Silicone Breast Implants: An Oncologic Perspective

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In 1992, the FDA decided that silicone gel-filled breast implants would be available only through controlled clinical studies, despite the fact that they had been used for mammoplasty in millions of women around the world.

Breast reconstruction is an important component of the multidisciplinary management of breast cancer. Between 10% and 30% of women with stage 0, I, or II breast carcinoma have medical contraindications to breast-conserving therapy,[1] but the availability of breast reconstruction provides them with an alternative to the use of an external breast prosthesis. Immediate breast reconstruction has always been a source of controversy. Initial concerns that immediate reconstruction would impede the detection of local recurrence or result in an excessive number of postoperative complications that delay the use of adjuvant therapy were not supported by the results of retrospective studies.

Reconstructive Surgery Using Implants

During the 1980s, the most common reconstructive technique employed was implant placement, as reported by Noone et al.[2] In this study of 306 women who underwent surgery between 1979 and 1988, 207 were reconstructed with implants, 84 with tissue expanders, and only 15 (5%) with myocutaneous flaps. The 1992 restrictions by the FDA on the use of silicone implants and the ensuing publicity led to a dramatic change in the patterns of breast reconstruction. At our institution, between 1995 and 1998, only 30% of breast reconstructions were done with implants or expanders. One of the major advantages of implant reconstruction is that it entails a more limited surgical procedure and a faster recovery than is seen with a flap reconstruction. While this is certainly true over the short term, studies with longer follow-up document a significant rate of complications after implants placed for breast reconstruction. Gabriel et al[3] reported that 34% of patients with implant reconstruction for breast cancer required reoperation within 5 years due to complications. However, only 4% of these complications occurred within 30 days of initial implant placement, supporting the idea that the use of implants is unlikely to delay the administration of adjuvant therapy.

Complications Associated With Implants

The most common complications were capsular contracture, implant rupture, hematoma, and wound infection. These complications do not result in major, long-term sequelae for patients. While they are certainly worth considering when weighing the risks and benefits of reconstruction and when selecting a type of reconstructive procedure, they do not constitute a reason to avoid implant reconstruction as an option in women with breast cancer. However, these complications were never the major focus of concern regarding silicone breast implants. Gerszten and Gerszten review the lack of convincing epidemiologic data supporting a relationship between autoimmune disease and silicone implants. At the time of the FDA moratorium on silicone implants, large-scale, properly conducted epidemiologic studies were not available to confirm or refute such an association. Since that time, a number of both cohort and case-control studies have failed to support an association between silicone implants and connective tissue disease in general, or such connective tissue diseases as scleroderma, rheumatoid arthritis, or systemic lupus erythematosus, in particular. This absence of scientific proof of harm, however, has done little to alleviate public concern about silicone implants. The lack of public or judicial interest in scientific fact in this matter is the subject of a chilling review by Marcia Angell.[4] In the eyes of the public, the damage is done.

Treating Cancer in Augmented Breasts

Important issues surrounding both silicone and saline implants still remain to be addressed by the oncologic community. It is estimated that between 1 and 2 million women have implants, and that 80% of these were performed for breast augmentation. As these women age, clinicians will increasingly have to confront the problem of treating the woman with breast cancer in an augmented breast. As reviewed in this article, 62 cases of breast conservation for women with...
implants have been reported, and results range from 85% with a good or excellent outcome to an equal number with contractures and fair or poor results. This is clearly an inadequate database for counseling patients. Answers to clinically relevant questions regarding the worsening of preexisting contractures and the relationship of cosmetic outcome to implant position and duration can be answered only by studies enrolling a larger group of patients.

It is also time to study the effect of chest wall irradiation on implant reconstructions. Recent data from the Danish[5] and British Columbia[6] trials suggest that postmastectomy irradiation not only reduces the risk of locoregional recurrence but also may have an impact on survival in remenopausal women. Although the management of women with involvement of one to three nodes remains controversial, the available data provide a strong impetus for chest wall and nodal irradiation in patients with metastases to more than four axillary nodes. Again, outcome data from a very limited number of patients irradiated after implant reconstruction are available for review, and the results are very mixed.

This is an area with important clinical implication: Should women at high risk for nodal metastases avoid breast implants, both silicone and saline? Whether the public attitude toward silicone implants will change is uncertain, even if the FDA revises its policy on these implants. In the meantime, better data on the outcome of breast-conserving therapy and postmastectomy irradiation in women with implants are sorely needed.

References:


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