about the fears

Despite legal interest and media publicity, scientific evidence for silicone-associated disease is lacking

Since its introduction in 1963, silicone gel implantation mammoplasty has become one of the most common procedures performed by plastic surgeons in the United States. Up to 1991 some 800,000 individuals in the United States have had a silicone breast implant. In Australia the number of recipients is about 50,000. In the 1980s, case reports linking a variety of connective tissue diseases and other symptoms to breast implantation appeared. These syndromes included fatigue, myalgia, arthralgia, arthritis, Raynaud’s phenomenon, skin rashes, memory loss, hair loss and, occasionally, well-documented systemic connective tissue diseases such as scleroderma.

In response to media coverage and petitions by public advocacy groups, the American Food and Drug Administration (FDA) convened several Advisory Panels to review the whole issue of silicone breast implantation. After extensive public hearings, the Advisory Panels concluded that more research was needed but that silicone breast implantation should continue to be available. In 1992, Dr David Kessler, Commissioner of the FDA, chose to override this advice and called for a voluntary moratorium on silicone implantation. Subsequently, he allowed silicone breast implants to be marketed in the United States for clinical trials in breast reconstruction.

An increase in litigation related to silicone implants has resulted in breast implant manufacturers withdrawing their products. Dow Corning, one of the largest suppliers, has established a fund to meet the expenses of removal of breast implants and, together with other manufacturers, has established a $4.25 billion fund to cover class action claims for damages.

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Media interest in these issues has been significant and has concentrated on the emotive and legal aspects at the expense of examining recent epidemiological evidence that questions the relationship between silicone breast implantation and any specific disease, be it scleroderma or breast cancer, or an association with non-specific conditions such as fatigue, myalgia or forgetfulness.

The current state of knowledge is still confusing. There is no doubt that silicone is not biologically inert. It may escape from the implant and concentrate in a surrounding capsule or migrate to distant locations. Silicone and/or other constituents may evoke an immune response, and a variety of immunological abnormalities have been described in patients who have received silicone injections or implants. These include the presence of autoantibodies commonly associated with connective tissue diseases. However, properly conducted studies suggest that these antibodies are seen with a similar frequency in a control population and are no different from those seen with idiopathic connective tissue diseases. Recently, it has been reported that silicone gel may act as an immunological adjuvant in rats. This research has yet to be confirmed. Accepting that silicone is not inert and that it may stimulate inflammatory and immunological reactions, the real issue is, does it cause disease in humans?

Up to June 1993, about 300 patients have been reported with rheumatic symptoms after receiving gel-filled breast implants. The most commonly reported connective tissue disease is scleroderma, but several other connective tissue disorders and vague musculoskeletal symptoms have also been described, particularly vague aches and pains (fibromyalgia), sleep disorders and fatigue — symptoms which are extraordinarily common in the community. Of interest in this context is the recent study by Croft et al., which shows that fibromyalgia does not exist as a distinct disease entity.

When a compound is used as extensively as silicone in implants, it is to be expected that some people will later develop other diseases, but does this mean that the disease is caused by the implant? Recently reported controlled epidemiological studies addressing the association of silicone breast implantation and disease would suggest not.

The first study, from Sydney, compared the frequency and temporal relationships of augmentation mammoplasty in a group of patients with scleroderma against matched controls. The rates of augmentation mammoplasty were similar between those suffering from scleroderma and the control group. The number of patients (251) and the number of controls (289) was not large, but the study carried a 90% chance of detecting a relative risk as low as 4.5, and (with further review of the data) an 80% chance of detecting a relative risk as low as 2.5.

Gabriel et al. studied 749 women who had had a breast implant for a mean of 7.8 years and compared this group to 1498 community controls followed up over the same period. There was no difference in the incidence of any connective tissue disease or cancer between breast implant recipients and the control group, and no difference in the incidence of abnormal results for antinuclear antibodies or symptoms of connective tissue disease, such as dryness of the eyes and muscle weakness.

The report of Gabriel et al. has been widely criticised, particularly by authors who used data from uncontrolled studies for rebuttal. On the other hand, Wong, in reviewing several small studies, found no association between breast implantation and disease, and comments on the remarkable consistency of this finding.

The most recently reported study on the association between silicone breast implants and connective tissue disease is a nested case-control study of a cohort of over 120,000 registered American nurses followed up since 1976 (including over 1200 who had had silicone breast implants for a mean time of 10 years). Four hundred and forty-eight individuals were identified with a definite connective tissue disease: rheumatoid arthritis, systemic lupus erythematosus, scleroderma, Sjögren's syndrome, dermatomyositis and mixed connective tissue disease. Ten controls per case were randomly selected from nurses with no rheumatic skeletal complaints. Odds ratio analysis failed to demonstrate an association between silicone breast implants and these connective tissue diseases.

If there is an association between silicone breast implants and disease, one might expect it to be strongest in those patients who suffer a breast implant failure (rupture or capsular contracture). A study of 65 patients reporting implant failure did not find any clinically evident adverse health problems over a median follow-up of 116 months.

Thus, an increasing body of evidence suggests that silicone implantation is not associated with significant disease, yet this information does not seem to have entered into the legal arguments that continue to be covered in the media. As Marcia Angel, Editor of the New England Journal of Medicine, points out, “There comes a time when the law must look at the scientific evidence”. With ongoing media attention generated by those who, to a large extent, have an interest in the continuing legal wrangles, women with breast implants are being frightened unnecessarily.

One might well argue that the manufacturers should have assured long term follow-up of patients receiving these devices (and this could be said about all devices) but this exercise is much more difficult than the postmarketing surveillance which is carried out following the introduction of a new drug, as problems with devices may take a long time to develop.

It is always easy to make these suggestions in retrospect, but it will also be a tragedy if the furore over silicone implants stifles our ability to develop new technologies that benefit society as a whole. Some medical device companies in the United States are closing down production and research and development activity. They are saying: “Why should we think of developing a new knee replacement, a...
new type of plastic artery or a heart valve, when we are going
to be sued eventually as they are not all going to work? A
recent report in Science detailed a number of instances where
biotechnology companies have either been forced to cease
production because raw materials will not be sold to them
by major chemical manufacturers, or have had to make
unnecessary design changes because of unavailability of bio-
materials. We need to look carefully at the legal processes
which have led to this state of affairs and which may well be
working against society’s benefit and the interests of the
workers concerned.

Women who have breast implants can be reassured that,
on the available evidence, they have little chance of de-
veloping a disease which can be directly attributable to the
breast implant itself. Those women who do have problems
should be advised that the disease they have is unlikely to
be related to their implant, and then given appropriate
support and therapy for their particular condition.

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